ENERGY EMPLOYEES OCCUPATIONAL ILLNESS COMPENSATION PROGRAM: ARE WE FULFILLING THE PROMISE WE MADE TO THESE COLD WAR VETERANS WHEN WE CREATED THIS PROGRAM? (PART IV)

HEARING

BEFORE THE

SUBCOMMITTEE ON IMMIGRATION, BORDER SECURITY, AND CLAIMS

OF THE

COMMITTEE ON THE JUDICIARY
HOUSE OF REPRESENTATIVES

ONE HUNDRED NINTH CONGRESS

SECOND SESSION

NOVEMBER 15, 2006

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ENERGY EMPLOYEES OCCUPATIONAL ILLNESS COMPENSATION PROGRAM: ARE WE FULFILLING THE PROMISE WE MADE TO THESE COLD WAR VETERANS WHEN WE CREATED THIS PROGRAM? (PART IV)

WEDNESDAY, NOVEMBER 15, 2006

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON IMMIGRATION,
BORDER SECURITY, AND CLAIMS,
COMMITTEE ON THE JUDICIARY,
Washington, DC.

The Subcommittee met, pursuant to notice, at 2:09 p.m., in Room 2141, Rayburn House Office Building, the Honorable John Hostettler (Chairman of the Subcommittee) presiding.

Mr. HOSTETTLER. The Subcommittee will come to order. Today's hearing is the fourth in a series of oversight hearings the Subcommittee has been holding on the Energy Employees Occupational Illness Compensation Act, or EEOICPA. The point of this hearing and the fifth hearing to follow in December is to review what the Committee's oversight efforts have revealed as weaknesses in the program, the status of any reforms made to address those weaknesses and discussion of any emerging issues that may need to be addressed in the next Congress.

Because of their complexity, the Subcommittee is compelled to make an effort to create as much of a roadmap of a program and its problems as possible for those who would provide future oversight. The Judiciary Committee's oversight did not begin with investigation on implementation of the OMB passback options. This Committee has taken an active role in policing its program from the start. And I sincerely hope that rigorous oversight by this Committee will continue in the 110th Congress and future Congresses until we can all say with confidence that, yes, we are fulfilling the promise we made to these veterans of the Cold War when we created this program.

I would have liked to have been able to say that already, but the record created by these hearings tells us that it is just not so.

Shortly after assuming the chairmanship of this Committee, I sent a letter to the General Accounting Office asking that they examine the key components of the program. That was May 2003. As time went on, the Subcommittee heard several complaints on the way the program was functioning and the behavior of officials involved in the program.

That prompted a November 2004 request to the Department of Health and Human Services for extensive documents and information concerning the functioning of the program, the Advisory Board of Radiation and Worker Health, and that board's audit contractor.

Subsequently, after the initial review of their submissions a request was made for GAO to expand the scope of their review of subtitle B, which they agreed to. During 2005, the Committee sent letters to various agencies regarding concerns with different actions taken with regard to the program.

One letter to the Attorney General concerned the use of classified information to decide a claim under the program and asserted that congressional intent was that transparency and the processing of claims be an essential principle of this program. A second letter concerned the removal of two board members, a worker and a doctor. No resolution to either of those concerns was forthcoming.

In the case of the request by Chairman Sensenbrenner that the removed board members be offered reinstatement so that the board would not lose their expertise and experience with the program, the Committee received a one-sentence letter thanking us for our comments.

On October 18, 2005 the White House announced the appointment of three new board members, one of whom had major conflicts of interest issues since a company he founded and whose employees included immediate family members had been contracted to do dose reconstructions for NIOSH. Only one new worker representative was included in the new appointments. When the OMB passback memo surfaced, the Subcommittee began planning hearings. Those hearings were, at a minimum, to include Department of Labor and the Office of Management and Budget.

The Committee's invitation was met with resistance by DOL and HHS. But they both eventually provided witnesses. That was not the case with OMB. Administration officials suggested that an exchange of letters between OMB and the Committee containing appropriate assurances and stating good faith actions that would be taken to assure the claimant community of the Administration's rejection of the passback options would be a more appropriate response than OMB testifying.

There were several exchanges of draft letters between OMB and Committee staff as well as a meeting between myself and the Administration to personally express the need for specific actions and/or statements that OMB had to make in lieu of testifying.

One of those actions was to either offer reappointment to the board members removed without cause, or provide a plausible explanation why they had been removed, while other less qualified members who had made their support of DOE management very clear, had been retained. When it became clear that action was not—was nonnegotiable for the Committee, OMB took the broad nonspecific letter of explanation with regard to the OMB passback and used it as the basis for letters responding to Senate and House Member offices. They refused to consider reversing the actions of the Administration with regard to the 2 pro worker Advisory Board members.

During the first week of August 2006, NIOSH was notified by the White House office of personnel that Wanda Munn and Roy Dehart

had been retired from the board effective immediately, as part of the ongoing activity of rotating board members.

Dr. Dehart had filled one of the medical slots on the advisory board, Ms. Munn, an engineer and strong supporter of the DOE complex does not appear to have been qualified to fill any of the statutorily required board slots, medical, scientific or worker.

It was brought to the Subcommittee's attention that Ms. Munn was unhappy with her retirement and hoped to utilize a means to get back on the board. Amazingly on August 11, 2006, NIOSH was notified by the White House that Dr. Dehart and Ms. Munn were to be reappointed for another 3-year term. While Dr. Dehart declined reappointment, Ms. Munn, not surprisingly, accepted.

When the White House was asked why reappointment was so quickly offered to an individual who didn't even meet the statutory qualifications for serving on the board after the request of the Chairman of the Judiciary Committee for the reappointment of two qualified board members was ignored, the Administration never provided an explanation.

The board currently has only two worker representatives and a reappointed member who has stated her position that none of these workers are sick because of their exposure to radiation.

Obviously, an impartial review of the validity of the science used to determine whether to approve claims for radiation exposure won't be forthcoming from that particular board member.

I strongly encourage those who police this program in the future to aggressively pursue balancing this board and legislation to provide for a more transparent appointment process appears to be the only real solution.

A February 22, 2006 letter requested that DOL's Employment Standards Administration or ESA provide all documents related to the 5 options outlined in the OMB passback prior to the Subcommittee hearing on March 1, 2006. The Subcommittee received a box of about 4,500 pieces of paper from DOL on March 17, 2006. None of them substantive information related to the request.

After DOL complained that the request was overly broad, the Subcommittee reduced its request of the documents of 25 key DOL ESA staff. No further documents were received until the beginning of July. No documents or communications were received regarding the OMB passback, and no communications between Labor and OMB were forthcoming.

The Committee was informed on July 21 that the office within DOL that handles the EEOICPA claims indicated to the Legislative Affairs Office that there was no need to provide any of the communications with OMB because they constituted internal budget negotiations—privileged documents not available to anyone.

Labor was told by the Committee that ESA had misinformed them.

In support of that position, the Subcommittee requested and received a congressional research analysis of the appropriateness of the document requests made to the Labor Department, which makes it clear that no privilege could be assigned to the documents in communications that were part of the Committee's inquiry.

On the eve of a vote to authorize a subpoena to DOL, high level assurances were made to the Committee to provide all but a few

documents to the Committee, and the rest were made available in a reading room for Committee viewing.

HHS had withheld several binders and allowed all but one to be reviewed by Committee staff.

It is the Committee's understanding that the binder withheld contained HHS's communication with OMB regarding the passback. So much resistance from these agencies fortifies the argument that their actions would not bear well under scrutiny. Those involved in this backroom manipulation of the program have destroyed the Government credibility again.

This program was supposed to ensure workers that the deceit was over and the Government was finally going to do right by them. Those tasked with implementing the program have failed that purpose miserably, and they need to be exposed for what they have done.

I will be including a record of the Committee's correspondence on our concerns in the hearing record as well as other pertinent documents that provide a clear view of the actions of those running this program.

Under oath, the OMB witness on July 20, 2006 rejected each of these 5 options and assured us they were not pursuing any of them. We received the same assurances under oath on March 1st, 2006, in DOL. Evidence included in both DOL and HHS-submitted documents or included in the documents withheld and only viewable to the Committee staff do not support those statements, and the hostile attitude of those running this program toward the claimants and their advocates gives me little confidence that there is any sincere efforts to change by these officials.

Obviously, the babysitting of these individuals must continue and I encourage it wholeheartedly. Time is of the essence for fulfilling our promise to this quickly aging population of atomics weapons employees. Perhaps soon those who run this program will do the right thing and take care of these workers and their families competently and with an attitude of respect that is clearly not present at this time.

At this time, the Chair recognizes the gentlelady from Texas, Ms. Jackson Lee, for purposes of an opening statement.

Ms. JACKSON LEE. Thank you, Mr. Chairman. Let me, first of all, thank you for joining me in persisting on what I think is a call for the restoring of the integrity of this program. Thank you for joining me and insisting that the Federal Government do the right thing. And thank you for your leadership on this issue.

I echo and join the Chairman in announcing publicly that it is my fear that the Energy Employees Occupational Illness Compensation Program's integrity is in jeopardy.

Mr. Chairman, I want to indicate to you that over the recess, I went to Texas City in Texas and saw the faces of individuals who have been impacted by the failure of this particular program to function.

I looked in the faces of elderly persons who asked—and begged frankly—that we would come to their area and hear their stories and find out that they are nothing but great patriots, and good Americans, and they love their country, and they entrusted their

hopes and dreams for their families, for their livelihood, and for their longevity to this great nation.

I think it is a besmirching of the commitment that we make to Americans when they rise to the highest call, calling, and that is to serve America, that we have found ourselves in this quagmire.

So I join you in the level of frustration that your accounting has generated. And I am hoping and I view and feel that our collective effort before we end the 109th Congress, will see fruition. And so I begin by thanking the witnesses for being here. It looks like we are climbing up the rough side of the mountain, but I do believe that we have a collective body of interested Members of Congress who are willing to pursue the Federal Government doing the right thing.

The Department of Energy and its predecessor, the Atomic Energy Commission, have employed tens of thousands of workers to develop, build and test nuclear weapons. The Energy Employees Occupational Illness Compensation Program Act of 2000 provides compensation for workers who have contracted radiation related cancers, beryllium disease or silicosis disease from exposure to radiation at these work sites.

They may be eligible for a lump sum payment of $150,000 and prospective medical benefits. In processing radiation-related cancer claims, the National Institute for Occupational Safety and Health is required to estimate a workers exposure to radiation, which is referred to as a radiation dose.

Sometimes this is not possible. During the early years of the nuclear weapons program, some of the workers were not monitored for radiation exposure, and records have been lost. We found these cases in similar situations of compensation requests throughout the other history of the United States.

Remember, folks, we did not always have the Internet or the computer. We didn't always have the Blackberry. People were either writing things down or assuming that the immediate supervisor knew the story.

And of course, we have not yet found the cure for aging and loss of life through aging. And people have passed on who knew the stories, companies have closed who had the information, documents have been either lost, displaced or disposed of because history has marched on.

The Act provides a remedy for cases in which it is not feasible to estimate radiation doses. But it is clear that the health of workers may have been in danger by radiation exposure. They can petition to be designated as members of a Special Exposure Cohort which provides an unrebuttable assumption certain cancers are work related. Members of a Special Exposure Cohort may be eligible for benefits if they have 1 of 22 specified radio sensitive cancers, and they must have worked as a covered facility for at least 1 year in a job that exposed them to radiation.

I deviate for a moment and cite as an example Agent Orange, recognizing that we first challenged the existence of Agent Orange disease after Vietnam and after long studies and determinations in lost records and misinformation, we have discovered that that is a valid disease, or exposure that Vietnam vets had and Mr. Chairman, while I was home in the District again, a Vietnam vet who

was in Thailand has now raised the specter that that group was left out, and those Agent Orange planes landed on those airfields, and he is, of course, by his medical doctor, determined to be 100 percent disabled, but yet paperwork and lack of designation has him as a case that we have to pursue in front of the Veterans' Affairs.

I use that as an example because this is what these cohorts have been facing. In an internal passback memorandum from the Office of Management and Budget to the Department of Labor, OMB states that the Administration will convene a White House-led interagency work group to develop options for administrative procedures to contain the growth in the costs of the program, cost over patriotism and the service of these patriots.

OMB states further that the discussions would include but not be limited to a requirement for the Administration's clearance, of Special Exposure Cohort determination, addressing imbalances in the membership of the Advisory Board, requiring an expedited review by outside experts of the Special Exposure Cohort recommendations by NIOSH, requiring NIOSH to apply a conflict of interest rules and constraints to the Advisory Board's contractor, which we see by the Chairman's remarks, that has not been done, and requiring that NIOSH demonstrate that its site profiles and other dose reconstruction guidances are balanced.

I am concerned that such cost cutting measures would conflict with the Special Exposure Cohort review procedures established by the Compensation Program Act and that it would result in unwarranted denials of compensation applications.

Instead of cost-cutting measures, the Administration should be considering whether measures are needed to increase the number of applications that are granted. On average, approximately 70 percent of the applications are denied.

We are not serious. We are playing at the game of responding to the needs of the faces that I saw in Texas City, Texas this past fall.

Government witnesses have testified that cost containment is not a factor in deciding which claims to pay. But this has not eliminated concern. The Subcommittee asked DOL to provide all documents related to the 5 options outlining the OMB passback. The Subcommittee received a box of about 4,500 pieces of paper from DOL, but none of these documents provided the necessary information.

When this was brought to DOL's attention, its response was that the request was overly broad. The Subcommittee reduced its requests to the documents of 25 key DOL ESA staff. But the Government still would not cooperate fully. The debate reached a point at which a subpoena was considered. Most documents were made available to the Subcommittee, but the integrity of the application process is still in doubt.

I have introduced a bill to address these problems. The Energy Employees Occupational Illness Compensation Program Improvement Act of 2006, H.R. 5840. Among other things, it would shift the authority from making Advisory Board appointments to the Congress. It would require HHS Secretary to abide by the recommendations of the Advisory Board unless there is a clear error.

It would establish enforceable conflict of interest requirements with respect to NIOSH's dose reconstruction contractors.

Also, it would eliminate unfairness by making benefits available to some subcontractor employees who worked at atomic weapons employer facilities, but presently are not covered by the Act.

I know that we want to do the right thing. I would imagine, Mr. Chairman, if we interviewed individual members of the Administration, I give them the benefit of the doubt, they would know that they have not been completely forthright in doing the right thing, and they would acknowledge that we have been asking the important and hard questions, and our questions need to be answered, documents need to be produced, and as well, we need to move forward on a reconstructive program.

I would ask prospectively as my colleagues are listening that we would begin to hold hearings on H.R. 5840, a field hearing as well, but more importantly, that we move forward and address the concerns of patriotic Americans.

Mr. Chairman, thank you again for your leadership and I yield back.

Mr. HOSTETTLER. I thank the gentlelady. At this time, I will introduce members of our distinguished panel of witness.

Laurence Fuortes is professor of occupational and environmental health at the college of public health at the University of Iowa.

Dr. Fuortes received his B.S. In biophysics at Northern Illinois University and his M.D. At the University of Illinois. He has published dozens of article on a wide range of medical subjects, though much of his research has focused on occupational health hazards and the development of potential policy solutions.

John Mauro is the project manager for Dose Reconstruction Consulting Services for the Advisory Board on Radiation and Worker Health under EEOICPA. He has personally performed eight dose reconstruction reviews and directed 60 other reviews. Dr. Mauro has appeared before the Advisory Board at every public bimonthly meeting of the board and has presented and defended the audit reports of the audit contractor, Sanford Cohen & Associates.

He has served as the principal investigator for the preparation of the environmental and safety analysis reports for 10 commercial nuclear power plants.

Kathy Bates is a surviving claimant under the Energy Employees Occupational Illness Compensation Program Act. She attended the University of Tennessee and graduated with honors in 1984 with a degree in computer science. She has 22 years of experience as an information technology professional. Mrs. Bates is married and has two children and she resides in Knoxville, Tennessee.

Richard Miller is a senior policy analyst at the Government Accountability Project. Mr. Miller has led that group's efforts to reform EEOICPA as part of the fiscal year 20O5 Defense Authorization Act.

Mr. Miller is an expert on the program, having been actively involved in creating the original EEOICPA law. He has testified before this panel on the OMB passback document on containing the cost of EEOICPA.

In 2003, he appeared before the Senate Committee on Energy and Natural Resources where he testified on the flawed implemen-

tation of EEOICPA by the Department of Energy. He holds a B.A. in industrial and labor economics from the University of Massachusetts.

Lady and gentlemen, you will see that we have a time system. We respectfully ask that you limit your oral statements to 5 minutes or as close as possible to that.

Without objection, your entire written statement will be made a part of the record.

Dr. Fuortes, you are recognized for 5 minutes for an opening statement.

TESTIMONY OF LAURENCE FUORTES, M.D., PROFESSOR, DEPARTMENT OF OCCUPATIONAL AND ENVIRONMENTAL HEALTH, UNIVERSITY OF IOWA

Dr. FUORTES. Thank you. I have been working with several AEC DOE sites in Iowa for about 5 years and it has been one of the most changing—life-changing experiences of my life. I have been very affected by this work.

On behalf of these workers and the families of those who are deceased, I would like to thank you very much for this oversight of the policies in response to the health risks and resultant diseases experienced by this workforce.

They labored under a weight of secrecy and uncertainty regarding the health risks of nuclear weapons work. We owe these workers a debt of gratitude and as you have suggested, a fair and open system.

When this program began, the workers in Iowa said that their Government was just waiting for them to die. And sadly some of our actions appear to bear this out.

On a positive note, scores of workers' lives have been saved by the early detection of cancers and other diseases through the DOE medical screening process.

Unfortunately, the tone of the OMB memo that led to these hearings is that some feel the risks to these early era workers have been overstated. Worker protections may have been interpreted as adequate in the early era, but they are clearly not adequate by today's standards. This was prior to the studies of Hiroshima and Nagasaki survivors and radium dial painters and prior to decades of biological studies of cancerous effects of radiation.

It was also prior to technologic advances in radiation monitoring before the OSHA Act.

These workers are disadvantaged in the SEC anddose reconstruction processes, by a lack of transparency and a lack of access to expertise.

In the SEC process, the petitioners are asked to prove the negative, something that cannot be proven. All the while, they are not given access to the same data that NIOSH and its contracts have. And the petitioners have to rely on a cumbersome FOIA process to try to get dose information.

It took 3½ years just for the SEC rules to be written. Meanwhile many of these elderly workers died. In the Iowa case after the Advisory Board went on record in April of 2005 agreeing that accurate, defensible, and timely dose reconstructions could not be per-

formed, there was a flurry of activity, which seemed to be designed to frustrate these workers.

SEC and claimed decisions should not be based on financial implications, but on a fair balanced scientific judgment. The petitioners are further disadvantaged by the dense technical aspects and jargon of health physics and typically are asked to take, at face value, the dose calculations made by NIOSH contractors.

The petitioners deserve a process independent of bias or political pressure. The board must be scientifically based and its judgments must be impartial and there must be a representation of environmental and radioepidemiology expertise.

The SEC process has also not addressed risks from residual radiation. At the Ames lab, one worker described to us his tasks in the 1960's of tearing out the exhaust ventilation systems and the building materials of one of the most highly contaminated areas. All of his co-workers are now deceased from cancer. When we shared this information with the Ames laboratory, their director and health and safety staff helped us immediately to amend our SEC petition, submit it to NIOSH to extend the period of coverage.

This issue of residual risk is pertinent in all of the DOE sites probably that we are dealing with radionuclide processing.

As regards the dose reconstruction claims processes, there is a perceived problem of this being litigious which places unfair burdens of proof on the claimants. Although the dose reconstructions developed by NIOSH give the numerical appearance of precision, the process is often not exact or scientifically defensible.

Take, for example, an Iowa worker who received a probability of causation of 48 percent for a radiogenic cancer and imagine his disbelief when he amended his claim based on a newly-diagnosed radiogenic cancer and the NIOSH recalculated probability of causation is now 32 percent.

Despite the best intentions of claimant friendliness, this DOE claims process operates disturbingly like a conventional insurance claims process, functionally placing obstacles in the claimants path. This claims process must also be made transparent and subject to review and oversight.

I know of several cases of people whose claims were denied based on faulty assumptions by the Department of Labor. Examples include a Kansas City native from the Bendix plant whose proof of employment came from the headquarters in New Jersey. He was denied. Another employee whose proof of disease came from a CT scan was denied because under the language of the Act they required a CAT, CAT scan. Others denied because diseases such as Polycythemia Rubra Vera were decided by the claims examiners not being covered under the Act, where as, in fact, they are. There are numerous such examples.

These workers are typically elderly and not well versed in health, physics, medical or legal terminology, and they are easily frustrated and dissuaded from pursuing valid claims. Cases such as these, I mentioned, suggest a need of a systematic review of denied claims and a change in policy from placing the burden of proof entirely on claimants to a system which claimants are assisted in identifying and locating requisite information.

All of these workers who were exposed to radiation Beryllium and related toxins in our atomic weapons industry deserve no less than an equitable, just and open approach to the evaluation of causality and compensation for work-related disease. Thank you very much.

Mr. HOSTETTLER. Thank you, Dr. Fuortes.

[The prepared statement of Dr. Laurence Fuortes follows:]

PREPARED STATEMENT OF DR. LAURENCE FUORTES

Honorable Members of the Subcommittee on Immigration, Border Security and Claims, thank you for the opportunity to share with you my perspectives on the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) and the Special Exposure Cohort process. My name is Laurence Fuortes, I am a physician and Professor of Occupational and Environmental Health and of Internal Medicine at the University of Iowa (UI). For approximately five years, my staff and I have been working with former Atomic Bomb assembly workers and more recently Uranium and Thorium processing workers in Iowa and surrounding states. Through a Department of Energy program, UI provides medical screening examinations and medical care to former workers, and we have gotten to know many of these workers quite well.

On behalf of these former Atomic Energy Commission and Energy Department workers and the families of those no longer alive I thank you for addressing questions of appropriate policy in response to recognized health risks and disease experienced by this workforce. These workers labored under a great weight of secrecy, as well as significant uncertainty, in regards to health risks associated with employment in the nuclear weapons industry. We owe these workers a tremendous debt of gratitude for their patriotism, placing themselves in harms way in defense of our country during both World War 2 and subsequently during the Cold War.

One of the primary things I hope to convey at these hearings is a sense of the effect of these programs on individuals as well as the community. I have spent hours with grown women and men in tears as they helped me identify those of their coworkers who are deceased. Without the benefit of a funded scientific study, I would have to say that anecdotally we are seeing a higher than expected rate of cancers and lung disease in this population, (as compared to what I have experienced in other medical screenings). These workers and their families said at first that the government was only waiting for them to die. Sadly the facts and history appeared to bear this out. The impression among many workers and their families is that the workers had been put at risk, made ill, and died as a result of their work, yet the government was merely going to stall and deny. Throughout our and other Former Worker Programs scores of former workers lives have fortunately been saved as a result of early detection of cancers and other conditions.

The approval of the SEC for the atomic weapons workers at the Iowa Army Ammunition Plant has rekindled the faith and participation in government.

To adequately understand the significance of these programs, it is first necessary to understand that safe working conditions in the earliest years of nuclear weapons production were severely lacking. Worker protection in terms of radiation shielding and monitoring—although state of the art for the time—was not adequate. Production was the primary focus for the operating contractors. The Health and Safety staff at these facilities used the best available knowledge and directives from the AEC to address and minimize workers' health risks. This was prior to the epidemiologic data that resulted from follow up studies of Hiroshima and Nagasaki victims and the radium dial painters. This was prior to decades of biological study which enlightened the field significantly as regards risks of ionizing radiation. There have also been dramatic technologic improvements in radiation monitoring. The measures taken to minimize exposures to these early workforces would clearly be deemed inadequate and inappropriate today. This was decades previous to the Occupational Health and Safety Act and the protections it brought to the nations workforces. Under an oath of secrecy, there was little opportunity or incentive for complaints despite a real sense of uncertainty regarding their risks.

I am concerned that in addition to having been placed at historical risk in defense of our country, these workers are now at bureaucratic risk of being frustrated and disadvantaged by the processes for implementing EEOICPA. Both in the SEC process and in the dose reconstruction process there is a lack of transparency and access to expertise, which places petitioners and claimants at a tremendous disadvantage.

SEC. In the SEC case petitioners are tasked with proving the negative—that something cannot by definition, be proved. As a logical or philosophic process this is quite difficult and workers and petitioners need assurances that this process is workable and transparent. Workers and their representatives often have to rely on a cumbersome FOIA process and are unable to obtain the same data which is used by NIOSH and it's contractors in the creation of Site Profiles and Dose Reconstructions.

Dose Reconstructions. There is at least a perceived problem of this being a litigious process and one can understand why workers feel wronged by the unfair burdens of proof placed upon them. The Dose Reconstructions developed by NIOSH provide the appearance of precision, but this process is not exact nor at times defensible. As an example, a worker at the Iowa Army Ammunition Plant was determined to have a 48% probability of causation of a radiogenic cancer attributable to exposures at the plant. Imagine this worker's disbelief, when amending their filing based on a second and newly diagnosed radiogenic cancer, on being told that the newly calculated probability of causation dropped to 32%.

As background, allow me to describe the industrial processes, exposures, historical health and safety procedures and reflections on the SEC petition experiences at the two facilities I know best.

In the case of the Iowa Army Ammunition Plant, in Burlington, Iowa, workers were exposed to ionizing radiation from enriched and depleted uranium, plutonium, and tritium in the course of assembly and disassembly of nuclear weapons from 1949 until 1975. Workers routinely handled the radioactive components directly in their hands with only cotton gloves and without lead aprons. They had little or no radiation monitoring and little or no shielding from the radiation.

There are no reports documenting the internal doses of radionuclides in this workforce at any time. Only limited external dosimetry was provided to record the doses of external penetrating radiation to which such workers were exposed.

A Special Exposure Cohort petition was submitted on behalf of these workers on the basis of a near total lack of relevant exposure or estimated dose data. The SEC petition process was long and frustrating to the community. It took 3 1/2 years just for the rules for evaluating SEC petitions to be developed. The argument was made by contracted Health Physicists that despite the lack of individual exposure data, doses could be reconstructed based upon classified information. All the subsequent cancer claims, even those considered radiogenic, resulted in denials initially. Statements were made by NIOSH contractors that this was a low exposure workplace despite a lack of records and without the benefit of worker interviews. This perceived a priori position seemed to permeate the actions and statements made early on by NIOSH and their contractors and may have resulted in resistance to take in to account information from workers which contradicted the a priori assumptions noted. NIOSH had stated that they could reconstruct the doses of workers at IAAAP despite a near total lack of exposure data by dint of theoretical models and data from workers at another worksite, Pantex, handling different warheads, in a different era. Petitioners are further disadvantaged by the technical nature and jargon of health physics and typically must take at face value the more technical calculations made by NIOSH. The Radiation Advisory Board is beset with complicated decisions and would benefit from the addition of persons recognized for strong environmental epidemiology skills. The functions of the Radiation Advisory Board and of their technical contractor, SC&A, must be guaranteed to be independent of any real or perceived bias of involved federal agencies. SEC and claims decisions should not be based on financial implications but fair and balanced on scientific judgment.

There were significant weaknesses in NIOSH's assumptions that they could reconstruct dose without worker exposure data. Examples include NIOSH's use of ambient outdoor levels of radon gas for calculating respired doses experience by underground workers in Iowa despite the fact that Iowa has among the highest geologic sources and reported indoor air concentrations of radon. NIOSH assumed that those badged had the highest exposures. Production workers reported a less than systematic radiation monitoring program and a pattern of inspectors and engineers with less hands on responsibility for assembling weapons were more likely than others to be monitored. It turns out that those workers exposed to the greatest numbers of warheads at any time and for whom the area monitoring reflected the highest exposure, (guards), were never monitored.

In April 2005 the President's Advisory Board on Radiation and Worker Health went on record agreeing with the workers' petition that asserted that accurate, defensible and timely dose reconstructions could not be performed.

The approval of the SEC has rekindled the faith and participation in government.

At the Ames Laboratory, former workers processed African pitchblende ores and radioactive thorium for use in the nuclear weapons program from 1942–1955. The

scientific, technical, and administrative workers at the Ames Lab were involved in a heavy industry processing tons of uranium and thorium. This process generated large quantities of radioactive dust, and workers performed their duties without personal protection, engineering controls or radiation monitoring to protect them from radionuclide exposures and risks. Exposure data are available for small subsets of the workforce from very limited points in time, and without supporting documentation regarding both work and dosimetry protocols and methods. Review of Ames Lab medical records from individual workers involved in these processes has revealed no personal dosimetry records. Workers were exposed to extremely high levels of airborne uranium and thorium dusts, radon and thorium, even relative to the standards in effect during the time. In fact, some workers were excreting hundreds of micrograms of uranium per day in their urine.

My impression from the tone of the OMB memo that led to these hearings is that there is a sense among some that the risk to these workers has been over stated or that their employment resulted in minimal risk. Unfortunately, because of a severe lack of exposure records and the deaths of many potential claimants, it is not feasible to conduct valid dose reconstructions for the Iowa Army Ammunition Plant, IAAAP, facility or Ames Laboratory workers. At IAAP workers were in intimate contact with strong sources of radiation, handling the fissile central components of these weapons inches from their bodies without lead aprons. Work histories of Ames workers include reports of "blow-outs" with dissemination of both uranium and thorium from uncontrolled exothermic reactions occurring on a routine basis. These exposures would not be tolerated by any means under today's expectations of acceptable risk. Throughout our and other Former Worker Programs scores of former workers lives have fortunately been saved as a result of early detection of cancers and other conditions.

The SEC process has not fully addressed the risk of residual radiation among the workers performing maintenance and repair of these facilities. Recently an Ames Lab worker described to me his tasks including tearing out all the equipment, ceilings and exhaust ventilation in the building in which tons of thorium had been smelted and refined. The Ames Laboratory health and safety staff assisted in submitting an update to the Ames SEC petition to address this issue and to ask NIOSH to extend the period of coverage of the Ames SEC and add this subset of workers. The question of residual radiation risk is relevant to many of the AEC/DOE sites involved in manufacture and refining of radionuclides.

As regards the DOL claims process, despite the best of intentions for claimant friendliness, it operates at times disturbingly like a conventional property or health insurance claims process and functionally places obstacles in the paths of claimants. The claims process should also be as transparent as possible given any confidentiality constraints.

I know of at least ten people whose claims were denied and whom upon review of their cases and a letter of clarification to the Director of the DOL Division of EEOICP resulted in these denials being promptly rescinded. These denials resulted from such things as:

- Proof of employment coming for a DOE site worker coming from the parent company headquarters in New Jersey instead of the plant site in Kansas City.
- Evidence of disease coming from a 'CT' scan and being denied because the term used was not 'CAT' scan.
- Statements that specific diseases—Polycythemia Vera, MAST cell lymphoma, myelodysplasia—are not covered under the SEC list of presumptive cancers when in fact they are.

These workers are typically elderly and not well versed in medical or legal terms and are unfortunately easily frustrated and dissuaded from pursuing valid claims. Cases such as those above suggest that there would be a benefit to a systematic review of denied cases and a change in policy from placing the burden of proof entirely on the claimants to a system in which claimants are assisted in identifying and locating missing information.

All the workers who were exposed to radiation, Beryllium and related toxins as part of our Atomic weapons industry deserve no less than a fair and open approach to the evaluation of causality and compensation for work related disease.

Mr. HOSTETTLER. Dr. Mauro.

TESTIMONY OF JOHN MAURO, PROJECT MANAGER, DOSE RECONSTRUCTION CONSULTING SERVICES, ADVISORY BOARD ON RADIATION AND WORKER HEALTH UNDER EEOICPA, SANFORD COHEN & ASSOCIATES

Mr. MAURO. Thank you very much. Good afternoon. My name is John Mauro. I am an employee at Sanford Cohen & Associates located in Vienna, Virginia.

For the past 3 years, SC&A has served as the technical support contractor for the Advisory Board on radiation worker health. I serve at the SC&A as project manager for that contract.

I would like to thank the Subcommittee for inviting me here today to discuss two topics. The first pertains to emerging issues related to the review of SEC petitions. And the second is to respond to allegations made during the March 1st, 2006 hearing regarding the possibility that SC&A may have a conflict of interest with respect to the, some of the work we are performing for the Advisory Board.

With respect to the first topic, I have prepared a written statement that addresses four separate issues. However, for the sake of expediency, it is convenient to combine these issues into a single issue that has to do with finding and then dealing with inadequacies in the radiation protection records for workers at DOE and AWE facility.

When all is said and done, one of the most important responsibilities we all have under the Act is to identify the nature and extent of the deficiencies of the radiation protection and other records at each facility and determine if it is scientifically plausible to find a way to deal with these deficiencies and reconstruct the doses to all workers in a manner that is scientifically robust and claimant favorable. If we cannot do this for any group of workers, we must recommend an SEC petition.

To date, SC&A has reviewed numerous SEC petitions and NIOSH evaluation reports of those petitions. The single most important issue that continues to emerge is gaining a complete understanding of the myriad operations that occurred at a facility over time and understanding where the gaps exist in the records that challenge our ability to reconstruct doses.

I don't think anyone realized that this program, when it began, how difficult it was going to be to identify those gaps. For example, at the Y-12 and Mallinckrodt facilities, we all knew that uranium exposures were important and a highly concerted effort was made to understanding the uranium exposures that occurred at these facilities. However, during our review of these petitions for these facilities, it became apparent that there were many more radionuclides and activities that took place at these facilities that needed to be understood.

It is essential that we all recognize the complexity of these facilities and make sure we do not overlook potentially important sources of exposures and exposure scenarios, especially during the early years.

We need to have complete and unfettered access to all DOE historical records in order to achieve a level of confidence that we have not missed anything important.

I believe the single most important issue that has emerged to date is the recognition that it is very difficult to gain a full understanding of the myriad activities that took place at these facilities, and that NIOSH, the board and their contractors, SC&A, must accept this reality and the challenges that go with it.

Once we understand the extent and complexity of the activities that took place at a given facility, and the magnitude of the deficiencies and the gaps, we must develop robust decision criteria for determining when we can develop end develop methods that can fill the gaps in a scientifically defensible and claimant favorable manner and when we cannot. I do not believe we have yet reached the point where we all agree on the process by which this best can be accomplished.

With respect to the second issue, I disagree with the statement—the second issue being the conflict of interest statements that were made at the—during the previous hearings. I disagree with the statements made by Mr. Hallmark at the March 2006 hearing that SC&A has a conflict of interest.

In my prepared statement, I explain why I believe Mr. Hallmark's statements are not correct.

The bottom line is, and I am looking for one way to convince the Subcommittee, is that when you review our record of findings, just about 40 percent of our findings are that the dose reconstruction deficiencies have either—have underestimated and about 60 percent have found overestimated. So I believe we have been very objective with respect to how we approach the problem. And we do not have a conflict of interest. I am not going to go into the details. They are all in my record.

There are a couple of other matters I would like to discuss, but I can see that my time is running out. And I would like to thank you for the opportunity to speak to you.

Mr. HOSTETTLER. Thank you, Dr. Mauro.

[The prepared statement of John Mauro follows:]

PREPARED STATEMENT OF JOHN MAURO

Testimony of

John Mauro, Ph.D., CHP
Project Manager
S. Cohen & Associates (SC&A, Inc.)

Before the

HOUSE JUDICIARY SUBCOMMITTEE ON IMMIGRATION, BORDER SECURITY AND CLAIMS

Oversight Hearing on

"The Energy Employees Occupational Illness Compensation Program Act—Are We Fulfilling the Promise We Made to these Veterans of the Cold War When We Created the Program?"

Wednesday, November 15, 2006
2142 Rayburn House Office Building

Chairman Hostettler, Ranking Member Jackson-Lee, and Members of the Subcommittee, thank you for the opportunity to appear before you today to more fully address certain issues regarding my firm, S. Cohen & Associates (SC&A, Inc.), that were raised before the Subcommittee at previous hearings. We will also present to the Subcommittee SC&A's perspectives regarding some of the issues that have emerged during our support of the Advisory Board on Radiation and Worker Health (the Advisory Board) on matters related to the review of Special Exposure Cohort Petitions and NIOSH's evaluation of those petitions under the Energy Employees Occupational Illness Compensation Program Act (the Act or EEOICPA).

SC&A previously submitted a statement to the Subcommittee at the hearings held here on March 1, 2006. In that statement, we provided an overview of who we are, our role in support of the Advisory Board, and how we approached our technical work. We also provided descriptions of our contractual requirements and our accomplishments up until that date. This information is not repeated here, except to reintroduce who we are and update some of the previously filed information to the extent that it is pertinent to the subject of this hearing.

SC&A is a small business providing professional services in the radiation sciences. The majority of our work over the past 25 years has been for government clients, including the Environmental Protection Agency, Nuclear Regulatory Commission, Centers for Disease Control and Prevention, and the Defense Nuclear Facilities Safety Board. Under a contract with the National Institute of Occupational Safety and Health (NIOSH), SC&A has been the technical support contractor to the Advisory Board since October 14, 2003. SC&A's role under this contract is to provide technical assistance to the Board in fulfilling its mandate under EEOICPA, which has

amongst its charges the task of reviewing a reasonable sample of dose reconstructions for scientific validity and quality, assessing the methods and procedures for dose reconstruction, reviewing Special Exposure Cohort (SEC) petitions, and advising the Secretary of Health and Human Services (HHS) in these matters. I am the SC&A project manager. I have a PhD in health physics, am certified by the American Board of Health Physics, and have over 30 years professional experience in the field of radiation protection.

My statement today is divided into two parts. The first part presents SC&A's perspectives regarding emerging technical issues pertaining to the review of SEC petitions and NIOSH's evaluation reports of SEC petitions. The second part presents SC&A responses to issues raised at previous hearings pertaining to SC&A's role in support of the Advisory Board and allegations regarding any possible SC&A conflicts of interest.

Emerging Technical Issues Pertaining to SEC Petitions

At the March 1, 2006 hearing, SC&A described the following scope of services for the Advisory Board with respect to SEC petition reviews that were authorized at that time: (1) prepare a report that presents a review of the procedures developed by NIOSH for use in evaluating SEC petitions, (2) prepare procedures to be used by SC&A and the Advisory Board for reviewing SEC petitions and/or SEC evaluations prepared by NIOSH, (3) review the Ames Laboratory SEC petition, and (4) perform focused reviews of Board-selected issues related to the Y-12 and Rocky Flats SEC petitions. We were also directed to provide technical support to the Board on the Mallinckrodt and Iowa Army Ammunition Plant SEC petitions by evaluating the relevance of certain issues raised in the site-profile review process to determining the feasibility of dose reconstruction under the SEC regulation (42 CFR Part 83).

With the exception of our review of the Rocky Flats SEC petition and NIOSH's evaluation of that petition, the above-described SEC-related services have been completed. In addition, since that time, SC&A was directed by the Advisory Board to perform additional SEC-related investigations. The additional services include a review of the Chapman Valve SEC petition and NIOSH's evaluation of that petition, and the so-called "250 work-day investigations." The scope of work regarding the former is self-explanatory, but the latter requires some explanation. The 250 work-day investigation specifically addresses technical issues related to whether the Special Exposure Cohort status that was granted to the Nevada Test Site, Pacific Proving Grounds, and Iowa Laboratory petitioners should be expanded to include members of the cohort who worked at these facilities for less than 250 days. These investigations are currently underway.

We have been requested by the Subcommittee to address "emerging SEC-related issues" that have surfaced in the conduct of the SEC-related work we have performed to date. The following briefly responds to this request. These issues have emerged during the performance of our SEC-related investigations, and we believe that they have broader applicability to the review of SEC petitions in general.

1. Issue No. 1: Boundaries on the "maximizing" approach for determining whether radiation doses can be estimated with sufficient accuracy

Part 83.13 (c)(1) of Title 42 of the Code of Federal Regulations states that:

> *Radiation doses can be estimated with sufficient accuracy if NIOSH has established that it has access to sufficient information to estimate the maximum radiation dose, for every type of cancer for which radiation doses are reconstructed, that could have been incurred in plausible circumstances by any member of the class, or if NIOSH has established that it has access to sufficient information to estimate the radiation doses of members of the class more precisely than an estimate of the maximum radiation dose [42CFR83.13(c)(1)] .*

In support of the Advisory Board with respect to the Iowa Army Ammunition Plant (IAAP) SEC petition, SC&A found that a large portion of the data required to evaluate whether doses could be reconstructed with "sufficient accuracy" involved the review of classified data pertaining to the radiation fields in the vicinity of nuclear weapon warheads. Because of the classified nature of some of the data required to reconstruct the doses to some members of the cohort, NIOSH developed a dose reconstruction strategy for the early period of IAAP operation up to and including 1962, that employed highly conservative "upper bound" estimates that were, in the main, not based on measurements but on a hypothetical "generic pit." This "generic pit" did not correspond to any real device, but was a paper artifact constructed to ensure that the estimated doses would be higher than those actually experienced by workers. However, our investigations revealed that the use of this "work around" for dealing with classified data led to the introduction of upper-bound estimates that were about ten times higher than those estimated for workers who did the same or similar type of work at the same facility during or after 1963, when the restriction on classification of data no longer applied. This appeared to be arbitrary and inequitable to the later workers, since there was a real possibility that they would be denied compensation for the same type of work for which the earlier period workers, up to 1962, would receive compensation. This situation arose purely from the approach adopted to protect classified data and was not related to working conditions. Furthermore, since there were no radon data for the IAAP for the structures in which nuclear weapons were assembled, radon data from Pantex, situated at a low radon area, were applied. SC&A questioned whether such strategies to reconstruct doses met the intent of the criteria of "sufficient accuracy" and whether it was appropriate to apply such bounding approaches to some workers but not to others who might have performed similar job functions. At what point does advancing maximizing assumptions stretch technical plausibility to levels that are inappropriate?

The generic SEC-related issue that emerged from these investigations can be stated as follows:

> ***The use of maximizing assumptions for classified information should be consistent with maximizing assumptions used for other workers.***

2. Issue No. 2: Constraints placed on the independent technical review of an SEC petition due to the classified nature of some of the records required for dose reconstruction

SC&A was directed by the Advisory Board to review the IAAP SEC on an accelerated schedule with much of the scope of the review pre-established. Such expedited reviews were certainly within the scope of SC&A services. However, they do have certain drawbacks that need to be appreciated. Specifically, SC&A was not provided the opportunity to conduct an independent records' review and retrieval, particularly for the available classified information. Instead, NIOSH arranged a DOE briefing with NIOSH-collected documents present for restricted onsite review. All notes taken had to be submitted for DOE classification review and clearance before they could be used in SC&A's report to the Board. In the meantime, no communication was permitted between the cleared members of SC&A team for IAAP and non-cleared members, necessitating two separate reports. Some of these restrictions are recognized as necessary for national security, but they could result in reviews that are not as thorough as might be needed to support decision-making.

The generic SEC-related issue that emerged from these investigations can be stated as follows:

> ***Is there a procedure that could be developed to better allow integration of classified information?***

3. Issue No. 3: Access to data and records

SC&A's evaluation of the "completeness" and "adequacy" of a site's radiation dose records to validate NIOSH's basis for denial rests substantially on SC&A's ability to access those records upon which NIOSH is basing its conclusion, and to cross-compare petitioners' allegations of exposure with this record. Even if full access is granted, SC&A believes that there are some technical issues that require SC&A to access original DOE records that are not necessarily part of the NIOSH database. Under new policies recently implemented by NIOSH to protect Privacy Act records, constraints have been placed on SC&A's access to claimant records. Since this is a recent policy change, it is difficult to judge at this time the magnitude of the impacts the new policy will have on our ability to complete our investigations in a timely manner. However, to date, the new access restrictions have hampered SC&A's work on the Rocky Flats SEC petition and its investigation of the issues relating to the addition of Nevada Test Site workers with less than 250 days of employment in the 1951–1962 period to the Special Exposure Cohort. It has also hampered other non-SEC-related work. As of today, we understand that NIIOSH is re-evaluating this data access issue.

The generic SEC-related issue that emerged from these investigations can be stated as follows:

> ***In order to fulfill its contractual obligations to the Advisory Board, SC&A must have unfettered access to not only NIOSH's database upon which dose reconstructions are based, but also access to DOE records that may not be part of NIOSH's database. Of course, where classified data are concerned, SC&A assigns personnel with the appropriate level of clearances to access those***

documents, and all material must be managed under approved Privacy Act controls, as applicable.

4. Issue No. 4: Data integrity issue resolution

A major issue raised by Rocky Flats SEC petitioners is the reliability of the database upon which dose reconstructions are based, including the possibility of fraudulent record keeping and the deliberate destruction of records. We refer to this as the "data integrity issue." Decisions regarding a given SEC petition cannot be made until a determination can be made regarding the integrity of the data. At present, no guidance exists regarding the process by which data integrity can be judged, nor the criteria to be used when sufficient evidence exists that data integrity issues may be so pervasive as to prevent the Board from making a determination that doses can be reconstructed with "sufficient accuracy." A conclusion of systemic problems with the records (as opposed to isolated, individual ones) is only likely with a "smoking gun" memo, record, or other incontrovertible piece of evidence. There is also a complementary issue of data completeness. There are sometimes gaps in dose records and in databases of varying degrees. The significance of these gaps varies, depending on their extent and the nature of the complementary data available to fill the gaps. This issue is linked to the question of whether available records are adequate for dose reconstruction. For instance, the investigation of the external dose data completeness and adequacy at Y-12 was lengthy because NIOSH asserted that the monitored employees were the ones at highest risk of exposure, while the SC&A analysis indicated that that was sometimes not the case in some time periods relevant to the SEC.

Under these circumstances, the workers collectively can file affidavits and show considerable circumstantial evidence regarding data integrity and completeness issues, but be ultimately denied compensation because there may be hypothetical explanations that can be used to dismiss the allegations. There may exist analytical methods and decision criteria that can be developed to help make data integrity and completeness judgments, but they have not yet been developed.

The generic SEC-related issue that emerged from these investigations can be stated as follows:

While the "integrity" of dose data is a fundamental basis for judging an SEC, there is no guidance or threshold criteria for judging how documented instances of fraud or error rise to an overall systemic concern. Further, the petitioners have no or limited access to the NIOSH and DOE records that would enable them to develop evidence of a systemic problem. Further confounding the ability to judge data integrity are limitations on the ability of the Board and its contractors to gain timely access to NIOSH and DOE records, including claimant records that have and have not been adjudicated. The issue of data completeness and adequacy as well as verification of databases has also emerged as a significant one. In the absence of agreed criteria for determining data integrity, adequacy and completeness, the investigation of these issues can become rather prolonged.

Responses to Issues Raised Regarding SC&A at Previous Subcommittee Hearings

During the March 1, 2006 hearing, Mr. Shelby Hallmark, Director, Office of Workers Compensation Programs, U.S. Department of Labor, responded to post-hearing questions from the Honorable John N. Hostettler. Chairman Hostettler asked the following question, "What is the definition of "balance" as referred to in the OMB document in your opinion? Do you think there is a problem with the audit contractor employees because of conflicts of interest or bias? If so, how do you see that as negatively affecting the claims process?"

Mr. Hallmark responded as follows:

> *It would not be appropriate to comment on internal deliberations involved in the development of the President's budget. However, as I testified on March 1, 2006, in my view, the process whereby the SC&A contract staff have critiqued NIOSH's dose reconstruction, site profiles, and SEC petition evaluations appears to have exceeded the statutory mandate to the Board, which is to evaluate the scientific validity and accuracy of NIOSH's work. SC&A representations before the Board have instead focused almost exclusively on whether or not the assumptions utilized by NIOSH in a given context could have been even more "claimant favorable" – that is, whether there might be assumptions or statistical techniques that would even further overestimate the dose to which a worker or group or workers were exposed. This has meant that the contractor (and subsequently the Board) has spent little time focusing on whether NIOSH's assumptions are plausible, realistic, valid, and sufficiently accurate for compensation determinations, and almost all their time considering whether there might be some possibility that the exposure could have been even greater that estimated.*
>
> *The issue of the contractor's potential conflict of interest was also addressed in my testimony on March 1. Since that time, SC&A's specific conflict of interest with respect to the Pacific Proving Ground and the Nevada Test Site has been noted by the Advisory Board, and I believe SC&A has been recused from involvement at those sites. I understand that individual employees of SC&A may also have potential conflicts at various sites, either due to former employment with DOE or the U.S. Government. Individuals who are currently employed as advisors to plaintiffs in such suits would have a vested interest in magnifying exposures and the potential for health endangerment at those sites. Such conflicts of interest need not distort the findings of the program if they are fully reported with respect to previous work for DOE or DOE contractors and employment with plaintiff groups, if appropriate recusal actions are taken, and if the Board and the support contractor apply the statutory criteria ("scientifically valid and accurate") in evaluating NIOSH's activities.*

This statement and several other statements made by Mr. Hallmark at the March 1, 2006 hearing raise questions regarding SC&A's ability to provide unbiased technical support to the Advisory Board. SC&A would like to take this opportunity to rebut these statements.

I would like to begin by repeating some of the material I provided in my March 1, 2006 statement that has applicability here, as follows.

All tasks under this contract are performed in accordance with Federal acquisition regulations and protocols mandated by the Federal Advisory Committee Act (FACA). In summary, the Board, in open session, identifies tasks that they would like SC&A to perform, and that are within SC&A's contractual statement of work. The NIOSH Designated Federal Official, who currently also serves as the NIOSH Project Officer for this contract, and the NIOSH Contracting Officer participate in this process. Once the Board agrees on the scope of a given task order, the Board, in cooperation with the NIOSH Project Officer and Contracting Officer, issues a Task Order Request for Proposal (TORP). In response to the TORP, SC&A prepares a proposal of work, which includes the task order scope of work, a budget, schedule, technical approach, and assigned personnel. The Board and the NIOSH Contracting Officer review SC&A's proposal, provide any comments or additional direction to SC&A, and SC&A submits a revised proposal, as required. During open session, the Board approves the proposal of work and work begins.

Before work on a task order can begin, SC&A is required to submit a quality assurance plan and a conflict of interest plan to implement controls over documents as needed in order to meet the requirements of the Privacy Act, and to prepare written technical procedures that must be reviewed and approved by the Board in open session. The procedures that SC&A has prepared to date flow directly from the Act and the regulations that implement the Act, namely 42 CFR Part 82, which deals with dose reconstructions, and 42 CFR Part 83, which deals with SEC petitions. Hence, everything we do is designed to assess the degree to which NIOSH work products under the Act meet the letter and intent of the Act and its implementing regulations. I would like to refer the Committee to a statement placed on the record by Dr. Sanford Cohen, President and CEO of SC&A, Inc. at the March 1, 2006 meeting. In that statement, Dr. Cohen testified that, " SC&A has never performed work on behalf of workers claiming benefits under the EEOICPA." However, Mr. Hallmark's statements might pertain to work SC&A performed under contract to the People of the Republic of the Marshall Islands, where SC&A, including Dr. Hans Behling and I, provided testimony on behalf of the people of the northern atolls of the Marshall Islands seeking compensation from the government of the Republic of the Marshall Islands. This work does not constitute a conflict of interest under our contract with NIOSH or under our conflict of interest plan.

Our conflict of interest plan, which has been approved by NIOSH and the Advisory Board has only two "bright lines." The first is that no individual who has ever defended the Government against a claim can work on this project. The second is that neither SC&A nor any of its subcontractors can work on this project at the same time that they are under contract with NIOSH or any of its subcontractors on the EEOICPA program. We are also required to disclose work that any of our personnel or contractors ever performed for DOE. Individuals that have worked at a given DOE site cannot serve as the lead investigator for investigations pertaining to

that site. SC&A maintains a web site where everyone working on this project is required to provide a signed disclosure statement.

In addition, SC&A has recently installed a "firewall" to prevent conflicts of interest between this work that we are performing for NIOSH and other dose reconstruction work that the firm is performing for DTRA. The provisions of our conflict of interest plan are rigorously maintained by our conflict of interest project officer, Dr. Steven Ostrow. Dr. Ostrow diligently ensures that all personnel adhere to the conflict of interest plan by training new personnel on the implementation of the plan and verifying that monthly billings are in accord with the plan. If Mr. Hallmark is aware of any deviations from these requirements, we will take this very seriously and take corrective actions as necessary.

By the nature of his statements, we believe that Mr. Hallmark may be concerned with the fact that Dr. Makhijani has in the past provided expert testimony for workers (in one lawsuit in the 1990s) or for neighbors of some nuclear weapons' facilities. Such activities do not constitute a conflict of interest under the terms of our conflict of interest plan which explicitly follow the requirements set forth in the original NIOSH solicitation and which has been approved by NIOSH and the Advisory Board.

SC&A has conflict of interest criteria defined by its contract that were put in place by NIOSH and the Board. Serving as an expert witness on behalf of plaintiffs against the DOE is not part of the conflict of interest criteria set by the Board. Moreover, SC&A goes beyond formal conflict of interest requirements that we must fulfill in assuring the scientific validity and objectivity of our reports. We have senior staff members and associates who are exceptionally well qualified and are among the world leaders in their fields. Their backgrounds are varied and range from work in the nuclear industry to work in the public interest sector to contracting with government. Many serve or have served in expert capacities on advisory committees and on bodies such as the International Commission on Radiological Protection and the International Atomic Energy Agency. SC&A's review procedures ensure that findings are reviewed independently of the authors of the report. I have complete confidence in the scientific integrity of our process. As for SC&A team members having served as plaintiff experts, SC&A is aware of this. We are also aware of work in industry or the Department of Energy by other team members. It is a strength of our team in that its members are all committed to scientific integrity of our work and come from varying backgrounds and experience.

Finally, Mr. Hallmark believes that SC&A's audit findings consistently find that NIOSH's dose reconstructions underestimate doses. Mr. Hallmark is not correct in this belief. As part of our audit services, SC&A maintains a relational database that allows the user to prepare summary statistics that characterize the various SC&A audit report findings. One such audit report was prepared on February 28, 2006. (This report can certainly be updated if so requested by the Board.) At that time, SC&A had completed the audits and issue resolution discussions with NIOSH for 60 dose reconstruction cases selected by the Advisory Board. We evaluated these 60 case reviews to assess whether the associated findings were considered by SC&A to have resulted in (1) an underestimate of the NIOSH-derived dose, (2) an overestimate of the NIOSH-derived dose, or (3) no consequential effect on the dose. The results of this evaluation are summarized in the following table.

	Number of Findings			Total Findings
	Underestimated Dose	Overestimated Dose	No Effect on Dose	
1st Set of 20 Cases	40	21	10	71
2nd Set of 18 Cases	29	36	48	113
3rd Set of 22 Cases	33	27	5	65
Total	102 (41%)	84 (34%)	63 (25%)	249

Note that as of February 28, 2006, we completed our audits of 60 cases and believe that the distribution of the findings is relatively balanced and what might be expected for this type of review.

Mr. HOSTETTLER. Mrs. Bates.

TESTIMONY OF KATHY BATES, SURVIVING CLAIMANT UNDER THE ENERGY EMPLOYEES OCCUPATIONAL ILLNESS COMPENSATION PROGRAM ACT

Ms. BATES. I would like to thank Chairman Hostettler and Ranking Member Jackson Lee for inviting me to testify today. My name is Kathy Bates, and I am representing my mother Mildred Gore, my brothers James and Gregory Gore and myself with respect to our EEOICPA claim under subtitle B for my father, James Gore.

My father worked at Y-12 in Oak Ridge, Tennessee as a production engineer in nuclear weapons fabrication from August 1988 to October 1994. He was diagnosed with basal cell carcinoma in July 1992. He was diagnosed with ocular melanoma in July 1997 and died in April 2001.

My testimony briefly summarizes our experience with the claims process and the apparent lack of quality control in NIOSH and DOL. My mother filed a survivor claim in January 2003. In July 2005, she received a draft dose reconstruction from NIOSH and a recommended decision from DOL in November 2005 stating the claim was denied. Both the draft reconstruction and DOL's recommended decision contained significant errors. The first major errors that the draft dose reconstruction stated that there were no records of monitoring for my father and no information relating to his job title, job responsibilities or locations where he worked.

My mother told NIOSH that he was a monitored employee but this was given no credit. Nonetheless, he was assigned a dose based on NIOSH's assumption that he was not regularly monitored.

The second major error which I identified for NIOSH in February 2006 is that NIOSH mistyped my father's Social Security number when they requested records from DOE. As a result DOE, found no records for my father. The third major error is that the recommended decisions stated "the probability of causation for the primary colon cancer was determined to be 25 percent." Ny father did not have colon cancer nor was he diagnosed with colon cancer.

We filed an appeal with DOL in January 2006 based upon the fact that NIOSH stated they had no records or information for my father, and thus any dose estimate would have been in error. I spoke at the Advisory Board public session in January 2006. At that meeting, we were pleased to meet senior administrators from DOL NIOSH and ORAU who gave us their personal assurances that these problems would be corrected. This level of attention certainly exceeded our expectations.

In June of 2006, we received a letter from DOL stating our appeal was approved. I had filed a Freedom of Information Act to DOE and did obtain records for my father, including his radiation exposure records, which I e-mailed to NIOSH in August 2006. I also provided contact information on co-workers and identified the building he worked in.

I obtained an e-mail acknowledgement of receipt and NIOSH indicated they would put this information into the administrative file. I thought the problem was on track and it would be fixed.

On November 22nd 2006, we received the second draft dose reconstruction from NIOSH. The report stated there were no radiation exposure records for my father end quote, Mr. Gore's work location is not known. NIOSH's dose reconstruction report stated "external electron radiation not considered in this dose reconstruction because Mr. Gore did not work directly with radioactive materials and any external doses would have been attributable primarily to photons."

Despite sending NIOSH's radiation exposure records, NIOSH continued to contend that he did not work directly with radioactive materials. The net result of course is that his dose reconstruction is not correct again. To quote my mother, "it is as if your father never existed."

I do not know if NIOSH is going to immediately address these problems and start their dose reconstruction for the third time. Even if a dose reconstruction is completed for my father using the records available, I can honestly say at this point that we have little or no faith in the validity of the results.

Is our claim experience an aberration or are there real and systemic problems with the EEOICPA claims process that may have resulted in the unwarranted denial of other claims? We hope this Subcommittee will continue its oversight and enact legislative reforms such as those in Representative Jackson Lee's bill.

In this context, we have several recommendations. We urge you to extend the responsibility for the DOL's office of the ombudsman to include subtitle B and authorize the ombudsman to act as an advocate on behalf of claimants seeking benefits. The Special Exposure Cohort provision should continue to receive the highest level of attention. For many claimants, the SEC process may be the only hope of receiving a fair assessment. We recommend that the role of the Advisory Board should be extended to execution of the claims process itself. At present, it does not appear that there is an external organization not controlled by the agencies which is responsible for overall administrative and claimant process audits.

I hope that my testimony today will be of value. We mourn the loss of my father every day. We were blessed to have such an extraordinary man as our father. We are proud of his service to our country as a U.S. Navy veteran and of his service, however small, in ensuring the safety and security of the United States of America as a DOE employee for so many years. On behalf of my family and myself, I thank you again for your efforts to support key improvements in this program and allowing me to testify here today. Thank you.

Mr. HOSTETTLER. Thank you Mrs. Bates.

[The prepared statement of Kathy Bates follows:]

PREPARED STATEMENT OF KATHY BATES

Testimony of Kathy Bates

before the

Subcommittee on Immigration, Border Security and Claims

Committee on the Judiciary

U.S. House of Representatives

"The Energy Employees Occupational Illness Compensation Program Act – Are We Fulfilling The Promise We Made to These Veterans of the Cold War When We Created the Program?"

November 15, 2006

Kathy Bates
1023 Glensprings Drive
Knoxville, Tennessee 37922
865-531-0885
kathy.bates@webtechteam.com

I would like to thank Chairman Hostettler, the Honorable Sheila Jackson-Lee, and members of the subcommittee for permitting me to testify here today. My name is Kathy Bates and I am representing my mother Mildred Gore, my brothers James and Gregory Gore, and myself with respect to our EEOICPA claim under Subtitle B for my father, James Gore. My father worked as a production engineer at the Y-12 facility in Oak Ridge, Tennessee from August 1968 to October 1994. He was diagnosed with a basil cell carcinoma (BCC) on his face in July 1992. He was diagnosed with ocular melanoma in July 1997, and died in April 2001 from the melanoma which had metastasized to the liver.

As claimants, we are the direct recipients of the output of the EEOICPA program. My testimony today is intended to communicate our frustration with this process and the serious issues with the claims process that we believe, through personal experience, appear to be prevalent. I would also like to comment on the bill Representative Jackson-Lee has introduced, the Energy Employees Occupational Illness Compensation Improvement Act of 2006.

Through hundreds of hours of personal research, I have educated myself on the EEOICPA program and the 42 Code of Federal Regulations (CFR) Part 82 and 42 CFR Part 81 documents that govern the program and its processes. I have read thousands of pages of technical documents, reports, presentations, meeting proceedings, public comment, and testimony from this subcommittee. To the extent that I understand the program and the process created to develop dose reconstructions for claimants, I must say that it is overwhelming. To the average person, I would conclude that it is incomprehensible.

Recently, the focus of this subcommittee appears to be on a variety of very critical issues related to the EEOICPA program, including: the OMB pass back memo which apparently recommends reduction in benefits to claimants associated with Special Exposure Cohort (SEC) classes, changes in the Advisory Board members, perceived issues with respect to the Advisory Board's auditing consultant, Sanford, Cohen and Associates (SC&A), and resolution of conflict of interest

issues across all parties, amongst others. We ask you to consider adding quality control with respect to the claims process to your list of concerns.

We have grave concerns regarding the apparent lack of quality control and assurance that is applied to the processing of claims. Specifically, given our particular case, we have to wonder if there is any quality control at all. In this written statement submitted for the record, I have outlined the problems and errors that occurred with our claim.

My mother filed a claim for my father in January 2003. On or about July 1, 2005, she received the NIOSH Draft Dose Reconstruction. The fact that this report was not for my father – but for a security guard in Paducah, KY – was the first red flag. My mother immediately contacted the NIOSH case worker via telephone and informed him that she had received the wrong report. The case worker told her to "throw away" the incorrect report and that the correct report would be sent in the mail. Within a short time after receiving the incorrect report, a case worker called my mother to conduct the closing interview. Even though she stated she did not have the Draft Dose Reconstruction for James Gore, the interviewer continued with the closing interview. This is in clear violation of 42 CFR 82.10(l).

On July 29, she did receive a Draft Dose Reconstruction from NIOSH for James Gore. She also received a follow-up telephone call from a NIOSH case worker to verify that she had in fact received the Draft Dose Reconstruction Report. During this call, her comment was "I can't understand how he worked there for 26 years, wore a dosimetry badge every day, and there are no records." The NIOSH case work answered, in essence, "that happens."

The Draft Dose Reconstruction Report did not contain or reference all of the information she had provided via telephone communications with NIOSH, including the initial telephone interview which occurred on December 4, 2003. There is no evidence in the Draft Dose Reconstruction Report that NIOSH made any attempt, as described in various sections of 42 CFR 82, to develop a reasonable estimate of Mr. Gore's potential radiation dose in the event that records may be missing or inadequate or to initiated an SEC petition under Section 83.14..

- NIOSH states that DOE did not provide any records of external monitoring. NIOSH did not accept my mother's information that my father routinely wore a dosimetry badge, yet considered him an "unmonitored" (and minimally exposed) employee as the basis of the dose reconstruction.
- It is not apparent that NIOSH received any information from any source other than me regarding his job history with respect to positions he may have held over his 26 year career at Y-12. NIOSH did accept my mother's information that my father was a "weapons production supervisor" and assumed, apparently, that this was his position for his entire 26 year career even though information was provided that he held at least one other position towards the end of his career by her in the initial telephone interview.
- NIOSH stated that "*Mr. Gore's work location is unknown*." It is not apparent that NIOSH received any information from any other source regarding his job history with respect to work location(s) including site names(s), building numbers(s), technical area(s), and duration of relevant employment or tasks for any period of his employment.

- There is no indication in the Draft Dose Reconstruction Report that my mother provided the name of at least one co-worker, his supervisor, Mr. K. O. Pearson. There is no evidence in the Draft Dose Reconstruction Report that NIOSH made any attempt to contact this individual to confirm or refute her information or to even to provide supplemental information regarding Mr. Gore's employment history. Unfortunately, Mr. Pearson died in 2005.
- There is no indication in the Draft Dose Reconstruction Report that she provided any information regarding biological radiation-monitoring programs that Mr. Gore may have participated in during his years of employment. While she did initially answer "no" to this question during the initial telephone interview, she subsequently called NIOSH to inform them that Mr. Gore was subjected to at least one a 24-hour urinalysis test sometime in the mid to late 1970's that she could recall. Since a 24-hour urinalysis is something that would have had a portion of it conducted at home, she did observe this event.

In the original Draft Dose Reconstruction from NIOSH dated July 29, 2005, it was stated:

- *"Records received from the Department of Energy were reviewed, and it was indicated that* ***Mr. Gore was not monitored for radiation exposure****."*
- *"****Since no monitoring records were available****, the maximum 50th percentile dose for each given year of employment from Oak Ridge National Laboratory, Oak Ridge Gaseous Diffusion Plant, Hanford Site, Paducah Gaseous Diffusion Plant, Savannah River Site, and Portsmouth Gaseous Diffusion Plant* ***was assigned as an unmonitored dose for Mr. Gore****.*
- *"The record of the telephone interview was evaluated carefully by the dose reconstructor. No radiological incidents were documented in either the telephone interview summary or the records provided by the Department of Energy. However,* ***the telephone interview indicated that Mr. Gore was routinely monitored****, but since no external monitoring data were present in the records supplied by the Department of Energy, complex wide co-worker dose was assigned."*
- *"****The majority of Mr. Gore's radiation exposure was received during employment as a weapons production supervisor according to the information provided in the interview process****."*
- *"As a weapons production supervisor (engineer),* ***Mr. Gore's work location is not known****. In this capacity, he would have likely been exposed to photon and electron radiation, even though no monitoring records were found. However, due to the possibility of lost records or unmonitored occupational dose, external dose was assigned based on the maximum 50th percentile complex wide co-worker dose for the given years of employment.* ***External electron radiation was not considered in this dose reconstruction because Mr. Gore did not work directly with radioactive materials****, and any external doses would have been attributable primarily to photons. For the purposes of estimating probability of causation, all photon doses are assumed to be accurate."*

To quote the some of the applicable guidelines for dose reconstruction, in brief:

42 CFR 82.2 What are the basics of dose reconstruction? *The basic principle of dose reconstruction is to characterize the radiation environments to which workers were exposed and to then place each worker in time and space within this exposure environment. Then methods are applied to translate exposure to radiation into quantified radiation doses at the specific organs or*

tissues relevant to the types of cancer occurring among the workers. A hierarchy of methods is used in a dose reconstruction, depending on the nature of the exposure conditions and the type, quality, and completeness of data available to characterize the environment. (a) If found to be complete and adequate, individual worker monitoring data, such as dosimeter readings and bioassay sample results, are given the highest priority in assessing exposure. These monitoring data are interpreted using additional data characterizing the workplace radiation exposures. If radiation exposures in the workplace environment cannot be fully characterized based on available data, default values based on reasonable and scientific assumptions may be used as substitutes. For dose reconstructions conducted in occupational illness compensation programs, this practice may include use of assumptions that represent the worst case conditions. For example, if the solubility classification of an inhaled material can not be determined, the dose reconstruction would use the classification that results in the largest dose to the organ or tissue relevant to the cancer and that is possible given existing knowledge of the material and process. ***(b) If individual monitoring data are not available or adequate, dose reconstructions may use monitoring results for groups of workers with comparable activities and relationships to the radiation environment.*** *Alternatively, workplace area monitoring data may be used to estimate the dose. As with individual worker monitoring data, workplace exposure characteristics are used in combination with workplace monitoring data to estimate dose.* ***(c) If neither adequate worker nor workplace monitoring data are available, the dose reconstruction may rely substantially on process description information to analytically develop an exposure model.*** *For internal exposures, this model includes such factors as the quantity and composition of the radioactive substance (the source term), the chemical form, particle size distribution, the level of containment, and the likelihood of dispersion.*

In addition to (1) no evidence of external monitoring records, (2) no description of job history (positions held year by year), (3) no information relating to work locations (site names(s), building numbers(s), technical area(s)), and (4) no information relating to duration of relevant employment or tasks for any period of Mr. Gore's employment, NIOSH also apparently did not have any other type of information that is considered to be relevant to the dose reconstruction. Specifically, NIOSH states that there were no records of bioassay results. They also imply that they have no "medical" records for Mr. Gore that may have been available from routine visits to the Y-12 infirmary for events like his annual physical which may have included X-rays.

How was NIOSH able to establish a Draft Dose Reconstruction for my father if they did not even have the most basic information such as job title and work locations? Why was he "just assigned" to the "50th percentile complex wide co-worker dose" as an "unmonitored employee" if in fact enough information did not exist to perform a "reasonable" dose reconstruction? What information existed…nothing more than the fact that he worked at Y-12?

Even though all of these questions were asked in the appeal, they have **never** been addressed with us the claimants, either verbally or in writing, by NIOSH, ORAU, or DOL

We received the DOL Recommended Decision dated November 17, 2005 which, in addition to repeating the same statements from the Draft Dose Reconstruction, concluded with:

> *"A copy of the case file along with a National Institute for Occupational Safety and Health (NIOSH) Referral Summary was forwarded to NIOSH for dose reconstruction on April 17,*

2003. On October 7, 2005, the district office received the "NIOSH Report of Dose Reconstruction under EEOICPA" dated July 28, 2005 which provided the estimate of dose to the primary right eye site. NIOSH estimated the annual dose totaling 18.842 rem to Mr. Gore. Based on this dose estimate, the calculation of probability of causation was completed using NIOSH-IREP, which is an interactive software program. ***The probability of causation for the primary colon cancer was determined to be 25.40%."***

My father did not have colon cancer nor was he ever diagnosed with colon cancer. This is a completely unacceptable error. This type of error causes grave concern regarding the quality control and quality assurance associated with this process.

We subsequently filed an appeal to the Recommended Decision with DOL on January 10, 2006, outlining, as required, *"...the specific finding of fact or conclusion of law with which you agree, including any objective to any dose reconstruction performed."* In our appeal, to the best of my ability, I outlined the specific findings with respect to CFR 42 Part 82 and CFR 42 Part 81 as appropriate.

On that same day, I filed a request under the Freedom of Information Act (FOIA) through the U.S. Department of Energy, Oak Ridge Operations, to disclose to me all records available pertaining to James Z. Gore's employment history including medical, personnel, radiation exposure, and industrial hygiene. I also submitted a request under the Freedom of Information Act (FOIA) to Larry J. Elliott, MSPH, CIH, Director, Office of Compensation Analysis and Support, to disclose to me all administrative records pertaining to EEOICPA Claim #12438 for James Z. Gore.

In the meantime, I started searching the internet for any type of advocacy groups for EEOIPCA claimants. After much fruitless searching, I resorted to reading the public comment that had been posted *prior* to the final guidance of CFR 42 Part 82 and CFR 42 Part 81. By searching the internet for e-mail addresses of people who had provided pubic commentary, I sent a number of e-mails to these individuals in hopes of a response regarding guidance on what to do next. I did receive a response that directed me to Richard Miller, who is a Senior Policy Advisor for the Government Accountability Project (GAP). While I do not think it is Richard's job to be an advocate for EEOICPA claimants, he graciously took the time to talk to me and tell me about various opportunities for escalation, including the public sessions held by the Advisory Board. Until I talked to Richard, I had no idea that any of this existed.

I then spoke at the Advisory Board public session held in Oak Ridge, TN on January 23, 2006. My mother and I were outraged and appalled at the apparent level of carelessness that seemed to be prevalent in this entire process, from start to finish, and I hoped that my testimony would at least create some level of visibility to these problems. At this session, I basically outlined our issues with the process and the denial of the claim. Amazingly, when I was preparing for this session, I happened to notice that the "file number" is supposed to be my father's social security number. In the NIOSH correspondence, I had assumed that it was correct, and so I assumed that it was incorrect on the DOL Recommended Decision. I posed a question as to the significance of this as part of my public session statement.

At that meeting, we were pleased to meet senior administrators from DOL, NIOSH, and ORAU. They were most sincere in their apologies with respect to how this could have happened, and we

had their *personal assurances* that these problems would be addressed and corrected. This level of attention certainly exceeded our expectations.

After the Advisory Board meeting, I had several e-mail correspondences with senior administrative officials from NIOSH. On 2/1/06, I sent an e-mail to NIOSH stating that the wrong SSN was on NIOSH's documentation. I received assurances that the SSN would be corrected. When I received the administrative records from NIOSH for my father's claim, I could see that in fact, they did have the correct SSN on a variety of documents, but at some point in time, a "3" had turned into an "8." Two records requests were submitted to DOE by NIOSH on 5/29/03 and 11/28/04 with the **wrong** SSN. As a result, DOE returned "no records" for my father. Further research based upon the administrative records I received from NIOSH via the FOIA request indicated that the Social Security number was correct on numerous documents in NIOSH's possession.

So my basic question is – if something as important as the SSN is the major key in retrieving records for any DOE employee – what are the quality controls and checks in place to ensure that this vital piece of information is correct?

In the interim, all of the correspondence between me and/or my mother was initiated by us, either via e-mail or phone calls. I did receive at least one phone call from NIOSH and one phone call from DOL as a "return call" to my inquiries. Other than that, we had no idea what the status of our claim was. In particular, the common answer from the DOL office in Jacksonville when I would call was that "it is going through the process." All of my e-mails to NIOSH were answered promptly, within 24 hours. However, until DOL returned the claim to NIOSH, there was not much NIOSH could do in terms of providing a status.

A letter from DOL dated June 8, 2006, stated that the appeal was approved, but the basis for the return of the claim to NIOSH was the fact that we had indicated my father was diagnosed with a basal cell carcinoma (which was not included as part of the first claim, mainly through our initial ignorance of the process), not the result of the errors that created the first incorrect dose reconstruction. As part of the appeal process, we had included the information that my father had been diagnosed with BCC, and we subsequently obtained the medical records related to this diagnosis and submitted them to DOL as per their request.

Regardless, we were pleased that the appeal was approved. Since at this time, the issue of the incorrect Social Security number for the DOE records search was known, at least to NIOSH, we had some degree of confidence that we would eventually receive a proper dose reconstruction. I did in fact receive a copy of my father's records that I had requested via a Freedom of Information Act request to DOE on 5/16/06, so, records did in fact exist. *"Enclosed are copies of Mr. Gore's medical records, chest x-rays, personnel records,* ***radiation exposure records*** *and personnel security file…"* I subsequently received his chest x-rays (films) from DOE and other records from the U.S. Office of Personnel Management Center for Federal Investigation Services.

I finally received an affirmative response from NIOSH on 8/21/06 in response to my e-mail inquiry if NIOSH had received the claim from DOL.

Subsequently, I spoke directly to a Claimant Contact at NIOSH on August 22, 2006, and verified that the DOE records included Radiation Exposure Records for my father, at least for dosimetry badge readings from 1968 through 1988. The Claimant Contact indicated that NIOSH had "not yet" received records from DOE and she asked me if I would mind sending her a copy of the Radiation Exposure Records. I immediately scanned and e-mailed all of the pages for these records to her, and she acknowledged the receipt of the files and indicated that she would forward to the appropriate parties as well as place this information in the administrative record. Again, I felt some degree of confidence that the process was working.

On November 2, 2006, I received the second Draft Dose Reconstruction from NIOSH. I had to read no further than page 5 to see that **the problem had not been resolved**.

Aside from my initial shock, I was even more confused. The Draft Dose Reconstruction dated October 27, 2006 (received November 2, 2006) stated that (quote) "**Records received from the Department of Energy were reviewed, and it was indicated that Mr. Gore was not monitored for radiation exposure."** (end quote) Further on the same page, the report stated (quote) **"Since no monitoring records were available for Mr. Gore, the maximum 50th percentile doses for each given year of employment from … (and it lists all the sites)… was assigned as an unmonitored dose for Mr. Gore in accordance with guidance…."** (end quote) And further, on the same page, the report stated (quote) **"As an engineer and weapons production supervisor (engineer), Mr. Gore's work location is not known."** (end quote)

My mother and I were stunned. This is the exact same wording from the original Draft Dose Reconstruction received July 29, 2005. To quote my mother: "it's as if your father never existed." Interestingly enough, the SSN on the fourth page, which is the cover page for the Draft Dose Reconstruction, **is correct**.

Not only did I personally have a copy of my father's DOE records, I had sent the Radiation Exposure Records directly to NIOSH. And, if you slog through all of the records, you can certainly find instances of my father's job title, job description, and building location over the years of his employment on various documents. So if you had the records and you actually went through them carefully, you could build a small history of his employment with respect to what job duties he may have performed based on his job title, the department he worked under, and the buildings where he worked.

Just from the medical records (appear to be routine visits to the Y-12 plant physician), I am able to discern, to some degree, his job locations and even his job titles over the years. For example:

- **7-19-78** Plant address = 9212 MS 1, supervisor = K. O. Pearson, job title = production engineer, division = Fabrication
- **11-11-76** Plant address = 9212, RM 54, supervisor = K. O. Pearson, job title = engineer III, division = Fabrication
- **11-22-74** = Plant address = 9212, supervisor = K. O. Pearson, job title = production engineer, division = Fabrication
- His starting position based upon his employment application in 1968 was "engineer."

I was able to develop this very crude type of job history through 1993.

That evening (11/2/06), I sent an e-mail that evening to two senior administrators at NIOSH and ORAU outlining the issues with the second dose reconstruction. I did receive phone calls from both NIOSH and ORAU early in the morning of November 3, 2006. At this time, I learned that, once again, it appeared that the NIOSH records request to DOE had been submitted with the wrong social security number. I assume, and have yet to verify, that NIOSH is going to immediately address this problem and start on the dose reconstruction for the *third time*. We are entering our *fifth year* of this process in January.

How could this have happened? I would have assumed that at a minimum, with the level of visibility we had received from senior administrators within NIOSH, ORAU, and DOL, that these problems would have resulted in corrective actions to ensure such errors could not occur again. The fact that they occurred again – on our specific claim given the level of visibility it had – is both outrageous and appalling.

Even if a dose reconstruction is completed for my father using the records that are available, I have to honestly say, at this point, that we have little or no faith in the validity of the results. Our case is, in my opinion, a stunning example of very significant errors that should have been identified and corrected prior to us ever receiving the output of the process – on both occasions to date.

We can only wonder how many claims have been processed with the same level of apparent negligence which may have resulted in a denial of the claim. How many claimants actually have the wherewithal to even be able to understand the Draft Dose Reconstruction or the Final Recommendation, much less understand enough to see that is may be wrong? My mother said to me, "if you had not read these documents and realized that they were wrong, I would have just tossed them in the garbage and been done with it." My mother is not an uneducated woman. She had a very successful career in the medical profession as both a nurse and administrator. If you have never actually seen or read one of these reports, I encourage you to do so, and try to imagine yourself as a claimant.

Our fundamental question is: is our claim experience an aberration, or are there real and systemic problems associated with the EEIOCPA claims process that could have resulted in the denial of other claims?

We hope this subcommittee will continue to work together to pass Representative Jackson-Lee's bill. In this context, we have several recommendations which reflect our opinion. While I cannot speak to all of the sections of the bill, there are several that we feel are of great importance to all claimants.

1. I urge you to support the extension of responsibilities for the DOL's Office of the Ombudsman to include Subtitle B, and expand its responsibilities to act as an advocate on behalf of claimants seeking benefits. From direct personal experience, I can assure you that this is an overwhelming and in some aspects, incomprehensible process. I would assume that many people just "give up" because they have no idea what to do or where to go for help. How many Denise Brock's are out there, taking up this cause and

dedicating enormous personal resources to help claimants? Establishing the Ombudsman for Subtitle B claimants would be a most welcome resource in support of the program.

2. The Special Exposure Cohort provision should be modified to facilitate entry into the SEC when records are missing or non-existent. There is extensive documentation that has been generated on the technical difficulties in recreating dose reconstructions for workers who were employed up to 60 years ago and as recent as 30 years ago and the fact that many records are missing or incomplete. For many claimants, the SEC process may be the only hope they have of receiving a fair assessment.
3. Our perception of the Advisory Board and its consultant is that it performs a critical function with respect to checks and balances. This is an incredibly complex process – both scientifically and administratively – and what we have seen (and read) of this Board is that they are trying to the best of their ability to ensure the integrity of the EEOICPA program in a variety of areas. The Board must be a neutral party and not be biased towards any agency or party involved in this process. To the extent that the reforms will enable the Advisory Board to successfully fulfill the intent of its mission, we encourage you to provide your support.
4. I would recommend that the role of the Advisory Board should extend to the execution of claims process itself. At present, it does not appear that there is an external organization not affiliated with the EEOICPA program that is responsible for overall administrative and claimant process audits. If appropriate, SC&A's responsibilities should be extended to this area. If not, the addition of a third-party auditor for this purpose should be considered.

I hope that my testimony today will be of value. We mourn the loss of my father every day. We were blessed to have such an extraordinary man as our father. We are proud of his service to our country as a U.S. Navy veteran and of his service, however small, in ensuring the safety and security of the United States of America as a DOE employee for so many years. On behalf of my family and myself, I thank you again for your efforts to support key improvements in this program and for allowing me to testify here today.

Mr. HOSTETTLER. Mr. Miller.

TESTIMONY OF RICHARD MILLER, SENIOR POLICY ANALYST GOVERNMENT ACCOUNTABILITY PROJECT

Mr. MILLER. Before I begin my testimony, I would like to just take an informal moment to offer a personal thank you to the Chairman and to the Ranking Member for your efforts this session of Congress to unmask the problems facing nuclear workers seeking justice from a Government that had put them in harm's way.

And Mr. Chairman, I realize that you will not be returning next year, but your willingness to pursue two additional oversight hearings in this lame-duck session of Congress is particularly noteworthy and it serves an important role in laying the groundwork, and I believe creating momentum for legislative reforms next year. And we genuinely thank you both.

Today my testimony will assess the Department of Labor's efforts to pursue initiatives that would reduce benefits to sick nuclear workers, particularly new Special Exposure Cohorts, two, to review the Administration's failure to constitute the Advisory Board on radiation and worker health in conformance with the law, and three, to highlight emerging issues that are threatening the integrity of the audit process.

At the Subcommittee's March 1 hearing regarding the OMB passback to DOL, a document which outlined five options for limiting Special Exposure Cohort, the Department of Labor's witness, Shelby Hallmark, stated, and I quote, "cost containment is not part of any strategy or involvement that the Department of Labor has had in this process." Excerpts of e-mails under preparation for the Office of Management and Budget to use in the passback, which were made available to me by the Subcommittee in preparing for this hearing state, "the single most effective way to prevent billions of dollars in spending is by requiring HHS to clear its determinations to add additional employees to the SEC, with the OMB, after an opportunity for interested agencies, such as the Department of Labor, to comment on the analysis and determination."

The Department of Labor has actively led lobbying efforts to reduce benefits paid out under NIOSH's Special Exposure Cohort regulations, with respect to Special Exposure Cohort bills covering facilities in Iowa, Missouri, New York and Colorado, Mr. Hallmark says in an e-mail, "we should do everything possible to oppose these SEC amendments." and his entire logic is budget driven without regard to the data deficiencies.

The Department of Labor has also disparaged the Advisory Board on Radiation and Worker Health. Excerpts of an e-mail state, and I quote, "the Advisory Board has totally failed to take a balanced approach to examining NIOSH activities." And an October 2005 memo under preparation for the Office of Management and Budget the Department of Labor recommended that the Advisory Board be "refreshed."

Excerpts from the e-mail state "we believe replacing these members could provide an opportunity to add board members willing and able to advocate a scientifically valid approach in carrying out NIOSH's responsibilities under EEOICPA." And given DOL's stated agenda, this appears to be a simple case of desiring to pack the

courts in order to oppose SEC designations all wrapped up in the pretext of scientific validity.

In sum, Mr. Hallmark's words in the March hearing, cost containment is not part of any strategy or involvement that the Department of Labor has had in its process are contradicted by documents uncovered by this Subcommittee.

More damaging is the DOL's loss of credibility as an impartial claims administrator. Austin Smythe, acting Deputy Director of OMB, testified before the Subcommittee on July 20, 2006, "we are not pursuing any of these items that were listed in the passback." It was inappropriately leaked. It has now been inappropriately characterized as Administration policy which it is not. And yet, despite Mr. Smythe's testimony, the OMB passback was put on the agenda for a joint NIOSH DOL meeting held in January 2006, months after the OMB passback was issued.

There were indications that Mr. Hallmark may have moved forward with a sequel to the OMB passback. Judiciary Committee notes from an early February 2006 e-mail communication from Shelby Hallmark to Melissa Benton at the Office of Management and Budget raises a red flag. An excerpt states "I am uncomfortable with even an unofficial sharing of my briefing piece for today's meeting with my second floor people," which is the Secretary of Labor. "but if you promise not to spread it and if you don't use the language in your document such that NIOSH will know where the verbiage came from, I will share it, but I am still smarting from your citation of your ideas in the budget passback as having been suggested by the employment standards Administration." and he asks, "is that agreeable?"

Well, we would urge the Subcommittee to secure this briefing paper and to ascertain its implementation status so we know what he was referring to.

The Department of Labor's benefits containment agenda has found its way into the day-to-day adjudication of claims. In October of 2005, the Department of Labor began sending certain compensable claims back to NIOSH, "based on increasing DOL management concern over a potential increase in compensable claims for cancers perceived as normally or previously not compensable."

The Director of the Department of Labor's final adjudication branch remanded cases back to DOL without ever telling claimants their cases were being second-guessed by DOL. In fact, one DOL e-mail says, when we send remand orders to claimants, I don't want them to know they are part of a "management plan."

To the extent there are errors, such as work history or incorrect cancer diagnoses that are within the ambit of the Labor Department's regulations, then DOL clearly has a role here. But an internal DOL e-mail by a health physicist concedes that NIOSH dose reconstructions have not been overestimating dose as Mr. Hallmark has contended. In fact, this DOL e-mail says, "now that I think about it, most of the dose reconstructions for the special cancers we are reviewing that resulted in a probability of over 50 percent are appropriately performed by NIOSH and no rework is required."

However, "the need for maintaining secrecy seems to be a concern." This DOE e-mail added "I hope no one is mentioning the fact that we took another look at these dose reconstructions and said

it was fine in the recommended or final decisions." But the concern is that documents show that the DOL's final adjudicative branch cooperated in advancing this management plan to reduce the payment of claims and thus they compromised their independence as an adjudicator.

There may be a need for legislative reforms to separate the adjudicative branch from control of program officials and OMB.

I notice my time is close to wrapping up. I just have one other point.

The OMB passback called for changing the membership of the President's Advisory Board on Radiation and Worker Health, which audits the scientific quality of dose reconstructions and reviews SEC petitions.

Today the composition of the board as the Chairman noted is not in compliance with EEOICPA, which requires a balance of scientific, medical and worker perspectives. There are only two of the four required worker slots, and only two of the four required medical slots.

The Board also lacks the balance and diversity of viewpoints that is called for under the Federal Advisory Committee Act, thus compromising its independence. We recommend that Congress enact legislation to shift the appointing authority from the President to Congress.

And on November 3, 2006, NIOSH compensation program director Larry Elliott—and this is just an emerging issue—unilaterally suspended all access by the Advisory Board and its audit contractor to the claimant database.

As of November 13th—2 days before this hearing—the Advisory Board's access to the electronic database of records was reinstated—although the constraints are unknown. However, Mr. Elliott told the board that access of the claims filed by Sanford Cohen & Associates or any contract entity must be granted on a case-by-case basis with an established purpose as authorized by the manager of the system of records, which is Mr. Elliott. The board's audit contractor is now reduced to a mother-may-I situation where the entity is audited. Mr. Elliott's actions raise questions about the degree to which there is a conflict of roles.

In November 2004, Mr. Elliott was removed as the designated Federal official to the Advisory Board due to his conflict of roles as manager of both the dose reconstruction program and controlling the board.

The GAO's recent report to this Subcommittee warned NIOSH to be alert for a conflict of roles in managing the program, yet this conflict has resurfaced.

We recommend legislation to ensure that the Advisory Board and the audit contractor have full and unfettered access to all NIOSH files they deem necessary to carry out their responsibilities under that Act consistent with the Privacy Act. Thank you for your time.

Mr. HOSTETTLER. Thank you, Mr. Miller.

[The prepared statement of Richard Miller follows:]

PREPARED STATEMENT OF RICHARD D. MILLER

GOVERNMENT ACCOUNTABILITY PROJECT
NATIONAL OFFICE
1612 K STREET, NW SUITE #1100 • WASHINGTON, D.C. 20006
202.408.0034 • WWW.WHISTLEBLOWER.ORG

TESTIMONY OF RICHARD D. MILLER
SENIOR POLICY ANALYST
GOVERNMENT ACCOUNTABILITY PROJECT

BEFORE THE

COMMITTEE ON JUDICIARY
SUBCOMMITTEE ON IMMIGRATION, BORDER SECURITY & CLAIMS
U.S. HOUSE OF REPRESENTATIVES

THE ENERGY EMPLOYEES OCCUPATIONAL ILLNESS COMPENSATION PROGRAM ACT: ARE WE FULFILLING THE PROMISE WE MADE TO THESE VETERANS OF THE COLD WAR WHEN WE CREATED THE PROGRAM?
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OVERSIGHT HEARING #4

NOVEMBER 15, 2006

Summary of Testimony
Richard Miller, Senior Policy Analyst, Government Accountability Project

Congress enacted Special Exposure Cohort (SEC) provisions under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA), P.L. 106-398, to provide claimants with a presumption that their cancer was work related and should be compensated in cases where radiation exposure records were missing, incomplete or altered, or workers were not monitored for the radiation hazards to which they were exposed. Claimants may petition to be added to the SEC, if they can demonstrate that "it is not feasible to estimate radiation dose with sufficient accuracy."

The OMB's "Passback" to DOL for the FY 07 budget outlines 5 options to reduce the approval of SECs as a way to contain the growth in the cost of benefits under EEOICPA. The Passback calls for OMB clearance of SECs; changing the balance in the Advisory Board on Radiation and Worker Health (ABRWH); imposing constraints on the board's audit contractor; and securing additional external reviews of NIOSH work products.

DOL maintains that "cost containment is not part of any strategy or involvement that the Department of Labor has had in this process."

However, excerpts of documents provided by the House Judiciary Committee indicate that the Department of Labor (DOL) developed the specific mechanisms which were embodied in the OMB's Passback. DOL has criticized details of nearly all proposed SECs in an effort to reduce benefits, and sought to impose hurdles in the HHS regulations governing SEC petitions to make it more difficult to qualify.

DOL has injected its cost containment agenda into the dose reconstruction process as well. Starting in October 2005, DOL staff started culling out compensable dose reconstruction cases which involve "infrequently" compensated types of cancers, due to unexplained "management concerns." When compensable cases were found, DOL had its Final Adjudicative Branch remand cases back to NIOSH to be "reworked," but without explaining the rationale to claimants. The FAB lacks sufficient independence from DOL program officials, and reforms should be implemented.

The composition of the Advisory Board on Radiation and Worker Health is not in compliance with the requirements of EEOICPA, despite repeated efforts to secure Administration cooperation. EEOICPA requires a balance of medical, scientific and worker perspectives. At present this 12 member board has only 2 of 4 worker representatives and only 2 of 4 medical professionals. The Board is not balanced in perspectives, as required by the Federal Advisory Committee Act. Congress should amend EEOICPA to provide for Congress to appoint the Advisory Board members.

Beginning November 3, 2006, the Advisory Board's audit contractor has been cut off from access to files needed for audits by NIOSH program staff. Legislation is needed to ensure that Board and its contractor have full and unfettered access to this data needed for audits and SEC petition reviews.

I am Richard Miller, a Senior Policy Analyst with the Government Accountability Project ("GAP"), a non profit organization based in Washington, D.C. In addition to whistleblower advocacy, GAP's work includes the oversight of the three agencies implementing EEOICPA. GAP serves as an information hub for claimants, Congress, workers and the media. GAP assisted with the EEOICPA reform amendments which were included in the FY 05 Defense Authorization Act (P.L.108-375). Prior to working at GAP, I was a staff representative for DOE atomic weapons employees, and worked on the bi-partisan effort to enact EEOICPA[1] as part of the FY 01 Defense Authorization Act (P.L.106-398).

Today, my testimony will underscore new challenges facing the program since I last testified 8 months ago, and compare reality with the testimony provided to this Subcommittee by the Department of Labor (DOL) and the Office of Management and Budget (OMB) witnesses regarding the FY 2007 OMB Passback. The Passback outlined 5 options to constrain the number of new Special Exposure Cohorts (SEC) and otherwise limit benefit payments under the law. These options would circumvent the legal authorities assigned to both the Advisory Board on Radiation and Worker Health (ABRWH) and the Secretary of Health and Human Services (HHS), and deprive claimants of due process.

I. BACKGROUND ON THE REASON FOR SPECIAL EXPOSURE COHORTS IN THE EEOICPA

Congress included opportunities for claimants to petition to be members of the SEC to ensure that those workers employed in nuclear weapons factories who were unmonitored or inadequately monitored for occupational exposure to ionizing radiation would not face the insurmountable hurdle of establishing their radiation dose to prove their claim for cancer. Congress created this safety valve because there was ample evidence that radiation exposure records were missing, incomplete, unreliable or altered, and that many workers were not adequately monitored for the radiation hazards to which they were exposed.

If designated a member of the SEC, claimants with one of 22 specified cancers listed in EEOICPA and who worked at least 250 days during the covered time period for the SEC, are entitled to presumptive compensation of $150,000 lump sum plus prospective medical benefits for the covered illness. As members of the SEC, claimants would not require a radiation dose

[1] *See*: Testimony of Richard Miller before the Senate HELP Committee, Subcommittee on Employment, Safety & Training, May 15, 2000; the House Judiciary Committee, Subcommittee on Immigration & Claims (http://www.house.gov/judiciary/mill0921.htm) on September 21, 2000 and March 1, 2006; and the Senate Energy Committee, November 21, 2003 (S. Hrg. Report 108-334)

estimate to determine if their claim would qualify for compensation. Presumptive benefits are common in radiation compensation programs: claimants under the Radiation Exposure Compensation Act and the Atomic Veterans Act are presumptively eligible for listed cancers.

The process for adding new groups of workers to the SEC requires: (1) a NIOSH staff "Evaluation Report" and a recommendation for approval or denial, which is sent to the ABRWH, (2) an Advisory Board review of the NIOSH evaluation report in public, on-the-record proceedings, (3) a decision by the Secretary of HHS to approve or deny a petition, and (4) a 30-day "Congressional Notice and Review" the Secretary's final decision (pursuant to 42 U.S.C. 7384l(14)(C)(ii)). Denials by the Secretary of HHS may be appealed to a review panel established by the Secretary.

II. CBO Scoring on Administratively Added SECs

The Congressional Budget Office, when it scored EEOICPA in 2000, did not estimate a cost for designating additional SECs--beyond the initial 4 sites in Ohio, Kentucky, Tennessee and Alaska, which were mandated when EEOICPA was enacted in 2000. There was no basis for developing a cost estimate for the extent of missing records. To ensure budget and scientific control over unwarranted additions to the SEC, all SEC designations are transmitted to Congressional committees of jurisdiction, who can hold hearings or legislatively block such additional SEC designations.

During the Congressional "Notice and Review" process, DOL has never presented a case against a particular SEC, nor has it issued any public analyses of why the Advisory Board and the HHS Secretary are in error on any specific SEC designation. DOL's reputation for fairness has been tainted by its aggressive efforts to undermine a key element of EEOICPA outside of public view.

III. DOL Testimony Contradicted by Evidence of Quiet Campaign to Reduce EEOICPA Benefits

DOL publicly states that they do not have a vested interest in the outcome of any SEC Petition or the deliberations of the Advisory Board, but evidence shows that DOL has quietly gone to the Office of Management and Budget (OMB) with shrill warnings about adverse precedents set by SECs that were approved for Mallinckrodt Chemical (1949-1957) in Missouri and the Iowa Army Ammunition Plant in Burlington, Iowa. The Director of the DOL's Office of Worker Compensation Programs (OWCP) warned OMB that the precedent set by these

approvals were going to open the floodgates and projected that this will lead to a vast expansion of benefit costs "approaching $7 billion." This prediction has not panned out; new SECs constitute only about 10% of the claims approved to date.

Nonetheless, OMB responded positively. Excerpts of notes taken by the Judiciary Committee staff regarding an October 5, 2005 e-mail from OMB to the OWCP Director state:

> "Thanks Shelby, we share your concerns. If there are any programmatic reforms—legislative, administrative, regulatory, you name it—that we could potentially tee up for our policy officials, we're all ears. At this point, nothing should be ruled out. These would be OMB ideas, not DOL ideas. My bosses typically expect the identification of a problem to be accompanied by options to solve it. Legislation options are not first option, because they are hard to get enacted."

The resulting options subsequently outlined by DOL and transmitted to OMB were written into the FY 07 OMB "Passback" to the DOL. The Passback states:

- ***Energy Employees Occupational Illness Compensation Program Act (EEOICPA) Part B.*** *ESA[2] is to be commended for identifying the potential for a large expansion of EEOICPA Part B benefits through the designation of Special Exposure Cohorts (SEC). The Administration will convene a White House-led interagency work group including HHS and Energy to develop options for administrative procedures to contain growth in the cost of benefits provided by the program. Discussions are not limited to, but will involve, the following five options.*

    1. *Require Administration clearance of SEC determination[s];*
    2. *Address any imbalance in membership of President's Advisory Board on Radiation and Worker Health;*
    3. *Require an expedited review by outside experts of SEC recommendations by NIOSH;*
    4. *Require NIOSH to apply "conflict of interest" rules and constraints to the Advisory Board's contractor; and*
    5. *Require that NIOSH demonstrate that its site profiles and other dose reconstruction guidance are balance[d].*

IV. DOL DRAFTED OMB PASSBACK OPTIONS TO AS A WAY TO CONTAIN BENEFIT COSTS

In his March 1, 2006 testimony before this Subcommittee, Shelby Hallmark, OWCP Director, responded to questions from the Chair about the role of DOL in developing the OMB Passback:

[2] ESA is the Employment Standards Administration within the DOL. The Office of Workers' Compensation Programs (OWCP) which administers EEOICPA is part of ESA.

> "Well, Mr. Chairman, as I said, cost containment is not part of any strategy or involvement that the Department of Labor has had in this process."

When the Chair pressed the question of who developed the OMB Passback, Mr. Hallmark responded:

> "It wouldn't be appropriate for me to discussion the internal deliberations about budget, which are always out of the general discussion, but that's part of my role."

This Subcommittee's oversight appears to have resolved that question.

Mr. Hallmark's statement that DOL had no interest in cost containment is at odds with the excerpts of DOL e-mails and memos made available to me by the Judiciary Committee in preparing for this hearing. For example, notes taken by Judiciary Committee staff of a DOL memo apparently under preparation for OMB states:

- "The single most effective way to prevent billions of dollars {in spending} is by requiring HHS to clear its determinations to add additional employees to the SEC with the OMB after an opportunity for interested agencies, such as the DOL to comment on the analysis and determination. DOL has unsuccessfully requested an opportunity to review the HHS analysis and determination of SEC petitions. While recognizing that Congress provided an unreasonably short deadline of 30 days from receipt of a recommendation of the Advisory Board on Radiation and Worker Health for HHS to act, we still believe OMB clearance is crucial to preventing unjustified admission to several of the recent petitions considered by the Advisory Board.

Further evidence of DOL's active efforts to reduce costs of benefits involves the HHS proposed rules for petitioning HHS to designate additional SECs. Excerpts of emails provided by the Subcommittee state that:

- DOL urged NIOSH to propose SECs where claimants would be compensated for as few as 1 cancers, even though Congress required that all SEC members are compensated for any of the 22 cancers listed in the law. Mr. Hallmark complained that the Advisory Board rejected this approach. He said "Did NIOSH not do any selling on this?" … "Allowing the Board to go against this makes for a steep climb in the final rule." An excerpt of another DOL e-mail says, "We should keep a close eye on these issues so that NIOSH does just fold on them." DOL urged NIOSH to adopt a test for determining "health endangerment" that would require estimating cancer risk from radiation exposure, even though the whole reason to designate an SEC is that radiation dose could not be estimated with sufficient accuracy. Fortunately, the Advisory Board rejected this DOL-recommended approach because it posed insurmountable hurdles for claimants and was infeasible to implement.

- DOL opposed legislation to clarify NIOSH criteria for designating SECs that was introduced by Senators Clinton and Schumer. In an excerpt of an e-mail, Shelby

Hallmark says: "This would be a massive SEC expansion. Hopefully it has no chance of moving, but given the recent Senators' letter and other wacky happenings, I am not sure we can afford to simply ignore it." The same cost driven posture was taken on site specific SEC bills covering facilities in Iowa, Missouri, New York, and Colorado. In another e-mail excerpt, Hallmark says: "We should do everything possible to oppose these SEC amendments." In none of these cases does he assess whether there is a meritorious case for an SEC, or whether the NIOSH rule is so subjective that legislation might be in order to provide clearer criteria for who should or should not qualify for an SEC when data is lacking. His entire logic is budget driven.

- DOL has disparaged the Advisory Board on Radiation and Worker Health, and urged a change in the composition of the Board so that it would recommend more SEC denials. An excerpt of notes taken by Judiciary Committee staff of a DOL memo under preparation for OMB states: "the Advisory Board has totally failed to take a balanced approach to examining NIOSH activities. Nearly all of its members have operated as unwavering advocates of any action that would expand benefits, while the remaining members occasionally raise dissenting views but are unwilling to forcefully advocate any position likely to upset the claimant community. This unwillingness to fulfill their statutory responsibility by carefully examining issues such as whether so called "claimant-friendly" devices increasingly adopted by NIOSH are overestimating and overcompensating claimants has been magnified by NIOSH's decision to provide technical support through a contractor, Sanford Cohen & Associates (SC&A) rather than through its own staff. SC&A has relentlessly pursued an agenda that appears to be designed to result in maximizing payments to claimants regardless of scientific validity."

DOL's suggestion that the NIOSH program staff should be serving as the technical support staff for the Advisory Board's audit activities would result in a significant conflict of roles. It would also undermine the Congressionally-mandated independence of the Board's review of SEC and the dose reconstruction process. This DOL suggestion is geared to weaken the independence of the Board's oversight, which is all the more imperative--given the plethora of conflicts of interest which have infected this program as a result of NIOSH hiring DOE and DOE contractors to run the dose reconstruction program. NIOSH circumvented the spirit of Congressional restrictions that prohibit DOE from performing dose reconstructions (42 U.S.C. 7384n). Instead, NIOSH hired DOE contractors and consultants, many of whom worked at DOE sites and have conflicts of interest. These conflicts underscore the imperative that the Board be supported by individuals independent of NIOSH (and the DOE).

- In an October 2005 memo prepared for OMB, DOL recommended that the Advisory Board be "refreshed." The draft communications states: "A number of Advisory Board member's terms have expired…We believe replacing these members could provide an opportunity to add Board members willing and able to advocate a scientifically valid approach to carrying out NIOSH's responsibilities under EEOICPA." DOL does not

explain what it means by "scientifically valid." Given its stated agenda to reduce the number of SECs, this appears to be a simple case of "packing the courts" to oppose added SEC designations dressed up as "scientific validity."

- Excerpts from an October 5, 2005 communication to OMB and senior DOL political officials, Hallmark pointed to a press release from Senator Maria Cantwell, who flagged data inadequacies at Hanford as evidence for a partial SEC, based on findings in an SC&A audit report. Hallmark asserts that evaluations by the Board's audit contractors lead to a "lopsided and extreme exaggerations of radiation dose." Hallmark argues that "the Advisory Board has allowed, even encouraged SC&A to pursue this unbalanced course, and NIOSH has shown no willingness to stand up to it, and recently doesn't even try to refute SC&A's more outlandish assertions. This is not the slippery slope, it is the expert downhill chute."

Mr. Hallmark's words from the March 1 hearing—"cost containment is not part of any strategy or involvement that the Department of Labor has had in this process"-- are plainly contradicted by the actions of DOL in promoting the policy options in the OMB Passback and opposing legislation to improve the program. DOL's credibility as an impartial claims administrator has been undermined by the actions of key officials.

Hiding behind generalizations, (e.g., NIOSH's criteria is "fuzzy"), Hallmark has failed to document a single specific technical error in designating an SEC. Moreover, he does not account for a 6-step comment resolution process overseen by the Board members and the public that has resulted in NIOSH and SC&A/Board reaching mutual agreement on technical issues, while identifying major omissions in NIOSH site profiles and SEC evaluations. Mr. Hallmark seems unwilling to recognize that there is a case for a robust Board-led peer review process. NIOSH is breaking a lot of new ground, mistakes are likely because they are speeding up the process to deal with a large claims backlog, and the program is being operated by a closed community of health physicists, most of whom have conflicts of interest from managing health physics programs at these DOE sites. Hallmark sees no need for a strong scientific peer review to counterbalance these conflicts. DOL supported an NAS review where they planned to "steer the work plan" and use the results to "defend our decisions."

It is a credit to the integrity of the process that the Secretary of HHS has followed the advice of the Advisory Board on SECs based on the deliberations contained in the transcript of the administrative record, rather than uncritically accepting the advice of the NIOSH program staff or the hysterical allegations of the DOL.

The Advisory Board has operated as an independent enterprise applying due diligence in a considered manner. NIOSH Director John Howard described the importance of the Board ensuring a credible peer review in his March 1 testimony before this Subcommittee. Denise Brock, a claimant, underscored the importance of the Advisory Board in providing a public forum for debating the technical and policy issues involved in an SEC in her July 20, 2006 hearing before this Subcommittee.

For example, to deal with the knotty issue of estimating radiation doses from raffinates (actinium, protactinium and thorium) that were never monitored at Mallinckrodt in St. Louis, the Advisory Board requested 4 audit reports over 2 years, and then evaluated NIOSH's responses to the audit reports at 4 Board meetings, 4 additional subcommittee meetings and numerous conference calls. In the case of the Iowa Army Ammunition Plant, NIOSH conceded there were no internal radiation dose records, and the Board deliberations exposed the fact that the scant external radiation dose records were not representative of the most exposed workers. To rely on these unrepresentative records will cause radiation dose to be underestimated for unmonitored workers. The vote for the Iowa SEC was unanimous. The system of checks and balances, which was put into place at the recommendation of the GAO, is a gossamer thin thread which is tenuously holding this program together.

V. OMB DISAVOWS OMB PASSBACK, BUT FAILS TO ENSURE THAT DOL COMPLIANCE

Austin Smythe, Acting Deputy Director of the OMB, testified before the Subcommittee on July 20, 2006 that the Administration was not implementing any of the options in the OMB Passback. He stated:

> "We are not pursuing any of these items that were listed. It was inappropriately leaked. It has now been inappropriately characterized as Administration Policy, which it is not."

The Chair asked whether the OMB Passback represented Administration policy. Mr. Smythe responded:

> "A Passback, just to give the subcommittee background—there is a process that we use to put together the budget. That process begins in September when the agencies submit to us their proposals, and all of their proposals in terms of what they want to do in the budget.
>
> "We review those proposals in the October time frame and sometime, usually in late November we pass back our proposals back to them. It doesn't represent—the agency's

> submissions to us don't represent administration policy and our Passback to them does not represent administration policy."
>
> "This is a very rigorous process where we go through various options and so forth. In this instance, none of these options were accepted in terms of what the president's ultimate policy was and what was in the president's budget."

Despite Mr. Smythe's testimony that the OMB Passback does not represent administration policy, the OMB Passback was put on the agenda for a joint NIOSH-DOL meeting held on January 4, 2006. Excerpts of communications between NIOSH and DOL raised the question of whether certain policies to limit the years of coverage at the Linde facility in New York arose out the cost containment goals encompassed in the OMB Passback.

There is also concern that Mr. Hallmark moved forward with a sequel to the Passback to impose additional controls on HHS or NIOSH. Notes taken by the Judiciary Committee staff from materials which DOL would allow it to view but not duplicate, identified an early February 2006 e-mail communication from Shelby Hallmark to Melissa Benton at OMB. It indicates that Mr. Hallmark has developed a briefing paper which outlines additional policy options for dealing with NIOSH and HHS. The email to OMB says:

> "I am uncomfortable with even an unofficial sharing of my briefing piece for today's meeting with my second floor people [Secretary's office], since I am not at all convinced they will be willing to argue directly for any or all the actions it proposes, and I know they are very reluctant to be on the cutting edge of this argument. I feel pretty sure their response is going to be: 'OMB such [sic] be holding HHS accountable here – DOL isn't in any position to try to do that.'
>
> But if you promise not to spread it, and if you don't use the language in your documents such that NIOSH will know where the verbiage came from, I'll share it (I'm still smarting from your … citation of the ideas in the budget passback as having been suggested by ESA). Is that agreeable?"

We would urge the Subcommittee to secure the "briefing paper" and ascertain its implementation status, since it appears to represent another benefits reduction initiative.

VI. "Increasing Management Concern" Drives Secret DOL Review of Compensable Cases for Remand to NIOSH

DOL's benefits containment agenda has found its way into a sensitive, non-public review of certain dose reconstruction (DR) claims. Beginning in October 2005, DOL began sending certain compensable claims back to NIOSH "based on increasing [DOL] management concern

over a potential increase in compensable claims for cancers perceived as normally/previously non compensable," according to excerpts of documents provided by the Judiciary Committee. DOL staff health physicists began dissecting NIOSH dose reconstructions which had a probability of causation over 50% (e.g., they were compensable). In response to requests from the DOL program officials, the Final Adjudication Branch remanded some cases back to NIOSH without ever telling claimants their case was being reviewed because DOL headquarters was second guessing NIOSH dose reconstructions. One DOL e-mail excerpt says:

> "When we send remand orders to claimants, I don't want them to know they are part of a management plan."

To the extent there are factual errors, such as work history or incorrect cancer diagnoses that are within the ambit of DOL regulations, then DOL has a role in remanding cases back to NIOSH. However, DOL singled out whole category compensable claims in the hope of getting NIOSH to reduce the radiation dose and bring the claim under 50% probability of causation—which would lead to a denial.

An internal DOL e-mail by a health physicist concedes that NIOSH dose reconstructions have not been over-estimating radiation dose. It states:

> "Now that I think about it, most of the DRs for the "special cancers" we are reviewing that result in a POC of >50% are appropriately performed by NIOSH (no rework required).

The need for maintaining secrecy seems to be a concern. This DOL e-mail added:

> "I hope no one is mentioning the fact that we took another look at these DRs and said it was fine—in the recommended or final decisions."

Some of the cases that were selected by DOL involved glove box workers at the Rocky Flats and Savannah River sites. Glove boxes, which provided an inert environment for working on pyrophoric metals such as plutonium, were not adequately shielded for many years. Film badge readings did not necessary capture the neutron dose from leaky glove boxes, since the badges were not positioned near the parts of the glove boxes that leaked radiation. If DOL has a problem with the model used by NIOSH for glove box workers, they should be raising this issue with NIOSH staff and the Advisory Board on Radiation and Worker Health in a public forum—not as part of a secret "management plan." The Advisory Board has the statutory authority to

review scientific issues related to radiation dose reconstruction methods. However, DOL seems intent on circumventing the Board, if it cannot control it.

In an ironic twist, DOL regulations will not permit claimants the right to challenge NIOSH dose estimation methods in their administrative appeals, but DOL has granted itself this authority as part of an undisclosed initiative.

It appears that the neutrality of the DOL's Final Adjudicative Branch (FAB) has been used to advance the Administration's cost containment goals. Further investigation is necessary. If the Chief of the FAB is obligated to compromise her adjudicative independence, then perhaps there is a needed for legislative reforms to separate the FAB from the control by program officials and OMB. The appeals body for the Black Lung Program and the Longshore and Harbor Workers Act—the Benefits Review Board--is a separate adjudicative entity within the DOL and may be an appropriate model to replicate.

VII. IMBALANCE IN COMPOSITION OF ADVISORY BOARD THREATENS CHECKS AND BALANCES: LEGISLATIVE ACTION NEEDED

The OMB Passback called for "addressing any imbalance in membership of President's Advisory Board on Radiation and Worker Health." The composition of the Board is not in compliance with EEOICPA (42 U.S.C. 7384o) which requires a balance of scientific, medical and worker perspectives." Today, the 12 member Board only has 2 of the 4 required worker representatives. Likewise, the Board only has 2 of 4 medical representatives. This Advisory Board, which plays a critical role in overseeing this program and providing a check and balance, also lacks the balance and diversity of viewpoints that is called for under the Federal Advisory Committee Act.

Chairman James Sensenbrenner wrote to the President about the need for ensuring balance and independence on the Advisory Board. His June 9, 2005 letter said:

> *"New appointments, and the discharging of current members, may negatively affect the Board's balance and independence, thus compromising the Board's ability to fulfill its mandates under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA)."*
>
> *"Every attempt must be made to assure the Board appointees are independent of NIOSH's program, its contractors, the Department of Energy (DOE) and the Labor Department, inasmuch as the Board is tasked with an independent audit function. Specifically, 42 U.S.C. 7384(n) provides that 'the President shall*

> *establish an independent review process using the Advisory Board on Radiation and Worker Health' to assess methods used for dose reconstruction and verify dose estimates. If [NIOSH] OCAS staff provided the list of candidates to the White House, an appearance of conflict arises, as it is they who will be the subject of the Board's audit. Hopefully, a direct dialogue between the White House and Congress can resolve this problem."*

New Board Members were added in early 2006 who were recruited by the NIOSH program staff whose work is being audited. This is an inherent conflict. The son of one of the new Board members works as a subcontractor on the NIOSH radiation dose reconstruction program. The change in balance of the Advisory Board which had been called for by DOL and included in the OMB Passback has been achieved. Subsequent communications have followed from a bipartisan group of Members from the New Mexico, Washington, Iowa and Illinois delegation which urged the White House to balance the Board with new appointments. These communications and communications from this Subcommittee appear to have had no discernable effect.

Given the apparent unwillingness of the Administration to comply with EEOICPA, we recommend that Congress enact legislation to shift the appointing authority from the President to Congress—which would make appointments on a bipartisan basis. The Energy Employees Occupational Illness Program Improvement Act of 2006 (HR 5840), which was introduced by the Ranking Member, outlines a plan to have Congress assume this responsibility.

VIII. NIOSH Interference with the Work of the Advisory Board and its Audit Contractor

On November 3, 2006, NIOSH Compensation Program Director Larry Elliott unilaterally suspended all access by the Advisory Board and its audit contractor to the claimant data base. This action followed an audit report on data completeness related to the Rocky Flats SEC petition, because he and the NIOSH lawyers were concerned over 1) the possible inclusion of a non-adjudicated claim in the data review (none were included); and 2) the possibility that the identity of a claimant could be "back extrapolated" by combining the data parameters. All members of the Board and audit staff have been authorized to have access to Privacy Act protected records and received the requisite training.

At the Advisory Board's workgroup meeting on November 6, 2006, Mr. Elliott indicated that assuring Privacy Act requirements were being protected fell to him as the Manager of the System

of Records. Further, he said he intended to restore access to the Advisory Board, but would provide data to the audit contractor only when provided with a specific request for access to certain files and an explanation why they are needed. As of November 13, two days before this hearing, Advisory Board access to the electronic data base of records was reinstated (although the constraints are unknown); however, the Board's audit contractor is still restricted.

A November 13, 2006 communication from Mr. Elliott to the Board states:

> "Access of NOCTS claim files by SC&A (or any contract entity) must be granted on a case-by-case basis with an established purpose as authorized by the Manager of the System of Records."

This raises practical as well as policy concerns. How can the Board and the audit contractor effectively communicate if they have varying access clearances? Can the Board's audit contractor perform adequately, if NIOSH has access to data that is withheld from the audit contractor?

Mr. Elliott, as the manager of the program being audited, is using his additional legal authority as Manager of the System of Records to demand that the Board's audit contractor justify each and every request for data. This allows Mr. Elliot to impact the scope, depth and breadth of the audit, and impair the efficiency of the audit contractor. Mr. Elliott's actions raise questions about the degree to which there is a conflict of roles, and whether there whether there needs to be a non-conflicted entity ensuring access to all records for purposes of the Board's efforts auditing the NIOSH program and evaluating SEC petitions.

Mr. Elliot was removed as the designated federal official for the Advisory Board due his conflict of roles as manager of the dose reconstruction program and controlling the activities of the Board which was auditing his program. The GAO's recent report on the Advisory Board[3] warned NIOSH to be alert for conflict of roles in managing this program.

> "The roles of certain key federal officials initially involved in the advisory board's review of the dose reconstructions may not have been sufficiently independent and actions were taken to replace these officials. Nonetheless, continued diligence by HHS is required to prevent such problems from recurring…"

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[3] *ENERGY EMPLOYEES COMPENSATION: Adjustments Made to Contracted Review Process, But Additional Oversight and Planning Would Aid the Advisory Board in Meeting Its Statutory Responsibilities,* February 2006, GAO-06-177, pp. 3

Legislation may be required to ensure that the Advisory Board and the audit contractor have full and unfettered access to all files necessary to carry out their responsibilities under EEOICPA, consistent with the Privacy Act, and without interference from NIOSH Program staff.

IX. SUMMARY

We urge the Subcommittee to continue its oversight on problems with this program. Subtitle E has not been examined, and also needs a detailed review. We would urge the Subcommittee to take all necessary actions to secure the records that were withheld by the DOL and HHS. We recommend that the briefing papers developed by DOL and sent to OMB in February 2006 be obtained and reviewed. We understand there are approximately 8 binders at DOL and nearly that many at HHS. We also recommend that EEOICPA be amended to give Congress the authority to appoint the Advisory Board and to adopt the provisions included in the Energy Employees Occupational Illness Compensation Program Improvement Act of 2006 (HR 5840); to modify the appeals process in DOL to ensure its independence; to strengthen conflict of interest provisions and penalties; and to provide the Advisory Board and its audit contractor with the legal authority to have full and unfettered access to all records in the control of HHS which the Board and the contractor deem necessary to carry out their functions, consistent with national security laws and the Privacy Act.

Mr. HOSTETTLER. At this time, the Subcommittee will turn to questions.

Dr. Fuortes, what specific recommendations would you offer to improve this program, either administratively or legislatively?

Dr. FUORTES. Thank you.

Well, there are several issues. I think that one of the issues that comes up is—has come up repeatedly is the independence and the ability of the board and the auditor to do their functions.

I think that that could be done legislatively or by a variety of mechanisms. But I think that is certainly the functions of the Board and the functions of the auditor need to be recognized as very valuable functions to the claimants and petitioners. They have no other access to that sort of expertise. And I don't think that that request falls into the line of requesting worker advocacy. I think it is access to scientific acumen.

There are several issues, I guess, as regards the SEC process and the SEC cancers, but one issue would be that the SEC process should be facilitated I think and if it is NIOSH that can help petitioners, if it is an agency such as the Advisory Board, if it is another agency that is fine. But I think that former workers and their families are disadvantaged. They don't know what their exposures were. So somebody has to assist them in educating them. This was the situation historically. Maybe it is the Department of Energy's responsibility. But that should be looked at.

Another issue, I raise just briefly is that the list of SEC cancers itself might be reviewed. And I think that there is probably—this is a point in time in which MCI or NIOSH or some other agency could get involved in examining that list. I think that there is—there are some deficiencies in the inclusion of that list. You asked a very broad question and maybe this is something that I am rambling on about.

Mr. HOSTETTLER. Appreciate it. Thank you.

Dr. Mauro, a DOL memo prepared for OMB states the following, "the Advisory Board has totally failed to take a balanced approach to examining by NIOSH activities. This unwillingness to fulfill their statutory responsibility by carefully examining issues such as whether so-called claimant friendly devices increasingly adopted by NIOSH are overestimating or overcompensating claimants has been magnified by NIOSH's decision to provide technical support through a contractor, Sanford Cohen & Associates, rather than through its own staff. SC&A has relentlessly pursued an agenda that appears to be designed to result in maximizing payments to claimants regardless of scientific validity."

Please explain how SC&A does its auditing work. For example, does SC&A only examine underestimates, or does it also assess overestimates of doses that would lead to inappropriate compensation decisions?

Likewise, has SC&A actually identified such overestimates and pointed this out to NIOSH or the Board?

Mr. MAURO. To answer the question, first, it must be understood that the cases that we review are given to us by the Advisory Board. They select the ones to make sure they get a good cross section that represents as many different facilities, different types of

cancers, different time periods, as possible. And we receive these cases from them.

Then we have a process of systematically checking each and every dose reconstruction to give an individual for every year we check how they calculate, how NIOSH has calculated that dose.

And we determined whether or not they followed their own procedures, whether or not the procedures they followed were appropriate.

The bottom line is for each dose reconstruction that we audit, we prepare a list of findings and identify deficiencies.

Now, it turns out we have completed 60 such audits. We have 249 findings out of the 60 audit reports.

Out of those, we found 102 had errors that resulted in underestimates of the dose. And we have we had, we found 84 that resulted in an overestimate of the dose. And we found 63 that were errors but they really didn't affect the dose one way or the other.

We are virtually—when we approach the process, we are really blind to whether or not the outcome is going to be over or under. We just look for errors in science, errors in the ability for them to access the proper data and use the proper procedures. And what falls out of that is the finding. And then at the end, you can make a determination, well, does that finding have the effect of resulting in an underestimate or the overestimate in the dose?

We then sort all that out in our database, and I just sort of summarize for you so the outcome of this is one that we do both. We identify places where the science and the procedures are flawed and where it needs to be fixed.

Mr. HOSTETTLER. Thank you. Thank you, Dr. Mauro.

Ms. Jackson Lee.

Ms. JACKSON LEE. Thank you very much, and thank you all for your testimony, and please know that this Committee remaining constituted as it is in terms of its jurisdiction will continue to work to solve this problem, and I think this injustice to many who have served so well.

Let me, Mrs. Bates, start with you, and thank you and thank your mother and brothers and also thank your late father for not only his service to the Department of Energy but to the United States Navy.

And I, frankly, just want to get on the record the fact that you relate to us a painstaking effort on your behalf, on behalf of your family.

The good news is that there was a family member who had the wherewithal to engage.

Many of those these individuals who are themselves victims are elderly. Many of them may not have the wonderful support system that you provide.

Just tell me how you felt going through all of this and then ultimately seeing your Social Security number mistyped? You know we always say to err is human. But putting the burden on you to get all of these activities in order and then to see a representation of a cavalier approach or attitude of a misprinted Social Security number.

Ms. BATES. Well, I can tell you, it is very frustrating from a personal standpoint. And I will honestly admit for the first few years

of the process I was kind of disengaged. My mother had all the correspondence, filled out the forms and you would occasionally have a follow-up call with a case worker.

When she got the original dose reduction, after a series of other errors which are outlined in my statement, she called me and said, I can't read this, what does it say? And that is when I really sat down and looked at it. And I couldn't read it either. And I had to sit down and I have spent hundreds of hours of my time reading thousands of pages. I did know what the Code of Federal Regulations was and so I knew where to go on the Internet, look it up. And that is how I came to be able to read 42 CFR part 82 for the dose reconstruction once required.

I think my biggest frustration has been not knowing what to do or where to do for help, because you don't get any help out of calling the agency directly and saying I need help. The common answer I would get—even when trying to get a status was—it is in the process. That is not an answer. I felt like I was being blown off.

And I think in your bill, the position of the ombudsman, I might not be here today if that position existed and there was an effective mechanism for people to go to and ask for help, at all levels. And many of the claimants I am sure are elderly, and many don't have the wherewithal to read these documents and even know where to go. So I think that would be one of the most effective things you could go do for the process.

And the claim process itself, not the dose reconstruction, not the technical, the scientific part of it but you know as a claimant, I give information, there is this magic black box and out spits an answer. If it is right or wrong, I don't know. If it is not right, I don't know how to get help. I don't know even know who to ask.

Ms. JACKSON LEE. Would you say then that elderly senior citizens who don't have a support system can be completely frustrated by this process?

Ms. BATES. Absolutely. My mother's comments to me when we received the recommended decision which is sent to you after the dose reconstruction was that if I did not have you to help me, I would have simply thrown it in the garbage and been done with it. Because what do you do? You are not even sure what it says. You are really not even sure what it says. You do get to the end and it says you will not be compensated if the claim is denied. But reading between, you know, dear Mrs. Gore, and you will not be compensated, the 6 or 7 pages is incomprehensible for many people, I would imagine.

Ms. JACKSON LEE. I do understand Government documents.

Might I also say that it is a challenge for individuals who are living with the disease. Tragically, your father passed. But I imagine if you had to entertain those elderly—those who are trying to be compensated it must be a piquing frustration.

Ms. BATES. I can just imagine. I can just imagine. My mother is an educated woman. She is not uneducated. But knowing, having someone to ask questions of, is I think a primary responsibility of the program. And if that is the role of the ombudsman and that is the mechanism you can put in place as a help system, I don't know how you would approach helping people who don't have the

wherewithal. How many people that are elderly have Internet access and use it regularly and know where to go and what to do?

So to the extent that these mechanisms are available you have a very broad and probably varied audience with different levels of capability to even understand or even use the office or use the tool.

Ms. JACKSON LEE. Dr. Mauro, I wonder why your, the integrity of the auditor has now been challenged. And I wonder would you describe your work as a free for all for any claimant to claim that they are entitled, or do you do the appropriate vetting and research that is necessary to do the dose reconstruction?

Mr. MAURO. The process that we—our contract is very well defined in how it works.

We are really part of a large process. The Advisory Board has a mandate under the Act to independently provide oversight of the dose reconstruction process.

We serve them in a technical capacity. They will deliver to us the cases that they would like us to look at. The only cases that we formally audit are the ones that are delivered to us by the Advisory Board.

Then we follow procedures that have been developed and that we are held accountable to that have been approved by the Advisory Board. We have checklists. And everything we do, I would have to say, is very deliberative. It is not a free for all. It is—what we are—very often there are many, many people who would like us to look at their cases. But we have—our mandate is very well defined. Our role is to support the Board and review those audit, those cases that are given to us by the Board and report back to them.

Ms. JACKSON LEE. What is your explanation that you are being charged, having followed the rules by the book with wanting to give everyone money or to approve every case? How do you answer that? What is behind that?

Mr. MAURO. I don't have an answer. I don't have a ready answer.

Ms. JACKSON LEE. You feel you are following the rules?

Mr. MAURO. Our rules are laid out before us very clearly and we are following them.

Ms. JACKSON LEE. It may be the accusations are made by individuals who want no one to be compensated or don't view this as a realistic claim that so many people are suffering. It might be the case.

Mr. Miller, I might throw this to you and thank you for the leadership you have given on these issues.

My legislation, H.R. 5840, I think, answers Mrs. Bates's questions and some of the points you have made. Might you share how 5840 can get us started, at least in answering the question I posed to Dr. Mauro? Why is his integrity being challenged? He has argued that he is following the rules and he has nowhere to go in terms of raising his defense because he is being charged with a free for all in this process.

Mr. MILLER. Well, first, if I might say, having been to, I think, 41 of the Advisory Board meetings and watched the deliberations, I would assume that if there were technical acumen provided to claimants in order to assess whether, in fact, their claims may have been, the dose may have been underestimated or that an SEC might be warranted, and you viewed your role over in the Depart-

ment of Labor as second guessing that, and that your job was to engage in cost containment measures, and that appealing to the office of management and budget's natural inclination to look at budget issues and to curry favor accordingly, and then to pursue an agenda where you reshape the program, not as Congress has intended it, but as you wished Congress had done it, and to do so in secrecy might explain why these nonpublic documents which the Subcommittee has been so capably obtaining and now making public for the first time, I think illustrate a larger overarching agenda to undermine congressional intent.

And really, I think the Labor Department is undermining the integrity of the program by attacking Sanford Cohen & Associates with really—without an iota of substance or credibility.

And I say that because the Labor Department has not once come before the Advisory Board and said technically we disagree with the finding of the audit contractor, or we disagree with the conclusion on a special cohort that the Board voted out. Instead they do this in secret with the Office of Management and Budget seeking to undercut this process or working with the White House to stack the Advisory Board.

This is the problem that we are facing is that there is a backdoor operation underway here that is undermining what goes on in public. And I certainly hope that we can continue to explore this further.

With respect to your legislation, I think it makes an excellent start. It captured a number of the ideas that both Congressmen Tom and Mark Udall presented before this Subcommittee in their testimony, and I was pleased to see you incorporate some of their recommendations as well, and I will also note that they cosponsored your legislation, but this legislation, I think the most important and central part is that congressional intent has got to be reinstated in this program. How do we go about doing that.

Well, I think the first step that your legislation takes is let us have Congress make directed appointments. Let us take this out of the Administration. There is too much temptation by OMB and the green eye shades to undermine congressional intent here. Let us have Congress on a bipartisan basis make directed appointments consistent with the statutory criteria of medical, scientific and worker perspectives.

So I think that is a first and important start, and we have other suggestions as well.

Ms. JACKSON LEE. Mr. Chairman, may I just make this point? I am not sure if you are going on a second round. I have a military briefing that I am being called to, and so if I depart and the Chairman is having a second round, I am not sure.

Mr. HOSTETTLER. I am having a second round, yes.

Ms. JACKSON LEE. If I move, then you will know where I am going. If I am still here, I am getting word that I can stay a little bit longer, but Mr. Chairman, I just wanted to say that with your leadership and the opportunity for another hearing to finish this out when we return, please accept our commitment that this is not going to be left undone. There are too many patriots that we have to respond to, and I will—listen, I might be here for the second round, and I thank the witnesses very much.

Mr. HOSTETTLER. I thank the gentlelady. We will now go to a second round of questions.

Ms. Bates, you have spoken on this at some length, but more directly do you feel the process today is claimant-favorable?

Ms. BATES. From the claimant perspective, no, because—and I think we have addressed this—I felt the burden of proof was on me, and when I say "claimant-favorable," I know there is a lot of language in 42 CFR 82 that addresses claimant-favorable with respect to the dose reconstruction, but from the claimant's perspective of how is the process going, not when I have to literally prove to NIOSH that records do exist and that this was his job and this is the building where he worked, that cannot be perceived as claimant-favorable.

Mr. HOSTETTLER. Thank you.

Mr. Miller, your testimony indicated that the NIOSH program's staff had cut off access to claims data for the board and the audit contractor. We understand that NIOSH has restored board access to data. However, the audit contractor has not had access to the claims database. How would you recommend that this problem be resolved?

Mr. MILLER. Well, Mr. Chairman, I certainly know that the Director of NIOSH has now been made aware of this problem. John Howard has received communications on this. Secondly, I think that the situation that NIOSH has taken has told the audit contractor—and they are here to confirm it for themselves—that they must provide a rationale and a justification for the records they want to look at when they do an audit, which to me seems to be placing the audited entity in the position of putting up obstacles, and it certainly leads to the inefficiency of the process, and I would argue it deters the depth and breadth with which the auditor can pursue his job or her job.

My recommendation is that either something be done in the appropriations bills this year or in some legislative vehicle that provides full and unfettered access for the board and the audit contractor based on what they deem is necessary, not what NIOSH deems is necessary. That is point one and, two, that, you know, obviously the usual constraints of the Privacy Act and national security in terms of dealing with classification would apply, but they need to be able to see and access those documents without any interference whatsoever, and I think Congress needs to provide crystal clear authority for that to happen.

One would have thought that with a program where its leadership boasts of its transparency that it would not engage in this kind of activity, but it is going on, and I do not know what is really driving it, but there is something motivating this that is not entirely transparent, Mr. Chairman.

Mr. HOSTETTLER. Thank you.

Dr. Mauro, in pursuing that, that notion of access and the lack thereof, has lack of access been a challenge in meeting deadlines in carrying out your work?

Mr. MAURO. Well, this new—the new set of ground rules were only instituted about a week ago, and the nature of the ground rules are that we have to inform or request access to specific information, which we have done. Normally, we would have had directly

accessed that information and have already gotten the information we need and we would have gotten the work done, but right now we have requests in under this process, waiting for the material to be released to us. So, in the respect of the past week, I would say, yeah, there has been—because of the process, there are records that we have not looked at yet that we normally would have if this access was not restricted.

I would like to point out, however, on my way here today I did receive a phone call from the contracting officer, Mr. David Stout, who informed me that they are taking a real close look at this and that there is a good possibility that SC&A will be granted free and unfettered access to the records, but they are discussing that right now and looking into that further.

But to answer your question, the degree to which it will prevent us from getting our job done, there is no doubt it is an inconvenience. It will slow down the process. It already has to a certain degree. As I mentioned, there are certain documents we would have liked to have looked at today that we really have not been able to look at.

Mr. HOSTETTLER. So free and unfettered access would probably be the optimal arrangement with regard to access for your work?

Mr. MAURO. Yes.

Mr. HOSTETTLER. And this is what it was for how long prior to this recent evolution in the process?

Mr. MAURO. Well, when we first started the program about 3 years ago, we had some serious difficulties gaining access to the records we needed, and it made it very, very difficult, and it was a painful process to get to the point where we did have access. So the machinery—they are these large computer programs containing tons of information. Little by little we were granted access to the point where we did have what I considered to be very good access to the records, and that may have gone on. I would say for the past 6 months things were in pretty good shape, but now with this new policy we sort of took a step back.

Mr. HOSTETTLER. Thank you.

The Chair now recognizes the gentlelady from Texas for 5 minutes.

Ms. JACKSON LEE. Let me just again conclude by indicating that you have given us a great deal of insight on how we can expand H.R. 5840 and also some insight, Mr. Chairman, possibly on working with the Appropriations Committee to at least get, maybe, points that we agree with particularly on the advisory committee aspect.

Dr. Mauro, could you just give an example of where you have identified significant omissions or holes in the data that were generated by your access to the material? Do you have like one example or have you discovered something? If you had not had any access, you would not have been able to secure that information?

Mr. MAURO. Yes. I guess the most important one is what is happening right now. Right now we are in the middle of reviewing the Rocky Flats SEC petition. There are some very serious issues before us on whether or not the record is complete with regard to the doses to workers. Are there significant gaps? There are some ques-

tions of falsification of records and destruction of records deliberately. All of these are part of the record of the petition's concern.

Now, in order for us to investigate these matters, not only us but also NIOSH, the only way to determine whether the seriousness of these gaps and the statements made in the petition is to go into the records. Without having access to those records, these questions cannot be answered, and to place certain constraints on, you know, the degree to which we can access our protocol, it is going to make it difficult, and we do not know how difficult it will be, and let us say we do have to live with this new set of ground rules. It will make it difficult for us to do the investigations that we would like to be able to do, but of course if those are the ground rules, that is what we will do.

So that is one very important example of where having access to records is important. I hope that answers your question.

Ms. JACKSON LEE. And so, in essence, it is a question of fairness. Do you have any access to determine what is right, what is wrong, what is a fact, what is not a fact?

Mr. MAURO. In the end the records is what the whole program is about.

Ms. JACKSON LEE. Not your favoritism. You are not in the business of favoritism, I take it?

Mr. MAURO. No, of course not.

Ms. JACKSON LEE. You are in the business of independent research and auditing——

Mr. MAURO. Yes.

Ms. JACKSON LEE.—and I think, Mr. Chairman, that this is one of the harshest discoveries that we have made, and it is interesting that the call was made to reconsider this, but a fact finder cannot be a true transparent fact finder without having access to documents.

Dr. Fuortes, do you have any quick suggestion on this issue that you raised that was dealing with any improvements to the Special Exposure Cohort process?

Dr. FUORTES. Well, as I said, I think workers need some assistance or sites need some assistance, and as I said, I think this could be in several fashions, but that is one issue.

Ms. JACKSON LEE. An ombudsman or someone advocating?

Dr. FUORTES. Well, most of what I have been working with has in fact been claims-oriented, and the ombuds-—I work a bit with the ombudsperson's office, and I think that that—what you have suggested of expanding that role would be fantastic. The claimants are elderly. They do have a great deal of difficulty in collecting and interpreting medical information. They have the responsibility of collecting all of this information, and if you can, imagine somebody without Kathy to help them. I think that we can see that there is a real need for some assistance in this process. I do not know if the resource centers are supposed to do this work or not, but I believe that the ombudsperson's office being expanded to fulfill that role of claims assistance and, in particular, assistance with the evaluation or the auditing of the denied claims by DOL would be very, very helpful.

So this is not exactly answering your question of problems with the SEC but how I view improvement of the overall program.

Ms. JACKSON LEE. Let me just say that the two devils in the details are the DOL acting as the handmaiden of the OMB as it relates to doing their job and cost-cutting, and what we have found is that cost-cutting seems to have carried the day as opposed to fact finding. When you find the facts, you will define the pool of applicants that are legitimate, and then you begin to make the case for how they are compensated, but if you start out with an OMB cost-cutting challenge, then you are cutting the edges in terms of finding out the truth, and I hope that that is not what my understanding of the Advisory Board and this process was to be about.

So I, again, think this is my second expression of appreciation. Thank you for the insight that has been given and some of the additions, Ms. Bates—Mrs. Bates—that we would like to add to the existing legislation, issues that you have given us for consideration. Again, thank you.

Thank you, Mr. Chairman.

Mr. HOSTETTLER. I am going to ask a couple more questions. First of all, Dr. Fuortes, what is your view on the current balance of the Advisory Board?

Dr. FUORTES. My impression is that even the term "balance" is confusing. To me, it is very confusing because, from documents that were made available to me, it appears that people view the balance on the Advisory Board being a balance of the employer's perspective and worker advocacy.

I think the Advisory Board is tasked with making scientific judgments, so worker's perspective is important in terms of knowing the worker's language, knowing about the processes involved in facilities, not worker advocacy, and so I am very disturbed by that terminology in those documents. I think that I would prefer people follow through with the concept of difficulty in ascertaining risk and determining how to fulfill the language and intent of the EEOICPA Act on the basis of scientific judgments.

In that case, I would say that instead of balance the skill sets reflected on the—which is what you are getting at—the skill sets reflected on the Advisory Board would suggest to me that they probably need a little bit more medical epidemiology/radioepidemiology background. The one radioepidemiologist is, I think, very, very overburdened with the current tasks, and I would say that I would look at skill sets instead of balance because, to me, the concept of "balance" really implies advocacy roles and antagonism between two separate advocacy roles.

Mr. HOSTETTLER. With the notion of skill sets, how would that be redundant with the task of the contractor itself, or would it be?

Dr. FUORTES. Oh. Well, I do not know that the contractors are medical epidemiologists per se. I would say that their skill sets lie more in radiophysics dose ascertainment, and medical epidemiology was—certainly, there is an overlap between the fields, but I would say that they are separate areas.

Mr. HOSTETTLER. Okay. Thank you.

Mr. Miller, has it been your experience that the shoddy processing of Ms. Bates' survivor claim is unique or is it systemic?

Mr. MILLER. The circumstance that Ms. Bates brings up certainly brings to mind for me several other recent cases where the mechanics of the claims processing is deficient. Let me give you an ex-

ample from the Nevada test site, for example. The Nevada test site—they are—NIOSH concedes that in their site profile documents that they cannot reconstruct dose for a whole group of workers who were out at this nuclear weapons test facility. When they did certain underground tests, the tests did not stay contained. They blew out. They vented, so to speak, euphemistically. Some of these ventings went on for 30 hours and traveled all the way to Utah. So, when we say "venting," we mean a large amount of particulate debris that was forced into the atmosphere over a protracted period of time. Huge amounts of pressure built up underground. The workers around it were not necessarily monitored or monitored adequately, and NIOSH does not have a clear way to estimate their dose, but what they put is—they say that workers will self-identify if they have been in these events. They assume that claimants will self-identify and survivors will self-identify, that one of these ten out of—you know, over the hundreds and hundreds and hundreds of tests that have been conducted there that they will flag that and that NIOSH will know it, and then, if they know that, they will set it aside.

Well, the fact is claimants are not even asked if they were involved in these tests by NIOSH, so NIOSH just goes ahead willy-nilly and is reconstructing doses while omitting these events that they cannot reconstruct dose for. So you are supposed to be setting these aside and either pending them or perhaps putting them in another special cohort.

Instead, what is happening is due to the administrative failures of NIOSH in its claimant interview process the failure to obtain the information that these workers should not be dose-reconstructed, because NIOSH already admits they lack the data and the wherewithal to do it, and yet they are running it through the process. How is a claimant, when they get this gibberish back in their dose reconstruction report, ever going to fathom that their case was so grossly mishandled? And I have had the privilege of working with the Senator's office from Nevada who has fed me a number of these cases, and I am astounded at the degree of ineptitude in the basic bureaucratic processing of the claims by NIOSH.

Mr. HOSTETTLER. Thank you.

Those are all the questions I have.

The gentlelady from Texas.

Ms. JACKSON LEE. I am prepared to yield, and I think that we have made a very, very good record particularly by all of the witnesses coming from different perspectives, and I would appreciate, Mr. Chairman, if we could collaborate in this period between now and the close of this session to see how—at least the strengthening of the Advisory Board subtitle (B), but the integrity of Dr. Mauro's process, I think, is key. He must be unfettered, and he must be able to view documents with integrity. There will be several elements that will help move these cases along, and I thank you very much, and I yield back my time.

Mr. HOSTETTLER. I look forward to working with the gentlelady from Texas.

Without objection, all Members will have 5 legislative days to make additions to the record. The Chair will also notify the witnesses that we will have a set of a few questions. I have some ques-

tions for some of the witnesses that are here today that I was not able to ask, and so I would request that the witnesses would respond to those questions in a timely fashion, and that time frame will be made known in correspondence that we will make with you.

The business before the Subcommittee being completed today without——

Ms. JACKSON LEE. I will join you in written questions as well. Thank you.

Mr. HOSTETTLER. Without objection, the Subcommittee is adjourned.

[Whereupon, at 3:30 p.m., the Subcommittee was adjourned.]

APPENDIX

Material Submitted for the Hearing Record

PREPARED STATEMENT OF THE HONORABLE JOHN N. HOSTETTLER, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF INDIANA, AND CHAIRMAN, SUBCOMMITTEE ON IMMIGRATION, BORDER SECURITY, AND CLAIMS

STATEMENT OF

THE HONORABLE JOHN HOSTETTLER

CHAIRMAN

SUBCOMMITTEE ON IMMIGRATION, BORDER SECURITY, AND CLAIMS

ON THE OVERSIGHT HEARING ON

THE ENERGY EMPLOYEES OCCUPATIONAL ILLNESS COMPENSATION PROGRAM ACT

NOVEMBER 15, 2006

Today's hearing is the fourth in the series of oversight hearings the Subcommittee has been holding on the Energy Employees Occupational Illness Compensation Act (EEOICPA). The point of this hearing and the fifth hearing to follow in December is to review what the Committee's oversight efforts have revealed as weaknesses in the program; the status of any reforms made to address those weaknesses; and discussion of any emerging issues that may need

to be addressed in the next Congress.

Because of their complexity, the Subcommittee is compelled to make an effort to create as much of a road map of the program and its problems as possible for those who would provide future oversight.

The Judiciary Committee's oversight did not begin with the investigation on implementation of the OMB passback options.

This Committee has taken an active role in policing this program from the start and I sincerely hope that rigorous oversight by this Committee will continue in the 110th Congress and future Congresses until we can all say with confidence that "Yes, we are fulfilling the promise we made to these veterans of the Cold War when we created this program." I would have liked to have been able to say that already, but the record created by these hearings tells us that is just not so.

Shortly after assuming the chairmanship of this subcommittee, I sent a letter to the General Accounting Office asking that they examine the key components of the program. That was May 2003. As time went on, the Subcommittee heard several complaints on the way the program was functioning and the behavior of officials involved in the program.

That prompted a November 2004 request to the Department of Health and Human Services for extensive documents and information concerning the functioning of the program, the Advisory Board of Radiation and Worker Health, and that Board's audit contractor.

Subsequently, after the initial review of their submissions, a request was made for GAO to expand the scope of their review of Subtitle B which they agreed to. During 2005, the Committee sent letters to various agencies regarding concerns with different actions taken

with regard to the program.

One letter to the Attorney General concerned the use of classified information to decide a claim under the program and asserted that congressional intent was that transparency in the processing of claims be an essential principle of this program. A second letter concerned the removal of two Board members - a worker and a doctor. No resolution to either of those concerns was forthcoming.

In the case of the request by Chairman Sensenbrenner that the removed Board members be offered reinstatement so that the Board would not lose their expertise and experience with the program, the Committee received a one sentence letter thanking us for our comments.

On October 18, 2005, the White House announced the appointment of three new Board members, one of whom had major conflict of interest issues since he was associated with a

company whose employees included immediate family members and that had been contracted to do dose reconstructions for NIOSH. Only one new worker representative was included in the new appointments.

When the OMB passback memo surfaced, the Subcommittee began planning hearings. Those hearings were, at a minimum, to include the Department of Labor and the Office of Management and Budget. The Committee's invitation was met with resistance by DOL and HHS, but they both eventually provided witnesses. That was not the case with OMB.

Administration officials suggested that a exchange of letters between OMB and the Committee containing appropriate assurances and stating good faith actions that would be taken to assure the claimant community of the Administration's rejection of the passback options would be more appropriate then OMB testifying.

There were several exchanges of draft letters between OMB and Committee staff as well as a meeting between myself and the Administration to personally express the need for specific actions and/or statements that OMB had to make in lieu of testifying.

One of those actions was to either offer reappointment to the Board members removed without cause or provide a plausible explanation why they had been removed while other less qualified members who had made their support of DOE management very clear had been retained.

When it became clear that action was non-negotiable for the Committee, OMB took the broad, non-specific letter of explanation with regard to the OMB passback and used it as the basis for letters responding to Senate and House

Member offices.

They refused to consider reversing the actions of the Administration with regard to the two pro-worker Advisory Board members.

During the first week of August 2006 NIOSH was notified by the White House Office of Personnel that Wanda Munn and Roy Dehart had been retired from the Board effective immediately as part of the ongoing activity of rotating Board Members.

Dr. Dehart had filled one of the medical slots on the Advisory Board. Ms. Munn, an engineer and strong supporter of the DOE complex, does not appear to have been qualified to fill any of the statutorily required Board slots - medical, scientific, or worker.

It was brought to the Subcommittee's attention that Ms. Munn was unhappy with her retirement and hoped to utilize means to get back on the

Board.

Amazingly, on August 11, 2006, NIOSH was notified by the White House that Dr. DeHart and Ms. Munn were to be reappointed for another 3 year term. While Dr. DeHart declined reappointment, Ms. Munn, not surprisingly, accepted.

When the White House was asked why reappointment was so quickly offered to an individual who didn't even meet the statutory qualifications for serving on the Board after the request of the Chairman of the Judiciary Committee for the reappointment of two qualified Board members was ignored, the Administration never provided an explanation.

The Board currently has only 2 worker representatives –and a reappointed member who has stated her position that none of these workers are sick because of their exposure to

radiation.

Obviously, an impartial review of the validity of the science used to determine whether to approve claims for radiation exposure won't be forthcoming from that Board member.

I strongly encourage those who police this program in the future to aggressively pursue balancing this Board and legislation to provide for a more transparent appointment process appears to be the only real solution.

A February 22, 2006 letter requested that DOL's Employment Standards Administration (ESA) provide all documents related to the 5 options outlined in the OMB passback prior to the Subcommittee hearing on March 1, 2006. The Subcommittee received a box of about 4,500 pieces of paper from DOL on March 17, 2006 -- none of them substantive information related to the request.

After DOL complained that the request was overly broad, the Subcommittee reduced its request to the documents of 25 key DOL-ESA staff.

No further documents were received until the beginning of July. No documents or communications were received regarding the OMB passback and no communications between Labor and OMB were forthcoming.

The Committee was informed on July 21st that the office within DOL that handles EEOICPA claims indicated to the Legislative Affairs office that there was no need to provide any of the communications with OMB because they constituted internal budget negotiations – privileged documents not available to anyone. Labor was told by the Committee that ESA had misinformed them.

In support of that position, the Subcommittee requested and received a Congressional Research analysis of the appropriateness of the document request made to the Labor Department which makes it clear that no privilege could be assigned to the documents and communications that were part of the Committee's inquiry.

On the eve of a vote to authorize a subpoena to DOL, high level assurances were made to the Committee to provide all but a few documents to the Committee and the rest were to be made available in a reading room for Committee viewing.

HHS had withheld several binders and allowed all but one to be viewed by Committee staff. It is the Committee's understanding that the binder withheld contained HHS' communications with OMB on the passback. So much resistance from

these agencies fortifies the argument that their actions would not bear well under scrutiny.

Those involved in this backroom manipulation of the program have destroyed the Government credibility again. This program was supposed to assure workers the deceit was over and their government was finally going to do right by them. Those tasked with implementing the program have failed that purpose miserably and they need to be exposed for what they have done. I will be including a record of the Committee's correspondence on our concerns in the hearing record as well as other pertinent documents that provide a clear view of the actions of those running this program.

Under oath, the OMB witness on July 20, 2006, rejected each of these 5 options and assured us they were not pursuing any of them. We received the same assurances under oath on March 1, 2006, from DOL. Evidence included in both DOL and HHS submitted documents or

included in the documents withheld and only viewable to Committee staff do not support those statements and the hostile attitude of those running this program towards the claimants and their advocates gives me little confidence that there is any sincere effort to change by these officials. Obviously, the babysitting of these individuals must continue and I encourage it wholeheartedly.

Time is of the essence for fulfilling our promise to this quickly aging population of atomic weapons employees. Perhaps soon those who run this program will do the right thing and take care of these workers and their families competently and with an attitude of respect that is clearly not present at this time.

PREPARED STATEMENT OF THE HONORABLE SHEILA JACKSON LEE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS, AND RANKING MEMBER, SUBCOMMITTEE ON IMMIGRATION, BORDER SECURITY, AND CLAIMS

SHEILA JACKSON LEE
18TH DISTRICT, TEXAS

COMMITTEES:
COMMITTEE ON HOMELAND SECURITY
SUBCOMMITTEES:
INFRASTRUCTURE AND BORDER SECURITY
CYBERSECURITY, SCIENCE, AND RESEARCH & DEVELOPMENT

JUDICIARY
SUBCOMMITTEES:
CRIME
RANKING MEMBER
IMMIGRATION AND CLAIMS

SCIENCE
SUBCOMMITTEE:
SPACE AND AERONAUTICS

MEMBER
DEMOCRATIC CAUCUS POLICY AND STEERING COMMITTEE

1ST VICE CHAIR
CONGRESSIONAL BLACK CAUCUS

Congress of the United States
House of Representatives
Washington, DC 20515

WASHINGTON OFFICE:
2435 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-3816

DISTRICT OFFICE:
1919 SMITH STREET, SUITE 1180
THE GEORGE "MICKEY" LELAND FEDERAL BUILDING
HOUSTON, TX 77002
(713) 655-0050

ACRES HOME OFFICE:
6719 WEST MONTGOMERY, SUITE 204
HOUSTON, TX 77019
(713) 691-4882

HEIGHTS OFFICE:
420 WEST 19TH STREET
HOUSTON, TX 77008
(713) 861-4070

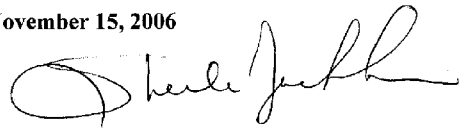
Statement

Congresswoman Sheila Jackson Lee

Oversight hearing on "The Energy Employees Occupational Illness Compensation Program Act – Are We Fulfilling the Promise We Made to these Veterans of the Cold War When We Created the Program?" Part Four in a Series

Subcommittee on Immigration, Border Security, and Claims

November 15, 2006



The Department of Energy and its predecessor, the Atomic Energy Commission, have employed tens of thousands of workers to develop, build, and test nuclear weapons. The Energy Employees

Occupational Illness Compensation Program Act of 2000 provides compensation for workers who have contracted radiation related cancers, beryllium disease, or silicosis from exposure to radiation at these worksites. They may be eligible for a lump sum payment of $150,000 and prospective medical benefits.

In processing radiation related cancer claims, the National Institute for Occupational Safety and Health (NIOSH) is required to estimate a worker's exposure to radiation, which is referred to as a "radiation dose." Sometimes, this is not possible. During the early years of the nuclear weapons programs, some of the workers were not monitored for radiation exposure, and records have been lost.

The Act provides a remedy for cases in which it is not feasible to estimate radiation doses but it is clear that the health of workers may have been endangered by radiation exposure. They can petition to be designated as members of a "Special Exposure Cohort," which provides an unrebuttable presumption that certain cancers are work related. Members of a Special Exposure Cohort

I am concerned that such cost cutting measures would conflict with the Special Exposure Cohort review procedures established by the Compensation Program Act and that it would result in unwarranted denials of compensation applications. Instead of cost cutting measures, the Administration should be considering whether measures are needed to increase the number of applications that are granted. On average, approximately 70% of the applications are denied.

Government witnesses have testified that cost containment is not a factor in deciding which claims to pay, but this has not eliminated concern. The Subcommittee asked DOL to provide all documents related to the five options outlined in the OMB passback. The Subcommittee received a box of about 4,500 pieces of paper from DOL but none of these documents provided the necessary information. When this was brought to DOL's attention, its response was that the request was overly broad. The Subcommittee reduced its request to the documents of 25 key DOL-ESA staff, but

the government still would not cooperate fully. The debate reached a point at which a subpoena was considered. More documents were made available to the Subcommittee, but the integrity of the application process is still in doubt.

I have introduced a bill to address these problems, the Energy Employees Occupational Illness Compensation Program Improvement Act of 2006, H.R. 5840. Among other things, it would shift the authority for making Advisory Board appointments to the Congress. It would require the HHS Secretary to abide by the recommendations of the Advisory Board, unless there is a clear error. It would establish enforceable conflict of interest requirements with respect to NIOSH's dose reconstruction contractors. Also, it would eliminate unfairness by making benefits available to some subcontractor employees who worked at atomic weapons employer facilities but presently are not covered by the Act.

may be eligible for benefits if they have one of 22 specified radiosensitive cancers, and they must have worked at a covered facility for at least one year in a job that exposed them to radiation.

In an internal passback memorandum from the Office of Management and Budget (OMB) to the Department of Labor (DOL), OMB states that the Administration will convene a White House-led interagency workgroup to develop options for administrative procedures to contain the growth in the costs of the program. OMB states further that the discussions would include but not be limited to a requirement for the Administration's clearance of Special Exposure Cohort determinations; addressing imbalances in the membership of the Advisory Board; requiring an expedited review by outside experts of Special Exposure Cohort recommendations by NIOSH; requiring NIOSH to apply conflict of interest rules and constraints to the Advisory Board's contractor; and requiring that NIOSH demonstrate that its site profiles and other dose reconstruction guidance are balanced.

MEMORANDUM FROM MORTON ROSENBERG, SPECIALIST IN AMERICAN PUBLIC LAW, AMERICAN LAW DIVISION, CONGRESSIONAL RESEARCH SERVICE

Memorandum July 20, 2006

TO: Honorable John N. Hostettler, Chairman
House Judiciary Subcommittee on Immigration, Border Security and Claims

FROM: Morton Rosenberg
Specialist in American Public Law
American Law Division

SUBJECT: Substantiality of an Agency's Legal and Policy Objections in Refusing to Comply with Requests for Documents and the Testimony of Agency Personnel

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Pursuant to your Subcommittee's authority under Rules X and XI of the House of Representatives, you initiated, in late 2005, an investigation with respect to the implementation of the Energy Employees Occupational Illness Compensation Program Act (EEOICPA or the Act)[1] by the Office of Management and Budget (OMB), and the Departments of Health and Human Services (HHS), Labor (DOL), and Energy (DOE). The Act set up a program to provide for compensation of DOE employees who developed disabling or fatal illnesses as a result of exposure to beryllium, ionizing radiation and other hazards unique to nuclear weapons productions and testing. Often, these workers were neither adequately protected from, nor informed of, the occupational hazards to which they we exposed.

Further, in some instances DOE and its contractors did not properly monitor workers' exposures to radiation, or the records of those exposures no longer exist. To accommodate workers who may have been exposed to dangerous levels of radiation but whose exposure doses cannot be documented, the President, by Executive Order 13179, directed the Secretary of HHS, in conjunction with an Advisory Board on Radiation and Worker Health (the Advisory Board), to designate members of a "Special Exposure Cohort" (SEC). Determining who qualifies for SEC membership is to be initiated by petitions from classes of possibly affected workers.

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[1] Pub. L. 106-398, Div. C, title XXXVI, secs. 3602 *et seq.*, 1654, 1654A *et seq.*, *codified at* 42 U.S.C.7384 *et seq.*

The Advisory Board itself also was established by Executive Order 13179, [2] pursuant to a directive in the Act.[3] The Act states that members are to be appointed by the President and such appointments are "to ensure that the membership of the Board reflects a balance of scientific, medical and worker perspectives."[4] The principal duty of the Advisory Board is to receive, consider and evaluate petitions for SEC status and to recommend such status to the President's designee, the Secretary of HHS. The Board's advice "shall be based on exposure assessments by radiation health professionals, information provided by the Department of Energy, and such other information as the Advisory Board considers appropriate."[5] The Executive Order designates the Secretary of Labor as having "primary responsibility for administering the program" with regard to "all questions arising under the Act not assigned to other agencies by the Act or this order."[6]

The current investigation was spurred by the Subcommittee's receipt of a communication – a "passback" during the budget preparation process - from OMB to DOL discussing ways to contain a potential cost increase in payment of claims by limiting SEC petition approvals. The document detailed five options which appeared to the Subcommittee to be aimed at cutting benefits and payments to potentially legitimate beneficiaries as contemplated by the Act. The Subcommittee initially requested that OMB provide a witness for a March 2006 hearing to testify about the nature and purpose of the five options or, in the alternative, provide a disavowal of the passback options. In response, OMB claimed that the passback was a "deliberative process" document about which it would not provide public testimony. OMB, however, agreed to draft a clarifying document. Its submission was deemed non-responsive to the Subcommittee's concerns. Continued attempts over the next several months failed to yield an accommodation. Meanwhile, additional concerns were raised with respect to the balance in the membership of the Advisory Board required by the Act (only two of the current 11 members represent workers' interests), and to the issuance of a Department of Justice legal opinion supporting the use of classified information in SEC petition determinations. The Subcommittee requested that the administration advise that, due to the essential need for transparency in the Act's claims process, classified information not be used as the primary basis for denial of an SEC petition.

You inquire as to the substantiality of the OMB refusal to provide a witness to explain the origins, nature and purpose of the passback document, as well as its refusal to provide documents to inform the Subcommittee whether the EEOICPA program is being implemented in the manner intended by Congress. Two access issues appear to be raised by OMB's refusals: Whether a claim of "deliberative process" privilege by an entity in the Executive Office of the President (EOP) is appropriate in these circumstances to withhold confidential communications from scrutiny by a jurisdictional committee; and whether OMB can dictate the manner, form and timing of responses to congressional information requests.

Our review of the historical experience and legal rulings on access to information indicates that claims exactly like those asserted here -- deliberative process, confidential

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[2] 65 Fed. Reg. 77487 (December 7, 2000).

[3] 42 U.S.C. 7384o.

[4] 42 U.S.C. 7384o (2). Section 4(a) of Executive Order 13179 provides that the Board "shall consist of no more than 20 members."

[5] 42 U.S.C. 7384q.

[6] E.O. 13179, sec. 2(a)(1).

communications, and an agency's prerogative to determine who will be interviewed or testify before a jurisdictional committee – have been consistently rejected and compliance has been forthcoming.

Such assertions have predominately emanated from the Department of Justice (DOJ), the principal executive law enforcement agency, but have been raised by other departments and agencies in the past, including OMB, HHS, DOL and DOE. In the last 80 years Congress has consistently sought and obtained from DOJ deliberative prosecutorial memoranda, and the testimony of line attorneys, FBI field agents and other subordinate agency employees, regarding the conduct of open and closed cases in the course of innumerable investigations of DOJ activities. It appears that the fact that an agency, such as the Justice Department, or any other agency exercising law enforcement authority, has determined for its own internal purposes that a particular item should not be disclosed, or that the information sought should come from one agency source rather than another, does not prevent either House of Congress, or its committees or subcommittees, from obtaining and publishing information it considers essential for the proper performance of its constitutional functions. We are aware of no court precedent that imposes a threshold burden on committees to demonstrate, for example, a "substantial reason to believe wrongdoing occurred" before they may seek disclosure with respect to the conduct of specific open and closed criminal and civil cases, and certainly not with respect to committee oversight of agency implementation of statutory mandates. Indeed, the case law is quite to the contrary. An inquiring committee need only show that the information sought is within the broad subject matter of its authorized jurisdiction, is in aid of a legitimate legislative function, and is pertinent to the area of concern. There has been no claim by OMB of a lack of jurisdiction of your committee, or that your inquiry is for an improper legislative purpose, or that testimony of an OMB witness is not pertinent to the investigation.

Our discussion will proceed as follows. We will briefly review the legal basis for investigative oversight and then describe several prominent instances of congressional oversight, principally using examples involving DOJ, that reflect the milestones in the establishment of oversight prerogatives vis- a- vis all executive departments and agencies. In light of this history, and the case law developed in conjunction with these proceedings, we assess the efficacy of the OMB claims.

The Legal Basis for Congressional Oversight

Numerous Supreme Court precedents establish and support a broad and encompassing power in the Congress to engage in oversight and investigation that reaches all sources of information that enable it to carry out its legislative function. In the absence of a countervailing constitutional privilege or a self-imposed statutory restriction upon their authority, Congress and its committees have virtually plenary power to compel information needed to discharge their legislative function from executive agencies, private persons and organizations, and within certain constraints, the information so obtained may be made public.

Although there is no express provision of the Constitution that specifically authorizes Congress to conduct investigations and take testimony for the purposes of performing its legitimate function, numerous decisions of the Supreme Court have firmly established that the investigatory power of Congress is so essential to the legislative function as to be implicit

in the general vesting of legislative power in Congress.[7] Thus, in *Eastland v. United States Servicemen's Fund*, the Court explained that "[t]he scope of its power of inquiry ... is as penetrating and far-reaching as the potential power to enact and appropriate under the Constitution."[8] In *Watkins v. United States*, the Court further described the breadth of the power of inquiry: "The power of the Congress to conduct investigations is inherent in the legislative process. That power is broad. It encompasses inquiries concerning the administration of existing laws as well as proposed or possibly needed statutes."[9] The Court did not limit the power of congressional inquiry to cases of "wrongdoing." It emphasized, however, that Congress' investigative power is at its peak when the subject is alleged waste, fraud, abuse, or maladministration within a government department. The investigative power, it stated, "comprehends probes into departments of the Federal Government to expose corruption, inefficiency, or waste."[10] "[T]he first Congresses," it continued, held "inquiries dealing with suspected corruption or mismanagement of government officials"[11] and subsequently, in a series of decisions, "[t]he Court recognized the danger to effective and honest conduct of the Government if the legislative power to probe corruption in the Executive Branch were unduly hampered."[12] Accordingly, the Court recognizes "the power of the Congress to inquire into and publicize corruption, maladministration, or inefficiencies in the agencies of Government."[13]

The breadth of a jurisdictional committee's investigative authority may be seen in the two seminal Supreme Court decisions emanating from the Teapot Dome inquiries of the mid-1920's. As part of its investigation, a Senate select committee issued a subpoena for the testimony of Mally S. Daugherty, the brother of the Attorney General. After Daugherty failed to respond to the subpoena, the Senate sent its Deputy Sergeant at Arms to take him into custody and bring him before the Senate. Daugherty petitioned in federal court for a writ of *habeas corpus* arguing that the Senate in its investigation had exceeded its constitutional powers. The case ultimately reached the Supreme Court, where, in a landmark decision, *McGrain v. Daugherty*,[14] the Court upheld the Senate's authority to investigate these charges concerning the Department:

> [T]he subject to be investigated was the administration of the Department of Justice - whether its functions were being properly discharged or were being neglected or misdirected, and particularly whether the Attorney General and his assistants were performing or neglecting their duties in respect of the institution and prosecution of proceedings to punish crimes and enforce appropriate remedies against

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[7] *E.g., McGrain v. Daugherty*, 273 U.S. 135 (1927); *Watkins v. United States*, 354 U.S. 178 (1957); *Barenblatt v. United States*, 360 U.S. 109 (1950); *Eastland v. United States Servicemen's Fund*, 421 U.S. 491 (1975); *Nixon v. Administrator of General Services*, 433 U.S. 425 (1977); see also, *United States v. A.T.T.*, 551 F.2d 384 (D.C. Cir. 1976) and 567 F.2d 1212 (D.C. Cir. 1977).

[8] 421 U.S. at 504 n. 15 (quoting *Barenblatt, supra*, 360 U.S. at 111).

[9] 354 U.S. at 187.

[10] *Id.*

[11] *Id.* at 182.

[12] *Id.* at 194-95

[13] *Id.* at 200 n. 33.

[14] 273 U.S. 135 (1927).

> the wrongdoers - specific instances of alleged neglect being recited. Plainly the subject was one on which legislation could be had and would be materially aided by the information which the investigation was calculated to elicit. This becomes manifest when it is reflected that the functions of the Department of Justice, the powers and duties of the Attorney General and the duties of his assistants, are all subject to congressional legislation, and that the department is maintained and its activities are carried on under such appropriations as in the judgment of Congress are needed from year to year.[15]

The Court thus underlined that the Department of Justice, like all other executive departments and agencies, is a creature of the Congress and subject to its plenary legislative and oversight authority.

In another Teapot Dome case that reached the Supreme Court, *Sinclair v. United States,*[16] a different witness at the congressional hearings refused to provide answers, and was prosecuted for contempt of Congress. The witness had noted that a lawsuit had been commenced between the government and the Mammoth Oil Company, and declared, "I shall reserve any evidence I may be able to give for those courts... and shall respectfully decline to answer any questions propounded by your committee."[17] The Supreme Court upheld the witness' conviction for contempt of Congress. The Court considered and rejected in unequivocal terms the witness' contention that the pendency of lawsuits provided an excuse for withholding information. Neither the laws directing that such lawsuits be instituted, nor the lawsuits themselves, "operated to divest the Senate, or the committee, of power further to investigate the actual administration of the land laws."[18] The Court further explained: "It may be conceded that Congress is without authority to compel disclosure for the purpose of aiding the prosecution of pending suits; but the authority of that body, directly or through its committees to require pertinent disclosures in aid of its own constitutional power is not abridged because the information sought to be elicited may also be of use in such suits."[19]

Illustrative Instances of Congressional Committees Obtaining Prosecutorial Deliberative Materials and the Testimony of Line Personnel

The Senate select committee in the Teapot Dome scandal was constituted to investigate "charges of misfeasance and nonfeasance in the Department of Justice"[20] in failing to prosecute the malefactors in the Department of the Interior, as well as other cases.[21] The select committee heard from scores of present and former attorneys and agents of the Department and its Bureau of Investigation, who offered detailed testimony about specific

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[15] 273 U.S. at 177-78.

[16] 279 U.S. 263 (1929).

[17] *Id.* at 290.

[18] *Id.* at 295.

[19] *Id.*.

[20] *McGrain v. Daugherty,* 273 U.S. 135, 151 (1927).

[21] Investigation of Hon. Harry M. Daugherty, Formerly Attorney General of the United States: Hearings Before the Senate Select Committee on Investigation of the Attorney General, vols. 1-3, 68th Congress, 1st Session (1924).

instances of the Department's failure to prosecute alleged meritorious cases. Not all of the cases upon which testimony was offered were closed, as one of the committee's goals in its questioning was to identify cases in which the statute of limitations had not run out and prosecution was still possible.[22]

The committee also obtained access to Department documentation, including prosecutorial memoranda on a wide range of matters. However, given the charges of widespread corruption in the Department and the imminent resignation of Attorney General Daugherty, it would appear that some of the documents furnished the committee early in the hearings may have been volunteered by the witnesses and not officially provided by the Department. Although Attorney General Daugherty had promised cooperation with the committee, and had agreed to provide access to at least the files of closed cases,[23] such cooperation apparently had not been forthcoming.[24]

In two instances immediately following Daugherty's resignation, the committee was refused access to confidential Bureau of Investigation investigative reports pending the appointment of a new Attorney General who could advise the President about such production,[25] though witnesses from the Department were permitted to testify about the investigations that were the subject of the investigative reports and even to read at the hearings from the investigative reports. With the appointment of the new Attorney General, Harlan F. Stone, the committee was granted broad access to Department files. Committee Chairman Smith Brookhard remarked that "[Stone] is furnishing us with all the files we want, whereas the former Attorney General, Mr. Daugherty, refused nearly all that we asked."[26] For example, with the authorization of the new Attorney General, an accountant with the Department who had led an investigation of fraudulent sales of property by the Alien Property Custodian's office appeared and produced his confidential reports to the Bureau of Investigation. The reports described the factual findings from his investigation and his recommendations for further action, and included the names of companies and individuals suspected of making false claims. The Department had not acted on those recommendations, though the cases had not been closed.[27] A similar investigative report, concerning an inquiry into the disappearance of large quantities of liquor under the control of the Department during the prior administration of President Harding, was also produced.[28]

One of the most prominent congressional investigations of the Department of Justice grew out of the highly charged confrontation at the end of the 97th Congress concerning the refusal of Environmental Protection Agency Administrator Ann Gorsuch Burford, under orders from the President, to comply with a House subcommittee subpoena requiring the production of documentation about EPA's enforcement of the hazardous waste cleanup legislation. This dispute culminated in the House of Representative's citation of Burford for contempt of Congress, the first head of an Executive Branch agency ever to have been so

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[22] *See, e.g., id.* at 1495-1503, 1529-30,2295-96.

[23] *Id.* at 1120.

[24] *Id.* at 1078- 79.

[25] *Id.* at 1015-16 and 1159-60.

[26] *Id.* at 2389.

[27] *Id.* at 1495-1547.

[28] *Id.* at 1790.

cited by a House of Congress. It also resulted in the filing of an unprecedented legal action by the Department, in the name of the United States, against the House of Representatives and a number of its officials to obtain a judicial declaration that Burford had acted lawfully in refusing to comply with the subpoena.

Ultimately, the lawsuit was dismissed,[29] the documents were provided to Congress, and the contempt citation was dropped. However, a number of questions about the role of the Department during the controversy remained: whether the Department, not EPA, had made the decision to persuade the President to assert executive privilege; whether the Department had directed the United States Attorney for the District of Columbia not to present the contempt certification of Burford to the grand jury for prosecution and had made the decision to sue the House; and, generally, whether there was a conflict of interest in the Department's simultaneously advising the President, representing Burford, investigating alleged Executive branch wrongdoing, and enforcing the congressional criminal contempt statute. These and related questions raised by the Department's actions were the subject of an investigation by the House Judiciary Committee beginning in early 1983. The committee issued a final report on its investigation in December 1985.[30]

Although the Judiciary Committee ultimately was able to obtain access to virtually all of the documentation and other information it sought from the Department, in many respects this investigation proved as contentious as the earlier EPA controversy from which it arose. In its final report, the committee concluded that:

> [T]he Department of Justice, through many of the same senior officials who were most involved in the EPA controversy, consciously prevented the Judiciary Committee from obtaining information in the Department's possession that was essential to the Committee's inquiry into the Department's role in that controversy. Most notably, the Department deliberately, and without advising the Committee, withheld a massive volume of vital handwritten notes and chronologies for over one year. These materials, which the Department knew came within the Committee's February 1983 document request, contained the bulk of the relevant documentary information about the Department's activities outlined in this report and provided a basis for many of the Committee's findings.[31]

Among the other abuses cited by the committee were the withholding of a number of other relevant documents until the committee had independently learned of their existence,[32] as well as materially "false and misleading" testimony before the committee by the head of the Department's Office of Legal Counsel.[33]

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[29] *U.S. v. House of Representatives*, 557 F. Supp. 150 (D.D.C. 1983).

[30] See, Report of the House Comm. on the Judiciary on Investigation of the Role of the Department of Justice in the Withholding of Environmental Protection Agency Documents from Congress in 1982-1983, H.R. Rep. No.99-435, 99th Cong., 1st Sess (1985) ("EPA Withholding Report").

[31] EPA Withholding Report at 1163; *see* also 1234-38.

[32] *Id.* at 1164.

[33] *Id.* at 1164- 65 & 1191-1231.

The committee's initial request for documentation was contained in a February 1983 letter from its chairman, Peter Rodino, to Attorney General William French Smith. The committee requested the Department to "supply all documents prepared by or in the possession of the Department in any way relating to the withholding of documents that Congressional committees have subpoenaed from the EPA."[34] The letter also specifically requested, among other things, a narrative description of the activities of each division or other unit of the Department relating to the withholding of the EPA materials, information about the Department's apparent conflict of interest in simultaneously advising the Executive Branch while being responsible for prosecuting the Burford contempt citation, and any instructions given by the Department to the United States Attorney for the District of Columbia not to present the Burford contempt to the grand jury.

At first the Department provided only publicly available documents in response to this and other document requests.[35] However, after a series of meetings between committee staff and senior Department officials, an agreement was reached whereby committee staff were permitted to review the materials responsive to these requests at the Department to determine which documents the committee would need for its inquiry.[36] Committee staff reviewed thousands of documents from the Land and Natural Resources Division, the Civil Division, the Office of Legal Counsel, the Office of Legislative Affairs, the Office of Public Affairs, and the offices of the Attorney General, the Deputy Attorney General, and the Solicitor General.[37]

In July 1983, the committee chairman wrote to the Attorney General requesting copies of 105 documents that committee staff had identified in its review as particularly important to the committee's inquiry.[38] By May 1984, only a few of those documents had been provided to the committee, and the chairman again wrote to the Attorney General requesting the Department's cooperation in the investigation. In that letter, the chairman advised the Attorney General that the committee's preliminary investigation had raised serious questions of misconduct, including potential criminal misconduct, in the actions of the Department in the withholding of the EPA documents.[39] The committee finally received all of the 105 documents in July 1984, a full year after it had initially requested access. The committee at that time also obtained the written notes and a number of other documents that had been earlier withheld.[40]

There was also disagreement about the access that would be provided to Department employees for interviews with committee staff. The Department demanded that it be permitted to have one or more Department attorneys present at each interview. The committee feared that the presence of Department representatives might intimidate the Department employees in their interviews and stated that it was willing to permit a Department representative to be present only if the representative was "walled-off" from

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[34] *Id.* at 1167 & 1182-83.

[35] *Id.* at 1184.

[36] *Id.* at 1168 & 1233.

[37] *Id.* at 1168.

[38] *Id.* at 1169.

[39] *Id.* at 1172.

[40] *Id.* at 1173.

Department officials involved with the controversy, if the substance of interviews was not revealed to subsequent interviewees, and if employees could be interviewed without a Department representative present if so requested. The Department ultimately agreed to permit the interviews to go forward without its attorneys present. If a Department employee requested representation, the Department employed private counsel for that purpose. In all, committee staff interviewed twenty-six current and former Department employees, including four Assistant Attorney Generals, under this agreement.[41]

Partly as a result of these interviews, as well as from information in the handwritten notes that had been initially withheld, the committee concluded that it also required access to Criminal Division documents concerning the origins of the criminal investigation of former EPA Assistant Administrator Rita Lavelle in order to determine if the Department had considered instituting the investigation to obstruct the committee's inquiry. The committee also requested information about the Department's earlier withholding of the handwritten notes and other documents to determine whether Department officials had deliberately withheld the documents in an attempt to obstruct the committee's Investigation.[42] The Department at first refused to provide the committee with documents relating to its Lavelle investigation "[c]onsistent with the longstanding practice of the Department not to provide access to active criminal files."[43] The Department also refused to provide the committee with access to documentation related to the Department's handling of the committee's inquiry, objecting to the committee's "ever- broadening scope of ...inquiry."[44]

The committee chairman wrote the Attorney General and objected that the Department was denying the committee access even though no claim of executive privilege had been asserted.[45] The chairman also maintained that "[i]n this case, of course, no claim of executive privilege could lie because of the interest of the committee in determining whether the documents contain evidence of misconduct by executive branch officials."[46] With respect to the documents relating to the Department's handling of the committee inquiry, the chairman demanded that the Department prepare a detailed index of the withheld documents, including the title, date, and length of each document, its author and all who had seen it, a summary of its contents, an explanation of why it was being withheld, and a certification that the Department intended to recommend to the President the assertion of executive privilege as to each withheld document and that each document contained no evidence of misconduct.[47] With respect to the Lavelle documents, the chairman narrowed the committee's request to "predicate" documents relating to the opening of the investigation and prosecution of Lavelle, as opposed to FBI and other investigative reports reflecting actual investigative work conducted after the opening of the investigation.[48] In response, after a

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[41] *Id.* at 1174-76.

[42] *Id.* at 1176- 77 & 1263-64.

[43] *Id.* at 1265.

[44] *Id.* at 1265.

[45] *Id.* at 1266.

[46] *Id.*

[47] *Id.* at 1268-69.

[48] *Id.* at 1269-70.

period of more than three months from the committee's initial request, the Department produced those two categories of materials.[49]

But this was not the last chapter of this affair. Prosecutorial discretion was said to be off limits to congressional inquiry and access demands were asserted to interfere with the discretion traditionally enjoyed by the prosecutor. That argument was raised to a constitutional level in litigation that ensued after the Judiciary Committee filed its report and asked the Attorney General to appoint an independent counsel to pursue a criminal investigation of Department officials based on the Committee's findings. The appointment was made and during the course of the investigation one of the subjects, Theodore Olson, who at the time of the Burford affair was the Assistant Attorney General for the Office of Legal Counsel, was served with a subpoena and refused to comply, claiming that the independent counsel statute was unconstitutional on a variety of constitutional grounds.

Subsequently, the Supreme Court rejected the notion that prosecutorial discretion in criminal matters is an inherent or core executive function. Rather, the Court noted in *Morrison v. Olson,* [50] sustaining the validity of the appointment and removal conditions for independent counsels under the Ethics in Government Act, that the independent counsel's prosecutorial powers are executive in that they have "typically" been performed by Executive Branch officials, but held that the exercise of prosecutorial discretion is in no way "central" to the functioning of the Executive Branch.[51] The Court therefore rejected a claim that insulating the independent counsel from at-will presidential removal interfered with the President's duty to "take care" that the laws be faithfully executed. Interestingly, the *Morrison* Court took the occasion to reiterate the fundamental nature of Congress' oversight function: " . . . [R]eceiving reports or other information and oversight of the independent counsel's activities . . . [are] functions that we have recognized as generally incidental to the legislative function of Congress" (citing *McGrain v. Daugherty*).[52]

A subsequent relevant case study involved a 1992 inquiry of the Subcommittee on Investigations and Oversight of the House Committee on Science, Space, and Technology commenced a review of the plea bargain settlement by the Department of Justice of the government's investigation and prosecution of environmental crimes committed by Rockwell International Corporation in its capacity as manager and operating contractor at the Department of Energy's (DOE) Rocky Flats nuclear weapons facility.[53] The settlement was a culmination of a five-year investigation of environmental crimes at the facility, conducted by a joint government task force involving the FBI, the Department of Justice, the Environmental Protection Agency (EPA), EPA's National Enforcement Investigation

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[49] *Id.* at 1270.

[50] 487 U.S. 654 (1988).

[51] *Id.* at 691-92.

[52] *Id.* at 694.

[53] See Environmental Crimes at the Rocky Flats Nuclear Weapons Facility: Hearings Before the Subcomm. on Investigations and Oversight of the House Committee on Science, Space and Technology, 102d Cong., 2d Sess., Vols. I and II (1992) ("Rocky Flats Hearings"); Meetings: To Subpoena Appearance by Employees of the Department of Justice and the FBI and To Subpoena Production of Documents From Rockwell International Corporation, Before the Subcomm. on Investigations and Oversight of the House Comm. on Science, Space, and Technology, 102d Congress, 2d Sess., (1992)("Subpoena Meetings").

Centers, and the DOE Inspector General. The subcommittee was concerned with the size of the fine agreed to relative to the profits made by the contractor and the damage caused by inappropriate activities; the lack of personal indictments of either Rockwell or DOE personnel despite a DOJ finding that the crimes were "institutional crimes" that "were the result of a culture, substantially encouraged and nurtured by DOE, where environmental compliance was a much lower priority than the production and recovery of plutonium and the manufacture of nuclear "triggers"; and that reimbursements provided by the government to Rockwell for expenses in the cases and the contractual arrangements between Rockwell and DOE may have created disincentives for environmental compliance and aggressive prosecution of the case.

The subcommittee held ten days of hearings, seven in executive session, in which it took testimony from the United States Attorney for the District of Colorado; an assistant U.S. Attorney for the District of Colorado; a DOJ line attorney from Main Justice; and an FBI field agent; and received voluminous FBI field investigative reports and interview summaries, and documents submitted to the grand jury not subject to Rule 6(e).[54]

At one point in the proceedings all the witnesses who were under subpoena, upon written instructions from the Acting Assistant Attorney General, Criminal Division, refused to answer questions concerning internal deliberations in which decisions were made about the investigation and prosecution of Rockwell, the DOE and their employees. Two of the witnesses advised that they had information and, but for the DOJ directive, would have answered the subcommittee's inquiries. The subcommittee members unanimously authorized the chairman to send a letter to President Bush requesting that he either personally assert executive privilege as the basis for directing the witnesses to withhold the information or direct DOJ to retract its instructions to the witnesses. The President took neither course and the DOJ subsequently reiterated its position that the matter sought would chill Department personnel. The subcommittee then moved to hold the U.S. Attorney in contempt of Congress.

A last minute agreement forestalled the contempt citation. Under the agreement (1) DOJ issued a new instruction to all personnel under subpoena to answer all questions put to them by the subcommittee, including those which related to internal deliberations with respect to the plea bargain. Those instructions were to apply as well to all Department witnesses, including FBI personnel, who might be called in the future. Those witnesses were to be advised to answer all questions fully and truthfully and specifically instructed that they were allowed to disclose internal advice, opinions, or recommendations connected to the matter. (2) Transcripts were to be made of all interviews and provided to the witnesses. They were not to be made public except to the extent they needed to be used to refresh the recollection or impeach the testimony of other witnesses called before the subcommittee in a public hearing. (3) Witnesses were to be interviewed by staff under oath. (4) The subcommittee reserved the right to hold further hearings in the future at which time it could call other Department witnesses who would be instructed by the Department not to invoke the deliberative process privilege as a reason for not answering subcommittee questions.[55]

The most recent and definitive exploration and resolution of the question of the nature and breadth of Congress' oversight prerogative with respect to DOJ operations occurred as a consequence of the President's December 2001 claim of executive privilege in response

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[54] Rocky Flats Hearing, Vol. I, at 389-1009, 1111-1251; Vol. II.

[55] Rocky Flats Hearings, Vol. I at 9-10,25-31,1673-1737; Subpoena Hearings, at 1-3,82-86, 143-51.

to a subpoena by the House Government Reform Committee. That subpoena sought, among other material, Justice Department documents relating to alleged law enforcement corruption in the Federal Bureau of Investigation's Boston office that occurred over a period of almost 30 years. During that time, FBI officials allegedly knowingly allowed innocent persons to be convicted of murder on the false testimony of two informants in order to protect the undercover activities of those informants, then knowingly permitted the two informants to commit some 21 additional murders during the period they acted as informants, and, finally, gave the informants warning of an impending grand jury indictment and allowed them to flee. The President directed the Attorney General not to release the documents because disclosure "would inhibit the candor necessary to the effectiveness of the deliberative processes by which the Department makes prosecutorial decisions," and that committee access to the documents "threatens to politicize the criminal justice process" and to undermine the fundamental purpose of the separation of power doctrine, "which was to protect individual liberty." In defending the assertion of the privilege the Justice Department claimed a historical policy of withholding deliberative prosecutorial documents from Congress in both open and closed civil and criminal cases.[56]

Initial congressional hearings after the claim was made demonstrated the rigidity of the Department's position. The Department later agreed there might be some area for compromise, and on January 10, 2002, White House Counsel Gonzales wrote to Chairman Burton conceding that it was a "misimpression" that congressional committees could never have access to deliberative documents from a criminal investigation or prosecution. "There is no such bright-line policy, nor did we intend to articulate any such policy." But, he continued, since the documents "sought a very narrow and particularly sensitive category of deliberative matters" and "absent unusual circumstances, the Executive Branch has traditionally protected these highly sensitive deliberative documents against public or congressional disclosure" unless a committee showed a "compelling or specific need" for the documents.[57] The documents continued to be withheld until a further hearing, held on February 6, 2002, when the committee heard expert testimony describing over 30 specific instances since 1920 of the Department of Justice giving access to prosecutorial memoranda for both open and closed cases and providing testimony of subordinate Department employees, such as line attorneys, FBI field agents and U.S. attorneys, and included detailed testimony about specific instances of DOJ's failure to prosecute meritorious cases. In all instances, investigating committees were provided with documents respecting open and closed cases that often included prosecutorial memoranda, FBI investigative reports, summaries of FBI interviews, memoranda and correspondence prepared during undercover operations, and documents presented to grand juries not protected by Rule 6(e), among other similar "sensitive materials." Six days after the hearing the Committee was given access to the disputed documents.[58]

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[56] Louis Fisher, "The Politics of Executive Privilege," Carolina Academic Press, 108 (2004)(Fisher).

[57] Fisher, *Id.*

[58] "Everything Secret Degenerates: The FBI's Use of Murderers As Informants," House Report No. 108-414, 108th Cong., 2d Sess. 121-134 (2004); Hearings, " Investigation Into Allegations of Justice Department Misconduct In New England-Volume I", House Comm. on Government Reform, 107th Cong., 1st and 2d Sess's. 520-556, 562-604 (May 3, December 13, 2001; February 6, 2002) (Hearings); *McIntyre v. United States*, 367 F.3d 38, 42-51 (1st Cir. 2004)(recounting background of FBI corrupt activities); *United States v. Salemme*, 91 Fed. Supp. 2d 141, 148-63, 208-15, 322 (D.Mass. 1993) (same); *United States v. Flemmi*, 195 F. Supp 243, 249-50 (D. Mass. 200); (same)

(continued...)

The instances of successful committee access to DOJ documents and witnesses cataloged in the above referenced hearing encompassed a wide number of divisions, bureaus, and offices at Main Justice and U.S. Attorneys offices in the field, and involved the Department's "sensitive" Public Integrity Section,[59] and provide a substantial basis for arguing that no element of the DOJ is exempt from oversight by a jurisdictional committee of the Congress. Indeed, other congressional investigations not cataloged have reached still other DOJ elements, including the DOJ Office of Professional Responsibility. That occurred during the 1995 investigation by the Senate Judiciary Committee's Subcommittee on Terrorism, Technology and Government Information of allegations that several branches of the Department of Justice and the Department of the Treasury had engaged in serious criminal and professional misconduct in the investigation, apprehension and prosecution of Randall Weaver and Kevin Harris at Ruby Ridge, Idaho. The Subcommittee held 14 days of hearings in which it heard testimony from 62 witnesses, including Justice, Federal Bureau of Investigation, and Treasury officials, line attorneys and agents, and obtained various Justice, FBI and Treasury internal reports,[60] and issued a final report.[61]

The Subcommittee's hearings revealed that the involved federal agencies conducted at least eight internal investigations into charges of misconduct at Ruby Ridge, none of which has ever been publically released.[62] DOJ expressed reluctance to allow the Subcommittee to see the documents out of a concern they would interfere with the ongoing investigation but ultimately provided some of them under conditions with respect to their public release. The most important of those documents was the Report of the Ruby Ridge Task Force.[63] The Task Force was established by the DOJ after the acquittals of Randy Weaver and Kevin Harris of all charges in the killing of a Deputy United States Marshal[64] to investigate charges that federal law enforcement agents and federal prosecutors involved in the investigation, apprehension and prosecution of Weaver and Harris may have engaged in professional misconduct and criminal wrongdoing. The allegations were referred to DOJ's Office of Professional Responsibility (OPR). The Task Force was headed by an Assistant Counsel from OPR and consisted of four career attorneys from DOJ's Criminal Division and a number of FBI inspectors and investigative agents. The Task Force submitted a 542 page report to OPR on June 10, 1994, which found numerous problems with the conduct of the

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[58] (...continued)
Charles Trefer, "President Bush's First Executive Privilege Claim: The FBI/Boston Investigation", 33 Pres. Stud. Q. 201(2003).

[59] See Hearings, *supra*, at 549-50, 555.

[60] Hearings, "The Federal Raid on Ruby Ridge, Idaho," before the Senate Subcomm. On Terrorism, Technology, Government Information, Comm. on the Judiciary, 104th Cong., 1st Sess. (1995) (Ruby Ridge Hearings).

[61] Ruby Ridge: Report of the Subcommittee on Terrorism, Technology and Government Information of the Senate Committee on the Judiciary (Ruby Ridge Report). The 154-page document appears not to have been officially reported by the full Committee. A bound copy may be found in the United States Senate Library, catalogue number HV 8141.U56 1995.

[62] Ruby Ridge Report at 1; Ruby Ridge Hearings at 722, 954, 961.

[63] The Task Force Report was never publically released or printed in the Subcommittee's hearing record. A bound copy of the Report provided the Subcommittee may be found in the United States Senate Library, catalogue number HV8141.U55 1995.

[64] Weaver was convicted for failure to appear for a trial and for commission of an offense while on release.

FBI, the U.S. Marshals Service, and the U.S. Attorneys office in Idaho, and made recommendations for institutional changes to address the problems it found. It also concluded that portions of the rules of engagement issued by the FBI during the incident were unconstitutional under the circumstances, and that the second of two shots taken by a member of the FBI's Hostage Rescue Team (HRT), which resulted in the death of Vicki Weaver, was not reasonable. The Task Force recommended that the matter of the shooting be referred to a prosecutorial component of the Department for a determination as to whether a criminal investigation was appropriate. OPR reviewed the Task Force Report and transmitted the Report to the Deputy Attorney General with a memorandum that dissented from the recommendation that the shooting of Vicki Weaver by the HRT member be reviewed for prosecutorial merit based on the view that given the totality of circumstances, the agent's actions were not unreasonable. The Deputy Attorney referred the Task Force recommendation for prosecutorial review to the Criminal Section of the Civil Rights Division, which concluded that there was no basis for criminal prosecution. The Task Force Report was the critical basis for the Subcommittee's inquiries during the hearings and its discussion and conclusions in its final report.[65]

Claims of Deliberative Process Privilege

Assertions of deliberative process privilege by agencies have not been uncommon in the past. In essence it is argued that congressional demands for information as to what occurred during the policy development process of an agency would unduly interfere, and perhaps "chill," the frank and open internal communications necessary to the quality and integrity of the decisional process. Assertions of privilege may also be grounded on the contentions that it protects against premature disclosure of proposed policies before they are fully considered or actually adopted by the agency, and to prevent the public from confusing matters merely considered or discussed during the deliberative process with those on which the decision was based. However, as with claims of attorney-client privilege and work product immunity, congressional practice has been to treat their acceptance as discretionary with the committee. Moreover, a 1997 appellate court decision underlines the understanding that the deliberative process privilege is a common law privilege of agencies that is easily overcome by a showing of need by an investigatory body, and other court rulings and congressional practice have recognized the overriding necessity of an effective legislative oversight process.

The appeals court ruling in *In re sealed Case (Espy)*[66] is of special note. The case involved, *inter alia*, White House claims of executive and deliberate process privileges for documents subpoenaed by an independent counsel. At the outset of the appeals court's unanimous ruling it carefully distinguished between the "presidential communications privilege" and the "deliberative process privilege." Both, the court observed, are executive privileges designed to protect the confidentiality of executive branch decisionmaking. But the deliberative process privilege applies to executive branch officials generally, is a

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[65] See, *e.g.*, Ruby Ridge Hearings at 719-737, 941-985; Ruby Ridge Report at 10-11 ("With the exceptions of the [Ruby Ridge] Task Force Report, which was partially disavowed by the Department, and the April 5, 1995 memorandum of Deputy Attorney General Jamie Gorelick, it appeared to the Subcommittee that the authors of every report we read were looking more to justify agency conduct than to follow the facts wherever they lead."), 61-69, 115, 122-23, 134-35, 139, 145-49.

[66] 121 F. 3d 729 (D.C. Cir. 1997).

common law privilege which requires a lower threshold of need to be overcome, and "disappears" altogether when there is any reason to believe government misconduct has occurred.[67] The court's recognition of the deliberative process privilege as a common law privilege which, when claimed by executive department and agency officials, is easily overcome, and which "disappears" upon the reasonable belief by an investigating body that government misconduct has occurred, may severely limit the common law claims of agencies against congressional investigative demands. A demonstration of need of a jurisdictional committee would appear to be sufficient, and a plausible showing of fraud waste, abuse or maladministration would be conclusive.

Even before *Espy,* courts and committees had consistently countered such claims of agencies as attempts to establish a species of agency privilege designed to thwart congressional oversight efforts. Thus it has been pointed out that the claim that such internal communications need to be "frank" and "open" does not lend it any special support and that coupling that characterization with the notion that those communications were part of a "deliberative process" will not add any weight to the argument. In effect, such arguments have been seen as attempting to justify a withholding from Congress on the same grounds that an agency would use to withhold such documents from a citizen requester under Exemption 5 of the Freedom of Information Act (FOIA).[68]

Such a line of argument is likely to be found to be without substantial basis. As has been indicated above, Congress has vastly greater powers of investigation than that of citizen FOIA requesters. Moreover, in the FOIA itself, Congress carefully provided that the exemption section "is not authority to withhold information from Congress."[69] The D.C. Circuit in *Murphy v. Department of the Army,*[70] explained that FOIA exemptions were no basis for withholding from Congress because of:

> the obvious purpose of the Congress to carve out for itself a special right of access to privileged information not shared by others . . . . Congress, whether as a body, through committees, or otherwise, must have the widest possible access to executive branch information if it is to perform its manifold responsibilities effectively. If one consequence of the facilitation of such access is that some information will be disclosed to congressional authorities but not to private persons, that is but an incidental consequence of the need for informed and effective lawmakers.[71]

Further, it may be contended that the ability of an agency to assert the need for candor to ensure the efficacy of internal deliberations as a means of avoiding information demands

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[67] 121 F. 3d at 745, 746; see also *id.* at 737-738("[W]here there is reason to believe the documents sought may shed light on government misconduct, the [deliberative process] privilege is routinely denied on the grounds that shielding internal government deliberations in this context does not serve 'the public interest in honest, effective government'").

[68] 5 U.S.C. 553 (b)(5)(1994).

[69] 5 U.S. C. 552 (d).

[70] 613 F. 2d 1151 (D.C. Cir. 1979).

[71] *Id.* at 1155-56, 1158.

would severely undermine the oversight process. If that were sufficient, an agency would be encouraged to disclose only that which supports its positions, and withhold those with flaws, limitations, unwanted implications, or other embarrassments. Oversight would cease to become an investigative exercise of gathering the whole evidence, and become little more than a set-piece of entertainment in which an agency decides what to present in a controlled "show and tell" performance.

Moreover, every federal official, including attorneys, could assert the imperative of timidity that congressional oversight, by holding up to scrutiny the advice he gives, will frighten him away from giving frank opinions, or discourage others from asking him for them. This argument, not surprisingly, has failed over the years to persuade legislative bodies to cease oversight. Indeed, when the Supreme Court discussed the "secret law" doctrine in *NLRB v. Sears, Roebuck & Co.*[72] it addressed why federal officials – including those giving legal opinions – need not hide behind such fears:

> The probability that an agency employee will be inhibited from freely advising a decisionmaker for fear that his advice, if *adopted*, will become public is slight. First, when adopted, the reasoning becomes that of agency and becomes its responsibility to defend. Second, agency employees will generally be encouraged rather than discouraged by public knowledge that their policy suggestions have been adopted by the agency. Moreover, the public interest in knowing the reasons for a policy actually adopted by an agency supports . . .[disclosure].[73]

Finally, without question, under House Rules your Subcommittee has jurisdictional responsibility and authority to conduct an investigation into the propriety and efficacy of the administration of the EEOICPA by OMB and other governmental entities that have roles, responsibilities and authorities in implementing that statutory program. That investigative authority reaches the White House and concerned elements of the Executive Office of the President.[74] We are aware of no legal authority that allows a targeted entity, whether it is a government agency, including the EOP, or private party, to dictate to a jurisdictional committee the manner, order or timing of the exercise of its exercise of investigative authority. The courts have consistently held that under the Speech or Debate Clause of the Constitution[75] the courts may not enjoin, condition or require any delay of the receipt of requested information or documents, "for the judiciary must refrain from slowing or otherwise interfering with the legitimate investigating functions of Congress."[76] Nor may

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[72] 421 U.S. 132 (1975).

[73] *Id.* at 161 (emphasis in original).

[74] Congressional investigations reaching the White House are hardly unknown. See "Presidential Advisers' Testimony Before Congressional Committees: An Overview," CRS Report No. RL31351, which provides a comprehensive list of White House advisors called before investigation committees since the 1940's.

[75] U.S. Const., Art. I, sec. 6, cl. 1.

[76] Eastland v. U.S. Servicemen's Fund, 421 U.S. 491, 501 n.15 (1975); see also United States v. U.S. Houses of Representatives, 556 F. Supp. 150, 152 (D.D.C. 1983) (court refused to enjoin

(continued...)

a court block congressional disclosure of information obtained from an agency or private party, at least when disclosure would serve a valid legislative purpose.[77] Moreover, the legal obligation to surrender requested documents has been held to arise from the official request,[78] and the courts have agreed in construing 18 U.S.C. 1505, a criminal law proscribing the obstruction of congressional proceedings, that the statue is broad enough to cover obstructive acts in anticipation of a subpoena.[79]

Conclusion

Past congressional history and practice, as well as pertinent judicial precedent, appear to support the Subcommittee's demands for the documents and testimony called for in its investigative demands. In the absence of a legitimate claim of executive privilege, the oversight needs of your Subcommittee are sufficient to trump a claim of deliberative process privilege.

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[76] (...continued)
transmission of contempt of Congress citation to a U.S. attorney for prosecution); In re Grand Jury Proceedings of Grand Jury No. 81-1 (Miami), 669 F. Supp. 1072, 1075-76 (D. Fla. 1987), aff'd 883 F. 2d 1438, 1444-45 (11th Cir. 1987); FTC v. Owens-Corning Fiberglass Corp., 626 F.2d 966, 970 (D.C. Cir. 1980); FTC v. Anderson, 631 F. 2d 741, 747 (D.C. Cir. 1980); Exxon Corp. V. FTC, 589 F.2d 582, 589 (D.C. Cir. 1978).

[77] Doe v. McMillan, 412 U.S. 306 (1973); FTC v. Owens-Corning Fiberglass Corp., 626 F. 2d at 970.

[78] Ashland Oil Co. v. FTC, 598 F. 2d 977-81 (D.C. Cir. 1976).

[79] See, e.g., United States v. Mitchell, 877 F. 2d 297, 300-01 (9th Cir. 1979); United States v. North, 708 F. Supp. 372, 374 (D.D.C. 1988); United States v. North, 708 F. Supp. 380, 381-82 (D.D.C. 1988); United States v. Tallant, 407 F. Supp. 878, 888 (D.N.D. Ga. 1975).

PREPARED STATEMENT OF ROBERT ALVAREZ, SENIOR SCHOLAR, INSTITUTE FOR PUBLIC STUDIES

The Risks of Making Nuclear Weapons

By

Robert Alvarez
(Senior Scholar, Institute for Policy Studies)

August 23, 2006

Introduction

When I first met Dr. Thomas F. Mancuso in the fall of 1977, he was poring over computer print-outs in his small, cluttered L-shaped office at the University of Pittsburgh. Spry, with a trim mustache and horn-rimmed glasses, Mancuso's passion for data collection often compelled him to bring his work home. Despite his efforts to transform his large spacious home into a research archive, Mancuso's wife Rae, kept the place spotless. Occasionally, data would be strewn on the dining room table, but most of the records were kept in dozens of filing cabinets in the basement like a highly guarded treasure.

Since 1945, he had mastered the art of assembling millions of bits of information into groundbreaking studies to determine long-term workplace health hazards. Before his pioneering research, "the major focus on workplace health dealt with on-the-job injuries," said, Bernard Goldstein, Dean of the Pittsburgh University School of Public Health in 2004. Mancuso "developed techniques to look at the long-term health effects of working." [1]

Having given away his car to one of his children several years before, the bespecled physician walked every day to his office in the somber Graduate School building, often stopping first to attend Catholic Mass. In contrast to his contemplative side, Mancuso's temper was legendary. But his stubborn quest for perfection was more than offset by his loyalty and kind generosity. These qualities had served him well over the years, but now they were being sorely tested in a struggle over the effects of ionizing radiation on nuclear workers.

Conflict over his studies was nothing new. But it was the unprecedented ferocity of this assault against his research that surprised him. Now as he approached the closing years of his illustrious career, Mancuso had not expected that his tedious sorting of statistics would put him at odds with the U.S. nuclear weapons program, one of the most powerful scientific establishments in the world.

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[1] Michael Taylor, Dr. Thomas Mancuso, long-time advocate for worker's health, Obituary, San Francisco, Chronicle, July 9, 2004. http://www.sfgate.com/cgi bin/article.cgi?file=/chronicle/archive/2004/07/09/BAGRN7IPGL1.DTL

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Early Radiation Exposure Problems

Since World War II, the amassing of nuclear arms resulted in the creation of one of the largest and potentially most dangerous industrial enterprises in the nation. At the outset, the hazardous magnitude of nuclear weapons work was recognized by the scientific members of the Manhattan Project. These concerns led to the creation of the Health Division of the Manhattan Project led by Dr. Robert Stone, chairman of the Radiology Department at the University of California Medical School in San Francisco. According to Stone:

> It was estimated that the pieces of uranium that would have to be removed from the pile [reactor] after fission had occurred would contain materials far more radioactive than any that had been encountered in the radium industry. The chemical process of separating the plutonium from other extremely radioactive elements was recognized as another tremendously hazardous procedure. The effect that plutonium itself might have on workers was unknown.[2]

During the war, Stone concluded that, "the whole clinical study of the personnel is one vast experiment." [3] Like Stone, other officials, such as John Wirth Medical Director at the Oak Ridge, TN recognized that the health consequences to workers could result in "the unexpected appearance of dangerous changes months or years after exposure."[4] Wirth recounted problems where "minute invisible fragments might make an entire building uninhabitable. . . . It always amazing what widespread contamination can be caused by a minute quantity of hot material once it has been allowed to get out of a container."[5]

The Manhattan Project had standard worker compensation insurance, which only covered illnesses or disabilities that appeared within 90 days of an accident or 30 days after leaving the project. But Cyril Stanley Smith, chief metallurgical chemist at Los Alamos, denounced it as "inhumane, unethical and unfair," as he and his fellow chemists refused to work without extra insurance. Bending to their wishes, the U.S. government set up a secret one million dollar fund for the plutonium chemists at Los Alamos.[6]
Ordinary workers in the Manhattan Project fared less well. Ted Lombard was an enlisted man in the U.S. Army assigned to work at the Los Alamos Laboratory during the war who recalled less-than-ideal working conditions:

> We used to go to Fort Douglas, Utah in ambulances, [to] pick up uranium and plutonium. We carried dosimeter badges in our pockets because you couldn't display them. . . . Then [after the badges were turned over to an officer] we would

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[2] Stone, Robert S., "Health Protection Activities of the Manhattan Project," Proceedings of the American Philosophy Society," Vol. 90, no. 1, January 1948, pp-11-19. (Hereafter known as Stone 1948).
[3] Stone 1948, p. 14.
[4] Hacker 1987, p.55.
[5] Hacker 1987 p. 44-5.
[6] Hacker p. 62.

> proceed to unload uranium and plutonium barchanded . . . the fumes and dust were constantly in the air; there was no ventilation system. The dust was on the floor. Uranium chips would be in your shoes that you continued to wear. You went to eat with the same clothes on. You went to the barracks with the same clothes and sat on the beds. . . .[7]

Given widespread exposure problems, concerns over financial and legal liabilities also influenced radiation protection decisions. An overriding concern according to Stafford Warren, medical advisor to General Leslie Groves, military chief of the Manhattan Project, was to protect "the government interests" against legal claims. [8]

By 1980, Ted Lombard was suffering from fibrosis of the lungs, severe bone marrow and blood forming organ damage. Four of his five children born after working at Los Alamos had severe medical problems, including neuromuscular and blood disorders. When Lombard filed a claim with the U.S. Department of Veterans Affairs, he was denied repeatedly on the grounds that his medical and exposure records were missing.

Shortly after World War II and through the early 1960's, senior ranks of DOE and its predecessors were informed that large numbers of workers were being over exposed. at federal nuclear sites in New Mexico, Washington, New York, Kentucky, Ohio, Colorado and Tennessee. In 1948, the Atomic Energy Commission Advisory Committee on Biology and Medicine (ACBM) was provided data and analysis regarding large occupational doses to radiation from leaking radiochemical facilities at the Hanford site in Washington. According to Hanford's chief health physicist, radioactive particles that deposited in areas containing thousands of construction workers on the site "can produce radiation damage" and that "the theoretical possibility of injury developing 10 to 15 years from now poses a serious problem."[9]

That same year, the AEC manager of the Oak Ridge site "submitted a report on radiation history of employees," which recommend that a terminating employee be informed if he or she was exposed to levels above official limits; and that medical assistance be provided if that person believes he or she was made ill or injured by radiation. [10] [11]

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[7] Invisible Violence, Proceedings of the National Hearing on Radiation Victims, April 26, 1980.
[8] Hacker 1987, p.51.
[9] U.S. Senate Committee on Governmental Affairs, Majority Staff Report, *Early Health Problems of the U.S. Nuclear Weapons Program and their Implications for Today*, December 1989.

[10] U.S. Atomic Energy Commission, Advisory Committee For Biology and Medicine, Thirteenth Meeting, December 10-11, 1948, U.S. Department of Energy Archives, 1947-51 Secretariat Files, Box 1217, Folder 337, Germantown, MD. The report recommended:

> (1) a terminating employee be provided with a statement that he has not exceeded the permissible exposure to radiation, or **if he has exceeded the permissible exposure he be made aware of this fact by the physician giving the exit interview**; [Emphasis added] (2) that there be a clearer policy on release of information on radiation exposure records and other medical records to the contractor's insurance and life insurance companies; (3) that the terminating employee be advised that if he is to work with radiation in the future his new employer can make arrangements to procure his past radiation exposure history; (4) **that a group of qualified radiologists and**

However, the Committee rejected this recommendation, and proposed instead that "a terminating employee should be advised at the exit interview as to the care that the AEC utilizes in protecting each employee." [12]

At the time, fears over liability and lack of public trust that might result from disclosure of workplace hazards was of dominant concern. In a memo regarding possible declassification of a study suggesting that occupational radiation exposure levels "may be too high," the head of the Insurance Branch of the AEC declared:

> We can see the possibility of a shattering effect on the morale of the employees if they become aware that there was substantial reason to question the standards of safety under which they are working. In the hands of labor unions the results of this study would add substance to demands for extra-hazardous pay . . . knowledge of the results of this study might increase the number of claims of occupational injury due to radiation.[13]

By June 1949, the ACBM was informed of excessive exposure to workers in uranium processing plants. [14] Some workers were being exposed at levels 125 times greater than the default standard adopted in World War II.[15] By this time it was recognized that this standard was not protective against radiation hazards.[16]

Dr Ernest Goodpasture, Vice Chairman of the ACBM made repeated efforts to convince the commission to conduct radiation-related cancer studies. In December 1951, he wrote to AEC Chairman, Gordon Dean stating that, "Cancer is a significant industrial hazard of the Atomic energy business. . . . the Committee recommends the cancer program be pursued as a humanitarian duty to the nation." [17] His plea went unheeded.

The Mancuso Study

Although high-ranking officials were aware of potentially serious health risks to workers and were urged by its advisors to conduct health studies, the Atomic Energy Commission did not initiate occupational epidemiological research until 1964. That year Dr. Thomas F. Mancuso, Professor of Occupational Medicine at the University of Pittsburgh, was

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physicians be available for consultation by any person who feels that he has been damaged by radiation at an AEC installation. [emphasis added][10]

[11] Ibid.
[12] Ibid.
[13] Report of the President's Advisory Committee on Human Radiation Experiments, Part II, Chapter 13, http://www.eh.doe.gov/ohre/roadmap/achre/chap13_3.html
[14] U.S. Atomic Energy Commission, Advisory Committee for Biology and Medicine, 16th meeting, June 11, 1949, transcript, U.S. Department of Energy Archives, AEC Division of Biology and Medicine Collection, Box 3218, Folder ACBM Meeting, Germantown, MD.
[15] Ibid.
[16] Ibid.
[17] Goodpasture, E.W., Letter to Gordon dean, Chairman of the Atomic Energy Commission, December 1, 1951 U.S. Department of Energy Archive, Germantown, MD.

approached by staff of the AEC's Division of Biology and Medicine in 1964 to undertake a feasibility study. According to Mancuso the AEC staff asked him if there were sufficient data to "answer a basic question, that is, whether there were or were not any effects of low-level ionizing radiation." [18] Based on a review of records at 14 AEC facilities, Mancuso concluded it was possible, and was awarded a five-year research contract in 1965.

By that time, Mancuso had established himself as a highly respected figure in the field of occupational epidemiology. While serving as chief of the Ohio Division of Industrial Hygiene between 1945 and 1962, Mancuso published a series of ground-breaking studies showing the toxicological and carcinogenic effects of cadium, manganese, mercury, hydrogen sulfide, asbestos, aromatic amines, and chromate. [19] [20] [21] With the encouragement of his mentor, Wilhelm Huper, at the National Cancer Institute, [22] Mancuso designed and published the first cohort mortality studies on occupational cohorts in the United States. [23] In doing so Mancuso invented a revolutionary methodology using Social Security death benefit claims that enabled researchers for the first time to follow exposed workers over the many years necessary to detect latent diseases such as cancer. [24] "In 1961 he had been given a career award by the National Cancer Institute for his impressive body of work.

Mancuso was also known for his honesty and fierce independence. In the 1950's, Phillip Carey Corp., a manufacturer of asbestos insulation hired Mancuso with the expectation that he would provide evidence refuting compensation claims by workers dying from respiratory diseases following exposure to asbestos. Instead Mancuso's research supported the worker's claims. He strongly advised the company that it had a responsibility to inform the workers of potential risks. Because Phillip Carey ignored

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[18] Statement of Thomas F. Mancuso Before the House Energy and Commerce Subcommittee on Health and the Environment, Hearings, Effect of Radiation on Human Health, U.S. Congress, House Committee on Interstate and Foreign Commerce, Subcommittee on Health and the Environment, *Effect of Radiation on Human Health*, 95th Cong., 2nd Sess., January 24-26, February 8, 9, 14, and 28, 1978, Serial No. 95-179, Vol. 1, p. 523. (Hereafter known as "Effect of Radiation on Human Health 1978.")

[19] Thomas F. Mancuso, Occupational Cancer Survey in Ohio, Proceeding of the Public Health Cancer Association of America, 1949, 50-60

[20] Michael Gochfeld, Chronologic History of Occupational Medicine, Journal of Occupational Medicine, Vol. 47, No. 2, February 2005. (Hereafter known as Gochfeld 2005)

[21] David Michaels, Comings and Goings, Thomas Mancuso, NYCOSH, July 8, 2004, (Hereafter known as Michaels 2005) http://www.nycosh.org/UPDATE/printableArticle.php?articleid=454

[22] Interview with Thomas F. Mancuso, September 6, 1980.

[23] Michaels 2005.

[24] Thomas F. Mancuso, "Methods of Study of the Relations of Employment and Long-term Illness by Cohort Analysis," *American Journal of Public Health*, 1959.

Mancuso's warning throughout the 1960's, his research was subsequently used by claimants. [25]

What motivated the AEC officials to approach Mancuso? A key factor was that the national security imperative to exercise control over radiation heath effects research was loosening as Cold war tensions reduced. Moreover, the AEC suffered a serious blow to its credibility in 1963, when the United States, Great Britain and the Soviet Union ratified the Limited Nuclear Test Ban Treaty, which prohibited atmospheric nuclear weapons tests.

Beginning in the1950's a major and often contentious debate was sparked by scientists, such as Nobel Prize winners, Herman Mueller, and Linus Pauling who warned that radioactive fallout from testing was harming human health across the globe. The AEC and its scientists vigorously defended the tests claiming they posed little if no harm. "There developed what I consider to be a strange psychological frame of mind," Dr. Karl Z. Morgan, founder and director of the AEC's Oak Ridge Health Physics Lab reflected several years later. "It became unpatriotic and perhaps unscientific to suggest that atomic weapons testing might cause deaths throughout the world from fallout." Morgan found many of his AEC colleagues holding "onto untenable and extremely shallow arguments [and making] comparisons with medical and natural background exposures as if they were harmless." [26] Official repudiation of the AEC's claims about fallout came in 1997, when the National Cancer Institute (NCI) revealed that atmospheric nuclear weapons detonations at the Nevada Test Site resulted in significant radiological contamination of the nation's milk supplies. NCI researchers estimated that fallout exposure to Iodine -131 from Nevada tests might cause 11,000 to 212, 000 excess thyroid cancers in the United States. [27]

Other factors included the curtailment of fissile material production for nuclear weapons and the emergence of the U.S. nuclear power industry. By 1964, the U.S. nuclear arsenal was shrinking as more accurate delivery systems were deployed. This in turn, significantly reduced demand for plutonium and highly enriched uranium – leading to the closure of several large production reactors and radiochemical processing facilities.

Concurrently, dozens of new power reactors were now planned for construction in the United States. The AEC, which was responsible for commercializing nuclear energy was gearing up to accommodate this major growth, while setting the stage for a new

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[25] United States Congress, House of Representatives, 106th Congress, 2nd Session, House Report 106-782 – Asbestos Compensation Act of 2000, July 24, 2000. http://thomas.loc.gov/cgi-bin/cpquery/T?&report=hr782&dbname=106&

[26] Karl Z. Morgan, "History of Developments in Nuclear Safety and the Development of International Standards," unpublished article submitted to Energy Department's Office of Consumer Affairs, December 1980, p. 2.

[27] Steven L. Simon, Andre Bouville, and Charles E. Land, Fallout from nuclear weapons tests and cancer risks, American Scientists online, Vol. 94. No. 1 P. 48 http://www.americanscientist.org/template/AssetDetail/assetid/48543?fulltext=true&print=yes

generation of reactors that would use plutonium as fuel. To pave the way for these developments, the AEC needed to strengthen its credibility. In particular, the formalization of occupational radiation protection standards in 1959, which limited annual external exposure to 5 rem* per year, provided a necessary framework for both the continuation of civilian and military nuclear energy activities.

AEC managers received assurances from its scientific advisors that Mancuso's work would not lead to unpleasant surprises. In his 1980 paper about the Mancuso affair, Theodore D. Sterling, public health professor at Simon Fraser University in Canada, explores this concern and concludes: "It was firmly believed by all scientific advisors and by management that the study design was not adequate to lead to [findings of adverse effects]. Rather, the study was implemented and supported for frankly admitted *political* reasons" (original emphasis). [28] After initiating the study, some AEC officials referred to it as "Mancuso's folly" and openly viewed it as a public-relations sham. [29] The political need to have Mancuso continue this study is reflected in review comments made in November 1967, by Dr. Brian MacMahon an AEC consultant from Harvard University.

> In my opinion this study does not have, and never (in any practical sense) will have any possibility of contributing to knowledge of radiation effects in man __I recognize that much of the motivation for starting this study arose from the 'political' need for assurances that AEC employees are not suffering harmful effect. [30]

MacMahon was seconded in November 1967 by Dr. William Schull, a geneticist who had worked on the Japanese Atomic Bomb Survivor study. Like previous advisors, Schull was interested in protecting the AEC against compensation claims.

> It seems highly improbable that if one went through the mechanics of calculating the kinds of radiation effects, which a study of the present magnitude might detect, one would be led to conclude that the undertaking is a hopeless one. However, as earlier recognized, it may have other merit in that it may provide a firmer basis for settlement of claims against the Atomic Energy Commission. [31]

During the 1960's and early 1970's, Mancuso compiled data on workers at several facilities. He focused on the Hanford site in Washington State and the Oak Ridge site in Tennessee because they were the oldest and largest federal nuclear facilities. Throughout

* Roentgen equivalent for man, a roentgen (an international unit of X- or gamma-radiation) adjusted for the atomic makeup of the human body.

[28] Theodore P. Sperling, The Health Effects of Low-Dose Radiation on Atomic Workers. A case study of Employer Directed Research, International Journal of Health Services, Vol 10, No. 1, 1980, PP 37-47.

[29] Thomas F. Mancuso, interview, October 1980

[30] Ibid.
[31] Ibid.

this period, AEC officials were eager for him to publish. "Repeatedly ...I had been urged by [the AEC and its successor the Energy Research and Development Administration—now the Department of Energy] to publish in scientific journals, the negative findings of the progress reports, and I refused to do so," stated Mancuso. "I believed that the findings would be misleading, no matter how well qualified in the presentation and could be misused." [32]

By February 1973, Dr. Sidney Marks, Mancuso's AEC worker study contract officer grew frustrated and suggested "early replacement of the contractor."

> Unless an immediate replacement [for Mancuso] is found, a public charge may be made that the AEC is stopping the program out of fear that positive findings may emerge. Overtures to possible candidates may be carried out in a clandestine atmosphere. . . . [33]

Nonetheless, AEC officials tolerated Mancuso's reluctance to publish until the situation was abruptly transformed in late June of 1974. This is when Dr. Samuel Milham, an epidemiologist with the Washington State Department of Social and Health Services, met with AEC officials to report findings of a study he had just completed. Encompassing 300,000 deaths from 1950 to 1974, Milham compared the mortality of different occupations in the state and found that:

> Men who worked at the Atomic Energy Commission Hanford facility in Richland Washington showed increased mortality from cancer, especially in men under age 64 at death. An excess was seen for cancer of the tongue, mouth, and pharynx, colon, pancreas, lung and bone. Excess mortality was also seen for aplastic anemia and amyotrophophic sclerosis. . . . [34]

He concluded that, "since the Hanford facility is involved in the handling, fabrication, processing and storage of an array of radioactive materials, most of which are of proven carcinogenicity, I suggest that these materials are the most likely source for the observed cancer excess." [35]At the meeting in Richland Washington, Milham recalled that the atmosphere was "like a funeral, quiet, no smile. . . . The impression I got at the meeting with the AEC was that the release of my finding might cause concern and problems in the industry."[36] After the meeting Milham decided to not to publish his findings, "because I was convinced that the appropriate population-based studies were in progress [under Mancuso's direction]. I felt that publication of my findings at this time might disturb the continuity of the study in progress and might cause undue concern in workers."[37]

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[32] Statement of Dr. Thomas F. Mancuso, M.D. Effect of Radiation on Human Health 1978. p. 544
[33] Effect of Radiation on Human Health. P. 750.
[34] Statement of Samuel Milham, M.D. Effect of Radiation on Human Health 1978, p. 495.
[35] Ibid.
[36] Milham, Effect of Radiation on Human Health 1978, P. 495-496.
[37] Ibid.

Shortly after, Mancuso "was on the phone by the hour over a period of weeks" with AEC officials in the Division of Biology and Medicine. Dr. Sidney Marks, Mancuso's AEC contract officer, urged Mancuso to endorse a draft press release which stated "there is no evidence of cancer or other deaths attributable to ionizing radiation occurring more often among Hanford workers."[38] But Mancuso refused explaining to Marks that Milham's findings could not be dismissed because they were based on more recent mortality data Mancuso had yet to obtain. Furthermore, Milham's study included construction workers at the Hanford site, which were not part of the AEC-sponsored study. Hanford construction workers, according to Mancuso, were "acknowledged to have more exposure" than operators, and his repeated attempts to have this group incorporated into his study over the years were denied.[39]

It was then that AEC officials started to end their relationship with Mancuso. In the summer of 1974, the AEC initiated a process to transfer a major portion of Mancuso's study to Oak Ridge Associated Universities (ORAU) in Tennessee. For several years AEC, the National Acronautics and Space Administration (NASA) and the Defense Department sponsored studies involving total body irradiation of animals and dozens of human patients in specially designed radiation chambers at ORAU, but funding for the research program was about to end. According to a 1975 report to NASA, ORAU study director, Dr. Clarence C. Lushbaugh, justified the experiments in part because, "unbiased clinical observations were sorely needed to defend existing environmental and occupational exposure constraints from attack by well-meaning but impractical theorists."[40]

Termination of this study was prompted in April 1974 by a critical extramural medical review, which gave it an "unfavorable rating." The panel reported that "the clinical facilities were substandard with respect to licensing and accreditation guidelines." [41]In particular, the reviewers took issue with the clinical hematology program and sloppy research practices that may have endangered patients. Underneath the wood floor of one of the radiation chambers in which cancer patients were treated, researchers suspended cages of mice—creating sanitary hazards. According to the review:

> . . . animal caretakers enter the area twice a week to change the cages and provide. Dirty cages are taken through the patient area to an elevator and on to the cage washer...This entire arrangement seems questionable because of the necessity of transporting animal, animal wastes and equipment through areas used by patients who frequently have compromised host defense mechanisms. Also this area would appear to be highly prone to severe infestations of vermin.[42]

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[38] Mancuso Statement, Effect of Radiation on Human Health, P. 559
[39] Mancuso Statement, Effect on Radiation on Human Health, P. 531.
[40] Studies Relative to Radiosensitivity of Man: Based on Retrospective Evaluations of Therapeutic and Accidental Total-Body Irradiation, Oak Ridge Associated Universities, (NASA-CR-144439), pp. 6-8.
[41] U.S. Atomic Energy Commission, Extramural Reviews of Oak Ridge Associated Universities, Specific Comments on LETBI and METBI Programs, April 16, 1974.
[42] Ibid.

"In view of accepted therapeutic modalities," the reviewers reported, "*ethical questions were raised with respect to the protocol employed in these studies*" (emphasis added). [43]

Despite these problems, AEC officials appeared more interested in shoring up ORAU with new work. This was underscored by its decision to award ORAU with a large contract without the benefit of peer review, scientific protocol, principal investigator, and to an institution which had not performed epidemiological research before. [44]According

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[43] Ibid.

[44] Effect of Radiation on Human Health, p-783. Hearings before the U.S. House Energy and Subcommittee in February 1978 explored the process in which the contract Mancuso held was transferred. The questioning of DOE official, Dr. Walter Weyzen, and Dr. Sidney Marks, then at Battelle, by Subcommittee Chair, Rep. Paul Rogers is most revealing:

Mr. Rogers:	So you didn't know the person who was going to be charge of the study, but you transferred it anyway?
Dr. Weyzen:	It was transferred, yes, sir.
Mr. Rogers:	And you did not know who would be the chief investigator would be?
Dr. Weyzen:	Certainly, I didn't know at the time.
Mr. Rogers:	Did you, Dr. Marks?
Dr. Marks:	May I say that the decision to transfer would be contingent on proper staffing. The transfer was not made in March 1975. Discussions were held at the time in anticipation of the transfer on July 31, 1977 if proper staffing were developed.
Mr. Rogers:	Then you told me before that the judgment was made to transfer the study back then, but you didn't even have a chief investigator. And now you come and divide it up again, where you have Dr. Marks at the meeting who is beneficiary from his corporation and you have Lushbaugh, who is a beneficiary. That group gets together and divides up a study, without any peer review.
Dr. Marks:	Mr. Chairman, at the meeting of September of 1977?
Mr. Rogers:	Yes.
Dr. Marks:	The question of dividing up the study did not come up. The session was largely devoted to questions regarding the data base and the manner in which the study will be heard, carried forth in the future.
Mr. Rogers:	Well now I thought Dr. Weyzen told us that it was on that basis that he made the judgment for separating the study.
Dr. Weyzen:	That is correct, sir.

to a memorandum prepared by the division of Biology and Medicine in January 1976, "Since ORAU medical division has been informed that, *if they developed the necessary expertise,* the health and mortality study will be transferred to ORAU and is to be phased in during the last year of Mancuso's contract which would begin in August 1, 1976" (emphasis added). [45]

The AEC also took steps to move Mancuso's research to Battelle, which ran the Hanford laboratory. Dr. Ethyl Gilbert, a statistician working for Battelle at Hanford's Pacific Northwest was first tasked review the Milham study. Around the summer of 1975, Gilbert submitted her analysis, in which she stated, "Our data exhibit no clear-cut relationship of death from cancer and radiation exposure"[46] A key table in her study, however, did show a relationship between radiation exposure and excess deaths.[47]

Alex Fremling, the AEC Manager at the Hanford also reached a much different conclusion than Gilbert when he reported "there is a relationship between cancer as a cause of death and the total dose of external radiation received....the message is clear that Battelle's data suggests that Hanford has a higher proportion of cancer deaths for those under 65 than the U.S." [48] ...even more disturbing from our standpoint" was that "the analysis tends to show a much higher incidence of certain types of cancer" at doses below official limits.[49] Fremling continued, "We hoped to get a good answer to the Milham report, and instead it looks like we have confirmed it." [50] The Battelle study remained buried until it was submitted into the record by Dr. Milham at 1978 at a hearing of the U.S. Congress.[51]

In March 1975 the Energy Research and Development Administration (ERDA), the AEC's successor, informally notified Mancuso of its intentions when he was asked at a meeting by Marks "you don't want to continue on with his project do you."[52] Mancuso replied "clearly and definitively" that he wanted to devote the rest of his professional career to this research. [53] But, Mancuso knew the die was cast after his colleagues approached Dr. James Liverman, Director of AEC's Division of Biology and Medicine in 1975 and were told that an administrative decision to give the research to Oak Ridge Associated Universities and Battelle was already made. In January 1976, the University

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[45] Effect on Radiation and Human Health. P. 533.
[46] Milham Statement, Effect on Radiation on Human Health, p. 514

[47] Millham Statement, Effect on Radiation on Human Health, p. 516 According to this table, Workers who received the highest dose of 2.14 rems or more ten years prior to death showed elevated death rates for al cancers (27%) colon cancer (200%), pancreas (52%), lymphosarcoma (334%) and other lymphatic cancers (783%).

[48] Draft AEC Memorandum, from Alex Fremling, Director, Atomic Energy Commission, Richland Operations Office, July 17, 1975.
[49] Ibid.
[50] Ibid.
[51] Effect of Radiation on Human Health pp. 515, 516.
[52] Ibid
[53] Ibid.

of Pittsburgh was formally notified by the Department of Energy (DOE), which succeeded ERDA, that it would not renew Mancuso's contract when it expired in 1977. [54]

In March of 1976, Mancuso asked Dr. Alice M. Stewart and George Kneale, her statistician from the University of Birmingham in England, to analyze his data. Dr. Stewart, a member of Mancuso's advisory committee, was internationally recognized as establishing the link between fetal x-rays and childhood cancers. Since 1955, when she and her colleagues first reported this finding, Stewart had constructed one of the world's largest epidemiological studies of low dose ionizing radiation, the Oxford Survey of Childhood Cancers.

By the summer of 1976, Mancuso Stewart and Kneale produced a cohort analysis based on 3,710 deaths among Hanford workers collected up to 1973. They found a 5 to 7 percent excess in cancer deaths attributable to radiation. Workers exposed after the age of 45 showed higher sensitivity to cancer. Most significantly, the risk of dying from radiation-induced cancer appeared to be about ten times greater than current protection standards assumed. As soon as the analysis was finalized Mancuso and his colleagues briefed the Energy Department, in the October 1976. [55] "They were clearly unhappy," Mancuso said. "They urged us not to publish. . . . My job in their eyes was simply to transfer the data to them."[56] Present at the meeting was Sidney Marks. After helping to orchestrate Mancuso's firing, Marks left his government employment in June 1976 to administer the Hanford worker study at Battelle, where Ethyl Gilbert worked under his supervision.[57]

By the fall of 1977 Mancuso's research funds had run out. In November he published his paper in *Health Physics*, creating a firestorm of controversy. Though he continued to draw a salary from the University of Pittsburgh, Mancuso had no funds with which to continue his research. Though it was a bare fraction of what was needed, Mancuso began

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[54] Effect of Radiation on Human Health, p. 554

[55] Thomas F. Mancuso, Alice M. Stewart, and George W. Kneale, "Radiation Exposures of Hanford Workers Dying from Cancer and Other Causes," *Health Physics Journal* 33, No. 5 (November 1977)

[56] Mancuso Interview, September 10, 1980..

[57] Effect of Radiation on Human Health., P. 719

Hearing Excerpt: Questioning of Dr. Sidney Marks by Congressman Paul Rogers

Mr. Rogers: When did you leave ERDA, Dr. Marks?

Dr. Marks: I left in June 1976.

Mr. Rogers: When were you hired by Battelle?

Dr. Marks: June 1976.

Mr. Rogers: Are you now doing part of the work that was originally covered in its contract in your organization?

Dr. Marks: I am assisting Dr. Gilbert. She is the principal investigator.

Mr. Rogers: Is it under your supervision?

Dr. Marks: Only in the sense that all environmental heath and safety work is under the supervision of ---

Mr. Rogers: That is all I am asking. Is it under your office, as I understand it in Battelle?

Dr. Marks: Yes it is.

cutting into his personal retirement money to continue working on the Hanford study. Meanwhile the federal government persisted in its attempts to take the data away from him and most disturbingly, to destroy data Mancuso had collected.

Upon assuming control over the DOE worker study, in 1977 Dr. Lushbaugh, Chief of radiation studies at ORAU, proceeded to shred and incinerate medical records from the Oak Ridge Hospital preserved by Mancuso. [58] All told, 21 out of 40 filing cabinets spanning the period 1952 to 1961 were destroyed. Mancuso took custody of the records after the old hospital, owned by the federal government, was transformed into the Methodist Medical Center. In November 1985, when allegations were made about the destruction, Lushbaugh claimed "we would never destroy these records."[59] Several days later, ORAU officials conceded that the records were destroyed and they were unaware they had been set aside by Mancuso. In his final report to the DOE in November 1977, Mancuso had clearly identified these records as part of his research program. [60]

But in early 1978, the Energy department had come under Congressional scrutiny for its handling of Mancuso's contract. At the hearings before the House Energy and Commerce Subcommittee on Health and the Environment, it was brought out that the Energy department had not informed Mancuso of the ostensible reason for his termination—that being his "imminent retirement" at age 62 from the University of Pittsburgh. Mancuso only learned of this reason in September1977 in a letter from James Liverman to Karl Z. Morgan. [61] However, the AEC had not bothered to learn the university's policy, which set the mandatory retirement age at 70 years.

In his testimony to the Subcommittee, Liverman backed away from the excuse of Mancuso's *"imminent retirement."* Instead he charged that early peer reviews of Mancuso's work had been critical of him, when in fact they had lauded his capabilities and recommended that the study be continued under his control.[62] In the course of the hearings, Subcommittee Chair Paul Rogers (D-FL) concluded:

> It's the most disordered, unstructured mess that I have looked into some time. If our research programs are being carried out in this manner, where you just take a study from one scientist and give it to another group without knowing who the principal investigator will be or his qualifications, this is a very inefficient, poor way of managing a research program and is not a competent way to spend tax dollars.[63]

Congressmen Paul Rogers (D-FL.) and Tim Lee Carter (D-KY.) subsequently reported to Energy Secretary Schlesinger, that the justifications for the decision to fire Mancuso were

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[58] Interview with Lushbaugh, June 3, 1989.
[59] Richard Powellson, DOE health data destroyed, probers told, Knoxville News- Sentinel, November 15, 1985.
[60] Richard Powellson, Agency destroyed OR heath records, Knoxville News- Sentinel, November 21, 1985.
[61] Letter from: James Liverman, Director of Division of Biology and Medicine, Atomic Energy, Commission, To: Karl Z. Morgan, Neeley Professor, Georgia Institute for Technology, September 8, 1977.
[62] Ibid.
[63] Effect of Radiation on Human Health, p-783.

"not supported" and the decision to transfer Mancuso's study to Oak Ridge was "highly questionable at best." The whole process, they said, reflected "serious mismanagement and is of highly questionable legality." [64]

In 1979, in response to Congressional hearings regarding the handling of Mancuso's contract and revelations about radiation exposure to military personnel and civilians from U.S. atmospheric nuclear weapons tests, a Federal Interagency Taskforce on Ionizing Radiation was convened by President Carter. The Taskforce, chaired by Health, Education and Welfare Secretary, Joseph Califano, reported in 1980 that the Energy department maintained a virtual monopoly over the funding of radiation health effects research; and that DOE had a potential conflict-of-interest between its missions of military and civilian nuclear energy development and assessing their health impacts. Califano proposed removing radiation health effects research from DOE's control and placing it in public health agencies.[65]

Even so Mancuso continued to face opposition. He managed to continue the study through private donations and his retirement money until labor unions pressured the National Institute of Occupational Safety and Health to reinstate the study in August 1979. This lasted until the spring of 1981 when the Reagan administration informed Mancuso his funding would once again be terminated.

Despite the difficulty in obtaining funding, Mancuso, Stewart and Kneale persisted in their research and publications in the scientific literature. [66] [67] [68] By 1990, the Three Mile Island Public Health Fund, established as part of a legal settlement resulting from the Three-Mile Island nuclear accident in 1979, funded the continued work of Dr. Stewart and Kneale. While strongly supportive of their efforts, Dr. Mancuso had effectively withdrawn from the work, as a result of the difficult experience. However, in 1993, Mancuso published an analysis of Hanford workers, which clearly indicated that he had not given up the struggle.

> The search for the biological effects among worker cohorts has been mostly in terms of mortality experience. Yet it is well known that the primary and secondary causes of death on a death certificate do not reflect the diseases or illnesses which may have occurred prior to death...The consequences have been the underestimation of the true nature and magnitude of occupational health effects when based solely on death certificates... The death certificate provides a

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[64] U.S. Representatives Paul Rogers and Tim Lee Carter, letter to James Schlesinger, secretary, Department of Energy, May 4, 1978.
[65] U.S. Senate Committee Report 1989.
[66] Mancuso, et al., "A Reanalysis of Data Relating to the Hanford Study of the Cancer Risks of Radiation Workers," *International Atomic Agency Symposium Proceedings on the Late Biological Effects of Ionizing Radiation*, Vienna, Austria, 1978, IAEA-SM-224/510.
[67] Stewart, et al., "Hanford IIb, The Hanford Data--a Reply to Recent Criticisms," *Ambio* 9 (June 1980).
[68] "Hanford III, a Cohort Study of the Cancer Risks from Radiation to Workers at Hanford (1944 to 1977 deaths) by Method of Regression Models in Life-Tables," *British Journal of Industrial Medicine* summer 1981.

gross underestimate of the biological effects which may have occurred in that population. [69]

The Aftermath of the Mancuso Affair

The contract with Dr. Mancuso was in a sense a failed experiment by the federal nuclear program to enter the mainstream of public health. Most importantly, the Mancuso contract deviated from standard practices established by the nuclear weapons program in which a system of "in-house" contractors whose existence depended primarily on the federal nuclear program was fostered deliberately. By terminating Mancuso's study the Department of Energy returned to business as usual. But, as events unfolded, the federal nuclear program never truly recovered from the aftermath of this failed experiment.

In 1989, in response to Congressional pressure and a growing lack of public trust, Energy Secretary James Watkins convened the Secretarial Panel for the Evaluation of Epidemiologic Research Activities. The Panel reported that Energy's research lacked coordination and suffered from lack of peer review and competition for funding.[70] In 1990 DOE entered into a formal agreement with the Department of Health and Human Services to manage and conduct DOE worker health studies paid for by the Department of Energy. Since that time, these studies were obscured from public attention and went unappreciated. This all changed when the Secretary of Energy, Bill Richardson, announced on July 14, 1999 that the Clinton Administration would seek to establish a federal compensation program for sick Energy Department contract employees.

In early 2000, the Department of Energy compiled a selected group of health studies of Department of Energy contractor employees from the most recent editions of published articles and unpublished technical reports. Additional recent published studies were obtained from peer-reviewed scientific journals. Based on the studies complied, this author analyzed twenty-seven studies of workers at DOE sites and nuclear sites in the United Kingdom and Canada.

All told, workers at fourteen DOE facilities were found to have increased risks of dying from various cancers and nonmalignant diseases. [71] [72] [73] [74] [75] [76] [77] [78] [79] [80] [81] [82] [83] [84] [85] [86] [87] [88] [89] [90] [91] They include:

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[69] Thomas F. Mancuso, Methodology in Industrial Health Studies: Social Security Disability Data and the Medical Care System, American Journal of Industrial Medicine, 1993, 23:653-671.

[70] David Richardson, Low-Dose Radiation Exposure, Public Meeting on Worker Health, September 25, 1997, Transcript, http://www.sea-us.org.au/roxstop97/tdave3.htm

[71] Thomas F. Mancuso, Alice M.. Stewart and George W. Kneale, *Radiation exposures of Hanford workers dying from cancer and other causes.* Health Physics 1977, 33:369-385.

[72] Ethyl S. Gilbert, Ellen Omohundro, Jeffery A. Buchanan, and Nancy A. Holter, *Mortality of Workers at the Hanford Site,* Health Physics, June 1993, 64:6:577-590.

[73] Alice M. Stewart and George W. Kneale, *Relations between age at occupational exposure to ionizing radiation and cancer risk,* Occupational and Environmental Medicine, 1996, 53:225-230.

[74] Thomas F. Mancuso, Methodology in Industrial Health Studies: Social Security Disability Data and the Medical Care System, American Journal of Industrial Medicine, 1993, 23:653-671.

[75] David Richardson and Steve Wing, Radiation and Mortality of Workers at Oak Ridge National Laboratory: Positive Associations for Doses Received at Older Ages, Environmental Health Perspectives, August, 1999. 107: 8 (Mortality study)

[76] Steve Wing, Cary M. Shy, Joy Wood, Susanne Wolf, Donna Cragle, and E.L. Frome, *Mortality Among Workers at Oak Ridge National Laboratory, Evidence of Radiation Effects in Follow-up Through 1984,* Journal of the American Medical Association, March 20, 1991, 265: 1397-1402. (Mortality study)

[77] Steve Wing, Carl M. Shy, Joy L. Wood, Susanne Wolf, Donna Cragle, William Tankersley, and E.L. Frome, *Job Factors, Radiation and Cancer Mortality at Oak Ridge National Laboratory: Follow-up through 1984,* American Journal of Industrial Medicine, 1993, 23:265-279.

[78] Dana P. Loomis and Susanne H. Wolfe, *Mortality of Workers at a Nuclear Materials Production Plant at Oak Ridge, Tennessee, 1947-1990,* American Journal of Medicine, 1996, 29:131-141.

[79] Harvey Checkoway, Neil Pierce, Douglas J. Crawford-Brown, and Donna Cragle, *Radiation Doses and Cause-Specific Mortality Among Workers at a Nuclear Materials Fabrication Plant,* American Journal of Epidemiology, 1998, 127:2:255-266.

[80] Elizabeth A. Dupree, Susan M. Wells, Janice P. Watkins, Phillip W. Wallace, Nancy C. Davis, *Mortality Among Workers Employed between 1945 and 1984 at a Uranium Gaseous Diffusion Facility,* Draft Report, Oak Ridge Institute for Science and Education. (no date)

[81] Donna L. Cragle, Janice P. Watkins, J. Nicholas Ingle, Kathryn Robertson-Demers, William G.. Tankersley, Charles M. West, *Mortality Among a Cohort of White Male Workers at a Uranium Processing Plant: Fernald Feed Materials Production Center* [FMPC], Radiation Research (not sure if it is published)

[82] Laurie D. Wiggs, Emily R. Johnson, Carol A. Cox-DeVore, and George L. Voelz, Mortality through 1990 Among White Male Workers at the Los Alamos National Laboratory: Considering Exposures to Plutonium and External Ionizing Radiation, Health Physics, December 1994, 67:6:557-586.

[83] Elizabeth A. DuPree, Donna Cragle, Richard, W. McLain, Douglas Crawford-Brown, M. Jane Teta, *Mortality among workers at a uranium processing facility, the Linde Air Products Company Ceramics Plant, 1943-49,* Scandinavian Journal of Worker and Environmental Health, 1987, 13:100-107.

[84] Elizabeth A. DuPree, Donna Cragle, Richard, W. McLain, Douglas Crawford-Brown, M. Jane Teta, *Mortality among workers at a uranium processing facility, the Linde Air Products Company Ceramics Plant, 1943-49,* Scandinavian Journal of Worker and Environmental Health, 1987, 13:100-107.

[85] E. DuPree Ellis, J.P. Watkins, J.N. Ingle, J.A. Phillips, *External Radiation Exposure and Mortality Among a Cohort of Uranium Processing Workers,* Oak Ridge Associated Universities, Oak Ridge TN, (unpublished report).

[86] Laurie D. Wiggs, Carol A. Cox-DeVore and George Voelz, *Mortality Among a Cohort of Workers Monitored for Polonium-210 Exposure: 1944-1972,* Health Physics, July 1991, 61:1:71-76.

[87] Wilkinson, G.S., G.L. Teitjen, L.D. Wiggs, W.A. Gaike, J.F. Aquavella, M. Reyes, G..L. Voelz and R.J. Waxweiler, *Mortality Among Plutonkum and other Radiation Workers at a Plutonium Weapons Facility,* American Journal of Epidemiology, 1987, 125:2.

- The Hanford nuclear materials production site in Washington.
- The Oak Ridge National Laboratory in Tennessee.
- The Oak Ridge Tennessee Eastman Electromagnetic Separation facility (TEC).
- The Oak Ridge Y-12 weapons facility.
- The Oak Ridge K-25 Gaseous Diffusion Plant.
- The Feed Materials Production Center in Fernald, Ohio.
- The Los Alamos National Laboratory in New Mexico.
- The Linde Air Products uranium processing operation in New York.
- The Mallikrodt Chemical Works in Missouri.
- The Mound Laboratory in Ohio.
- The Rocky Flats facility in Colorado.
- The Savannah River Site in South Carolina.
- The Rocketdyne/Atomic International Facility in California.
- The Lawrence Livermore National Laboratory in California.

By the end of the 20th century, the Department of Energy (DOE) occupational epidemiological studies constituted one of the world's largest and most extensive follow ups of people exposed to low-level ionizing radiation and other substances. Dr. Mancuso had put in place a foundation that eventually provided a basis for the study of some 600,000 people who worked for federal contractors at industrial and research sites.

In December 2000 the United States enacted the Energy Employee Occupational Illness Compensation Act. The law represents the first time any nation has officially acknowledged that its workers were harmed from the production of nuclear weapons; and has established a entitlement program to compensate workers and their survivors. All told some 700,000 people who worked at over 300 facilities in the United States can file for compensation.

This unprecedented law would not have been possible without the pioneering work of Dr. Thomas F. Mancuso, who passed away on July 7, 2004 at the age of 92.

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[88] Donna Cragle, Kathryn Robertson-Demeyers, and Janice P. Watkins, Mortality Among Workers at a Nuclear Fuels Production Facility: The Savannah River Site, 1952-1986, Oak Ridge Institute for Science and Education, (submitted manuscript).

[89] Beate Ritz, Hal Morgenstern, John Froines, and Bambi Batts, Effects to External Ionizing Radiation on Cancer Mortality in Nuclear Workers Monitored for Radiation at Rocketdyne/Atomics International, American Journal of Industrial Medicine, 1999, 35:21-31.

[90] DF, Reynolds PJ. Investigation of an excess of melanoma among employees of the Lawrence Livermore National Laboratory. American Journal of Epidemiology 1997; 145:524-531.

[91] DF, Reynolds PJ. Investigation of an excess of melanoma among employees of the Lawrence Livermore National Laboratory. American Journal of Epidemiology 1997; 145:524-531.

The groundbreaking contributions to occupational cancer epidemiology that Mancuso left behind remain today as primary sources used to protect the public and workers, as well as for compensation for illness and injury. "He was for a half century a leading light in occupational epidemiology," wrote public health physician Michael Gochfeld in 2005. [92] While Dr. Mancuso may be most remembered for the controversy surrounding his last struggle to bring the risks of radiation in the nuclear work-place to light, his quest for the truth and his deep respect for working people will serve as his lasting heritage.

[92] Gochfeld 2005.

OFFICE OF MANAGEMENT AND BUDGET MEMORANDUM

DEPARTMENT OF LABOR
EMPLOYMENT STANDARDS ADMINISTRATION
(dollars in thousands)

		2005 Actual	2006 Estimate*	2007 Estimate
Total Discretionary	BA	400,847	415,216	420,859
	FTE	3,539	4,090	4,195
Of which: General Funds	BA	398,824	413,168	415,927
	FTE	3,529	4,080	4,185
Longshore Trust	BA	2,023	2,048	2,048
	FTE	10	10	9
BLDTF (ESA)	*BA*	*32,615*	*33,050*	*32,643*
	FTE	*197*	*214*	*198*
Black Lung Part B	*BA*	*5,191*	*5,250*	*5,250*
	FTE	*16*	*17*	*16*
EEOICPA Part B	*BA*	*40,321*	*96,081*	*102,307*
	FTE	*275*	*275*	*275*
Fair Share	*BA*	*39,668*	*45,001*	*48,001*
	FTE	*146*	*133*	*129*

** The 2006 Estimate is based on the November 16th Conference level.*

The 2007 total discretionary funding level of $420.9 million and 4,195 FTE is a $5.6 million increase from the 2006 Estimate. With some exceptions on the mandatory side (which are noted), the 2007 estimate includes no program or inflationary increases and is based on the 2006 Estimate. FTE levels for fiscal years 2006 and 2007 reflect estimates of financeable FTE. We will work with the Department to finalize these estimates. Detail of the increases and decreases are reflected on the attached crosswalk table. The 2007 estimate includes:

- **Wage and Hour Division – $173.4 million and 1,339 FTE.** This includes a $6 million increase above the 2006 Conference level. This program increase should be used to finance at least 40 new inspectors. The remainder should be directed to compliance assistance initiatives and/or hiring additional inspectors, in excess of the 40 mentioned above. We applaud WHD efforts to focus enforcement and compliance activities on

industries with high concentrations of immigrants in the workforce and advise that such a focus continue in the 2007 Budget.

- **Office of Federal Contract Compliance Programs – $81.1 million and 670 FTE.** This includes a $1 million decrease below the 2006 Conference level. It is noted that the K-OFIS business case did not meet requirements to warrant support for the system in the 2007 Budget. OFCCP should revisit the K-OFIS business case and address existing deficiencies, specifically the lack of analysis of alternatives and the structure of the lifecycle costs.

- **Office of Labor-Management Standards – $47.2 million and 355 FTE.** This includes a $1 million increase over 2006 Conference level. OLMS is asked to provide quarterly updates regarding the development and implementation of business processes associated with increases in LMRDA enforcement responsibilities.

- **Office of Workers Compensation Programs – Discretionary program level of $102.177 million and 905 FTE.**

  - **Mandatory resources.** In addition to discretionary resources described above, the 2007 estimate includes the following mandatory amounts:

    - $48.001 million and 125 FTE for Fair Share, including $3 M for the central bill processing contract.

    - $102.307 million and 275 FTE for administration of Part B of the Energy Employees Occupational Illness Compensation Program Act (EEOICPA). This includes:

      - $49.971 million for DOL.

      - $52.336 million for NIOSH. $4.712 million below the request. The estimate excludes requested amounts for CDC overhead.

    - $59.531 million and 219 FTE for administration of Part E of the Energy Employees Occupational Illness Compensation Program Act (EEOICPA).

  - $37.893 million and 221 FTE for OWCP's administration of the Black Lung Benefits Act, including $32.643 million and 204 FTE for Part C and $5.250 million and 17 FTE for Part B.

- **Program Direction and Support – $17.098 million and 93 FTE.** This includes $400,000 for servers. ESA is requested to develop a plan to incrementally upgrade its servers over a four-year period.

- **Legislative proposals.** The 2007 Budget assumes DOL will continue to work with Congress regarding legislation to deter repeat violations of child labor and union financial integrity laws; and reforms to improve the efficiency, fairness, and fiscal integrity of the FECA and Black Lung programs.

- **FECA benefit reforms.** The 2007 Budget will again include changes to FECA to improve benefit fairness, deter frivolous claims, and update and rationalize the benefit structure. No later than December 9th, DOL should provide final savings estimates for this package for inclusion in the 2007 Budget.

- **Black Lung Disability Trust Fund Refinancing.** The 2007 Budget will re-propose legislation to restructure the Black Lung Disability Trust Fund debt. The Department is recognized for its efforts to gain Congressional support for this reform, and should continue its work to enact H.R. 3915 - Black Lung Disability Trust Fund Debt Restructuring Act.

Program Management. The 2007 estimate assumes the following with respect to major components of ESA programs.

- **Central bill processing contract.** While ESA is working to address cost and implementation issues related to the central medical bill processing contract, concerns remain, and ESA is requested to provide periodic status reports on its status.

- **Energy Employees Occupational Illness Compensation Program Act (EEOICPA) Part B.** ESA is to be commended for identifying the potential for a large expansion of EEOICPA Part B benefits through the designation of Special Exposure Cohorts (SEC). The Administration will convene a White House-led interagency workgroup including HHS, and Energy to develop options for administrative procedures to contain growth in the costs of benefits provided by the program. Discussions are not limited to, but will involve, the following five options:
  1. Require Administration clearance of SEC determination;
  2. Address any imbalance in membership of President's Advisory Board on Radiation and Worker Health;
  3. Require an expedited review by outside experts of SEC recommendations by NIOSH;
  4. Require NIOSH to apply "conflict of interest" rules and constraints to the Advisory Board's contractor; and
  5. Require that NIOSH demonstrate that its site profiles and other dose reconstruction guidance are balance.

- **PART assessments.** ESA is encouraged to implement quickly and deliberately recommendations made in PART assessments for each of its activities. We look forward to working with DOL on each of these reforms.

- **OLMS performance measures and independent program evaluation.** As the OLMS 2006 PART assessment found, the absence of rigorous, reliable multi-year performance targets undermines agency efforts to measure program performance fully and effectively. Additionally, the PART assessment found that OLMS lacked an appropriate performance target for the union democracy activities. By February 24, 2006 OLMS should propose new, multi-year performance targets as well as a new indicator for union democracy. Finally, as recommended in the PART assessment, OLMS should plan to conduct an independent program evaluation. An update on the independent program evaluation process should be provided by March 24, 2006.

- **Longshore comprehensive evaluation.** As the Longshore PART assessment for 2006 found, the absence of a comprehensive evaluation on program outputs, outcomes, cost-effectiveness, or efficiency. The program is aware of a need for a broader-scope evaluation to compare the program's effectiveness and efficiency with other similar programs and the program will continue to complete a contract for an outside evaluation.

Employment Standards Administration
Summary of Changes

11/28/2006

Discretionary Salaries and Expenses (Includes LBT)

	FY 2006 Request		FY 2006 Enacted		
	FTE	Dollars	FTE	Dollars	
	3,439	418,715	3,333	418,315	
WHD	1,334	167,359	1,308	167,359	Reflects 3.5% decrease from request
OFCCP	516	62,305	505	62,305	Reflects 7.5% decrease from request
OLMS	369	49,779	355	49,779	Reflects 9.5% decrease from request
FOAS (without BL)	140	19,304	69	17,375	Reflects 9.5% decrease from request
OWCP Total	641	162,177	606	162,177	
FECA General Funds	530	60,538	495	60,538	
Longshore General Funds	91	99,889	96	99,789	
Longshore Trust	11	2,048	9	2,048	

	FY 2007 Request		FY 2007 Estimate		
	FTE	Dollars	FTE	Dollars	
Built-in Increases	0	26,748	39	6,242	
WHD	0	11,172	34	6,899	Funding for Inspectors
Pay and benefits only		11,387			
Rent only		(215)			
OFCCP	0	2,308	5	0	
Pay and benefits only		2,043			
Rent only		265			
OLMS	0	3,886	0	929	
Pay and benefits only		3,586		929	
Rent only		300			
FOAS – GFs	0	832	0	(977)	Inflationary increases
Pay and benefits only		848			
Rent only		65			
OWCP – FECA GFs	0	7,719	0	0	
Pay and benefits only		4,861			
Rent only		258			
OWCP – LS/HW GFs	0	167	0	0	
Pay and benefits only		81			
Rent only		81			
OWCP – LS/HW Trust	0	65	0	0	
Pay and benefits only		67			
Rent only		0			

11/28/2005

Built-In Decreases	0	(487)	(12)	0	
WHD	0	0	0	0	
OFCCP	0	0	12	0	Reflects estimate of supportable FTE
OLMS	0	0	(26)	0	Reflects estimate of supportable FTE
FDS& – GFs	0	(162)	0	0	
OWCP – FECA GFs	0	0	0	0	
OWCP – LSH/W GFs	0	(225)	0	0	
OWCP – LSH/W Trust	0	0	0	0	
Program Increases	27	7,759	0	400	
OFCCP (K-OFIS)	0	1,200	0	0	
OLMS	22	[illegible]	0	0	
FDS (Servers and Contract)	0	2,000	0	400	Funding for servers
FECA (Liability Management)	5	3,000	0	0	
Program Decreases	0	0	0	(1,000)	
OFCCP	0	0	0	(1,000)	Targeting of contractors
FY 2007 Estimate	3,467	469,897	3,380	428,868	
Reimbursables, FY 2006 Budget/Enacted	0	0	0	0	
Built-In Increases	0	0	0	0	
Built-In Decreases	0	0	0	0	
Program Increases	0	0	0	0	
Program Decreases	0	0	0	0	
FY 2007 Request	0	0	0	0	

Mandatory Salaries and Expenses

11/26/2006

BLDTF FY 2006 Request	217	33,853	201	33,853	
Trust Funds – OWCP portion	214	32,854	0	0	
Trust Funds – FDSS portion	3	201	0	0	
Built-in Increases	0	1,201	0	0	
Built-in Decreases	0	0	0	0	
Program Increases	0	0	0	0	
Program Decreases	0	0	0	0	
Non-add: Departmental Management total	0	28,984	0	0	
Non-add: DM total	0	0	0	0	
Non-add: Treasury total	0	0	0	0	
FY 2007 Request, Black Lung (BLA)	217	34,201	201	33,853	
Non-add: FY 2007 Request, Total Black Lung admin.	217	61,185	201	33,853	
Special Benefits for Disabled Coal Miners (FY 2006 Request)	17	5,250	16	5,250	
Built-in Increases	0	172	0	0	
Built-in Decreases	0	0	0	0	
Program Increases	0	0	0	0	
Program Decreases	0	0	0	0	
FY 2007 Request, Disabled Coal Miners	17	5,422	16	5,250	
FECA Fair Share FY 2006 Request	123	45,081	123	45,081	
Built-in Increases	0	1,278	0	0	
Built-in Decreases	0	0	0	0	
Program Increases	0	0,200	0	3,200	medical bill processing required
Program Decreases	0	0	(3)	0	reflects estimate of appropriate FTE
FY 2007 Request, Fair Share	123	52,279	123	48,081	
EEOICPA Administration	494	166,931	494	166,931	
Built-in Increases	0	12,040	0	0	
Built-in Decreases	0	(10,537)	0	0	
Program Increases	0	8,107	0	8,087	FY06 (52.3 M) Restoration of FY06 reduction
Program Decreases	0	0	0	0	
FY 2007 Request, EEOICPA	494	166,991	494	161,836	

Grand Total ESA, FY 2006 Budget	4,281	669,847	4,172	654,546		11/28/2006
Bill-in Increases	0	42,410	30	6,243		
Bill-in Decreases	0	(19,864)	(13)	0	Reflects estimate of supportable FTE	
Program Increases	27	21,917	0	9,267		
Program Decreases	0	0	(2)	(1,000)		
Total, FY 2007 Request	4,310	709,309	4,188	668,056		
ESA TOTAL by program	4,310	709,309	4,188	668,056	669,993	
WHD	1,304	170,672	1,304	173,285		
OFCCP	575	81,224	575	81,100		
OLMS	350	65,124	335	47,119		
Program Direction and Support	163	19,356	65	9,000	19,505	
General Funds	163	19,861	65	19,691	17,698	
BLDTF	3	497	3	497		
DWCP	1,884	271,102	1,728	249,109		
DWCP discretionary	649	172,925	592	162,177		
DWCP – FECA GPs	944	46,660	948	46,339		
DWCP – LS&HW GPs	21	10,732	20	10,700		
DWCP – LS&HW Trust	11	2,014	0	2,040		
DWCP – Black Lung	214	23,694	199	22,843		
DWCP – Rehabcor	127	42,378	128	40,604		
DWCP – CEDCOPA	404	146,881	404	151,038		
DWCP – Special Benefits for Disabled Coal Miners	17	5,422	14	5,320		
Reimbursables – WHD	0	0	0	1,000		

PREPARED STATEMENT OF PAULA GRAHAM, MEMBER, ADVISORY BOARD TO THE HEALTH RESEARCHERS OF THE UNIVERSITY OF IOWA, DEPARTMENT OF ENERGY

NOV-13-2006 14:32 319 372 4533 319 372 4533 P.01/17

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To: Dr. Lawrence Porter	**From:** Paula Graham-Lacey
Fax: 319-353-5649	**Pages:** 17 (including cover sheet)
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Fax # 1-319-353-564

Attention: Dr. Lawrence Fuortes

Nov. 13, 2006

16 pages including cover page

November 13, 2006

Dear Honorable Members of the Subcomittee on Immigration, Border Security and Claims,

We are members of the DOE Advisory Board to the health researchers of the University of Iowa, Iowa City, Iowa, who are doing the health studies for the Former Workers Program (FWP) for the former workers of the Iowa Army Ammunition Plant, Middletown, Iowa. (IAAP)

We, Lasca Yerington and Paula Graham, work helping a number of former workers of the IAAP file their claims for compensation of the EEOICPA.

Many of the former workers are up in years and they don't understand what to do about filing. Many are dead and more are dying all the time. They can't understand why, when they developed cancer from working there, serving their country, that they aren't compensated. If it wasn't for these Cold War Warriors making the weapons, bombs, mines, shells, etc., then our military would be badly equipped to fight a war.

During the past 7 years of our working with the former workers and their family, we have gained a lot of knowledge from talking w/ these workers and the research we have done, we have found the workers were exposed w/o their knowledge to harmful levels of toxic substances and radiation.

These workers lacked protection, such as: lead aprons, gloves, etc., especially in the earlier years there was no individual worker monitoring. In the later years only a small per cent were monitored. In addition, there is a lack of adequate records. Many of the records that do exist, are classified. This put the former workers at a distinct disadvantage.

Because of this lack of records and protection, the Radiation Advisory Board voted unanimously to grant the IAAP a Special Exposure Cohort (SEC). The EEOICPA lists 22 radiation induced cancers. We are convinced that more cancers should be added to this list, to be compensated under Part B.

The following is a list of cancers to be added to the list of 22 cancers.

1. Prostate Cancer We have found in the former workers that we help, that 7 out of 12 have prostate cancer. This is far more than is predicted for the general population. These men had their cancerous prostate removed. It has left them incontinent, impotent, with no sexual function. These workers held the pits w/ no lead aprons, and exposed all their organs below the waist to radiation – kidneys, bladder, colon, prostate and testicles. Although

prostate is not listed as one of the radio-sensitive cancers, and is not included in the list of SEC cancers, there is a weight of evidence from studies of the AEC, DOE and military personnel, exposed to nuclear weapons, that supports prostate cancer more frequent among the nuclear workers and hence, work related. We are sure that none of you men would want to have worked w/ the radiation, that would never again to enjoy and have sex with your mate. One man even had a device implanted so he could have sex, but it did not do what it was supposed to do - according to what he said.

2. Testicular Cancer Men w/ testicular cancer have contacted us for help in filling out claims for them. Since we have been asked for help in filling out claim forms, we wonder if this isn't a beginning of a new wave of radiation induced cancer. Congress should add this to the SEC list.

3. Hodgkin's Lymphoma is not compensated, but non-Hodgkins Lymphoma is. They are from the same cell type. There are 30 different types of non-Hodgkins Lymphoma. They are both caused by being exposed to radiation. Review of the research literature shows that there is an increase of Hodgkins Lymphoma among nuclear workers in many plants.

4. Vocal Chord Cancer This is part of the larnyx and Therefore, this type of cancer should be compensated, as larnygeal cancer is compensated as an SEC cancer.

5. Chronic Lymphocitic Leukemia. This should be added as a radiation induced cancer.

Congress needs to change Part E in the EEOICPA Act to say that, when there is no surviving spouse, the Part E compensation should be paid to the surviving children, regardless of the age of the children at the time of the parents death, in school or disabled. This is only fair as some children are compensated and others are not because there is no surviving spouse and no children meeting the above criteria. That leaves some of the Cold War Warriors without compensation for giving their lives for their country. In addition, during the illness of the parent, the older children had to take care of them financially, and attending to their physical needs. In a lot of cases, the children had to pay for their parent's burial services, as the sick parent had used all their money during their long illness. These illnesses were caused by their working with radiation and other chemicals on the nuclear line I at the IAAP.

Another thing to talk about is the fact that the former workers at the (IAAP) worked overtime months on end. Some worked 10 hrs. days, 6 days a week, which totaled 60 hrs (the equivalent of 7½ days in those six days.

Some worked these overtime hrs., four to 6 months straight to get out the production that was needed. We have found that some have worked 365 days w/o time off. This means they were more exposed than what NIOSH states and often records were not kept.

When claims go to NIOSH for dose reconstruction, and comes back to the worker when it is finished. The worker finds the dose is only consistent w/ their yearly exp. No other radiation of any kind is included in the percentage. NIOSH states they do not have the records, hence, they cannot do anymore. It appears to us, that doing this (so-called) reconstruction is a waste of time and money. We are spending millions to keep a few former workers or survivors from receiving a paltry "125,000" Part E compensation.

In their letter of denial, NIOSH states in bold letters, "This is a recommended decision only." A lot of these older former workers or survivors take that to mean they will not be compensated for their hard work for their country. They just stick the letter in the drawer and try to forget it. We have helped so many like this.

NIOSH should construct a letter that is more easily understood by these sick and elderly people.

We have yet to hear of NIOSH giving a Probability of Causation of 50% or more in order to have a person compensated.

After the SEC for the IAAP was passed in June 19, 2005, I, Lasca Yerington, called NIOSH to check on a claim we were helping on. It was Dec. 29, 2005, at 1:15 PM. The gentleman I talked to, said "the SEC hurt more than helped nuclear workers." I keep a log of all my phone calls. If you need his name, I can give it to you.

A few months ago, Paula Graham, called John Vance, in the DOL, to get information about skin cancers and Mr. Vance mentioned something about our resource center here for the IAAP. Paula replied, "John, Lasca and I are the resource center working w/o pay." We do not have a resource center here – the closest is in Denver, Colorado.

We not only have willingly helped people here with filling out their claims, but we have received telephone calls from people around the country asking for help, which we have provided over the telephone. Perhaps, we need a resource person in Burlington, to help the Burlington and Ames people. Not only have we helped people fill out claims, but have written their appeals when they were denied

their compensation. We have represented them at their appeal hearings when the hearing representative came from Washington, D.C.

We are asking your committee to recommend that Congress make the needed changes we have asked for these deserving people. Also, investigate the NIOSH dose reconstruction process.

We want to thank you for the opportunity to share w/ you our perspectives on the EEOICPA and special exposure process.

Sincerely

Paula Graham
1123 48th St., Apt. 6
Ft. Madison, Ia. 52627
Phone # (319) 372-2388

Larea Gerrington
3457 475th St.
Wever, Iowa 52658
Ph. # (319) 372-3600

Prostate

Listed below are references of studies annotated by the National Academy of Sciences and the Center for Environmental Health Studies that looked at prostate cancer and workplace exposures among nuclear workers in the United States, the United Kingdom and at nuclear test sites.

US Nuclear Test Sites: Increased mortality from prostate cancer was seen in 70,000 military personnel participating in one of five nuclear weapons tests. The five series study: Mortality of military participants in U.S. nuclear weapons tests. National Academy Press, 2000

Fernald, Ohio: Increased prostate cancer death was found in 4,014 males employed between 1951 and 1989, followed through 1989. Ritz B. Radiation exposure and cancer mortality in uranium processing workers. Epidemiology 1999;
10(5):531-538.

Lawrence Livermore, California: Increased incidence of prostate cancer was seen in men employed between 1969 and 1980. Reynolds P, Austin DF. Cancer incidence among employees of

Prostate

the Lawrence Livermore National Laboratory, 1969-1980. The Western Journal of Medicine 1985;142(2):214-218.

Mallinckrodt, St. Louis, Missouri: Increased prostate cancer death was found in 2,514 males employed between 1942 and 1966, followed-up through 1993. Dupree-Ellis EA, Watkins JP, Ingle JN, Phillips J. External radiation exposure and mortality in a cohort of uranium processing workers. American Journal of Epidemiology 2000;152(1):91-95.

Oak Ridge, Tennessee: Increased in prostate cancer death was found in 8,375 males employed for between 1943 and 1972, followed through 1977. Wing S, Shy CM, Wood JL, Wolf S, Cragle DL, Frome EL. Mortality among workers at Oak Ridge National Laboratory. Evidence of radiation effects in follow-up through 1984. JAMA 1991;265(11):1397-1402.

Oak Ridge Y-12, Tennessee: Increased in prostate cancer death was seen in 7,043 males employed between 1947 and 1990, followed through 1990. Loomis DP, Wolf SH. Mortality of workers at a nuclear materials production plant at Oak Ridge, Tennessee, 1947-1990. American Journal of Industrial Medicine 1996;29:131-141.

Rocky Flats, Colorado: Increased prostate cancer death was found in 5,413 males employed between 1952 and 1979, followed through 1979. Wilkinson GS, Tietjen GL, Wiggs LD, Galke WA, Acquavella JF, Reyes M, Voelz GL, Waxweiler RJ. Mortality among plutonium and other radiation workers at a plutonium weapons facility. American Journal of Epidemiology 1987;125(2):231-250.

Savannah River Site, South Carolina: Increased prostate cancer death was seen in salaried employees and white males employed before 1955. Cragle DL, McLain RW, Qualters JR, Hickey JLS, Wilkinson GS, Tankersley WG, et al. Mortality among workers at a nuclear fuels production facility. American Journal of Industrial Medicine 1988;14:379-401.

Atomic Energy of Canada: Increased prostate cancer death was found in 8,977 men who were employed between 1956 and 1985. Gribbin MA, Weeks JL, Howe GR. Cancer mortality (1956-1985) among male employees of Atomic Energy of Canada limited with respect to occupational exposure to external low-linear-energytransfer ionizing radiation. Radiation Research 1993;133:375-380.

Atomic Weapons Establishment of the U.K.: Increased prostate cancer death was found in 9,389 workers employed between 1951 and 1982, followed through 1982. Beral V, Fraser P, Carpenter L, Booth M, Brown A, Rose G. Mortality of employees of the Atomic Weapons Establishment, 1965-1982. British Medical Journal 1988;297(6651):757-770.

Sellafield, England: Increased prostate cancer death and benign prostatic hyperplasia was found in radiation workers employed between 1947 and 1975, followed to 1992, compared to nonradiation workers. Omar RZ, Barber JA, Smith PG. Cancer mortality and morbidity among plutonium workers at the Sellafield plant of British Nuclear Fuels. British Journal of Cancer 1999; 79(7/8):1288-1301.

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Hodgkin's Disease and Exposure to Ionizing Radiation

Summary: Little evidence has been recorded of a possible connection between Hodgkin's disease and exposure to ionizing radiation. However, there is evidence from studies conducted at Los Alamos National Laboratory and other nuclear sites that suggests an increased likelihood of developing Hodgkin's disease for workers who have been exposed to ionizing radiation. The National Research Council's BEIR V committee did not address the issue of radiation-induced Hodgkin's disease. Hodgkin's disease is not a "specified" cancer under the EEOICPA. Historically, Hodgkin's disease incidence ranked among the lowest in the state for Los Alamos County but among the highest in the state for Rio Arriba County. Hodgkin's disease mortality ranked among the highest reported in the state for both counties. Incidence means new cases of cancer, while mortality means deaths due to cancer.

Studies show an increase in Hodgkin's Lymphoma

What Is Hodgkin's Disease?

Hodgkin's disease is one of a group of cancers called lymphomas. Lymphoma is a general term for cancers that develop in the lymphatic system. The lymphatic system is part of the body's immune system. It helps the body fight disease and infection. Hodgkin's disease, an uncommon lymphoma, accounts for less than 1 percent of all cases of cancer in this country. Other cancers of the lymphatic system are called non-Hodgkin's lymphomas. Because lymphatic tissue is present in many parts of the body, Hodgkin's disease can start almost anywhere (National Cancer Institute)

Both Hodgkin's + non-Hodgkin's start in the lymphatic system

Findings of Human Health Research Studies

Human health research studies compare the patterns of disease among groups of people with different amounts of exposure to a suspected risk factor. Below are results reported from such studies of Hodgkin's disease among people exposed to ionizing radiation.

The results of these studies found a mix of increased and possible increases in Hodgkin's disease among certain groups of exposed workers and no connection found among atomic bomb survivors. Statistically significant is a term used to mean that the connection between the health outcome and the exposure was strong enough that it was unlikely to be due to chance. An asterisk (*) was placed by statistically significant findings. Two of these studies found rates of Hodgkin's disease to increase with increasing personal exposure to radiation. The research included an incidence study, which looked at new cases of cancer. Incidence studies can track health more quickly and accurately than mortality studies of deaths due to cancer.

Important

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* *Findings were statistically significant (strong evidence)*

\+ *Evidence of a dose-response relationship (strongest evidence)*

2

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Studies of Los Alamos National Laboratory (LANL) Workers

Research conducted of LANL workers provides the most direct evidence about possible relationships between a health problem and workplace exposures at LANL.

- **Mortality Study up to 1991:** Increasing rates of deaths due to Hodgkin's disease with increasing doses of external radiation in a study of 15,727 men employed between 1943 and 1977, followed through 1991 (assuming either a 2- or 10-year latent period)[21 *+]

Important

This study presents strong evidence that was unlikely to be due to chance (was statistically significant). Supporting the evidence of a relationship, a pattern, called a dose-response trend was seen where the proportion of workers who died Hodgkin's disease increased among those who received higher exposures. Further adding to the strength of this study is that it is based on direct personal measurements of exposure. A weakness of the study may be that mortality is not as good a measure of Hodgkin's disease as incidence.

Studies of Other Nuclear Workers in U.S.

The next most relevant evidence comes from studies done on workers in similar occupations facing the same types of exposures. Below are studies that observed Hodgkin's disease in possible connection with certain exposures among nuclear workers in the United States.

- **Fernald, Ohio:** Possible increase in deaths due to Hodgkin's disease in a study of 4,014 uranium processing workers employed between 1951 and 1989, followed through 1989.[1]
- **Hanford, Washington:** Increasing rates of death from Hodgkin's disease with increasing doses of external radiation in a study of 44,100 workers employed between 1944 and 1978, followed through 1986.[49 *+] However, the researchers who conducted the study did not think it was due to radiation exposure. Contradiction
- **Portsmouth, Ohio:** Possible increase in deaths due to Hodgkin's disease in a study of 8,887 workers employed between 1954 and 1991.[8]
- **Oak Ridge:** Possible increase in deaths due to Hodgkin's disease in a study of 8,375 males employed for at least 30 days between 1943 and 1972, followed through 1977.[30]
- **Combined Hanford, Oak Ridge and Rocky Flats:** Increasing rates of death from Hodgkin's disease with increasing doses of external radiation in a study of 45,000 workers employed for at least six months.[48 *+]

Studies of Other Nuclear Workers World-Wide

Below are studies of nuclear workers outside of the United States that looked at Hodgkin's disease in connection with radiation exposures.

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* *Findings were statistically significant (strong evidence)*

\+ *Evidence of a dose-response relationship (strongest evidence)*

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- **Sellafield, England:** Possible increased incidence of Hodgkin's disease in plutonium workers when compared to other radiation workers.[7]

Studies of Other Ionizing Radiation Exposures

Studies among other groups of people who were not nuclear workers can also be significant as evidence of possible increases in Hodgkin's Disease among those who have been exposed to ionizing radiation. Most other research has been conducted of people exposed to atomic bombs.

- **Atomic bomb Survivors:** In studies performed to date, there is no reported evidence of increased rates of Hodgkin's disease among A-bomb survivors

This is a one time exposure, whereas, nuclear workers were exposed multiple times.

Other Research and Policy Findings

The National Research Council advises the U.S. government on scientific matters. Their Committee on Biological Effects of Exposure to Ionizing Radiations (BEIR) V reviewed sensitivity of parts of the body to radiation. Their findings are based mostly on studies of cancer among atomic bomb survivors, as well as on some of the available information on the biology of the body, animal studies, and other evidence. The greatest risk is at high exposure levels.

The National Research Council was mostly concerning atomic bomb survivors + not radiation induced Hodgkins Disease.

The National Research Council's BEIR V committee did not address the issue of radiation-induced Hodgkin's disease.[9]

Is Hodgkin's Disease a "Specified" Cancer Under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA)?

- **No.** Hodgkin's disease is not a "specified" cancer under the EEOIC Act consideration of Special Exposure Cohorts

Policy makers have identified certain types of cancer among energy employees at nuclear facilities, including those employed at Los Alamos National Laboratory, as being potentially related to occupational exposures under the EEOICPA.

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* *Findings were statistically significant (strong evidence)*

\+ *Evidence of a dose-response relationship (strongest evidence)*

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What Are Other Risk Factors Associated with Hodgkin's Disease?

In considering the cancer risk from exposure to ionizing radiation at work, it is important to understand other risk factors. The following is a list of other possible risk factors for Hodgkin's Disease.

- Brothers and sisters of those with Hodgkin's disease have a higher-than-average chance of developing this disease.
- Epstein-Barr virus is an infectious agent that may be associated with an increased chance of getting Hodgkin's disease.

These factors may add to any risk due to workplace exposure to ionizing radiation. Hodgkin's disease occurs most often in people between 15 and 34 and in people over the age of 55. It is more common in men than in women. It is important to note that smoking is not related to Hodgkin's disease.

Rates of Hodgkin's Disease in Exposed Counties

Los Alamos County

There have been low rates of Hodgkin's disease incidence reported in Los Alamos County and high rates of Hodgkin's disease mortality

- Ranked 25th in incidence of Hodgkin's disease and
- Ranked 6th highest in mortality among the 33 counties in New Mexico from 1970 to 1996.
- In recent years, about one case occurred every five years. [13, 14]

Rio Arriba County

There have been very high rates of Hodgkin's disease reported in Rio Arriba County for both cancer incidence and mortality.

- Ranked second highest in incidence of Hodgkin's disease and
- Ranked first highest in mortality among the 33 counties in New Mexico from 1970 to 1996. [33]

Taken together, these statistics for Los Alamos and Rio Arriba counties indicate that more needs to be done to detect and treat these cancers early.

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* *Findings were statistically significant (strong evidence)*

† *Evidence of a dose-response relationship (strongest evidence)*

external ionizing radiation and tritium were observed for cancers of the brain/central nervous system, the esophagus, and Hodgkin's disease.

Hodgkins Lymphoma

PMID: 7960779 [PubMed - indexed for MEDLINE]

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Exhibit 1

Search PubMed for Go Clear

Display UI List Show 20 Sort by Send to

Hodgkins Lymphoma

1: 1994 Dec;67(6):577-88.

Mortality through 1990 among white male workers at the Los Alamos National Laboratory: considering exposures to plutonium and external ionizing radiation.

Los Alamos National Laboratory, NM 87545.

A cohort mortality study was conducted of 15,727 white men employed by the Los Alamos National Laboratory, a nuclear research and development facility. Some of the workers at this facility have been exposed to various forms of ionizing radiation and other potentially hazardous materials. These analyses focused on whole-body ionizing radiation exposures and internal depositions of plutonium. The results indicated that overall mortality among this cohort is quite low, even after nearly 30 y of follow-up. No cause of death was significantly elevated among plutonium-exposed workers when compared with their unexposed coworkers; however, a rate ratio for lung cancer of 1.78 (95% CI = 0.79-3.99) was observed. A case of osteogenic sarcoma, a type of cancer related to plutonium exposure in animal studies, was also observed. Dose-response relationships for whole-body dose from

RESPONSE TO POST-HEARING QUESTIONS FROM LAURENCE FUORTES, M.D., PROFESSOR, DEPARTMENT OF OCCUPATIONAL AND ENVIRONMENTAL HEALTH, UNIVERSITY OF IOWA

RESPONSES TO FOLLOW UP QUESTIONS FOR NOVEMBER 15th HEARING ON EEOICPA FROM DR. LAURENCE J. FUORTES

1. **Please provide your assessment of the documents provided to you by the subcommittee, showing that NIOSH decided to deny the Iowa Army Ammunition Plant (IAAP) Special Exposure Cohort petition before it had obtained the classified data needed to develop a credible site profile. Part of the analysis reflects a staff perspective that too many claims would be paid under a SEC, and that it would be better to do a site profile because it would reduce the costs to the Treasury for benefit payments.**

   A) **Should NIOSH staff be weighing costs to the Treasury of paying benefits to claimants when making a recommendation on an SEC Petition? Or is this a technical decision which should be based solely on the data or lack thereof?**

   I am in total agreement with the tone of the question, that NIOSH staff should clearly not be involved in cost analyses regarding SEC decisions and that this issue is outside of their mandate. NIOSH is entrusted with a set of scientific and technical questions regarding historical exposure to ionizing radiation and subsequent risk for cancers among these workers. The compensation program should be totally separate from the questions of potential risk from ionizing radiation at a site and adequacy of exposure data from which to assess that risk for individuals at that site.

   B) **NIOSH consulted with both DOE and DOL about whether to recommend an SEC. Should NIOSH/HHS be consulting with these agencies on whether to approve or deny an SEC?**

   The potential for conflicts of interest in this program is very great and even the perception of collusion between government agencies in order to limit rights and benefits to this workforce must be guarded against. What is most unfortunate about the tone of the documents provided for review is that they give credence to the fears of workers that their government was not sincere in offers to compensate for work related illnesses. The Radiation Advisory Board is designed to assess the validity of SEC petitions and as such should not be bypassed by NIOSH in deliberations regarding the appropriateness and economic or political implications of SEC designations.

   C) **As one of the SEC petitioners, were you aware that NIOSH staff had prejudged the SEC Petition before finalizing its site profile? What process would you recommend to prevent NIOSH staff from prejudging the outcome of SEC petitions prior to completing the profile?**

   We were quite aware from statements made by the NIOSH scientific staff that they

had already determined that the IAAP site was a relatively 'low exposure' setting on the basis of statements they made upon first meeting scientific and production staff. It is quite possible that there is a culture of defensiveness in the process of development of site profiles wherein the scientific staff on the one hand must rely on the exposure and health and safety data provided by the employer, (DOE and it's contractors), and very likely many of these scientists were employed in some fashion by this industry and may have had responsibilities specific to health and safety for DOE workers and facilities themselves. The assumption of low risk was reflected in a variety of assumptions made by NIOSH scientists. One of the most glaring examples was the reliance upon above ground radon measurements in assessments of dose attributable to radon for workers in the underground bays at IAAP. Iowa has among of the highest geologic sources of radon recorded in the US and the underground bay workers could be fairly presumed as having had exposures more akin to underground miners than those reflected by ambient above ground measurements as were used by NIOSH. Production workers must be included in the process of data collection and review in assessing exposure and adequacy of available records.

D) You note that claimants are tasked with proving the negative in the case of an SEC Petition. Should there be basic presumptions or metrics written into the law to level the playing field?

At the very least the SEC petitioners and EEOICPA claimants should have access to the same exposure data as is used by NIOSH and the contractors they entrust with developing Technical Basis documents, Site Profiles performing Dose Reconstructions.

As the claimants and petitioners are at a disadvantage as regards access to exposure data and technical aspects of risk assessment it behooves the oversight committee to review the obstacles experienced by such petitioners and try to minimize same. I would suggest the roles and responsibilities of the Radiation Advisory Board, their technical consultants and the Ombudsman's Office could be reviewed and thought be given to tasking one or all of these groups with provision of technical services to claimants and petitioners and assisting same with access to and interpretation of exposure data and reviewing rationales for SEC petitions. The SEC petition process itself is quite complicated and efforts should be made to assist petitioners in collating records and compiling petitions. The appearance of the various agencies' actions in response to the Iowa and other early SEC petitions suggests an emphasis by such agencies on the public policy implications of awarding an SEC not on the language and intent of the EEOICPA legislation.

Where there is a reasonable presumption of potential for risk of radiation induced cancer, from occupational exposure to radiation but insufficient radiation monitoring from which to develop accurate and timely dose reconstructions a presumption should be made of work-relatedness and or SEC status.

2. Do you agree with the DOL's contention that the Advisory Board's criteria for approving the SEC at IAAP was "fuzzy"? Do you agree with DOL that the outcome at IAAP was based more on political pressure than on a reasoned basis? Please explain.

I believe the strong bipartisan support by the Iowa delegation for SEC status for the IAAP was not evidence of unreasoned political action but was the result of careful review by these legislators' offices of the language of the EEOICPA legislation and a review of the work histories reported by this workforce and of the dearth of exposure records from which to reconstruct dose and develop POC's. I fell on the other hand that the arguments used by the DOL and NIOSH against the SEC were somewhat "fuzzy" in that they appear to have begun with the favored outcome, denial of an SEC, and developed their arguments from that starting point. Evidence for this is reflected in the documents provided for review and in the actions and statements of these offices. For example the arguments made by NIOSH scientists that IAAP was a low exposure workplace were the result of assumptions that the lack of radiation exposure records was evidence for low exposure. The assumptions of low exposure were based on very few numbers of radiation badges without the benefit of any documentation from a site specific radiation safety protocol, without any evidence of a quality control program and without the benefit of interviews of production workers. The argument made was that the DOE contractors knew enough to monitor all the highest exposed workers and that the small number of exposure records found for IAAP workers reflected the worst case scenario or were indicative of the highest exposure scenarios. Assumptions were made that exposure records from different workers, (a later era Pantex Plant workforce), monitored decades later with different weapons systems and different health and programs; could be used to assess exposures and risks at the IAAP. There is little to support such assumptions other than an unjustifiable faith in the good intentions and superior professionalism and knowledge of early era radiation safety staff. The impression given by the DOL emails is that DOL and NIOSH intended to set policy on the basis of economic implications and not on the basis of the intent of the EEOICPA SEC language. NIOSH scientists were determined to develop Dose Reconstructions despite having to rely on all manner of assumptions instead of admitting that these assumptions precluded the ability to accurately assess dose for individuals at this facility.

3) NIOSH was required to deliver a report to Congress identifying additional radiosensitive cancers by June 30, 2006. This report has not been delivered. As a doctor and epidemiologist, is it your view that there are additional cancers which are radiosensitive and are not on the list of 22 cancers compensated under the SEC? Which specific cancers do you believe there is a scientific basis to add to the list?

There is both laboratory and epidemiologic evidence suggesting that ionizing radiation most likely increases the risk of all malignancies through genetic injury and increased mutation. The magnitude of risk or susceptibility from radiation appears to vary for

different sites but it is unlikely for a site to be totally resistant to cancerous effects from ionizing radiation. As regards the list of 22 presumptive radiologic cancers, there are certainly some omissions that deserve reevaluation. There is valid controversy regarding the science of radiation risks of cancers and such controversy should be viewed as reason to reexamine the weight of scientific evidence and construct the most fair and appropriate policy as regards compensation. For example the list includes oral cavity, throat, bronchus and lung as radiogenic cancers but for unknown reason(s) excludes laryngeal or vocal cord cancers. There is no anatomic, histological, pathophysiologic or epidemiologic rationale for such a distinction or omission. The epithelium lining the larynx is in continuity with the pharynx above and bronchus below and inhaled carcinogenic exposures would affect all of these tissues in a similar fashion. There have been several epidemiologic studies of radiation exposed workers, (from both US DOE sites and UK workers), indicating increases in Prostate Cancer, Testicular Cancer, Hodgkin's Disease or Hodgkin's Lymphoma and Chronic Lymphocytic Leukemia among these workers. The exclusion of these sites or their designation as 'non-radiogenic' does not appear to be defensible based upon what is known regarding mechanisms of radiation induced cancer and on epidemiologic studies of radiation exposed workers.

4) What specific legislative improvements would you recommend to improve the process? What administrative improvements would you recommend (ones that would not necessarily require legislation) to improve the process?

There are several improvements one could imagine to the overall process. At the very least there must be recognition and response to at least the perception that workers and families are experiencing unintended frustration that amounts to insult upon injury. The legacies of a culture of secrecy and the history of workers being placed at risk through employer's and government's ignorance or possibly at times frank malfeasance has led to a pattern of mistrust. Maximizing transparency in all aspects of the programs related to the EEOICPA and minimizing potential for even perceived conflicts of interest on behalf of the agencies involved in carrying out the various aspects of EEOICPA related programs is necessary to reestablish trust and do right by these workers.

The entire process should be made transparent and subject to oversight and audit. The costs and efficiencies or inefficiencies of the various aspects of the programs related to EEOICPA should be examined thoroughly. The costs and rationales for Dose Reconstructions should be carefully reviewed. It is likely that this process could be streamlined and the number and cost of some Dose Reconstructions be decreased significantly. Certainly the program should be maximizing the benefits to claimants as opposed to contractors and the potential for the latter to occur must be recognized and precluded.

Both Parts B and E of the claims process should be within the purview of the Ombudsman's Office. The DOL claims process is cumbersome, often protracted and it appears that all too often valid cases of clearly occupational disease are denied for technical problems. So many of these inappropriately denied cases have come to light that

consideration must be given to developing a system for reviewing such denied claims for likelihood of these representing valid claims for occupational illnesses arising from DOE employment, examining the rationale for denial and exploring means of assisting the claimants in submitting any requisite information.

There should not be distinctions between how so called DOE versus AWE workforces are dealt with under the law. AWE workers should be eligible for medical screenings under the associated DOE Former Worker Program and should be eligible for compensation under both Parts B and E as are DOE workers.

All these workers should be made eligible for medical screenings by experienced Occupational Physicians to detect early and treatable stages of occupational diseases, (radiation induced cancers, Beryllium sensitization and Beryllium lung disease, other pneumoconioses and other toxin induced diseases arising from work in the nuclear weapons industry). Consideration ought to be given to expanding the medical screenings to include screenings for breast, ovarian, cervical and prostate cancers and to including state of the art screening methods including capitalizing on improvements in detection methods such as spiral CT scanning for screening for lung cancers for these workers. Consideration should be given to integrating the DOE Former Worker Program medical screenings with the DOL claims process as these activities could thus be mutually improved. Information could be better shared and utilized to claimants' advantage through such integration of skills and services.

RESPONSE TO POST-HEARING QUESTIONS FROM JOHN MAURO, PROJECT MANAGER, DOSE RECONSTRUCTION CONSULTING SERVICES, ADVISORY BOARD ON RADIATION AND WORKER HEALTH UNDER EEOICPA, SANFORD COHEN & ASSOCIATES

RESPONSES TO FOLLOW UP QUESTIONS FOR NOVEMBER 15th HEARING ON EEOICPA FROM JOHN MAURO, SANFORD COHEN & ASSOCIATES

1. **At the November 15, 2006 hearing, Kathy Bates testified as a survivor about quality control problems with her father's dose reconstruction. She testified that NIOSH assumed there were no radiation exposure records because they gave the Energy Department an erroneous social security number. The lack of records under that social security number then led NIOSH to assume her father never worked with radioactive materials. SC&A's audits have also found technical errors, such as badge numbers being used to quantify radiation dose instead of dosimeter readings.**

   A) **Does NIOSH, in your opinion, have an adequate quality control system? How could it be improved?**

   NIOSH and ORAU have a very well developed quality assurance/quality control program on paper. We have completed a comprehensive review of many of their QA/QC documents and have provided reports to the Board on these matters. However, we have identified numerous deficiencies in the quality of several site profiles and individual dose reconstruction reports. The implications of these findings are that, though NIOSH/OCAS has prepared good QA/QC plans and procedures, implementation of those plans and procedures has been deficient. We have apprised NIOSH and the Board of these issues and NIOSH has committed to correcting these deficiencies.

   B) **When reviewing NIOSH's site profiles, have you uncovered data sources that have been missed by NIOSH, or which NIOSH failed to review, and as a result could have led to unwarranted denials of claims or SEC Petitions?**

   Though SC&A has identified a number of deficiencies with respect to missed data sources in both site profiles and SEC evaluation reports, we are not in a position to state whether these deficiencies have resulted in unwarranted denials because our scope of work does not include capturing and analyzing the missed data sources and then reperforming dose reconstructions and POC calculations. SC&A identified omissions and/or deficiencies in regard to analysis of some radionuclides at Mallinckrodt (trace radionuclides such as Th-230, Ac-227, and Pa-231) and Y-12 (thorium-232 and several others) that the Board found important in its deliberations for the SEC petitions for those sites for the late 1940s through 1957. The Board eventually recommended granting both SEC's.

   C) **Please provide three examples where you have identified significant omissions or holes in the data.**

   The major areas where we have identified sources of missing data include data characterizing the exposure of workers to thorium, actinium, protactinium, and a

large number of so called "exotic" radionuclides. These findings affected the site profiles for Mallinckrodt, Y-12, Rocky Flats, and Hanford. In addition, the subject of possible "holes" in the data has become an important issue in our review of the Rocky Flats SEC petition and evaluation report. The prepared statement that I submitted to the Subcommittee at the November 15, 2006 hearing identified "other isotopes" (such as thorium-232) as the most important emerging issue related to SEC petition reviews. This issue has been acknowledged by NIOSH and is one of the primary reasons for recommending SEC status at many AWE and one DOE facility (Y-12).

2) NIOSH was constraining access to data needed for the audit at the time of the November 15th hearing.

A) Does SCA have full and unfettered access to data at this time? If not, please outline the ground rules which apply at this time.

SC&A now has full an unfettered access to all claimant records. The only constraints we have are that we must carefully control the release and distribution of our work products in accordance with our approved Privacy Act procedures. I am happy to report that it appears that our problem with "access" is behind us.

B) Have Board deliverables been delayed as a result of this lack of access to data?

We had about a 2 to 3 week setback in our work on Rocky Flats due to the access problems we encountered last month.

C) What are the consequences with respect to the audit, in your view, if the auditor has access to less data than NIOSH has in its files?

In answering this question, it is important to make a distinction between the various types of audits we are performing on behalf of the Board. With respect to site profiles reviews (Task Order 1), when the project began, we had a great deal of difficulty gaining access to the reports used by NIOSH to prepare site profiles. These initial access problems were resolved over a period of about 6 months by NIOSH providing SC&A personnel with passwords and training for accessing the controlled document list that represent the source documents that NIOSH/OCAS use to prepare site profiles. On Task Order 1, we continually encounter difficulty in accessing classified records and data. However, we believe that this is a problem that NIOSH also has to deal with. The level of difficulty we have encountered to date in accessing classified data varies by site. It is essential that SC&A have access to all the information used by NIOSH to prepare its site profiles, procedures, dose reconstructions and SEC evaluation reports. In fact, it is essential that we have access to DOE and other records, perhaps not used by NIOSH, in

order to meet our obligations to the Board under our contract.

An issue that we have raised in the past and is now being more aggressively addressed by NIOSH has to do with providing information related to incidents in site profiles. NIOSH had adopted a strategy whereby information regarding incidents at a given site is not provided in the site profiles. It has been our position that NIOSH needs to provide more information to its dose reconstructors regarding historical incidents that have occurred at sites in order to ensure that all dose reconstructions explicitly consider exposure to incidents. We believe that NIOSH could do a better job in explicitly considering exposures associated with incidents. SC&A will need to have better access to incident reports in order to perform a more comprehensive review of site profiles and also dose reconstructions.

With respect to the performance of individual dose reconstruction audits (Task Order 4), we always had access to claimant files. The Board would identify the cases that they would like us to review, and then NIOSH would send us a CD containing the case files. These CDs would then be managed within SC&A under our Privacy Act procedures. However, we encountered a great deal of difficulty in getting access to "workbooks'" used by NIOSH to perform dose reconstructions. As it turns out, though the procedures used by NIOSH are described in a large number of site-specific and generic documents, these documents are often confusing, incomplete, and contradictory. As a result, we encountered difficulty in auditing the dose reconstructions. It was not until we were about 1 year into the project when we found out that NIOSH and OCAS used "workbooks" to perform dose reconstructions. Workbooks are spreadsheet computer codes that automate the dose reconstruction process to a degree. It turns out that these workbooks are the actual tools that NIOSH uses for dose reconstruction, and that it is essential that they are made available to us to perform our audits. I believe NIOSH was hesitant in initially providing us with the workbooks because they were in the developmental stage when we came aboard. However, I believe that NIOSH should have been more forthcoming in informing us of the workbooks and providing them to us. Fortunately, this is all behind us now. NIOSH has provided us with all workbooks, including training on the use of the workbooks, and are very helpful in helping us understand and use to workbooks in our review of dose reconstructions.

With respect to SEC petition reviews (Task order 5), access to claimant files became a major issue with respect to our review of the Rock Flats SEC petition. Normally, an SEC petition review would not require access to individual claimant files. However, on Rocky Flats, we found that the aggregate database summarizing worker exposures were incomplete. In addition, the petitioners claimed in their petition that the records for individual workers were unreliable. These concerns, which were also presented by the claimants and petitioners at the Denver Board meeting, represent one of the most important issues associates with the Rocky Flats SEC petition. In order to determine the reliability and completeness of the

worker records, it became necessary for SC&A to access individual claimant records. Due to concerns regarding Privacy Act (PA) issues, NIOSH terminated our access to the claimant files for these purposes until they could be assured that all PA files were under adequate control. During this time period, NIOSH and the Board had either no or only limited access to claimant files which hindered our work for about a 3 week period of time.

We have also had some difficulty in gaining access to NIOSH interview records. This may be because the interview records have not been well maintained or were not created in the first place when the interviews were done. This has been an issue because NIOSH makes reference to site expert interviews, but only partial records are available for review and sometimes there are essentially none.

D) What is the optimal arrangement, in your view, with respect to records access?

I believe we now have an optimal arrangement for access to claimant records. We have provided NIOSH with a complete list of all SC&A personnel that need complete access to all claimant files, and that access has been provided without any constraints on time period of access. I addition, NIOSH has assigned an individual to help us if we run into any problems in gaining access to the information we need. We still have issues associated with access to classified information, which we deal with on a case by case basis. I don't know if there are arrangements that can be made to facilitate access to classified documents. Joe Fitzgerald may have some suggestions since he has overall responsibility for accessing classified data under this project.

E) Does SC&A have procedures to ensure compliance with the Privacy Act? What are these? Has NIOSH made a determination that SC&A violated the Privacy Act?

SC&A has formal procedures and a training program regarding accessing and managing records and other information covered by the Privacy Act. These procedures are part of SC&A Quality Assurance plan that was approved by the NIOSH and the Board. Dr. Steven Ostrow with SC&A is responsible for ensuring that SC&A meets all Privacy Act requirements. At a working group meeting, SC&A distributed material that NIOSH determined was Privacy Act material. We have since taken steps to ensure that this doesn't occur again.

3) Your company has been tasked by the Advisory Board to undertake a technical review of site profiles and SEC petitions. DOL argues that additional conflict of interest restrictions are needed, because individuals such as yourself, have served as expert witnesses against the U.S. Government involving radiation-related claims.

A) Please respond to the charge of bias. What is your view of the DOL's contention that, because you have served as a witness against the U.S., you cannot be relied upon to provide unbiased scientific assessments in a government claims program?

I completely disagree with the contention that I or any member of our team or SC&A as a corporation have violated the letter or intent of our Conflict of Interest plan or obligations under this contract. I have not served as a witness against the U.S. Government. I served as a witness on behalf of the people of the Marshall Islands in hearing held before the Nuclear Claims Tribunal of the Republic of the Marshall Islands. The U.S. Government was not involved in these hearings. In addition, there is nothing in our COI plan or obligations under this contract that precludes any member of the project team from working on this project because he or she may have defended a claimant. The only bright line COI requirements on this project are that no individual has ever defended the Government against a claim and no individual or company working on this project can also concurrently work on a separate contract with NIOSH or its subcontractors. On those occasions where it was deemed by the Board to be in the best interest of the Board's mandate, the Board and NIOSH have granted well defined exceptions to our COI plan. This issue arose with regard to our contract with the Defense Threat Reduction Agency (DTRA). SC&A informed NIOSH that we were bidding on this contract. When we were awarded the contract, SC&A informed NIOSH and the Board. NIOSH determined that SC&A had a COI in that it could not perform dose reconstructions on the DTRA program for military personnel who were exposed at the Nevada Test Site (NTS) and Pacific Proving Grounds (PPG) and simultaneously perform audits of dose reconstructions for civilians that worked at the NTS or PPG. In order to resolve this COI issue, SC&A instituted a COI mitigation program that included a "firewall' between the two program, which was accepted by NIOSH and the Board.

On another occasion, SC&A determined that Drs. Lynn Anspaugh and Jeff Klemm had highly specialized and unique experience related to the NTS that would help to address certain issues related to the NTS. We requested an exemption from our COI requirements, under highly prescribed conditions, which were approved by NIOSH and the Board. We believe that we have been in complete compliance with our COI commitments to the best of our knowledge. When informed by NIOSH that we had a COI non-compliance, we acted expeditiously to mitigate the issue.

With respect to the issue of bias. The scientific analyses performed in the past by SC&A and the SC&A and subcontractor staff stand on their own merit. We do not agree with the proposition that, if a scientist performed an investigation in the past on a particular subject, he automatically is biased regarding that subject. I also want to note that while allegations of bias have been made, not a single specific instance of bias or distortions of data to fit a preconcieved conclusion has actually been put forward. We have a very diverse team, which includes individuals who

have worked long years in official capacities and those who have worked in public interest roles and some who have done both. The constants in their work are integrity and competence. The diversity of our team as well as out internal review procedures further protects against any bias.

B) Does SC&A have conflict of interest restrictions in its contract with the government? What are they? Has SC&A violated any of the restrictions?

SC&A does have COI restrictions in its contract with the government. Those restrictions are summarized above and are contained in our COI plan, which was approved by NIOSH and the Board. A copy of that plan will be provided upon request. In addition, SC&A maintains a web site with COI disclosures for each of its scientific staff working on the NIOSH project.

4. Excerpts of a draft DOL memo prepared for the OMB (as part of the development of the OMB passback) state:

"the Advisory Board has totally failed to take a balanced approach to examining NIOSH activities. . . . This unwillingness to fulfill their statutory responsibility by carefully examining issues such as whether so called "claimant-friendly" devices increasingly adopted by NIOSH are overestimating and overcompensating claimants has been magnified by NIOSH's decision to provide technical support through a contractor, Sanford Cohen & Associates (SC&A) rather than through its own staff. SC&A has relentlessly pursued an agenda that appears to be designed to result in maximizing payments to claimants regardless of scientific validity."

A) Please explain the methods used by SC&A in its auditing work. Does SC&A only examine underestimates, or does it also assess over estimates of dose that would lead to inappropriate compensation decisions? Has SC&A actually identified such overestimates and notified NIOSH or the Board?

All SC&A analyses are performed and documented in accordance with prescribed procedures that have been approved by NIOSH and the Board. A strong indication that SC&A is providing unbiased audits of NIOSH's work products is provided in my prepared statement, which includes a table that documents that we have found deficiencies in NIOSH's dose reconstruction that include both underestimates and overestimates of doses. Our mandate is to ensure that NIOSH performs all its work in accordance with the applicable regulatory requirements, which includes assessing the scientific validity of its work products. In addition, in cases where there is uncertainty on the appropriate scientific method or data to be employed, we also ensure that NIOSH gives the benefit of the doubt to the claimants. This is all documented in our procedures and is reflected in our work products.

B) Does SCA consider whether claims are paid or denied when it undertakes an audit? If not, is it fair to say that SC&A has an agenda to maximize payments to claimants regardless of scientific validity? Please explain.

Dose reconstruction audits performed by SC&A give no consideration whether a claim has been granted or denied. The Board selects the adjudicated claims that SC&A audits, and they include claims that have been granted and claims that have been denied. The procedures we use to audit the dose reconstruction reports prepared by NIOSH are identical for both types of dose reconstruction reports. SC&A has absolutely no agenda to maximize payments to claimants. Our contract is clear. We are to determine whether NIOSH dose reconstruction are scientifically valid, perfomed in accordance with their procedures, and give the benefit of the doubt to the claimants. Our procedures are a matter of public record, and anyone can read our procedures and our work products and determine for themselves whether we are following our approved procedures and whether the scientific analyses we have performed is valid.

C) Do Advisory Board procedures used in auditing dose reconstructions and site profiles require SC&A to assess whether, in the absence of complete and reliable records, that the assumptions used by NIOSH are appropriately claimant favorable?

Yes.

D) Congress identified that a major challenge to dose reconstruction is the lack of sufficient data leading to underestimates of radiation dose. Based on your audits, is there a greater risk that NIOSH will underestimate or over estimate radiation dose in this program?

In my opinion, NIOSH procedures used to reconstruct doses tend to overestimate, as opposed to underestimate the doses in cases where NIOSH sets out to do maximum dose reconstructions for denial. The matter in regard to "best case" estimates" is not as clear. SC&A has audited few of these because very few have been done by NIOSH and the Board has assigned some such cases for review by SC&A only recently.

5. In the case of the Bethlehem Steel Site profile review, DOL argued that SC&A's audit exaggerated doses to unrealistic levels. DOL also argued that SC&A was excessive because it issued an 85-page audit of a 15-page site profile.

We believe our audit reports speaks for itself. We found numerous important deficiencies in the original site profile for Bethlehem Steel. We believe there were significant and numerous deficiencies in the scientific methods employed by NIOSH, in their interpretation and use of the limited Bethlehem Steel data, and the way in which Simonds

Saw data was used to supplement the limited Bethlehem Steel data. We also believe that, though many aspects of the NIOSH site profile gave the benefit of the doubt to the claimants, there were instances where the methods adopted by NIOSH did not give the claimants the benefit of the doubt. Our report was several times larger than NIOSH's site profile because the site profile was very brief (15 pages) and did not provide the detailed data and analyses that established the basis for the exposure matrix adopted by NIOSH in the site profile. Our review of the site profile included a detailed description of the data and all analyses that we used to arrive at our conclusions.

A) Why was this audit report longer than the site profile? How many of SC&A technical recommendations at Bethlehem Steel were adopted as consensus recommendations accepted by NIOSH and the Advisory Board after the comment resolution process? How many were rejected? How many were left unresolved?

Our audit report was not large; it was about 85 pages. NIOSH's site profile report was short. Most of NIOSH's site profiles, including those for AWEs, are larger than 15 pages. Our report was of the length required to provide the scientific basis for our findings. It should be noted that SC&A reviews contain extensive attachments, documenting our interviews and exchanges of questions and answers on technical matters with NIOSH. This is essential for our own accountability for the work we have done. Bethlehem Steel was also our first Site Profile review and we felt it necesssary to elaborate on a number of issues that have turned out to be generic (such as careful consideration of incidents, oro-nasal breathing, the use of lognormal distributions, resuspension intakes, and ingestion of radionuclides). It is noteworthy that after careful consideration, NIOSH has agreed that all the major issues that SC&A raised were valid. Some of the eventual revisions were along the lines suggested by SC&A, while the specifics of others evolved into new solutions after prolonged scientific investigations, which illustrated the difficulty and complexity of the issues that NIOSH had not addressed. NIOSH has extensively revised its site proflie as a result of this process. NIOSH has also initiated generic reviews of several topics that apply not only to AWEs but also across the DOE complex. When seen in light of its impact on a range of issues relating to the whole dose reconstruction program, an 85 page review was eminently justified and may, indeed, be regarded as succinct. Of the various issues we raised, NIOSH agreed to revise the site profile to address most of our concerns. One issue related to particle size, we retracted, agreeing that NIOSH was correct and we were incorrect. One issue related to oro-nasal breathing was set aside as not important to this site. On an issue related to inadvertent ingestion of dust, both SC&A and NIOSH agreed that the the approach used by NIOSH and the one suggested by SC&A had deficiencies. NIOSH developed an new procedure and presented it to the Board. SC&A concurs that the new procedure for addressing inadvertent ingestion of soot and dust resolves the concerns we raised in a scientifically robust and claimant favorable manner. Inspection of the NIOSH web site reveals that the Bethlehem Steel site profile has been revised. SC&A has not been tasked with reviewing the

revised site profile to determine the degree to which all issues have been resolved. However, based on presentations made by NIOSH, it is our understanding that all issues have been resolved.

It is important to keep in mind that this was the first site profile that SC&A was asked to review, and the ground rules for the review and issue resolution, though developed in principle, were tested for the first time on this site profile review.

B) In terms of claims paid, what has the net effect been of the SC&A recommendations on claims paid? Based on NIOSH Program Evaluation Reports, have there been a significant increase in the number of claims paid as a result of the changes made to the Bethlehem Steel site profile?

Though SC&A found a large number of deficiencies in the dose reconstruction reports, we believe that the vast majority of the adjudicated decisions will be unaffected. However, among the realistic analyses that we only recently reviewed, there may be one or two cases where, if NIOSH and the Board accepts our findings as valid, a formerly non-compensated case may be compensated. However, we also have performed audits that reveal deficiencies that, if accepted as valid by NIOSH and the Board, could result in reversals where the probability of causation will be reduced from the compensable range to the non-compensable range.

With respect to Bethlehem Steel, I am not in a position to judge whether the revised site profile will result in any reversals, in either direction. However, many of our comments on some of the site profiles, especially those for Hanford, if accepted by NIOSH and the Board, have the potential for at least some reversals from non-compensated to compensated. SC&A has not been tasked with reviewing Program Evaluation Reports for the purpose of determining whether there have been any reversals based on the results of our audit reports.

The main effect of SC&A's work in relation to claims paid has been via the work done on the Iowa Army Ammunition Plant, Mallinckrodt and Y-12 SEC petitions recommended by the Board after consideration of work done by SC&A and its exchanges with NIOSH on the relevant issues. SC&A's work on thorium in the latter two cases also appears to have increased NIOSH's awareness of the lack of thorium data at other sites, as evidenced by several SEC petitions that NIOSH has initiated under 42 CFR 83.14 subsequent to the Mallinckrodt and Y-12 Board decisions.

C) Claimants believe the exposure data at Bethlehem Steel too thin and a Special Exposure Cohort is warranted. They point to the fact that NIOSH used data from other uranium rolling facilities to try to compensate for the lack of data at Bethlehem Steel. Did your audit assess whether EEOICPA allows NIOSH to use data from other facilities, or is that outside of the scope

of your audit contract?

Our review of the Bethlehem Steel site profile included an evaluation of NIOSH's use of Simonds Saw data to supplement the limited Bethlehem Steel data. We believe that under 42 CFR 82 the Simonds Saw data can be used to supplement the Bethlehem Steel data. However, we did not agree with NIOSH on how they used that data. It should be noted that SC&A has not reviewed the petition and the issues in it and we are not commenting on that at this time and will not do so unless the Board requests an analysis from us. The Bethlehem Steel petition is currently under review by NIOSH.

6. **Some members of your audit team have Q clearances to review classified records. Are these Q clearances up to date? How often have you had to have someone with a Q level clearance involved in the audit process?**

We have a limited number of Q-Cleared individuals and recently additional members of our team have received clearances. Our personnel resources have been sufficient to address all issues of reviewing classifed data to date. The main issue in that regard is access to data and the delays that are inherent (understandably) in ensuring that classified material is properly protected. Our reviews of several site profiles, especially the site profile for the Iowa Army Ammunition Plant, required Q-Cleared individuals. We are currently performing site profile reviews where Q-Clearance is essential to performing our reviews.

RESPONSE TO POST-HEARING QUESTIONS FROM KATHY BATES, SURVIVING CLAIMANT UNDER THE ENERGY EMPLOYEES OCCUPATIONAL ILLNESS COMPENSATION PROGRAM ACT

RESPONSES TO FOLLOW UP QUESTIONS
FOR NOVEMBER 15th HEARING ON EEOICPA
FROM KATHY BATES

1) Your testimony pointed to a situation where NIOSH's dose reconstruction was erroneous because they failed to obtain the radiation monitoring data for your father from the Oak ridge Y-12 facility. Even after you obtained the radiation monitoring data and gave it to NIOSH, your testimony states that NIOSH ignored this in their second dose reconstruction report. Please provide a copy of both radiation dose reconstruction reports, and identify the paragraphs that repeated this error.

Copies of the two Draft Dose Reconstruction Reports received from NIOSH are attached.

The paragraphs from the two distinct NIOSH Draft Dose Reconstruction reports are denoted by date and paragraph reference.

July 29, 2005 Draft Dose Reconstruction, Page 4 of 9, first two paragraphs:

> "The Office of Compensation Analysis and Support has performed a dose reconstruction for James Z. Gore in accordance with the applicable requirements of the Energy Employees Occupational Illness Compensation Program Act. The records provided by the Department of Labor (DOL) indicate that Mr. Gore worked at the Y-12 Plant from August 19, 1968, through October 31,1994, and that he was diagnosed with ocular melanoma in 1997.
>
> The majority of Mr. Gore's radiation exposure was received during employment as a weapons production supervisor according to information provided in the interview process. *Mr. Gore's dose reconstructed under the Energy Employees Occupational Illness Compensation Program Act of 2000 was* ***18.843 rem to the eye***. The dose was calculated only for this organ because of the specific type of cancer associated with this claim."

October 26, 2006 Draft Dose Reconstruction, Page 7 of 16, first two paragraphs:

> The Office of Compensation Analysis and Support has performed a dose reconstruction for James Zehner Gore in accordance with the applicable requirements of the Energy Employees Occupational Illness Compensation Program Act. The records provided by the Department of Labor (DOL) indicate that Mr. Gore worked at the Y-12 Plant from August 19,1968, through October 31,1994, and that he was diagnosed with basal cell carcinoma of the skin on the left cheek in 1992, and ocular melanoma of the right eye in 1997.
>
> The majority of Mr. Gore's radiation exposure was received during employment as an engineer and a weapons production supervisor according to information provided in the interview process. *Mr. Gore's dose reconstructed under the Energy Employees Occupational Illness Compensation Program Act was 8.899 rem to the skin and* ***10.606 rem to the eye.*** The dose was calculated only for these organs because of the specific types of cancer associated with this claim.(4)

On February 8, 2006, we provided (via fax) medical records to Roseanne Dumar in the DOL Washington, DC office regarding James Gore's basal cell carcinoma. This information was received and is indicated in the second Draft Dose Reconstruction (10/26/06).

In **both** of the Dose Reconstructions, James Gore was considered an "unmonitored" employee and was assigned the 50TH percentile complex wide co-worker dose (yet the dose estimated is different), so the second Draft Dose Reconstruction Report is still based upon incorrect information. Why did the dose estimate for the eye ***decrease*** the second time?

October 26, 2006 Draft Dose Reconstruction, Page 4 of 13, last paragraph on page:

> During this dose reconstruction, the primary data sources were the Y-12 Plant Site Profiles.(6-8) In instances in which specific information useful for estimating doses to the eye was lacking, parameters were selected that maximized the dose estimate.
>
> In addition to the above information, *the record of the computer assisted telephone interview was reviewed carefully by the dose reconstructor*. The information provided was considered in the dose estimation process. Additional information on the evaluation of the interview is provided in subsequent sections of this report, as applicable.

There is no indication in this paragraph or any other section in the second Draft Dose Reconstruction Report that we provided any additional information to NIOSH, such as copies of my father's Radiation Exposure Records from DOE, the names of other coworkers, or information as to where my father worked with respect to the second dose reconstruction. The second Draft Dose Reconstruction Report **does** acknowledge the second cancer (basal cell carcinoma). The information regarding the second cancer was provided to DOL in support of the appeal process.

On January 10. 2006, I filed a FOIA request for my father's records from DOE. On May 16, 2006 I received my father's DOE records. Included in those records were his Radiation Exposure Records. On 8/22/06, I had a follow-up conversation with Pat Kraps, a "Claimant Contact" at ORAU who called me after I had sent an e-mail to Larry Elliott. I subsequently sent her an e-mail that included scanned copies of 11 pages of the DOE Radiation Exposure Records, including the title page. This information included three pages of "Y-12 TLD Data" that indicated monitoring from 1968 through 1988.

I received a confirmation from Pat Kraps within about 15 minutes that said:

> "Thanks very much Kathy, I will forward to all the appropriate parties needed. In addition, I will ask this email and attachments to be included in the administrative file. We do appreciate you providing this information, thanks again."

I sent a second e-mail to Pat on that same day that contained the names of five individuals that worked with my father. This information also included some brief information from my uncle, Howard Dyer, who is my father's brother and did work with him at Y-12 until 1981. The e-mail exchanges with Pat Kraps are attached.

There was **no** second telephone interview or review of the first telephone interview (conducted December 4, 2003) from NIOSH or ORAU with either me or my mother (Mildred Gore).

July 29, 2005 Draft Dose Reconstruction, Page 4 of 9, first paragraph under heading "External Dose":

> Dose Estimate
> External Dose
> External dose is received from radiation originating outside the body and is typically measured by dosimetry worn on the body. Radiation dose measured on a film badge or a thermoluminescent dosimeter (TLD) may have been delivered quickly (acute exposure) or slowly over the period of time that the employee was exposed (chronic exposure). *Records received from the Department of Energy were reviewed, and it was indicated that Mr. Gore was not monitored for radiation exposure. Therefore, external doses assessed in this dose reconstruction include doses estimated from complex-wide co-worker doses and occupational medical X-rays*

October 26, 2006 Draft Dose Reconstruction, Page 5 of 13, first paragraph under heading "External Dose":

> Dose Estimate
> External Dose
> External dose is received from radiation originating outside the body and is typically measured by dosimetry worn on the body. Radiation dose measured on a film badge or a thermoluminescent dosimeter (TLD) may have been delivered quickly (acute exposure) or slowly over the period of time that the employee was exposed (chronic exposure). *Records received from the Department of Energy were reviewed, and it was indicated that Mr. Gore was not monitored for radiation exposure. Therefore, external doses assessed in this dose reconstruction include doses estimated from complex-wide coworker doses and occupational medical X-rays.*

In the second Draft Dose Reconstruction (10/26/06), the Social Security number listed for James Z. Gore **is correct**. But, if NOISH did receive records for my father, they must not have received the same ones I received! Since I did in fact receive my father's DOE records on May 16, 2006, I know they existed and I know that there were three pages of TLD data from 1968 through 1988. As noted above, I had sent copies of these Radiation Exposure records to Pat Kraps at ORAU on 8/22/06.

July 29, 2005 Draft Dose Reconstruction, Page 4 of 9, second paragraph under heading "External Dose" and Page 5 of 9, first paragraph:

> As a weapons production supervisor (engineer), Mr. Gore's work location is not known. In this capacity, he would have likely been exposed to photon and electron radiation, even though no monitoring records were found. However, due to the possibility of lost records or monitored occupational dose, external dose was assigned based on the maximum 50th

percentile complex wide co-worker dose for the given years of employment. *External electron radiation was not considered in this dose reconstruction because Mr. Gore did not work directly with radioactive materials, and any external doses would have been attributable primarily to photons.* For the purpose of estimating probability of causation, all photon doses are assumed to be acute.

October 26, 2006 Draft Dose Reconstruction, Page 5 of 13, second paragraph under heading "External Dose":

As an engineer and weapons production supervisor (engineer), Mr. Gore's work location is not known. In this capacity, he would have likely been exposed to photon and electron radiation, even though no monitoring records were found. However, due to the possibility of lost records or unmonitored occupational dose, external dose was assigned based on the maximum 50th percentile complex wide coworker dose for the given years of employment. *External electron radiation was not considered in this dose reconstruction because Mr. Gore did not work directly with radioactive materials, and any external doses would have been attributable primarily to photons.*

For the purpose of estimating probability of causation, all photon doses are assumed to be acute.(3)

This wording is nearly identical in both Draft Dose Reconstructions reports. If his work location is not known, how can NIOSH even make assumptions about what my father was or was not exposed to? Based upon the incorrect assumption that he was unmonitored, the next assumption is that he did not work directly with any radioactive materials. In the second note I sent to Pat Kraps on 8/22/06, I included a brief statement from my uncle, Howard Dyer.

"Here are some of the things I remember (up through 1981, when I went to K-25):

Jim's office was in 9212, just outside a large depleted uranium machine shop (I think it was called the 9212 "A" Shop - there was also another shop adjacent to that one, but I do not remember its name). Across the hall was a tool grinding shop (supervised by Reg Lovell, who currently lives in Norris). Jim was in most all of the shops at Y-12 (enriched and depleted uranium machine shops). He did have a "Q" security clearance - which everybody there had to have. Also, at this time we all worked for the Union Carbide Corp, Nuclear Division.

He was in a group called Machine Liaison, but I do not know which department. Bruce Dyer was (I think) his supervisor and Tom Rowe was also in the group - both were at the funeral."

To understand where my father worked, I went through the DOE records of his annual trips to the Y-12 plant physician, which was quite extensive. I am able to discern, to some degree, his job locations, and even his job titles over the years (see below). I am sure a more thorough examination of the records would yield a more accurate picture of his employment history.

- 10-27-93 Building/RM/MS 9119/2295/8235, department = 2624, div = 24 Mechanical Operations
- 10-22-91 Supervisor's name = R. J. Sharp, job title = production engineer, division name = Fabrication
- 6-6-88 Plant address = 9201-S MS 162, supervisor = N. D. Woodall, job title = production engineer, division = Fabrication
- 11-25-86 Plant address = 9107, supervisor = R. C. Marcum, job title = engineering supervisor, division = Fabrication
- 1-8-85 Plant address = 9212 MS 51, supervisor = F. B. McDonald, job title = supervisor engineering section, division = Fabrication
- 8-7-81 Plant address = 9212, supervisor = L. G. Whitten, job title = supervisor engineering, division = Fabrication
- 5-20-80 Plant address = 9212 MS 1, supervisor = L. G. Whitten, job title = supervisor engineering section, division = Fabrication
- 7-19-78 Plant address = 9212 MS 1, supervisor = K. O. Pearson, job title = production engineer, division = Fabrication
- 11-11-76 Plant address = 9212, RM 54, supervisor = K. O. Pearson, job title = engineer III, division = Fabrication
- 11-22-74 = Plant address = 9212, supervisor = K. O. Pearson, job title = production engineer, division = Fabrication
- His starting position based upon his employment application in 1968 was "engineer."

Apparently, he spent quite a few years in **Building 9212** and worked primarily in the **Fabrication** division. From information readily available on the Internet:

> "Historically, Building 9212 operations included wet chemistry processing and metal casting to produce HEU (Highly Enriched Uranium) metal components for the nuclear weapons program and HEU oxides for other programmatic missions. Most of the facility has been in standby since September 1994 when the Y-12 Plant shut down to correct criticality safety and conduct of operations deficiencies identified by the Board's staff."

From "STATUS OF HIGHLY ENRICHED URANIUM PROCESSING CAPABILITY AT BUILDING 9212 OAK RIDGE Y-12 PLANT," December 8, 1995.

<u>July 29, 2005 Draft Dose Reconstruction, Page 5 of 9, first paragraph under heading "Co-worker Dose":</u>

Co-worker Dose

Since no monitoring records were available for Mr. Gore, the maximum 50th percentile dose for each given year of employment from Oak Ridge National Laboratory, Oak Ridge Gaseous Diffusion Plant, Hanford Site, Paducah Gaseous Diffusion Plant, Savannah River Site, and Portsmouth Gaseous Diffusion Plant was assigned as an unmonitored dose for Mr. Gore. The values assigned were assumed to be 100% 30-250 keV photons and had an organ dose correction factor of 1.236 applied. Because these were not recorded results, no uncertainty factor was applied. The total co-worker dose assigned was 10.879 rem to the eye. These unmonitored doses exceed the Y-12 co-worker doses and provide a maximizing approach for this dose reconstruction. The published co-worker data have been modified slightly to account for recent NIOSH guidance regarding the treatment of missed dose in co-worker dose evaluations.

October 26, 2006 Draft Dose Reconstruction, Page 5 of 13, first paragraph under heading "Coworker Dose":

Coworker Dose

Since no monitoring records were available for Mr. Gore, the maximum 50th percentile dose for each given year of employment from Hanford Site, Oak Ridge National Laboratory, Oak Ridge Gaseous Diffusion Plant, Paducah Gaseous Diffusion Plant, Portsmouth Gaseous Diffusion Plant, and Savannah River Site was assigned as an unmonitored dose for Mr. Gore in accordance with guidance provided in the Technical Information Bulletin: Use of Coworker Dosimetry Data for External Dose Assignment.(10) The values assigned were assumed to be 100%30-250 keV photons and had an organ dose conversion factor of 1.00 applied for the skin and 1.236 applied for the eye.(3) Because these were not recorded results, no uncertainty factor was applied. The total coworker dose assigned was 8.232 rem to the skin and 10.268 rem to the eye. These unmonitored doses exceed the Y-12 coworker doses and provide a maximizing approach for this dose reconstruction. The published coworker data have been modified slightly to account for NIOSH guidance regarding the treatment of missed dose in coworker dose evaluations.

Again, these sections are nearly identical. Both indicate the assignment of the 50th percentile complex wide co-worker dose as the basis for the dose reconstruction. Thus, the dose reconstruction for the eye in the second Draft Dose Reconstruction Report is based upon the assumption that James Gore was an unmonitored employee, which is incorrect.

July 29, 2005 Draft Dose Reconstruction, Page 5 of 9, first paragraph under heading "Occupational Medical Dose":

Occupational Medical Dose

Although the telephone interview indicated uncertainty about required X-ray procedures, in addition to the estimated dose received from site operations, the dose received from diagnostic X-ray procedures that were probably required as a condition of employment was also included in the overall dose to the eye. Based on information in the Technical Basis Document for the Y-12 National Security Complex - Occupational Medical Dose(6) and an assumed annual X-ray procedure each year of employment, a total X-ray dose of 0.1 15 rem was assigned. This X-ray dose is considered claimant favorable as it likely exceeds the true

X-ray dose to the eye.

October 26, 2006 Draft Dose Reconstruction, Page 6 of 13, first paragraph under heading "Occupational Medical Dose":

Occupational Medical Dose

Although the telephone interview indicated uncertainty about required X-ray procedures, in addition to the estimated dose received from site operations, the dose received from diagnostic X-ray procedures that were probably required as a condition of employment was also included in the overall dose to the eye. Based on information in the Technical Basis Document for Y-12 National Security Complex - Occupational Medical Dose(6) and an assumed annual X-ray each year of employment, until the date of cancer diagnosis for the skin cancer, total X-ray doses of 0.478 rem to the skin and 0.088 rem to the eye were assigned. These X-ray doses are considered claimant favorable as they likely exceed the true X-ray dose to the skin and eye based on the assumed frequency of procedures. The X-ray doses were assigned as a normal distribution with 30% uncertainty.

I actually received a package of 12 x-ray films from DOE as part of my father's records. A second telephone interview or follow-up was not conducted for the second dose reconstruction, and I was not asked for information other than the Radiation Exposure Records. Specifically, I was not asked about medical x-rays with respect to the second dose reconstruction.

July 29, 2005 Draft Dose Reconstruction, Page 6 of 9, first paragraph:

Employment records for Mr. Gore were reviewed, and no records of bioassay monitoring results were found. This is consistent with Mr. Gore's job description given the absence of any external dosimetry results. Internal monitoring programs are applied to individuals who are likely to be exposed to radiation from internally-deposited radioactive material. Personnel who are not selected for internal dose monitoring programs are less likely to be exposed. However, to account for any incidental dose that may have been received but not documented, internal dose was assigned based on a hypothetical intake assuming an intake of 12 radionuclides. This results in an intake that greatly exceeds any possible actual intake by Mr. Gore because this level of activity would be expected to be detectable by workplace indicators and is inconsistent with his work description. Additionally, these nuclides would not all be found in a single location on site.

October 26, 2006 Draft Dose Reconstruction, Page 6 of 13, second paragraph under heading "Internal Dose":

Employment records for Mr. Gore were reviewed and no records of bioassay monitoring results were found. This is consistent with his job description, given the absence of any external dosimetry results. Internal monitoring programs are applied to individuals who are likely to be exposed to radiation from internally-deposited radioactive material. Personnel who are not selected for internal dose monitoring programs are less likely to be exposed. However, to account for any incidental dose that may have been received but not

> documented, internal dose was assigned based on the maximum coworker internal data for the Y-12 Site.(5, 11)
>
> A computer code, the Integrated Modules for Bioassay Analysis (IMBA), was used to estimate the annual organ doses based on the coworker intakes. The IMBA Expert OCAS-Edition was used for this dose reconstruction. The ICRP 66 lung model with default aerosol characteristics was assumed, in conjunction with ICRP 68 metabolic models. It should be emphasized that intake dates, scenarios, and intake levels were based upon mathematical models and do not necessarily prove that such intakes occurred on the given dates. These dates and scenarios provide an acceptable explanation of exposure and dose based upon the bioassay data provided. This approach is in accordance with the provisions of the Radiation Dose Reconstruction Rule (42 CFR $ 82)' and guidance in the Internal Dose Reconstruction Implementation Guideline.

Aside from the fact that I really do not understand what this is telling me, the DOE records for my father indicate "no data found" for bioassay monitoring. But, my mother did provide some information to NIOSH regarding bioassay monitoring. There is no indication in either Draft Dose Reconstruction Report that she provided any information regarding biological radiation-monitoring programs that James Gore may have participated in during his years of employment. While she did initially answer "no" to this question during the initial telephone interview, she subsequently called NIOSH to inform them that James. Gore was subjected to at least one a 24-hour urinalysis test sometime in the mid to late 1970's that she could recall. Since a 24-hour urinalysis is something that would have had a portion of it conducted at home, she did observe this event.

If there are no bioassay monitoring records for James Gore, we have no way of "proving" that he did in fact participate in at least one 24-hour urinalysis test. Absence of data is not necessarily evidence of absence.

<u>July 29, 2005 Draft Dose Reconstruction, Page 6 of 9, second paragraph:</u>

> *The total internal dose assigned was 7.849 rem.* The assigned internal doses are based on the information provided in the Technical Information Bulletin: Maximum Internal Dose Estimates for Certain DOE Complex Claims(5) and the application of assumptions that maximize the dose estimate to the eye.

<u>October 26, 2006 Draft Dose Reconstruction, Page 6 of 13, last paragraph under heading "Internal Dose" and Page 7 of 13, first paragraph:</u>

> Both solubility classes Type M and Type S uranium-234 were evaluated, and Type S provided the higher dose and was used for the dose estimate. Associated recycled uranium components including neptunium-237, plutonium-239, technetium-99, and thorium-228 were applied based on Table 5-8." The coworker intakes from the Technical Information Bulletin: Internal Dosimetry Coworker Data for Y-12 are only calculated through 1988; however, as a claimant favorable assumption, the 1988 intakes from Table 5-1-were applied from 1989 through the cancer diagnosis date for each of the cancers evaluated.' The internal dose

calculated for technetium-99 was less then 0.001 rem and was not used for the dose estimate. The total internal dose assigned was *0.189 rem to the skin and 0.250 rem to the eye.*

If both of the Draft Dose Reconstruction reports utilize the same process or algorithm for estimating internal dose as part of the dose reconstruction, and both Draft Dose Reconstruction Reports are based upon the same assumption that James Gore was an unmonitored employee and applied the 50th percentile complex wide co-worker dose, how are the discrepancies in the internal dose calculation to the explained?

July 29, 2005 Draft Dose Reconstruction, Page 7 of 9, first paragraph under heading "Summary":

Summary

James Z. Gore was exposed to various sources of radiation during his employment at the Y-12 Plant. The estimated dose to Mr. Gore was *18.843 rem.*

The reported dose is a significant *overestimate* of Mr. Gore's occupational radiation dose which will support claim determination.

October 26, 2006 Draft Dose Reconstruction, Page 7 of 13, first paragraph under heading "Summary":

Summary

James Zehner Gore was exposed to various sources of radiation during his employment at the Y-12 Plant. The estimated dose to Mr. Gore was *8.899 rem to the skin and 10.606 rem to the eye.* The reported dose is a significant overestimate of Mr. Gore's occupational radiation dose which will support claim determination.

I find the comparison of the first Draft Dose Reconstruction (7/29/05) and the second Draft Dose Reconstruction (10/26/06) to be very interesting. If James Gore was assessed same way in both dose reconstructions – as an unmonitored employee assigned the 50th percentile complex wide co-worker dose – how does he end up with a **different** "dose" to the eye? Obviously, the internal dose calculation represents the majority of the difference.

			EYE
7/29/2005	**Page 4 of 9**	**OVERALL**	**18.843**
[redacted]	[redacted]	[redacted]	[redacted]
7/29/200	Page 5 of 9	Occupational Medical Dose	0.11
7/29/200	Page 6 of 9	Internal Dose	7.84
		TOTAL	**18.843**

			EYE	SKIN
10/26/2006	**Page 4 of 13**	**OVERALL**	**10.606**	**8.899**
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
10/26/200	Page 6 of 13	Occupational Medical Dose	0.08	0.47
10/26/200	Page 7 of 13	Internal Dose	0.2	0.18

TOTAL 10.606 8.899

2) You testified that after you spoke at an Advisory Board meeting, NIOSH and ORAU officials offered to assist you. Who provided that assistance and was it effective?

Immediately after I spoke at the Advisory Board public session held in Oak Ridge, TN on January 23, 2006, I met Mr. Peter Turcic from DOL and Mr. Larry Elliott from NIOSH. As I indicated in my testimony on 11/15/06 to the House Subcommittee on Immigration, Border Security and Claims, they were most sincere in their apologies with respect to how this could have happened. I also met Ms. Kate Kimpan from ORAU. Both Mr. Elliott and Ms. Kimpan gave me their *personal assurances* that these problems would be addressed and corrected. And as I indicated in my previous testimony, this level of attention certainly exceeded our expectations.

On January 30, 2006, my mother and I received a letter from Larry Elliott referencing the issues with our claims. My mother received the paper copy in the mail, and I received an electronic copy from Mr. Elliott via e-mail. In the letter, it stated:

> "I was very disappointed to learn that the close-out interview on the dose reconstruction for your claim was mishandled. I apologize for the inconvenience and confusion that was caused by contacting you for a close-out interview before you had even received the draft dose reconstruction report. Furthermore, I was dismayed when Kathy told me that another person's dose reconstruction report had been mistakenly sent to you. I also understood that the Department of Labor (DOL) provided you with a "recommended decision" which further extended the procedural errors in processing your claim by indicating your husband's cancer to be colon cancer when in fact it was ocular melanoma. My sincere apology is not sufficient enough, I am sure, to make up for the frustration and disappointment these administrative mistakes have caused.

I promised Kathy that I would personally review your claim file and accordingly provide any advice as appropriate. In reviewing your claim, I note that we made two requests (May 29, 2003 and November 28, 2004) to the Department of Energy (DOE), Oak Ridge Operations Office for any radiation monitoring information relevant to your husband's work at the Y-12 facility. DOE reported back to us (June 19, 2003 and January 3, 2005) that no monitoring information was found for your husband. Evidently, your husband's monitoring records have been lost or destroyed. The Energy Employees Occupational Illness Compensation Program Act (EEOICPA) recognizes that radiation monitoring records may have been lost, destroyed, or inadequate for documenting the radiation dose received by workers at DOE facilities."

Kate Kimpan and Pete Turcic were .cc'd on this correspondence. At the time, I felt that we had the attention of people who could ensure that the problems associated with our claim would be addressed.

Unfortunately, with the exception of two phone calls to my mother from Roseanne Dumar in the Washington, DC DOL office in early February and Richard McCarthy from NIOSH on Larry

Elliott's behalf on 4/27/06, no one else from DOL, NOISH, or ORAU personally contacted us. Ms. Dumar contacted my mother to request the medical records for my father's basal cell carcinoma, which we provided. Mr. McCarthy called my mother to indicate that there were no records of my father visiting Los Alamos National Laboratory (LANL). As part of our appeal to the first DOL Recommended Decision (1/10/06), we had indicated that my father did travel as part of his job. We specifically mentioned LANL. In fact, my father also traveled to the Nevada Test Site and Rocky Flats facilities. He did not travel frequently, but I do recall him taking these trips in the 1970's and possibly into the early 1980's.

We did receive two letters from the DOL office in Jacksonville. One was dated 5/5/06 asking if we had any additional medical records and stating that there were no records of visits to LANL. The second letter from DOL was dated June 8, 2006 and indicated that the claim must be returned to NIOSH. I found it interesting that DOL's "reason" for returning the claim to NIOSH was the additional information regarding the basal cell carcinoma cancer, not the comedy of errors that produced the first Draft Dose Reconstruction Report.

Larry Elliott also addressed the LANL issue in his letter to my mother dated 1/30/06:

"In completing the dose reconstruction process, you indicated in an attachment to the OCAS-1 form that your husband visited the Los Alamos National Laboratory (LANL) several times. I do not see that we requested radiation monitoring information from LANL, nor do I see any mention of those visits in the dose reconstruction report. The only advice that I can offer regarding the DOL recommended decision would be to point out that the visits your husband made to LANL should be accounted for in the dose reconstruction report. While I can not guarantee that any exposure your husband may have received at LANL will substantially change the recommended decision from DOL, this exposure should be addressed in the dose reconstruction. If you raise this with DOL, they may return your claim to NIOSH for rework of the dose reconstruction. I assure you we will request any monitoring information that LANL may have for your husband and account for any potential dose in a revised dose reconstruction that he may have acquired at that site."

There was no reference in the second Draft Dose Reconstruction Report (10/26/06) of accounting for any possible exposures from visits to LANL. Again, my mother and I cannot inform DOL or NIOSH of exactly when these trips occurred because we have nothing in the way of documentation. Even if we did, we have no idea what my father did in his work or what he did when he went on trips to these facilities. My father ***never*** talked about his job.

Aside from these communications, all communication with DOL or NIOSH was initiated by me by phone or by email. If required, I can submit a log of these correspondences (date, time, content) to the subcommittee. In particular, on 8/14/06, I sent an e-mail to Larry Elliott asking if the NIOSH had received the claim. I asked:

> "(1) Has DOL sent the claim back to NIOSH? To date, we have not received any notification - either letter or phone call - from any NIOSH representative that this claim has been returned for review.

(2) If you do have the claim, did DOL send you the pathology report for the BCC?

I am somewhat concerned that the DOL letter made no mention of the fact that (1) DOE records for my father do in fact exist - I have them from DOE via a FOIA request, and that (2) he was a monitored employee (there are some TLD results in the DOE records). The original dose reconstruction asserted there were no DOE records for James Z. Gore and the DR was based his assignment to the 50th percentile complex wide co-worker dose as an "unmonitored employee."This error results from the initial NIOSH request to DOE for his records under the wrong SSN. My father's job titles and department information is also available in the DOE records, which should assist in understanding where in the facility he worked and what he may have been exposed to.None of this information was available to support the original NIOSH DR.

If you have the claim, can you please let me know what the process will be for the review?Do we need to provide any additional information? I was able to obtain the names of some other Y-12 employees who worked with my father (who are still living), but I have made no attempt to solicit additional information from them pending a requirement for me to do so personally.

If there is someone at NIOSH who I should contact regarding the status, please let me know."

Mr. Elliott responded:

"Dear Ms. Bates:

Yes, DOL has returned the claim to NIOSH for revision of the dose reconstruction in light of the skin cancer diagnosis. DOL has provided us with the medical confirmation of BCC. I have asked staff to follow-up on the current status of the dose reconstruction and to contact you with that status. Also, the dose reconstructor will need to determine if co-worker interviews are necessary, if so they will call you for the contact information of the Y-12 former employees who worked with you father so that they may be interviewed. If you have not already provided copy of the DOE dose records, it may be helpful to provide a copy for the claim file here at NIOSH - we want to be sure that we have all data and it is appropriately used in the dose reconstruction.

You will be hearing from a Public Health Advisor soon about the status of the revised dose reconstruction."

On 8/22/06, Pat Kraps, a Claimant Contact from ORAU called me to and asked if I could send her the radiation exposure records as they had "not yet received Mr. Gore's records from DOE." As noted above, I sent Ms. Kraps copies of the Radiation Exposure Records via e-mail.

After this correspondence with Ms. Kraps, there was no correspondence until we received the second Draft Dose Reconstruction Report on 11/02/06 in the mail.

So to answer the question "How effective was their assistance?" I would submit that it obviously was not very effective seeing as the second Draft Dose Reconstruction report was based upon the same incorrect assumptions that my father was an unmonitored employee and was assigned the 50th percentile complex wide co-worker dose as the basis of his dose reconstruction.

3) Dose reconstructions are signed off by three people. One of these is a peer reviewer. Why do you think the process failed twice?

In my own opinion, I cannot believe there is a formal, rigorous process for quality control specifically as it relates to the administrative process which should include data integrity and the review and approval process. In our case, while I would not assume that Mr. Elliott or Ms. Kimpan would actually personally administer the second dose reconstruction process for an individual claim, I would have expected that there would have been some kind of "flag" in the claim file to indicate that there were problems with the first Draft Dose Reconstruction Report. Given that we had Mr. Elliott's personal assurance that he would personally review the claim, I would have expected that he – or his subordinates – would have known about the problem with the first dose reconstruction and that there would have been some scrutiny of the second dose reconstruction to ensure that the original problems were resolved. Both NIOSH and ORAU knew my father had radiation exposure records – because as I previously indicated, I told Larry Elliott I had received his records from DOE, and I sent the records to Pat Kraps at ORAU. She acknowledged the receipt and indicated that she would place them in the administrative record. Clearly, if Pat Kraps actually put this information into the claim file or administrative record as she said she would, then the individuals who perfumed the second dose reconstruction and performed the peer review were either not aware of it or ignored it. Clearly, there is some kind of disconnect. If a peer reviewer looked at the administrative record to verify that information is correct for the dose reconstruction, and the Radiation Exposure Records were in the administrative file, how could a dose reconstruction based upon the dose for unmonitored employee have been approved during the peer review?

I would have expected that the specific error, the fact that NIOSH requested DOE records under the wrong Social Security Number (SSN), would have been highlighted and would not have been repeated. When I received the second Draft Dose Reconstruction Report on 11/02/06, I sent Larry Elliott a rather long e-mail indicating my frustration with the report in that it was almost a carbon copy of the first based upon the assumption that my father was an unmonitored employee, which he was not. Mr. Elliott called me on the morning of 11/03/06 and again, personally apologized. He indicated that the request for DOE records for my father had been resubmitted with the wrong SSN – again. I asked him how that could have happened, given all the (negative) visibility that this particular claim had generated. He stated: "I do not know how this could have happened."

I do not know how dose reconstruction process works with respect to data integrity checks and approvals. Given my case, if there *are* data quality checks, then either the wrong things are being checked and/or the *quality* of the quality control process is poor.

I cannot comment on the quality of the actual dose reconstruction, because honestly, I do not understand how the various radiation exposure values are determined or how the dose reconstruction is calculated. However, I am very curious to understand how the first Draft Dose Reconstruction Report yielded a total of 18.843 rem to the eye and the second Draft Dose Reconstruction Report yielded a total of 10.606 rem to the eye if both dose reconstructions were based upon the same assumptions.

4) Did NIOSH follow up on the data sources you gave them, such as living co workers?

Not that I am aware of. In fact, I had a telephone conversation with Larry Elliott on 11/30/06 regarding the status of the now third attempt at the dose reconstruction. This was the first contact I had from NIOSH since my telephone discussion with Mr. Elliott on the morning of 11/03/06. Mr. Elliott informed me that NIOSH had in fact received my father's DOE records and that the third dose reconstruction was underway. I asked him if he had the information I sent Pat Kraps on 8/22/06 indicating five current or retired Y-12 employees and asked if NIOSH was going to contact them for more information. To my surprise, Mr. Elliott stated that employee references are typically not contacted unless there are issues such as missing data. To the extent that there are DOE records for my father, they certainly do not provide any type of day to day description of the work he performed or specifically what areas of the facility he may have worked other than building and department numbers. I indicated to Larry that 42 CFR 82 states that confirming information with coworkers was part of the dose reconstruction process. He said, "I know but it is not usually done."

For the record, 42 CFR 82.10(c)(4) states:

> (c) Information provided by the claimant will be accepted and used for dose reconstruction, providing it is reasonable, supported by substantial evidence, and is not refuted by other evidence. In assessing whether the information provided by the claimant is supported by substantial evidence, NIOSH will consider:
>
> > (1) Consistency of the information with other information in the possession of NIOSH, from radiation safety programs, research, medical screening programs, labor union documents, worksite investigations, dose reconstructions conducted by NIOSH under EEOICPA, or other reports relating to the circumstances at issue;
> >
> > (2) Consistency of the information with medical records provided by the claimant;
> >
> > (3) Consistency of the information with practices or exposures demonstrated by the dose reconstruction record developed for the claimant; and,
> >
> > *(4) Confirmation of information by coworkers or other witnesses.*

5) When you testified at the NIOSH Advisory Board meeting in January 2006, your testimony

was transcribed. Did anyone from NIOSH or ORAU call you up after the transcript was completed to review the issues raised in your testimony?

As previously indicated, we were contacted by Roseanne Dumar from the DOL Washington, DC office requesting the medical records related to my father's basal cell carcinoma. We received the letter from Larry Elliott on January 30, 2006 expressing his regrets with respect to how our claim was handled.

As I indicated in my written statement from the 11/15/06 testimony to the subcommittee, I sent an e-mail to Larry Elliott on 02/01/06 indicating that there was a problem with the SSN.

> "Larry, I just received a copy of the death certificate for my father as it was required to obtain some additional information. The SSN on it is 422-**38**-0100. When I commented that the SSN on the DOL letters was incorrect, that is because I was basing that assumption on the SSN recorded on the NIOSH initial telephone interview and draft dose reconstruction report, which was 422-**88**-0100. I personally do not have any materials with my father's SSN on it other than the death certificate I just received. I immediately called my mother to verify - from tax returns - my father's correct SSN number.
>
> It is: James Zehner Gore, SSN **422-38-0100**.
>
> The incorrect SSN may be the root cause of the problem that there were apparently "no records" - at all - for my father. No job history, no idea of where he worked, no monitoring, etc. If a DOE records search was performed for 422-**88**-0100, it would not have returned any records for James Z. Gore. It may also explain why another individual's dose reconstruction report was sent to my mother. It does not explain the overall issues with the process, but at least this may resolve the "missing records" issue.
>
> In your letter to my mother, you indicated that you had made two requests to DOE on 5/29/03 and 11/28/04 for my father's records. I would request that you check the SSN on those requests as it is my understanding that these records are tied to an individual by their SSN."

Mr. Elliott's response was:

> Dear Kathy:
>
> Thank you for this follow-up information. We will correct the SSN record here in your mother's claim file and pursue whether or not the wrong SSN led to no recovery of monitoring data from DOE. Someone from my staff will get back to you on that once a determination has been made. The correct SSN will be useful for requesting data from LANL for sure.
>
> ljc.

Specifically, the questions I asked at the Advisory Board meeting were as follows:

> "Exactly what information **did** NIOSH base my father's dose reconstruction on other than my mother's information that he was a "weapon's production supervisor?"
>
> "If, as NIOSH asserts, there were no DOE records of monitoring and apparently there was no information relating to his job history or where he worked, how could any type of assumptions be made? It is conceivable that my father's records may be missing or lost. If this is in fact the case, how could NIOSH develop a reasonable dose reconstruction?"
>
> "The ***"probability of causation for "the primary colon cancer"*** in the Recommended Decision is the proverbial icing on the cake. I am absolutely appalled that this type of error occurred. What are the procedures for quality control and quality assurance that govern this process? Is what we have experienced in our claim process an isolated event…or a systemic problem? Who is responsible for ensuring that, within reason, 42 CFR 82 is followed to the extent possible?"

To the extent that I ascertained that the SSN was wrong, and Larry Elliott subsequently confirmed that the wrong SSN had been used to request DOE records, I have not had any direct conversation with anyone from NIOSH or ORAU with respect to these particular questions.

Aside from this, no one addressed any major issues outlined in our appeal, which included:

> However, when it comes to Mr. Gore's job position, NIOSH did accept my (Mrs. Gore's) statement in the initial telephone interview that Mr. Gore was a "weapons production supervisor." This is not consistent. Why would my statement regarding his job position be more "reasonable" than my (Mrs. Gore's) statement that he routinely wore a dosimetry badge?
>
> NIOSH also asserts in the Draft Dose Reconstruction Report, page 4, seventh paragraph: "***External electron radiation was not considered in this dose reconstruction because Mr. Gore did not work directly with radioactive materials…"*** This is an astonishing statement. Is this a factual statement? If NIOSH does not have an accurate record of Mr. Gore's employment history including job positions by year, and NIOSH does not know where Mr. Gore worked in the Y-12 facility, how can NIOSH assert that Mr. Gore did not work directly with radioactive material?
>
> What exactly **did** NIOSH receive from DOE regarding Mr. Gore's employment history other than his date of hire and his date of termination?
>
> "If the ERR per Sv coefficients for cancer of the eye (ICD-9 190) are based upon analysis of bone cancer and male breast cancer, which are listed as types of cancer that, pursuant to 20 CFR part 30, may qualify a member of the Special Exposure Cohort, should eye cancer be included in this listing?

To date, none of these questions have been directly addressed by either NIOSH or ORAU

6) Do you think that NIOSH should make sure that social security numbers are correct in their peer review check list? If so, do you think NIOSH should go back and check to see if other claims were denied because the social security number was provided in error?

Yes and yes. I would expect that this would be a very important part of the quality assurance process in that the employee's SSN appears to be the key to all of that employee's data.During my phone conversation with Larry Elliott on 11/30/06, he did say, and I am paraphrasing here, "we have done an internal review of the process and we have not found any other claims that resembled your father's in terms of the errors that occurred." Quite frankly, given the ***number*** of errors that occurred with the first dose reconstruction for our claim – not just the SSN problem - I just find it hard to believe that it was an isolated incident. The fact that the same error with the SSN and the DOE records request occurred the second time is just outrageous. The only way I would be convinced that our claim was simply a single gross anomaly would be if an independent auditor assessed a statistically acceptable sample of the claims that have been processed. I can't imagine how much that would cost or how long that would take, but I personally think that is the only way the quality of the process can be verified.

7) To increase accountability, should NIOSH reimburse ORAU's costs for making the same mistake twice?

I have no insight into how costs are incurred or allocated within the EEOICPA program. To the extent that ORAU is NIOSH's subcontractor for dose reconstruction, and ORAU is dependent upon NIOSH for accurate data, then I think it would be reasonable for NIOSH to bear the costs of ORAU having to perform a second (or third, as in our case) dose reconstruction if in fact NIOSH provided bad data.

If our case is an isolated incident (dose reconstruction redo), then maybe it is a non-issue. If ORAU is performing multiple dose reconstructions per claim because of faulty data from NIOSH, then that is inflating the subcontractor's cost for performing dose reconstructions through no fault of their own.

However, having said that, one would think that ORAU would have its own internal quality control process, independent of NIOSH, to ensure data integrity. Since I do not have visibility into the extent of collaboration that goes on between NIOSH and ORAU regarding the administrative process for each individual dose reconstruction, I can't comment on if they should or should not know if an employee name and associated SSN are in fact correct.

ATTACHMENT

Form OCAS -1
August 2001

OMB No. 0920-0530
Exp. Date 5/31/05

Statement by the Claimant Closing the Record on a NIOSH Dose Reconstruction under the Energy Employees Occupational Illness Compensation Program Act

I, Mildred L. Gore, a claimant under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA), certify that I have completed providing information to the National Institute for Occupational Safety and Health (NIOSH) and its representatives information relating to potential radiation doses incurred by James Z. Gore while under the employment of DOE, a DOE contractor, or an Atomic Weapons Employer. In signing this form, I also certify that I have read, understand, and agree with the following statements:

a) I am not aware of any additional information available to me that may be relevant to NIOSH in completing a dose reconstruction to estimate the radiation doses incurred by the employee as specified above; and,

b) I have reviewed the draft NIOSH dose reconstruction report and agree that it identifies all of the relevant information I provided to NIOSH to complete the dose reconstruction; and,

c) NIOSH should forward a final dose reconstruction report to the Department of Labor (DOL), so that DOL can continue adjudication of my claim and produce a recommended decision to accept or reject my claim; and,

d) I understand that my opportunity to seek a review of the NIOSH dose reconstruction occurs only if DOL were to produce a recommended decision to deny my claim; and,

e) By signing this form, I do NOT certify or imply that I agree with NIOSH decisions indicated in the draft NIOSH dose reconstruction report concerning how NIOSH has used or not used information I have provided for the dose reconstruction; and,

f) By signing this form, I do NOT certify or imply that I agree with the findings of the NIOSH dose reconstruction.

Notice: Any person who knowingly makes any false statement, misrepresentation, concealment of fact or any other act of fraud to obtain compensation as provided under EEOICPA or who knowingly accepts compensation to which that person is not entitled is subject to civil or administrative remedies as well as felony criminal prosecution and may, under appropriate criminal provisions, be punished by a fine or imprisonment or both. I affirm that the information provided on this form is accurate and true.

Signature_____ Date _____
Mildred L. Gore

NIOSH ID: 12438

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NIOSH Tracking Number: 12438

National Institute for Occupational Safety and Health
Robert A. Taft Laboratories
4676 Columbia Parkway
Cincinnati, OH 45226-1998
Phone: 513-533-6800
Fax: 513-533-6817

July 29, 2005

Mrs. Mildred L. Gore
5305 Jonathan Way
Knoxville, TN 37920 USA

Dear Mrs. Mildred Gore:

This letter is to provide you with information on the status of the dose reconstruction for the claim you filed under the Energy Employees Occupational Illness Compensation Program Act (NIOSH Tracking Number 12438).

The National Institute for Occupational Safety and Health's (NIOSH) Office of Compensation Analysis and Support (OCAS) has completed a reconstruction of the radiation dose. Enclosed you will find a copy of a Draft NIOSH Report of Dose Reconstruction under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA). During the next two weeks, we will attempt to contact you to schedule a convenient date and time for conducting a closing interview with you. The purpose of the closing interview is to review the dose reconstruction results and the basis on which the results were calculated. This will be the final opportunity during the dose reconstruction process for you to provide additional relevant information that may affect the dose reconstruction or indicate that you are in the process of obtaining such information. To facilitate the scheduling of the interview, you can contact us at the following telephone number 1-800-790-6728 (1-800-790-ORAU). If, after three weeks from the date of this letter, we have not heard back from you regarding a convenient time to schedule the interview, then we will assume that you have decided not to participate in the interview.

We have also enclosed a copy of a form (OCAS-1) that should be signed and returned to us within 60 days. In the event that NIOSH prepares a revised draft dose reconstruction report based upon any additional information provided by you, then the OCAS-1 form will be due no later than 60 days from the date you receive the revised draft dose reconstruction report. Your signature on this form certifies that you agree with the following statements: 1) you are not aware of any additional information that may be relevant to the dose reconstruction; 2) you have reviewed the draft dose reconstruction report and agree that it identifies all of the relevant information you provided to NIOSH regarding the dose reconstruction; and 3) the dose reconstruction report is ready to be forwarded to the Department of Labor (DOL) for a determination regarding your claim. Your signature on this form is not an indication that you agree with the decisions NIOSH made concerning how to use or not use information you provided for dose reconstruction or that you agree with the findings of the NIOSH dose reconstruction. DOL's Office of Workers' Compensation Programs (OWCP) will notify you of any action that it may take regarding your claim, and of any rights you may have to raise objections. You will have an opportunity to raise objections to the final NIOSH Dose Reconstruction Report under EEOICPA following your receipt of a copy of the recommended decision on your claim from DOL by following the procedures described in the notice accompanying the recommended decision.

Once we receive the signed OCAS-1 form from you, we will send the final copy of the dose reconstruction report to the DOL for adjudication of your claim. We will also send you and the Department of Energy a copy of the final dose reconstruction report. It is important that you return the properly signed OCAS-1 to us within the above-described time frame so that there is no delay in the adjudication of your claim. We will not forward the dose reconstruction report to DOL for adjudication without receipt of a properly signed OCAS-1. If we do not receive the OCAS-1 within the timeframe described above, we may administratively close the dose reconstruction and notify DOL of this action. PLEASE USE THE ENCLOSED PRE-ADDRESSED, POSTAGE-PAID ENVELOPE TO RETURN THE SIGNED OCAS-1 TO US.

If you have any additional questions regarding this dose reconstruction report, please contact our dose reconstruction contractor, Oak Ridge Associated Universities, toll-free at 1-800-322-0111.

Sincerely yours,

Larry J. Elliott, MSPH, CIH
Director
Office of Compensation Analysis and Support

Enclosures

cc: File 12438

NIOSH *OCAS*

NIOSH Report of Dose Reconstruction under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA)

NIOSH ID:	Social Security No.	DOL District Office
012438	422-88-0100	Jacksonville

Energy Employee Name:	Gore *Last*	James *First*	Z. *Middle*	10/14/34 *Date of Birth*

Covered Employment:	08/19/68 – 10/31/94 *Dates*	Y-12 Plant Oak Ridge, TN *Location*

Cancer:	Ocular melanoma, rt eye *Type*	190.9 *ICD Code*	07/31/1997 *Date of Diagnosis*

Calculations Performed By:	William H. Barley *Name*	7/26/2005 *Date*
Peer Review Completed By:	Steven R. Reed *Name*	7/26/2005 *Date*
Dose Reconstruction Approved By:	L.B. Rutherford *Signature* LaVon B. Rutherford, CHP *Name*	7/28/2005 *Date*

Covered Employee	NIOSH ID#	Social Security #
James Z. Gore	12438	422-88-0100

Introduction

The Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA), Executive Order No. 13179 and the Radiation Dose Reconstruction Rule (42 CFR 82)[1]

EEOICPA established a compensation program to provide a lump sum payment of $150,000 and medical benefits as compensation to covered employees suffering from designated illnesses incurred as a result of their exposure to ionizing radiation, beryllium, or silica while in the performance of duty for the Department of Energy and certain of its vendors, contractors, and subcontractors. This legislation also provided for payment of compensation to certain survivors of these covered employees.

In Presidential Executive Order No. 13179, the President designated the U.S. Department of Labor to administer this program for claims by current and former employees of nuclear weapons production facilities and their survivors who seek compensation for cancers caused by radiation exposures sustained in the performance of duty. The Executive Order also directed the Department of Health and Human Services to estimate (reconstruct) the radiation doses received by these employees. The Department of Labor uses the reconstructed radiation dose in evaluating whether the employee's cancer was at least as likely as not related to employment at the facilities covered by EEOICPA. To fulfill the responsibilities assigned to the Department of Health and Human Services, the National Institute for Occupational Safety and Health's (NIOSH) Office of Compensation Analysis and Support (OCAS) completes dose reconstructions using the methods described in the Radiation Dose Reconstruction Rule (42 CFR 82)[1] for the Department of Labor's use in making compensation decisions.

The Purpose of Radiation Dose Reconstruction
A radiation dose reconstruction is used to estimate the radiation dose received by the specific organ(s) in which a worker developed cancer, particularly when radiation monitoring data are unavailable, incomplete, or of poor quality. Even in instances when radiation dosimetry data are available, they rarely specify dose to an organ and often are based on monitoring procedures that do not meet modern standards.

The basic principle of dose reconstruction is to characterize the occupational radiation environment to which a worker was exposed using available worker and/or workplace monitoring information. In cases where radiation exposures in the workplace environment cannot be fully characterized based on available data, default values based on reasonable scientific assumptions are used as substitutes.

EEOICPA recognized that the process of estimating radiation doses would require dealing with uncertainties and limited data and thus required that the government establish methods for arriving at reasonable estimates of radiation dose received by an individual who was not monitored or inadequately monitored for exposures to radiation, or for whom exposure records are missing or incomplete. To the extent that the science and data involve uncertainties, these uncertainties are typically handled to the advantage, rather than to the detriment, of the claimant. NIOSH has used the best available science to develop the methods and guidelines for dose

reconstruction. These methods have been reviewed and commented upon by the public, including experts in the field of dose reconstruction, and the Presidentially-appointed Advisory Board on Radiation and Worker Health.

How Radiation Doses Are Reconstructed
NIOSH reconstructs radiation doses by evaluating all available, appropriate data relevant to the employee's radiation exposure. Some examples of data that may be included in the dose reconstruction include, but are not limited to, internal dosimetry (such as results from urinalysis), external dosimetry data (such as film badge readings), workplace monitoring data (such as air sample results), workplace characterization data (such as type and amount of radioactive material processed), and descriptions of the type of work performed at the work location.

Although the specific methods used for each dose reconstruction may vary, after a claim has been referred by the Department of Labor to NIOSH for a dose reconstruction, NIOSH typically requests the worker's personal radiation monitoring information from the Department of Energy. Upon receipt of the requested information, at least one voluntary informational interview with the claimant and/or survivors is conducted and a copy of the interview report is sent for review. After all of the necessary and available information is gathered, a dose is estimated, using the methods in the Radiation Dose Reconstruction Rule. After a NIOSH health physicist reviews the information, methods, and results, the claimant receives a draft copy of the dose reconstruction report followed by a concluding interview, during which the claimant can add any additional relevant information that may affect the dose reconstruction. If the claimant certifies that he/she has completed providing information and that the record for dose reconstruction should be closed, a final dose reconstruction report is sent to the claimant, the Department of Labor, and the Department of Energy.

As applied in the EEOICPA, dose reconstructions must rely on information that can be developed on a timely basis and on carefully stated assumptions. Therefore, the guiding principle in conducting these dose reconstructions is to ensure that the assumptions used are fair, consistent, and well-grounded in the best available science, while ensuring that uncertainties in the science and data are handled to the advantage, rather than to the detriment, of the claim when feasible. When dose information is not available, is very limited, or the dose of record is very low, NIOSH may use the highest reasonably possible radiation dose, based on reliable science, documented experience, and relevant data, to complete a claimant's dose reconstruction. In other instances, NIOSH may not need to complete fully a dose reconstruction because a partial dose reconstruction results in an estimated dose which produces a probability of causation of 50% or greater.

How Radiation Dose Reconstructions Are Used in Final Compensation Determinations
The results of an employee's dose reconstruction are used by the Department of Labor to determine the probability that a worker's cancer was "at least as likely as not" due to his/her occupational exposure to ionizing radiation during employment at a covered facility. Criteria and guidelines for making this determination are established by EEOICPA and the Probability of Causation Guidelines (42 CFR 81).[2] The dose reconstruction is not the final determination of a claim, but rather an interim product that is used by the Department of Labor in making its final decision. Final determinations are made by the Department of Labor based on standards determined by EEOICPA and its implementing regulations.

Covered Employee	NIOSH ID#	Social Security #
James Z. Gore	12438	422-88-0100

Dose Reconstruction Overview

The Office of Compensation Analysis and Support has performed a dose reconstruction for James Z. Gore in accordance with the applicable requirements of the Energy Employees Occupational Illness Compensation Program Act. The records provided by the Department of Labor (DOL) indicate that Mr. Gore worked at the Y-12 Plant from August 19, 1968, through October 31, 1994, and that he was diagnosed with ocular melanoma in 1997.

The majority of Mr. Gore's radiation exposure was received during employment as a weapons production supervisor according to information provided in the interview process. Mr. Gore's dose reconstructed under the Energy Employees Occupational Illness Compensation Program Act of 2000 was 18.843 rem to the eye. The dose was calculated only for this organ because of the specific type of cancer associated with this claim.

For the purposes of this dose reconstruction Mr. Gore's radiation dose was overestimated using maximizing assumptions related to radiation exposure and intake, based on current science, documented experience, and relevant data. Even under these assumptions, NIOSH has determined that further research and analysis will not produce a level of radiation dose resulting in a probability of causation of 50% or greater. In accordance with 42 CFR § 82.10(k),[1] NIOSH has determined that sufficient research and analysis have been conducted to consider this dose reconstruction complete. Per the requirements of 42 CFR § 82.10(j),[1] only the dose incurred up to the point of cancer diagnosis was included in this dose reconstruction.

Information Used

During this dose reconstruction, the primary data source was the Y-12 Plant Site Profile.[6-8] In instances in which specific information useful for estimating doses to the eye was lacking, parameters were selected that maximized the dose estimate.

In addition to the above information, the record of the computer assisted telephone interview was reviewed carefully by the dose reconstructor. The information provided was considered in the dose estimation process. Additional information on the evaluation of the interview is provided in subsequent sections of this report, as applicable.

Dose Estimate

External Dose

External dose is received from radiation originating outside the body and is typically measured by dosimetry worn on the body. Radiation dose measured on a film badge or a thermoluminescent dosimeter (TLD) may have been delivered quickly (acute exposure) or slowly over the period of time that the employee was exposed (chronic exposure). Records received from the Department of Energy were reviewed, and it was indicated that Mr. Gore was not monitored for radiation exposure. Therefore, external doses assessed in this dose reconstruction include doses estimated from complex-wide co-worker doses and occupational medical X-rays.

As a weapons production supervisor (engineer), Mr. Gore's work location is not known. In this capacity, he would have likely been exposed to photon and electron radiation, even though no

monitoring records were found. However, due to the possibility of lost records or unmonitored occupational dose, external dose was assigned based on the maximum 50th percentile complex wide co-worker dose for the given years of employment. External electron radiation was not considered in this dose reconstruction because Mr. Gore did not work directly with radioactive materials, and any external doses would have been attributable primarily to photons. For the purpose of estimating probability of causation, all photon doses are assumed to be acute.[3]

Radiation Type, Energy, and Exposure Geometry
To maximize the probability of causation, a photon energy range of 100% 30–250 keV was applied. The determination of exposure geometry was not relevant to this dose reconstruction.

Co-worker Dose
Since no monitoring records were available for Mr. Gore, the maximum 50th percentile dose for each given year of employment from Oak Ridge National Laboratory, Oak Ridge Gaseous Diffusion Plant, Hanford Site, Paducah Gaseous Diffusion Plant, Savannah River Site, and Portsmouth Gaseous Diffusion Plant was assigned as an unmonitored dose for Mr. Gore. The values assigned were assumed to be 100% 30–250 keV photons and had an organ dose correction factor of 1.236 applied. Because these were not recorded results, no uncertainty factor was applied. The total co-worker dose assigned was 10.879 rem to the eye. These unmonitored doses exceed the Y-12 co-worker doses and provide a maximizing approach for this dose reconstruction. The published co-worker data have been modified slightly to account for recent NIOSH guidance regarding the treatment of missed dose in co-worker dose evaluations.

On-Site Ambient Dose
Because the unmonitored doses assigned for Mr. Gore were based on actual dosimetry results from the DOE sites mentioned above, no on-site ambient doses were assigned in accordance with the information provided in the External On-Site Ambient Dose Reconstruction for DOE Sites.[9] The assigned co-worker doses would account for any ambient doses at the Y-12 Plant.

Occupational Medical Dose
Although the telephone interview indicated uncertainty about required X-ray procedures, in addition to the estimated dose received from site operations, the dose received from diagnostic X-ray procedures that were probably required as a condition of employment was also included in the overall dose to the eye. Based on information in the Technical Basis Document for the Y-12 National Security Complex – Occupational Medical Dose[6] and an assumed annual X-ray procedure each year of employment, a total X-ray dose of 0.115 rem was assigned. This X-ray dose is considered claimant favorable as it likely exceeds the true X-ray dose to the eye.

Internal Dose
Internal dose is caused by radioactive materials that are taken into the body. A chronic intake is an intake of radioactive material that occurs over an extended period of time (typically weeks or longer). An acute intake is an intake of radioactive material that occurs over a short period of time (typically minutes to hours). Regardless of the rate at which the intake occurs, the internal dose received from radioactive materials having long half-lives occurs over an extended period of time and is, therefore, considered chronic. The internal dose to the eye was determined by using the dose calculated for the skin.[4]

Employment records for Mr. Gore were reviewed, and no records of bioassay monitoring results were found. This is consistent with Mr. Gore's job description given the absence of any external dosimetry results. Internal monitoring programs are applied to individuals who are likely to be exposed to radiation from internally-deposited radioactive material. Personnel who are not selected for internal dose monitoring programs are less likely to be exposed. However, to account for any incidental dose that may have been received but not documented, internal dose was assigned based on a hypothetical intake assuming an intake of 12 radionuclides. This results in an intake that greatly exceeds any possible actual intake by Mr. Gore because this level of activity would be expected to be detectable by workplace indicators and is inconsistent with his work description. Additionally, these nuclides would not all be found in a single location on site.

The total internal dose assigned was 7.849 rem. The assigned internal doses are based on the information provided in the Technical Information Bulletin: Maximum Internal Dose Estimates for Certain DOE Complex Claims[5] and the application of assumptions that maximize the dose estimate to the eye.

Dose from Radiological Incidents
The record of the telephone interview was evaluated carefully by the dose reconstructor. No radiological incidents were documented in either the telephone interview summary or the records supplied by the Department of Energy. However, the telephone interview indicated that Mr. Gore was routinely monitored, but since no external monitoring data were present in the records supplied by the Department of Energy, complex wide co-worker dose was assigned. During the interview it was also indicated that Mr. Gore was exposed to beryllium. However, this dose reconstruction only includes an evaluation of exposure to radiation and radioactive material.

Uncertainty
Point estimates (constant values) were used for organ dose input into the NIOSH-Interactive RadioEpidemiological Program (NIOSH-IREP).

Possible Overestimate of Radiation Dose
There are a number of reasons to believe that this dose estimate represents a larger dose than Mr. Gore's true radiation dose received while working at the Y-12 Plant. The most important reasons for this include:

- Internal doses were estimated by using claimant-favorable assumptions regarding hypothetical intakes that were unlikely to have occurred. The actual internal doses received by Mr. Gore would have been considerably smaller than those calculated using these assumptions.

- The actual doses to the eye from occupational medical X-ray procedures are likely to be smaller than were calculated based on the maximizing assumptions used in this dose reconstruction.

- The co-worker doses estimated for Mr. Gore exceed the Y-12 co-worker doses and are likely much larger than any doses that were unmonitored or unrecorded.

Covered Employee	NIOSH ID#	Social Security #
James Z. Gore	12438	422-88-0100

Summary

James Z. Gore was exposed to various sources of radiation during his employment at the Y-12 Plant. The estimated dose to Mr. Gore was 18.843 rem.

The reported dose is a significant *overestimate* of Mr. Gore's occupational radiation dose which will support claim determination.

Attachment 1 contains the IREP dose reconstruction summary sheets that will be used by the Department of Labor to make the final probability of causation determination of the claim.

References

1. 42 CFR 82, *Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000*; Final Rule, Federal Register/Vol.67, No. 85/Thursday, May 2, 2002, p 22314.

2. 42 CFR 81, *Guidelines for Determining the Probability of Causation Under the Energy Employees Occupational Illness Compensation Program Act of 2000*; Final Rule, Federal Register/Vol.67, No. 85/Thursday, May 2, 2002, p 22296.

3. NIOSH, (2002) *External Dose Reconstruction Implementation Guideline, Rev 1*, OCAS-IG-001, National Institute for Occupational Safety and Health, Office of Compensation Analysis and Support, Cincinnati, Ohio.

4. ORAUT (Oak Ridge Associated Universities Team), ORAUT-OTIB-0005, *Technical Information Bulletin: IMBA Organ, External Dosimetry Organ, and IREP Model Selection by ICD-9 Code, Rev 01 PC-3*, October 29, 2004.

5. ORAUT (Oak Ridge Associated Universities Team), ORAUT-OTIB-0002, *Technical Information Bulletin: Maximum Internal Dose Estimates for Certain DOE Complex Claims, Rev 01 PC-2*, May 7, 2004.

6. ORAUT (Oak Ridge Associated Universities Team), ORAUT-TKBS-0014-3, *Technical Basis Document for the Y-12 National Security Complex – Occupational Medical Dose, Rev 00 PC-1*, September 9, 2004.

7. ORAUT (Oak Ridge Associated Universities Team), ORAUT-TKBS-0014-6, *Technical Basis Document for the Y-12 National Security Complex – Occupational External Dosimetry, Rev 00*, November 19, 2003.

8. ORAUT (Oak Ridge Associated Universities Team), ORAUT-TKBS-0014-4, *Technical Basis Document for the Y-12 National Security Complex – Occupational Environmental Dose, Rev 00 PC-2*, October 15, 2004.

9. ORAUT (Oak Ridge Associated Universities Team), ORAUT-PROC-0060, *External On-Site Ambient Dose Reconstruction for DOE Sites, Rev 00*, March 7, 2005.

Covered Employee
James Z. Gore

NIOSH ID#
12438

Social Security #
422-88-0100

ATTACHMENT 1: IREP Input Tables

PERSONAL INFORMATION								
Claimant Name	NIOSH ID #	Claimant SSN	DOL District Office	Gender	Birth Year	Year of Diagnosis	Cancer Model	Should all model be run?
James Z. Gore	012438	422-88-0100	JA	Male	1934	1987	Yes	No

CLAIMANT CANCER DIAGNOSIS						
	Primary Cancer #1	Primary Cancer #2	Primary Cancer #3	Secondary Cancer #1	Secondary Cancer #2	Secondary Cancer #3
Cancer Type	colon/ rectum/ra	N/A	N/A	N/A	N/A	N/A
Date of Diagnosis	1987	N/A	N/A	N/A	N/A	N/A

EXPOSURE INFORMATION								
Number of exposures								
114								
Exposure #	Exposure Year	Exposure Rate	Radiation Type	Dose Distribution Type	Parameter 1	Parameter 2	Parameter 3
1	1968	acute	photons E=30-250keV	Constant	0.904	0.000	0.000
2	1969	acute	photons E=30-250keV	Constant	0.904	0.000	0.000
3	1970	acute	photons E=30-250keV	Constant	0.904	0.000	0.000
4	1971	acute	photons E=30-250keV	Constant	0.964	0.000	0.000
5	1972	acute	photons E=30-250keV	Constant	0.963	0.000	0.000
6	1973	acute	photons E=30-250keV	Constant	0.964	0.000	0.000
7	1974	acute	photons E=30-250keV	Constant	1.032	0.000	0.000
8	1975	acute	photons E=30-250keV	Constant	0.360	0.000	0.000
9	1976	acute	photons E=30-250keV	Constant	0.340	0.000	0.000
10	1977	acute	photons E=30-250keV	Constant	0.316	0.000	0.000
11	1978	acute	photons E=30-250keV	Constant	0.264	0.000	0.000
12	1979	acute	photons E=30-250keV	Constant	0.290	0.000	0.000
13	1980	acute	photons E=30-250keV	Constant	0.260	0.000	0.000
14	1981	acute	photons E=30-250keV	Constant	0.237	0.000	0.000
15	1982	acute	photons E=30-250keV	Constant	0.236	0.000	0.000
16	1983	acute	photons E=30-250keV	Constant	0.305	0.000	0.000
17	1984	acute	photons E=30-250keV	Constant	0.237	0.000	0.000
18	1985	acute	photons E=30-250keV	Constant	0.262	0.000	0.000
19	1986	acute	photons E=30-250keV	Constant	0.232	0.000	0.000
20	1987	acute	photons E=30-250keV	Constant	0.241	0.000	0.000
21	1988	acute	photons E=30-250keV	Constant	0.232	0.000	0.000
22	1989	acute	photons E=30-250keV	Constant	0.223	0.000	0.000
23	1990	acute	photons E=30-250keV	Constant	0.063	0.000	0.000
24	1991	acute	photons E=30-250keV	Constant	0.049	0.000	0.000
25	1992	acute	photons E=30-250keV	Constant	0.048	0.000	0.000
26	1993	acute	photons E=30-250keV	Constant	0.049	0.000	0.000
27	1994	acute	photons E=30-250keV	Constant	0.041	0.000	0.000
28	1968	chronic	alpha	Constant	0.644	0.000	0.000
29	1969	chronic	alpha	Constant	0.264	0.000	0.000
30	1970	chronic	alpha	Constant	0.258	0.000	0.000
31	1971	chronic	alpha	Constant	0.252	0.000	0.000
32	1972	chronic	alpha	Constant	0.246	0.000	0.000
33	1973	chronic	alpha	Constant	0.240	0.000	0.000
34	1974	chronic	alpha	Constant	0.243	0.000	0.000
35	1975	chronic	alpha	Constant	0.240	0.000	0.000
36	1976	chronic	alpha	Constant	0.228	0.000	0.000
37	1977	chronic	alpha	Constant	0.228	0.000	0.000
38	1978	chronic	alpha	Constant	0.228	0.000	0.000
39	1979	chronic	alpha	Constant	0.333	0.000	0.000
40	1980	chronic	alpha	Constant	0.232	0.000	0.000
41	1981	chronic	alpha	Constant	0.213	0.000	0.000
42	1982	chronic	alpha	Constant	0.130	0.000	0.000
43	1983	chronic	alpha	Constant	0.228	0.000	0.000
44	1984	chronic	alpha	Constant	0.237	0.000	0.000
45	1985	chronic	alpha	Constant	0.228	0.000	0.000
46	1986	chronic	alpha	Constant	0.228	0.000	0.000
47	1987	chronic	alpha	Constant	0.224	0.000	0.000
48	1988	chronic	alpha	Constant	0.222	0.000	0.000
49	1989	chronic	alpha	Constant	0.221	0.000	0.000
50	1990	chronic	alpha	Constant	0.220	0.000	0.000
51	1991	chronic	alpha	Constant	0.218	0.000	0.000
52	1992	chronic	alpha	Constant	0.217	0.000	0.000
53	1993	chronic	alpha	Constant	0.215	0.000	0.000
54	1994	chronic	alpha	Constant	0.215	0.000	0.000
55	1985	chronic	alpha	Constant	0.215	0.000	0.000
56	1986	chronic	alpha	Constant	0.213	0.000	0.000
57	1987	chronic	alpha	Constant	0.218	0.000	0.000
58	1988	chronic	electrons E=10keV	Constant	0.528	0.000	0.000
59	1989	chronic	electrons E=10keV	Constant	0.511	0.000	0.000
60	1970	chronic	electrons E=10keV	Constant	0.005	0.000	0.000
61	1971	chronic	electrons E=10keV	Constant	0.001	0.000	0.000

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62	1972	chronic	electrons E=16keV	Constant	0.000	0.000	0.000
63	1973	chronic	electrons E=16keV	Constant	0.000	0.000	0.000
64	1974	chronic	electrons E=16keV	Constant	0.000	0.000	0.000
65	1975	chronic	electrons E=16keV	Constant	0.000	0.000	0.000
66	1976	chronic	electrons E=16keV	Constant	0.000	0.000	0.000
67	1977	chronic	electrons E=16keV	Constant	0.000	0.000	0.000
68	1978	chronic	electrons E=16keV	Constant	0.000	0.000	0.000
69	1979	chronic	electrons E=16keV	Constant	0.000	0.000	0.000
70	1980	chronic	electrons E=16keV	Constant	0.000	0.000	0.000
71	1981	chronic	electrons E=16keV	Constant	0.000	0.000	0.000
72	1982	chronic	electrons E=16keV	Constant	0.000	0.000	0.000
73	1983	chronic	electrons E=16keV	Constant	0.000	0.000	0.000
74	1984	chronic	electrons E=16keV	Constant	0.000	0.000	0.000
75	1985	chronic	electrons E=16keV	Constant	0.000	0.000	0.000
76	1986	chronic	electrons E=16keV	Constant	0.000	0.000	0.000
77	1987	chronic	electrons E=16keV	Constant	0.000	0.000	0.000
78	1988	chronic	electrons E=16keV	Constant	0.000	0.000	0.000
79	1989	chronic	electrons E=16keV	Constant	0.000	0.000	0.000
80	1990	chronic	electrons E=16keV	Constant	0.000	0.000	0.000
81	1991	chronic	electrons E=16keV	Constant	0.000	0.000	0.000
82	1992	chronic	electrons E=16keV	Constant	0.000	0.000	0.000
83	1993	chronic	electrons E=16keV	Constant	0.000	0.000	0.000
84	1994	chronic	electrons E=16keV	Constant	0.000	0.000	0.000
85	1995	chronic	electrons E=16keV	Constant	0.000	0.000	0.000
86	1996	chronic	electrons E=16keV	Constant	0.000	0.000	0.000
87	1997	chronic	electrons E=16keV	Constant	0.000	0.000	0.000
88	1998	acute	photons E=30-250kev	Constant	0.004	0.000	0.000
89	1999	acute	photons E=30-250kev	Constant	0.004	0.000	0.000
90	1970	acute	photons E=30-250kev	Constant	0.004	0.000	0.000
91	1971	acute	photons E=30-250kev	Constant	0.004	0.000	0.000
92	1972	acute	photons E=30-250kev	Constant	0.004	0.000	0.000
93	1973	acute	photons E=30-250kev	Constant	0.004	0.000	0.000
94	1974	acute	photons E=30-250kev	Constant	0.004	0.000	0.000
95	1975	acute	photons E=30-250kev	Constant	0.004	0.000	0.000
96	1976	acute	photons E=30-250kev	Constant	0.004	0.000	0.000
97	1977	acute	photons E=30-250kev	Constant	0.004	0.000	0.000
98	1978	acute	photons E=30-250kev	Constant	0.004	0.000	0.000
99	1979	acute	photons E=30-250kev	Constant	0.004	0.000	0.000
100	1980	acute	photons E=30-250kev	Constant	0.004	0.000	0.000
101	1981	acute	photons E=30-250kev	Constant	0.004	0.000	0.000
102	1982	acute	photons E=30-250kev	Constant	0.004	0.000	0.000
103	1983	acute	photons E=30-250kev	Constant	0.004	0.000	0.000
104	1984	acute	photons E=30-250kev	Constant	0.004	0.000	0.000
105	1985	acute	photons E=30-250kev	Constant	0.004	0.000	0.000
106	1986	acute	photons E=30-250kev	Constant	0.004	0.000	0.000
107	1987	acute	photons E=30-250kev	Constant	0.004	0.000	0.000
108	1988	acute	photons E=30-250kev	Constant	0.004	0.000	0.000
109	1989	acute	photons E=30-250kev	Constant	0.004	0.000	0.000
110	1990	acute	photons E=30-250kev	Constant	0.004	0.000	0.000
111	1991	acute	photons E=30-250kev	Constant	0.004	0.000	0.000
112	1992	acute	photons E=30-250kev	Constant	0.004	0.000	0.000
113	1993	acute	photons E=30-250kev	Constant	0.004	0.000	0.000
114	1994	acute	photons E=30-250kev	Constant	0.004	0.000	0.000

OTHER ADVANCED FEATURES			
Sample Size	Random Seed		
10000	54		
User Defined Uncertainty Distribution			
Dose Distribution Type	Parameter 1	Parameter 2	Parameter 3
Lognormal	1.000	1.000	0.000

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OTHER ADVANCED FEATURES			
Random Seed	Random Seed		
2000	50		
User Defined Uncertainty Distribution			
Dose Classification Type	Parameter 1	Parameter 2	Parameter 3
Lognormal	1.000	1.000	0.000

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NIOSH Tracking Number: 12438

National Institute for Occupational Safety and Health
Robert A. Taft Laboratories
4676 Columbia Parkway
Cincinnati, OH 45226-1998
Phone: 513-533-6800
Fax: 513-533-6817

October 27, 2006

Mrs. Mildred L. Gore
5305 Jonathan Way
Knoxville, TN 37920 USA

Dear Mrs. Mildred Gore:

This letter is to provide you with information on the status of the dose reconstruction for the claim you filed under the Energy Employees Occupational Illness Compensation Program Act (NIOSH Tracking Number 12438).

The National Institute for Occupational Safety and Health's (NIOSH) Office of Compensation Analysis and Support (OCAS) has completed a revised reconstruction of the radiation dose based upon additional relevant information that NIOSH has obtained. Enclosed you will find a copy of a revised Draft NIOSH Report of Dose Reconstruction under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) that supercedes any previous dose reconstruction reports we have sent you. During the next two weeks, we will attempt to contact you to schedule a convenient date and time for conducting a new closing interview with you. The purpose of the closing interview is to review the revised dose reconstruction results and the basis on which the results were calculated. This will be the final opportunity during the dose reconstruction process for you to provide additional relevant information that may affect the dose reconstruction or indicate that you are in the process of obtaining such information. To facilitate the scheduling of the interview, you can contact us at the following telephone number 1-800-790-6728 (1-800-790-ORAU). If, after three weeks from the date of this letter, we have not heard back from you regarding a convenient time to schedule the interview, then we will assume that you have decided not to participate in the interview.

We have also enclosed a copy of a form (OCAS-1) that should be signed and returned to us within 60 days. You should sign and return this form even though you may have previously signed and returned a similar form after reviewing a previous version of a draft dose reconstruction report. Your signature on this form certifies that you agree with the following statements: 1) you are not aware of any additional information that may be relevant to the dose reconstruction; 2) you have reviewed the revised draft dose reconstruction report and agree that it identifies all of the relevant information you provided to NIOSH regarding the dose reconstruction; and 3) the revised dose reconstruction report is ready to be forwarded to the Department of Labor (DOL) for a determination regarding your claim. Your signature on this form is not an indication that you agree with the decisions NIOSH made concerning how to use or not use information you provided for dose reconstruction or that you agree with the findings of the NIOSH dose reconstruction. DOL's Office of Workers' Compensation Programs (OWCP) will notify you of any action that it may take regarding your claim, and of any rights you may have to raise objections. You will have an opportunity to raise objections to the final NIOSH Dose Reconstruction Report under EEOICPA following your receipt of a copy of the recommended decision on your claim from DOL by following the procedures described in the notice accompanying the recommended decision.

Once we receive the signed OCAS-1 form from you, we will send the final copy of the dose reconstruction report to the DOL for adjudication of your claim. We will also send you and the Department of Energy a copy of the final dose reconstruction report. It is important that you return the properly signed OCAS-1 form to us within the above-described time frame so that there is no delay in the adjudication of your claim. We will not forward the dose reconstruction report to DOL for adjudication without receipt of a properly signed OCAS-1 form. If we do not receive the OCAS-1 form within the time frame described above, we may administratively close the dose reconstruction and notify DOL of this action. PLEASE USE THE ENCLOSED PRE-ADDRESSED, POSTAGE-PAID ENVELOPE TO RETURN THE SIGNED OCAS-1 FORM TO US.

If you have any additional questions regarding the revised dose reconstruction report, please contact our dose reconstruction contractor, Oak Ridge Associated Universities, toll-free at 1-800-322-0111.

Sincerely yours,

LJ Elliott

Larry J. Elliott, MSPH, CIH
Director
Office of Compensation Analysis and Support

Enclosures

cc: File 12438
Kathlyn G. Bates

Form OCAS-1
May 2005

OMB No. 0920-0530
Exp. Date 1/31/09

Statement by the Claimant Closing the Record on a NIOSH Dose Reconstruction under the Energy Employees Occupational Illness Compensation Program Act

I, Mildred L. Gore (NIOSH Tracking Number 12438), a claimant under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA), certify that in signing this form, I have read, understand, and affirm that the following statements are true:

1) I am not in possession of any additional information that has not already been provided to NIOSH for completing a dose reconstruction to estimate the radiation doses incurred by the employee; and,

2) I understand that NIOSH will forward a final dose reconstruction report to the Department of Labor (DOL), so that DOL can continue adjudication of my claim and produce a recommended decision and then a final decision to accept or reject my claim; and,

3) I understand that NIOSH can not forward the dose reconstruction report to DOL for adjudication without receipt of a properly signed OCAS-1 form within 60 days of my receipt of this form and NIOSH may administratively close the dose reconstruction and notify DOL of this action if I do not provide a properly signed OCAS-1 form within this 60-day period; and,

4) I understand that my opportunity to seek a review of the NIOSH dose reconstruction occurs when my claim is with DOL and occurs only after DOL produces a recommended decision to deny my claim; and;

5) By signing this form, I do NOT certify or imply that I agree with NIOSH decisions indicated in the draft NIOSH dose reconstruction report concerning how NIOSH has used or not used information I have provided for the dose reconstruction; and,

6) By signing this form, I do NOT certify or imply that I agree with the findings of the NIOSH dose reconstruction and I understand that I may seek review of this NIOSH dose reconstruction after DOL makes a recommended decision on my claim.

Notice: I affirm that the information provided on this form is accurate and true. Any person who knowingly makes any false statement, misrepresentation, concealment of fact or any other act of fraud to obtain compensation as provided under EEOICPA or who knowingly accepts compensation to which that person is not entitled is subject to civil or administrative remedies as well as felony criminal prosecution and may, under appropriate criminal provisions, be punished by a fine or imprisonment or both.

Signature_____ Date _____
Mildred L. Gore

Public Burden Statement
Public reporting burden for this collection of information is estimated to average 5 minutes per response, including time for reviewing instructions, gathering the information needed, and completing the form. If you have any comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, send them to CDC Reports Clearance Officer, 1600 Clifton Road, MS-D-74, Atlanta, GA 30333; ATTN:PRA 0920-0530. Do not send the completed interview form to this address. Please complete and return this form using the enclosed pre-addressed, postage-paid envelope. Persons are not required to complete this form unless a currently valid OMB number is displayed.

NIOSH ID: 12438

NIOSH **OCAS**

NIOSH Report of Dose Reconstruction under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA)

NIOSH ID:	Social Security No.	DOL District Office
012438	422-38-0100	Jacksonville

Energy Employee Name:	Gore *Last*	James *First*	Zehner *Middle*	10/14/34 *Date of Birth*

Covered Employment:	08/19/68 – 10/31/94 *Dates*	Y-12 Plant Oak Ridge, TN *Location*

Cancer:	Ocular melanoma, rt. eye.	190.9	07/31/1997
	BCC – Left Cheek	173.3	08/03/1992
	Type	*ICD Code*	*Date of Diagnosis*

Calculations Performed By:	William H. Barley *Name*	8/28/2006 *Date*
Peer Review Completed By:	Steven R. Reed *Name*	8/28/2006 *Date*
Dose Reconstruction Approved By:	*Signature*	10/27/2006 *Date*
	LaVon B. Rutherford, CHP *Name*	

Covered Employee	NIOSH ID#	Social Security #
James Zehner Gore	12438	422-38-0100

Introduction

The Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA), Executive Order No. 13179 and the Radiation Dose Reconstruction Rule (42 CFR 82)[1]

EEOICPA established a compensation program to provide a lump sum payment of $150,000 and medical benefits as compensation to covered employees suffering from designated illnesses incurred as a result of their exposure to ionizing radiation, beryllium, or silica while in the performance of duty for the Department of Energy and certain of its vendors, contractors, and subcontractors. This legislation also provided for payment of compensation to certain survivors of these covered employees.

In Presidential Executive Order No. 13179, the President designated the U.S. Department of Labor to administer this program for claims by current and former employees of nuclear weapons production facilities and their survivors who seek compensation for cancers caused by radiation exposures sustained in the performance of duty. The Executive Order also directed the Department of Health and Human Services to estimate (reconstruct) the radiation doses received by these employees. The Department of Labor uses the reconstructed radiation dose in evaluating whether the employee's cancer was at least as likely as not related to employment at the facilities covered by EEOICPA. To fulfill the responsibilities assigned to the Department of Health and Human Services, the National Institute for Occupational Safety and Health's (NIOSH) Office of Compensation Analysis and Support (OCAS) completes dose reconstructions using the methods described in the Radiation Dose Reconstruction Rule (42 CFR 82)[1] for the Department of Labor's use in making compensation decisions.

The Purpose of Radiation Dose Reconstruction

A radiation dose reconstruction is used to estimate the radiation dose received by the specific organ(s) in which a worker developed cancer, particularly when radiation monitoring data are unavailable, incomplete, or of poor quality. Even in instances when radiation dosimetry data are available, they rarely specify dose to an organ and often are based on monitoring procedures that do not meet modern standards.

The basic principle of dose reconstruction is to characterize the occupational radiation environment to which a worker was exposed using available worker and/or workplace monitoring information. In cases where radiation exposures in the workplace environment cannot be fully characterized based on available data, default values based on reasonable scientific assumptions are used as substitutes.

EEOICPA recognized that the process of estimating radiation doses would require dealing with uncertainties and limited data and thus required that the government establish methods for arriving at reasonable estimates of radiation dose received by an individual who was not monitored or inadequately monitored for exposures to radiation, or for whom exposure records are missing or incomplete. To the extent that the science and data involve uncertainties, these uncertainties are typically handled to the advantage, rather than to the detriment, of the claimant. NIOSH has used the best available science to develop the methods and guidelines for dose

reconstruction. These methods have been reviewed and commented upon by the public, including experts in the field of dose reconstruction, and the Presidentially-appointed Advisory Board on Radiation and Worker Health.

How Radiation Doses Are Reconstructed
NIOSH reconstructs radiation doses by evaluating all available, appropriate data relevant to the employee's radiation exposure. Some examples of data that may be included in the dose reconstruction include, but are not limited to, internal dosimetry (such as results from urinalysis), external dosimetry data (such as film badge readings), workplace monitoring data (such as air sample results), workplace characterization data (such as type and amount of radioactive material processed), and descriptions of the type of work performed at the work location.

Although the specific methods used for each dose reconstruction may vary, after a claim has been referred by the Department of Labor to NIOSH for a dose reconstruction, NIOSH typically requests the worker's personal radiation monitoring information from the Department of Energy. Upon receipt of the requested information, at least one voluntary informational interview with the claimant and/or survivors is conducted and a copy of the interview report is sent for review. After all of the necessary and available information is gathered, a dose is estimated, using the methods in the Radiation Dose Reconstruction Rule. After a NIOSH health physicist reviews the information, methods, and results, the claimant receives a draft copy of the dose reconstruction report followed by a concluding interview, during which the claimant can add any additional relevant information that may affect the dose reconstruction. If the claimant certifies that he/she has completed providing information and that the record for dose reconstruction should be closed, a final dose reconstruction report is sent to the claimant, the Department of Labor, and the Department of Energy.

As applied in the EEOICPA, dose reconstructions must rely on information that can be developed on a timely basis and on carefully stated assumptions. Therefore, the guiding principle in conducting these dose reconstructions is to ensure that the assumptions used are fair, consistent, and well-grounded in the best available science, while ensuring that uncertainties in the science and data are handled to the advantage, rather than to the detriment, of the claim when feasible. When dose information is not available, is very limited, or the dose of record is very low, NIOSH may use the highest reasonably possible radiation dose, based on reliable science, documented experience, and relevant data, to complete a claimant's dose reconstruction. In other instances, NIOSH may not need to complete fully a dose reconstruction because a partial dose reconstruction results in an estimated dose which produces a probability of causation of 50% or greater.

How Radiation Dose Reconstructions Are Used in Final Compensation Determinations
The results of an employee's dose reconstruction are used by the Department of Labor to determine the probability that a worker's cancer was "at least as likely as not" due to his/her occupational exposure to ionizing radiation during employment at a covered facility. Criteria and guidelines for making this determination are established by EEOICPA and the Probability of Causation Guidelines (42 CFR 81).[2] The dose reconstruction is not the final determination of a claim, but rather an interim product that is used by the Department of Labor in making its final decision. Final determinations are made by the Department of Labor based on standards determined by EEOICPA and its implementing regulations.

Covered Employee	NIOSH ID#	Social Security #
James Zehner Gore	12438	422-38-0100

Dose Reconstruction Overview

The Office of Compensation Analysis and Support has performed a dose reconstruction for James Zehner Gore in accordance with the applicable requirements of the Energy Employees Occupational Illness Compensation Program Act. The records provided by the Department of Labor (DOL) indicate that Mr. Gore worked at the Y-12 Plant from August 19, 1968, through October 31, 1994, and that he was diagnosed with basal cell carcinoma of the skin on the left cheek in 1992, and ocular melanoma of the right eye in 1997.

The majority of Mr. Gore's radiation exposure was received during employment as an engineer and a weapons production supervisor according to information provided in the interview process. Mr. Gore's dose reconstructed under the Energy Employees Occupational Illness Compensation Program Act was 8.899 rem to the skin and 10.606 rem to the eye. The dose was calculated only for these organs because of the specific types of cancer associated with this claim.[4]

To efficiently process this claim, the radiation dose assigned was overestimated using efficiency measures and claimant-favorable assumptions related to radiation exposure and intakes, based on current science, documented experience, and relevant data. Under these assumptions, NIOSH has determined that further research and analysis will not produce a level of radiation dose resulting in a probability of causation of 50% or greater. In accordance with 42 CFR § 82.10(k),[1] NIOSH has determined that sufficient research and analysis have been conducted to consider this dose reconstruction complete. Per the requirements of 42 CFR § 82.10(j),[1] only the dose incurred up to the point of cancer diagnosis was included in this dose reconstruction.

If the facts surrounding this dose reconstruction change (e.g., the date of diagnosis is modified, an additional covered cancer is diagnosed, or additional covered employment is identified), the efficiency measures used to reconstruct the dose may not be applicable. In this case, if the facts were to change, the dose reconstructed for the skin and the eye could be substantially lower than that reported using the efficiency process.

Information Used

During this dose reconstruction, the primary data sources were the Y-12 Plant Site Profiles.[6-8] In instances in which specific information useful for estimating doses to the eye was lacking, parameters were selected that maximized the dose estimate.

In addition to the above information, the record of the computer assisted telephone interview was reviewed carefully by the dose reconstructor. The information provided was considered in the dose estimation process. Additional information on the evaluation of the interview is provided in subsequent sections of this report, as applicable.

Covered Employee	NIOSH ID#	Social Security #
James Zehner Gore	12438	422-38-0100

Dose Estimate

External Dose

External dose is received from radiation originating outside the body and is typically measured by dosimetry worn on the body. Radiation dose measured on a film badge or a thermoluminescent dosimeter (TLD) may have been delivered quickly (acute exposure) or slowly over the period of time that the employee was exposed (chronic exposure). Records received from the Department of Energy were reviewed, and it was indicated that Mr. Gore was not monitored for radiation exposure. Therefore, external doses assessed in this dose reconstruction include doses estimated from complex-wide coworker doses and occupational medical X-rays.

As an engineer and weapons production supervisor (engineer), Mr. Gore's work location is not known. In this capacity, he would have likely been exposed to photon and electron radiation, even though no monitoring records were found. However, due to the possibility of lost records or unmonitored occupational dose, external dose was assigned based on the maximum 50th percentile complex wide coworker dose for the given years of employment. External electron radiation was not considered in this dose reconstruction because Mr. Gore did not work directly with radioactive materials, and any external doses would have been attributable primarily to photons.

For the purpose of estimating probability of causation, all photon doses are assumed to be acute.[3]

Radiation Type, Energy, and Exposure Geometry

To maximize the probability of causation, a photon energy range of 100% 30–250 keV was applied. The determination of exposure geometry was not relevant to this dose reconstruction.

Coworker Dose

Since no monitoring records were available for Mr. Gore, the maximum 50th percentile dose for each given year of employment from Hanford Site, Oak Ridge National Laboratory, Oak Ridge Gaseous Diffusion Plant, Paducah Gaseous Diffusion Plant, Portsmouth Gaseous Diffusion Plant, and Savannah River Site was assigned as an unmonitored dose for Mr. Gore in accordance with guidance provided in the Technical Information Bulletin: Use of Coworker Dosimetry Data for External Dose Assignment.[10] The values assigned were assumed to be 100% 30–250 keV photons and had an organ dose conversion factor of 1.00 applied for the skin[8] and 1.236 applied for the eye.[3] Because these were not recorded results, no uncertainty factor was applied. The total coworker dose assigned was 8.232 rem to the skin and 10.268 rem to the eye. These unmonitored doses exceed the Y-12 coworker doses and provide a maximizing approach for this dose reconstruction. The published coworker data have been modified slightly to account for NIOSH guidance regarding the treatment of missed dose in coworker dose evaluations.

On-Site Ambient Dose

Because the unmonitored doses assigned for Mr. Gore were based on actual dosimetry results from the DOE sites mentioned above, no on-site ambient doses were assigned in accordance with the information provided in the procedure, External On-Site Ambient Dose Reconstruction for DOE Sites.[7] The assigned coworker doses would account for any ambient doses at Y-12 Plant.

Occupational Medical Dose
Although the telephone interview indicated uncertainty about required X-ray procedures, in addition to the estimated dose received from site operations, the dose received from diagnostic X-ray procedures that were probably required as a condition of employment was also included in the overall dose to the eye. Based on information in the Technical Basis Document for Y-12 National Security Complex – Occupational Medical Dose[6] and an assumed annual X-ray each year of employment, until the date of cancer diagnosis for the skin cancer, total X-ray doses of 0.478 rem to the skin and 0.088 rem to the eye were assigned. These X-ray doses are considered claimant favorable as they likely exceed the true X-ray dose to the skin and eye based on the assumed frequency of procedures. The X-ray doses were assigned as a normal distribution with a 30% uncertainty.

Internal Dose
Internal dose is caused by radioactive materials that are taken into the body. A chronic intake is an intake of radioactive material that occurs over an extended period of time (typically weeks or longer). An acute intake is an intake of radioactive material that occurs over a short period of time (typically minutes to hours). Regardless of the rate at which the intake occurs, the internal dose received from radioactive materials having long half-lives occurs over an extended period of time and is, therefore, considered chronic. The internal dose to the skin and eye was determined by using the dose calculated for the skin.[4]

Employment records for Mr. Gore were reviewed and no records of bioassay monitoring results were found. This is consistent with his job description, given the absence of any external dosimetry results. Internal monitoring programs are applied to individuals who are likely to be exposed to radiation from internally-deposited radioactive material. Personnel who are not selected for internal dose monitoring programs are less likely to be exposed. However, to account for any incidental dose that may have been received but not documented, internal dose was assigned based on the maximum coworker internal data for the Y-12 Site.[5,11]

A computer code, the Integrated Modules for Bioassay Analysis (IMBA), was used to estimate the annual organ doses based on the coworker intakes. The IMBA Expert OCAS-Edition was used for this dose reconstruction. The ICRP 66 lung model with default aerosol characteristics was assumed, in conjunction with ICRP 68 metabolic models. It should be emphasized that intake dates, scenarios, and intake levels were based upon mathematical models and do not necessarily prove that such intakes occurred on the given dates. These dates and scenarios provide an acceptable explanation of exposure and dose based upon the bioassay data provided. This approach is in accordance with the provisions of the Radiation Dose Reconstruction Rule (42 CFR § 82)[1] and guidance in the Internal Dose Reconstruction Implementation Guideline.[9]

Both solubility classes Type M and Type S uranium-234 were evaluated, and Type S provided the higher dose and was used for the dose estimate. Associated recycled uranium components including neptunium-237, plutonium-239, technetium-99, and thorium-228 were applied based on Table 5-8.[11] The coworker intakes from the Technical Information Bulletin: Internal Dosimetry Coworker Data for Y-12 are only calculated through 1988; however, as a claimant-favorable assumption, the 1988 intakes from Table 5–1 were applied from 1989 through the cancer diagnosis date for each of the cancers evaluated.[5] The internal dose calculated for

technetium-99 was less then 0.001 rem and was not used for the dose estimate. The total internal dose assigned was 0.189 rem to the skin and 0.250 rem to the eye.

Dose from Radiological Incidents
The record of the telephone interview was evaluated carefully by the dose reconstructor. No radiological incidents were documented in either the telephone interview summary or the records supplied by the Department of Energy. However, the interview indicated that Mr. Gore was routinely monitored, but since no external monitoring data were present in the records supplied by the Department of Energy, complex wide coworker dose was assigned. During the interview, it was also indicated that Mr. Gore was exposed to beryllium. However, this dose reconstruction only includes an evaluation of exposure to radiation and radioactive material.

Uncertainty
Point estimates for coworker doses (constant values) were used for organ dose input into the NIOSH-Interactive RadioEpidemiological Program (NIOSH-IREP). Occupational medical dose was assigned as a normal distribution with a 30% error,[6] and the internal dose as a lognormal distribution.[5]

Possible Overestimate of Radiation Dose
There are a number of reasons to believe that this dose estimate represents a larger dose than Mr. Gore's true radiation dose received while working at the Y-12 Plant. The most important reasons for this include:

- Internal doses were estimated by using coworker intakes that were unlikely to have occurred. The actual internal doses received by Mr. Gore would have been smaller than those calculated using these assumptions.
- The actual doses to the skin and eye from occupational medical X-ray procedures are likely to be smaller than were calculated based on the frequency assumptions used in this dose reconstruction.
- The coworker doses estimated for Mr. Gore exceed the Y-12 coworker doses and are likely much larger than any doses that were unmonitored or unrecorded.

Summary

James Zehner Gore was exposed to various sources of radiation during his employment at the Y-12 Plant. The estimated dose to Mr. Gore was 8.899 rem to the skin and 10.606 rem to the eye. The reported dose is a significant *overestimate* of Mr. Gore's occupational radiation dose which will support claim determination.

Attachment 1 contains the IREP dose reconstruction summary sheets that will be used by the Department of Labor to make the final probability of causation determination of the claim.

References

1. 42 CFR 82, *Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000*; Final Rule, Federal Register/Vol.67, No. 85/Thursday, May 2, 2002, p 22314.

2. 42 CFR 81, *Guidelines for Determining the Probability of Causation Under the Energy Employees Occupational Illness Compensation Program Act of 2000*; Final Rule, Federal Register/Vol.67, No. 85/Thursday, May 2, 2002, p 22296.

3. NIOSH, (2002) *External Dose Reconstruction Implementation Guideline, Rev 1*, OCAS-IG-001, National Institute for Occupational Safety and Health, Office of Compensation Analysis and Support, Cincinnati, Ohio.

4. ORAUT (Oak Ridge Associated Universities Team), ORAUT-OTIB-0005, *Technical Information Bulletin: Internal Dosimetry Organ, External Dosimetry Organ, and IREP Model Selection by ICD-9 Code, Rev 02 PC-1*, February 10, 2006.

5. ORAUT (Oak Ridge Associated Universities Team), ORAUT-OTIB-0029, *Technical Information Bulletin: Internal Dosimetry Coworker Data for Y-12, Rev 00*, April 5, 2005.

6. ORAUT (Oak Ridge Associated Universities Team), ORAUT-TKBS-0014-3, *Technical Basis Document for the Y-12 National Security Complex – Occupational Medical Dose, Rev 00 PC-3*, April 18, 2006.

7. ORAUT (Oak Ridge Associated Universities Team), ORAUT-PROC-0060, *External On-Site Ambient Dose Reconstruction for DOE Sites, Rev 01*, June 28, 2006.

8. ORAUT (Oak Ridge Associated Universities Team), ORAUT-OTIB-0017, *Technical Information Bulletin: Interpretation of Dosimetry Data for Assignment of Shallow Dose, Rev 01*, October 11, 2005.

9. NIOSH, (2002) *Internal Dose Reconstruction Implementation Guideline, Rev 0*, OCAS-IG-002, National Institute for Occupational Safety and Health, Office of Compensation Analysis and Support, Cincinnati, Ohio.

10. ORAUT (Oak Ridge Associated Universities Team), ORAUT-OTIB-0020, *Technical Information Bulletin: Use of Coworker Dosimetry Data for External Dose Assignment, Rev 01*, October 7, 2005.

11. ORAUT (Oak Ridge Associated Universities Team), ORAUT-TKBS-0014-5, *Y-12 National Security Complex – Occupational Internal Dose, Rev 02*, August 3, 2006.

Covered Employee
James Zehner Gore

NIOSH ID#
12438

Social Security #
422-38-0100

ATTACHMENT 1: IREP Input Tables

PERSONAL INFORMATION									
Claimant Name	NIOSH ID #	Claimant SSN	DOL District Office	Gender	Birth Year	Year of Diagnosis	Cancer Model	Should IR equal be run?
James Zehner Gore	012438	422-38-0100	JA	Male	1934	1992	Non-malignant (NM)	No

CLAIMANT CANCER DIAGNOSES	Primary Cancer #1	Primary Cancer #2	Primary Cancer #3	Secondary Cancer #1	Secondary Cancer #2	Secondary Cancer #3
Cancer Type	BCC - cheek	acute coronaries	N/A	N/A	N/A	N/A
Date of Diagnosis	1992	1992	N/A	N/A	N/A	N/A

EXPOSURE INFORMATION

Number of exposures: 115

Exposure #	Exposure Year	Exposure Rate	Radiation Type	Dose Distribution Type	Parameter 1	Parameter 2	Parameter 3
1	1968	acute	photons E=30-250kvp	Constant	0.200	0.000	0.000
2	1969	acute	photons E=30-250kvp	Constant	0.750	0.000	0.000
3	1970	acute	photons E=30-250kvp	Constant	0.750	0.000	0.000
4	1971	acute	photons E=30-250kvp	Constant	0.750	0.000	0.000
5	1972	acute	photons E=30-250kvp	Constant	0.779	0.000	0.000
6	1973	acute	photons E=30-250kvp	Constant	0.780	0.000	0.000
7	1974	acute	photons E=30-250kvp	Constant	0.816	0.000	0.000
8	1975	acute	photons E=30-250kvp	Constant	0.285	0.000	0.000
9	1976	acute	photons E=30-250kvp	Constant	0.226	0.000	0.000
10	1977	acute	photons E=30-250kvp	Constant	0.206	0.000	0.000
11	1978	acute	photons E=30-250kvp	Constant	0.214	0.000	0.000
12	1979	acute	photons E=30-250kvp	Constant	0.222	0.000	0.000
13	1980	acute	photons E=30-250kvp	Constant	0.203	0.000	0.000
14	1981	acute	photons E=30-250kvp	Constant	0.191	0.000	0.000
15	1982	acute	photons E=30-250kvp	Constant	0.191	0.000	0.000
16	1983	acute	photons E=30-250kvp	Constant	0.208	0.000	0.000
17	1984	acute	photons E=30-250kvp	Constant	0.191	0.000	0.000
18	1985	acute	photons E=30-250kvp	Constant	0.180	0.000	0.000
19	1986	acute	photons E=30-250kvp	Constant	0.180	0.000	0.000
20	1987	acute	photons E=30-250kvp	Constant	0.185	0.000	0.000
21	1988	acute	photons E=30-250kvp	Constant	0.180	0.000	0.000
22	1989	acute	photons E=30-250kvp	Constant	0.180	0.000	0.000
23	1990	acute	photons E=30-250kvp	Constant	0.063	0.000	0.000
24	1991	acute	photons E=30-250kvp	Constant	0.340	0.000	0.000
25	1992	acute	photons E=30-250kvp	Constant	0.340	0.000	0.000
26	1968	acute	photons E=30-250kvp	Normal	0.270	0.001	0.000
27	1969	acute	photons E=30-250kvp	Normal	0.158	0.001	0.000
28	1970	acute	photons E=30-250kvp	Normal	0.003	0.001	0.000
29	1971	acute	photons E=30-250kvp	Normal	0.003	0.001	0.000
30	1972	acute	photons E=30-250kvp	Normal	0.003	0.001	0.000
31	1973	acute	photons E=30-250kvp	Normal	0.003	0.001	0.000
32	1974	acute	photons E=30-250kvp	Normal	0.003	0.001	0.000
33	1975	acute	photons E=30-250kvp	Normal	0.003	0.001	0.000
34	1976	acute	photons E=30-250kvp	Normal	0.003	0.001	0.000
35	1977	acute	photons E=30-250kvp	Normal	0.003	0.001	0.000
36	1978	acute	photons E=30-250kvp	Normal	0.003	0.001	0.000
37	1979	acute	photons E=30-250kvp	Normal	0.003	0.001	0.000
38	1980	acute	photons E=30-250kvp	Normal	0.003	0.001	0.000
39	1981	acute	photons E=30-250kvp	Normal	0.003	0.001	0.000
40	1982	acute	photons E=30-250kvp	Normal	0.003	0.001	0.000
41	1983	acute	photons E=30-250kvp	Normal	0.003	0.001	0.000
42	1984	acute	photons E=30-250kvp	Normal	0.003	0.001	0.000
43	1985	acute	photons E=30-250kvp	Normal	0.003	0.001	0.000
44	1986	acute	photons E=30-250kvp	Normal	0.003	0.001	0.000
45	1987	acute	photons E=30-250kvp	Normal	0.003	0.001	0.000
46	1988	acute	photons E=30-250kvp	Normal	0.003	0.001	0.000
47	1989	acute	photons E=30-250kvp	Normal	0.003	0.001	0.000
48	1990	acute	photons E=30-250kvp	Normal	0.003	0.001	0.000
49	1991	acute	photons E=30-250kvp	Normal	0.003	0.001	0.000
50	1992	acute	photons E=30-250kvp	Normal	0.003	0.001	0.000
51	1968	chronic	alpha	Lognormal	0.000	3.770	0.000
52	1969	chronic	alpha	Lognormal	0.001	3.770	0.000
53	1970	chronic	alpha	Lognormal	0.002	3.770	0.000
54	1971	chronic	alpha	Lognormal	0.003	3.770	0.000
55	1972	chronic	alpha	Lognormal	0.004	3.770	0.000
56	1973	chronic	alpha	Lognormal	0.004	3.770	0.000
57	1974	chronic	alpha	Lognormal	0.004	3.770	0.000
58	1975	chronic	alpha	Lognormal	0.005	3.770	0.000
59	1976	chronic	alpha	Lognormal	0.005	3.770	0.000
60	1977	chronic	alpha	Lognormal	0.006	3.770	0.000
61	1978	chronic	alpha	Lognormal	0.006	3.770	0.000

Covered Employee
James Zehner Gore

NIOSH ID#
12438

Social Security #
422-38-0100

62	1979	chronic	alpha	Lognormal	0.006	3.770	0.000
63	1980	chronic	alpha	Lognormal	0.006	3.770	0.000
64	1981	chronic	alpha	Lognormal	0.006	3.770	0.000
65	1982	chronic	alpha	Lognormal	0.006	3.770	0.000
66	1983	chronic	alpha	Lognormal	0.006	3.770	0.000
67	1984	chronic	alpha	Lognormal	0.006	3.770	0.000
68	1985	chronic	alpha	Lognormal	0.006	3.770	0.000
69	1986	chronic	alpha	Lognormal	0.006	3.770	0.000
70	1987	chronic	alpha	Lognormal	0.006	3.770	0.000
71	1988	chronic	alpha	Lognormal	0.006	3.770	0.000
72	1989	chronic	alpha	Lognormal	0.006	3.770	0.000
73	1990	chronic	alpha	Lognormal	0.006	3.770	0.000
74	1991	chronic	alpha	Lognormal	0.006	3.770	0.000
75	1992	chronic	alpha	Lognormal	0.006	3.770	0.000
76	1978	chronic	alpha	Lognormal	0.000	4.530	0.000
77	1979	chronic	alpha	Lognormal	0.000	4.530	0.000
78	1980	chronic	alpha	Lognormal	0.001	4.530	0.000
79	1981	chronic	alpha	Lognormal	0.001	4.530	0.000
80	1982	chronic	alpha	Lognormal	0.001	4.530	0.000
81	1983	chronic	alpha	Lognormal	0.001	4.530	0.000
82	1984	chronic	alpha	Lognormal	0.001	4.530	0.000
83	1985	chronic	alpha	Lognormal	0.001	4.530	0.000
84	1986	chronic	alpha	Lognormal	0.001	4.530	0.000
85	1987	chronic	alpha	Lognormal	0.001	4.530	0.000
86	1988	chronic	alpha	Lognormal	0.001	4.530	0.000
87	1989	chronic	alpha	Lognormal	0.001	4.530	0.000
88	1990	chronic	alpha	Lognormal	0.001	4.530	0.000
89	1991	chronic	alpha	Lognormal	0.001	4.530	0.000
90	1992	chronic	alpha	Lognormal	0.001	4.530	0.000
91	1968	chronic	alpha	Lognormal	0.000	4.910	0.000
92	1969	chronic	alpha	Lognormal	0.000	4.910	0.000
93	1970	chronic	alpha	Lognormal	0.000	4.910	0.000
94	1971	chronic	alpha	Lognormal	0.001	4.910	0.000
95	1972	chronic	alpha	Lognormal	0.001	4.910	0.000
96	1973	chronic	alpha	Lognormal	0.001	4.910	0.000
97	1974	chronic	alpha	Lognormal	0.001	4.910	0.000
98	1975	chronic	alpha	Lognormal	0.001	4.910	0.000
99	1976	chronic	alpha	Lognormal	0.001	4.910	0.000
100	1977	chronic	alpha	Lognormal	0.001	4.910	0.000
101	1978	chronic	alpha	Lognormal	0.002	4.910	0.000
102	1979	chronic	alpha	Lognormal	0.002	4.910	0.000
103	1980	chronic	alpha	Lognormal	0.002	4.910	0.000
104	1981	chronic	alpha	Lognormal	0.002	4.910	0.000
105	1982	chronic	alpha	Lognormal	0.002	4.910	0.000
106	1983	chronic	alpha	Lognormal	0.002	4.910	0.000
107	1984	chronic	alpha	Lognormal	0.003	4.910	0.000
108	1985	chronic	alpha	Lognormal	0.003	4.910	0.000
109	1986	chronic	alpha	Lognormal	0.003	4.910	0.000
110	1987	chronic	alpha	Lognormal	0.004	4.910	0.000
111	1988	chronic	alpha	Lognormal	0.004	4.910	0.000
112	1989	chronic	alpha	Lognormal	0.004	4.910	0.000
113	1990	chronic	alpha	Lognormal	0.004	4.910	0.000
114	1991	chronic	alpha	Lognormal	0.004	4.910	0.000
115	1992	chronic	alpha	Lognormal	0.004	4.910	0.000

OTHER ADVANCED FEATURES			
Sample Size	Random Seed		
2000	99		
Linear Dose/no Linear/Lathy Distribution			
Dose Distribution Type	Parameter 1	Parameter 2	Parameter 3
Lognormal	1.000	1.000	0.000

SEER CANCER INPUTS	
Single Grain	
Under Non-Hispanic	

Covered Employee
James Zehner Gore

NIOSH ID#
12438

Social Security #
422-38-0100

PERSONAL INFORMATION								
Claimant Name	NIOSH ID #	Claimant SSN	DOL Central Office	Gender	Birth Year	Year of Diagnosis	Cancer Name	Should we expect to find
James Zehner Gore	012438	422-38-0100	JA	Male	1934	1997	Eye	No

CLAIMANT CANCER DIAGNOSES							
	Primary Cancer #1	Primary Cancer #2	Primary Cancer #3	Secondary Cancer #1	Secondary Cancer #2	Secondary Cancer #3	
Cancer Type	SCC - cheek	squamous melanoma	N/A	N/A	N/A	N/A	
Date of Diagnosis	1989	1997	N/A	N/A	N/A	N/A	

EXPOSURE INFORMATION							
Number of exposures							
154							
Exposure #	Exposure Year	Exposure Rate	Radiation Type	Type Radiogenic Type	Parameter 1	Parameter 2	Parameter 3
1	1968	acute	photons E=30-250kv	Constant	0.382	0.000	0.000
2	1969	acute	photons E=30-250kv	Constant	0.984	0.000	0.000
3	1970	acute	photons E=30-250kv	Constant	0.984	0.000	0.000
4	1971	acute	photons E=30-250kv	Constant	0.984	0.000	0.000
5	1972	acute	photons E=30-250kv	Constant	0.983	0.000	0.000
6	1973	acute	photons E=30-250kv	Constant	0.984	0.000	0.000
7	1974	acute	photons E=30-250kv	Constant	1.000	0.000	0.000
8	1975	acute	photons E=30-250kv	Constant	0.308	0.000	0.000
9	1976	acute	photons E=30-250kv	Constant	0.395	0.000	0.000
10	1977	acute	photons E=30-250kv	Constant	0.265	0.000	0.000
11	1978	acute	photons E=30-250kv	Constant	0.264	0.000	0.000
12	1979	acute	photons E=30-250kv	Constant	0.260	0.000	0.000
13	1980	acute	photons E=30-250kv	Constant	0.250	0.000	0.000
14	1981	acute	photons E=30-250kv	Constant	0.237	0.000	0.000
15	1982	acute	photons E=30-250kv	Constant	1.238	0.000	0.000
16	1983	acute	photons E=30-250kv	Constant	0.309	0.000	0.000
17	1984	acute	photons E=30-250kv	Constant	0.237	0.000	0.000
18	1985	acute	photons E=30-250kv	Constant	0.222	0.000	0.000
19	1986	acute	photons E=30-250kv	Constant	0.222	0.000	0.000
20	1987	acute	photons E=30-250kv	Constant	0.241	0.000	0.000
21	1988	acute	photons E=30-250kv	Constant	0.222	0.000	0.000
22	1989	acute	photons E=30-250kv	Constant	0.223	0.000	0.000
23	1990	acute	photons E=30-250kv	Constant	0.085	0.000	0.000
24	1991	acute	photons E=30-250kv	Constant	0.048	0.000	0.000
25	1992	acute	photons E=30-250kv	Constant	0.048	0.000	0.000
26	1993	acute	photons E=30-250kv	Constant	0.048	0.000	0.000
27	1994	acute	photons E=30-250kv	Constant	0.041	0.000	0.000
28	1968	acute	photons E=30-250kv	Normal	0.008	0.000	0.000
29	1969	acute	photons E=30-250kv	Normal	0.001	0.001	0.000
30	1970	acute	photons E=30-250kv	Normal	0.003	0.001	0.000
31	1971	acute	photons E=30-250kv	Normal	0.003	0.001	0.000
32	1972	acute	photons E=30-250kv	Normal	0.003	0.001	0.000
33	1973	acute	photons E=30-250kv	Normal	0.003	0.001	0.000
34	1974	acute	photons E=30-250kv	Normal	0.003	0.001	0.000
35	1975	acute	photons E=30-250kv	Normal	0.003	0.001	0.000
36	1976	acute	photons E=30-250kv	Normal	0.001	0.001	0.000
37	1977	acute	photons E=30-250kv	Normal	0.003	0.001	0.000
38	1978	acute	photons E=30-250kv	Normal	0.003	0.001	0.000
39	1979	acute	photons E=30-250kv	Normal	0.003	0.001	0.000
40	1980	acute	photons E=30-250kv	Normal	0.003	0.001	0.000
41	1981	acute	photons E=30-250kv	Normal	0.003	0.001	0.000
42	1982	acute	photons E=30-250kv	Normal	0.003	0.001	0.000
43	1983	acute	photons E=30-250kv	Normal	0.003	0.001	0.000
44	1984	acute	photons E=30-250kv	Normal	0.003	0.001	0.000
45	1985	acute	photons E=30-250kv	Normal	0.003	0.001	0.000
46	1986	acute	photons E=30-250kv	Normal	0.003	0.001	0.000
47	1987	acute	photons E=30-250kv	Normal	0.003	0.001	0.000
48	1988	acute	photons E=30-250kv	Normal	0.003	0.001	0.000
49	1989	acute	photons E=30-250kv	Normal	0.003	0.001	0.000
50	1990	acute	photons E=30-250kv	Normal	0.003	0.001	0.000
51	1991	acute	photons E=30-250kv	Normal	0.003	0.001	0.000
52	1992	acute	photons E=30-250kv	Normal	0.003	0.001	0.000
53	1993	acute	photons E=30-250kv	Normal	0.003	0.001	0.000
54	1994	acute	photons E=30-250kv	Normal	0.003	0.001	0.000
55	1968	chronic	alpha	Lognormal	0.006	3.770	0.000
56	1969	chronic	alpha	Lognormal	0.001	3.770	0.000
57	1970	chronic	alpha	Lognormal	0.002	3.770	0.000
58	1971	chronic	alpha	Lognormal	0.002	3.770	0.000
59	1972	chronic	alpha	Lognormal	0.004	3.770	0.000
60	1973	chronic	alpha	Lognormal	0.004	3.770	0.000
61	1974	chronic	alpha	Lognormal	0.004	3.770	0.000

Covered Employee
James Zelmer Gore

NIOSH ID#
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422-38-0100

82	1975	chronic	alpha	Lognormal	0.005	3.770	0.000
83	1976	chronic	alpha	Lognormal	0.005	3.770	0.000
84	1977	chronic	alpha	Lognormal	0.005	3.770	0.000
85	1978	chronic	alpha	Lognormal	0.005	3.770	0.000
86	1979	chronic	alpha	Lognormal	0.005	3.770	0.000
87	1980	chronic	alpha	Lognormal	0.005	3.770	0.000
88	1981	chronic	alpha	Lognormal	0.005	3.770	0.000
89	1982	chronic	alpha	Lognormal	0.005	3.770	0.000
70	1983	chronic	alpha	Lognormal	0.005	3.770	0.000
71	1984	chronic	alpha	Lognormal	0.005	3.770	0.000
72	1985	chronic	alpha	Lognormal	0.005	3.770	0.000
73	1986	chronic	alpha	Lognormal	0.005	3.770	0.000
74	1987	chronic	alpha	Lognormal	0.005	3.770	0.000
75	1988	chronic	alpha	Lognormal	0.005	3.770	0.000
76	1989	chronic	alpha	Lognormal	0.005	3.770	0.000
77	1990	chronic	alpha	Lognormal	0.005	3.770	0.000
78	1991	chronic	alpha	Lognormal	0.005	3.770	0.000
79	1992	chronic	alpha	Lognormal	0.005	3.770	0.000
80	1993	chronic	alpha	Lognormal	0.005	3.770	0.000
81	1994	chronic	alpha	Lognormal	0.005	3.770	0.000
82	1995	chronic	alpha	Lognormal	0.005	3.770	0.000
83	1996	chronic	alpha	Lognormal	0.005	3.770	0.000
84	1997	chronic	alpha	Lognormal	0.005	3.770	0.000
85	1978	chronic	alpha	Lognormal	0.000	4.530	0.000
86	1979	chronic	alpha	Lognormal	0.000	4.530	0.000
87	1980	chronic	alpha	Lognormal	0.001	4.530	0.000
88	1981	chronic	alpha	Lognormal	0.001	4.530	0.000
89	1982	chronic	alpha	Lognormal	0.001	4.530	0.000
90	1983	chronic	alpha	Lognormal	0.001	4.530	0.000
91	1984	chronic	alpha	Lognormal	0.001	4.530	0.000
92	1985	chronic	alpha	Lognormal	0.001	4.530	0.000
93	1986	chronic	alpha	Lognormal	0.001	4.530	0.000
94	1987	chronic	alpha	Lognormal	0.001	4.530	0.000
95	1988	chronic	alpha	Lognormal	0.001	4.530	0.000
96	1989	chronic	alpha	Lognormal	0.001	4.530	0.000
97	1990	chronic	alpha	Lognormal	0.001	4.530	0.000
98	1991	chronic	alpha	Lognormal	0.001	4.530	0.000
99	1992	chronic	alpha	Lognormal	0.001	4.530	0.000
100	1993	chronic	alpha	Lognormal	0.001	4.530	0.000
101	1994	chronic	alpha	Lognormal	0.001	4.530	0.000
102	1995	chronic	alpha	Lognormal	0.001	4.530	0.000
103	1996	chronic	alpha	Lognormal	0.001	4.530	0.000
104	1997	chronic	alpha	Lognormal	0.001	4.530	0.000
105	1968	chronic	alpha	Lognormal	0.000	4.910	0.000
106	1969	chronic	alpha	Lognormal	0.000	4.910	0.000
107	1970	chronic	alpha	Lognormal	0.000	4.910	0.000
108	1971	chronic	alpha	Lognormal	0.001	4.910	0.000
109	1972	chronic	alpha	Lognormal	0.001	4.910	0.000
110	1973	chronic	alpha	Lognormal	0.001	4.910	0.000
111	1974	chronic	alpha	Lognormal	0.001	4.910	0.000
112	1975	chronic	alpha	Lognormal	0.001	4.910	0.000
113	1976	chronic	alpha	Lognormal	0.001	4.910	0.000
114	1977	chronic	alpha	Lognormal	0.001	4.910	0.000
115	1978	chronic	alpha	Lognormal	0.002	4.910	0.000
116	1979	chronic	alpha	Lognormal	0.002	4.910	0.000
117	1980	chronic	alpha	Lognormal	0.002	4.910	0.000
118	1981	chronic	alpha	Lognormal	0.002	4.910	0.000
119	1982	chronic	alpha	Lognormal	0.002	4.910	0.000
120	1983	chronic	alpha	Lognormal	0.002	4.910	0.000
121	1984	chronic	alpha	Lognormal	0.003	4.910	0.000
122	1985	chronic	alpha	Lognormal	0.003	4.910	0.000
123	1986	chronic	alpha	Lognormal	0.003	4.910	0.000
124	1987	chronic	alpha	Lognormal	0.004	4.910	0.000
125	1988	chronic	alpha	Lognormal	0.004	4.910	0.000
126	1989	chronic	alpha	Lognormal	0.004	4.910	0.000
127	1990	chronic	alpha	Lognormal	0.004	4.910	0.000
128	1991	chronic	alpha	Lognormal	0.004	4.910	0.000
129	1992	chronic	alpha	Lognormal	0.005	4.910	0.000
130	1993	chronic	alpha	Lognormal	0.005	4.910	0.000
131	1994	chronic	alpha	Lognormal	0.005	4.910	0.000
132	1995	chronic	alpha	Lognormal	0.005	4.910	0.000
133	1996	chronic	alpha	Lognormal	0.005	4.910	0.000
134	1997	chronic	alpha	Lognormal	0.005	4.910	0.000

Kathy Bates

From: Kathy Bates
Sent: Tuesday, August 22, 2006 2:36 PM
To: 'task4response@oraucoc.org'
Subject: Radiation Exposure Records - JZGore

Attachments: Rad Exp Title Sheet.PDF; Rad Exp JZGore Page 10 of 10.PDF; Rad Exp JZGore Page 1 of 10.PDF; Rad Exp JZGore Page 2 of 10.PDF; Rad Exp JZGore Page 3 of 10.PDF; Rad Exp JZGore Page 4 of 10.PDF; Rad Exp JZGore Page 5 of 10.PDF; Rad Exp JZGore Page 6 of 10.PDF; Rad Exp JZGore Page 7 of 10.PDF; Rad Exp JZGore Page 8 of 10.PDF; Rad Exp JZGore Page 9 of 10.PDF

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Thanks again for the follow-up.

You may contact me any time at 865-531-0885 (home) or on my cell at 865-607-1757.

My e-mail address is kathy.bates@webtechteam.com

Thanks!

Kathy Bates

Kathy Bates

From: Patricia A. Kraps [pkraps@oraucoc.org]
Sent: Tuesday, August 22, 2006 2:49 PM
To: Kathy Bates
Subject: RE: Radiation Exposure Records - JZGore

Thanks very much Kathy, I will forward to all the appropriate parties needed. In addition, I will ask this email and attachments to be included in the administrative file. We do appreciate you providing this information, thanks again.

Pat Kraps
Claimant Contacts
MJW Corp., ORAU Team
Dose Reconstruction Project
(513)924-5212
pkraps@oraucoc.org

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Subject: Employee Info

For Pat Kraps: Pat, here is a list of names I have complied of former Y-12 employees that knew and worked with my father, James Z. Gore. I do not have all the phone numbers, but I could do some searching and see if I can come up with them.

Robert J. Sharp
865-882-7576 (h)
865-574-3457 (c)
Robert Sharp actually approached me at the NIOSH OCAS Advisory Board meeting held in Oak Ridge, TN in January 24-26 and told me he worked with my father. He provided me with his name and telephone numbers and said he would be an employment reference.

N. D. Woodall (Doug)

Bruce Dyer

Tom Rowe

Howard R. Dyer *(no relation to Bruce)*
865-945-5376
Howard Dyer is my father's half brother. Howard worked at Y-12 until 1981 and then he worked at K-25 for the remainder of his career. The following is some information Howard provided to me with respect to where my father worked, at least during the time Howard was employed at Y-12.

Here are some of the things I remember (up through 1981, when I went to K-25):

Jim's office was in 9212, just outside a large depleted uranium machine shop (I think it was called the 9212 "A" Shop - there was also another shop adjacent to that one, but I do not remember its name). Across the hall was a tool grinding shop (supervised by Reg Lovell, who currently lives in Norris). Jim was in most all of the shops at Y-12 (enriched and depleted uranium machine shops). He did have a "Q" security clearance - which everybody there had to have. Also, at this time we all worked for the Union Carbide Corp, Nuclear Division.

He was in a group called Machine Liaison, but I do not know which department. Bruce Dyer was (I think) his supervisor and Tom Rowe was also in the group - both were at the funeral.

Thanks!

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RESPONSE TO POST-HEARING QUESTIONS FROM RICHARD MILLER, SENIOR POLICY ANALYST GOVERNMENT ACCOUNTABILITY PROJECT

Post Hearing Questions, November 15, 2006 Hearing

Richard D. Miller, Senior Policy Analyst, Government Accountability Project

1) Your testimony indicates that the Administration has failed to comply with the requirements of EEOICPA in its appointments to the Advisory Board. Given the efforts of this Committee and other Members of Congress to weigh in with the Administration, how would you recommend that Congress remedy this problem?

Congress should amend EEOICPA to provide for Congress to make appointments to the Advisory Board instead of the President. HR 5840, which was introduced in the 109th Congress, authorizes the House and Senate leadership to make Board appointments on a bipartisan basis.

2) Given that the OMB has declared that the 5 options in the OMB passback memo do not reflect Administration policy, is this issue now moot? Or does Congress still need to take actions to address any DOL and OMB actions which may be geared to containing the cost of benefits?

There is no verification that the benefits containment agenda of the Department of Labor (DOL) and OMB are not being implemented. Congress may want to request documents to ascertain whether the OMB Passback options or other benefit containment actions are being undertaken. DOL testified at the Subcommittee's December 5, 2006 hearing that DOL has received no formal communications from OMB suspending the implementation of the OMB Passback.

Even though OMB testified that the Passback options do not reflect Administration policy, not all branches of the Administration are presently in synch with this posture. One of the Passback options calls for altering the balance of the Advisory Board as a means to reduce Special Exposure Cohort (SEC) approvals. Despite repeated communications to the Office of Presidential Personnel by members of Congress and the public, as well as communications between the Judiciary Committee and the White House, the composition of the 12 member Board does not meet the statutory requirement for a balance of scientific, medical and worker perspectives.

To protect the integrity of the process, HHS should be insulated from OMB and DOL's political interference. DOL should not control NIOSH and the Advisory Board's administrative costs, to prevent DOL from using this as leverage over policy matters.

3) Your testimony indicated that DOL was seeking to restrict the size of the classes included in new Special Exposure Cohorts. Please explain.

Excerpts of an October 5, 2005 e-mail from DOL to OMB that was provided by the Judiciary Committee in preparation for my testimony stated: "DOL has also experienced problems in several cases with the description of the class adopted by the National Institute for Occupational Safety and Health (NIOSH). In view of the effect and costs of an over-expansive definition, we suggest that such determinations also be subject to

OMB clearance."

Other internal DOL communications reveal efforts to reduce the size SEC classes as a way to contain costs, including the Iowa Army Ammunition Plant and the Pacific Proving Grounds.

DOL presently reviews SEC class definitions before NIOSH's SEC Evaluation Reports are presented by NIOSH to the Advisory Board on Radiation and Worker Health. This consultation is justified on the grounds of ensuring that the proposed class definition is clear enough to adjudicate. This NIOSH-DOL consultation should be open to public review, as sunlight is a necessary disinfectant to inappropriate meddling by DOL.

4) In addition to the provisions outlined in the Energy Employees Occupational Illness Compensation Improvement Act of 2006 (HR 5840), what additional improvements, if any, should be considered for Subtitle B?

(a) Clarify the definition of "Department of Energy" to include both predecessors to the Manhattan Engineering District (and the agencies implementing such work), as well as successor agencies carrying out activities previously performed by the Department of Energy, including environmental remediation activities carried out by Army Corps of Engineers and its contractors at Formerly Utilized Sites Remedial Action Program (FUSRAP) locations.

(b) Modify the definition of a "Department of Energy facility" to include "research and development" contracts.

(c) Require the Department of Labor and NIOSH to provide the "benefit of the doubt" to the claimant with respect to occupational history and exposure assessments.

(d) Modify EEOICPA to ensure that above ground test site workers in Nevada and elsewhere who have accepted payments of $75,000 under the Radiation Exposure Compensation Act and are presently barred from applying for benefits under EEOICPA, will be eligible for benefits under Subtitle B of EEOICPA, including medical, with a total lump sum benefit not to exceed $150,000.

(e) Amend the definition of beryllium vendors to include those who contracted a covered beryllium illness from exposure to residual beryllium for the time periods set forth in the NIOSH report on residual beryllium and NIOSH report updates.

(f) Add radiosensitive cancers to the list of cancers covered under the SEC, based upon the NIOSH report to Congress required in the FY 06 Labor HHS Appropriations Act.

(g) Require DOE to update its list of beryllium vendors and atomic weapons employers on an annual basis.

(h) Require NIOSH to develop a probability of causation model for chronic

lymphocytic leukemia (CLL); to amend its regulations authorizing to it dose reconstruct CLL cases; and to require DOL to reopen all cases that were denied for CLL and remand these to NIOSH for re-evaluation.

(i) Require NIOSH to provide the Advisory Board and its audit contractor with full and unfettered access to records in the possession of NIOSH or its contractors.

(j) Require full transparency as a basis for dose reconstruction. Information which is used to deny a claim or an SEC petition must be publicly available.

(k) Establish an objective basis for determining whether to add classes of workers to the SEC.

(l) Establish a NIOSH Ombudsman to assist with SECs and dose reconstructions in the Office of Director of NIOSH.

(m) Move the Final Adjudication Branch to the Office of the DOL's Administrative Law Judge.

(n) Require NIOSH to establish an education and training program through universities to assist health science professionals in securing qualifications and credentials to perform radiation dose reconstructions and pursue training in health physics.

5) Do you have any recommendations for improvements to Subtitle E?

(a) Congress will need to extend the tenure of the DOL Ombudsman which expires on October 28, 2007. Congress should have authority to appoint an Ombudsman in the event that the Department of Labor leaves this position vacant for more than 30 days. When reauthorizing the Office of Ombudsman, Congress should solicit the views of the United States Ombudsman Association in enhancing the role of the DOL Ombudsman in implementing this act.

(b) Direct DOL to modify its Subtitle E regulations to require that the standards of causation for radiation-related cancers shall be identical to those used for all other toxic substances, as set forth in Subtitle E (e.g., the illness was aggravated, contributed to or caused by exposure to radiation), and to refrain from simply reiterating the standards of causation used under Subtitle B in Subtitle E.

(c) Require DOL-developed exposure matrices to be made available to claimants in electronic and paper form.

(d) Provide for the establishment of independent physicians' panels to review appeals of Subtitle E claims that were denied for failure to establish causation, and to require DOL to adopt such findings for disputes over causation.

(e) Increase DOL's accountability by establishing an Advisory Board which reviews and makes recommendations on scientific, medical and adjudicative issues

related to Subtitle E, with such members appointed by Congress.

6) Are there additional areas of oversight that are needed before Congress considers legislating reforms to EEOICPA?

With respect to Subtitle E, Congress should review the recommendations made by the DOL's Office of Ombudsman in its annual reports to Congress. Further, Congress should hold hearings on difficulties encountered by claimants in seeking benefits under Subtitle E.

7) NIOSH has recently issued a policy dealing with conflict of interest regarding its dose reconstruction contractors. What is your view on this new policy? Does it solve the problem?

NIOSH issued a revised Conflict of Interest Policy on October 17, 2006. This policy fails to adequately address organizational and corporate conflicts of interest, and should be modified. GAO is also reviewing this policy. We believe that claimants should have the right to have their claim re-evaluated if individuals or organizations developing the technical basis for a dose reconstruction have a conflict of interest.

8) Your testimony expresses concern about conflicts of interest or conflict of roles within NIOSH and its dose reconstruction contractor. Please give some examples of conflicts of interest that need to be addressed.

Oak Ridge Associated Universities (ORAU), and its subcontractors and teaming partners, have numerous organizational and individual conflicts of interest. ORAU discloses individual conflicts of interest on its web site at www.oraucoc.org. Summarized below are two significant examples of conflict of interest.

- Rocky Flats: ORAU and its key staff have corporate and individual conflicts of interest with respect to the Rocky Flats site profile and Special Exposure Cohort Evaluation Report. DOE retained ORAU to manage the Rocky Flats neutron dose reconstruction project, and then ORAU relied upon its previous work in estimating neutron dose for the NIOSH program. Roger Falk managed the Rocky Flats health physics program, worked on the ORAU neutron dose reconstruction project and served as an expert witness for DOE contractors in opposing workers' compensation claims. Mr. Falk also drafted major portions of the NIOSH site profile (which was not disclosed), and he currently serves as a key technical resource on the NIOSH Special Exposure Cohort evaluation.

Attached is an August 7, 2006 letter from ORAU to NIOSH informing NIOSH of its corporate conflict of interest (arising out of its work on the neutron dose reconstruction project) and removing Karin Jessin as the ORAU document owner. Mr. Falk's role is undiminished even though he is conflicted and is reviewing his previous work.

- Hanford: ORAU subcontracted the drafting of the site profile to Battelle/Pacific Northwest National Labs (PNNL) in 2003, and PNNL assigned its health physics

staff to serve as the "subject experts" to help draft NIOSH's site profile. PNNL has had a long standing contract to manage the health physics program at Hanford: Don Bihl was the PNNL manager for external and internal radiation dosimetry, and Jack Fix was responsible for key elements of the Hanford health physics program. Mr. Fix also served as a defense expert for DOE Hanford opposing claims for compensation. ORAU permitted Mssrs. Fix and Bihl to research, write and revise key portions of the site profile documents for Hanford. Mr. Fix's payroll employer was recently changed from Battelle to Dade Moeller & Associates, in an apparent effort to paper over the corporate conflict of interest; however, his individual conflict of interest remains unchanged.

Mr. Fix authored a 1997 paper for PNNL entitled *Retrospective Assessment of Personnel Neutron Dosimetry for Workers at the Hanford Site* (PNNL 11196), which set forth methods for neutron dose reconstruction and in which he asserted: "the general quality of Hanford radiation exposure records appears excellent." In December, 2006, Mr. Fix represented the ORAU team addressing the adequacy of neutron exposure data (and methodology) that was challenged by the Advisory Board's audit contractor, thereby placing Mr. Fix in the posture of reviewing his previously published work (which was cited in the NIOSH site profile). Although Mr. Fix disclosed the fact that he is conflicted, NIOSH is allowing an individual with a conflict of interest to keep working on the technical basis for key decision documents. Does the simple disclosure of a conflict of interest provide conflicted contractor staff with a permission slip to continue to work on this site profile? If so, how effective is the new NIOSH Conflict of Interest Policy?

GAP is not aware of any actions by the NIOSH/CDC contracting officer to assess whether ORAU was improperly paid for activities where there was a breach of its contractual conflict of interest requirements. NIOSH has not implemented its October 15, 2002 commitment to audit conflicts of interest.

9) What financial interests do you or any family members have in the outcome of any claims under EEOICPA?

I have no financial interests, nor do any members of my family, have any financial interests in the outcome of any claims under EEOICPA.

10) What financial interest does GAP have in the outcome of claims under EEOICPA? Has GAP represented any claimants under EEOICPA Subtitle B? How many? How many EEOICPA Subtitle B claimants is GAP presently representing at this time?

GAP has no financial interest in the outcome of any claims under EEOICPA, nor is GAP receiving any funding at this time to advocate on behalf of any particular claimants.

GAP has represented 1 claimant under EEOICPA. This claim involved a survivor at Bethlehem Steel. The purpose of this appeal was to test DOL Procedures for evaluating secondary cancers under Subtitle E. The appeal was denied. GAP received no reimbursement from this claimant for costs of the appeal.

GAP does not have any representation agreements at this time with respect to claims under EEOICPA.

Attachment: August 7, 2006 letter from Kate Kimpan (ORAU) to Larry Elliott (NIOSH) concerning ORAU's corporate conflict of interest at Rocky Flats

ORAU TEAM
Dose Reconstruction
Project for NIOSH

August 7, 2006

Larry Elliot
Director
Office for Compensation Analysis and Support
Robert A. Taft Building
4676 Columbia Parkway
MS C-46
Cincinnati, OH 45230

SUBJ: ORAU Team Corporate Disclosures

Dear Larry:

In my July 26, 2006 letter I informed you of corrections we have made to the individual disclosure statements posted on the ORAU Team Website. These corrections were posted on Friday, August 4.

As a follow up to that action, we are preparing to post on our website the Corporate Conflict of Interest (COI) Disclosure Statements provided by each of our project team members and our other contractors. These statements were used to assign corporate COI to individual employees. Before the statements are posted, any privileged or confidential information will be redacted. We intend to begin with Disclosure Statements from the three major ORAU Team partners, and will follow with remaining contractors as soon as possible. We will let you know when these statements are posted.

On a related matter, it has been determined that ORAU has a corporate conflict of interest with regard to Rocky Flats. As a result, Karin Jessin has been replaced as the Document Owner for the Rocky Flats SEC Evaluation Report by Matt McFee.

Please don't hesitate to contact me if you have any questions.

Best regards,

Kate Kimpan

(TLY)

Kate Kimpan
Project Director
ORAU Team Dose Reconstruction Project for NIOSH

Oak Ridge Associated Universities | Dade Moeller & Associates | MJW Corporation
4850 Smith Road Suite 200 Cincinnati, Ohio 45212
(513) 924-1000 1-800-322-0111

PREPARED STATEMENT OF SANDRA WOLFF BALDRIDGE

Statement for the record

John Hostettler
Chairman of the Subcommittee on Immigration Border Security and Claims.
Committee on the Judiciary, US House of Representatives, Washington, DC

I thank you for the opportunity to submit a statement for the record concerning the EEOICPA on Thursday, November 16, 2006

My name is Sandra Wolff Baldridge. I represent my mother Susanna K. Wolff, who filed a claim for benefits for my father Julius Wolff under the EEOICPA. My father was employed at FMPC in Fernald, OH from 01/23/1952 until 11/01/1963. I would briefly like to share our experience and the difficulties encountered throughout the process.

The application was submitted 08/07/2001 along with the Death Certificate for 04/29/1971, stating the cause of death as carcinoma of the rectum with metastasis. A Physicians Billing Statement for surgery 05/04/1967 stated the procedure performed was an Abdominalperineal Resection. This was a radical procedure done only for cancer of the rectum. The information was reviewed by the DOL and sent to NIOSH, who developed the Dose Reconstruction based on the death certificate rather than the physician's statement.

The unavailability of medical and hospital records due to statute of limitations, made it impossible to confirm Lung Cancer as a second primary cancer. We believe it may have already been evident in my father's body at the time he retired from FMPC in 11/1963. After examining my father's FMPC medical records, I noticed the routine notation about his lung condition had strangely been omitted from the 11/1963 medical exam report.

The Dose Reconstruction was completed 06/23/2004. We responded with our objections on 08/14/2004. We challenged the change of diagnosis date and the credibility of the data used in the dose reconstruction. During preparation for the 1994 trial, it was confirmed that FMPC/Fernald documents contain some fabricated data. Some of those documents were reports that had been submitted to the AEC and DOE as required under the Atomic Energy Act. That type of data was then passed to NIOSH and was used to develop the Site Profile for Fernald.

The Final Decision was dated 04/22/2005. We were told that the Fernald Site Profile characterized the occupational radiation environment. "In cases where radiation exposures in the workplace environment cannot be fully characterized based on available data, default values based on reasonable scientific assumptions are use as substitutes". They claimed our objection was a challenge of the Dose Reconstruction Methodology and could not be addressed by the Final Adjudication Board. The Final Decision letter

also informed us that we had 30 days in which to request reconsideration of the decision, provided we had new evidence to submit.
I immediately requested access to trial documents from the 1994 United States District Court case. I was provided with a dozen documents that involve my father's work assignment. Among them was one that was very informative. It began discussing high levels of exposure to thorium from processing in Plant 6. I immediately re-read the Dose Reconstruction searching form any mention of thorium. Years earlier, my father had been given a C Permanent classification as a result of contracting hepatitis while employed at Fernald. As a result he was restricted from the thorium buildings.

Next I searched the Technical Basis Document/Site Profile for references to thorium. The discovery was alarming. NIOSH/ORAU had failed to discover the Plant 6 thorium processing. The TBD claimed the thorium records had been destroyed in the early 1970s. Despite that fact, they claim they were able to reconstruct data and even though it is not based on actual measurements it is the product of the best science available. It's my opinion that the best science available would have discovered what I discovered, before thousands of claims were evaluated based on a deficient Site Profile.

I prepared our request for reconsideration and provided the valuable new evidence. The letter was mailed on 05/20/2005.

On 07/06/2005, we received the denial of our request for reconsideration of the 04/22/2005 decision of the Final Adjudication Branch. The basis for the denial was that the request had exceeded the 30day limit from the issuance of the Final Decision. "Specifically, May 23, 2005, which is the postmark date is the earliest date on which your reconsideration request was determined to have been filed." Signed… Mark Langowski, hearing representative.

On 07/11/2005, I spoke with Merlin Hill, a claims manager at the DOL Cleveland Office. I asked him to provide me with the postal information from the envelope in which the request had been submitted. He informed me that for some unexplained reason the envelope was not part of the file….. So, the evidence on which the denial had been based had been removed from the case file. He acknowledged the letter had, however been stamped 'received May 23, 2005'. Thereby confirming the actual mailing had been prior to that date. He informed me that the case was now closed. I would have to submit a request for reopening and the basis for the request. I prepared the letter and provided a copy of the Postal Delivery Confirmation Receipt.

Several days later I met the DOL, Cleveland Director at a town meeting to discuss EEOICPA part E. I relayed the incident to her and followed up with a call at her request. She assured me the case would be sent back to Washington DC immediately. I called one week later and was told by the case worker that the file had been sent. Months passed without any acknowledgement. On 10/20/2005 I called again to check on the status of the case. At that time I was informed that the file had never been submitted for reopening.

On 12/20/2005 we were notified the Director's Order had been vacated and the case was finally being sent for reconsideration of the 04/22/2005 Final Decision.

On 04/05/2006, Thomas Daughterty [hearing rep.FAB], writes "I must deny your request for reconsideration because you have not provided any new evidence or arguments which were not addressed in the April 22, 2005 Notice of Final Decision Following a Hearing". The letter also stated that the case file was being returned to Jacksonville, FL

On 04/10/2006 I called my case worker in Cleveland to find out why the case file was being sent to FL. In that call I was told the file was actually in Denver. I was given a number to call in Denver, they confirmed they had received it. They were unsure why they had it, but agreed to send it back to Cleveland where it belonged. After the file arrived in Cleveland, I had the case worker confirm that the evidence which had been submitted 05/20/2005 was in fact in the file and not misplaced as the envelope had been. This was necessary since the 04/05/2006 letter had claimed there was no new evidence submitted. Among that evidence was a NLO document describing the hazard from the thorium processing in Plant 6 during a 3 ½ year period omitted from the Site Profile.

Not satisfied that the evidence had ever been reviewed, I sent yet another request for reconsideration. On 06/26/2006, I received a response from the DOL Cleveland Director. She claimed the evidence didn't meet the requisite and definition of evidence according to 20C.F.R.~30.320(b). She also stated that my belief that deficiencies existed in the Site Profile was my individual opinion and was not supported by the current documentation on file. This was after Larry Elliott had announced that the Fernald Site Profile was being revised.

On 07/05/2006 I responded to Ms. Prindel's claim. I brought 20C.F.R. 30.320(a) to her attention, which allows a case to be reopened without regard to whether new evidence or information is presented or obtained.

On10/27/2006 Mr. Tursic denied reopening the case. He stated that "While thorium appears to have been present in Plant 6 according to the claimants document citations, Mr. Wolff's dose reconstruction was based on actual monitoring data". "NIOSH'S approach used in the dose reconstruction is unaffected by this information, since potential for thorium exposure was considered, there is no basis for reopening.

This type of reasoning astounds me. How can he say 3 1/2years of thorium exposure was considered by scientists who didn't even know it was present, and dismiss its significance because my father was monitored for uranium????????

The filing of the SEC Petition for Fernald will at least force NIOSH to revise the Site Profile. The evaluation just released, states they now have over 1000 pieces of thorium data. How can this be? They previously claimed most of the thorium data was destroyed in the early 1970's. One can only wonder what other radiation exposures remain undiscovered.

Respectfully Submitted by Sandra Baldridge

SIGNIFICANT DOCUMENTS AND COMMUNICATIONS RELATED TO THE SUBCOMMITTEE'S OVERSIGHT OF THE ENERGY EMPLOYEES OCCUPATIONAL ILLNESS COMPENSATION PROGRAM ACT

The following documents and communications are significant items the Subcommittee has come across during its oversight investigation on EEOICPA. The Subcommitte found that there is a continuous stream of communications too numerous to include in the record dating from 2002-2006 that reflect a general mentality in the DOL hierarchy from the Assistant Secretary level down to the health physicists reviewing cases that --

a. Costs are the primary consideration in DOL policy regarding the program.
b. Any other opinion (executive and legislative) that conflicts with DOL policy and opinions is borne of ignorance, an attempt to defraud the American taxpayer, politics, or some vague personal agenda.
c. Everyone except DOL is in the pocket of the worker advocates or pursuing an agenda for financial gain.
d. Exaggeration of the impact of every action by the Advisory Board and the Secretary of HHS is required when reporting to the Secretary of Labor.

Additionally, the Subcommittee found numerous communications dating from 2002-2006 within the HHS offices involved with EEOICPA as well as between those HHS offices and DOL strategizing on minimizing payouts. The following communications are a small sampling of such communications. Relevant correspondence as well as historical and research documents have also been included.

Gerstell, Amanda

From: Homoki, Zeda (Liz) E.
Sent: Wednesday, October 17, 2001 4:28 PM
To: Johnson, Sherman (OS); Gilchrist, Joseph A.
Cc: Neton, Jim; Armstrong, Mary M.
Subject: conflict of interest

Tracking:

Recipient	Delivery	Read
Johnson, Sherman (OS)		
Gilchrist, Joseph A.	Delivered: 10/17/2001 4:28 PM	Read: 10/18/2001 7:32 AM
Neton, Jim	Delivered: 10/17/2001 4:28 PM	Read: 10/17/2001 4:33 PM
Armstrong, Mary M.	Delivered: 10/17/2001 4:28 PM	

Sherman/Joe - I just wanted to check and see if any progress had been made on the conflict of interest issues for the OCAS/NIOSH contracts? OCAS prefers to have 1 contract with provisions for the contractor to hire a sub-cont. to do any conflicts work. Jim Neton is trying to work this out, he should be able to explain the issues and concerns directly better than I, do you want me to arrange for a conference call to get some closure on this? OCAS really wants to get this contract finalized ASAP! thanks for your help! - Liz

ZEDA E. (LIZ) HOMOKI
CDC/OGC
202-401-0834
HHH, RM. 724-H3

Gerstell, Amanda

From: Sundin, David S.
Sent: Tuesday, November 13, 2001 11:14 AM
To: Hornoki, Zeda (Liz) E.
Cc: Neton, Jim
Subject: conflict of interest issue for DR contract

Liz - Jim Neton is finalizing the responses to the comments received at the pre-bid conference on the dose reconstruction contract. One of the issues raised in those comments, which will also need to be addressed in the request for contract announcement concerns how to deal with potential conflicts of interest for bidders who previously worked under contract for DOE facilities managing some aspect of the exposure monitoring/reporting process. I believe you raised this issue with Sherman Johnson about a month ago. Have you heard anything back yet? Thanks.
dss

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Notes for DOL/HHS/DOE Deputy Secretary Conference Call
July 2, 2002

Coordination of EEOICPA activities with HHS/NIOSH continues to be excellent and very productive. The NIOSH regulations on Probability of Causation (POC) and Dose Reconstruction are fully implemented by both NIOSH and DOL. The first claim processed under these regulations for a claimant who worked at Oak Ridge Y12 Plant has received a Final Decision awarding benefits. This individual was involved in a "criticality" accident receiving extremely high doses of radiation. Eleven additional dose reconstruction reports are under final processing by NIOSH and will be sent to DOL shortly.

Coordination of activities with DOE has not been as smooth. While the utilization of the ORISE database has been very successful and continues to be improved, employment verification by DOE continues to be very problematic and in a number of situations appears to have deteriorated.

Other activities with NIOSH involve the NIOSH Notice of Proposed Rulemaking (NPRM) on Guidelines for Additions to Special Exposure Cohorts (SEC) published on June 25, 2002. DOL reviewed this NPRM and appreciates the cooperation by NIOSH in addressing our concerns. The initial reaction to this NPRM appears to involve issues with which DOL concurs with the NIOSH approach. These are:

- Stakeholders expressed concern regarding the methodology for determining the most radiogenic cancer to be used in determining whether to include a class of employees in the SEC. The approach taken by NIOSH in the NPRM was adopted in response to DOL suggestions in this area in order to more accurately reflect the actual possibility that members of the proposed class suffered cancers caused by their exposure to radiation.

- Objections were raised that the NPRM process would be limited to facilities or classes of workers where NIOSH could not perform a dose reconstruction.

- Concerns were expressed relating to the process for DOL adjudicating claims after a SEC was added. Stakeholders raised the possibility that DOL's SEC determination of claims of employees added to the SEC would be biased if DOL had previously rejected the claimant's non-SEC cancer claim. DOL will attend the four proposed NIOSH public meetings to explain the NPRM to address the integration of the process into the DOL claims process.

NOTE: Senator Harkin has written to DOL (and perhaps HHS?) raising concerns regarding delays in implementing the dose reconstruction process. We were

advised this week that NIOSH now believes its contract for mass processing of dose reconstructions – to address the more than 5000 cases DOL has already referred to NIOSH for this process and the thousands more expected – will not be let until late August. Given a built-in 90 transition/start-up period, this means that a significant number of dose reconstructions will not begin to flow back to DOL until December at the earliest.

The DOE Employment Verification process continues to be problematic. An interagency records working group has been actively working for several months, however DOE's response to DOL's concerns has consisted primarily of responding to problems that arise from unilateral process changes at the DOE Records Centers. **[These process changes cause significant delays and quality problems in the employment verification process, which could have been averted if DOE had coordinated operational changes with DOL prior to implementation by the DOE Records Center. These problems often arise after implementation of Directives issued by DOE Office of Workers Advocacy.]** These on-going record issues include:

- Timeliness of DOE responses to employment verification requests has not improved and in many instances has deteriorated. The only exceptions are cases where the ORISE database is sufficient to verify employment.

- A number of DOE Records Centers have become extremely lax and inconsistent in the extent of their record searches resulting in very serious problems with the quality of the DOE verification.

  - Some Records Centers are requiring DOL to provide them with a contract number for subcontractors before they will search the records, even though the subcontract was a DOE contract.

  - Some Centers will only search by employee SSN even though the necessary records may be included in records that are filed by date or by employee name. **[This issue was raised to the working group with the DOE resolution being that they will address this type of situation on a case by case basis when DOL finds out that the Center is using a process such as this.]**

  - Some Centers are merely scanning hundreds of pages of records – most of which are not employment records – and then sending them to DOL on a CD with no verification, or explanation.

  - The Oak Ridge Records Center recently had over 500 employment verification requests pending for over 60 days.

During the May 31st conference call preparing for the June 3rd public hearing in Oak Ridge, the DOE Records manager reported that about 500 verifications were sent to the District Office the previous evening. We modified our presentation based on this information. We have not yet received these verifications.

In early March 2002, it was agreed in a Deputy Secretaries conference call discussion about records problems that DOL District Directors and staff should meet with the individual DOE Records Centers to establish an efficient and effective process for the individual situations. The Office of Worker Advocacy was assigned responsibility to make arrangements for such visits – DOL has requested the status of these arrangements on a weekly basis. The first such visit was recently set up, but then cancelled by DOL because the primary DOE records contact person was not going to be available for the meeting.

- The FY 2003 Defense Authorization bill passed the Senate without any EEOICPA amendments. A number of amendments were discussed with DOL that caused serious concern, including a proposal to move all or part of the state workers' compensation assistance program for other occupational diseases from DOE to DOL. Apparently, a decision was made by interested members of the Senate to postpone any further amendments, but to hold hearings in the very near future on various EEOICPA issues.

Gerstell, Amanda

From: Naimon, David
Sent: Thursday, September 12, 2002 12:22 PM
To: Armstrong, Mary M.
Cc: Kelley, Alice A.; Homoki-Titus, Zada (Liz) E.
Subject: Contractor Conflict of Interest Rules

Dave Sundin just told me that they are interested in having someone speak at the contractor kick-off next Wednesday on the issue of what constitutes a conflict of interest -- and particularly the "appearance" of conflict of interest. Do you have any suggestions for someone who would be knowledgeable in this area? They will be talking with Larry Guest, but were also thinking there may be law in this area. My only thought was that the Office of Government Ethics must deal with "appearance" issues for employees every day, but I'm not sure how this translates for contractors. Thanks.

David

ORAU TEAM CONFLICT OF INTEREST POLICY (Rev. 1a OGC draft)

A. Overview

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In any situation that involves compensation for injury, whether a tort claim, a worker's compensation case, or a claim made under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA), the integrity of the process must be unimpeachable. This is particularly true under the EEOICPA, because one branch of the U.S. government (i.e., DOE) was responsible for the exposures to ionizing radiation and hazardous substances and is also charged with providing data to assist in adjudicating claims, while other branches of the government (i.e., NIOSH, DOL) are responsible for administering and operating the program. Many of the persons working for the government on this program, whether as federal or contractor employees, have had previous involvement in the conduct of radiation protection programs at DOE facilities; or they may have previously received or are currently receiving financial support or compensation from DOE.

The ORAU Team is extremely sensitive to the concerns in the stakeholder community regarding perceived or actual conflicts of interest (COI). We understand why the bar on perceived and actual conflicts of interest must be set higher for this project than is established by the COI provisions of the Federal Acquisition Regulations (FAR).

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The critical consideration is not whether the *potential* for COI exists – it does. The most important factors are that the contractor must have a rigorous and precise plan for identifying potential COI situations and avoiding them; and that NIOSH, and the stakeholder community, must be assured the contractor will carry out that process with absolute integrity. Although some may view it as not desirable that persons with any sort of DOE affiliation be involved in dose reconstruction or Special Exposure Cohort (SEC) petition review, it is inevitable that many such persons must be involved, especially in the process of research. For example, it is a simple fact that health physicists who have expertise in the internal radiation dosimetry of plutonium must have learned their trade at DOE facilities simply because that is where the plutonium is. Similarly, the research effort to develop Site Profiles for the various sites will necessarily involve persons with expert knowledge of the sites, and that knowledge will usually have been gained from having worked there. Therefore, given these inherent potential conflicts, the contractor selected for the dose reconstruction project, along with NIOSH, must do everything possible to prevent or manage actual and perceived conflicts of interest and to disclose all potential conflicts of interest.

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ORAU, a non-profit association of universities, was chartered in 1946. In the ensuing five decades, we have gained unparalleled experience in maintaining the integrity of technical processes while working with many issues of public concern. Lessons learned from those experiences have been woven into the culture and structures of ORAU. Providing objective science-based studies and analyses that withstand the COI challenge is more than something we do – it's a part of who we are.

ORAU and its employees are committed to the highest ethical standards. All ORAU employees receive mandatory initial and refresher training in ethics, with emphasis on the ethical issues covered by these policies. This training will be made mandatory for all persons working on this project, including subcontractors, and will be conducted during the start-up phase, with annual refreshers thereafter. Copies of the training materials can be provided to NIOSH for the project files. ORAU will maintain documentation of the successful completion of this (and other) training for all personnel working on this project, whether ORAU or subcontractor employees.

B. COI Policy

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ORAU is committed to full and open disclosure as the best way to prevent conflicts of interest.

Deleted: The Government Accountability Project has provided some useful guidance on avoiding conflicts

The ORAU Team will disclose, for each company and for each individual involved in dose reconstruction, preparation of Site Profiles, research supporting SEC determinations of whether or not to add a class of employees to the SEC, or any other work done for NIOSH on behalf of the EEOICPA program, information about their past and present work at DOE sites. In addition, the ORAU Team members will inform NIOSH of any new DOE work that they are awarded. ORAU and its subcontractors will be proactive in making its processes for avoiding COI available to all stakeholders.

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Deleted: NIOSH Dose Reconstruction Project. ORAU agrees completely that "sunshine is

Deleted: best disinfectant."¶ The ORAU Team will disclose, for each company and for each individual involved in dose reconstruction,

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There are three aspects to effective disclosure/avoidance of conflict of interest:

- Planning of the work by the contractor;
- Oversight by NIOSH of COI performance; and
- Disclosure to stakeholders of information sufficient to let them evaluate the resolution of potential concerns about conflict of interest.

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The ORAU Team will construct a database that lists all DOE sites where team members have worked, and outlines all potential areas of conflict of interest. This database will be used by the Project Director and Task Managers in making and checking work assignments for dose reconstruction, preparation of Site Profiles, or research supporting SEC determinations of whether or not to add a class of employees to the SEC. All individuals and companies on the ORAU team will provide the necessary information to populate the database initially, and will update it as necessary.

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Access to the database will be provided to NIOSH for oversight of this contract. Because few claimants or stakeholders are likely to be able to use the database itself, printouts about the persons performing individual dose reconstructions (and their companies) will be offered upon request. Requests will be fulfilled within the requirments of privacy interests. Beyond this, ORAU will work with NIOSH to find the best way to allow stakeholders to also request specific information.

Deleted: The ORAU Team believes that access to this information by individual

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The database will be constructed to provide the following information to the ORAU Team, to NIOSH, and upon request to claimants and other stakeholders:

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- Whether and where ORAU, a subcontractor, or individual employees of ORAU or a subcontractor is, was or will be (in the next 12 months) involved in managing or directing DOE radiation protection and health physics program policies, practices and /or procedures.

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- Whether and where ORAU, a subcontractor, or individual employees of ORAU or a subcontractor is, was or will be supporting, directly or indirectly, decision making in a radiation dosimetry program. This includes a contractor/subcontractor that is an (M&O/M&I), team member of an M&O/M&I, or a program manager of such a program.

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- Whether and where ORAU, a subcontractor, or individual employees of ORAU or a subcontractor has broad technical support contracts or task-based contracts in place at DOE sites whose Statement of Work permits them to currently complete or be broadened to include the above radiation dosimetry work.

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- Whether and where ORAU, a subcontractor, or individual employees of ORAU or a subcontractor has an active interest in bidding for the above DOE work activities and such interest has been properly disclosed elsewhere publicly (through public announcements, media or other disclosures.)

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- Whether and where any individuals conducting dose reconstruction, preparation of Site Profiles, or research supporting SEC determinations of whether or not to add a class of employees to the SEC for the ORAU team have acted as expert witnesses on behalf of DOE or a DOE contractor with respect to worker compensation claims or law suits involving the question of whether radiation exposure was responsible in whole or in part for an alleged injury.

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- Whether any individuals conducting dose reconstruction for ORAU or subcontractors have former colleagues or co-workers whose claims they may receive for dose reconstruction by virtue of the DOE facilities or sites assigned to them.

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- Whether ORAU and its subcontractors and their employees are reviewing reports, assessments, surveys, documents and records that they organizationally or individually have been responsible for authoring, developing, or submitting to DOE or its contractors. ORAU will further indicate if ORAU, a subcontractor, or individual employees of ORAU or a subcontractor was an unidentified contributor to any such reports, assessments, surveys, documents or records.

To avoid potential for actual or perceived conflicts of interest in dose reconstruction or other activities under this contract, ORAU, its subcontractors, and the individual employees of ORAU or a subcontractor will subscribe to the following restrictions:

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- No contractor, subcontractor, or employee will perform, review, or approve dose reconstructions for claimants from a given DOE/AWE site, prepare a Site Profile for that site, or provide support for an SEC determination of whether or not to add a class of employees to the SEC from that site, if they have previously performed work that affected or established policies on radiation dosimetry assessments, dosimetry programs or records at that site.

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- No contractor, subcontractor, or employee will perform, review, or approve dose reconstructions for claimants from a given DOE/AWE site if they have previously been involved with DOE funded dose assessments or reconstructions for workers from that site.

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- No contractor element will participate in or review dose reconstructions or participate in research supporting Site Profiles or SEC determinations of whether or not to add a class of employees to the SEC for those DOE sites or activities where it is the prime contractor (i.e., M&O/M&I), team member to a prime contractor, program manager or subcontractor managing dosimetry programs, or otherwise intends to be employed as such within 12 months of starting this contract (or ending this contract?).

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- No individual will perform, review, or approve radiation dose reconstructions, prepare Site Profiles, or conduct research supporting SEC determinations of whether or not to add a class of employees to the SEC, if he or she has voluntarily acted as an expert witness (including a non-testifying expert) on behalf of DOE or a DOE contractor in defense of radiation dose claims or suits. Restrictions for an individual who acts under subpoena will be determined on a case-by-case basis.

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- No individual will perform, review, or approve radiation dose reconstructions for co-workers, DOE facilities at which they were formerly employed, or for contractors by whom they have been employed. Site experts may be employed to advise on site specific issues and incidents as necessary.

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- No contractor or subcontractor element will be permitted to perform or bid for collateral work on DOE radiation dosimetry program support for those sites where it is conducting dose reconstructions, preparing a Site Profile (or scheduled to prepare a Site Profile), or performing work supporting an SEC determination of whether or not to add a class of employees to the SEC.

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- Key personnel of the ORAU team will not have a conflict of interest with respect to managing this project or carrying out or marketing radiation protection/health physics services elsewhere in DOE.

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- Each supervisor, dosimetrist, and reviewer, and each professional preparing a Site Profile or performing work supporting an SEC determination of whether or not to add a class of employees to the SEC, will be required to complete and sign the

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attached form agreeing to abide by the above requirements. The forms will be maintained as auditable records of this project.

Deleted: If NIOSH concurs, these forms will also be scanned and posted on a web page ORAU will maintain for this project; links to the ORAU page will be provided for the NIOSH/OCAS and DOL web pages for this project.

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- No contractor, subcontractor, or individual will perform, review, or approve radiation dose reconstructions, prepare Site Profiles, or conduct research supporting SEC determinations of whether or not to add a class of employees to the SEC if the company or individual has voluntarily provided expert witness services (including a non-testifying expert) on behalf of DOE or a contractor in defense of any claim filed under the EEOICPA. Restrictions for an individual who acts under subpoena will be determined on a case-by-case basis.

- A form identifying the dosimetrist who performed the dose reconstruction and the reviewer who approved it will be attached to each dose reconstruction and SEC determination, and provided to the claimant or petitioner(s) as appropriate, along with short biographical sketches.

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All subcontracts issued to support ORAU in EEOICPA will contain a clause to ensure that the subcontractor complies with ORAU policy (stated here) regarding conflict of interest.

Gerstell, Amanda

From: Kelley, Alice A.
Sent: Thursday, September 12, 2002 4:42 PM
To: Naimon, David; Armstrong, Mary M.
Cc: Homoki-Titus, Zeda (Liz) E.
Subject: RE: Contractor Conflict of Interest Rules

Who is Larry Guest? I couldn't find him in the directory.

If I remember correctly from my contract law days, the Federal Acquisition Regulation (48 CFR Chapter 1) has a section about contractor conflicts of interest. The contracts office may have someone who can talk about that, or you could call Skip Mancuso in the BAL Division and ask if one of the contract attorneys could join you (by phone?).

Alice A. Kelley
Senior Attorney

-----Original Message-----
From: Naimon, David
Sent: Thursday, September 12, 2002 12:22 PM
To: Armstrong, Mary M.
Cc: Kelley, Alice A.; Homoki-Titus, Zeda (Liz) E.
Subject: Contractor Conflict of Interest Rules

Dave Sundin just told me that they are interested in having someone speak at the contractor kick-off next Wednesday on the issue of what constitutes a conflict of interest -- and particularly the "appearance" of conflict of interest. Do you have any suggestions for someone who would be knowledgeable in this area? They will be talking with Larry Guest, but were also thinking there may be law in this area. My only thought was that the Office of Government Ethics must deal with "appearance" issues for employees every day, but I'm not sure how this translates for contractors. Thanks.

David

Elliott, Larry J.

From: Katz, Ted
ent: Wednesday, December 11, 2002 11 58 AM
To: Neton, Jim; Elliott, Larry J.; Sundin, David S.; Naimon, David
Subject: Board meeting, statement of work/evaluation criteria

Importance: High

Jim/Larry/Dave/Dave: Some thoughts about the SOW & EC to be discussed tomorrow. --Ted

SOW

Advanced Dose Reconstruction Review -- (1) I think it should be prescribed in the contract that if the review includes interviews with claimants to evaluate their satisfaction with NIOSH interviews, these interviews must be developed by qualified social scientists (not health physicists) and must be administered to a statistically representative sample of claimants, and evaluated using standard inferential statistical methods. (2) I do not think the contractor should be allowed to interview the claimants to evaluate the completeness and accuracy of the interviews ("effectiveness in ascertaining relevant work history information"), since claimants themselves are responsible for assuring completeness and accuracy of reported information and since, once a claim is denied, the claimant has first order conflict of interest with respect to the assessment of his/her interview.

NIOSH Site Profile and Worker Profile Review -- I'm very concerned by the provisions for the contractor to in effect, compete with us to tap as many sources as possible (unions, etc.) to identify information that might not be included or accurate in our site profiles. I have two issues with this: (1) Judgments of adequacy of the profiles have to be bounded by consideration of the DRs and SEC petitions that we have completed at that point in time. Our site profile is being developed in part by plan and in part by ad hoc collection of information through individual dose reconstructions and sec petition evaluations. Hence, at any given time, our site profile only needs to be as accurate and complete as was needed to complete the dose reconstructions we had in hand at the time or the SEC petitions we had evaluated up to that time. By plunging into non-primary data sources, such as unions or individual investigators at universities, the contractor would readily uncover information yet to be required for a NIOSH dose reconstruction, resulting in a finding that our profile was incomplete. Dr. Ziemer recognized the problem of reviewing the profiles at any point in time, but I don't recall anyone indicating that the judgment of adequacy has to take into account the specific DRs or SEC determinations that required or should have required the use of the profile information at that point in time. (2) Given the contractor will be seeking to discover any sources we might have missed, we probably need to have our contractor go systemmatically to ALL the sources identified by this SOW as part of the contractors site profile enterprise.

EC

Conflict of Interest -- There was some discussion at the last Board meeting about avoiding bias in any direction with respect to the DR reviews --specifically with respect to HPs that may have been involved in litigation involving DOE. I think this needs more discussion. The current plan limits the possibility that the awardees have a bias in favor of DOE but does not have any provisions to limit bias against the government. Some members of the Board thought this was unnecessary, because the point was to be certain that the auditor has the faith of the claimants. But this view seems wrong. The Board should have an equal interest in assuring the government is not treated unfairly either, since this would damage the effectiveness of the government program, the participation and views of

potential claimants, and the views of the public at large. Seems to me a principal of any auditing is that it must be disinterested. Hence, seems to me any contractor with a history of serving litigation against the government, or who has worked for an organization litigating against the government with respect to relevant matters (e.g., workers' compensation, toxic torts), should be treated by the evaluation criteria in similar fashion to those with links to DOE or NIOSH.

01/15/2003

NIOSH Responses to DOL 12/27/2002 Comments
Draft HHS Procedures for Designating Classes of Employees as Members of the Special Exposure Cohort under the EEOICPA; Notice of Proposed Rulemaking; Draft 12/11/02

DOL General Comments

1. Section 83.13(b)(3) of the HHS regulations states provides NIOSH with three options concerning the minimum duration requirement to qualify for inclusion in an additional SEC class. For classes established on the basis of a discrete incident, NIOSH can specify presence and potential exposure during the incident as the only duration requirement. NIOSH can also choose to specify that the duration requirement for a class as the same requirement imposed by Congress for employees of GDP's, i.e. an employment duration aggregating 250 workdays. The regulations provide a third alternative under which the minimum employment duration of less than 250 days is specified is based upon the number of workdays equaling the period of a DOE operation or AWE operation during which doses cannot be estimated with sufficient accuracy. DOL suggests that a more specific discussion of the duration requirement to be utilized in regard to classes where less than 250 workdays is required be included in the Preamble. Particularly in regard to classes that are not based on a specific incident, it would be useful to articulate whether the duration to be imposed is based upon duration of employment or upon actual exposure. It would also be useful to provide guidance concerning situations where a number of potential members of the additional class differ in the lengths of their employment in affected positions or in their exposure to the conditions justifying the establishment of the class.

   NIOSH Response: The DOL comment led NIOSH to recognize a problem with the "third alternative, which would have allowed HHS to specify a duration requirement of fewer than 250 days based on the fact that an operation persisted for fewer than 250 days. The problem is that, under this provision, employees would be required to have been employed for the full duration of the operation, which is arbitrary with respect to health endangerment. If an operation lasted 200 days, only employees who were employed for the full 200 days would be included in the class. But there is no rational basis for determining that health was not also endangered for employees employed for 190 of the 200 days. Under the provision, a positive determination of health endangerment would be simply an artifact of the duration of the operation. Moreover, any revision of this provision would confront the same basic problem, which is that it will be impossible to rationally define any duration of employment that equates with health endangerment, since we will not be able to estimate the dose rate of radiation exposures. At any duration we might specify, someone could argue with merit that a shorter duration might also have endangered health.

To solve this problem, we have eliminated this provision entirely. In its place, we will rely on the remaining provision concerning discrete incidents. This provision does not require HHS to specify any duration of employment requirement, recognizing that presence during the incident (for any duration) would constitute potential health endangerment. We have clarified this provision and our explanation of it in the preamble so that it does not restrict HHS from applying it to any operational conditions under which high radiation exposures are likely to have occurred.

2. In III. Summary of Public Comments, B. Accuracy of Dose Reconstructions, we recommend that NIOSH include in the text an explanation for the conclusion in the last sentence in the section that EEOICPA does not authorize HHS to limit the membership of a class to those employees incurring selected cancers from among the list of specified cancers. DOL is not aware of any provision in EEOICPA that specifically bars HHS from defining a class of employees for inclusion in the Cohort by specifying that each class member must have incurred a certain one or more specified cancers. In § 7384l(9), a "covered employee with cancer" is defined as including "[a]n individual with **a specified cancer** who is a member of the Special Exposure Cohort ..." (emphasis added). The definition of a class as limited to employees who sustained a particular cancer does not appear to be incompatible with that definition. Of course, once included in the SEC an individual would be entitled to benefits for any specified cancer that he or she incurred.

NIOSH Response: Based on the DOL interpretation of the statutory requirements of EEOICPA and further discussion within HHS, NIOSH concurs that EEOICPA would allow HHS to limit the membership of a class to those employees incurring selected cancers. Hence, NIOSH has added new provisions, section 83.13 (b)(1)(iv), 83.13(b)(2)(iii), and 83.13(c)(4), that would allow NIOSH to limit membership in a class to individuals incurring one or more types of cancer, when appropriate. These provisions make the rule fully consistent with the science of estimating radiation doses and with the statutory requirement that HHS find that it is not feasible to estimate radiation doses with sufficient accuracy for classes of employees that HHS would add to the Cohort.

3 The HHS regulations provide that after NIOSH has evaluated a petition for the addition of a class to the Cohort, it shall submit a report of its evaluation to the Board. The Board will then consider the NIOSH evaluation and other information it deems appropriate and will submit its recommendation to the Secretary of HHS. HHS will issue a final decision on the petition, after consideration of NIOSH's evaluation and the Board's recommendation. As the administrative process involves several determinations made by different expert bodies on the merits of the petition, we believe it would be prudent and might decrease the risk of premature litigation if the regulations affirmatively stated that the issuance of a final decision by HHS marks the exhaustion of all administrative review opportunities and the stage of the process at which petitioner(s) may

appropriately seek judicial review. For the same reason and for the purpose of achieving consistency within the HHS regulations, the procedures for petitions that do not meet the initial threshold requirements for evaluation should similarly provide that upon transmittal of the written report by NIOSH notifying the petitioner(s) that the petition has not been selected for evaluation, the administrative process has been completed and the petitioner(s) may seek judicial review.

DOL suggests that the following new section (d) be added to § 83.16 of the HHS regulations: "Upon the issuance of a final decision on the designation and definition of the class by HHS pursuant to (c) above, the petitioner(s) may seek judicial review of such final decision as all administrative review opportunities have been exhausted." Also, DOL suggests that the following new section (f) be added to § 83.11: "Upon the transmittal of a written report by NIOSH notifying the petitioner(s) of its finding to not select the petition for evaluation pursuant to (b) above, the petitioner(s) may seek judicial review of such NIOSH finding as all administrative review opportunities have been exhausted."

NIOSH Response: We have revised section 83.11 to clarify the order of the procedure, and have labeled NIOSH's decision under the new 83.11(d) as the "final decision that the petition has failed to meet the requirements for evaluation." We think a more detailed discussion of the possibility of judicial review would be counterproductive.

Section 83.16(c) already says that "HHS will issue a final decision on the designation and definition of the class" – which clearly indicates that all administrative review opportunities have been exhausted. We think a more detailed discussion of the possibility of judicial review would be counterproductive.

Suggested Clarifications

- II. Background, A. Statutory Authority – First paragraph, first sentence, delete the period before "EEOICPA" and substitute a comma, and insert a comma after "EEOICPA".

NIOSH Response: Change made.

- II. Background, A. Statutory Authority – Second paragraph, second sentence, strike "interim" and replace "May, 25, 2001 (66 FR 28948)" with "December 26, 2002 (xx FR xxxxx)." The proper citation to the Federal Register can be added when it becomes available.

NIOSH Response: Change made.

- II. Background, B. What is the Special Exposure Cohort? – First paragraph, second sentence, delete "who were or could have been monitored in those jobs using dosimetry badges;" and substitute, "who were monitored using dosimetry badges or worked in a job that had exposures comparable to a job that is or was monitored using dosimetry badges;".

NIOSH Response: Change made.

II. Background, B. What is the Special Exposure Cohort? – Footnote 1, second sentence, strike the language "and the provisions governing compensation for the Cohort".

NIOSH Response: Change made.

- II. Background, D. Statutory Requirements for Designating Classes of Employees as Members of the Cohort – First paragraph, second sentence, replace "DOE, and other such information as the Board considers appropriate" with "the Department of Energy, and such other information as the Advisory Board considers appropriate".

NIOSH Response: Change made.

- II. Background, D. Statutory Requirements for Designating Classes of Employees as Members of the Cohort – First paragraph, fourth sentence, after "employees" insert ". . ." in order to signify that language has been omitted from the quotation.

NIOSH Response: Change made.

- II. Background, E. Relationship of Proposed Procedures to Existing Rule Promulgated by HHS to implement EEOICPA – First paragraph, first sentence, insert "on May 2, 2002" after the second "HHS" and substitute "(67 FR 22314)." for "(67 FR 22314, May 2, 2002)."

NIOSH Response: Change made.

- III. Summary of Public Comments, B. Accuracy of Dose Reconstructions – Sixth paragraph, first sentence, substitute "qualitative" for "qualified".

NIOSH Response: No change made. The current standard is more qualified, in the sense of being more particular or specific, than the previous standard. Both the original and the current standard are qualitative.

- III. Summary of Public Comments, C. Health Endangerment – Third paragraph, first sentence, insert comma after "identify" then insert comma and delete "of" after "parameters".

NIOSH Response: Change made.

- III. Summary of Public Comments, D. Timeliness of Dose Reconstructions and Petition Decisions – Third paragraph, second sentence, insert "for evaluation" after "establish".

NIOSH Response: Change made.

- III. Summary of Public Comments, D. Timeliness of Dose Reconstructions and Petition Decisions – Seventh paragraph, third sentence, substitute "83.11" for "43.11".

NIOSH Response: Change made.

- III. Summary of Public Comments, F. Modifications and Cancellations of Cohort Additions – Second paragraph, delete the second sentence, "Persons interested in this issue should contact DOL." since DOL would find it difficult to provide useful guidance on the issue at this premature stage in the absence of specific factual scenarios.

NIOSH Response: Change made.

- III. Summary of Public Comments, T. Regulatory Approach – Fourth paragraph, delete second sentence beginning "To the extent".

NIOSH Response: No change made. NIOSH could not locate the text referred to in this comment.

- III. Summary of Public Comments, Y. Non-regulatory comment: Basis for Limiting Cohort Provisions to the 22 Specified Cancers – Third paragraph, first sentence, delete "for non-cancer health effects," and insert "contractor" after "DOE".

NIOSH Response: We clarified the paragraph consistently with this comment.

- IV. Recommendations of the Advisory Board on Radiation and Worker Health – Mark section headings, "Recommendation for Section 83.5", "Recommendations for Section 83.9", "Recommendation for Section 83.10", "Recommendation on Section 83.13", and "Recommendation on Section 83.15" as F., G., H., I., and J., appropriately. Also, in the section heading, "Recommendation on Section 83.15", substitute "83.14" for "83.15" and in the first paragraph, first sentence under that heading, again substitute "83.14" for "83.15".

NIOSH Response: Change made.

- V. Publication of a Second Notice of Proposed Rulemaking – First paragraph, second sentence, substitute "qualitative" for "qualified".

NIOSH Response: No change made. As discussed above, the current standard is more qualified, in the sense of being more particular or specific, than the previous standard. Both the original and the current standard are qualitative.

- VI. Regulatory Assessment Requirements, C. What are the Paperwork and Other Information Collection Requirements (Subject to the Paperwork Reduction Act) Imposed Under this Proposed Rule, and How Are Comments Submitted? – First paragraph, fourth sentence, substitute "The Centers for Disease Control and Prevention (CDC)" for "CDC".

NIOSH Response: Change made.

- Subpart B – Definitions, § 83.5(c) – Replace "such exposures" with "exposures to radiation".

NIOSH Response: Change made.

- Subpart B – Definitions, § 83.5(g) – After "was", insert ", for the purposes of EEOICPA,".

NIOSH Response: Change made.

- Subpart B – Definitions, § 83.5(k)(3) and (4) – Delete period and replace with semicolon.

NIOSH Response: Change made.

- Subpart B – Definitions, § 83.5(k)(5) – Delete colon and replace with semicolon.

NIOSH Response: Change made (although the grammar is unusual – lists are normally preceded by colons, rather then semicolons).

- Subpart B – Definitions, § 83.5(l) – After "employee", insert "as defined in EEOICPA"

NIOSH Response: Change made.

- Subpart C – Procedures for Adding Classes of Employees to the Cohort, § 83.6 – First paragraph, second sentence, replace "an employee" with "a class of employees" and replace "the employee" with "an employee".

NIOSH Response: Change made.

- Subpart C – Procedures for Adding Classes of Employees to the Cohort, § 83.7(b) – Insert "or their survivors" after "class of employees".

NIOSH Response: No change made. Labor organizations representing survivors, wherever they might work, are not eligible to petition on behalf of a class.

- Subpart C – Procedures for Adding Classes of Employees to the Cohort, § 83.9 – Footnote 1, substitute "§ 83.16" for "§ 83.14".

NIOSH Response: Change made.

- Subpart C – Procedures for Adding Classes of Employees to the Cohort, § 83.13 (b)(2)(i) – After "characteristics", insert "of employment".

NIOSH Response: Change made.

MAY 2003 PROGRESS REPORT FOR CONTRACT NO. 200-2002-00593, "Radiation Dose Estimation, Dose Reconstruction and Evaluation of SEC Petitions Under EEOICPA."

EXECUTIVE SUMMARY:

The NIOSH OCAS Claims Tracking System (NOCTS) is now "live" at the Cincinnati Operations Center (COC) and is being replicated across the dedicated T-1 line. Also, nationwide project staff can now log problems and requests for IT services through a newly-implemented support system with telephone helpline.

Health physics screening was completed on 983 cases, and 597 cases were forwarded to Claims Tracking. It has been decided to forward claims in spite of some dosimetry data gaps, thus increasing the percentage of cases that may be forwarded for dose reconstruction. Records staff met with NIOSH Public Health Advisors (PHAs) to resolve Department of Labor (DOL) discrepancies, working toward defining discrepancies and identifying which source documents may be used for information.

Data reconnaissance trips were made to Fernald Records Center; Atlanta Federal Records Center (FRC); National Archives and Records Administration (NARA) College Park, MD; and DOE Headquarters. The Savannah River Site (SRS) technical basis document (TBD) was submitted to NIOSH for official review and comment. Teams have been assembled to develop TBDs for 11 additional DOE sites.

Four hundred fifty-seven claimant interviews were completed during May. Of the original 900 claims, we have now completed 826 interviews. The backlog on reviewing of Computer Assisted Telephone Interview (CATI) reports has been eliminated. Starting in late May, interviews were generally reviewed and mailed within three business days of being performed.

Dose reconstruction activities for the month of May have been limited to Bethlehem Steel claims because very few cases from other sites are able to be processed, pending the completion and approval of the site TBDs. Effort was directed to identify alternate claims processing scenarios and subsequent identification of claims that can be completed.

PROGRESS TOWARD COMPLETION:

Task 1. Database Management:

General Activities

The designs and processes that were formulated in April were implemented in May 2003. On May 5, NOCTS became "live" at the COC and is now being replicated across the dedicated T-1 line. This enabled many of the COC staff to perform their respective tasks

document. The issue associated with the inclusion of radium exposure is still being evaluated by OCAS.

Other Activities

A meeting to promote communication between several Tasks is planned for June. The schedule includes training on NOCTS, Project Insight, and remote use of the terminal server for Dose Reconstructors. Also, Dose Reconstruction will give Claims Tracking and Tasks 2, 3 and 4 an overview of how a dose reconstruction is done, focusing on the information needed to accomplish this task. This presentation will be followed by a general discussion among the groups.

Task 6. Administrative and Technical Support:

Ten contract revisions and new contracts were issued during May to cover the quarter ending June 30, 2003. This reflects significant increases in staffing across the project, primarily focused on dose reconstructions and development of TBDs.

The MJW and Dade Moeller & Associates contracts were increased for staffing, subcontracting, and travel associated with dose reconstruction and information technology.

As noted in the Task 3 section of this report, 11 teams were assembled to develop TBDs. The ATL, ENSR, M. H. Chew, and Shonka contracts were modified to staff these teams. New contracts were established with Auxier and Associates, Intrepid Technologies and Resources, and MFG Incorporated to form additional TBD teams with expertise about specific DOE sites.

The StaffMe.Net contract was modified to cover additional staffing, including two new computer helpline operator positions.

Dr. Toohey and other ORAU Team personnel attended the meeting of the ABRWH held in Oak Ridge on May 19-20, 2003.

Quality Assurance Program:

Meeting with NIOSH Staff

On Thursday, May 29, 2003, Nancy Daugherty met with Grady Calhoun at his office in Cincinnati. Stuart Hinnefeld joined in the meeting, and the following issues were discussed:

1. Status of ORAUT-PROC-0006, Rev 00-A, External Dose Reconstruction

Elliott, Larry J.

From: DiMuzio, Martha A.
Sent: Thursday, July 17, 2003 4:50 PM
To: Elliott, Larry J.
Subject: FW: Letters from Congress

Do you have any problems with me giving Priscilla copies of the letters?
-----Original Message-----
From: Campbell, Priscilla [mailto:Campbepb@orau.gov]
Sent: Thursday, July 17, 2003 4:48 PM
To: 'DiMuzio, Martha A.'
Subject: Letters from Congress

Martha,

You may be aware that Larry Elliott had a conference call today with representatives of Akins Crisp Public Strategies. Larry asked Akins Crisp to develop a plan to manage claimants' expectations about the time required to adjudicate a claim, about the DR process, etc.

The Akins Crisp folks asked if they might be able to see a few sample letters from Members of Congress. They want to get a feel for the tone of these letters. If you can share a few letters, please purge any claimant identifying information, and fax or e-mail to me.

Larry and Ron Townsend gave Akins Crisp an August 1 deadline to develop a proposal, so they are anxious to see these letters by Monday, July 21, if possible.

Sincere thanks,
Priscilla

Priscilla Campbell
Oak Ridge Associated Universities
Phone: (865) 241-2871
Fax: (865) 241-9769
campbepb@orau.gov

Gerstell, Amanda

From: Naimon, David
nt: Wednesday, September 17, 2003 4:18 PM
J: Homoki-Titus, Zeda (Liz) E.
Subject: Fw: COI Addendum to BPA 7-5445

Importance: High

attach.zip (3 MB)

-----Original Message-----
From: Neton, Jim <jfn2@cdc.gov>
To: Naimon, David <dhn0@cdc.gov>
Sent: Wed Sep 17 12:29:17 2003
Subject: FW: COI Addendum to BPA 7-5445

-----Original Message-----
From: Neton, Jim
Sent: Wednesday, August 27, 2003 11:08 AM
To: Naimon, David
Cc: Elliott, Larry J.; Sundin, David S.
Subject: FW: COI Addendum to BPA 7-5445
Importance: High

avid,

Here is what Tony James sent me in response to my request for his contract with ORAU. Much of it appears to be our original solicitation, but I did find a completed conflict of interest disclosure form.

Jim

-----Original Message-----
From: Dr. Anthony C. James [mailto:consult@acj-associates.com]
Sent: Tuesday, August 26, 2003 2:41 PM
To: Neton, Jim
Cc: Craven, Gale; Dick Toohey
Subject: COI Addendum to BPA 7-5445
Importance: High

Jim:

Further to our telephone conversation this morning, I have attached an electronic copy of Addendum 1 to my Contract with ORAU - in which I agree to recuse myself from "performing or reviewing any dose reconstruction if I have acted as an expert witness (including a non-testifying expert) on behalf of DOE or a DOE contractor in defense of radiation dose claims or suits."

I have also attached the PDF files of my original contract with ORAU (BPA 7-5445).

et me know if your legal folks need anything further - or would prefer me to FedEx the ard copy of BPA 7-5445.

I look forward to hearing from your legal counsel soon.

Best regards,

Tony

Anthony C. James, Ph.D.
President, ACJ & Associates, Inc.
129 Patton Street
Richland, WA 99352-1618, USA
Toll Free: (888) 723-9234
Tel: (509) 375-7718
FAX: (509) 375-5190

Web Site: www.acj-associates.com

Adjunct Professor
College of Pharmacy (USTUR)
Washington State University
Richland, WA

SOLICITATION/OFFER/AWARD 7-5445, ADDENDUM 1

October 16, 2002

Reference: **Solicitation/Offer/Award 7-5445**
Title: CDC-NIOSH Dose Reconstruction and Related Services

Addendum No. 1 is issued to incorporate the following changes into Solicitation/Offer/Award 7-5445.

1. Addendum 1 incorporates the following Conflict of Interest policy as Attachment J-12

J-12 ORAU Policy: Conflict of Interest For Dose Reconstruction Under EEOICPA

OAK RIDGE ASSOCIATED UNIVERSITIES (ORAU) POLICY: CONFLICT OF INTEREST FOR DOSE RECONSTRUCTION UNDER EEOICPA

A. Overview

In any situation that involves compensation for injury, whether a tort claim, a worker's compensation case, or a claim made under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA), the integrity of the process must be unimpeachable. This is particularly true under the EEOICPA, because one branch of the U.S. government (i.e. DOE) was responsible for the exposures to ionizing radiation and hazardous substances and is also charged with providing data to assist in adjudicating claims, while other branches of the government (i.e., NIOSH, DOL) are responsible for administering and operating the program. Many of the persons working for the government on this program, whether as federal or contractor employees, have had previous involvement in the conduct of radiation protection programs at DOE facilities; or they may have previously received or are currently receiving financial support from DOE.

The ORAU Team is extremely sensitive to the concerns in the stakeholder community regarding conflict of interest (COI). We understand why the bar on perceived and actual conflicts of interest must be set higher for this project than is established by the COI provisions of the Federal Acquisition Regulations (FAR).

The critical consideration is not whether the potential for COI exists – it does. The most important factors are that the contractor has a rigorous and precise plan for identifying potential COI situations and avoiding them; and that NIOSH be assured the contractor will carry out that process with absolute integrity. Although some may view it as not desirable that persons with any sort of DOE affiliation be involved in the dose reconstruction, it is inevitable that many must be

involved, especially in the process of dose reconstruction research. For example, it is a simple fact that health physicists who have expertise in the internal radiation dosimetry of plutonium must have learned their trade at DOE facilities simply because that is where the plutonium is. Similarly, the research effort to develop job-exposure matrices for the various sites will necessarily involve persons with expert knowledge of the sites, and that knowledge will usually have been gained from having worked there. Therefore, given these inherent potential conflicts, the contractor selected for the dose reconstruction project must do everything possible to prevent or manage actual conflicts of interest and to disclose all potential conflicts of interest.

ORAU, a non-profit association of universities, was chartered in 1946. In the ensuing five decades, we have gained unparalleled experience in maintaining the integrity of technical processes while working with many issues of public concern. Lessons learned from those experiences have been woven into the culture and structures of ORAU. Providing objective science-based studies and analyses that withstand the COI challenge is more than something we do – it's a part of who we are.

ORAU and its employees are committed to the highest ethical standards. All ORAU employees receive mandatory initial and refresher training in the ethical issues covered by these policies. This training will be made mandatory for all persons working on this project, including subcontractors, and will be conducted during the start-up phase, with annual refreshers thereafter. Copies of the training materials can be provided to NIOSH for the project files. ORAU will maintain documentation of the successful completion of this (and other) training for all personnel working on this project, whether ORAU or subcontractor employees.

B. COI Policy/Procedure

ORAU is committed to full and open disclosure as the best way to prevent conflicts of interest. The Government Accountability Project has provided some useful guidance on avoiding conflicts of interest in the NIOSH Dose Reconstruction Project. ORAU agrees completely that "sunshine is the best disinfectant."

The ORAU Team will disclose, for each company and for each individual involved in dose reconstruction, information about their past and present work at DOE sites. In addition, the ORAU Team members will inform NIOSH of any new DOE work which they are awarded. ORAU and its subcontractors will be proactive in making its processes for avoiding COI available to all stakeholders

There are three aspects to effective disclosure/avoidance of conflict of interest:

- Planning of the work by the contractor;
- Oversight by NIOSH of COI performance; and
- Disclosure to stakeholders of information sufficient to let them evaluate for themselves the resolution of potential concerns about conflict of interest.

The ORAU Team will construct a database that lists all DOE sites where team members have worked, and outlines all potential areas of conflict of interest. This database will be used by the Project Director and Task Managers in making and checking work assignments for dose reconstruction. All individuals and companies on the ORAU team will provide the necessary information to populate the database initially, and will update it as necessary.

Access to the database will be provided to NIOSH for oversight of this contract. The ORAU Team believes that access to this information by individual claimants and by stakeholders is appropriate. Because few claimants are likely to be able to use the database itself, printouts about the persons performing individual dose reconstructions (and their companies) will be offered to those claimants. Beyond this, we will work with NIOSH to find the best way to provide stakeholder access to the information.

The database will be constructed to provide the following information to the ORAU Team, to NIOSH and to claimants and other stakeholders:

- Whether and where ORAU or a subcontractor is, was or will be (in the next 12 months) involved in managing or directing DOE radiation protection and health physics program policies, practices and /or procedures.
- Whether and where ORAU or a subcontractor is, was or will be supporting, directly or indirectly, decision making in a radiation dosimetry program. This includes a contractor/subcontractor that is an M&O/M&I, team member of an M&O/M&I, or a program manager of such a program.
- Whether and where ORAU or a subcontractor has broad technical support contracts or task-based contracts in place at DOE sites whose Statement of Work permits them to be broadened to include the above radiation dosimetry work.
- Whether and where ORAU or a subcontractor has an "active" interest in bidding for the above DOE work activities and such "interest" has been disclosed elsewhere publicly (through public announcements, media or other disclosures.)
- Whether and where any individuals conducting dose reconstruction for the ORAU team have acted as expert witnesses on behalf of DOE or a DOE contractor with respect to worker compensation claims or law suits involving the question of whether radiation exposure was responsible in whole or in part for an alleged injury.
- Whether any individuals conducting dose reconstruction for ORAU or subcontractors have former colleagues or co-workers whose claims they may receive for dose reconstruction by virtue of the DOE facilities or sites assigned to them.
- Whether ORAU and its subcontractors and their employees are reviewing reports, assessments, surveys, documents and records that they organizationally or individually have been responsible for authoring, developing, or submitting to DOE or its contractors.

To avoid potential for actual or perceived conflicts of interest in dose reconstruction activities, ORAU and its subcontractors will subscribe to the following restrictions:

- No contractor, subcontractor, or employee will supervise, perform, or review dose reconstructions for claimants from a given DOE/AWE site if they have previously

performed work that affected or established policies on radiation dosimetry assessments, dosimetry programs or records at that site.

- No contractor, subcontractor, or employee will supervise, perform, or review dose reconstructions for claimants from a given DOE/AWE site if they have previously been involved with dose assessments or reconstructions for workers from that site.
- No contractor element will participate in or review dose reconstructions for those DOE sites or activities where it is the prime contractor (i.e., M&O/M&I), team member to a prime contractor, program manager or subcontractor managing dosimetry programs, or intends to be within 12 months.
- No individual will perform, supervise, or review radiation dose reconstructions if he or she has acted as an expert witness (including a non-testifying expert) on behalf of DOE or a DOE contractor in defense of radiation dose claims or suits.
- No individual will perform, supervise, or review radiation dose reconstructions for co-workers, DOE facilities at which they were formerly employed, or for contractors by whom they have been employed.
- No contractor or subcontractor element will be permitted to perform or bid for collateral work on radiation dosimetry program support for those sites where it is conducting dose reconstruction.
- "Key personnel" of the ORAU team will not have a conflict of interest with respect to managing this project or carrying out or marketing radiation protection/health physics services elsewhere in DOE.
- Each supervisor, dosimetrist, and reviewer will be required to complete and sign the attached form agreeing to abide by the above requirements. The forms will be maintained as auditable records of this project. If NIOSH concurs, these forms will also be scanned and posted on a web page ORAU will maintain for this project; links to the ORAU page will be provided for the NIOSH/OCAS and DOL web pages for this project.
- A form identifying the dosimetrist who performed the dose reconstruction and the supervisor who reviewed and approved it will be attached to each dose reconstruction, and provided to the claimant, along with short biographical sketches.

All subcontracts issued to support ORAU in EEOICPA will contain a clause to ensure that the subcontractor complies with ORAU policy (stated here) regarding conflict of interest.

C. ORAU Corporate Disclosure Statement

ORAU was formed as the Oak Ridge Institute for Nuclear Studies in 1946, and in 1947 became a contractor to the Atomic Energy Commission (AEC) to manage educational programs in nuclear sciences in Oak Ridge. ORAU has managed the Oak Ridge Institute for Science and Education (ORISE) for DOE since the establishment of ORISE in 1991. ORISE conducts programs in science and engineering education; basic and applied research; radiation emergency response and dose assessment; radiological safety, assessment and training; national security operations; health, safety and emergency management; and performance systems.

ORAU manages and provides radiation protection services, including dosimetry, to radiation workers at ORAU and ORISE, and had previously done so at the AEC Oak Ridge Hospital

(closed in 1974). Consequently, all ORAU personnel will recuse themselves from any involvement in the dose reconstruction process for claimants from ORAU, ORISE, and the Oak Ridge Hospital. ORAU will work with NIOSH to develop a process for managing those claims (7 as of the date of the RFP) in a manner acceptable to all stakeholders.

ORAU also conducts radiation surveys at the Oak Ridge Y-12 and K-25 facilities, but does not perform work that affects or establishes policies on radiation dosimetry assessments, dosimetry programs or records at those sites.

INDIVIDUAL DISCLOSURE AND AGREEMENT FORM

Name: Dr. Anthony C. James **Employer:** ACJ & Associates, Inc. **Date:** February 10th, 2003

Previous DOE/Contractor employment:

Site	Contractor	Dates	Job Title	Duties
PNNL, Richland	Battelle Memorial Inst.	1988-94	Chief Scientist	Internal Dosimetry Research

Expert witness participation (including non-testifying); list all cases:

Case	Dates	Role
Martin v BNF plc (UK High Court)	1989	Expert witness (testifying) for Defense (internal radiation dosimetry)
Hope & Reay v BNF plc (UK High Court)	1993	Expert witness (non-testifying) for Defense (internal radiation dosimetry)
Billingsley v Dow Chemical et al.	1994	Expert witness (testifying) for DOE Contractor Defense (internal radiation dosimetry)
James v SCE et al.	1995	Expert witness (testifying) for NPP Utility Defense (internal radiation dosimetry)

See also attached list.

I hereby agree to recuse myself from supervising, performing, or reviewing any dose reconstruction for a claimant from DOE facilities at which I have previously worked, or otherwise been involved in managing, directing, developing, or implementing DOE radiation protection and health physics program policies, practices and/or procedures. I also agree to recuse myself from performing or reviewing any dose reconstruction for a claimant personally known to me. Furthermore, I agree to recuse myself from performing or reviewing any dose reconstructions if I have acted as an expert witness (including a non-testifying expert) on behalf of DOE or a DOE contractor in defense of radiation dose claims or suits.

Signed: [signature] **Witness:** [signature] **Date:** February 10th, 2003

Print witness name: Dr. Ronald E. Filipy, Washington State University

INDIVIDUAL DISCLOSURE AND AGREEMENT FORM (continued)

Name: Dr. Anthony C. James

Expert witness participation (including non-testifying); list all cases (continued):

Case	Dates	Role
Kennedy v. SCE et al.	1996-98	Expert witness (non-testifying) for NPP Utility Defense (internal radiation dosimetry – non-occupational).
Hanford Downwinders	1996	Consultant (non-testifying) to Plaintiffs' Counsel (internal dosimetry – non-occupational).
Merilyn Cook et al v Rockwell et al	1997	Consultant (non-testifying) for DOE Contractor Defense (internal radiation dosimetry – non-occupational).
Studholme v NORWEB (UK)	1997	Consultant (non-testifying) for Defense (internal radiation dosimetry – non-occupational).
O'Connor et al v Boeing et al	1997-	Expert witness (testifying) for DOE Contractor Defense (internal radiation dosimetry – non-occupational). Case in continuation.
Short et al v BNF plc (Irish Court)	1997-	Consultant to Defense Counsel (internal radiation dosimetry – non-occupational). Case in preparation.
Hall et al v Babcock & Wilcox et al	1998	Expert witness (testifying) for DOE Contractor Defense (internal radiation dosimetry – non-occupational). Case in continuation.

acf Ref

Expert witness participation (including non-testifying); list all cases (continued

Case	Dates	Role
Aleck v Klewit Centennial et al	1999	Expert witness (testifying) for DOE Contractor Defense (internal radiation dosimetry – occupational).
Tokerud v General Electric et al	2000	Expert witness (testifying) for DOE Contractor Defense (internal radiation dosimetry – occupational).
Schwinger et al v Verizon et al	2003	Expert witness (probably testifying) for DOE Contractor Defense (internal radiation dosimetry – non-occupational). Case in preparation.

Signed: [illegible] **Witness:** [illegible] **Date:** 2/10/03

Print witness name: Dr. Ronald E. Filipy, Washington State University

2. Addendum 1 incorporates the following new paragraphs, MAXIMUM HOURS BILLED AND ABROGATION

G-9 MAXIMUM HOURS BILLED

The normal workweek is considered 40 hours. Where circumstances require, the workweek may be extended. During the first four weeks of performance under the seller may bill for up to a maximum of 60 hours per week. After the initial 30 day period payment of more than 40 hours per week for any classification of employee must be approved in advance by the ORAU Technical Contact who is named in the official ORAU Release.

G-10 ABROGATION

This Agreement establishes the framework under which business will be conducted with Oak Ridge Associated Universities (ORAU). The Agreement may be modified in writing with additions, deletions, and changes by mutual consent of the parties (between ORAU Contract Specialist and Subcontractor with CDC-NIOSH approval, as required to provide enhancements for portions of or all of the original content in writing by abrogation.

The undersigned acknowledges these changes to ORAU Solicitation/Offer/Award 7-5445 and fully understands this Addendum will be incorporated by reference into any subcontract award.

NAME OF CONTRACTOR (Type or Print)

ACJ & Associates, Inc.

NAME & TITLE OF PERSON AUTHORIZED TO SIGN OFFER

Dr. Anthony C. James, President

BY: ACJames **DATE:** 2/10/03
(Signature of Person Authorized to Sign Offer)

09-20-0147

System name
Security classification
System location
Categories of individuals covered by the system
Categories of records in the system
Authority for maintenance of the system
Purpose(s)
Routine uses of records maintained in the system, including categories of users and the purposes of such uses
Policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system
  Storage
  Retrievability
Safeguards
  Authorized Users
  Physical Safeguards
  Procedural Safeguards
  Implementation Guidelines
Retention and Disposal
System manager(s) and address
Notification procedure
Record access procedure
Contesting record procedure
Record source categories
Systems exempted from certain provisions of the act
Appendix I - Potential Sources for Determination of Health Status, Vital Status and/or Last Known Address

System name: Occupational Health Epidemiological Studies. HHS/CDC/NIOSH.

Security classification: None.

System location: Division of Surveillance, Hazard Evaluation, and Field Studies (DSHEFS), National Institute for Occupational Safety and Health (NIOSH), Robert A. Taft Laboratories, 4676 Columbia Parkway, Cincinnati, OH 45226.

Division of Respiratory Disease Studies (DRDS), National Institute for Occupational Safety and Health (NIOSH), 1095 Willowdale Road, Morgantown, WV 26505-2888.

Administrative Services Branch, Pittsburgh Research Laboratory, NIOSH, 626 Cochrans Mill Road, Pittsburgh, PA 15236.

Spokane Research Laboratory, NIOSH, 315 E. Montgomery Avenue, Spokane, WA 99207.

and

Federal Records Center, 3150 Sertwynn Drive, Dayton, OH 45439.

Data are also occasionally located at contractor sites as studies are developed, data collected, and reports written. A list of contractor sites where individually identifiable data are currently located is available upon request to the system manager.

Also, occasionally data may be located at the facilities of collaborating researchers where analyses are performed, data collected and reports written. A list of these facilities is available upon request to the system manager. Data may be located only at those facilities that have an adequate data security program and the collaborating researcher must return the data to NIOSH or destroy individual identifiers at the conclusion of the project.

Categories of individuals covered by the system: Working population exposed to physical and/or chemical agents or other workplace hazards that may damage the human body in any way. Some examples are: 1) organic carcinogens; 2) inorganic carcinogens; 3) mucosal or dermal irritants; 4) fibrogenic materials; 5) acute toxic agents including sensitizing agents; 6) neurotoxic agents; 7) mutagenic (male and female) and teratogenic agents; 8) bio-accumulating non-carcinogen agents; and 9) chronic vascular disease-causing agents. Also included are those individuals in the general population who have been selected as control groups. Workers employed by the Department of Energy and its predecessor agencies and their contractors are also included.

Categories of records in the system: Physical exams, sputum cytology results, questionnaires, urine test records, X-rays, medical history, pulmonary function test records, medical disability forms, blood test records, hearing test results, smoking history, occupational histories, previous and current employment records, union membership records, driver's license data, demographic information, exposure history information and test results are examples of the records in this system. The specific types of records collected and maintained are determined by the needs of the individual study.

Authority for maintenance of the system: Public Health Service Act, Section 301, "Research and Investigation" (42 U.S.C. 241); Occupational Safety and Health Act, Section 20, "Research and Related Activities" (29 U.S.C. 669); and the Federal Mine Safety and Health Act of 1977, Section 501, "Research" (30 U.S.C. 951).

Purpose(s): Studies carried out under this system are to evaluate mortality and morbidity of occupationally related diseases, to determine the cause and prevention of occupationally related diseases, and to lead toward future prevention of occupationally related diseases.

Routine uses of records maintained in the system, including categories of users and the purposes of such uses: Disclosure may be made to a congressional office from the record of an individual in response to a verified inquiry from the congressional office made at the written request of that individual.

Portions of records (name, Social Security number if known, date of birth, and last known address) may be disclosed to one or more of the sources selected from those listed in Appendix I, as applicable. This may be done for obtaining a determination regarding an individual's health status and last known address. If the sources determine that the individual is dead, NIOSH may obtain death certificates, which state the cause of death, from the appropriate Federal, State or local agency. If the individual is alive, NIOSH may obtain information on health status from disease registries or on last known address in order to contact the individual for a health study or to inform him or her of health findings. This information on health status enables NIOSH to evaluate whether excess occupationally

related mortality or morbidity is occurring.

In the event of litigation where the defendant is: (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Department of Justice has agreed to represent such employee, for example, in defending a claim against the Public Health Service based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, disclosure may be made to the Department of Justice to enable that Department to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

Records subject to the Privacy Act are disclosed to private firms for data entry, scientific support services, nosology coding, computer systems analysis and computer programming services. The contractors promptly return data entry records after the contracted work is completed. The contractors are required to maintain Privacy Act safeguards.

Certain diseases or exposures may be reported to State and/or local health departments where the State has a legally constituted reporting program for communicable diseases and which provides for the confidentiality of the information.

In the event of litigation initiated at the request of NIOSH, the Institute may disclose such records as it deems desirable or necessary to the Department of Justice and to the Department of Labor, Office of the Solicitor, where appropriate, to enable the Departments to effectively represent the Institute, provided such disclosure is compatible with the purpose for which the records were collected. The only types of litigative proceedings that NIOSH is authorized to request are: (1) enforcement of a subpoena issued to an employer to provide relevant information; and (2) administrative search warrants to obtain access to places of employment and relevant information therein and related contempt citations against an employer for failure to comply with a warrant obtained by the Institute; and (3) injunctive relief against employers or mine operators to obtain access to relevant information.

Disclosure may be made to NIOSH collaborating researchers (NIOSH contractors, grantees, cooperative agreement holders, or other Federal or State scientists) in order to accomplish the research purpose for which the records are collected. The collaborating researchers must agree in writing to comply with the confidentiality provisions of the Privacy Act and NIOSH must have determined that the researchers' data security procedures will protect confidentiality.

Disclosure of epidemiologic study records pertaining to uranium workers may be made to the Department of Justice to be used in determining eligibility for compensation payments to the uranium workers or their survivors.

Records may be disclosed by CDC in connection with public health activities to the Social Security Administration for sources of locating information to accomplish the research or program purposes for which the records were collected.

Policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system:

Storage: Manager files, card files, computer tapes/disks and printouts, microfilm, microfiche, and other files as appropriate.

Retrievability: Name, assigned number, plant name, and year tested are some of the indices used to retrieve records from these systems. Other retrieval methods are utilized as individual research dictates.

Safeguards:

1. Authorized Users: A database software security package is utilized to control unauthorized access to the system. Access is granted to only a limited number of physicians, scientists, statisticians, and designated support staff or contractors, as authorized by the system manager to accomplish the stated purposes for which the data in this system have been collected.

2. Physical Safeguards: Hard copy records are kept in locked cabinets in locked rooms. Guard service in buildings provides screening of visitors. The limited access, secured computer room contains fire extinguishers and an overhead sprinkler system. Computer terminals and automated records are located in secured areas. Electronic anti-intrusion devices are in operation at the Federal Records Center.

3. Procedural Safeguards: Data sets are password protected and/or encrypted. Protection for computerized records both on the mainframe and the CIO Local Area Network (LAN) includes programmed verification of valid user identification code and password prior to logging on to the system, mandatory password changes, limited log-ins, virus protection, and user rights/file attribute restrictions. Password protection imposes user name and password log-in requirements to prevent unauthorized access. Each user name is assigned limited access rights to files and directories at varying levels to control file sharing. There are routine daily backup procedures and Vault Management System for secure off-site storage is available for backup tapes. Additional safeguards may be built into the program by the system analyst as warranted by the sensitivity of the data.

Employees and contractor staff who maintain records are instructed to check with the system manager prior to making disclosure of data. When individually identified data are being used in a room, admittance at either government or contractor sites is restricted to specifically authorized personnel. Privacy Act provisions are included in contracts, and the Project Director, contract officers and project officers oversee compliance with these requirements. Upon completion of the contract, all data will be either returned to CDC or destroyed, as specified by the contract.

4. Implementation Guidelines: The safeguards outlined above are developed in accordance with Chapter 45-13, "Safeguarding Records Contained in Systems of Records," of the HHS General Administration Manual; and Part 6, "Automated Information System Security," of the HHS Information Resources Management Manual. FRC safeguards are in compliance with GSA Federal Property Management Regulations, Subchapter B—Archives and Records. Data maintained in CDC Atlanta's Processing Center are in compliance with OMB Circular A-130, Appendix III. Security is provided for information collection, processing, transmission, storage, and dissemination in general support systems and major applications. The CIO LANs currently operate under Novell Netware v 4.11 and are in compliance with "CDC & ATSDR Security Standards for Novell File Servers."

Retention and disposal: Records are maintained in agency for three years after the close of the study. Records transferred to the Federal Records Center when no longer needed for evaluation and analysis are destroyed 75 years for epidemiologic studies, unless needed for further study. Records from health hazard evaluations will be retained at least 20 years, and then disposed of in accordance with the CDC Records Control Schedule. Disposal methods include erasing computer tapes and burning or shredding paper materials.

System manager(s) and address: Program Management Officer, Division of Surveillance, Hazard Evaluations, and Field Studies (DSHEFS), National Institute for Occupational Safety and Health (NIOSH), Robert A. Taft Laboratories, Rm. 40A, MS R12, 4676 Columbia Parkway, Cincinnati, OH 45226.

Director, Division of Respiratory Disease Studies (DRDS), National Institute for Occupational Safety and Health (NIOSH), Bldg. ALOSH, Rm. 222, MS 223, 1095 Willowdale Road, Morgantown, WV 26505-2888.

Management Operations Officer, Administrative Services Branch, Pittsburgh Research Laboratory, NIOSH, 626 Cochrans Mill Road, Pittsburgh, PA 15236.

Director, Spokane Research Laboratory, NIOSH, 315 E. Montgomery Avenue, Spokane, WA 99207.

Policy coordination is provided by: Director, National Institute for Occupational Safety and Health (NIOSH), Bldg. HHH, Rm. 715H, MS P-12, 200 Independence Avenue, SW, Washington, D.C. 20201.

Notification procedure: An individual may learn if a record exists about himself or herself by contacting the system manager at the above address. Requesters in person must provide driver's license or other positive identification. Individuals who do not appear in person must either: (1) submit a notarized request to verify their identity; or (2) certify that they are the individuals they claim to be and that they understand that the knowing and willful request for or acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Privacy Act subject to a $5,000 fine.

An individual who requests notification of or access to medical records shall, at the time the request is made, designate in writing a responsible representative who is willing to review the record and inform the subject individual of its contents at the representative's discretion. A subject individual will be granted direct access to a medical record if the system manager determines direct access is not likely to have adverse effect on the subject individual.

The following information must be provided when requesting notification: (1) full name; (2) the approximate date and place of the study, if known; and (3) nature of the questionnaire or study in which the requester participated.

Record access procedures: Same as notification procedures. Requesters should also reasonably specify the record contents being sought. An accounting of disclosures that have been made of the record, if any, may be requested.

Contesting record procedures: Contact the official at the address specified under System Manager above, reasonably identify the record and specify the information being contested, the corrective action sought, and the reasons for requesting the correction, along with

supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

Record source categories: Vital status information is obtained from Federal, State and local governments and other available sources selected from those listed in Appendix I. Information is obtained directly from the individual and employer records, whenever possible.

Systems exempted from certain provisions of the act: None.

APPENDIX I - Potential Sources for Determination of Health Status, Vital Status and/or Last Known Address:

Military records
Appropriate State Motor Vehicle Registration Departments
Appropriate State Driver's License Departments
Appropriate State Government Division of:
Assistance Payments (Welfare), Social Services, Medical Services, Food Stamp Program, Child Support, Board of Corrections, Aging, Indian Affairs, Worker's Compensation, Disability Insurance
Retail Credit Association follow-up
Veterans Administration files
Appropriate employee union or association records
Appropriate company pension or employment records
Company group insurance records
Appropriate State Vital Statistics Offices
Life insurance companies
Railroad Retirement Board
Area nursing homes
Area Indian Trading Posts
Mailing List Correction Cards (U.S. Postal Service)
Letters and telephone conversations with former employees of the same establishment as cohort member
Appropriate local newspaper (obituaries)
Social Security Administration
Internal Revenue Service
National Death Index
Health Care Finance Administration
Pension Benefit Guarantee Corporation
State Disease Registries
Commercial telephone directories

Return to the Table of Contents for Privacy Act System Notices

Attachment J-1

ORAU

OAK RIDGE ASSOCIATED UNIVERSITIES

CONFIDENTIALITY AGREEMENT

Discussions between our representatives indicate that ACJ & Associates, Inc., is interested in providing ORAU with the temporary professional services under Indefinite Quantity Term Agreement No. 7-5445. Since ORAU resources contain confidential information, we ask that you agree to the following.

1. All data, samples, materials and/or other information, whether oral or written, which are disclosed or made available to ACJ & Associates, Inc., directly or indirectly, will be treated as confidential and will not be disclosed or made available by ACJ & Associates, Inc., directly, or indirectly, to any third party nor used for any purpose other than to permit business and/or technical discussions between ACJ & Associates, Inc., and ORAU except as shall be provided for by paragraph four of this agreement or as provided for in the four exceptions listed hereinafter in paragraph one. All data, samples, materials, or other applicable written or oral information shall be regarded, to be of a proprietary or confidential nature. If confidential/proprietary information is conveyed orally then a condition of confidentially shall apply. ACJ & Associates, Inc, shall afford such confidential information the same security and care in handling and storage as ACJ & Associates, Inc., provides for its own confidential and proprietary information and data. ACJ & Associates, Inc., agrees to take all reasonable steps to preserve the confidentiality of all such data and information and agree that such data and information will be made available only to those of your associates, partners and employees as shall have executed a NON DISCLOSURE AGREEMENT in the individuals name directly with ORAU and have a legitimate need to know same and that, unless ACJ & Associates, Inc., has already done so, ACJ & Associates, Inc., will do all things necessary to obligate such associates, partners or employees to maintain such information in confidence. Your obligations as to such data, samples, materials, and/or other information under this paragraph shall not extend to any data, samples, materials, and/or other information which (i) can be shown by ACJ & Associates, Inc., to have been in your possession prior to the receipt thereof from ORAU or (ii) is now, or hereafter becomes, information in the public domain through no act or failure to act by ACJ & Associates, Inc., or by any of your associates, partners, or employees; or (iii) can be shown by ACJ & Associates, Inc., to have been received subsequently on a non-confidential basis from a third party who did not itself acquire same, directly or indirectly, from ORAU or (iv) is independently developed separate from the activities undertaken pursuant to this Agreement.

2. All written and oral data and information, any samples or materials furnished to ACJ & Associates, Inc., by ORAU and all copies, reproductions, and portions

thereof shall be and remain the exclusive property of ORAU; and agrees promptly to deliver the same to ORAU upon request. ACI & Associates, Inc., further agrees not to make any analysis not requested by ORAU of any data furnished to ACI & Associates, Inc., by ORAU nor to permit any third party to do so. ACI & Associates, Inc., also agrees to promptly disclose to ORAU, without any restrictions on our use thereof, all written data and information based on, or derived from the use of ORAU documents or oral information of any nature.

3. ACI & Associates, Inc., obligations under this letter agreement shall remain effective for a period of six (6) years from the date of receipt of the subject data, materials and/or other oral or written information and shall survive the termination of any other agreement, whether in date prior to or after this letter agreement, between ACI & Associates, Inc., or any of associates, partners or employees, and ORAU. This letter agreement shall not merge with or be terminated or superseded by any future agreement between ACI & Associates, Inc., or any of ACI & Associates, Inc.', associates partners or employees, and ORAU.

4. ACI & Associates, Inc., shall not be liable to ORAU for disclosure of any data, samples, materials and/or other information received hereunder if such disclosure is made pursuant to a governmental or judicial mandate, provided that ACI & Associates, Inc., shall have given ORAU prompt notice of such mandate prior to the submission of said data, samples, materials, and/or other information and, provided further, that ACI & Associates, Inc., shall have taken no action to prevent or interfere with efforts ORAU might take to intervene in any such proceeding or to otherwise prevent such disclosure.

5. Nothing in this agreement shall be understood as granting, expressly or by implication, any rights to ACI & Associates, Inc., under the patents, technical information or know-how of ORAU. No patent license, immunity or other patent right is hereby conferred by implication, estoppel, or otherwise.

6. Each party shall perform its obligations hereunder at its own costs.

7. In no event shall either party be liable to the other for any form of indirect, special, or consequential damages arising out of ensuing business activities whether such liability shall arise in contract, tort (including negligence), strict liability or otherwise. The parties acknowledge that monetary damages may be inadequate to protect ORAU against breach of this Agreement. ACI & Associates, Inc., agrees in advance to the granting of injunctive or other equitable relief in favor of ORAU without proof of actual damages, which may be in addition to actual damages for breach of this agreement.

8. This document contains the entire agreement between the parties and supersedes any previous understanding, commitments or agreements; oral or written with respect to the subject matter hereof. It shall not be varied, except by an

instrument in writing of subsequent date, duly executed by authorized representative of each party. If any of the provisions of the agreement are found unenforceable, such finding will not relieve the parties from full compliance with all other parts which shall not be affected thereby. The validity, construction, scope, and performance of this Agreement shall be governed by the laws of the State of Tennessee.

If ACJ & Associates, Inc., is in agreement please indicate by signing, dating and returning one copy of this letter agreement which is being submitted to ACJ & Associates, Inc., in duplicate.

AGREED AND ACCEPTED THIS

_____day of _____ 2002

_____
Typed or Printed Name and Title

_____
Signature

ACCEPTANCE:
OAK RIDGE ASSOCIATED UNIVERSITIES

_____
John E. Bennett Date
Procurement Manager

PART 5. THIS SECTION IS APPLICABLE TO ALL SUBCONTRACTS AWARDED UNDER NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH (NIOSH) REQUEST FOR PROPOSAL (RFP) No. 2002-N-00201

PART 5.A APPLICABLE TO ALL TRANSACTIONS

5.A.1 TITLE AND ADMINISTRATION

Any right and/or interest which is acquired under the terms of this Agreement shall pass directly from Seller to the Government. Company shall make payments under this Agreement from funds advanced by the Government and agreed to be advanced by NIOSH, and not from its own assets. Administration of this Agreement may be transferred, in whole or in part, to NIOSH or its designee(s), and to the extent of such transfer and notice thereof to Seller, Company shall have no further responsibilities hereunder.

5.A.2 INCORPORATION BY REFERENCE

This Agreement incorporates certain provisions by reference. These articles and clauses apply as if they were set forth in their entirety. For Federal Acquisition Regulation (FAR) provisions incorporated by reference, "Contractor" means Seller and "Contracting Officer" means Buyer/Contract Specialist. The FAR may be obtained from the Superintendent of Documents, U.S. Government Printing Office (GPO), Washington, D.C. 20402 or from Government web site at: (http://www.arnet.gov/far/). The full text of Health and Human Services Acquisition Regulation (HHSAR) clauses are contained at 48 CFR Chapter 3. Copies are available from the Superintendent of Documents, U.S. Government Printing Office (GPO), Washington, D.C. 20402 or from Government web site at: (http://www.os.dhhs.gov/ogam/oasa/procurement/hhsar.html).

The following clauses are incorporated by reference:

52.203-3	Gratuities (Apr 1984)
52.203-5	Covenant Against Contingent Fees (Apr 1984)
52.203-8	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Jan 1997)
52.203-10	Price or Fee Adjustment for Illegal or Improper Activity (Jan 1997)
52.204-4	Printed or Copied Double-Sided on Recycled Paper (Aug 2000)
52.209-6	Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment (Jul 1995)
52.215-8	Order of Precedence-Uniform Contract Format (Oct 1997)
52.216-7	Allowable Cost and Payment (Mar 2000)
52.219-16	Liquidated Damages – Subcontracting Plan (Jan 1999)
52.222-3	Convict Labor (Aug 1996)
52.222-4	Contract Work Hours and Safety Standards Act – Overtime Compensation (Sep 2000)
52.222-21	Prohibition of Segregated Facilities (Feb 1999)
52.222-22	Previous Contracts and Compliance Reports (Feb 1999)
52.222-26	Equal Opportunity (Feb 1999)
52.222-35	Affirmative Action For Disabled Veterans and Veterans Vietnam of the Era (Apr 1998)
52.222-36	Affirmative Action For Workers with Disabilities (Jun 1998)
52.222-37	Employment Reports on Disabled Veterans and Veterans of the Vietnam Era (Jan 1999)
52.223-5	Pollution Prevention and Right-to-Know Information (Apr 1998)
52.223-6	Drug Free Workplace (May 2001)
52.224-1	Privacy Act Notification (Apr 1984)
52.224-2	Privacy Act (Apr 1984)
52.225-13	Restrictions on Certain Foreign Purchases (Jul 2000)
52.227-1	Authorization and Consent (Jul 1995)
52.227-3	Patent Indemnity (Apr 1984)
52.227-14	Rights in Data – General (Jun 1987)
52.230-2	Cost Accounting Standards (Apr 1998)
52.230-6	Administration of Cost Accounting Standards (Nov 1999)
52.232-9	Limitation on Withholding of Payments (Apr 1984)
52.232-17	Interest (Jun 1996)

52.232-22	Limitation of Funds (Apr 1984)
52.232-23	Assignment of Claims (Jan 1986)
52.232.25	Prompt Payment (May 2001)
52.232-34	Payment by Electronic Funds Transfer – Other Than Central Contractor Registration (May 1999)
52.233-1	Disputes (Dec 1998)
52.233-3	Protest After Award (Alternate I) (Jun 1985)
52.239-1	Privacy or Security Safeguards (Aug 1996)
52.242-1	Notice of Intent To Disallow Costs (Apr 1984)
52.242-3	Penalties for Unallowable Costs (May 2001)
52.242-13	Bankruptcy (Jul 1995)
52.243-2	Changes – Cost Reimbursement (Alternate I) (Apr 1984)
52.243-7	Notification of Changes (Apr 1984)
52.244-2	Subcontracts (Aug 1998)
52.244-5	Competition in Subcontracting (Dec 1996)
52.245-1	Property Records (Apr 1984)
52.245-5	Government Property (Cost-Reimbursement, Time and Material, or Labor-Hour Contracts) (Jan 1986)
52.246-25	Limitation of Liability – Services (Feb 1997)
52.249-6	Termination (Cost-Reimbursement) (Sep 1996)
52.249-14	Excusable Delays (Apr 1984)
52.253-1	Computer Generated Forms (Jan 1991)

HHSAR SOURCE	TITLE and DATE
HHSAR 352.223-70	Safety and Health (Jan 2001)
HHSAR 352.224-70	Confidentiality of Information (Apr 1984)
HHSAR 352.228-7	Insurance – Liability to Third Persons (Dec 1991)
HHSAR 352.232-9	Withholding of Contract Payments (Apr 1984)
HHSAR 352.242-71	Final Decisions on Audit Findings (Apr 1984)
HHSAR 352.270-1	Accessibility of Meetings, Conferences, and Seminars to Persons with Disabilities (Jan 2001)
HHSAR 352.270-6	Publication And Publicity (Jul 1991)
HHSAR 352.270-7	Paperwork Reduction Act (Jan 2001)

PART 5.B APPLICABLE TO ALL AGREEMENTS IN EXCESS OF $100,000

5.B.1 INCORPORATION BY REFERENCE
For information on clauses incorporated by reference, see Part 5.A.2.

The following clauses are incorporated by reference:

52.202-1	Definitions (Oct 1995) (Deviations) HHSAR 352.202-1 (Jan 2001)
52.203-6	Restrictions on Subcontractor Sales to the Government (Jul 1995)
52.203-7	Anti-Kickback Procedures (Jul 1995)
52.203-12	Limitation on Payments to Influence Certain Federal Transactions (Jun 1997)
52.215-2	Audit and Records – Negotiation (Jun 1999)
52.219-8	Utilization of Small Business Concerns (Oct 2000)
52.223-14	Toxic Chemical Release Reporting (Oct 2000)
52.227- 2	Notice and Assistance Regarding Patent and Copyright Infringement (Aug 1996)

PART 5.C APPLICABLE TO ALL AGREEMENTS IN EXCESS OF $500,000

5.C.1 INCORPORATION BY REFERENCE
For information on clauses incorporated by reference, see Part 5.A.2.

The following clauses are incorporated by reference:

52.215-10	Price Reduction for Defective Cost or Pricing Data (Oct 1997)
52.215-11	Price Reduction for Defective Cost or Pricing Data—Modifications (Oct 1997)
52.215-12	Subcontractor Cost or Pricing Data (Oct 1997)
52.215-13	Subcontractor Cost or Pricing Data—Modifications (Oct 1997)
52.215-15	Pension Adjustments and Asset Reversions (Dec 1998)
52.215-18	Reversion or Adjustment of Plans for Postretirement Benefits (PRB) Other Than Pensions (Oct 1997)
52.215-19	Notification of Ownership Changes (Oct 1997)
52.215-21	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data – Modifications (Oct 1997)
52.219-9	Small Business Subcontracting Plan (Oct 2000)

Attachment J-4

Summary of Cyber Security Requirements for Outsourced CDC-NIOSH Software Development for Dose Reconstruction Project

In order to assure full compliance with all applicable federal regulations for cyber security, it is ORAU's policy that web pages and other online information, applications, or services must be hosted on an ORAU secure network. All software developed under the subcontract must be developed under one of the following scenarios:

- Distribution media such as floppy disks, zip disks, CD-ROM or DVD-ROM formats to be installed on individual PCs. ORAU's staff will work with the vendor to supply the required disclaimers and ownership information.
- Installation/hosting on the customer's own network with their acknowledged ownership of responsibility for all cyber security protections required by applicable regulators.
- Installation/hosting on an ORAU network with ORAU accepting all cyber security protection requirements

The items below refer only to software (databases, applications, procedure code, DLLs, etc) and assume that ultimate installation and hosting will be on ORAU's network.

1. Three major management ORAU roles. ORAU's Program Director or designated Project Manager is responsible for primary sponsor/client interface and for planning, review, and final quality approval of the software product to meet the customer requirements within time and cost ceilings. ORAU's Computer Protection Plan Manager (CPPM) for CDC-NIOSH Dose Reconstruction work will be Phil Wallace or his subsequent designee. The CPPM is responsible for initial plan, final review, and certification of security components of the software. ORAU's Custom Applications Development Manager (CADM) for this project is Phil Wallace, who is responsible for the initial plan, in process review, and final quality approval for technical aspects of software development. This encompasses adherence to CDC and DOE software development guidelines, and the ability of the software to operate correctly/efficiently on the ORAU or CDC networks.
2. Prior to application development. Development of or changes to custom written software shall not begin until requirements, design, and security plan are reviewed and approved by all three managers (program, CPPM, CADS). Work will be performed under a written project plan and/or requirements document.
3. Access to development for ORAU in-process review. ORAU CPPM and CADS will be permitted to review production code during development to perform security certifications, risk assessments, or security audits.
4. Supplier's POC. Supplier will designate a Point of Contact (name, phone, fax, and email) to respond to requests for security review or monitoring. This Point of Contact will be asked to provide assistance in meeting CDC-NIOSH and ORAU policy requirements.
5. Supplier will provide Cyber Security Documentation to be approved by ORAU's CPPM, (sample plan will be available from Phil Wallace) which covers elements

currently listed in DOE Notice N205.1, Unclassified Cyber Security Program; N205.2, Foreign National Access to DOE Cyber Systems; N205.3, Password Generation, Protection, and Use; and all subsequent regulations. The documentation must be accurate and updated under ORAU's change management procedure for any modifications (add, delete, edit code).

6. No live data designated Business Sensitive or Privacy-Act-Protected may be used by supplier for development or testing purposes outside an ORAU network unless a specific data protection plan covering all aspects of ORAU's cyber security requirements is executed in advance. ORAU's project manager will provide non-real test data or instructions on how supplier can create test data. Testing performed on an ORAU network can use copies of live data. Data must be protected at all times from abuse, misuse, theft, or fraud.
7. Supplier must follow ORAU's CT-100 policy regarding software development, including password guidance and computer security training requirements for all supplier employees who have access to systems devoted to ORAU work.
8. Personnel with access to the systems or data contained therein must be appropriately screened and trained. Their accounts and access privileges must be documented and responsibility acknowledged in writing by each administrator/user.
9. All Software developed under this contract must become the property of ORAU and the CDC-NIOSH. A copy of the original and all versions of the source code and current software with appropriate documentation must be provided to Phil Wallace for processing.

Gerstell, Amanda

From: Naimon, David
Sent: Thursday, October 02, 2003 3:10 PM
To: Neton, Jim
Cc: Elliott, Larry J.; Sundin, David S.; Homoki-Titus, Zeda (Liz) E.
Subject: RE: Tony James Issue

Nice work, Jim. And nice work, Liz, in getting us the legal ammunition we needed for this.

-----Original Message-----
From: Neton, Jim
Sent: Thursday, October 02, 2003 2:38 PM
To: Naimon, David
Cc: Elliott, Larry J.; Sundin, David S.
Subject: Tony James Issue

Dave,

I informed Tony James that NIOSH would view his participation as a witness in the Amchitka legal proceedings as a conflict of interest. If he were to testify, we would ask that he relinquish his role as a contracted consultant to ORAU. As soon as I mentioned this, he immediately said that he would notify his contacts in Anchorage that he is no longer interested in pursuing work with them.

Jim

Elliott, Larry J.

From: Naimon, David
Sent: Wednesday, November 05, 2003 12:46 PM
To: Neton, Jim; Elliott, Larry J.; Sundin, David S.
Cc: Herbert, Nichole L.; Homoki-Titus, Zeda (Liz) E.
Subject: Re: Request on Conflict of Interest

When Liz researched the COI issue related to Tony James, I'm pretty sure that she found the the FAR had COI requirements beyond the individual contracts. So if you'd like to go further with this, I think you might be able to. I'll consult with Liz when she calls in this afternoon, but please let me know if you'd like to go further as a policy matter, and I can try to find you legal support.

-----Original Message-----
From: Neton, Jim <jfn2@cdc.gov>
To: Elliott, Larry J. <ljel@cdc.gov>; Sundin, David S. <dss2@cdc.gov>
CC: Naimon, David <dhn0@cdc.gov>; Herbert, Nichole L. <nls3@cdc.gov>
Sent: Wed Nov 05 12:38:12 2003
Subject: RE: Request on Conflict of Interest

I spoke to Dick about this issue yesterday. Since ORAU's current contract with Auxier and Associates did not include a COI provision, and the contract is specific for providing TBD development support, they would like to allow the two Auxier employees working on the contract to complete their tasks. John Frazier has not and will not be working on this contract. Once the TBD work is complete, ORAU will not renew their contract with Auxier and Associates. For future contracts, ORAU will include COI provisions to prevent a reoccurrence of this situation. I have asked that they run this new clause by us before they incorporate it into their contract language.

They are prepared to do whatever we ask of them, so if this approach is not acceptable, let me know and I'll relay the message.

Jim

-----Original Message-----
From: Elliott, Larry J.
Sent: Wednesday, November 05, 2003 11:38 AM
To: Sundin, David S.
Cc: Neton, Jim; Naimon, David; Herbert, Nichole L.
Subject: Fw: Request on Conflict of Interest

Dave please check with Jim/ORAU on status of Auxier and prepare draft reply for review. I would like to send letter reply by early next week. Will need legal review and comment. Thanks, Lje.

Sent from my BlackBerry Wireless Handheld

-----Original Message-----
From: Sylvia Carlsson <sylvia@acsalaska.net>
To: Elliott, Larry J. <ljel@cdc.gov>
Sent: Wed Nov 05 11:32:46 2003
Subject: Request on Conflict of Interest

Good Morning Mr. Elliott:

How long will it take for me to get a response to my request regarding Dr. Frazier and the conflict of interest issue?

I also would like to know if that letter was presented to the advisory board as I requested.

Sylvia Carlsson
(907) 272-5620

<http://promos.hotbar.com/promos/promodll.dll?RunPromo&El=hotbar%5felement%3bst%3b&SG=sub272&RAND=19178> Upgrade Your Email - Click here!

Gerstell, Amanda

From: Naimon, David
Sent: Monday, November 10, 2003 8:31 AM
To: Homoki-Titus, Zeda (Liz) E.
Subject: FW: Carlsson response

Importance: High

Please find our work on the COI under FAR, and let's discuss this. I'm going to ask Larry for the incoming. Thanks.

David

-----Original Message-----
From: Elliott, Larry J.
Sent: Friday, November 07, 2003 4:25 PM
To: Naimon, David; Neton, Jim
Cc: Herbert, Nichole L.
Subject: FW: Carlsson response
Importance: High

David and Jim:
Please review and comment by 4:30p.m. Monday 11/10 with reply to me cc Niki.
Thanks,
Lje.

-----Original Message-----
From: Sundin, David S.
Sent: Friday, November 07, 2003 4:11 PM
To: Elliott, Larry J.
Subject: Carlsson response

Auder - Carlsson.doc (34 KB)

Sylvia M. Carlsson
3324 Lee Street, Apt. No. 6
Anchorage, Alaska 99504

Dear Ms. Carlsson:

This is in response to your letter of October 16, 2003 that described your concerns related to a claim you have filed under Subtitle D of the Energy Employees Occupational Illness Compensation Program Act (EEOICPA). You requested that Auxier and Associates withdraw from participating in work for NIOSH or withdraw its associates from testifying in cases like yours. You requested a response by November 15, 2003.

We are committed to identifying and avoiding conflicts of interest in all phases of our operations under EEOICPA. Our contract with Oak Ridge Associated Universities (ORAU) includes specific provisions that require full and open disclosure to stakeholders of information that is sufficient for them to evaluate the resolution of potential concerns about conflicts of interest. These provisions are available on our website at http://www.cdc.gov/niosh/ocas and are enclosed with this letter. We recognize that perceptions concerning conflicts of interest will differ between individuals, and we strive to strike a reasonable balance between such perceptions and the needs of this program to bring the best possible expertise to bear on carrying out our responsibility under EEOICPA on behalf of our claimants, to produce dose reconstructions that are as timely as possible, that are fair, and that are grounded in the best available science.

An important component of the work NIOSH is conducting to carry out our responsibilities under EEOICPA involves the initial development and ongoing updating of site profile documents for the sites where these employees worked. The completion of most dose reconstructions requires the use of information contained in the site profile document to allow us to properly interpret and augment any personal radiation exposure information we have obtained. ORAU has assembled a number of expert teams to collect and evaluate site-specific data and compile the site profile documents. These teams are typically comprised of individuals from a variety of backgrounds and corporate affiliations to ensure that the team has the necessary expertise and experience to produce

comprehensive, relevant, and useful documents. Individual disclosure and agreement forms for the individuals working on these teams are available on the ORAU website at www.orau.coc.org.

We are not aware that any members of the site profile development teams are currently participating in litigation related to any EEOICPA claim, nor does your letter make such an assertion. No employees of Auxier and Associates are currently conducting any work for NIOSH or ORAU that involves the Amchitcka Island underground nuclear tests. We are thus not aware of any direct conflicts of interest that would seem to call for the actions you asked us to consider.

As the Designated Federal Official for the Advisory Board on Radiation and Worker Health, I considered your request that the issue raised in your letter be made a part of the Board's meeting that was held on October 28 and 29, 2003. I decided that the specific circumstance outlined in your request was not a matter within the chartered purview of the Board and therefore it was not part of the Board's agenda.

Sincerely,
Lje

Enclosure (if you want)

Gerstell, Amanda

From: Elliott, Larry J.
Sent: Monday, December 22, 2003 9:03 AM
To: Naimon, David; McGolerick, Robert; Homoki-Titus, Zeda (Liz) E.; DiMuzio, Martha A.
Cc: Neton, Jim; Sundin, David S.
Subject: FW: ---CDC-NIOSH---REQUESTED CLAUSE---

David;
See attached and below. Please review and advise whether this will attend to the Auxier Assoc. perceived conflict example and/or the Roger Faulk (Rocky Flats) example.

Martha: Please get back to Priscilla and indicate that our legal counsel is reviewing and may have comments/suggestions and thus they (ORAU) should hold on this until they here back from us.

Thanks,
lje.
-----Original Message-----
From: DiMuzio, Martha A.
Sent: Thursday, December 18, 2003 2:56 PM
To: Elliott, Larry J.; Neton, Jim; Sundin, David S.
Subject: FW: ---CDC-NIOSH---REQUESTED CLAUSE---

Attached is the draft COI language that ORAU is proposing to have its subcontractors sign

Thanks,

Martha

-----Original Message-----
From: Campbell, Priscilla [mailto:Campbepb@orau.gov]
Sent: Thursday, December 18, 2003 2:40 PM
To: DiMuzio, Martha A.
Subject: FW: ---CDC-NIOSH---REQUESTED CLAUSE---

Martha,

Attached, sans signature blocks, is the COI language that ORAU proposes to add to all of its subcontracts. The signature blocks will include a place for CEO to sign for company, and for individual employees to sign for themselves.

Regards,
Priscilla

Priscilla Campbell
Oak Ridge Associated Universities
Phone: (865) 241-2871
Fax: (865) 241-9769
campbepb@orau.gov

-----Original Message-----
From: Bennett, John
Sent: Thursday, December 18, 2003 2:37 PM
To: Campbell, Priscilla
Subject: ---CDC-NIOSH---REQUESTED CLAUSE---
Importance: High

Priscilla, Here is the latest DRAFT of the requested COI clause for our CDC-NIOSH contracts. We need to finish by adding the appropriate signature language.

Thanks, John

<<NIOSHproject.COI.doc>>

Prohibition of Actions or Potential Actions Resulting in Questions of Independence or Conflict of Interest

In no case will any individual or business organization of any form whatsoever be allowed to furnish services as or in support of an ORAU Dose Reconstruction Project contractor or subcontractor if the individual or any employee of such business, or any sub-tier contractor of any such business, being engaged in writing (hereinafter referred to as Engaged Business) by ORAU to furnish such services, has any contemplation or implementation of activities that may lead to the furnishing of any similar or related services or information to any claimant having or intending to formally initiate any claim or challenge to a response rendered to a claim previously submitted by the claimant under the Dose Reconstruction program, or to individuals or organizations otherwise involved in any manner with any aspect of the EEOICPA or Dose Reconstruction program (including litigation regarding a claimant, or oversight activities), except with express prior written permission from ORAU.

The restrictions provided above shall apply to all employees or subcontractors of any Engaged Business, or any business proposed to be engaged, and are without exception for any reason whatsoever. The entire company and all its employees are restricted from becoming or continuing to function as an Engaged Business if the company, employees or subcontractors at any tier intend or actually provide such services or information to claimants outside the Dose Reconstruction program, or to individuals or organizations otherwise involved (as described above). The subject employees or subcontractors need not be directly or indirectly working on tasks or providing services that are related to the Dose Reconstruction program.

All current Engaged Businesses and those proposing to be so engaged for such services under any facet of the program sited above, and their employees engaged in activities under the program, shall execute a statement of full disclosure ensuring the independence and lack of conflicts of interest of their company, employees and subcontractors to the satisfaction of ORAU and to CDC-NIOSH reviewing officials.

Gerstell, Amanda

From: Naimon, David
Sent: Monday, January 05, 2004 12:55 PM
To: McGolerick, Robert
Cc: Homoki-Titus, Zeda (Liz) E.
Subject: FW: —CDC-NIOSH—REQUESTED CLAUSE—

I think this is the matter that Larry was referring to on today's agenda. Let's discuss before we call Larry.

David

—Original Message—
From: Elliott, Larry J.
Sent: Monday, December 22, 2003 9:03 AM
To: Naimon, David; McGolerick, Robert; Homoki-Titus, Zeda (Liz) E.; DiMuzio, Martha A.
Cc: Neton, Jim; Sundin, David S.
Subject: FW: —CDC-NIOSH—REQUESTED CLAUSE—

David:
See attached and below. Please review and advise whether this will attend to the Auxier Assoc. perceived conflict example and/or the Roger Faulk (Rocky Flats) example.

Martha: Please get back to Priscilla and indicate that our legal counsel is reviewing and may have comments/suggestions and thus they (ORAU) should hold on this until they here back from us.

Thanks,
lje.
—Original Message—
From: DiMuzio, Martha A.
Sent: Thursday, December 18, 2003 2:56 PM
To: Elliott, Larry J.; Neton, Jim; Sundin, David S.
Subject: FW: —CDC-NIOSH—REQUESTED CLAUSE—

Attached is the draft COI language that ORAU is proposing to have its subcontractors sign

Thanks,

Martha

—Original Message—
From: Campbell, Priscilla [mailto:Campbepb@orau.gov]
Sent: Thursday, December 18, 2003 2:40 PM
To: DiMuzio, Martha A.
Subject: FW: —CDC-NIOSH—REQUESTED CLAUSE—

Martha,

Attached, sans signature blocks, is the COI language that ORAU proposes to add to all of its subcontracts. The signature blocks will include a place for CEO to sign for company, and for individual employees to sign for themselves.

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Items where OCAS owes feedback to ORAU Team, arising from 1/28-04 meeting.

Revised 2/2/2004

Formatted: Right

Q. Is it OK to state, sort of as a matter of policy, that radon is relevant only for lung (or respiratory tract) cancers?

A. It will be necessary to prepare a TIB that shows radon doses to organs. Jim Neton suggests using Appendix A to ICRP 32 as a starting point.

Q. If an EE has been compensated for an SEC cancer and he/she has an additional, non-SEC cancer, is it necessary that a dose reconstruction be performed in order for medical expenses to be covered for the non-SEC cancer.

A. Jim intends to discuss this with DOL on Friday.

Deleted: Will get back to you after that.

At the January 30, 2004 meeting among Jim N., Larry, NIOSH Washington lawyer, and several DOL folks, including lawyers, the following path was decided.

Claims that have been compensated for SEC cancer(s) that are submitted for medical benefits for non-SEC cancer(s) will be forwarded to NIOSH for dose reconstructions. Those DRs, which will typically be done by the ORAU Team, must consider all primary cancers, including the SEC one(s). The combined POC will be used by DOL to determine if medical benefits are granted for the non-SEC cancer(s).

Q. For Mound polonium internal doses, is it acceptable to use the intakes calculated by MJW using ICRP-66 lung model and a "modified Type M" solubility, then plug those into IMBA?

A. No answer yet, but we would like to see a comparison of "modified Type M" to "default Type M" in terms of which is more claimant favorable (and how big is the difference).

Q. Can anything be done about MJW corporate COI at NTS?

A. No feedback yet.

Q. Who from OCAS will participate on the team to prepare the Construction Worker chapter of TBDs (specifically Savannah River, Hanford, others expected to follow), and what information has been received from organized labor on this topic?

A. Lavon "Bomber" Rutherford (533-6806) will be the OCAS participant or point of contact for this TBD chapter. The information available to date is several documents

Deleted: No feedback yet.

prepared by the Center for the Protection of Worker Rights that include a task analysis for the various construction trades. Packages exist for Savannah River, Hanford, Oak Ridge, Amchitka, and NTS. These will be provided as electronic files by Jim Neton.

Buelow, Helen M.

From: Elliott, Larry J.
nt: Tuesday, February 24, 2004 10:07 AM
: Neton, Jim
Subject: Re: Board HP nominations

Jim, looks good. Go aheadand send it. Thanks.
Lje.

Sent from my BlackBerry Wireless Handheld

-----Original Message-----
From: Neton, Jim <jfn2@cdc.gov>
To: Elliott, Larry J. <ljel@cdc.gov>
Sent: Tue Feb 24 08:51:31 2004
Subject: Board HP nominations

Larry,

Provided below is the text of an e-mail I'd like to send to [redacted] and [redacted] soliciting their interest in serving on the ABRWH. [redacted] was on the previous list, having been recommended by a congressional representative. [redacted] would be a new nominee who, in my opinion, is well qualified to sit on the Board. He is the current editor of the HP journal and would bring a balanced perspective to the Board. He has his Ph.D. from the University of Lowell and is currently at the Medical College of South Carolina.

Jim

r (submit name):

I have been asked to solicit names of qualified Health Physicists who would be willing to serve on the Advisory Board on Radiation and Worker Health. The Advisory Board on Radiation and Worker Health was appointed by the President to advise the Department of Health and Human Services on its activities under The Energy Employees Occupational Illness Compensation Program Act (EEOICPA). The Act specifies that the Board will include a balance of perspectives from scientists, physicians, and workers. A good deal of information concerning EEIOCPA, NIOSH's role under the Act, and the activities of the Board is posted on our website at www.cdc.gov/niosh/ocas. Based on your background and work experience, I believe that you would make an excellent candidate for membership on the Board.

I would like to know if you would be interested in having your name included on a list of nominees that NIOSH will forward to the White House for consideration. If so, I would need a recent electronic copy of your CV as soon as possible. The inclusion of your name on our list does not guarantee an appointment nor does it obligate you to accept an appointment if you are selected. All appointments are made by the White House based on input obtained from a variety of sources.

Sincerely,

Jim

James W. Neton, Ph.D., CHP
Technical Program Manager
Office of Compensation Analysis and Support National Institute for Occupational Safety and Health Cincinnati, Ohio

.ton@cdc.gov
(W) 513-533-6800
(F) 513-533-6817

uelow, Helen M.

rom: Neton, Jim
: Wednesday, February 25, 2004 7:43 AM
o: [redacted]
ubject: RE: Advisory Board Nomination

e,

thanks for being realistic. If you know of someone else who you think might make a good representative, please let me know.

-----Original Message-----
From: [redacted]
Sent: Tuesday, February 24, 2004 9:06 PM
To: Neton, Jim
Cc: Elliott, Larry J.
Subject: RE: Advisory Board Nomination

Jim,

I am honored to be asked to serve The Advisory Board on Radiation and Worker Health. Unfortunately, I am fully committed to several other activities and do not feel I could do the Board justice. Thank you sincerely for this invitation but I must decline.

Best regards,

[redacted]

From: Neton, Jim [mailto:jfn2@cdc.gov]
Sent: Tuesday, February 24, 2004 10:16 AM
To: [redacted]
Cc: Elliott, Larry J.
Subject: Advisory Board Nomination

Dea[redacted]

I have been asked to solicit names of qualified Health Physicists who would be willing to serve on the Advisory Board on Radiation and Worker Health. The Advisory Board on Radiation and Worker Health was appointed by the President to advise the Department of Health and Human Services on its activities under The Energy Employees Occupational Illness Compensation Program Act (EEOICPA). The Act specifies that the Board will include a balance of perspectives from scientists, physicians, and workers. A good deal of information concerning EEIOCPA, NIOSH's role under the Act, and the activities of the Board is posted on our website a www.cdc.gov/niosh/ocas. Based on your background and work experience, I believe that you would make an excellent candidate for membership on the Board.

I would like to know if you would be interested in having your name included on a list of nominees that NIOSH will forward to the White House for consideration. If so, I would need a recent electronic copy of your CV as soon as possible. The inclusion of your name on our list does not guarantee an appointment nor does it obligate you to accept an appointment if you are selected. All appointments are made by the White House based on input obtained from a variety of sources.

If you would like to discuss this further, please call me at the number listed below.

Sincerely,

Jim

Buelow, Helen M.

From: Neton, Jim
Sent: Wednesday, March 10, 2004 9:36 AM
To: 'poston@trinity.tamu.edu'
Cc: Elliott, Larry J.
Subject: Advisory Board on Radiation and Worker H

Dear Dr. Poston:

I have been asked to solicit names of qualified Health Physicists who would be willing to serve on the Advisory Board on Radiation and Worker Health (ABRWH). The ABRWH was appointed by the President to advise the Department of Health and Human Services on its activities under The Energy Employees Occupational Illness Compensation Program Act (EEOICPA). The Act specifies that the Board will include a balance of perspectives from scientists, physicians, and workers. A good deal of information concerning EEIOCPA, NIOSH's role under the Act, and the activities of the Board is posted on our website at www.cdc.gov/niosh/ocas. Based on your background and experience, I believe that you would make an excellent candidate for membership on the Board.

I would like to know if you would be interested in having your name included on a list of nominees that NIOSH will forward to the White House for consideration. If so, I would need a recent electronic copy of your CV as soon as possible. The inclusion of your name on our list does not guarantee an appointment nor does it obligate you to accept an appointment if you are selected. All appointments are made by the White House based on input obtained from a variety of sources.

If you would like to discuss this further, please call me at the number listed below.

Sincerely,

James W. Neton, Ph.D., CHP
Technical Program Manager
Office of Compensation Analysis and Support
National Institute for Occupational Safety and Health
Cincinnati, Ohio

jneton@cdc.gov
(W) 513-533-6800
(F) 513-533-6817

James W. Neton, Ph.D., CHP

Technical Program Manager

Office of Compensation Analysis and Support

National Institute for Occupational Safety and Health

Cincinnati, Ohio

jneton@cdc.gov

(W) 513-533-6800

(F) 513-533-6817

Buelow, Helen M.

From: Neton, Jim
: Wednesday, March 17, 2004 7:15 AM
To: 'Raymond Guilmette'
Subject: RE: Advisory Board on Radiation and Worker Health

ıy,

anks for your careful consideration of our offer. I'm glad you responded affirmatively, as I think you would make an excellent dition to the Board. I will forward your name and CV to our Director for inclusion on our list of nominees. Let's see what ppens.

ı

-----Original Message-----
From: Raymond Guilmette [mailto:rguilmet@lanl.gov]
Sent: Tuesday, March 16, 2004 5:36 PM
To: Neton, Jim
Cc: weisele@lanl.gov
Subject: Re: Advisory Board on Radiation and Worker Health

Dear Jim,

I have given serious consideration to your request for interest in being considered for appointment to the ABRWH, and would like to reply affirmatively. I have spoken to several members of the present Board and have a reasonable picture of the time commitment that the position would entail. I believe that I can accommodate such a commitment, even though the next year will be very busy.

I have attached a current resume that includes a list of my publications, but not my contributions to technical reports. I do not view the latter to be important enough to enumerate.

I don't know what the expected schedule for appointments will be, but I would ask a personal favor that, if I am appointed, my term not begin until at least August 2004. By then I will be President of the Health Physics Society, and the extensive travel with which I am currently involved will taper off.

Thank you for considering me for this position. I am confident that my background and experience fits into the scientific needs of the Board, and look forward to being able to contribute.

Best regards,

Ray

Raymond A. Guilmette, Ph.D.
Los Alamos National Laboratory
MS-E546, HSR-12
Los Alamos, NM 87545
(w) 505-665-5059
(f) 505-665-2052
rguilmet@lanl.gov

---- Original Message ----
From: Neton, Jim
To: Raymond Guilmette
Sent: Wednesday, March 10, 2004 8:44 AM
Subject: RE: Advisory Board on Radiation and Worker Health

Ray,

Thanks for getting back to me quickly. I don't think being the team leader of dose assessment will be a problem, as long as it is identified up front and you recuse yourself from any votes or discussions that deal with Los Alamos. The initial appointment is for two years, but can be extended one additional term if agreed to by both parties

Jim

-----Original Message-----
From: Raymond Guilmette [mailto:rguilmet@lanl.gov]
Sent: Wednesday, March 10, 2004 10:07 AM
To: Neton, Jim
Cc: weisele@lanl.gov
Subject: Re: Advisory Board on Radiation and Worker Health

Jim,

Thanks for considering me. One question that pops up is whether my current position as team leader of radiological dose assessments at LANL is a real or perceived conflict of interest? And what would the term of the appointment be?

Ray

Raymond A. Guilmette, Ph.D.
Los Alamos National Laboratory
MS-E546, HSR-12
Los Alamos, NM 87545
(w) 505-665-5059
(f) 505-665-2052
rguilmet@lanl.gov

---- Original Message ----
From: Neton, Jim
To: rguilmet@lanl.gov
Cc: Elliott, Larry J.
Sent: Wednesday, March 10, 2004 6:59 AM
Subject: Advisory Board on Radiation and Worker Health

Dear Ray,

I have been asked to solicit names of qualified Health Physicists who would be willing to serve on the Advisory Board on Radiation and Worker Health (ABRWH). The ABRWH was appointed by the President to advise the Department of Health and Human Services on its activities under The Energy Employees Occupational Illness Compensation Program Act (EEOICPA). The Act specifies that the Board will include a balance of perspectives from scientists, physicians, and workers. A good deal of information concerning EEIOCPA, NIOSH's role under the Act, and the activities of the Board is posted on our website at www.cdc.gov/niosh/ocas. Based on your background and work experience, I believe that you would make an excellent candidate for membership on the Board.

I would like to know if you would be interested in having your name included on a list of nominees that NIOSH will forward to the White House for consideration. If so, I would need a recent electronic copy of your CV as soon as possible. The inclusion of your name on our list does not guarantee an appointment nor does it obligate you to accept an appointment if you are selected. All appointments are made by the White House based on input obtained from a variety o sources.

If you would like to discuss this further, please call me at the number listed below.

Sincerely,

Jim

James W. Neton, Ph.D., CHP

Technical Program Manager

Office of Compensation Analysis and Support

National Institute for Occupational Safety and Health

Cincinnati, Ohio

jneton@cdc.gov

(W) 513-533-6800

(F) 513-533-6817

Gerstell, Amanda

From: Naimon, David
Sent: Wednesday, April 14, 2004 11:10 AM
To: Elliott, Larry J.
Cc: Neton, Jim; Howard, John; McGolerick, Robert; Homoki-Titus, Zeda (Liz) E.
Subject: RE: Revised COI policy

Larry: Yes, I would like to know if these changes are made, and would like to be involved if OFRAU resists changes (and would like to hear about real-life circumstances where parties to litigation subpoena a witness and then pay them). As I indicated below, we have just begun our review, and this is not clearance of the document. We may have more to say later, but will let you know either way. I would like to see any new document so that we are not reviewing an out-of-date version. Also, FYI, due to other work load issues, Liz will be handling this issue henceforth instead of Rob. Thanks. See you soon.

David

-----Original Message-----
From: Elliott, Larry J.
Sent: Wednesday, April 14, 2004 10:16 AM
To: Naimon, David
Cc: Neton, Jim; Howard, John; McGolerick, Robert
Subject: Re: Revised COI policy

Thank you. This is helpful and I appreciate the effort to react to this now. We will pursue questions with ORAU. S assume you wish to see this again if any changes are effected and would want to be involved if ORAU resists any changes. Lje.

Sent from my BlackBerry Wireless Handheld

-----Original Message-----
From: Naimon, David <dhn0@cdc.gov>
To: Elliott, Larry J. <ljel@cdc.gov>
CC: Neton, Jim <jfn2@cdc.gov>; Howard, John <zkz1@cdc.gov>; McGolerick, Robert <bku7@cdc.gov>
Sent: Wed Apr 14 09:52:43 2004
Subject: RE: Revised COI policy

Larry: Rob and I just did a cursory review of this policy. Here are our preliminary comments/questions (we may have more later):

1. The document makes several references to work supporting or in support of a Special Exposure Cohort determination. We think this language could be interpreted to include work on a decision to add a class of employees to the SEC, but not to deny adding a class of employees to the SEC. We think this language should be changed to a more neutral statement - perhaps work "concerning" a decision on whether or not to add a class of employees to the SEC.

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We will take a look at this document in further detail, and may have more comments in the future, but wanted to give you our initial thoughts right away. Hope this is helpful.

David

-----Original Message-----
From: Elliott, Larry J.
Sent: Tuesday, April 13, 2004 1:45 PM
To: Naimon, David
Cc: Neton, Jim
Subject: RE: Revised COI policy

Yes. The attached has been through ORAU legal review and approved by them. We need to say approved or not from our side so that they implement this ASAP (preferably so that we can say this has been done at the Board meeting next week).

-----Original Message-----
From: Naimon, David
Sent: Tuesday, April 13, 2004 1:40 PM
To: Elliott, Larry J.
Subject: RE: Revised COI policy

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David

-----Original Message-----
From: Elliott, Larry J.
Sent: Tuesday, April 13, 2004 1:28 PM
To: Naimon, David
Subject: FW: Revised COI policy

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See below and attached. We would like your review and comment before we provide an answer to the question from the Senate Committee hearing. we also would benefit from your comments in order to bring this issue to closure.

lje.

-----Original Message-----
From: Elliott, Larry J.
Sent: Tuesday, February 03, 2004 2:04 PM
To: Naimon, David; Neton, Jim
Cc: Sundin, David S.
Subject: FW: Revised COI policy

David, please review and comment on the attached and explanation below of each document. Jim, am I correct that this has passed ORAU legal review? Jim would you also respond as to when we need to turn this around; is the time ours to set, or are they working against a timeline to implement this based on new hires and/or sub-contract renewals?

-----Original Message-----
From: Neton, Jim
Sent: Tuesday, February 03, 2004 12:52 PM
To: Elliott, Larry J.
Cc: Sundin, David S.
Subject: FW: Revised COI policy

Larry,

FYI I suspect that we need to run this by our OGC folks.

JIm

-----Original Message-----
From: Toohey, Richard [mailto:TooheyR@orau.gov]
Sent: Tuesday, February 03, 2004 12:00 PM
To: Neton, Jim
Subject: Revised COI policy

Jim: two copies are attached; the one dated 2/2/04 is in track changes mode, so you can see exactly what was changed, and the one dated 2/3/04 is a clean final copy. I decided to leave Vern's suggested word "prepare" regarding site profiles, since we may not want to define that too strictly. Obviously we will still need site experts and consultants, who may do some writing and reviewing for a site, but will not be charged with "preparing" the site profile. Now we can tell Richard and the Board that a revised policy has been prepared and submitted! We'll run it thru the normal review cycle shortly. See you in Augusta.

Dick

p.s. I'm not planning on calling you today at 1:00 unless you have something we really need to discuss.

<<COI suggestions RET final 2-3-04.doc>> <<COI suggestions RET 2-2-04.doc>>

Gerstell, Amanda

From: Naimon, David
Sent: Monday, April 26, 2004 11:42 AM
To: Elliott, Larry J.
Cc: Neton, Jim; Howard, John; McGolerick, Robert; Homoki-Titus, Zeda (Liz) E.
Subject: RE: Revised COI policy

Larry: I understand from Liz that you mentioned this item at the huddle this morning as pending with us. Liz will work on this after we finish reviewing and responding to Ted's latest SEC draft (which of course will delay our responses on congressional controlled correspondence, many of which came to us after the deadline, although we're responsible for delay as well -- could we get extensions on those?). Also, have you heard anything back from ORAU concerning our initial suggestions below? Thanks.

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-----Original Message-----
From: Naimon, David <dhn0@cdc.gov>
To: Elliott, Larry J. <lje1@cdc.gov>
CC: Neton, Jim <jfn2@cdc.gov>; Howard, John <zkz1@cdc.gov>; McGolerick, Robert <bku7@cdc.gov>
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Sent: Tuesday, April 13, 2004 1:28 PM
To: Naimon, David
Subject: FW: Revised COI policy

David;

Gerstell, Amanda

From: Elliott, Larry J.
Sent: Monday, April 26, 2004 12:49 PM
To: Naimon, David
Cc: Neton, Jim; Howard, John; McGolerick, Robert; Homoki-Titus, Zeda (Liz) E.
Subject: RE: Revised COI policy

Thanks. I have not heard anything from ORAU but maybe Jim has.

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Sent: Monday, April 26, 2004 11:42 AM
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avid

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Cc: Neton, Jim
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avid

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lje.

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From: Elliott, Larry J.
Sent: Tuesday, February 03, 2004 2:04 PM
To: Naimon, David; Neton, Jim
Cc: Sundin, David S.
Subject: FW: Revised COI policy

David, please review and comment on the attached and explanation below of each document. Jim, am I correct that this has passed ORAU legal review? Jim would you also respond as to when we need to turn this around; is the time ours to set, or are they working against a timeline to implement this based on new hires and/or sub-contract renewals?

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From: Neton, Jim
Sent: Tuesday, February 03, 2004 12:52 PM
To: Elliott, Larry J.
Cc: Sundin, David S.
Subject: FW: Revised COI policy

Larry,

FYI I suspect that we need to run this by our OGC folks.

JIm

-----Original Message-----
From: Toohey, Richard [mailto:TooheyR@orau.gov]
Sent: Tuesday, February 03, 2004 12:00 PM
To: Neton, Jim
Subject: Revised COI policy

Jim: two copies are attached; the one dated 2/2/04 is in track changes mode, so you can see exactly what was changed, and the one dated 2/3/04 is a clean final copy. I decided to leave Vern's suggested word "prepare" regarding site profiles, since we may not want to define that too strictly. Obviously we will still need site experts and consultants, who may do some writing and reviewing for a site, but will not be charged with "preparing" the site profile. Now we can tell Richard and the Board that a revised policy has been prepared and submitted! We'll run it thru the normal review cycle shortly. See you in Augusta.

Dick

p.s. I'm not planning on calling you today at 1:00 unless you have something we really need to discuss.

<<COI suggestions RET final 2-3-04.doc>> <<COI suggestions RET 2-2-04.doc>>

Gerstell, Amanda

From: Neton, Jim
Sent: Monday, May 10, 2004 11:13 AM
To: Naimon, David; Brand, Anstice M.; Elliott, Larry J.; Katz, Ted; Sundin, David S.
Cc: Roemer, Jane; Homoki-Titus, Zeda (Liz) E.
Subject: RE: Final comments on HHS SENR Qs As on EEIOCPA

David,

In our discussion last week regarding ORAU's draft conflict of interest policy, I erroneously stated that the author of a site profile section could not be a past or present employee at that site. As written in Ted's original response to Cantwell's question #3, the conflict of interest requirement is that the principal author of a site profile must not have been employed at the site (by DOE or by a contractor or subcontractor) in managing the radiological protection program or developing its policies or procedures. I'm sorry for the confusion, but that's what usually happens when I rely on memory and don't check the facts first.

Jim

-----Original Message-----
From: Naimon, David
Sent: Saturday, May 08, 2004 1:09 PM
To: Brand, Anstice M.; Elliott, Larry J.; Katz, Ted; Sundin, David S.
Cc: Neton, Jim; Roemer, Jane; Homoki-Titus, Zeda (Liz) E.
Subject: RE: Final comments on HHS SENR Qs As on EEIOCPA

Anstice: I've added my responses and suggested changes in red and strikeout below. Thanks.

David

-----Original Message-----
From: Brand, Anstice M.
Sent: Friday, May 07, 2004 5:53 PM
To: Naimon, David; Elliott, Larry J.; Katz, Ted; Sundin, David S.
Cc: Neton, Jim; Roemer, Jane
Subject: RE: Final comments on HHS SENR Qs As on EEIOCPA

David et al...I am attaching my master document to which I have been adding all changes. This document doesn't include some of OMBs comments. That is why I just wrote that some of the changes were done even though the changes weren't reflected in the document I attached. Please see my response to David's comments and let me know if everyone is OK with the suggested changes. Please let me know ASAP Monday AM.

-----Original Message-----
From: Naimon, David
Sent: Friday, May 07, 2004 5:11 PM
To: Elliott, Larry J.; Katz, Ted; Brand, Anstice M.; Sundin, David S.
Cc: Neton, Jim; Roemer, Jane
Subject: RE: Final comments on HHS SENR Qs As on EEIOCPA

Anstice: We have the following comments based on Anstice's request that we respond today (we could have more if given more time, but we're also reviewing the SEC material). Please incorporate these comments and we'll review the next version:

1. Bingaman #8 - I don't understand if the response has been changed or not. The OMB comment says "[Does not HHS make recommendations for these appointments? If so, they should reflect that involvement.]" and Anstice's comment says "done", but the text (with which I did not have a problem) appears to be the same. If there has been text added, I'd need to see it before clearing it. See attached master document. I would recommend changing this as indicated below.

<< File: EEOICPA Howard Responses to Senate Energy Questions for the Record OMB Comments round 2.doc >>

I have added a comment to the master document that says..."Highlighting HHS's role in making recommendations to the Advisory Board may create controversy for the President if ~~members~~ Members of Congress pursue this line of questioning and ask for the recommendations made by HHS as compared to the President's appointments. The list of recommendations sent to the White House for the original appointments to this board was substantially different from the list of appointments that were made. ~~This may be the case with the next list of recommendations as well.~~" We do not want the response to this question to cause controversy for the President concerning future appointments to the board."

2. Cantwell #2 - There is an insertion in a comment for this question. Has it been inserted? There also is a statement in the middle of the response that says "[Please clarify how this limited utility was known prior to completion of the feasibility study on U.S. worker studies described in the following paragraph.]" I can't tell whether this has been addressed or not. See attached master document, I have inserted it. The insertion is intended to address that comment. This is fine with me.

3. Cantwell #3 - Ted has incorrectly described the current COI rules (although there is no current policy, since it is still under review). The current standard is that the principal author of a site profile must not have been employed at the site in any capacity. There is no limitation on "managing the radiological protection program or developing its policies or procedures." Also, since there is no current COI policy for site profiles, but merely a practice that is being followed while a policy is being developed, this response needs to be re-written to remove references to the "policy." It also is not appropriate to be discussing a proposed policy with Congress before it is finalized. (David, does the following address your concern? Ted and OCAS, Please also let me know if proposed rewrite is OK with you.)

I have recommended some changes to this response below. Jim Neton should review this carefully for accuracy. I think we should not discuss NIOSH's review of a proposed policy until the policy is ready for public consumption, and there are still a number of questions that need to be addressed. My impression about "NIOSH staff experts" is that our current practice is not our past practice, and that NIOSH reviewers rarely if ever have conflicts of their own (if NIOSH reviewers are required not to have worked at the sites they are reviewing, then that should be stated as well). The proposed response (with or without my suggestions) ignores the issue of firms with conflicts of interest, which is part of the question (which I have pasted below). Do you want to avoid this issue, or to address it?

What are the NIOSH conflict of interest criteria for contractors developing site profiles? I understand that site profiles can be developed by firms and individuals with conflicts of interest that would otherwise bar them from doing the actual dose reconstruction. Has NIOSH terminated any contract with consultants due to conflicts of interest? What entity prepared the site profile for Hanford?

NIOSH is currently reviewing its conflict of interest practices concerning site profiles, which have evolved over time. The ~~conflict of interest requirement in~~ current practice ~~(while a Conflict of Interest policy is being developed)~~ is that the principal author of a site profile must not have been employed at the site (by DOE or by a contractor or subcontractor) in any capacity. This ~~policy~~ does not preclude persons who were employed at the site and involved in radiological protection and monitoring activities from contributing to the site profile. ~~NIOSH is currently reviewing this policy.~~ NIOSH also solicits information from employees at the site, since they may have unique information. In addition, it should be noted that NIOSH staff experts, who normally have no ties to the site, review and approve each site profile before it is used for dose reconstructions.

NIOSH has not terminated a contract due to a conflict of interest. However, NIOSH's dose reconstruction contractor, after consulting with NIOSH, declined to renew a contract with a consultant agency as a result of conflict of interest concerns. Another NIOSH contractor declined to pursue a possible activity after NIOSH expressed conflict of interest concerns about it.

The site profile for Hanford was drafted principally by employees of Pacific Northwest National Laboratories (PNNL), which conducts radiation monitoring operations at Hanford. Under current conflict of interest practices, the principal author for this drafting effort could not have

been an employee of PNNL and revisions of this site profile will be led by persons who have not been employed at Hanford. As discussed above, NIOSH experts reviewed and approved the issuance of the Hanford site profile.

4. Reid #1 - I think it would be a big mistake for NIOSH to leave congressional readers with the impression that we simply began accepting work before we were ready, without indicating why. This could be fixed by changing the 3rd sentence to read, "Dose reconstructions have taken this length of time because NIOSH began receiving **cases from the Department of Labor** before **it NIOSH** had developed its dose reconstruction program and ~~before it~~ had the capacity to complete dose reconstructions." (changes in bold). NIOSH is certainly entitled to decide which battles to fight, but this does not strike me as being (1) a huge battle or (2) a change that is worth ignoring, given that NIOSH in fact had no choice but to accept these claims.

This is fine with me. Great - hope others agree too.

5. Reid #1 and Reid #2 - We strongly recommend deleting the prediction that the NTS site profile "should be issued this summer." Such predictions have proven to be wrong so many times in the past, since so many things can cause delay, and NIOSH's credibility is hurt every time such a prediction is made but does not happen.

David, I am not sure how else we can respond to this since OMB wants us to be more accountable for deadlines. What if we change it to "We hope it will be ready this summer." (which I actually don't think OMB will approve but we can try.)

First, NIOSH can show progress on this site profile by indicating that three of its six sections are already completed and available on the OCAS web site. I also would recommend making the two responses consistent in how they describe the review - one currently says the profile "is presently under review by NIOSH experts" and the other says it "is currently undergoing review." I would prefer the latter, but am more concerned with making them the same.

But I think if we are "picking battles" with OMB, then this is the one to pick, since Sen. Reid is quite likely to hold NIOSH to this estimate on completing the entire site profile. Neither of his questions actually ask when the site profile will be completed, and the proposal is to provide this estimate in response to both questions despite the fact that he didn't ask. In addition, this response could create the expectation that DRs will be coming very shortly after that, raising expectations this fall as well. I would suggest that we respond to OMB by saying that the last thing we want to do is unnecessarily raise the expectations of Nevada residents if it's possible that the expectations will be disappointed if the site profile is for some reason not completed by September.

If after that OMB still insists on including some estimate, then I would recommend saying that we hope the site profile will be completed "later this year."

Hope these comments are helpful.

David

-----Original Message-----
From: Sundin, David S. On Behalf Of Elliott, Larry J.
Sent: Friday, May 07, 2004 4:10 PM
To: Katz, Ted; Brand, Anstice M.
Cc: Elliott, Larry J.; Neton, Jim; Roemer, Jane; Naimon, David
Subject: RE: Final comments on HHS SENR Qs As on EEIOCPA

(Larry is unavailable.)
OCAS is fine with Ted's draft responses.

David S. Sundin
Deputy Director
OCAS/NIOSH
513-533-6802

Neton, Jim

From: Neton, Jim
Sent: Friday, May 14, 2004 4:03 PM
To: 'Toohey, Richard'
Subject: RE: Crisis du jour

Dick,

Thanks for the info. It's not necessary to check the ones already released. Are we going to release the upcoming TBDs with Rohrig and Martin as the authors?

Jim

-----Original Message-----
From: Toohey, Richard [mailto:TooheyR@orau.gov]
Sent: Friday, May 14, 2004 3:16 PM
To: Neton, Jim
Subject: Crisis du jour

I checked the author records for TBDs not yet approved against the disclosure forms, and we have the following hits:

Worked at the site, but not responsible for the RP or dosimetry program:
Mound: Hysong (Environmental TBD) and Proctor (External TBD)
ORNL: Burns (External TBD)

Worked at the site, and was responsible for RP/Dosimetry
INEEL: Rohrig (all TBDs)
Pantex: Martin (all TBDs)

Don't have the team members for the next round easily available yet, but I will check with Judson. Do you want me to check the site profiles already approved?

Dick

Richard E. Toohey, Ph.D., CHP, Director
ORAU Team Dose Reconstruction Project for NIOSH
Oak Ridge Associated Universities
POB 117 MS 23
Oak Ridge, TN 37831-0117
phone: 865-576-9561
fax: 865-241-9769
cell: 865-207-2565
Cinti phone: 513-458-8900
Cinti fax: 513-924-0189
toll-free: 800-322-0111

Gerstell, Amanda

From: Neton, Jim
Sent: Monday, June 28, 2004 5:10 PM
To: Elliott, Larry J.; Sundin, David S.
Cc: Homoki-Titus, Zeda (Liz) E.; McGolerick, Robert
Subject: RE: Revised COI policy

My comments on the revised policy are included in the attached document. For the most part this reads fine to me, I just think that we've been too restrictive in a couple of areas. If we can agree to a revised document after Larry and Dave comment, I'll prepare a final and forward it to Toohey for ORAU's reaction. We need to get this in front of them soon, so that we can have a final before the August Board meeting.

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I know (hope?!) that you and your staff will review this thoroughly, especially to ensure that we have covered all of the bases with the addition of the SEC to this policy. I have scaled back the comments and changes some in light of the fact that the basis for this document has already been published, but I think that the magnitude of this COI policy - covering all 3 major activities - allows for some modifications to be acceptable.

Did you or Jim ever hear back about the points David indicated below?

Talk to you soon. Thanks - Liz

Zeda E. (Liz) Homoki-Titus

Radiation Compensation Legal Team Attorney
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CDC/ATSDR Branch
1101 Wootton Parkway, Suite 560
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CC: Neton, Jim <jfn2@cdc.gov>; Howard, John <zkz1@cdc.gov>; McGolerick, Robert <bku7@cdc.gov>
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1. The document makes several references to work supporting or in support of a Special Exposure Cohort determination. We think this language could be interpreted to include work on a decision to add a class of employees to the SEC, but not to deny adding a class of employees to the SEC. We think this language should be changed to a more neutral statement - perhaps work "concerning" a decision on whether or not to add a class of employees to the SEC.

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Cc: Sundin, David S.
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Larry,

FYI I suspect that we need to run this by our OGC folks.

JIm

-----Original Message-----
From: Toohey, Richard [mailto:TooheyR@orau.gov]
Sent: Tuesday, February 03, 2004 12:00 PM
To: Neton, Jim
Subject: Revised COI policy

Jim: two copies are attached; the one dated 2/2/04 is in track changes mode, so you can see exactly what was changed, and the one dated 2/3/04 is a clean final copy. I decided to leave Vern's suggested word "prepare" regarding site profiles, since we may not want to define that too strictly. Obviously we will still need site experts and consultants, who may do some writing and reviewing for a site, but will not be charged with "preparing" the site profile. Now we can tell Richard and the Board that a revised policy has been prepared and submitted! We'll run it thru the normal review cycle shortly. See you in Augusta.

Dick

p.s. I'm not planning on calling you today at 1:00 unless you have something we really need to discuss.

<<COI suggestions RET final 2-3-04.doc>> <<COI suggestions RET 2-2-04.doc>>

ORAU TEAM CONFLICT OF INTEREST POLICY (Rev. 2 OGCa draft)

A. Overview

In any situation that involves compensation for injury, whether a tort claim, a worker's compensation case, or a claim made under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA), the integrity of the process must be unimpeachable. This is particularly true under the EEOICPA, because one branch of the U.S. government (i.e., DOE) was responsible for the exposures to ionizing radiation and hazardous substances and is also charged with providing data to assist in adjudicating claims, while other branches of the government (i.e., NIOSH, DOL) are responsible for administering and operating the program. Many of the persons working for the government on this program, whether as federal or contractor employees, have had previous involvement in the conduct of radiation protection programs at Department of Energy (DOE) facilities; or they may have previously received or are currently receiving financial support or compensation from DOE.

The ORAU Team is extremely sensitive to the concerns in the stakeholder community regarding perceived or actual conflicts of interest (COI). We understand why the bar on perceived and actual conflicts of interest must be set higher for this project than is established by the COI provisions of the Federal Acquisition Regulations (FAR).

The critical consideration is not whether the potential for COI exists – it does. The most important factors are that the contractor have a rigorous and precise plan for identifying potential COI situations and avoiding them; and that NIOSH be assured the contractor will carry out that process with absolute integrity. Although some may view it as not desirable that persons with any sort of DOE affiliation be involved in dose reconstruction, preparation of site profiles, or Special Exposure Cohort (SEC) petition review, it is almost inevitable that many such persons must be involved, especially in the process of research. For example, health physicists who have expertise in the internal radiation dosimetry of plutonium must have learned their trade at DOE facilities simply because that is where the plutonium is. Similarly, the research effort to develop Site Profiles and process SEC petitions for the various sites will necessarily involve persons with expert knowledge of the sites, and that knowledge will usually have been gained from having worked there. Therefore, given these inherent potential conflicts, the contractor selected for the dose reconstruction project, along with NIOSH, must do everything possible to prevent or manage actual and perceived conflicts of interest and to disclose all potential conflicts of interest.

ORAU, a non-profit association of universities, was chartered in 1946. In the ensuing five decades, we have gained unparalleled experience in maintaining the integrity of technical processes while working with many issues of public concern. Lessons learned from those experiences have been woven into the culture and structures of ORAU. Providing objective science-based studies and analyses that withstand the COI challenge is more than something we do – it's a part of who we are.

ORAU and its employees are committed to the highest ethical standards. All ORAU employees receive mandatory initial and refresher training in ethical issues. This training is mandatory not only for ORAU employees, but for all persons working on this project, including subcontractors, and was conducted during the start-up phase, with annual refreshers thereafter. Copies of the training materials can be provided to NIOSH for the project files. ORAU will maintain documentation of the successful completion of this (and other) training for all personnel working on this project, whether ORAU or subcontractor employees.

B. COI Policy

ORAU is committed to full and open disclosure as the best way to prevent conflicts of interest. ORAU agrees completely that "sunshine is the best disinfectant."

The ORAU Team will disclose, for each company and for each individual involved in dose reconstruction, preparation of Site Profiles, research supporting determinations of whether or not to add a class of employees to the SEC, [redacted] information about their past and present work at DOE sites. In addition, the ORAU Team members will inform NIOSH of any new DOE work that they are awarded. ORAU and its subcontractors will be proactive in making its processes for avoiding COI available to all stakeholders.

Comment: I'm concerned that this is too liquid a mind we would be held to disclosure statements for junior HP staff who have a limited technical role.

There are three aspects to effective disclosure/avoidance of conflict of interest:

- Planning of the work by the contractor;
- Oversight by NIOSH of COI performance; and
- Disclosure of information sufficient to let the public reach its own conclusions concerning the resolution of potential concerns about conflict of interest.

ORAU will construct a database that lists all DOE sites where EEOICPA team members have worked, and outlines all potential areas of conflict of interest. This database will be used by the Project Director and Task Managers in making and checking work assignments for dose reconstruction, preparation of site profiles, research supporting determinations of whether or not to add a class of employees to the SEC, [redacted]. All individuals and companies on the ORAU EEOICPA team will provide the necessary information to populate the database initially, and will promptly update it as necessary.

[redacted]

[redacted]

Printouts about the persons (and their companies) performing individual dose reconstructions, preparation of site profiles, research supporting determinations of whether or not to add a class of employees to the SEC, or any other work done for NIOSH on behalf of the EEOICPA program will be available upon request, subject to legal requirements concerning the protection of privacy interests. ORAU will work with NIOSH to find the best way to make this information available.

The database will be constructed to provide the following information to the ORAU EEOICPA Team, to NIOSH, and, as described above, to others:

- Whether and where ORAU, a subcontractor, or individual employees of ORAU or a subcontractor is, was or will be (in the next 12 months) involved in managing or directing DOE radiation protection and health physics program policies, practices and /or procedures.

- Whether and where ORAU, a subcontractor, or individual employees of ORAU or a subcontractor is, was or will be supporting, directly or indirectly, decision-making in a radiation dosimetry program. This includes a contractor/subcontractor that is an (M&O/M&I), team member of an M&O/M&I, or a program manager of such a program.

- Whether and where ORAU, a subcontractor, or individual employees of ORAU or a subcontractor has broad technical support contracts or task-based contracts in place at DOE sites whose Statement of Work permits them to currently complete or be broadened to include the above radiation dosimetry work.

- Whether and where ORAU, a subcontractor, or individual employees of ORAU or a subcontractor has an "active" interest in bidding for the above DOE work activities and such "interest" has been properly disclosed elsewhere publicly (through public announcements, media or other disclosures.)

- Whether and where any individual employees of ORAU or a subcontractor for the ORAU EEOICPA team have acted as expert witnesses on behalf of DOE or a DOE contractor with respect to worker compensation claims or law suits involving the question of whether radiation exposure was responsible in whole or in part for an alleged injury.

- Whether any individual employees of ORAU or a subcontractor for the ORAU EEOICPA team have former colleagues or co-workers whose claims they may receive for dose reconstruction by virtue of the DOE facilities or sites assigned to them.

- Whether ORAU and its subcontractors and their employees are reviewing reports, assessments, surveys, documents and records that they organizationally or individually have been responsible for authoring, developing, or submitting to DOE or its contractors. ORAU will further indicate if ORAU, a subcontractor, or individual employees of ORAU or a subcontractor was an unidentified contributor to any such reports, assessments, surveys, documents or records.

To avoid potential for actual or perceived conflicts of interest in dose reconstruction or other activities under this contract, ORAU, its subcontractors, and the individual employees of ORAU or a subcontractor will subscribe to the following restrictions:

- No contractor, subcontractor, or employee will perform, review, or approve dose reconstructions for claimants from a given DOE/AWE site, prepare a site profile for that site, or provide support for a determination of whether or not to add a class of employees to the SEC, if they have previously performed work that affected or established policies on radiation dosimetry assessments, dosimetry programs or records at that site.

Comment: This statement is too broad and will not allow us to use site experts to provide expert opinion on matters related to petitions. Much like the site profile situation, we should state that only the primary reviewer of an SEC petition must be unconflicted.

- No contractor, subcontractor, or employee will perform, review, or approve dose reconstructions for claimants from a given DOE/AWE site if they have previously been involved with DOE-funded dose assessments or reconstructions for workers from that site.

- No contractor element will participate in or review dose reconstructions or participate in research supporting site profiles or determinations of whether or not to add a class of employees to the SEC for those DOE sites or activities where it is the prime contractor (i.e., M&O/M&I), team member to a prime contractor, program manager or subcontractor managing dosimetry programs, or otherwise intends to be employed as such within 12 months of starting this contract (or ending this contract?).

- No individual will perform, review, or approve radiation dose reconstructions, prepare site profiles, or conduct research supporting determinations of whether or not to add a class of employees to the SEC, if he or she has voluntarily acted as an expert witness (including a non-testifying expert) on behalf of DOE or a DOE contractor in defense of radiation dose claims or suits. Restrictions for an individual who acts under subpoena will be determined on a case-by-case basis.

- No individual will perform, review, or approve radiation dose reconstructions, site profiles, or determinations of whether or not to add a class of employees to the SEC for co-workers, DOE facilities at which they were formerly employed, or for contractors by whom they have been employed. Site experts may be employed to advise on site specific issues and incidents as necessary.

- No contractor or subcontractor element will be permitted to perform or bid for collateral work on DOE radiation dosimetry program support for those sites where it is conducting dose reconstructions, preparing a site profile (or scheduled to prepare a site profile), or performing work supporting a determination of whether or not to add a class of employees to the SEC.

- Key personnel of the ORAU team will not have a conflict of interest with respect to managing this project or carrying out or marketing radiation protection/health physics services elsewhere in DOE.

- Each supervisor, dosimetrist, and reviewer, and each professional performing, reviewing or approving a dose reconstruction, preparing a site profile or performing work supporting a determination of whether or not to add a class of

employees to the SEC, will be required to complete and sign the attached form agreeing to abide by the above requirements. The forms will be maintained as auditable records of this project.

- No contractor, subcontractor, or individual will perform, review, or approve radiation dose reconstructions, prepare site profiles, or conduct research supporting determinations of whether or not to add a class of employees to the SEC if the company or individual has voluntarily provided expert witness services (including a non-testifying expert) on behalf of DOE or a contractor in defense of any claim filed under the EEOICPA. Restrictions for an individual who acts under subpoena will be determined on a case-by-case basis.

- A form identifying the dosimetrist who performed the dose reconstruction and the reviewer who approved it will be attached to each dose reconstruction and SEC determination, and provided to the claimant or petitioner(s) as appropriate, along with short biographical sketches.

All subcontracts issued to support ORAU in EEOICPA will contain a clause to ensure that the subcontractor complies with ORAU policy (stated here) regarding conflict of interest.

Gerstell, Amanda

From: Homoki-Titus, Zeda (Liz) E.
Sent: Tuesday, June 29, 2004 11:12 AM
To: Neton, Jim
Cc: Elliott, Larry J.; Sundin, David S.; McGolerick, Robert
Subject: RE: Revised COI policy

Tracking:

Recipient	Delivery	Read
Neton, Jim	Delivered: 6/29/2004 11:12 AM	Read: 6/29/2004 6:34 PM
Elliott, Larry J.	Delivered: 6/29/2004 11:12 AM	
Sundin, David S.	Delivered: 6/29/2004 11:12 AM	Read: 6/29/2004 11:25 AM
McGolerick, Robert	Delivered: 6/29/2004 11:12 AM	Read: 6/29/2004 11:18 AM

Jim - Thanks for your comments - I have made a few responses and attempted to accommodate the changes. I am available until 1230 and then again after 230 to discuss this if you have any questions about my comments. I had a few comments that included a question where the change was accepted, but the question was not responded to - I tried to indicate those again, or possibly someone else's comments will address them. Thanks - Liz
(sorry - I forgot to add my attachment)

Zeda E. (Liz) Homoki-Titus
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Subject: FW: Revised COI policy

Larry,

FYI I suspect that we need to run this by our OGC folks.

JIm

-----Original Message-----
From: Toohey, Richard [mailto:TooheyR@orau.gov]
Sent: Tuesday, February 03, 2004 12:00 PM
To: Neton, Jim
Subject: Revised COI policy

Jim: two copies are attached; the one dated 2/2/04 is in track changes mode, so you can see exactly what was changed, and the one dated 2/3/04 is a clean final copy. I decided to leave Vern's suggested word "prepare" regarding site profiles, since we may not want to define that too strictly. Obviously we will still need site experts and consultants, who may do some writing and reviewing for a site, but will not be charged with "preparing" the site profile. Now we can tell Richard and the Board that a revised policy has been prepared and submitted! We'll run it thru the normal review cycle shortly. See you in Augusta.

Dick

p.s. I'm not planning on calling you today at 1:00 unless you have something we really need to discuss.

<<COI suggestions RET final 2-3-04.doc>> <<COI suggestions RET 2-2-04.doc>>

ORAU TEAM CONFLICT OF INTEREST POLICY (Rev. 2 OGCa draft)

A. Overview

In any situation that involves compensation for injury, whether a tort claim, a worker's compensation case, or a claim made under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA), the integrity of the process must be unimpeachable. This is particularly true under the EEOICPA, because one branch of the U.S. government (i.e., DOE) was responsible for the exposures to ionizing radiation and hazardous substances and is also charged with providing data to assist in adjudicating claims, while other branches of the government (i.e., NIOSH, DOL) are responsible for administering and operating the program. Many of the persons working for the government on this program, whether as federal or contractor employees, have had previous involvement in the conduct of radiation protection programs at Department of Energy (DOE) facilities; or they may have previously received or are currently receiving financial support or compensation from DOE.

The ORAU Team is extremely sensitive to the concerns in the stakeholder community regarding perceived or actual conflicts of interest (COI). We understand why the bar on perceived and actual conflicts of interest must be set higher for this project than is established by the COI provisions of the Federal Acquisition Regulations (FAR).

The critical consideration is not whether the potential for COI exists – it does. The most important factors are that the contractor have a rigorous and precise plan for identifying potential COI situations and avoiding them; and that NIOSH be assured the contractor will carry out that process with absolute integrity. Although some may view it as not desirable that persons with any sort of DOE affiliation be involved in dose reconstruction, preparation of site profiles, or Special Exposure Cohort (SEC) petition review, it is almost inevitable that many such persons must be involved, especially in the process of research. For example, health physicists who have expertise in the internal radiation dosimetry of plutonium must have learned their trade at DOE facilities simply because that is where the plutonium is. Similarly, the research effort to develop Site Profiles and process SEC petitions for the various sites will necessarily involve persons with expert knowledge of the sites, and that knowledge will usually have been gained from having worked there. Therefore, given these inherent potential conflicts, the contractor selected for the dose reconstruction project, along with NIOSH, must do everything possible to prevent or manage actual and perceived conflicts of interest and to disclose all potential conflicts of interest.

ORAU, a non-profit association of universities, was chartered in 1946. In the ensuing five decades, we have gained unparalleled experience in maintaining the integrity of technical processes while working with many issues of public concern. Lessons learned from those experiences have been woven into the culture and structures of ORAU. Providing objective science-based studies and analyses that withstand the COI challenge is more than something we do – it's a part of who we are.

ORAU and its employees are committed to the highest ethical standards. All ORAU employees receive mandatory initial and refresher training in ethical issues. This training is mandatory not only for ORAU employees, but for all persons working on this project, including subcontractors, and was conducted during the start-up phase, with annual refreshers thereafter. Copies of the training materials can be provided to NIOSH for the project files. ORAU will maintain documentation of the successful completion of this (and other) training for all personnel working on this project, whether ORAU or subcontractor employees.

B. COI Policy

ORAU is committed to full and open disclosure as the best way to prevent conflicts of interest. ORAU agrees completely that "sunshine is the best disinfectant."

The ORAU Team will disclose, for each company and for each individual involved in dose reconstruction, preparation of Site Profiles, research supporting determinations of whether or not to add a class of employees to the SEC, or any other work done by primary authors or reviewers for NIOSH on behalf of the EEOICPA program, information about their past and present work at DOE sites. In addition, the ORAU Team members will inform NIOSH of any new DOE work that they are awarded. ORAU and its subcontractors will be proactive in making its processes for avoiding COI available to all stakeholders.

Comment: I'm concerned that this is too broad a and we would be held to disclosure statements for junior HP staff who have a limited technical role.

Comment: I am amenable to changing this language to limit the COI to more senior staff and welcome other suggestions, but I think it is an important disclosure statement and should remain. Does the location handle this issue? (same for each comment)

There are three aspects to effective disclosure/avoidance of conflict of interest:

- Planning of the work by the contractor;
- Oversight by NIOSH of COI performance; and
- Disclosure of information sufficient to let the public reach its own conclusions concerning the resolution of potential concerns about conflict of interest.

ORAU will construct a database that lists all DOE sites where EEOICPA team members have worked, and outlines all potential areas of conflict of interest. This database will be used by the Project Director and Task Managers in making and checking work assignments for dose reconstruction, preparation of site profiles, research supporting determinations of whether or not to add a class of employees to the SEC, [redacted] work done by primary authors or reviewers for NIOSH on behalf of the EEOICPA program. All individuals and companies on the ORAU EEOICPA team will provide the necessary information to populate the database initially, and will promptly update it as necessary.

Comment: Same comment as above and for all subsequent occurrences in the text.

Comment: DOC recommended that we should not allow public access to the ORAU database. The fact is that all disclosure statements have been on ORAU's website for some time now. It would be difficult to explain to the public why we are pulling this information now.

Comment: If the forms were previously public then we can maintain the availability of that information -- we must be clear to the individuals that we are posting the info for that data is information is being made available to the public. The main concern here is people getting the impression that they can come to ORAU or OCAS and ride through this database. Maybe this needs to be clarified, which we thought we had done by indicating that any information may be requested, but the situation must be different than we thought.

Access to the database will be provided to NIOSH for [redacted]. Printouts about the persons (and their companies) performing individual dose reconstructions, preparation of site profiles, research supporting determinations of whether or not to add a class of employees to the SEC, or any other work done by primary authors or reviewers for NIOSH on behalf of the EEOICPA program will be available upon request, subject to legal requirements concerning the protection of privacy

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[redacted]

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[redacted]

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To avoid potential for actual or perceived conflicts of interest in dose reconstruction or other activities under this contract, ORAU, its subcontractors, and the individual employees of ORAU or a subcontractor will subscribe to the following restrictions:

- No contractor, subcontractor, or employee will be the principle author, reviewer or give final approval of a dose reconstruction for claimants from a given DOE/AWE site, prepare a site profile for that site, or [redacted] if they have previously performed work that affected or established policies on radiation dosimetry assessments, dosimetry programs or records at that site.

- No contractor, subcontractor, or employee will be the principle author, reviewer or give final approval of a dose reconstruction for claimants from a given DOE/AWE site if they have previously been involved with DOE-funded dose assessments or reconstructions for workers from that site.

- [redacted] No contractor element will participate in or review dose reconstructions or participate in research supporting site profiles or determinations of whether or not to add a class of employees to the SEC for those DOE sites or activities where it is the prime contractor (i.e., M&O/M&I), team member to a prime contractor, program manager or subcontractor managing dosimetry programs, or otherwise intends to be employed as such within 12 months of starting this contract [redacted]

- No individual will perform, review, or approve radiation dose reconstructions, prepare site profiles, or conduct research supporting determinations of whether or not to add a class of employees to the SEC, if he or she has voluntarily acted as an expert witness (including a non-testifying expert) on behalf of DOE or a DOE contractor in defense of radiation dose claims or suits. Restrictions for an individual who acts under subpoena will be determined on a case-by-case basis.

- No individual will perform, review, or approve radiation dose reconstructions, site profiles, or determinations of whether or not to add a class of employees to the SEC for co-workers, DOE facilities at which they were formerly employed, or for contractors by whom they have been employed. Site experts may be employed to advise on site specific issues and incidents as necessary.

- No contractor or subcontractor element will be permitted to perform or bid for collateral work on DOE radiation dosimetry program support for those sites where it is conducting dose reconstructions, preparing a site profile (or scheduled to prepare a site profile), or performing work supporting a determination of whether or not to add a class of employees to the SEC.

- Key personnel of the ORAU team will not have a conflict of interest with respect to managing this project or carrying out or marketing radiation protection/health physics services elsewhere in DOE.

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Comment: This statement is too broad and will not allow us to use site experts to provide expert opinion on matters related to petitions. Much like the site profile situation, we should state that only the primary reviewer of an SEC position must be unconflicted.

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[redacted]

interests. ORAU will continue to make disclosure statements available to the public via ORAU's website.

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The database will be constructed to provide the following information to the ORAU EEOICPA Team, to NIOSH, and, as described above, to others:

- Whether and where ORAU, a subcontractor, or individual employees of ORAU or a subcontractor is, was or will be (in the next 12 months) involved in managing or directing DOE radiation protection and health physics program policies, practices and /or procedures.

- Whether and where ORAU, a subcontractor, or individual employees of ORAU or a subcontractor is, was or will be supporting, directly or indirectly, decision-making in a radiation dosimetry program. This includes a contractor/subcontractor that is an (M&O/M&I), team member of an M&O/M&I, or a program manager of such a program.

Comment: Still don't have an explanation of what an M&O/M&I is – this should be spelled out the first time and used in abbreviation from there on.

- Whether and where ORAU, a subcontractor, or individual employees of ORAU or a subcontractor has broad technical support contracts or task-based contracts in place at DOE sites whose Statement of Work permits them to currently complete or be broadened to include the above radiation dosimetry work.

- Whether and where ORAU, a subcontractor, or individual employees of ORAU or a subcontractor has an "active" interest in bidding for the above DOE work activities and such "interest" has been properly disclosed elsewhere publicly (through public announcements, media or other disclosures).

Comment: These terms are set off by quotes without defining them. Do they have a meaning outside their normal dictionary meaning, or usually indicated by quoting the words off, or are they [illegible] if you then don't use quotes around them – or emphasize them some other way. (more throughout)

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- Whether and where any individual employees of ORAU or a subcontractor for the ORAU EEOICPA team have acted as expert witnesses on behalf of DOE or a DOE contractor with respect to worker compensation claims or law suits involving the question of whether radiation exposure was responsible in whole or in part for an alleged injury.

- Whether any individual employees of ORAU or a subcontractor for the ORAU EEOICPA team have former colleagues or co-workers whose claims they may receive for dose reconstruction by virtue of the DOE facilities or sites assigned to them.

- Whether ORAU and its subcontractors and their employees are reviewing reports, assessments, surveys, documents and records that they organizationally or individually have been responsible for authoring, developing, or submitting to DOE or its contractors. ORAU will further indicate if ORAU, a subcontractor, or individual employees of ORAU or a subcontractor was an unidentified contributor to any such reports, assessments, surveys, documents or records.

To avoid potential for actual or perceived conflicts of interest in dose reconstruction or other activities under this contract, ORAU, its subcontractors, and the individual employees of ORAU or a subcontractor will subscribe to the following restrictions:

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- No contractor, subcontractor, or employee will be the principle author, reviewer or give final approval of a dose reconstruction for claimants from a given DOE/AWE site if they have previously been involved with DOE-funded dose assessments or reconstructions for workers from that site.

- No contractor element will participate in or review dose reconstructions or participate in research supporting site profiles or determinations of whether or not to add a class of employees to the SEC for those DOE sites or activities where it is the prime contractor (i.e., M&O/M&I), team member to a prime contractor, program manager or subcontractor managing dosimetry programs, or otherwise intends to be employed as such within 12 months of starting this contract [redacted]

- No individual will perform, review, or approve radiation dose reconstructions, prepare site profiles, or conduct research supporting determinations of whether or not to add a class of employees to the SEC, if he or she has voluntarily acted as an expert witness (including a non-testifying expert) on behalf of DOE or a DOE contractor in defense of radiation dose claims or suits. Restrictions for an individual who acts under subpoena will be determined on a case-by-case basis.

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Comment: Is this an appropriate limitation – or should it be removed?

Comment: Does this need to allow them the opportunity to not do the DR?

- Each supervisor, dosimetrist, and reviewer, and each professional performing, reviewing or approving a dose reconstruction, preparing a site profile or performing work supporting a determination of whether or not to add a class of employees to the SEC, will be required to complete and sign the attached form agreeing to abide by the above requirements. The forms will be maintained as auditable records of this project.

- No contractor, subcontractor, or individual will perform, review, or approve radiation dose reconstructions, prepare site profiles, or conduct research supporting determinations of whether or not to add a class of employees to the SEC if the company or individual has voluntarily provided expert witness services (including a non-testifying expert) on behalf of DOE or a contractor in defense of any claim filed under the EEOICPA. Restrictions for an individual who acts under subpoena will be determined on a case-by-case basis.

- A form identifying the dosimetrist who performed the dose reconstruction and the reviewer who approved it will be attached to each dose reconstruction and SEC determination, and provided to the claimant or petitioner(s) as appropriate, along with short biographical sketches.

All subcontracts issued to support ORAU in EEOICPA will contain a clause to ensure that the subcontractor complies with ORAU policy (stated here) regarding conflict of interest.

Calhoun, Grady

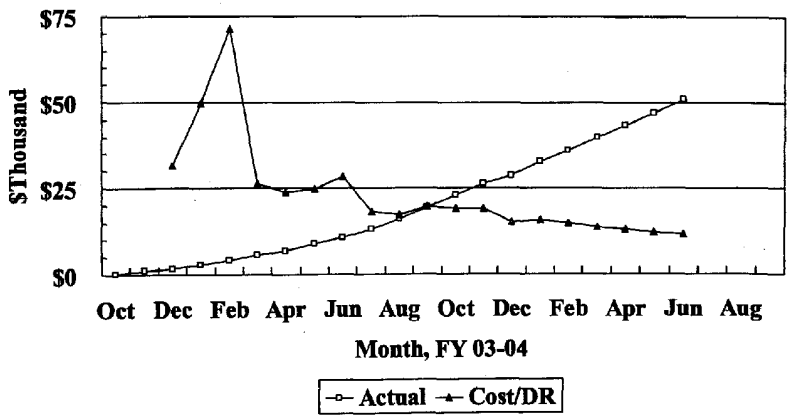
From: Toohey, Richard [ToheyR@orau.gov]
Sent: Friday, July 23, 2004 5:34 PM
To: Calhoun, Grady
Subject: Cost per DR

<<Cost per DR.ppt>>
$11.5k per Rev. 0 submitted to OCAS, as of June ledger. July closed today, so will have an update in a week or two.

Dick

Richard E. Toohey, Ph.D., CHP, Director
ORAU Team Dose Reconstruction Project for NIOSH
Oak Ridge Associated Universities
POB 117 MS 23
Oak Ridge, TN 37831-0117
phone: 865-576-9561
fax: 865-241-9769
cell: 865-207-2565
Cinti phone: 513-758-1507
Cinti fax: 513-924-0189
toll-free: 800-322-0111

COST per DR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Oct Dec Feb Apr Jun Aug Oct Dec Feb Apr Jun Aug
Month, FY 03-04
Actual
Cost/DR

Neton, Jim
From: Neton, Jim
Sent: Wednesday, August 18, 2004 9:29 AM
To: 'Toohey, Richard'
Cc: Elliott, Larry J.; Homoki-Titus, Zeda (Liz) E.
Subject: COI Policy

Dick,

We have finally completed our review of ORAU's modified COI policy. Could you please review the attached version and get back to me ASAP with any comments you might have? As you know, we'd like to get this finalized prior to the Board meeting next week. Please give me a call if you have any questions.

COI Policy - Final.doc (65 KB)...

Thanks,

Jim

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- Whether and where ORAU, a subcontractor, or individual employees of ORAU or a subcontractor has broad technical support contracts or task-based contracts in place at DOE sites whose Statement of Work permits them to currently complete or be broadened to include the above radiation dosimetry work.

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- No individual will perform, review, or approve radiation dose reconstructions, prepare site profiles, or conduct research supporting determinations of whether or not to add a class of employees to the SEC, if he or she has voluntarily acted as an expert witness (including a non-testifying expert) on behalf of DOE or a DOE contractor in defense of radiation dose claims or suits. Restrictions for an individual who acts under subpoena will be determined on a case-by-case basis.

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- Key personnel of the ORAU team will not have a conflict of interest with respect to managing this project or carrying out or marketing radiation protection/health physics services elsewhere in DOE.

- Each supervisor, dosimetrist, and reviewer, and each professional performing, reviewing or approving a dose reconstruction, preparing a site profile or performing work supporting a determination of whether or not to add a class of employees to the SEC, will be required to complete and sign the attached form agreeing to abide by the above requirements. The forms will be maintained as auditable records of this project.

- No contractor, subcontractor, or individual will perform, review, or approve radiation dose reconstructions, prepare site profiles, or conduct research supporting determinations of whether or not to add a class of employees to the SEC if the company or individual has voluntarily provided expert witness services (including a non-testifying expert) on behalf of DOE or a contractor in defense of any claim filed under the EEOICPA. Restrictions for an individual who acts under subpoena will be determined on a case-by-case basis.

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All subcontracts issued to support ORAU in EEOICPA will contain a clause to ensure that the subcontractor complies with ORAU policy (stated here) regarding conflict of interest.

ORAU TEAM CONFLICT OF INTEREST POLICY (Rev. 2 OGCa draft)

A. Overview

In any situation that involves compensation for injury, whether a tort claim, a worker's compensation case, or a claim made under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA), the integrity of the process must be unimpeachable. This is particularly true under the EEOICPA, because one branch of the U.S. government (i.e., DOE) was responsible for the exposures to ionizing radiation and hazardous substances and is also charged with providing data to assist in adjudicating claims, while other branches of the government (i.e., NIOSH, DOL) are responsible for administering and operating the program. Many of the persons working for the government on this program, whether as federal or contractor employees, have had previous involvement in the conduct of radiation protection programs at Department of Energy (DOE) facilities; or they may have previously received or are currently receiving financial support or compensation from DOE.

The ORAU Team is extremely sensitive to the concerns in the stakeholder community regarding perceived or actual conflicts of interest (COI). We understand why the bar on perceived and actual conflicts of interest must be set higher for this project than is established by the COI provisions of the Federal Acquisition Regulations (FAR).

The critical consideration is not whether the potential for COI exists – it does. The most important factors are that the contractor have a rigorous and precise plan for identifying potential COI situations and avoiding them; and that NIOSH be assured the contractor will carry out that process with absolute integrity. Although some may view it as not desirable that persons with any sort of DOE affiliation be involved in dose reconstruction, preparation of site profiles, or Special Exposure Cohort (SEC) petition review, it is almost inevitable that many such persons must be involved, especially in the process of research. For example, health physicists who have expertise in the internal radiation dosimetry of plutonium must have learned their trade at DOE facilities simply because that is where the plutonium is. Similarly, the research effort to develop Site Profiles and process SEC petitions for the various sites will necessarily involve persons with expert knowledge of the sites, and that knowledge will usually have been gained from having worked there. Therefore, given these inherent potential conflicts, the contractor selected for the dose reconstruction project, along with NIOSH, must do everything possible to prevent or manage actual and perceived conflicts of interest and to disclose all potential conflicts of interest.

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ORAU and its employees are committed to the highest ethical standards. All ORAU employees receive mandatory initial and refresher training in ethical issues. This training is mandatory not only for ORAU employees, but for all persons working on this project, including subcontractors, and was conducted during the start-up phase, with annual refreshers thereafter. Copies of the training materials can be provided to NIOSH for the project files. ORAU will maintain documentation of the successful completion of this (and other) training for all personnel working on this project, whether ORAU or subcontractor employees.

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Comment: I'm concerned that this is too broad a and we would be held to disclosure statements for junior HP staff who have a limited technical role.

Comment: I am amenable to changing this language to limit the COI to more senior staff and welcome other suggestions, but I think it is an important disclosure statement and should remain. Does the insertion handle this issue? (same for each comment)

There are three aspects to effective disclosure/avoidance of conflict of interest:

- Planning of the work by the contractor;
- Oversight by NIOSH of COI performance; and
- Disclosure of information sufficient to let the public reach its own conclusions concerning the resolution of potential concerns about conflict of interest.

ORAU will construct a database that lists all DOE sites where EEOICPA team members have worked, and outlines all potential areas of conflict of interest. This database will be used by the Project Director and Task Managers in making and checking work assignments for dose reconstruction, preparation of site profiles, research supporting determinations of whether or not to add a class of employees to the SEC, or any other work done by primary authors or reviewers for NIOSH on behalf of the EEOICPA program. All individuals and companies on the ORAU EEOICPA team will provide the necessary information to populate the database initially, and will promptly update it as necessary.

Comment: Same comment as above and for all subsequent occurrences in the text.

Comment: OGC recommended that we should not allow public access to the ORAU database. The fact is that all disclosure statements have been on ORAU's website for some time now. It would be difficult to explain to the public why we are pulling this information now.

Comment: If the forms were previously public then we can maintain the availability of that information – we must be clear to the individuals that we are posting the info for that their is information is being made available to the public. The main concern here is people getting the impression that they can come to ORAU or OCAS and rifle through this database. Maybe this needs to be clarified, which we thought we had done by indicating that any information may be requested, but the situation must be different from we thought.

Access to the database will be provided to NIOSH for oversight of this contract. Printouts about the persons (and their companies) performing individual dose reconstructions, preparation of site profiles, research supporting determinations of whether or not to add a class of employees to the SEC, or any other work done by primary authors or reviewers for NIOSH on behalf of the EEOICPA program will be available upon request, subject to legal requirements concerning the protection of privacy

interests. ORAU will continue to make disclosure statements available to the public via ORAU's website.

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The database will be constructed to provide the following information to the ORAU EEOICPA Team, to NIOSH, and, as described above, to others:

- Whether and where ORAU, a subcontractor, or individual employees of ORAU or a subcontractor is, was or will be (in the next 12 months) involved in managing or directing DOE radiation protection and health physics program policies, practices and /or procedures.

- Whether and where ORAU, a subcontractor, or individual employees of ORAU or a subcontractor is, was or will be supporting, directly or indirectly, decision-making in a radiation dosimetry program. This includes a contractor/subcontractor that is an (M&O/M&I), team member of an M&O/M&I, or a program manager of such a program.

Comment: Still don't have an explanation of what an M&O/M&I is – this should be spelled out the first time and used in abbreviation from there on.

- Whether and where ORAU, a subcontractor, or individual employees of ORAU or a subcontractor has broad technical support contracts or task-based contracts in place at DOE sites whose Statement of Work permits them to currently complete or be broadened to include the above radiation dosimetry work.

- Whether and where ORAU, a subcontractor, or individual employees of ORAU or a subcontractor has an "active" interest in bidding for the above DOE work activities and such "interest" has been properly disclosed elsewhere publicly (through public announcements, media or other disclosures).

Comment: These terms are set off by quotes without defining them. Do they have a meaning outside their normal dictionary meaning, as usually indicated by setting the words off. If so they should be explained, if not then don't use quotes around them – or emphasize them some other way. (same throughout)

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- Whether and where any individual employees of ORAU or a subcontractor for the ORAU EEOICPA team have acted as expert witnesses on behalf of DOE or a DOE contractor with respect to worker compensation claims or law suits involving the question of whether radiation exposure was responsible in whole or in part for an alleged injury.

- Whether any individual employees of ORAU or a subcontractor for the ORAU EEOICPA team have former colleagues or co-workers whose claims they may receive for dose reconstruction by virtue of the DOE facilities or sites assigned to them.

- Whether ORAU and its subcontractors and their employees are reviewing reports, assessments, surveys, documents and records that they organizationally or individually have been responsible for authoring, developing, or submitting to DOE or its contractors. ORAU will further indicate if ORAU, a subcontractor, or individual employees of ORAU or a subcontractor was an unidentified contributor to any such reports, assessments, surveys, documents or records.

To avoid potential for actual or perceived conflicts of interest in dose reconstruction or other activities under this contract, ORAU, its subcontractors, and the individual employees of ORAU or a subcontractor will subscribe to the following restrictions:

- No contractor, subcontractor, or employee will be the principle author, reviewer or give final approval of a dose reconstruction for claimants from a given DOE/AWE site, prepare a site profile for that site, or provide support for a determination of whether or not to add a class of employees to the SEC from that site, if they have previously performed work that affected or established policies on radiation dosimetry assessments, dosimetry programs or records at that site.

- No contractor, subcontractor, or employee will be the principle author, reviewer or give final approval of a dose reconstruction for claimants from a given DOE/AWE site if they have previously been involved with DOE-funded dose assessments or reconstructions for workers from that site.

- No contractor element will participate in or review dose reconstructions or participate in research supporting site profiles or determinations of whether or not to add a class of employees to the SEC for those DOE sites or activities where it is the prime contractor (i.e., M&O/M&I), team member to a prime contractor, program manager or subcontractor managing dosimetry programs, or otherwise intends to be employed as such within 12 months of starting this contract

- No individual will perform, review, or approve radiation dose reconstructions, prepare site profiles, or conduct research supporting determinations of whether or not to add a class of employees to the SEC, if he or she has voluntarily acted as an expert witness (including a non-testifying expert) on behalf of DOE or a DOE contractor in defense of radiation dose claims or suits. Restrictions for an individual who acts under subpoena will be determined on a case-by-case basis.

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- Key personnel of the ORAU team will not have a conflict of interest with respect to managing this project or carrying out or marketing radiation protection/health physics services elsewhere in DOE.

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Comment: This statement is too broad and will not allow us to use site experts to provide expert opinion on matters related to petitions. Much like the site profile situation, we should state that only the primary reviewer of an SEC petition must be unconflicted.

Comment: I agree that this may be limited to the primary reviewer.

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Comment: Is this an appropriate limitation – or should it be removed?

Comment: Does this need to allow them the opportunity to not do the DR?

- Each supervisor, dosimetrist, and reviewer, and each professional performing, reviewing or approving a dose reconstruction, preparing a site profile or performing work supporting a determination of whether or not to add a class of employees to the SEC, will be required to complete and sign the attached form agreeing to abide by the above requirements. The forms will be maintained as auditable records of this project.

- No contractor, subcontractor, or individual will perform, review, or approve radiation dose reconstructions, prepare site profiles, or conduct research supporting determinations of whether or not to add a class of employees to the SEC if the company or individual has voluntarily provided expert witness services (including a non-testifying expert) on behalf of DOE or a contractor in defense of any claim filed under the EEOICPA. Restrictions for an individual who acts under subpoena will be determined on a case-by-case basis.

- A form identifying the dosimetrist who performed the dose reconstruction and the reviewer who approved it will be attached to each dose reconstruction and SEC determination, and provided to the claimant or petitioner(s) as appropriate, along with short biographical sketches.

All subcontracts issued to support ORAU in EEOICPA will contain a clause to ensure that the subcontractor complies with ORAU policy (stated here) regarding conflict of interest.

ORAU TEAM CONFLICT OF INTEREST POLICY (Rev. 1 draft)

A. Overview

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The ORAU Team is extremely sensitive to the concerns in the stakeholder community regarding conflict of interest (COI). We understand why the bar on perceived and actual conflicts of interest must be set higher for this project than is established by the COI provisions of the Federal Acquisition Regulations (FAR).

The critical consideration is not whether the potential for COI exists – it does. The most important factors are that the contractor have a rigorous and precise plan for identifying potential COI situations and avoiding them; and that NIOSH be assured the contractor will carry out that process with absolute integrity. Although some may view it as not desirable that persons with any sort of DOE affiliation be involved in dose reconstruction, it is inevitable that many must be involved, especially in the process of dose reconstruction research. For example, it is a simple fact that health physicists who have expertise in the internal radiation dosimetry of plutonium must have learned their trade at DOE facilities simply because that is where the plutonium is. Similarly, the research effort to develop Site Profiles for the various sites will necessarily involve persons with expert knowledge of the sites, and that knowledge will usually have been gained from having worked there. Therefore, given these inherent potential conflicts, the contractor selected for the dose reconstruction project must do everything possible to prevent or manage actual conflicts of interest and to disclose all potential conflicts of interest.

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ORAU and its employees are committed to the highest ethical standards. All ORAU employees receive mandatory initial and refresher training in the ethical issues covered by these policies. This training will be made mandatory for all persons working on this project, including subcontractors, and will be conducted during the start-up phase, with annual refreshers thereafter. Copies of the training materials can be provided to NIOSH for the project files. ORAU will maintain documentation of the successful completion of this (and other) training for all personnel working on this project, whether ORAU or subcontractor employees.

B. COI Policy

ORAU is committed to full and open disclosure as the best way to prevent conflicts of interest. The Government Accountability Project has provided some useful guidance on avoiding conflicts of interest in the NIOSH Dose Reconstruction Project. ORAU agrees completely that "sunshine is the best disinfectant."

The ORAU Team will disclose, for each company and for each individual involved in dose reconstruction, preparation of Site Profiles, or research supporting Special Exposure Cohort determinations, information about their past and present work at DOE sites. In addition, the ORAU Team members will inform NIOSH of any new DOE work which they are awarded. ORAU and its subcontractors will be proactive in making its processes for avoiding COI available to all stakeholders.

There are three aspects to effective disclosure/avoidance of conflict of interest:

- Planning of the work by the contractor;
- Oversight by NIOSH of COI performance; and
- Disclosure to stakeholders of information sufficient to let them evaluate for themselves the resolution of potential concerns about conflict of interest.

The ORAU Team will construct a database that lists all DOE sites where team members have worked, and outlines all potential areas of conflict of interest. This database will be used by the Project Director and Task Managers in making and checking work assignments for dose reconstruction, preparation of Site Profiles, or research supporting Special Exposure Cohort determinations. All individuals and companies on the ORAU team will provide the necessary information to populate the database initially, and will update it as necessary.

Access to the database will be provided to NIOSH for oversight of this contract. The ORAU Team believes that access to this information by individual claimants and by stakeholders is appropriate. Because few claimants are likely to be able to use the database itself, printouts about the persons performing individual dose reconstructions (and their companies) will be offered to those claimants. Beyond this, we will work with NIOSH to find the best way to provide stakeholder access to the information.

The database will be constructed to provide the following information to the ORAU Team, to NIOSH and to claimants and other stakeholders:

- Whether and where ORAU or a subcontractor is, was or will be (in the next 12 months) involved in managing or directing DOE radiation protection and health physics program policies, practices and /or procedures.

- Whether and where ORAU or a subcontractor is, was or will be supporting, directly or indirectly, decision making in a radiation dosimetry program. This includes a contractor/subcontractor that is an M&O/M&I, team member of an M&O/M&I, or a program manager of such a program.

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- Whether and where ORAU or a subcontractor has an "active" interest in bidding for the above DOE work activities and such "interest" has been disclosed elsewhere publicly (through public announcements, media or other disclosures.)

- Whether and where any individuals conducting dose reconstruction, preparation of Site Profiles, or research supporting Special Exposure Cohort determinations for the ORAU team have acted as expert witnesses on behalf of DOE or a DOE contractor with respect to worker compensation claims or law suits involving the question of whether radiation exposure was responsible in whole or in part for an alleged injury.

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- Whether and where ORAU, a subcontractor, or individual employees of ORAU or a subcontractor has broad technical support contracts or task-based contracts in place at DOE sites whose Statement of Work permits them to currently complete or be broadened to include the above radiation dosimetry work.
- Whether and where ORAU, a subcontractor, or individual employees of ORAU or a subcontractor has an "active" interest in bidding for the above DOE work activities and such "interest" has been properly disclosed elsewhere publicly (through public announcements, media or other disclosures.)
- Whether and where any individual employees of ORAU or a subcontractor for the ORAU EEOICPA team have acted as expert witnesses on behalf of DOE or a DOE contractor with respect to worker compensation claims or law suits involving the question of whether radiation exposure was responsible in whole or in part for an alleged injury.
- Whether any individual employees of ORAU or a subcontractor for the ORAU EEOICPA team have former colleagues or co-workers whose claims they may receive for dose reconstruction by virtue of the DOE facilities or sites assigned to them.
- Whether ORAU and its subcontractors and their employees are reviewing reports, assessments, surveys, documents and records that they organizationally or individually have been responsible for authoring, developing, or submitting to DOE or its contractors. ORAU will further indicate if ORAU, a subcontractor, or individual employees of ORAU or a subcontractor was an unidentified contributor to any such reports, assessments, surveys, documents or records.

To avoid potential for actual or perceived conflicts of interest in dose reconstruction or other activities under this contract, ORAU, its subcontractors, and the individual employees of ORAU or a subcontractor will subscribe to the following restrictions:

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Comment: Each of these clauses should clearly indicate that individual employee information will be available as well as the info from ORAU or the subcontractor as an entity.

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Comment: To be clear to the layman these acronyms should be spelled out and included as a parenthetical definition of the terms for later use.

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Comment: Please explain why the words in quotes are in quotes – if they are defined terms in another document, then the definitions should be spelled out here.

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Deleted: conducting dose reconstruction for ORAU or subcontractor

Comment: Is this even possible to determine, and is it a feasible limitation?

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- No contractor, subcontractor, or employee will perform, review, or approve dose reconstructions for claimants from a given DOE/AWE site, prepare a site profile for that site, or provide support for a determination of whether or not to add a class of employees to the SEC from that site, if they have previously performed work that affected or established policies on radiation dosimetry assessments, dosimetry programs or records at that site.

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- No contractor, subcontractor, or employee will perform, review, or approve dose reconstructions for claimants from a given DOE/AWE site if they have previously been involved with DOE-funded dose assessments or reconstructions for workers from that site.

Comment: I am not sure if this is an appropriate limitation, but are there non-DOE funded experts that we may want to draw on the expertise of, from a University or NIOSH for example?

- No contractor element will participate in or review dose reconstructions or participate in research supporting site profiles or determinations of whether or not to add a class of employees to the SEC for those DOE sites or activities where it is the prime contractor (i.e., M&O/M&I), team member to a prime contractor, program manager or subcontractor managing dosimetry programs, or otherwise intends to be employed as such within 12 months of starting this contract (or ending this contract?).

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Comment: Again, these terms should be fully defined prior to use of the abbreviations here.
Comment: Would it be appropriate to include this limitation – if so which is most appropriate?

- No individual will perform, review, or approve radiation dose reconstructions, prepare site profiles, or conduct research supporting determinations of whether or not to add a class of employees to the SEC, if he or she has voluntarily acted as an expert witness (including a non-testifying expert) on behalf of DOE or a DOE contractor in defense of radiation dose claims or suits. Restrictions for an individual who acts under subpoena will be determined on a case-by-case basis.

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- No individual will perform, review, or approve radiation dose reconstructions, site profiles, or determinations of whether or not to add a class of employees to the SEC for co-workers, DOE facilities at which they were formerly employed, or for contractors by whom they have been employed. Site experts may be employed to advise on site specific issues and incidents as necessary.

- No contractor or subcontractor element will be permitted to perform or bid for collateral work on DOE radiation dosimetry program support for those sites where it is conducting dose reconstructions, preparing a site profile (or scheduled to prepare a site profile), or performing work supporting a determination of whether or not to add a class of employees to the SEC.

Comment: Again, I am not sure of this limitation or exemption but we may want prior to this review strike this type of work for a non-DOE entity, e.g. NIOSH?
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Comment: I think this limitation should be considered whether work as we did it run into a DOE problem later.
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- Key personnel of the ORAU team will not have a conflict of interest with respect to managing this project or carrying out or marketing radiation protection/health physics services elsewhere in DOE.

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- Each supervisor, dosimetrist, and reviewer, and each professional performing, reviewing or approving a dose reconstruction, preparing a site profile or performing work supporting a determination of whether or not to add a class of

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employees to the SEC, will be required to complete and sign the attached form agreeing to abide by the above requirements. The forms will be maintained as auditable records of this project.

- No contractor, subcontractor, or individual will perform, review, or approve radiation dose reconstructions, prepare site profiles, or conduct research supporting determinations of whether or not to add a class of employees to the SEC if the company or individual has voluntarily provided expert witness services (including a non-testifying expert) on behalf of DOE or a contractor in defense of any claim filed under the EEOICPA. Restrictions for an individual who acts under subpoena will be determined on a case-by-case basis.

- A form identifying the dosimetrist who performed the dose reconstruction and the reviewer who approved it will be attached to each dose reconstruction and SEC determination, and provided to the claimant or petitioner(s) as appropriate, along with short biographical sketches.

All subcontracts issued to support ORAU in EEOICPA will contain a clause to ensure that the subcontractor complies with ORAU policy (stated here) regarding conflict of interest.

Comment: I don't think these forms should be posted publicly. I think it moves PA issues and allows too much public access. Claimants and stakeholder are free to request this information that can be distributed in a controlled manner in keeping with the legal requirements of the PA.

Deleted: If NIOSH concurs, these forms will also be scanned and posted on a web page ORAU will maintain for this project; links to the ORAU page will be provided for the NIOSH/OCAS and DOL web pages for this project.

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Comment: There may be PA issue here that we should discuss.

Page 2: [1] Comment Liz Hemold-Titus 5/5/2004 12:19 PM

I disagree that stakeholders or claimants should have unfettered access to this database. It raises too many PA questions. People can request info and after it is cleared for release it can be provided to them. We are not limiting the amount of info that can requested, but we should control access and dissemination of the information.

Page 2: [2] Deleted Liz Hemold-Titus 4/28/2004 10:22 AM

The ORAU Team believes that access to this information by individual claimants and by stakeholders is appropriate.

Page 2: [3] Deleted David Nelson 5/14/2004 2:39 PM

Because few claimants are likely to be able to use the database itself, p

ORAU TEAM CONFLICT OF INTEREST POLICY (Rev. 1 draft)

A. Overview

In any situation that involves compensation for injury, whether a tort claim, a worker's compensation case, or a claim made under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA), the integrity of the process must be unimpeachable. This is particularly true under the EEOICPA, because many of the persons working for the government on this program, whether as federal or contractor employees, have had previous involvement in the conduct of radiation protection programs at DOE facilities; or they may have previously received or are currently receiving financial support or compensation from DOE.

ORAU is extremely sensitive to the concerns in the stakeholder community regarding perceived or actual conflicts of interest (COI). ORAU understands that the bar on perceived and actual conflicts of interest must be set high for this project.

It is understood that the potential for COI exists, the most important factors are that the contractor must have a rigorous and precise plan for identifying potential COI situations and avoiding them; and that NIOSH, and the stakeholder community, must be assured by those plans and the actions of the contractor that the contractor will carry out that process with absolute integrity. Although some may view it as not desirable that persons with any sort of DOE affiliation be involved in dose reconstruction or Special Exposure Cohort (SEC) petition review, it is inevitable that many such persons must be involved, especially in the process of research. For example, health physicists who have expertise in the internal radiation dosimetry of plutonium must learn their trade at DOE facilities because that is where plutonium is available for study and processing. Similarly, the research effort to develop Site Profiles for the various sites will necessarily involve persons with expert knowledge of the sites, and that knowledge will usually have been gained from having worked there. Therefore, given these inherent potential conflicts, the contractor selected for the dose reconstruction project, along with NIOSH, must do everything possible to prevent or manage actual and perceived conflicts of interest and to disclose all potential conflicts of interest.

ORAU, a non-profit association of universities, was chartered in 1946. In the ensuing five decades, ORAU has gained unparalleled experience in maintaining the integrity of technical processes while working with many issues of public concern. Lessons learned from those experiences have been woven into the culture and structures of ORAU.

ORAU and its employees are committed to the highest ethical standards. All ORAU employees receive mandatory initial and refresher training in ethics, with emphasis on the ethical issues covered by these policies. This training is mandatory for all persons working on this project, including subcontractors, and was conducted during the start-up phase, with annual refreshers thereafter. ORAU will maintain documentation of the successful completion of this (and other) training for all personnel working on this project, whether ORAU or subcontractor employees.

Comment: I think the whole document has a very chit-chatty feel – I would recommend that the conversationalisms seen be removed as indicated below.

Comment: Is this a standard to high for anyone to meet? Would "above reproach" be better?

Comment: I don't think that all of this information is necessary or adds to the COI statement. I also think it is to conversational for a policy statement.

Deleted: one branch of the U.S. government (i.e., DOE) was responsible for the exposures to ionizing radiation and hazardous substances and is also charged with providing data to assist in adjudicating claims, while other branches of the government (i.e., NIOSH, DOL) are responsible for administering and operating the program. M

Comment: I would include "organization logo because I think "project" implies something like a grant fact sheet, or statement page, so I think "organization" and support covers all applications.

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Comment: I would recommend that this sentence be removed completely, or if not then make the recommendation ... [1]

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Comment: I think this would be ... [4]

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Comment: I think it is important ... [5]

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B. COI Policy

ORAU is committed to full and open disclosure as the best way to prevent conflicts of interest.

The ORAU Team will disclose, for each company and for each individual involved in dose reconstruction, preparation of Site Profiles, research supporting SEC determinations of whether or not to add a class of employees to the SEC, or any other work done for NIOSH on behalf of the EEOICPA program information about their past and present work at DOE sites. In addition, the ORAU Team members will inform NIOSH of any new DOE work that they are awarded. ORAU and its subcontractors will be proactive in making its processes for avoiding COI available to all stakeholders.

There are three aspects to effective disclosure/avoidance of conflict of interest:

- Planning of the work by the contractor;
- Oversight by NIOSH of COI performance; and
- Disclosure to stakeholders of information sufficient to let them evaluate the resolution of potential concerns about conflict of interest.

The ORAU Team will construct a database that lists all DOE sites where team members have worked, and outlines all potential areas of conflict of interest. This database will be used by the Project Director and Task Managers in making and checking work assignments for dose reconstruction, preparation of Site Profiles, or research supporting SEC determinations of whether or not to add a class of employees to the SEC. All individuals and companies on the ORAU team will provide the necessary information to populate the database initially, and will update it as necessary.

Access to the database will be provided to NIOSH for oversight of this contract. Because few claimants or stakeholders are likely to be able to use the database itself, printouts about the persons performing individual dose reconstructions (and their companies) will be offered upon request, within the proper bounds of Privacy Act disclosures. Beyond this, ORAU will work with NIOSH to find the best way to allow stakeholders to also request specific information.

The database will be constructed to provide the following information to the ORAU Team, to NIOSH, and upon request to claimants and other stakeholders:

- Whether and where ORAU, a subcontractor, or individual employees of ORAU or a subcontractor is, was or will be (in the next 12 months) involved in managing or directing DOE radiation protection and health physics program policies, practices and /or procedures.

- Whether and where ORAU, a subcontractor, or individual employees of ORAU or a subcontractor is, was or will be supporting, directly or indirectly, decision making in a radiation dosimetry program. This includes a

Comment: I don't think that ORAU should recognize any outside organizations influence in this process. This should be an ORAU/NIOSH improvement on the current practices.

Deleted: The Government Accountability Project has provided some useful guidance on avoiding conflicts of interest in the NIOSH Dose Reconstruction Project. ORAU agrees completely that "sunshine is the best disinfectant."

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Comment: This should be a blanket statement to cover any work the contractor does for NIOSH, not just limited to those three tasks; other tasks may come up where COI avoidance is necessary. So strength the author of this COI policy should not have a COI that it would appear he is trying to allow by [illegible]

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Comment: I don't think we should state that we want the stakeholders to make determinations on their own, they will do this anyway, but at least we can avoid the release of some information if necessary.

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[illegible]

Deleted: The ORAU Team believes that access to this information by individual claimants and by stakeholders is appropriate.

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Comment: I think each of these clauses should clearly indicate that individual employee information will by available on-site on the info from ORAU or the subcontractor to as only.

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contractor/subcontractor that is an (M&O/M&I), team member of an M&O/M&I, or a program manager of such a program.

- Whether and where ORAU, a subcontractor, or individual employees of ORAU or a subcontractor has broad technical support contracts or task-based contracts in place at DOE sites whose Statement of Work permits them to currently complete or be broadened to include the above radiation dosimetry work.

- Whether and where ORAU, a subcontractor, or individual employees of ORAU or a subcontractor has an active interest in bidding for the above DOE work activities and such interest has been properly disclosed elsewhere publicly (through public announcements, media or other disclosures.)

- Whether and where any individuals conducting dose reconstruction, preparation of Site Profiles, or research supporting SEC determinations of whether or not to add a class of employees to the SEC for the ORAU team have acted as expert witnesses, either voluntarily or under subpoena, on behalf of DOE or a DOE contractor with respect to worker compensation claims or law suits involving the question of whether radiation exposure was responsible in whole or in part for an alleged injury.

- Whether any individuals conducting dose reconstruction for ORAU or subcontractors have former colleagues or co-workers whose claims they may receive for dose reconstruction by virtue of the DOE facilities or sites assigned to them.

- Whether ORAU and its subcontractors and their employees are reviewing reports, assessments, surveys, documents and records that they organizationally or individually have been responsible for authoring, developing, or submitting to DOE or its contractors. ORAU will further indicate if ORAU, a subcontractor, or individual employees of ORAU or a subcontractor was an unidentified contributor to any such reports, assessments, surveys, documents or records.

To avoid potential for actual or perceived conflicts of interest in dose reconstruction or other activities under this contract, ORAU, its subcontractors, and the individual employees of ORAU or a subcontractor will subscribe to the following restrictions:

- No contractor, subcontractor, or employee will perform, review, or approve dose reconstructions for claimants from a given DOE/AWE site, prepare a Site Profile for that site, or provide support for an SEC determination of whether or not to add a class of employees to the SEC from that site, if they have previously performed work that affected or established policies on radiation dosimetry assessments, dosimetry programs or records at that site.

- No contractor, subcontractor, or employee will perform, review, or approve dose reconstructions for claimants from a given DOE/AWE site if they have previously

Comment: I am unsure what an M&O and M&I is – although I am sure that there are standard terms in the DOE work world, to be clear to the laymen these should be spelled out and included as a parenthetical definition of the terms for later use.

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Comment: It appears as to put these words in quotes without defining them – therefore I recommend removing the quotes or indicating why they mean something different from their common day meanings. Same for 'interest' below.

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Comment: Based on your previous comments, I have added an indicator that all original witnesses, whether voluntary or by subpoena will be reviewed and discussed. I agree that it should not make a difference if you gave testimony under subpoena or voluntarily.

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been involved with DOE funded dose assessments or reconstructions for workers from that site.

- No contractor element will participate in or review dose reconstructions or participate in research supporting Site Profiles or SEC determinations of whether or not to add a class of employees to the SEC for those DOE sites or activities where it is the prime contractor (i.e., M&O/M&I), team member to a prime contractor, program manager or subcontractor managing dosimetry programs, or otherwise intends to be employed as such within 12 months of starting this contract (or ending this contract?).
- No individual will perform, review, or approve radiation dose reconstructions, prepare Site Profiles, or conduct research supporting SEC determinations of whether or not to add a class of employees to the SEC, if he or she has voluntarily or under subpoena acted as an expert witness (including a non-testifying expert) on behalf of DOE or a DOE contractor in defense of radiation dose claims or suits.
- No individual will perform, review, or approve radiation dose reconstructions for co-workers, DOE facilities at which they were formerly employed, or for contractors by whom they have been employed. Site experts may be employed to advise on site specific issues and incidents as necessary.
- No contractor or subcontractor element will be permitted to perform or bid for collateral work on DOE radiation dosimetry program support for those sites where it is conducting dose reconstructions, preparing a Site Profile (or scheduled to prepare a Site Profile), or performing work supporting an SEC determination of whether or not to add a class of employees to the SEC.
- Key personnel of the ORAU team will not have a conflict of interest with respect to managing this project or carrying out or marketing radiation protection/health physics services elsewhere in DOE.
- Each supervisor, dosimetrist, and reviewer, and each professional preparing a Site Profile or performing work supporting an SEC determination of whether or not to add a class of employees to the SEC, will be required to complete and sign the attached form agreeing to abide by the above requirements. The forms will be maintained as auditable records of this project.
- No contractor, subcontractor, or individual will perform, review, or approve radiation dose reconstructions, prepare Site Profiles, or conduct research supporting SEC determinations of whether or not to add a class of employees to the SEC if the company or individual has voluntarily or under subpoena provided expert witness services (including a non-testifying expert) on behalf of DOE or a contractor in defense of any claim filed under the EEOICPA.

Comment: I am not sure if this is an appropriate limitation, but are there non-DOE funded experts that we may want to draw on the expertise of, from a University or NIOSH for example?

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Comment: Again, these terms should be fully defined above for use of the abbreviations here.

Comment: Would it be appropriate to include this limitation – if so which is more appropriate?

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Deleted: Restrictions for an individual who acts under subpoena will be determined on a case-by-case basis.

Comment: Again, I am not sure of this limitation is appropriate but we may want people to be able to move on to this type of work for a non-DOE entity, e.g. NIOSH?

Comment: I think this limitation should be extended to scheduled work as we don't want into a CXII problem here.

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Comment: I don't think these forms should be posted publicly. I think it raises PA issues and allows too much public access. Claimants and stakeholder are free to request this information that can be identified in a controlled manner in keeping with the legal requirements of the law.

Deleted: If NIOSH concurs, these forms will also be scanned and posted on a web page ORAU will maintain for this project. Links to the ORAU page will be provided for the NIOSH/OCAS and DOL web pages for this project.

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Deleted: Restrictions for an individual who acts under subpoena will be determined on a case-by-case basis.

- A form identifying the dosimetrist who performed the dose reconstruction and the reviewer who approved it will be attached to each dose reconstruction and SEC determination, and provided to the claimant or petitioner(s) as appropriate, along with short biographical sketches.

Comments: ODC should review this form and sketches should be reviewed for PA info.

All subcontracts issued to support ORAU in EEOICPA will contain a clause to ensure that the subcontractor complies with ORAU policy (stated here) regarding conflict of interest.

Page 1: [1] Comment Liz Homold-Titus 5/5/2004 12:19 PM

I would recommend that this sentence be removed completely, or if not then make the recommended changes. I am not sure that I agree that this COI policy goes beyond the FAR see: FAR 3.101-1 General. "The general rule is to avoid strictly any conflict of interest or even the appearance of a conflict of interest in Government-contractor relationships." This type of COI agreement may be allowed under FAR 9.5, but I don't think that allowing even perceived COI with the secondary reviewers allows this COI statement to be 'beyond the FAR.'.

Page 1: [2] Deleted Liz Homold-Titus 5/5/2004 11:55 AM

than is established by the COI provisions of the Federal Acquisition Regulations (FAR)

Page 1: [3] Deleted Liz Homold-Titus 4/28/2004 5:22 PM

The critical consideration is not whether the

Page 1: [4] Comment Liz Homold-Titus 5/5/2004 12:19 PM

I think this would be a good place to mention the stakeholder community so that it is more of a generalized commitment to involve them rather than specific commitments later in the document.

Page 1: [5] Comment Liz Homold-Titus 5/5/2004 12:19 PM

I think it is important to include NIOSH as an element as important as the contractor in this process.

Page 1: [6] Deleted Liz Homold-Titus 5/5/2004 11:59 AM

Providing objective science-based studies and analyses that withstand the COI challenge is more than something we do – it's a part of who we are.

Page 1: [7] Comment Liz Homold-Titus 5/5/2004 12:18 PM

I think it sounds better to indicate that ethics training will not be limited to just the issues in this document, there are ethics issues for government employees and contractors that are not covered in this document. I think NIOSH can expect their contractors and subcontractors to be well versed in and held to all appropriate ethical standards, nit just those in this document.

Page 1: [8] Deleted Liz Homold-Titus 5/5/2004 12:00 PM

Copies of the training materials can be provided to NIOSH for the project files.

ORAU TEAM CONFLICT OF INTEREST POLICY (Rev. 1a OGC draft)

A. Overview

In any situation that involves compensation for injury, whether a tort claim, a worker's compensation case, or a claim made under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA), the integrity of the process must be unimpeachable. This is particularly true under the EEOICPA, because one branch of the U.S. government (i.e., DOE) was responsible for the exposures to ionizing radiation and hazardous substances and is also charged with providing data to assist in adjudicating claims, while other branches of the government (i.e., NIOSH, DOL) are responsible for administering and operating the program. Many of the persons working for the government on this program, whether as federal or contractor employees, have had previous involvement in the conduct of radiation protection programs at DOE facilities; or they may have previously received or are currently receiving financial support or compensation from DOE.

Comment: I would include compensation here because I think "support" implies something like a grant for research, or retirement pay, so I think "compensation" and support covers all possibilities.

The ORAU Team is extremely sensitive to the concerns in the stakeholder community regarding perceived or actual conflicts of interest (COI). We understand why the bar on perceived and actual conflicts of interest must be set higher for this project than is established by the COI provisions of the Federal Acquisition Regulations (FAR).

The critical consideration is not whether the potential for COI exists – it does. The most important factors are that the contractor must have a rigorous and precise plan for identifying potential COI situations and avoiding them; and that NIOSH, and the stakeholder community, must be assured the contractor will carry out that process with absolute integrity. Although some may view it as not desirable that persons with any sort of DOE affiliation be involved in dose reconstruction or Special Exposure Cohort (SEC) petition review, it is inevitable that many such persons must be involved, especially in the process of research. For example, it is a simple fact that health physicists who have expertise in the internal radiation dosimetry of plutonium must have learned their trade at DOE facilities simply because that is where the plutonium is. Similarly, the research effort to develop Site Profiles for the various sites will necessarily involve persons with expert knowledge of the sites, and that knowledge will usually have been gained from having worked there. Therefore, given these inherent potential conflicts, the contractor selected for the dose reconstruction project, along with NIOSH, must do everything possible to prevent or manage actual and perceived conflicts of interest and to disclose all potential conflicts of interest.

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Comment: I think it is important to include NIOSH as an element as important as the contractor in this process.

ORAU, a non-profit association of universities, was chartered in 1946. In the ensuing five decades, we have gained unparalleled experience in maintaining the integrity of technical processes while working with many issues of public concern. Lessons learned from those experiences have been woven into the culture and structures of ORAU. Providing objective science-based studies and analyses that withstand the COI challenge is more than something we do – it's a part of who we are.

ORAU and its employees are committed to the highest ethical standards. All ORAU employees receive mandatory initial and refresher training in ethics, with emphasis on the ethical issues covered by these policies. This training will be made mandatory for all persons working on this project, including subcontractors, and will be conducted during the start-up phase, with annual refreshers thereafter. Copies of the training materials can be provided to NIOSH for the project files. ORAU will maintain documentation of the successful completion of this (and other) training for all personnel working on this project, whether ORAU or subcontractor employees.

B. COI Policy

ORAU is committed to full and open disclosure as the best way to prevent conflicts of interest.

The ORAU Team will disclose, for each company and for each individual involved in dose reconstruction, preparation of Site Profiles, research supporting SEC determinations of whether or not to add a class of employees to the SEC, or any other work done for NIOSH on behalf of the EEOICPA program, information about their past and present work at DOE sites. In addition, the ORAU Team members will inform NIOSH of any new DOE work that they are awarded. ORAU and its subcontractors will be proactive in making its processes for avoiding COI available to all stakeholders.

There are three aspects to effective disclosure/avoidance of conflict of interest:

- Planning of the work by the contractor;
- Oversight by NIOSH of COI performance; and
- Disclosure to stakeholders of information sufficient to let them evaluate the resolution of potential concerns about conflict of interest.

The ORAU Team will construct a database that lists all DOE sites where team members have worked, and outlines all potential areas of conflict of interest. This database will be used by the Project Director and Task Managers in making and checking work assignments for dose reconstruction, preparation of Site Profiles, or research supporting SEC determinations of whether or not to add a class of employees to the SEC. All individuals and companies on the ORAU team will provide the necessary information to populate the database initially, and will update it as necessary.

Access to the database will be provided to NIOSH for oversight of this contract. Because few claimants or stakeholders are likely to be able to use the database itself, printouts about the persons performing individual dose reconstructions (and their companies) will be offered upon request. Requests will be fulfilled within the requirments of privacy interests. Beyond this, ORAU will work with NIOSH to find the best way to allow stakeholders to also request specific information.

The database will be constructed to provide the following information to the ORAU Team, to NIOSH, and upon request to claimants and other stakeholders:

Comment: I think it sounds better to indicate that ethics training will not be limited to just the issues in this document, there are ethics issues for government employees and contractors that are not covered in this document. I think NIOSH can expect their contractors and subcontractors to be well versed in and held to all appropriate ethical standards, all just done in this document.

Comment: I don't think that ORAU should recognize any outside organizations influence in this process. This should be an ORAU/NIOSH improvement on the current practices.

Deleted: The Government Accountability Project has provided some useful guidance on avoiding conflicts of interest in the NIOSH Dose Reconstruction Project. ORAU agrees completely that "sunshine is the best disinfectant."

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Comment: This should be a blanket statement to cover any work the contractor does for NIOSH, not just limited to these three tasks, other tasks could arise in which COI avoidance is important, for example the author of this COI policy should not have a COI that it would appear he is trying to allow by writing the policy a certain way.

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Comment: I don't think we should stop that we want the stakeholders to make determinations on their own, they will do this anyway, but at least we can avoid the release of some information if necessary.

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Deleted: The ORAU Team believes that access to this information by individual claimants and by stakeholders is appropriate.

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- Whether and where ORAU, a subcontractor, or individual employees of ORAU or a subcontractor is, was or will be (in the next 12 months) involved in managing or directing DOE radiation protection and health physics program policies, practices and /or procedures.

- Whether and where ORAU, a subcontractor, or individual employees of ORAU or a subcontractor is, was or will be supporting, directly or indirectly, decision making in a radiation dosimetry program. This includes a contractor/subcontractor that is an (M&O/M&I) team member of an M&O/M&I, or a program manager of such a program.

- Whether and where ORAU, a subcontractor, or individual employees of ORAU or a subcontractor has broad technical support contracts or task-based contracts in place at DOE sites whose Statement of Work permits them to currently complete or be broadened to include the above radiation dosimetry work.

- Whether and where ORAU, a subcontractor, or individual employees of ORAU or a subcontractor has an active interest in bidding for the above DOE work activities and such interest has been properly disclosed elsewhere publicly (through public announcements, media or other disclosures.)

- Whether and where any individuals conducting dose reconstruction, preparation of Site Profiles, or research supporting SEC determinations of whether or not to add a class of employees to the SEC for the ORAU team have acted as expert witnesses on behalf of DOE or a DOE contractor with respect to worker compensation claims or law suits involving the question of whether radiation exposure was responsible in whole or in part for an alleged injury.

- Whether any individuals conducting dose reconstruction for ORAU or subcontractors have former colleagues or co-workers whose claims they may receive for dose reconstruction by virtue of the DOE facilities or sites assigned to them.

- Whether ORAU and its subcontractors and their employees are reviewing reports, assessments, surveys, documents and records that they organizationally or individually have been responsible for authoring, developing, or submitting to DOE or its contractors. ORAU will further indicate if ORAU, a subcontractor, or individual employees of ORAU or a subcontractor was an unidentified contributor to any such reports, assessments, surveys, documents or records.

To avoid potential for actual or perceived conflicts of interest in dose reconstruction or other activities under this contract, ORAU, its subcontractors, and the individual employees of ORAU or a subcontractor will subscribe to the following restrictions:

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Comment: I think each of these clauses should clearly indicate that individual employee information will be available as well as the info from ORAU or the subcontractor as an entity.

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Comment: I am unsure what an M&O and M&I is – although I am sure that these are standard terms in the DOE work world, so be clear in the lessons these should be spelled out once and included as a parenthetical definition of the terms for later use.

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Comment: It concerns me to put these words in quotes without defining them – therefore I recommend removing the quotes or indicating why they mean something different from their common day meanings. Same for 'interest' below.

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Comment: I don't know if there is anyway to know this, or if it should be included, but I thought I'd throw it out.

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- No contractor, subcontractor, or employee will perform, review, or approve dose reconstructions for claimants from a given DOE/AWE site, prepare a Site Profile for that site, or provide support for an SEC determination of whether or not to add a class of employees to the SEC from that site, if they have previously performed work that affected or established policies on radiation dosimetry assessments, dosimetry programs or records at that site.

- No contractor, subcontractor, or employee will perform, review, or approve dose reconstructions for claimants from a given DOE/AWE site if they have previously been involved with DOE funded dose assessments or reconstructions for workers from that site.

- No contractor element will participate in or review dose reconstructions or participate in research supporting Site Profiles or SEC determinations of whether or not to add a class of employees to the SEC for those DOE sites or activities where it is the prime contractor (i.e., M&O/M&I), team member to a prime contractor, program manager or subcontractor managing dosimetry programs, or otherwise intends to be employed as such within 12 months of starting this contract (or ending this contract?).

- No individual will perform, review, or approve radiation dose reconstructions, prepare Site Profiles, or conduct research supporting SEC determinations of whether or not to add a class of employees to the SEC, if he or she has voluntarily acted as an expert witness (including a non-testifying expert) on behalf of DOE or a DOE contractor in defense of radiation dose claims or suits. Restrictions for an individual who acts under subpoena will be determined on a case-by-case basis.

- No individual will perform, review, or approve radiation dose reconstructions for co-workers, DOE facilities at which they were formerly employed, or for contractors by whom they have been employed. Site experts may be employed to advise on site specific issues and incidents as necessary.

- No contractor or subcontractor element will be permitted to perform or bid for collateral work on DOE radiation dosimetry program support for those sites where it is conducting dose reconstructions, preparing a Site Profile (or scheduled to prepare a Site Profile), or performing work supporting an SEC determination of whether or not to add a class of employees to the SEC.

- Key personnel of the ORAU team will not have a conflict of interest with respect to managing this project or carrying out or marketing radiation protection/health physics services elsewhere in DOE.

- Each supervisor, dosimetrist, and reviewer, and each professional preparing a Site Profile or performing work supporting an SEC determination of whether or not to add a class of employees to the SEC, will be required to complete and sign the

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Comment: I am not sure if this is an appropriate limitation, but are there non-DOE funded experts that we may want to draw on the expertise of, from a University or NIOSH for example?

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Comment: Again, these terms should be fully defined above for use of the abbreviations here.

Comment: Would it be appropriate to include this limitation – if so, which is more appropriate?

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Comment: Again, I am not sure if this limitation is appropriate but we may want people to be able to move on to this type of work for a non-DOE entity, e.g. NIOSH?

Comment: I think this limitation should be extended to scheduling work on my desk/from just a COI perspective here.

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attached form agreeing to abide by the above requirements. The forms will be maintained as auditable records of this project.

- No contractor, subcontractor, or individual will perform, review, or approve radiation dose reconstructions, prepare Site Profiles, or conduct research supporting SEC determinations of whether or not to add a class of employees to the SEC if the company or individual has voluntarily provided expert witness services (including a non-testifying expert) on behalf of DOE or a contractor in defense of any claim filed under the EEOICPA. Restrictions for an individual who acts under subpoena will be determined on a case-by-case basis.

- A form identifying the dosimetrist who performed the dose reconstruction and the reviewer who approved it will be attached to each dose reconstruction and SEC determination, and provided to the claimant or petitioner(s) as appropriate, along with short biographical sketches.

All subcontracts issued to support ORAU in EEOICPA will contain a clause to ensure that the subcontractor complies with ORAU policy (stated here) regarding conflict of interest.

Comment: I don't think these forms should be posted publicly. I think it raises PA issues and allows too much public access. Claimants and stakeholder are free to request this information that can be distributed in a controlled manner in keeping with the legal requirements of the PA.

Deleted: If NIOSH concurs, these forms will also be scanned and posted on a web page ORAU will maintain for this project; links to the ORAU page will be provided for the NIOSH/OCAS and DOL web pages for this project.

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ORAU TEAM CONFLICT OF INTEREST POLICY (Rev. 1a OGC draft)

A. Overview

In any situation that involves compensation for injury, whether a tort claim, a worker's compensation case, or a claim made under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA), the integrity of the process must be unimpeachable. This is particularly true under the EEOICPA, because one branch of the U.S. government (i.e., DOE) was responsible for the exposures to ionizing radiation and hazardous substances and is also charged with providing data to assist in adjudicating claims, while other branches of the government (i.e., NIOSH, DOL) are responsible for administering and operating the program. Many of the persons working for the government on this program, whether as federal or contractor employees, have had previous involvement in the conduct of radiation protection programs at DOE facilities; or they may have previously received or are currently receiving financial support or compensation from DOE.

Comment: I would include compensation here because I think "support" implies something like a grant for research, or retirement pay, so I think "compensation" and support covers all possibilities.

The ORAU Team is extremely sensitive to the concerns in the stakeholder community regarding perceived or actual conflicts of interest (COI). We understand why the bar on perceived and actual conflicts of interest must be set higher for this project than is established by the COI provisions of the Federal Acquisition Regulations (FAR).

The critical consideration is not whether the potential for COI exists – it does. The most important factors are that the contractor must have a rigorous and precise plan for identifying potential COI situations and avoiding them; and that NIOSH, and the stakeholder community, must be assured the contractor will carry out that process with absolute integrity. Although some may view it as not desirable that persons with any sort of DOE affiliation be involved in dose reconstruction or Special Exposure Cohort (SEC) petition review, it is inevitable that many such persons must be involved, especially in the process of research. For example, it is a simple fact that health physicists who have expertise in the internal radiation dosimetry of plutonium must have learned their trade at DOE facilities simply because that is where the plutonium is. Similarly, the research effort to develop Site Profiles for the various sites will necessarily involve persons with expert knowledge of the sites, and that knowledge will usually have been gained from having worked there. Therefore, given these inherent potential conflicts, the contractor selected for the dose reconstruction project, along with NIOSH, must do everything possible to prevent or manage actual and perceived conflicts of interest and to disclose all potential conflicts of interest.

Delete: dose reconstruction

Comment: I think it is important to include NIOSH as an element as important as the contractor in this process.

ORAU, a non-profit association of universities, was chartered in 1946. In the ensuing five decades, we have gained unparalleled experience in maintaining the integrity of technical processes while working with many issues of public concern. Lessons learned from those experiences have been woven into the culture and structures of ORAU. Providing objective science-based studies and analyses that withstand the COI challenge is more than something we do – it's a part of who we are.

ORAU and its employees are committed to the highest ethical standards. All ORAU employees receive mandatory initial and refresher training in ethics, with emphasis on the ethical issues covered by these policies. This training will be made mandatory for all persons working on this project, including subcontractors, and will be conducted during the start-up phase, with annual refreshers thereafter. Copies of the training materials can be provided to NIOSH for the project files. ORAU will maintain documentation of the successful completion of this (and other) training for all personnel working on this project, whether ORAU or subcontractor employees.

B. COI Policy

ORAU is committed to full and open disclosure as the best way to prevent conflicts of interest.

The ORAU Team will disclose, for each company and for each individual involved in dose reconstruction, preparation of Site Profiles, research supporting SEC determinations of whether or not to add a class of employees to the SEC, or any other work done for NIOSH on behalf of the EEOICPA program, information about their past and present work at DOE sites. In addition, the ORAU Team members will inform NIOSH of any new DOE work that they are awarded. ORAU and its subcontractors will be proactive in making its processes for avoiding COI available to all stakeholders.

There are three aspects to effective disclosure/avoidance of conflict of interest:

- Planning of the work by the contractor;
- Oversight by NIOSH of COI performance; and
- Disclosure to stakeholders of information sufficient to let them evaluate the resolution of potential concerns about conflict of interest.

The ORAU Team will construct a database that lists all DOE sites where team members have worked, and outlines all potential areas of conflict of interest. This database will be used by the Project Director and Task Managers in making and checking work assignments for dose reconstruction, preparation of Site Profiles, or research supporting SEC determinations of whether or not to add a class of employees to the SEC. All individuals and companies on the ORAU team will provide the necessary information to populate the database initially, and will update it as necessary.

Access to the database will be provided to NIOSH for oversight of this contract. Because few claimants or stakeholders are likely to be able to use the database itself, printouts about the persons performing individual dose reconstructions (and their companies) will be offered upon request. Requests will be fulfilled within the requirements of privacy interests. Beyond this, ORAU will work with NIOSH to find the best way to allow stakeholders to also request specific information.

The database will be constructed to provide the following information to the ORAU Team, to NIOSH, and upon request to claimants and other stakeholders:

Comment: I think it sounds better to indicate that ethics training will not be limited to just the issues in this document, there are ethics issues for government employees and contractors that are not covered in this document. I think NIOSH can/expect their contractors and subcontractors to be well versed in and held to all appropriate ethical standards, not just those in this document.

Comment: I don't think that ORAU should recognize any outside organizations influence in this process. This should be an ORAU/NIOSH improvement on the current practices.

Deletedt: The Government Accountability Project has provided some useful guidance on avoiding conflicts of interest in the NIOSH Dose Reconstruction Project. ORAU agrees completely that "sunshine is the best disinfectant."

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Comment: This should be a blanket statement to cover any work the contractor does for NIOSH, not just limited to dose recon work, other tasks and teams of subject COI determinations is unclear. For example the author of this COI policy should not have a COI that it would appear by its trying to allow by writing the policy in certain way.

Deletedt: which

Comment: I don't think we should state that we want the stakeholders to make determinations on their own, they will do this anyway, but at least we can avoid the release of more information if anyway.

Deletedt: for themselves

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Comment: [illegible] stakeholders [illegible] should have unlimited access to this database. It raises too many [illegible]. People can request info [illegible] for release it can be [illegible]. When just thinking the [illegible] that was released, but we [illegible] and documentation of [illegible].

Deletedt: The ORAU Team believes that access to this information by individual claimants and by stakeholders is appropriate.

Deletedt: to those claimants

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- Whether and where ORAU, a subcontractor, or individual employees of ORAU or a subcontractor is, was or will be (in the next 12 months) involved in managing or directing DOE radiation protection and health physics program policies, practices and /or procedures.

- Whether and where ORAU, a subcontractor, or individual employees of ORAU or a subcontractor is, was or will be supporting, directly or indirectly, decision making in a radiation dosimetry program. This includes a contractor/subcontractor that is an (M&O/M&I), team member of an M&O/M&I, or a program manager of such a program.

- Whether and where ORAU, a subcontractor, or individual employees of ORAU or a subcontractor has broad technical support contracts or task-based contracts in place at DOE sites whose Statement of Work permits them to currently complete or be broadened to include the above radiation dosimetry work.

- Whether and where ORAU, a subcontractor, or individual employees of ORAU or a subcontractor has an active interest in bidding for the above DOE work activities and such interest has been properly disclosed elsewhere publicly (through public announcements, media or other disclosures.)

- Whether and where any individuals conducting dose reconstruction, preparation of Site Profiles, or research supporting SEC determinations of whether or not to add a class of employees to the SEC for the ORAU team have acted as expert witnesses on behalf of DOE or a DOE contractor with respect to worker compensation claims or law suits involving the question of whether radiation exposure was responsible in whole or in part for an alleged injury.

- Whether any individuals conducting dose reconstruction for ORAU or subcontractors have former colleagues or co-workers whose claims they may receive for dose reconstruction by virtue of the DOE facilities or sites assigned to them.

- Whether ORAU and its subcontractors and their employees are reviewing reports, assessments, surveys, documents and records that they organizationally or individually have been responsible for authoring, developing, or submitting to DOE or its contractors. ORAU will further indicate if ORAU, a subcontractor, or individual employees of ORAU or a subcontractor was an unidentified contributor to any such reports, assessments, surveys, documents or records.

To avoid potential for actual or perceived conflicts of interest in dose reconstruction or other activities under this contract, ORAU, its subcontractors, and the individual employees of ORAU or a subcontractor will subscribe to the following restrictions:

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Comment: I think each of these clauses should clearly indicate that individual employee information will be available as well as the info from ORAU or the subcontractor as an entity.

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Comment: I am unsure what an M&O and M&I is – although I am sure that these are standard terms in the DOE work world, so be sure to the layman these should be spelled out once and included as a parenthetical definition of the terms for first use.

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Comment: It concerns me to put these words in quotes without defining them – therefore I recommend removing the quotes or indicating why they mean something different from their common dictionary meanings. Same for 'interest' below.

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Comment: I don't know if there is anyway to leave this, or if it should be included, but I thought I'd throw it out.

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- No contractor, subcontractor, or employee will perform, review, or approve dose reconstructions for claimants from a given DOE/AWE site, prepare a Site Profile for that site, or provide support for an SEC determination of whether or not to add a class of employees to the SEC from that site, if they have previously performed work that affected or established policies on radiation dosimetry assessments, dosimetry programs or records at that site.

- No contractor, subcontractor, or employee will perform, review, or approve dose reconstructions for claimants from a given DOE/AWE site if they have previously been involved with DOE funded dose assessments or reconstructions for workers from that site.

- No contractor element will participate in or review dose reconstructions or participate in research supporting Site Profiles or SEC determinations of whether or not to add a class of employees to the SEC for those DOE sites or activities where it is the prime contractor (i.e., M&O/M&I), team member to a prime contractor, program manager or subcontractor managing dosimetry programs, or otherwise intends to be employed as such within 12 months of starting this contract (or ending this contract?)

- No individual will perform, review, or approve radiation dose reconstructions, prepare Site Profiles, or conduct research supporting SEC determinations of whether or not to add a class of employees to the SEC, if he or she has voluntarily acted as an expert witness (including a non-testifying expert) on behalf of DOE or a DOE contractor in defense of radiation dose claims or suits. Restrictions for an individual who acts under subpoena will be determined on a case-by-case basis.

- No individual will perform, review, or approve radiation dose reconstructions for co-workers, DOE facilities at which they were formerly employed, or for contractors by whom they have been employed. Site experts may be employed to advise on site specific issues and incidents as necessary.

- No contractor or subcontractor element will be permitted to perform or bid for collateral work on DOE radiation dosimetry program support for those sites where it is conducting dose reconstructions, preparing a Site Profile (or scheduled to prepare a Site Profile), or performing work supporting an SEC determination of whether or not to add a class of employees to the SEC.

- Key personnel of the ORAU team will not have a conflict of interest with respect to managing this project or carrying out or marketing radiation protection/health physics services elsewhere in DOE.

- Each supervisor, dosimetrist, and reviewer, and each professional preparing a Site Profile or performing work supporting an SEC determination of whether or not to add a class of employees to the SEC, will be required to complete and sign the

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Comment: I am not sure if this is an appropriate limitation, but are there non-DOE funded experts that we may want to draw on the expertise of, from a University or NIOSH for example?

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Comment: Again, these terms should be fully defined above for ease of the abbreviations here.

Comment: Would it be appropriate to include this limitation – if so which is more appropriate?

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Comment: Again, I am not sure of this limitation as I agree that we only want people to do this to avoid ties to this type of work for a non-DOE entity, e.g. NIOSH.

Comment: I think this limitation should be stated as potential work so we don't run into a COI problem later.

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attached form agreeing to abide by the above requirements. The forms will be maintained as auditable records of this project.

- No contractor, subcontractor, or individual will perform, review, or approve radiation dose reconstructions, prepare Site Profiles, or conduct research supporting SEC determinations of whether or not to add a class of employees to the SEC if the company or individual has voluntarily provided expert witness services (including a non-testifying expert) on behalf of DOE or a contractor in defense of any claim filed under the EEOICPA. Restrictions for an individual who acts under subpoena will be determined on a case-by-case basis.

- A form identifying the dosimetrist who performed the dose reconstruction and the reviewer who approved it will be attached to each dose reconstruction and SEC determination, and provided to the claimant or petitioner(s) as appropriate, along with short biographical sketches.

All subcontracts issued to support ORAU in EEOICPA will contain a clause to ensure that the subcontractor complies with ORAU policy (stated here) regarding conflict of interest.

Comment: I don't think these forms should be posted publicly. I think it raises PA issues and allows too much public access. Claimants and stakeholder are free to request this information that can be distributed in a controlled manner in keeping with the legal requirements of the PA.

Deleted: If NIOSH concurs, these forms will also be scanned and posted on a web page ORAU will maintain for this project; links to the ORAU page will be provided for the NIOSH/OCAS and DOL web pages for this project.

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Neton, Jim

From: Toohey, Richard [TooheyR@orau.gov]
Sent: Wednesday, August 18, 2004 9:32 AM
To: Neton, Jim
Subject: RE: COI Policy

ASAP may not be until Friday; we have our internal management review today and tomorrow.

Dick

-----Original Message-----
From: Neton, Jim [mailto:JFN2@CDC.GOV]
Sent: Wednesday, August 18, 2004 9:29 AM
To: Toohey, Richard
Cc: Elliott, Larry J.; Homoki-Titus, Zeda (Liz) E.
Subject: COI Policy

Dick,

We have finally completed our review of ORAU's modified COI policy. Could you please review the attached version and get back to me ASAP with any comments you might have? As you know, we'd like to get this finalized prior to the Board meeting next week. Please give me a call if you have any questions.

<<COI Policy - Final.doc>>

Thanks,

Jim

Neton, Jim

From: Neton, Jim
Sent: Friday, August 20, 2004 9:39 AM
To: 'tooheyr@orau.gov'
Subject: Fw: COI Policy

Dick,

Would the proposed language tweak below be more palatable to ORAU? If so, I'll add it and reissue the document when I return to the office. I'm curently at a doctor's appointment, but should be in the office by 11:00.

Jim

-----Original Message-----
From: Homoki-Titus, Zeda (Liz) E. <ZAH9@CDC.GOV>
To: Neton, Jim <JFN2@CDC.GOV>
Sent: Fri Aug 20 09:31:38 2004
Subject: RE: COI Policy

Jim - What if we recommend the addition of DRs and SEC so the phrase would now say, "or any other work done by primary authors or reviewers for NIOSH on dose reconstruction or SEC petitions on behalf of the EEOICPA program...." Would that cover us and take care of their concern? If so that is ok by me. Thanks - Liz

Zeda E. (Liz) Homoki-Titus
Acting Team Leader
Radiation Compensation Legal Team
HHS Office of the General Counsel
Public Health Division
CDC/ATSDR Branch
1101 Wootton Parkway, Suite 560
Rockville, Maryland 20852
301-443-0115 - PHN
202-315-6336 - Cell
301-594-0041 - FAX
zhomoki@cdc.gov

-----Original Message-----
From: Neto << File: COI Policy - Final.doc >> , Jim
Sent: Friday, August 20, 2004 9:18 AM
To: Homoki-Titus, Zeda (Liz) E.
Cc: Elliott, Larry J.
Subject: Fw: COI Policy

Liz,

If ORAU objects to the new phrase, can we delete it to move the COI policy forward? I know that it's intended to cover any other unexpected issue, but I'd rather not hold this up over the new phrase.

Jim

-----Original Message-----
From: Dick E. Toohey <dtoohey@oraucoc.org>
To: Townsend, Ronald <ron.townsend@orau.org>; Donna Cragle (ORAU) <cragled@orau.gov>; mmoeller@moellerinc.com <mmoeller@moellerinc.com>; David A. Dooley <ddooley@mjwcorp.com>
CC: Neton, Jim <JFN2@CDC.GOV>
Sent: Thu Aug 19 18:46:29 2004
Subject: FW: COI Policy

Got this from Jim Neton yesterday, and just now looked at it; Jim would like to tell the Advisory Board next Tuesday it is approved and in place. However, although I felt secure approving it for the ORAU Team with regard to SEC petition work being included, the text now reads, in addition to SEC work, "or any other work done by primary authors or reviewers for NIOSH on behalf of the EEOICPA program...." (Section B, second paragraph, 3rd line, and elsewhere). To me, this means that anyone who writes or reviews a procedure, or anything else for that matter, needs a disclosure form posted, which may practically include all employees. Are we willing to agree to this?

Dick

-----Original Message-----
From: Toohey, Richard [mailto:ToheyR@orau.gov]
Sent: Thursday, August 19, 2004 6:32 PM
To: Dick E. Toohey
Subject: Fw: COI Policy

Sent from my BlackBerry Wireless Handheld

-----Original Message-----
From: Neton, Jim <JFN2@CDC.GOV>
To: Toohey, Richard <ToheyR@orau.gov>
CC: Elliott, Larry J. <LJE1@CDC.GOV>; Homoki-Titus, Zeda (Liz) E. <ZAH9@CDC.GOV>
Sent: Wed Aug 18 09:28:46 2004
Subject: COI Policy

<<COI Policy - Final.doc>> Dick,

We have finally completed our review of ORAU's modified COI policy. Could you please review the attached version and get back to me ASAP with any comments you might have? As you know, we'd like to get this finalized prior to the Board meeting next week. Please give me a call if you have any questions.

<<COI Policy - Final.doc>>

Thanks,

Jim

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Effective Date: 12/02/2002	Revision No. 0	Document No. ORAUT-FORM-0005	Page 2 of 3

ORAU
OAK RIDGE ASSOCIATED UNIVERSITIES

DOSE RECONSTRUCTION PROJECT TEAM

NONDISCLOSURE OF PROPRIETARY INFORMATION AGREEMENT

I, JOHN W. POSTON, SR., an employee of FOXFIRE SCIENTIFIC, INC. have been requested to conduct work as a member of the Oak Ridge Associated Universities (ORAU) Team on CDC/NIOSH Contract # 200-2002-00593, entitled "Radiation Dose Estimation, Dose Reconstruction and Evaluation of SEC Petitions under EEOICPA." I understand that, in the course of activities for this contract, I may be given access to information regarding certain business activities or research and development efforts at CDC, ORAU, or subcontractors to ORAU. I also understand that some information that may be shared with me during my work on the project may be otherwise considered proprietary, business confidential, procurement sensitive, or trade secret (hereinafter "proprietary information"). By execution of this document, I agree to treat all such information in a confidential manner, for a period of six years after disclosure, as described below.

1. In order for proprietary information to be protected in accordance with this agreement, it must be clearly identified by the information provider as proprietary information at the time I am provided access to the information. If the information is provided during a briefing, the information provider must clearly state what information in the briefing is considered to be proprietary. If the information is in documentary form, each page that contains proprietary information must be clearly marked with the legend "Proprietary Information of (Information provider)," and the proprietary information on that page must be clearly identified by margin markings. If the proprietary information is in electronic format, the portion that is proprietary must be clearly identified.

2. Proprietary information meeting the above requirements may be used by me only in my activities for the above named project.

3. I will take appropriate precautions to prevent disclosure to third parties, including the public, of proprietary information meeting the above requirements. I will be considered to have taken appropriate precautions to prevent disclosure to the public of proprietary information if I utilize the same controls I would use to avoid disclosure, publication or dissemination of my employer's proprietary information.

4. All written data and information, including any samples or materials, furnished to the undersigned, and all copies, reproductions and portions thereof, shall be and remain the exclusive property of the originator. I agree to promptly deliver the same to the originator upon request. I further agree not to make any analysis of any materials furnished to me, or to permit any third party to do so, except as directed or authorized by the originator.

5. I recognize that all information I receive in performance of my responsibilities related to the work may be considered "Business Sensitive;" that such information has potential value to

Effective Date: 12/02/2002	Revision No. 0	Document No. ORAUT-FORM-0005	Page 3 of 3

organizations who are potential competitors on future contract matters regardless of whether the information is considered proprietary as defined above; and that Business Sensitive information must be properly protected at all times.

6. I will treat all information obtained in the performance of my responsibilities as Business Sensitive information.

7. I will not be required to treat as proprietary or Business Sensitive any information which is:

   a. in the public domain,
   b. known by me prior to the time I am given access to the information by the information provider,
   c. rightfully received by me from a third party without restriction on disclosure, or
   d. required to be disclosed by law.

With intent to be bound by this agreement, I have executed it on the date indicated below.

Signed

Date: Sept 20, 2004

Effective Date: 04/09/2003	Revision No. 02	Document No. ORAUT-FORM-0006	Page 2 of 2

Individual Disclosure and Agreement Form

(Please complete, abbreviating as necessary and using the tab to travel through the form. If needed, type a continuation page in **Arial 9 pt**, referencing the item number). Continuation page? ☐Y ☐N.

Name: [redacted]

1) Previous Department of Energy (DOE)/Contractor employment:

Using one input box per site/contractor combination, please indicate **Site**, **Contractor**, **Number of Years Worked at Site**, and **Duties.**

Oak Ridge National Lab, Union Carbide, 13 years, Health Physicist

2) Previous Atomic Weapons Employer (AWE)/AWE Contractor employment:

Using one input box per site/contractor combination, please indicate **Site**, **Contractor**, **Number of Years Worked at Site**, and **Duties.**

none

3) Expert witness participation (including non-testifying); list all cases:

Using one input box per case, please indicate **Case**, **Dates**, and **Role**.

Tang v. Southern California Edison, witness for defense, 1994

Kennedy v. Southern California Edison, witness for defense, 1998

Takarud v. Bechtel, et al., deposition, expert witness, 1999

Mull v. Duke Power, deposition, expert witness, 2000

Gaume v. Jamison, deposition, expert witness, 2002

Hanford downwinders, expert report for defense, 2004 - no dose assessment or defense thereof. Strictly acting as a historian discussing contemporary health physics practices at the Hanford site

4) I have no known relatives by blood or marriage that have been employed at any DOE or AWE site or employed by any DOE or AWE contractor, except the following:

Using one input box per relative, please indicate **Name of relative and DOE/AWE Site(s) of Employment.**

John W. Poston, Jr., Hanford-Rockwell, Radiological Engineer

Martha P. Brown, Bechtel-Jacobs, Oak Ridge, Health Physicist

I hereby agree to recuse myself from supervising, performing, or reviewing any dose reconstruction for a claimant from DOE or AWE facilities at which I have previously worked, or otherwise been involved in managing, directing, developing, or implementing DOE or AWE radiation protection and health physics program policies, practices and/or procedures. I also agree to recuse myself from performing or reviewing any dose reconstruction for a claimant personally known to me or related to me to any degree. Furthermore, I agree to recuse myself from supervising, performing or reviewing any dose reconstruction if I have acted as an expert witness (including a non-testifying expert) on behalf of DOE or a DOE contractor or an AWE or AWE contractor in defense of radiation dose claims or suits.

Signed: J. W. Poston Jr. Witness: Robert O. Berry Date: 09/20/04

Print witness name: Robert O. Berry

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ORAU RECORD COPY	INDIVIDUAL DISCLOSURE AND AGREEMENT	ORAU TEAM Dose Reconstruction Project for NIOSH

(Complete lines 1 - 4, abbreviating as necessary and using the tab to travel through the form. If needed, type a continuation page in Arial 9 pt, referencing the item number.) Continuation page? ☐ Y ☐ N

Name: John W. Poston, Jr. Employer: Foxfire Scientific Date: 11/11/05

1. **Previous Department of Energy (DOE)/DOE Contractor employment (including consulting): Using one input box per site/contractor combination, indicate Site, Contractor, Number of Years Worked at or for Site, and Duties.**

Hanford, Rockwell and Westinghouse, 1 year, Regulatory Compliance and Environmental Health Physics

ANL-West, Univ. of Chicago, 4 years, Internal Dosimetry Program and Operational Health Physics

2. **Previous Atomic Weapons Employer (AWE)/AWE Contractor employment (including consulting): Using one input box per site/contractor combination, indicate Site, Contractor, Number of Years Worked at or for Site, and Duties.**

None

3. **Expert witness participation (including non-testifying); list all cases: Using one input box per case, indicate Case, Dates, and Role.**

None

4. **I have no known Relatives by blood or marriage that have been employed at or for any DOE or AWE site or employed by any DOE or AWE contractor, except the following: Using one input box per relative, indicate Name of relative and DOE/AWE Site(s) of Employment.**

John W. Poston, Sr., Oak Ridge

Martha Poston Brown, Oak Ridge

I hereby agree to recuse myself from serving as Dose Reconstructor or Peer Reviewer for the ORAU Team of any dose reconstruction for a claimant from DOE or AWE facilities at or for which I have previously worked, or otherwise been involved in managing, directing, developing, or implementing DOE or AWE radiation protection and health physics program policies, practices, and/or procedures. I also agree to recuse myself from performing or reviewing any dose reconstruction for a claimant personally known by me or that I know is related to me by blood or marriage. Furthermore, I agree to recuse myself from performing or reviewing any dose reconstructions, or participating as Lead Technical Evaluator or Peer Reviewer of any draft Special Exposure Cohort petition evaluation if I have acted as an expert witness (including a non-testifying expert) on behalf of DOE or a DOE contractor or an AWE or AWE contractor in defense of radiation dose claims or suits related to a particular facility. I agree to recuse myself from participating as the Document Owner (Team Leader) of any site profile document or Lead Technical Evaluator or Peer Reviewer of any draft Special Exposure Cohort petition evaluation dealing with a DOE or AWE facility at or for which I have previously worked or otherwise been involved in managing, directing, developing, or implementing DOE or AWE radiation protection and health physics program policies, practices, and/or procedures. I have been made aware that I am also precluded from performing any of the work functions specifically listed above where it has been established that my employer has a corporate conflict of interest at the relevant site, including anticipated (i.e., formal bid status) work that involves the management or direction of radiation protection and health physics program policies, practices, or procedures.

Signed: John W. Poston Date: 11/11/05 Print name: John W. Poston, Jr.

Witness: Martha Poston Brown Date: 11/11/05 Print name: Martha Poston Brown

DATE: September 24, 2004

TO: Larry Elliott, Director, OCAS
Dave Sundin, Deputy Director, OCAS _____
James Neton, Associate Director for Science, OCAS _____
Stuart Hinnefeld, Acting Health Science Administrator, OCAS _____

FROM: Timothy Taulbee and Mark Rolfes

Subject: Iowa Army Ammunition Plant (IAAP) Special Exposure Cohort and Dose Reconstruction - DECISION

ISSUE

Dose reconstruction concerns have been raised by workers at the public meeting in June 2004 and the follow-up meeting with workers held in July 2004. In addition, during the public meeting in June 2004, a petition was submitted for Special Exposure Cohort (SEC) status for IAAP workers. Through this petition and subsequent petitions, additional concerns were raised.

Following the first public meeting, the Office of Compensation Analysis and Support (OCAS) began researching the issues to determine the validity of these assertions. In June 2004, OCAS requested assistance from the Department of Energy (DOE) to identify individuals familiar with early weapons designs that could assist us in addressing the concerns raised by energy employees and their survivors. The DOE identified Mr. John Leonowich of the Pacific Northwest National Laboratory (PNNL) as a point of contact who could provide assistance. Our research has also included two reviews of, and subsequent discussions about classified documents with DOE contractor personnel at PNNL. Unfortunately, due to the sensitive nature of the materials reviewed, we cannot provide specific details; however, outlined below are our discoveries / findings and some options for your consideration as to how we should proceed.

Decision: Should OCAS pursue development of dose reconstruction methodologies to correct discrepancies in the Site Profile / Technical Basis Document and address the concerns raised by energy employees and their survivors, or should SEC status be considered due to the time required to conduct the necessary research and development?

BACKGROUND

During the public meeting, the meeting with workers, and from the SEC petitions several issues were raised that required additional research. The major issues that were raised are outlined below and the dose reconstruction implications are discussed further in the text of this memorandum.

- Handling of Bare Pits
- Fissile Materials On Site

- Cladding and Low Energy Photons
- Lack of Monitoring and Shielding
- Hydroshots vs. High explosives Test
- Uranium Particle Size
- Exposure Geometry

Handling of Bare Pits
During the public meeting and in the subsequent SEC petition, there was discussion that not all of the pits were clad with depleted uranium or beryllium and that some of the pits were bare and thermally warm.

Through our investigations and those by PNNL personnel for the Pantex site, the terminology "bare pit" commonly referred to the pit without High Explosives (HE). Since the context of the statement in the SEC Petition specifically refers to cladding and the memorandum from Pantex discusses that the term bare was used in reference to pits without explosives, there is concern that the two pieces of evidence do not refer to the same issue.

Prior to the startup of Rocky Flats, the plutonium pits were manufactured at Hanford. According to PNNL personnel, all plutonium pits shipped from Hanford were clad. The thickness and material used for cladding remains classified. From the energy employee standpoint the clad pit could appear to be bare metal. Energy employees also indicated that these pits were thermally warm. Depending on thickness and material (heat transfer properties) this is certainly possible and likely probable with some designs.

Regardless of how the pits physically appeared and felt, discussions with PNNL personnel, provide sufficient evidence that the plutonium pits were clad and thus there would only be a minimal potential for internal exposure if the pit were damaged (i.e. cladding damaged). External dose issues associated with the handling of pits is discussed in subsequent sections of this memorandum.

Remaining issue
There is still some question about the uranium pits. Currently Jack Beck from ORAU is trying to track down the question of cladding with the enriched uranium parts from Y-12. Current Y-12 personnel are only knowledgeable of more modern designs. Jack is currently trying to locate an early Y-12 worker that he knows to answer this question. There are other sources that we will use in order to answer this question, such as the National Atomic Weapons Museum in Alburqueque, NM.

While this lack of information may seem critical to this evaluation, there are only two outcomes. If the uranium pits were clad, there was then minimal potential for internal exposure during assembly and disassembly operations. If the pits were not clad, uranium bioassay from the Y-12 plant pit assembly and disassembly experience could be used as an upper bound of the expected uranium exposure since IAAP energy employees only handled finished products. As a result this exposure potential can be reasonably bound.

Fissile Materials Onsite

Another expressed concern with dose reconstruction, centers on when exposures to fissile materials first occurred onsite. The current version of the Technical Basis Document (TBD) indicates that the weapons assembled at IAAP prior to 1957 were *In-Flight-Insertable* (IFI). The TBD implies that fissile materials were not onsite prior to 1957. This assumption was further asserted since routine radiological monitoring was not conducted, thus the potential for exposure was low. Based on our review of unclassified documentation, the inception and preparation for a radiological protection / monitoring program appeared in 1958.

Our records reviews, indicate that some fissile materials were onsite prior to 1958 and radiography was conducted from the beginning of operations. As a result, some types of workers were exposed to radioactive materials prior to 1958, but the number of workers was likely relatively small (probably less than 50). The major focus of the work at IAAP prior to 1958 was manufacture and assembly of high explosives. The majority of the IAAP workforce would not have been exposed to radiation and/or radioactive materials prior to about 1958. Since no radiation monitoring data has been located prior to November 1955 and is very limited until about 1968 a dose reconstruction model is considered necessary to accurately estimate radiation doses for those workers exposed to radiation.

Development of this model (exposure matrix) could be time consuming depending on the assumptions. If a detailed exposure matrix were considered necessary, the development could take 6-12 months and likely require 2-3 full time equivalents (FTEs). However, there are some simplifying assumptions that can be made that would greatly reduce this time.

1. Instead of determining which pits were onsite and when, the claimant favorable assumption can be made that the *In-Flight Insertable (IFI)* pits were onsite and selected energy employees (worker categories) were exposed.
2. The year with the highest production and configuration that resulted in the highest external dose (most claimant favorable) could be used to estimate all years (especially pre-1958), instead of modeling the variability of production and design on a year by year basis.

These simplification would greatly reduce the research required and could likely be completed within 2-3 months using the same number of FTEs. The major problem with these simplifications is that the dose will be overestimated and some non-compensable cases would likely become compensable.

Cladding and Low Energy Photon Dose

The issue of "bare" pits and cladding identified a new concern that had not been articulated by energy employees and the survivors. The issue deals with low energy photon dose. The TBD currently assumes the entire external photon dose is in the 30-250 keV range. While this is true for some designs, those that have minimal cladding or cladding with low Z materials could transmit significant quantities of low energy photons (< 30 keV) such that the organ dose could be significantly underestimated.

Based on discussions with PNNL personnel, this is considered a potential exposure scenario. From our review of IAAP Semi-annual reports (1957), it appears that low energy radiation was

recognized at IAAP. In 1957, there were a series of courses conducted to train personnel on the safe handling of radioactive materials with mention of low energy radiation dose.

Unfortunately, the IAAP dosimetry records "combine" the x-ray dose and the gamma dose together. Based on the typical two-element film badge design of this era, the penetrating (deep) dose (shielded window) would have underestimated this low energy photon dose. As a result a ratio of the low energy to measured deep dose is needed to accurately determine the "true" deep dose. This can be developed by comparing the exposure rate from various weapons designs. The time required to conduct this comparison on a weapon design by design basis will be very time consuming and probably take 6-12 months for one FTE.

Perhaps most important in dealing with the low energy photon dose is skin exposure. In general, the low energy photon (< 30 keV) dose conversion factors for deep organs is approximately 0.10 or one tenth of the incident dose on the body. This is due to attenuation through the skin and muscle tissue. However, due to minimal attenuation, the skin dose would be significant and could be rather high (compensable) depending on the given scenario.

Although the time required developing the low energy photon dose could be extensive (up to a year), there is a simplification that could greatly reduce the time required to make a reasonable estimate.

1. Instead of modeling the low energy photon dose of various pit designs, no cladding could be assumed for external dose calculations.

This simplification would greatly reduce the time required to develop the low energy photon dose from approximately 6-12 months to 1-2 months for one FTE. Like the previous simplifications this would also overestimate the true dose. For some designs, the simplification results in a very large overestimate as low energy photons were negligible, however, for other designs this simplification is *roughly* estimated to result in a dose that is 10-20% higher than if the actual design cladding were used. The major confounding problem with the exposure matrix approach is that multiple weapons models were assembled at the same time. As a result the configuration with the highest low energy photon dose ratio would likely have to be used since we have not found work history data with this level of detail.

Lack of Monitoring

The general lack of monitoring for all workers is a recurring concern raised by several IAAP SEC petitioners. The dosimetric issue, with the lack of monitoring presents a question as to whether or not we can reconstruct a radiation dose with sufficient accuracy without individual monitoring data. With most AWE sites, there is a general lack of individual monitoring data, however we conduct dose reconstruction using source term information. In those instances, we have generally included claimant favorable assumptions setting an upper bound of the radiation dose.

In the case of IAAP, now that we know the source term and have some personnel dosimetry, we believe there are sufficient records to set an upper bound of the radiation dose. In order to develop these doses, information from the classified records which have been reviewed will be

needed. From this information, an exposure matrix can be developed to estimate the radiological doses and incorporate uncertainty.

The time required to develop this exposure matrix greatly depends on the acceptance of the simplifications proposed in the previous sections and the FTEs allotted to complete this work. Assuming 1-2 OCAS FTEs and 1-2 ORAU FTEs, the time required to develop this exposure matrix could be a short as 3 months to as long as 12-18 months.

Based on our review of the records and our professional experience, much of the information required to develop this exposure matrix will remain classified. However, the cooperation from DOE contractors to date has been exemplary. We are confident that the dose reconstruction matrix (annual dose values) could be released. The details of how the values were developed would likely not be released. In order to document the details and assumptions that went into the development of the dose reconstruction matrix, we envision a classified Technical Basis Document (TBD) or Technical Information Bulletin (TIB). The development of this document will require coordination with DOE and security personnel. This is likely to be the most significant time delay, however, as noted earlier, the cooperation has been exemplary.

It should be noted, that significant OCAS staff involvement will be necessary since it is clear that the Oak Ridge Associated Universities (ORAU) team does not have a sufficient number of cleared knowledgeable personnel to address these issues in a timely manner.

In addition, there are some details that still need worked out such as; 1) where this document would permanently reside, 2) who would routinely reviews it for classification *(We think this would be DOE, but which operations office?...probably Pantex, however Hanford has been much more helpful)*, and 3) retention schedule for the document. We don't believe any of these details will effect the development of a dose reconstruction matrix nor the temporary storage. We believe that staff at PNNL would be accommodate on an interim basis.

Hydroshots versus High Explosives (HE) test shots
Several energy employees raised concerns about the "claimant favorable" assumptions in Site Profile / TBD. The IAAP Site Profile assumes intermittent short duration exposures to depleted uranium only during hydroshots, although workers felt the exposure was more routine.

We have discovered and reviewed additional information related to internal dosimetry that is absent from the IAAP Technical Basis Document which includes the resuspension of depleted uranium from non-hydroshot tests of high explosives. In addition to the hydroshots involving depleted uranium, multiple tests of high explosives at the firing site resulted in the resuspension of DU contaminated soil. There is very limited air monitoring data describing this in an IAAP report entitled Decontamination Report FS-12 (1974).

In memorandums from Pantex (1971), air monitoring results taken during a hydroshot and 2 HE shots were presented. Currently the TBD considers the hydroshot to be the greatest radiological hazard since uranium is directly involved in the test. However, based on the air monitoring results, the HE shots resulted in a 3-4 times higher uranium air concentration. This is currently believed to be the result of resuspension of uranium contaminated soils. The current IAAP TBD

does not account for the resuspension of DU contaminated soil during the HE tests, but can and should be modified to address this issue.

Uranium Particle Size
Pantex data obtained from Dillard Shipler at PNNL indicated a large fraction (> 94%) of the DU particles from hydroshots were of sizes less than 5 microns. The current assumption in the TBD is to use the ICRP default of 5 micron AMAD, however this can and should be modified relatively easily in a revision to the TBD.

Exposure Geometry
Several IAAP workers have indicated that some of the weapons work was conducted with the bulk of the weapon closer to the floor. As a result there was concern that the dose measured by their dosimeter on their lapel would not accurately reflect the dose to the organs in the lower abdomen.

Based on our review at other facilities and exposure settings (i.e. glove box workers) this can be an important parameter. Like with glovebox workers, claimant favorable correction factors can and should be developed and added to the TBD to correct for this effect.

OPTIONS AND DISCUSSION

DECISION. Should OCAS pursue development of dose reconstruction methodologies to correct discrepancies in the Technical Basis Document and address the concerns raised by energy employees and their survivors, or should SEC status be considered due to the time required to conduct the necessary research and development?

OPTION 1: NIOSH/OCAS will develop dose reconstruction methodology (exposure matrix) to reconstruct doses with sufficient accuracy.

DISCUSSION
Rationale: Sufficient data exists to develop a radiation exposure matrix which could then be used to conduct accurate and claimant favorable dose reconstructions.

Pros

- This option is the most scientifically credible.
- Since skin cancer is a possible health outcome (compensable) and the SEC does not award skin cancer claims, dose reconstruction will be necessary for the skin cancer claims. As a result, the development of the exposure matrix is necessary to accurately reconstruct the skin cancer claims.
- The IAAP Site Profile will need to be updated to correct for discrepancies in internal and external exposure assumptions. These discrepancies will still require some time to correct, thus some additional work to develop the exposure matrix can be rolled into this time through parallel development.
- The knowledge gained during the development of the exposure matrix would facilitate dose reconstructions at other Department of Energy sites (Pantex, Los Alamos National Laboratory, Lawrence Livermore National Laboratory, Sandia National Laboratory,

Nevada Test Site, Medina Facility, Clarksville Facility) where nuclear weapons were assembled, disassembled, or stored and monitoring data is insufficient.

- This option would potentially avoid costs to the U.S. taxpayers by awarding compensation to those with a probable cancer causation (skin cancer) and not to a large population for whom it can be scientifically demonstrated that the probability of causation was less than 50%. Based on the number of claims received, the cost avoidance would be over $50 million dollars.

Cons

- This option will involve the use of classified materials to develop the exposure matrix. As a result, this could be time consuming considering travel to "secure" locations to facilitate the development and review of the exposure matrix. In order to meet a six month deadline, significant OCAS staff time will be required to lead the exposure matrix development and site profile corrections.
- Substantial challenges to the dose reconstruction methodology through litigation would need to be addressed during "secure" proceedings.
- NIOSH/OCAS will not be able to communicate to workers the details of how the exposure model was developed, thus open review by labor organizations and workers would not be possible.
- Since OCAS management has limited clearances (one team leader), substantial reliance on professional staff and their judgment will be required.

OPTION 2: NIOSH/OCAS will develop a simplified and claimant favorable dose reconstruction methodology (exposure matrix) to reconstruct doses with sufficient accuracy.

DISCUSSION

Rationale: As noted in Option #1, sufficient data exists to develop a dose reconstruction matrix. However, the time required to develop the matrix could be considered by some to be excessive and unreasonable. This option includes simplifications to reduce *(not eliminate);* 1) the use of classified materials, 2) some of the complexity of the exposure matrix, and 3) should reduce the exposure matrix development time from an estimated 6-12 months to approximately three months (end of calendar year). The following is an abbreviated list of simplifications that could greatly reduce the reliance on classified information, the complexity of the matrix and thus the time to develop the exposure matrix.

- Instead of determining which pits were onsite and when, the claimant favorable assumption can be made that the In-Flight Insertable (IFI) pits were onsite and thus selected energy employees (worker categories) were exposed.
- Instead of modeling the low energy photon dose of various pit designs, no cladding could be assumed as a worst case scenario for external dose calculations.
- The year with the highest productivity (read highest exposure) could be used to estimate all years (especially pre-1958), instead of modeling the variability of production and design from year to year.

Pros

- This option provides a balanced approach to scientific research, compassion for the claimants (timeliness), and general fairness among the worker population. While each of the assumptions listed above is claimant favorable and will result in an overestimation of the energy employee's dose, these assumptions will still result in significantly fewer compensable claims than if the entire site were made an SEC (cost reduction).
- The option would significantly reduce the use of classified material. It is likely that only references to classified documents would be necessary to indicate the exposure matrix was an overestimate.
- The Site Profile will still need to be updated to correct for discrepancies in internal exposure assumptions. The development of a simplified exposure matrix would be much closer to the same time frame of three months.
- Although overestimates of organ dose will be used for compensation decisions, by revising the Site Profile future options are not preempted. A future revision of the Site Profile could reduce the overestimates to scientifically credible estimates without the additional time pressures resulting from holding dose reconstructions.
- This option is the fiscally responsible, and would potentially avoid costs to the U.S. taxpayers by awarding compensation to those with a probable causation (skin cancer) and not a large population for whom it can be scientifically demonstrated that the probability of causation was less than 50%. Based on the number of claims received, the savings could be on the order of $50 million dollars.

Cons

- The overestimations resulting from the simplification will result in more compensable claims than would be scientifically credible under option 1.
- For likely compensable and best estimate claims, overestimates of organ dose will be used for probability of causation calculations.
- NIOSH/OCAS will not be able to communicate to workers all of the details of how the exposure model was developed. It should be noted, however, that the simplifications can be discussed and it is doubtful that there will be many challenges to them.

OPTION 3: NIOSH/OCAS will recommend SEC status for select IAAP workers over the entire course of operation due to the time delays required to develop an appropriate exposure matrix for accurate dose reconstructions. The identification of IAAP workers into a class will be based solely on the potential for exposure to radioactive materials without regard to the level of exposure. This worker class would be defined as energy employees who; 1) worked in Division B, 2) were involved in Line 1 operations, 3) worked as a radiographer, 4) worked at the firing site or burn area, and 5) were involved in the transportation and security of fissile materials.

According to Roger Anders, the University of Iowa has developed a database with work history information. This data base was purportedly developed from individual work history cards. As a result, the Department of Labor should not have great difficulty in identifying workers by category.

DISCUSSION
Rationale: Due to the time and logistics required for Option 1, the six month delay in processing dose reconstruction may be considered by some stakeholders to be unreasonable. Even with the simplifications proposed in Option #2, there is still some time required to develop the dose reconstruction matrix. Since some claimants have been waiting for almost three years, any further delay may seem unreasonable.

Pros

- This option is obviates the need to do dose reconstructions for approximately 60% of the IAAP cohort. This will result in a reduction of our backlog by approximately 360 claims.
- OCAS will demonstrate a willingness to balance research time and costs with the need to respond to claimants in a timely manner.
- This option will be viewed by organized labor as being compassionate towards energy employees and their families.
- There will be some reduction in political pressure by recommending SEC status. *(There will not be a complete reduction since approximately 40% of the claims are non-SEC cancer types. Thus a relatively large number of dose reconstructions will still be required.)*

Cons

- Since dose reconstructions are technically and scientifically feasible, this option could set a precedent that all AWE and DOE research takes too long, thus all sites could be viewed as taking to too long for dose reconstruction. *(It should be noted that Site Profiles for many sites have not even begun at this point, even though we have been receiving claims for nearly three years.)*
- The time delay to develop the methodology is short term, approximately 6 months. Many Site Profiles have taken over a year to produce. This delay while seemingly too long is not unusual considering the intricacies of dose reconstruction and classification issues at this site.
- OCAS will have enabled / promoted compensation awards for claims with a known low probability of causation. This will result in an additional and unnecessary cost to the U.S. taxpayers. *(The emphasis here is known low probability of causation for some SEC cancers. This is known through back of the envelope calculations. Documenting this fact will, however, take time.)*
- Research will still be necessary for non-SEC cancer types, such as skin cancer claims, some of which are likely compensable.

OPTION 4: NIOSH will recommend SEC status for only select workers from the early operations time period (pre 1958) when routine external and internal monitoring was insufficient. The identification of IAAP workers into a class will be based solely on the potential for exposure to radioactive materials without regard to the level of exposure. This worker class would be defined as energy employees who; 1) worked in Division B, 2) were involved in Line 1 operations, 3) worked as a radiographer, 4) worked at the firing site or burn area, and 5) were involved in the transportation and security of fissile materials.

DISCUSSION

Rationale: Due to the time and logistics required for Option 1 or Option 2, the six month delay in processing dose reconstruction may be considered by some stakeholders to be unreasonable. A limited scope would be to focus on corrections necessary to the Site Profile. The exposure matrix for the early time period, although necessary for skin cancer claims would no longer be time critical since most dose reconstructions / compensation decisions could be completed.

Pros

- More balanced approach to research, timeliness, and fairness along the SEC lines. For example, more research will be required for the early time period, which will take more time to conduct. Limiting the SEC to the early time period is fairer from the standpoint that fewer claims will be affected. As a result, the unfairness between awarding SEC cancers with a known low probability of causation quickly and those with a high probability of causation but requiring more time and research will be reduced.
- Awarding even a partial SEC petition will reduce some political pressure. *(As with Option 3, there will not be a complete reduction since approximately 40% of the claims are non-SEC cancer types, and approximately half of the all IAAP claims have some employment pre-1958. As a result, a relatively large number of dose reconstructions will still be required.)*

Cons

- Although not routinely monitored for radiation exposure, there is evidence that most occupations and even those listed above were not routinely exposed to radiation or radioactive materials. Although some fissile materials were onsite prior to 1958, it appears to be more intermittent than routine. The intermittent nature of the exposure would therefore be significantly less than the later time period when monitoring was conducted. As a result, the organ dose and resulting probability of causation is expected to be lower for the early time period compared to later years. *(It should be noted that some calculations are needed to verify this expectation.)*
- The Site Profile will still need to be updated to correct for discrepancies in internal exposure assumptions. Although much reduced, these discrepancies will still require some time to correct *(approximately one month)*.
- Research will still be necessary for non-SEC cancer types, such as skin cancer claims, some of which are likely compensable.

RECOMMENDATION

It is recommended that the necessary research be conducted to accurately determine the energy employee's dose. This will award compensation to those for which radiation exposure could have caused their cancer and not to those whose radiation exposure is likely not to have caused their cancer. Although difficult and somewhat time consuming, we recommend Option #2. We believe this option is the most scientifically sound, compassionate (timely), and fairest option.

OPTION 1: NIOSH/OCAS will develop dose reconstruction methodology (exposure matrix) to reconstruct doses with sufficient accuracy.

Approved_____ Disapproved_____ Date _____

OPTION 2: NIOSH/OCAS will develop a simplified and claimant favorable dose reconstruction methodology (exposure matrix) to reconstruct doses with sufficient accuracy.

Approved_____ Disapproved_____ Date _____

OPTION 3: NIOSH/OCAS will recommend SEC status for select IAAP workers over the entire course of operation due to the time delays required to develop an appropriate exposure matrix for accurate dose reconstructions. The identification of IAAP workers into a class will be based solely on the potential for exposure to radioactive materials without regard to the level of exposure. This worker class would be defined as energy employees who; 1) worked in Division B, 2) were involved in Line 1 operations, 3) worked as a radiographer, 4) worked at the firing site or burn area, and 5) were involved in the transportation and security of fissile materials.

Approved_____ Disapproved_____ Date _____

OPTION 4: NIOSH will recommend SEC status for only select workers from the early operations time period (pre 1958) when routine external and internal monitoring was insufficient. The identification of IAAP workers into a class will be based solely on the potential for exposure to radioactive materials without regard to the level of exposure. This worker class would be defined as energy employees who; 1) worked in Division B, 2) were involved in Line 1 operations, 3) worked as a radiographer, 4) worked at the firing site or burn area, and 5) were involved in the transportation and security of fissile materials.

Approved_____ Disapproved_____ Date _____

-----Original Message-----
From: Hallmark, Shelby - ESA
Sent: Tuesday, November 16, 2004 8:23 PM
To: Lipnic, Victoria
Subject: NIOSH pickle

Vicki – I discussed the Advisory Board issue further with Jeff N. and Pete this PM, following up on your question as to whether the audit report on Bethlehem Steel has any validity.

They report that they've reviewed the Board's audit contractor's (SCA) report on the Bethlehem Steel site profile. This is the report that went on for 85 pages about a 14 page site profile, and apparently resulted in the contractor spending all (or more than all) of its allocated funds for site profile reviews on its first one. Jeff and Pete were unanimous in stating that the report was blatantly unbalanced. It ignores NIOSH's methodology that strongly leaned in the claimants' favor, and nitpicked every situation where, despite taking an overall exceedingly claimant friendly posture, NIOSH "failed" to choose the most claimant friendly posture conceivable (as opposed to a "plausible option"). Pete noted that the report accepted at face value certain plant employee statements that had been considered in the course of OWCP case adjudication and found not to be credible. Had DOL found those statements credible, we would have returned the dose reconstructions to NIOSH to reevaluate the additional exposure being alleged. We did not, and it's our position that the Board's contractor has no business, in the course of an audit of the scientific sufficiency of the NIOSH process, trying to "readjudicate" evidentiary matters that are DOL's purview.

Jeff indicated that he asked an audit contractor employee why the report frequently criticized NIOSH for not taking the absolutely most claimant friendly assumption, but never once questioned whether a NIOSH assumption or approach was likely to be overly claimant friendly or result in approvals that would be inappropriate. The SCA employee apparently admitted that they would never make such a comment, and considered it outside of their mandate.

This was pretty clearly a biased report, which set out to undermine a Beth Steel site profile that resulted in a far higher acceptance rate (over 40%) than anyone imagined, or that was likely appropriate in terms of the actual exposures. Just to cite one example, NIOSH assumed that there were 48 uranium rolling events during the four years that Beth did AEC work (one per month), even though there was evidence for only 13 such events.

Apparently NIOSH has developed a set of comments/replies to the SCA report, but to our knowledge, hasn't shared those with the Board yet for reasons we don't know. In addition to the noise about "conflict of interest", there have also been allegations that NIOSH is trying to "hush up" the report and won't let it be published because it reveals the errors in their site profile process (and by extension, in the entire dose reconstruction process). We will try to convince NIOSH to move ahead with a direct response to the SCA report, and let the Board hear everyone's position.

Meanwhile, if you have any brainstorms about Cindy, let me or John Howard know – I'm sure he could use some creative suggestions about now. Thanks, sh

From: Homer, Corrine
Sent: Wednesday, November 17, 2004 1:50 PM
To: Elliott, Larry J.
Subject: ABRWH Nomination Table.05.doc

Attachments: ABRWH Nomination Table.05.doc

Larry, it might be early on this, but here's the nomination table for 2005's nomination package with names, expertise, geographic area, and any applicable minority/female status identified.

Cori

ABRWH Nomination Table.05.doc ...

ABRWH Nomination Table – 2005

Members to be replaced, expertise, geographic area, and term end date	Principal & Alternate replacements, with expertise
Gibson, Michael H. – PACE/Union/Labor Central - 8/3/05	Principal: Alternate:
Griffon, Mark A. – Health Physics East – 8/3/05	Principal: Alternate:
Melius, James M., M.D., Dr.P.H. – Environmental Epidemiology East - 8/3/05	Principal: Alternate:
Munn, Wanda I. – Nuclear Engineering (female) West - 8/3/04	Principal: Alternate:

11/17/04

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November 19, 2004

Honorable Tommy G. Thompson
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Thompson:

The Committee on the Judiciary has jurisdiction over claims against the Government. As part of that responsibility, the Committee has jurisdiction over the Energy Employees Occupational Illness Compensation Program Act (EEOICPA).

There have been ongoing problems with the implementation of EEOICPA that are of deep concern to the Committee. As a result, the Committee is evaluating the independent audit function of the Advisory Board on Radiation and Worker Health and the implementation of the Special Exposure Cohort regulations (10 CFR Part 83), as well as the contracting processes, costs and quality of the radiation dose reconstructions that are prepared for use by the Department of Labor in adjudicating claims under the program. Additionally, in tandem with a previous request for review of Subtitle B processing under the Act, we have requested that GAO expand that review to assist us in this evaluation.

The Committee requests the following documents, communications, and information from the Department of Health and Human Services, the Center for Disease Control (CDC), and the National Institute for Occupational Safety and Health (NIOSH) pertaining to their roles and responsibilities under EEOICPA (please see Attachment A for definitions of the term "document" and "communication").

Documents, Communications, Memorandum, Policies and Contracts

1) The Bethlehem Steel Site Profile review prepared for the Advisory Board on Radiation and Worker Health ("Board") by Sanford Cohen and Associates.
2) The internal and external dosimetry procedure reviews prepared for the Board by SC&A.
3) The audits of the first 20 individual dose reconstructions prepared for the Board by SC&A.
4) The procedures for site profile and dose reconstruction audits, and all other deliverables provided to Board by SC&A.
5) The monthly/quarterly progress reports submitted to NIOSH/CDC by SC&A. All task orders awarded to SC&A, invoices submitted by SC&A, and payments issued to SC&A.
6) The person delegated as the SC&A Project Manager for the audit contract. Please provide name, address, phone number and e-mail.
7) All written communications and correspondence sent and received between NIOSH/CDC and SC&A on the audit contract.
8) All written communications and correspondence, in the possession of NIOSH/CDC, sent and received between NIOSH/CDC and all Board members; between NIOSH/CDC and individual Board members; and/or exclusively between NIOSH/CDC and the Chairman of the Board concerning the audit contract.
9) All internal NIOSH/CDC communications regarding the award of the audit contract, the award of task orders, expenditures made by the audit contractor, the performance of the audit contractor, the scope of the audit contract, and issues pertaining to the public release of documents prepared by the audit contractor to the public or Congress.
10) The contract between CDC and Oak Ridge Associated Universities (ORAU), including all contract modifications. Please provide copies of all NIOSH/CDC performance evaluations, award fee evaluations, and award fees paid to ORAU. Please provide the number of dose reconstructions expected to be produced under the contract awarded to ORAU in 2002.
11) All invoices submitted by ORAU and payments issued to ORAU by NIOSH/CDC. The amounts authorized under the ORAU contract, amounts expended each year, and the amount of each modification to that contract, and the estimated total cost to complete the current inventory of dose reconstructions.
12) ORAU performance history, including number of completed dose reconstructions per month completed since contract was awarded, number of site profiles completed by ORAU, and number of completed Special Cohort petition reviews.
13) A list of all meetings held with workers on site profiles by date and location. Please provide a summary of such meetings, and a detailed description of what NIOSH has done with the information for each site derived from such meetings.

14) All communications, written or otherwise, between ORAU and NIOSH on matters involving ORAU's performance – including productivity, expenditures and cost overruns.
15) All internal and external communications, written or otherwise, on NIOSH/CDC evaluation of the quality of ORAU's dose reconstructions, site profiles, technical performance, conflict of interest involving ORAU contractor personnel performing site profiles, and ORAU's compliance with conflict of interest requirements.
16) All communications between ORAU and NIOSH regarding the activities of the Board's audit contractor. All communications between DOL and NIOSH regarding the audit by the Board's audit contractor.
17) The conflict of interest disclosures by ORAU and its subcontractors, and any NIOSH/CDC evaluation of such disclosures. All communications and analyses of conflict of interest policies pertaining to preparation of site profiles and dose reconstructions.
18) All internal communications between NIOSH, CDC, and HHS regarding actual, or appearance of, conflict of interest issues related to NIOSH's administration of the SC&A audit contract.
19) NIOSH's Quality Assurance/Quality Control procedures for dose reconstruction reviews.
20) Monthly/quarterly statistics on NIOSH's Quality Assurance/Quality Control on dose reconstructions performed by ORAU.

Information on the Advisory Board

1) Who is the designated Federal Official to the Advisory Board on Radiation and Worker Health? Who has authority to appoint this individual? Who actually appointed this individual? Who has authority to remove and replace such official?
2) Please provide the names, addresses, phone numbers and e-mail addresses for each member of the Board. Please provide the curriculum vitae for each member of the Board. Please provide financial disclosure forms for each member of the Board. Please provide the conflict of interest disclosures and, if applicable, waivers for each members of the Board.
3) How many meetings per year does the Board conduct? How many meetings are planned for the Board in 2005?
4) Who is the contracting officer for the Board's audit contractor? Please provide the individual's name, phone number and e-mail address. Who is the NIOSH/CDC technical contracting representative for the audit contractor? Who is the NIOSH/CDC project manager for the audit contractor?

5) Please provide the budget for the Board for FY02, FY03, FY04 and FY05, excluding the costs of the audit?
6) What specific authorities does the Board have with respect to the audit contractor? Please provide specific policies which govern Board authority on contracting, budget and performance evaluation.
7) What authorities does the chairman of the Board possess? Please provide documents which establish these authorities? What actions and authorities have been delegated to the chairman beyond chairing Board meetings? What procedures is the chairman required to follow with respect to notification of all Board members of communications with NIOSH/CDC and/or SC&A?
8) When the audit contractor prepares documents for the Board, who has authority over the use of those documents and what provides that authority to them?
9) There are four task orders issued to date. How many additional task orders were anticipated in the initial request for proposals to provide technical support to the Board?
10) What is the ceiling on the amount of the audit contract, if any? Who set this value and under what authority? Did the contractor bid a maximum amount to perform this contract on a fixed price basis? Is there Congressional limitation on amount to be expended on the audit?

The Committee requests receipt of this information not later than December 13, 2004, and would welcome receiving individual documents and information as soon as they become transmittable by the Department. Please contact Cindy Blackston at (202) 225-5727 if you have any questions concerning this request. Thank you for your assistance.

Sincerely,

F. JAMES SENSENBRENNER, JR.
Chairman

Attachment

cc: Honorable Julie E. Gerberding, Director
Center for Disease Control and Prevention

Honorable John Howard, Director
National Institute for Occupational Safety and Health

ATTACHMENT A

DEFINITIONS FOR PURPOSES OF NOVEMBER 19, 2004 COMMITTEE REQUEST TO THE SECRETARY OF HEALTH AND HUMAN SERVICES

1. The term "document" means any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to, the following: memoranda, reports, expense reports, books, manuals, instructions, financial reports, working papers, records notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, interoffice and intra office communications, electronic mail (e-mail), contracts, cables, notations of any type of conversation, telephone call, meeting or other communication, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments of any of the foregoing, as well as any attachments or appendices thereto), and graphic or oral records or representations of any kind (including without limitation, photographs, charts, graphs, microfiche, microfilm, videotape, recordings and motion pictures), and electronic, mechanical, and electric records or representations of any kind (including, without limitation, tapes, cassettes, disks, and recordings) and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, disk, videotape or otherwise. A document bearing any notation not a part of the original text is to be considered a separate document. A draft or non-identical copy is a separate document within the meaning of this term.

2. The term "communication" means each manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, electronic, by document or otherwise, and whether face-to-face, in a meeting, by telephone, mail, telexes, discussions, releases, personal delivery, or otherwise.

Rolfes, Mark R.

From: Hinnefeld, Stuart L
Sent: Friday, November 19, 2004 8:36 AM
To: Tomes, Thomas P
Cc: Neton, Jim; Calhoun, Grady; Ulsh, Brant A; Allen, David (NIOSH); Calvo, Sebastian; Crawford, Chris; Darnell, Peter A.; Johnson, John J.; Macievic, Gregory; Nelson, Chuck; Rolfes, Mark R.; Rutherford, LaVon B; Taulbee, Timothy D.
Subject: RE: Hanford DR

I will tell Griffin, Maher, and Tomes about this situation. Also am copying all the HPs and Jim.

Stu

-----Original Message-----
From: Tomes, Thomas P
Sent: Friday, November 19, 2004 8:32 AM
To: Hinnefeld, Stuart L
Subject: Hanford DR

Stu,

The Hanford claim number 11897 we briefly spoke about yesterday (the one you were interested in looking at) is a very good one for evaluating the incorrect interpretation of construction worker monitoring results, or lack thereof.

The Hanford form letter response for this claim says that "The lifetime external whole body dose for Mr. Pelela is less than 100 mrem and in conformance with the NIOSH statement of August 20, 2002, only annual summaries of external dose are included in this listing." The annual summaries that Hanford enclosed with the letter were obviously database search printouts for Mr. Pelela that resulted no records found, i.e., there was nothing on the page except the form header with Mr. Pelela's name and SSN (no years were listed at all). It certainly appears that a search was performed, however, Hanford sent out an incorrect form letter because the search they did was limited.

The individual in question had a lifetime deep dose of 420 mrem (not <100 mrem); the highest single year dose for th s EE was 340 mrem in 1952. This is evident because dosimetry records supplied to DOL by the claimant from a FOIA request included Mr. Pelela's monitoring results, both summary and details (the summary results are in units of centirem). This is not a rarity. Both Hanford and SRS have often supplied more complete dose and monitoring records when requested under the FOIA as compared to EEOICPA requests.

ORAU has recently sent several DRs to us that assign an annual doses of 0.100 rem based on the above discussed Hanford response. Although each claim should be judged on its own merit, the basis for the DRs on some them have been a bounding dose based on results that do not exist, or at least may or may not exist. This particular claim also has unsupported very low internal lung dose. I will work on comment for this claim. Do you want to include a global comment on handling similar claims?

Tom

-----Original Message-----
From: Hallmark, Shelby - ESA
Sent: Friday, November 26, 2004 11:54 AM
To: Lipnic, Victoria
Subject: RE: NIOSH pickle

Just to bring you up to speed on this controversy regarding the NIOSH site profile for Bethlehem Steel, the Advisory Board's contractor's 85 page audit report re same, and related issues:

John Howard and a bunch of NIOSH folks met with us on Tuesday. The auditor's report has been shared with the Board, but NIOSH still has not provided its comments on that report to the Board. John indicated they plan to do that in the next week or two. I urged that they move as swiftly as possible, since this issue is clearly getting blown out of proportion by Cindy Blackston and others, based on their understanding of only the auditor's perspective. The Board will discuss this report, and presumably the larger issue as to how the auditor's work is to be overseen, at their Dec. 13-15 meeting. John seemed to have a very legalistic, step by step approach to how the auditor's products would be handled with the Board, but we argued NIOSH needs to be more aggressive, and in the Beth Steel case in fact should have rejected the auditor's report as inadequate before it even went to the Board; having let that happen, they certainly need to issue their strongly countervailing comments (which should include the strong comments that we will give NIOSH on that report) to the Board asap, so that the discussion during the meeting will be at least somewhat balanced. John agreed to an extent with that, but NIOSH is clearly playing catch up here.

Cindy Blackston has continued to raise havoc regarding this audit report, NIOSH's handling of the contractor, and NIOSH's handling of the Advisory Board. She has peppered John Howard with emails objecting to this or that small change in the agenda for the Board's Dec. meeting, demanding to know why one session is being held as a closed meeting (which is required for Privacy Act reasons), etc. And as you know, she got Sensenbrenner to send HHS a letter with dozens of questions/interrogatories that would take many boxes to fully respond to. Although NIOSH is taking all sorts of steps to defuse the so-called "conflict of interest" charges here, John discussed the possibility of somehow going to Sensenbrenner to find out from him just what it is that he has in mind – what's his desire here? Cindy appears to be pursuing these issues at Richard Miller's behest and in furtherance of his agenda – is that really Sensenbrenner's agenda? It's not clear what his jurisdiction is on this whole issue, but John is clearly looking for political help on this. From my corner, it would be better to get this resolved and put to bed now, before the drumbeat for DOL to take over running the auditor and/or the whole Board gathers momentum.

Pete, Jeff and I will all be attending this Board meeting, for several reasons. First, I'm presenting the DOL status on takeover of Part D/E, and our general progress under EEOICPA. Second, we need to know how the Board is going to address itself to the review of dose reconstructions and site profiles, of which this Beth Steel controversy is only one small part. The Board is going to be considering the auditor's review of 20 individual dose reconstructions during the meeting, and we have a very strong interest in seeing to it that those audits don't turn into a method for the auditor and the Board to "readjudicate" the claim. The scope of their audits needs to be clear such that they focus on the accuracy and appropriateness of NIOSH's science and procedures, not judgements about factual matters that are DOL's to decide. Finally, NIOSH will be addressing its status in carrying out its SEC petition process – although the latter

segment will not address their specific findings on whether an SEC will be declared for Mallinckrodt (Missouri) and Iowa Ammunition Plant -- those reports are still under construction.

Sorry to be so voluminous. Let me know if I need to clarify, or if I need to do something different on any of these fronts. sh

-----Original Message-----
From: Lipnic, Victoria
Sent: Tuesday, November 16, 2004 8:21 PM
To: Hallmark, Shelby - ESA
Subject: RE: NIOSH pickle

No brainstorms yet, but NIOSH needs to not hide their views about this report and publicly say so.

From: Hallmark, Shelby - ESA
Sent: Tuesday, November 16, 2004 8:23 PM
To: Lipnic, Victoria
Subject: NIOSH pickle

Vicki -- I discussed the Advisory Board issue further with Jeff N. and Pete this PM, following up on your question as to whether the audit report on Bethlehem Steel has any validity.

They report that they've reviewed the Board's audit contractor's (SCA) report on the Bethlehem Steel site profile. This is the report that went on for 85 pages about a 14 page site profile, and apparently resulted in the contractor spending all (or more than all) of its allocated funds for site profile reviews on its first one. Jeff and Pete were unanimous in stating that the report was blatantly unbalanced. It ignores NIOSH's methodology that strongly leaned in the claimants' favor, and nitpicked every situation where, despite taking an overall exceedingly claimant friendly posture, NIOSH "failed" to choose the most claimant friendly posture conceivable (as opposed to a "plausible option"). Pete noted that the report accepted at face value certain plant employee statements that had been considered in the course of OWCP case adjudication and found not to be credible. Had DOL found those statements credible, we would have returned the dose reconstructions to NIOSH to reevaluate the additional exposure being alleged. We did not, and it's our position that the Board's contractor has no business, in the course of an audit of the scientific sufficiency of the NIOSH process, trying to "readjudicate" evidentiary matters that are DOL's purview.

Jeff indicated that he asked an audit contractor employee why the report frequently criticized NIOSH for not taking the absolutely most claimant friendly assumption, but never once questioned whether a NIOSH assumption or approach was likely to be overly claimant friendly or result in approvals that would be inappropriate. The SCA employee apparently admitted that they would never make such a comment, and considered it outside of their mandate.

Hinnefeld, Stuart L

From:	Linda Lampack [llampack@mjwcorp.com]
Sent:	Monday, November 29, 2004 11:32 AM
To:	Hinnefeld, Stuart L
Subject:	FW: "Restrictions" list
Follow Up Flag:	Follow up
Due By:	Wednesday, August 25, 2004 6:00 AM
Flag Status:	Flagged

-----Original Message-----
From: Hinnefeld, Stuart L [mailto:HLS8@CDC.GOV]
Sent: Friday, August 20, 2004 5:00 PM
To: James P. Griffin (MJW)
Cc: Edward F. Maher (Home); Matt McFee; Neton, Jim
Subject: "Restrictions" list

Jim,

We've compiled a first shot at something we call a restrictions list. It's a list of reasons why some case can't be completed under current techniques.

Preliminary draft is attached. First section is a table sorted by site with approved TBD. Second section is a list applicable to all or several sites.

Wonder if you agree with our list, and I'm interest in yours if you have one.

Stu

<<Restrictions_Aug18_04_draft.doc>>

August 18, 2004

The following information describes the types of cases that are "restricted" from dose reconstruction as things stand today. It describes broad classes of cases that involve open questions of methodology, so dose reconstructions can't always be completed. However, there may be some cases within these broad categories that can be done based on some type of case-specific information. Just because one case that fits one of these broad "restricted" categories has been completed, that doesn't mean the restriction is ended.

Information is provided in two parts. The first is a table of approved Site Profiles that describes cases that are restricted for that site. The second is a list of general restrictions that apply to cases from all sites.

Completed Site Profile Restrictions

SITE	TYPES OF CASES THAT CURRENTLY CAN'T BE DONE
Bethlehem Steel	No restrictions except for general ones.
Blockson Chemical	Can't do lung cases because of question as to whether radon is covered exposure.
FEMP	Can't do unmonitored radiation workers; can't do lung cases that aren't compensable without radon exposure because we don't have a radon exposure model.
Hanford	Can't do "early" unmonitored radiation workers; can't do "early" construction workers; can't do glove box workers for many types of cancer; can't do "early" reactor operators.
Huntington PP	No restrictions except for general ones.
Iowa Ordnance	All cases currently on hold.
Mallinckrodt	Can't do cases with employment before 1946 if they're not compensable based on exposure during 1946 and later.
Rocky Flats	Can't do [potentially] non-compensable cases with neutron exposure before 1974; can't do glove box workers for many types of cancer.
Savannah River	Can't do "early" unmonitored construction workers; can't do glove box workers for many types of cancer; can't do [potentially] non-compensable cases with employment before 1960 (if photofluorography through 1960 would make case compensable).
TVA	Can't do lung cases because of question as to whether radon is covered exposure.
Y-12	Can't do many [potentially] non-compensable cases involving unmonitored workers with employment before 1961; can't do [potentially] non-compensable cases with employment during criticality in June 1958; can't do many cases prior to 1950 because of very limited monitoring data.
ORNL (X-10)	Can't do "early" construction workers; can't do glove box workers for many types of cancer.

General Restrictions

- Can't do "best estimate" dose reconstructions that result in POC between 45% and 50%.
- Can't do [potentially] non-compensable skin cancers if EE was exposed to mixture of electrons and low energy photons and monitoring was done with film badges.
- Can't do cases involving skin cancer on an extremity (e.g. hand or arm) with no extremity radiation monitoring.
- Can't do leukemia cases with large extremity doses.
- Can't do glove box workers for many types of cancer.

Search 3

From: Nesvet, Jeffrey L - ESA
Sent: Thursday, December 02, 2004 10:38 AM
To: Hallmark, Shelby - ESA; Turcic, Peter - ESA
Cc: Culp, James - ESA; Turley, Sheldon - ESA
Subject: RE: Our EEOICPA briefing

We will get something to you this afternoon. I think getting this on the radar screen of the HHS political level is a major plus, however we manage it.

What do you think about a pitch from Kris to HHS that there should be a joint DOL-HHS approach to Sensenbrenner on this issue? If they buy that we might be able to weigh in to keep HHS from caving too easily if Sensenbrenner pushes back.

JEFFREY L. NESVET
Associate Solicitor for Federal Employees'
and Energy Workers' Compensation
Office of the Solicitor
United States Department of Labor
200 Constitution Avenue, N.W., Room S-4325
Washington, D.C. 20210
(202) 693-5320 693-5360 (fax)

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-----Original Message-----
From: Hallmark, Shelby - ESA
Sent: Thursday, December 02, 2004 10:33 AM
To: Turcic, Peter - ESA; Nesvet, Jeffrey L - ESA
Subject: FW: Our EEOICPA briefing

I was trying to get Kris to offer to help HHS, not harangue them on how to support NIOSH. But I guess any kind of conversation between Kris and her counterpart could help, so let's give her some broad points about what's at stake in the whole SCA/Board issue, and why it's important not to just keep surrendering point by point to Cindy (and Miller), but instead to take the bull by the horns and try to ease the political pressure. Jeff, can you take a first cut at this? Pete, do you have any sense from Larry E as to whether HHS or CDC congressional folks (other than staffers) have actually weighed in on this issue at all? If not, I'll take some discovery with Howard or Larry.

-----Original Message-----
From: Iverson, Kristine
Sent: Wednesday, December 01, 2004 7:28 PM
To: Hallmark, Shelby - ESA; Lipnic, Victoria; Dugas, Peter - OCIA; Nesvet, Jeffrey L - ESA
Subject: RE: Our EEOICPA briefing

Shelby, if you or Pete can get me some talking points, I will call the Assistant Secy for Legislative Affairs at HHS. Specifically, I will need to persuade her that there is more at stake here and that it warrants her attention.

-----Original Message-----
From: Hallmark, Shelby - ESA

Sent: Wednesday, December 01, 2004 5:32 PM
To: Lipnic, Victoria; Iverson, Kristine; Dugas, Peter - OCIA; Nesvet, Jeffrey L - ESA
Subject: Our EEOICPA briefing

Went extremely well - nobody raised the awkward questions we expected. But Cindy Blackston went off again (after the meeting per se) telling us that Judiciary was going to drag HHS through hell if they so much as touch the "auditor" (the Advisory Board's contractor) or his funding. As I told Peter, John Howard knows what a disaster this whole crusade of Cindy's could be for the dose recon process, but I don't get a sense that he's getting any substantive help from the HHS legis affairs people. NIOSH is prone to collapsing. I really think we need to try to help out with the Committee. sh

[redacted]

From: Hallmark, Shelby - ESA
Sent: Wednesday, January 26, 2005 12:40 PM
To: Mosier, Roberta - ESA; Kotsch, Jeffrey - ESA
Subject: FW: Draft FRN
Importance: High

I can't get hold of Jeff Nesvet and crew -- or Pete, of course -- so you two need to start looking at this NHGM piece on the SEC petitions ASAP! Thanks, sh

-----Original Message-----
From: Hallmark, Shelby - ESA
Sent: Wednesday, January 26, 2005 12:18 PM
To: 'Howard, John'
Cc: Wade, Lewis; Elliott, Larry J.; Turcic, Peter - ESA; Nesvet, Jeffrey L - ESA; Lipnic, Victoria
Subject: RE: Draft FRN
Importance: High

Thanks, John. We very much appreciate the opportunity to review this, and will do so just as rapidly as we can. As discussed, I've alerted my deputy secretary about this issue and conveyed the urgency (and gravity) I believe it entails. He's just now gotten back to me via email indicating that his office is having "discussions with counterparts in the Administration to try to arrive at a coordinated response". I don't know any more than that, but will certainly keep you posted if I hear anything. Thank you again for your willingness to include us in this very difficult and conflicted issue. sh

-----Original Message-----
From: Howard, John [mailto:ZKZ1@CDC.GOV]
Sent: Wednesday, January 26, 2005 11:54 AM
To: Hallmark, Shelby - ESA
Cc: Wade, Lewis; Elliott, Larry J.
Subject: Draft FRN

Shelby:

Here's the Notice. Let me know if you need anything else.

JH

<<FRN.SECs.StLouis.2~5.doc>>

[redacted]

From: Hallmark, Shelby - ESA
Sent: Tuesday, February 01, 2005 4:53 PM
To: Wilson, Mark; Krishnamoorti, Mala
Cc: Nesvet, Jeffrey L - ESA; Turcic, Peter - ESA; Svenonius, Diane - ESA
Subject: RE: Edited NIOSH FR Notice
Importance: High

Attached, per NIOSH, is the doc that is actually on the table at the Federal Register. It seems to be the same as the 11am version (that we hated). I now have time to add my further objection to the critically split infinitive ("to publicly evaluate") in the critical sentence regarding Iowa.

As discussed with Mala, NIOSH advised me that they are modifying the Mallinckrodt evaluation for the period 1949-1957 to remove their recommendation that those years be made an SEC cohort, leaving only the conflicting discussion about on the one hand, we have the info needed to reconstruct, and on the other, we have allegations that the data are not reliable, so we're asking the Board for advice. While that is seemingly a positive step, I don't think the Board will hesitate to resolve the conflict in favor of recommending an SEC class. I wasn't told whether the Iowa evaluation report would be similarly non-evaluative.

I was told that NIOSH will share the actual evaluation reports with us, but only when they are shared with the Board members. The eventual impact of the Mallinckrodt "shroud of secrecy/data corruption" test will now turn on exactly what is said about the NATURE of the data errors/falsifications alleged at Mallinckrodt. So the actual language of the evaluation report takes on enormous importance. If it mirrors either of the two FR Notice documents, it won't provide any kind of organized structure around which NIOSH (and DOL) could construct arguments that might keep other sites from simply following SEC suit based on monitoring errors, badges purposefully defeated, etc., etc. We'll find out in St. Louis how that long and arduous debate will start off, and where it's likely to lead. Thanks, sh

---Original Message---
From: Wilson, Mark [mailto:Wilson.Mark@dol.gov]
Sent: Tuesday, February 01, 2005 3:52 PM
To: Hallmark, Shelby - ESA; Krishnamoorti, Mala
Cc: Nesvet, Jeffrey L - ESA; Turcic, Peter - ESA; Svenonius, Diane - ESA
Subject: RE: Edited NIOSH FR Notice

I figured as much. The only good news is that nobody reads the Federal Register.

D. Mark Wilson
Deputy Assistant Secretary
Employment Standards Administration
U.S. Department of Labor
(202) 693-0200

From: Hallmark, Shelby - ESA
Sent: Tuesday, February 01, 2005 3:47 PM
To: Wilson, Mark; Krishnamoorti, Mala
Cc: Nesvet, Jeffrey L - ESA; Turcic, Peter - ESA; Svenonius, Diane - ESA
Subject: RE: Edited NIOSH FR Notice
Importance: High

This is ok, but I was just advised that HHS has already sent its notice forward to the Federal Register and

it's been "on public display" since 2:15pm today. Unfortunately, I don't have a copy of the final version -- I hear it's changed several times -- but am trying to get it now. Thanks, sh

-----Original Message-----
From: Wilson, Mark [mailto:Wilson.Mark@dol.gov]
Sent: Tuesday, February 01, 2005 3:02 PM
To: Hallmark, Shelby - ESA; Krishnamoorti, Mala
Subject: Edited NIOSH FR Notice
Importance: High

Please take a quick look at my edits on page 3. If you are comfortable with them, I will pass them along to NIOSH.

The language that I added comes directly from the longer summary in the previous FR notice.

From: Hallmark, Shelby - ESA
Sent: Friday, February 04, 2005 09:33
To: Lipnic, Victoria; Iverson, Kristine
Cc: Dugas, Peter - OCIA; Wilson, Mark
Subject: FW: Agenda 2~5.doc
Importance: High

I'd say thoughtful deliberation by the Board, not something toward which they've shown a tendency anyway, will be extremely limited under these conditions.

-----Original Message-----
From: Turcic, Peter - ESA
Sent: Friday, February 04, 2005 9:27 AM
To: Hallmark, Shelby - ESA; Nesvet, Jeffrey L - ESA; Svenonius, Diane - ESA
Cc: Mosier, Roberta - ESA
Subject: FW: Agenda 2~5.doc
Importance: High

This meeting is really shaping up to be a real party -- Bond coming and our Resource Center reports that Harkin has arranged for bus loads to come in from Iowa. The room holds 500.
-----Original Message-----
From: Homer, Corrine [mailto:CBH4@CDC.GOV]
Sent: Friday, February 04, 2005 9:09 AM
To: mackat116@msn.com; ANDERHA@DHFS.STATE.WI.US; andrade@lanl.gov; c_owens01@comcast.net; Larry J. Elliott (Elliott, Larry J.); wimunn@aol.com; Mellus@NYSLIUNA.org; roy.dehart@vanderbilt.edu; espoladd@aol.com; Mikehgibson@cincl.rr.com; gnrsslr@frontiernet.net; pl.ziemer@insightbb.com; Mark Griffon
Cc: Underwood, Lewis A; gree806@bellsouth.net; Wade, Lewis; Turcic, Peter - ESA; Hallmark, Shelby - ESA; Nichole L. Herbert (Herbert, Nichole L.); Kotsch, Jeffrey - ESA; Porter, Diane; Blosser, Fred; Brand, Anstice M.; Caswell, Gay McInnes; Howard, John; Katz, Ted; Kendrick, Charlotte
Subject: Agenda 2~5.doc

Board Members,

We have again, revised the draft agenda to include a Board Welcome from Senator Bond on Monday. Revised agenda is attached.

Thank you,
Cori

<<Agenda 2~5.doc>>

Herbert, Nichole L.

>m: Neton, Jim
t: Friday, February 04, 2005 1:47 PM
DiMuzio, Martha A.
Subject: Transparency Section

For dose reconstructions, Section 7384 n (e)(2) of EEOICPA requires that "The Secretary of Health and Human Services and the Secretary of Energy shall make available to researchers and the general public information on the assumptions, methodology, and data used in establishing radiation doses." Because some records and information used in this evaluation are withheld for national security reasons, it is apparent to NIOSH that a transparent and full disclosure of the assumptions, methodology, and data used to evaluate this petition cannot be made available to the public. Given that access to this information is constrained, and there is no likelihood of timely public access to such information, it is not feasible to estimate doses with sufficient accuracy for the petitioned class with the remaining publicly available information."

Snow, Cindy

From: Campbell, Priscilla
Sent: Wednesday, February 09, 2005 10:56 AM
To: Carlene Stewart (stewartc@orau.gov); Bingham, Pam
Cc: Snow, Cindy
Subject: FW: Changes to Foxfire staffing?

All,

I'm trying hard to keep up with the ever-changing landscape of the DR Project, and to keep you apprised as changes occur.

For now, please expect Dr. Ian Hamilton to charge to Tasks 0005 and any 0003 sub-task, effective February 1. Not sure what the percentage split is. As I receive better information, I'll share with you.

Thanks,
Priscilla
-----Original Message-----
From: Matthew Arno [mailto:arno@foxfirescientific.com]
Sent: Wednesday, February 09, 2005 10:45 AM
To: Campbell, Priscilla
Subject: RE: Changes to DR Project staffing?

Priscilla,

My understanding is that Dr. Poston, Sr. will be recused effective March 1. He is finishing up the review of a couple things for Task 3 this month. His appointment to the ABRWH has not been confirmed and would not take effect regardless until after March 1.

Dr. Hamilton will take over Dr. Poston, Sr's responsibilities to Task 3. Dr. Hamilton has started working Task 3 in addition to Task 5 effective Feb. 1.

My understanding from David Hearnsberger is that there are other changes in Task 3 organization and staffing that may occur which may result in Foxfire personnel in addition to Dr. Hamilton being requested to work on Task 3.

I will send you a staffing spreadsheet as soon as I have firm confirmation of the changes.

Matt

From: Campbell, Priscilla [mailto:Campbepb@orau.gov]
Sent: Wednesday, February 09, 2005 9:02 AM
To: 'arno@foxfirescientific.com'
Cc: Stewart, Carlene
Subject: Changes to DR Project staffing?

Matt,

I caught wind of the possibility that Dr. Poston, Sr. may be offered a seat on the ABRWH. You're considering recusing him from the dose reconstruction project, effective immediately. Please confirm that this is correct.

Also, please confirm that Dr. Ian Hamilton would assume the responsibilities currently performed by Dr. Poston.

I suppose the best way to ensure that your agreement with ORAU is in sync with Foxfire's anticipated staffing is to create a revised staffing spreadsheet. When you know that these changes are really to occur, please send me a revised spreadsheet with effective date. We'll bring your contract paperwork into line.

If questions, please give me a call.

Thanks,
Priscilla

Priscilla Campbell
Oak Ridge Associated Universities
Phone: (865) 241-2871
Fax: (865) 241-9769
campbepb@orau.gov

[redacted]

From: Hallmark, Shelby - ESA
Sent: Thursday, February 24, 2005 4:42 PM
To: Iverson, Kristine; Dugas, Peter - OCIA; Krishnamoorti, Mala
Cc: Lipnic, Victoria; Turcic, Peter - ESA
Subject: RE: call from Tom Horgan of Bond's staff

I fear you are exactly right, Kris. But we'll keep trying.....

> -----Original Message-----
> **From:** Iverson, Kristine [mailto:Iverson.Kristine@dol.gov]
> **Sent:** Thursday, February 24, 2005 4:37 PM
> **To:** Hallmark, Shelby - ESA; Dugas, Peter - OCIA; Krishnamoorti, Mala
> **Cc:** Lipnic, Victoria; Turcic, Peter - ESA
> **Subject:** RE: call from Tom Horgan of Bond's staff
>
> **Thanks, Shelby. I would say that we will take care of Tom, but I don't think anyone can do that.**
>
> > -----Original Message-----
> > **From:** Hallmark, Shelby - ESA
> > **Sent:** Thursday, February 24, 2005 4:14 PM
> > **To:** Dugas, Peter - OCIA; Iverson, Kristine; Krishnamoorti, Mala
> > **Cc:** Lipnic, Victoria; Turcic, Peter - ESA
> > **Subject:** call from Tom Horgan of Bond's staff
> >
> > Peter, FYI, Mr. Horgan, who we met during the St. Louis EEOICPA Advisory Board meeting, called me to complain about not having been invited to the briefing yesterday. He may be contacting you on the same topic. I said we understood that the invitation had been general, but apologized if it didn't get to him. I'm sending him a copy of the powerpoint presentation for his further edification.
> >
> > Kris/Mala, Mr. Horgan renewed his assertion that Senator Bond "was going to be calling the Secretary" regarding the Mallinckrodt Special Exposure Cohort petition, and presumably regarding my comments to the Board during the St. Louis meeting. I didn't discuss that issue further, nor did he - just a "heads up," per Mr. Horgan. The talking points that we discussed last week are presumably not in need of any change on this score. Mr. Horgan's grasp of these issues appears to be partial.
> >
> > Thanks, sh

March 3, 2005

MEMORANDUM FOR THE SECRETARY

FROM: SHELBY HALLMARK
Director, OWCP

SUBJECT: Update on Status of EEOICPA Programs (Parts B and E)

This is to provide a brief update on progress and issues involved in the implementation of the New Part E program under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA), enacted October 28, 2004.

The Department's roll-out of the new program is proceeding according to plan, and is on schedule. ESA/OWCP established a task force to lead the implementation, with heavy participation by SOL (the Federal Employees and Energy Workers Compensation Division) and support from OASAM, OCIA, and OPA. An FY 2005 budget of about $48 million has been agreed upon with OMB to support administration of the new Part E.

The first major task was to accomplish a smooth transition of responsibilities between the Department of Energy (for the old Part D program) and DOL (for the new Part E). This has been done successfully, with full cooperation from DOE. A formal MOU is in place, DOL has taken full possession of all 25,000 old DOE Part D claims, and we are managing the residual Part D physician panel process. (The statute called for the old Part D panel process to continue until DOL issues its regulations, but in fact all the cases in that pipeline have now been acted upon by the panels.) We have also taken over full management of the contract RESOURCE CENTERS located in the ten major weapons sites, such as Paducah.

To get the new program off the ground and establish credibility with the thousands of claimants who have been waiting for years, OWCP/SOL devised a "Preliminary" Part E case processing approach, under which we are able to approve and pay straightforward cases even before our regulations are published. Special teams in our district offices were set up to make these early decisions. To date, more than 140 cash payments ($125,000 each) have been made – a total of nearly $18 million – and over 280 cases have been initially approved for payment. Our goal is to make over 1200 payments by the end of the fiscal year.

Work on the Interim Final Rule for Part E is well underway; we hope to get it to the PPB by early March so that we can beat our goal of publishing it by May 25, 2005. The rule will allow us to decide the whole range of cases under Part E.

Our publicity campaign for the new program is working well. A series of check events and public recognitions has been held at Ashland, Kentucky (Sen. Bunning – December 16); Knoxville (Sen. Alexander – January 10); and last week, in Anchorage, Alaska (Sen. Murkowski).

We have also launched a major series of town hall meetings to be held throughout the DOE weapons complex.

- Oak Ridge (January 25);
- Alaska (February 24);
- Rocky Flats (Denver) March 1
- Hanford, Savannah River, and Idaho the week of March 7
- Los Alamos the week of March 21
- Paducah – March 29-30 (Congressman Whitfield to attend on March 29)

Each of these meetings is well publicized in the local media and with the local Congressional delegation in advance, to maximize participation and ensure that stakeholders are able to participate. Many more meetings will be scheduled through the summer.

In summary, the DOL start-up has been viewed favorably in the media and among the served population in the DOE weapons complex -- so far.

Part E Risks

While the program is off to an excellent start, any delay in getting our regulations cleared through PPB and OMB could slow our progress, and will likely cause an upsurge in public and Congressional criticism. It is imperative that we move the backlog of old cases through the system quickly to avert charges that claimants are being made to wait yet again. Our efforts in FY 2005 are likely to yield about 1200 payments as we ramp up, but most of the backlog must be cleared during FY 2006.

Part B Issues

DOL continues to perform steadily and effectively in adjudicating and paying Part B claims. Our only real vulnerability in Part B is the substantial delay in case processing caused by the HHS/NIOSH dose reconstruction process. Many claims have been awaiting dose reconstruction at NIOSH for three or more years.

In addition, there is growing controversy around the dose reconstruction process:

NIOSH and the Presidential Advisory Board recently initiated approval of two new "Special Exposure Cohorts" – similar to Paducah – for the Iowa plant and the Mallinckrodt plant in St. Louis.

In reaction to this action, similar SEC status will be sought for other sites throughout weapons complex. This could threaten the stability of the current Part B program, and would cause a $7 billion increase over 10 years if all sites become SECs – a very real possibility.

HHS has in part acquiesced to claimant, Advisory Board, and political pressure in the SEC process, and has allowed the Advisory Board to operate as essentially a worker advocacy organization. The HHS unwillingness to take unpopular stances places DOL in an awkward position – we end up being the only strong defender of the logic of a scientifically based dose reconstruction process, as opposed to a presumptive (SEC) eligibility test. [Note that Senator Bond was said to be calling you or Deputy Secretary regarding what his staff considered to be a negative posture on the part of DOL with respect to the Mallinckrodt (St. Louis) SEC petition.]

Pressure for more SECs will only grow. You received a letter last week from the Denver Steelworkers' local seeking your support for their petition for an SEC for the Rocky Flats (Denver) facility.

We look forward to providing more information on the new program in the Friday briefing.

Cc: Lipnic

From: Hinnefeld, Stuart L
Sent: Tuesday, January 17, 2006 1:53 PM
To: Elliott, Larry J.; Wade, Lewis
Cc: Neton, Jim; Sundin, David S.
Subject: RE: Suggested SC&A agenda items

Lew,

Status of procedures review is this:

The Board Working Group (Griffon, Gibson or Espinosa, Munn, and Presley), SC&A and OCAS discussed the findings on external dosimetry procedures at a Working Group meeting in Cincinnati. We are proceeding to implement the recommendations that the Board made as a result of those discussions.

On November 10, OCAS provided to the Working Group and SC&A our initial responses to the findings on internal dosimetry and CATI procedures, anticipating that they might be discussed at the November 16 Working Group meeting. Because of time constraints the Working Group did not get to them on November 16, and there has not yet been a discussion on them.

Rather than review the recommendations from the external dosimetry procedure findings, as SC&A proposes, it might be preferable for OCAS to provide a status report on actions being taken in response to Board recommendations with respect to the external dosimetry procedures.

Stu

-----Original Message-----
From: Elliott, Larry J.
Sent: Tuesday, January 17, 2006 12:04 PM
To: Wade, Lewis
Cc: Neton, Jim; Hinnefeld, Stuart L; Sundin, David S.
Subject: RE: Suggested SC&A agenda items

Lew:
I am concerned that the two SC&A proposals on the SEC procedures are very problematic (Mauro is proposing that Arjun make a presentation to the Board). I hope that we can at least indicate to the Board that we have not yet had time to evaluate these proposals, provide comments to SC&A and the Board; and these should be subject to the 6-step process. I also wonder how these will intersect with the Melius thought paper on sufficient accuracy and as well on timely handling of SEC Evaluation Reports - seems to me the proposals augment and complicate the former and competes against the latter.

I am also concerned with the review of the 4th set of DR reviews. There are three cases in that review that will need to be removed from SC&A's and the Board's review due to DOL recalling the cases for re-work of the dose reconstructions - thus they are not "final adjudicated claims". These three cases were inappropriately completed using an overestimating approach with the POC finding as compensable. This will be a public relations nightmare - we need to discuss ASAP.

I have not heard from Stu yet but he may or may not have thoughts on the procedures review.

Jim may or may not have heartburn over other items. He and Stu should get to you ASAP if they have any comments.
Lje.

-----Original Message-----
From: Wade, Lewis

Sent: Tuesday, January 17, 2006 10:52 AM
To: Elliott, Larry J.; Neton, Jim
Subject: FW: Suggested SC&A agenda items

Guys:
Let me know if this causes you any gas.
Lew

-----Original Message-----
From: John Mauro [mailto:jmauro@scainc.com]
Sent: Wednesday, January 11, 2006 3:39 PM
To: Arjun Makhijani; Joe Fitzgerald; Kathy Behling; Wade, Lewis
Subject: Suggested SC&A agenda items

Lew,

As a followup to our conversation regarding agenda items for the subcommittee and full Board meeting, the following presents my understanding and some suggestions regarding SC&A's role in the agenda.

1. Y-12 - Joe Fitgerald will be prepared to answer questions and/or give a presentation before the subcommittee and/or full Board regarding on the status of each item in the matrix, as recently discussed at the working group meeting.

2. Rocky Flats - Joe Fitzgerald will be prepared to give a brief overview of the matrix recently delivered to NIOSH and the Board regarding our findings pertaining to the Rocky Flats site profile. We also recognize that a close-out process will be initiated and SC&A will be prepared to participate in working group group meetings that will take place subsequent to the Board meeting.

3. Hanford - A matrix summarizing the major issues resulting from our review of the Hanford site profile is being transmitted to NIOSH and the Board this week. Joe Fitzgerald will be prepared to give a brief presentation on the issues.

4. With respect to the dose reconstruction audit reports, I discussed this matter with Hans and Kathy Behling, and we have the following suggestions:

- Hans can give a brief overview of the status of the 4 packages. In summary, the first set of 20 cases is complete and is on the NIOSH web site. For the second set of audits, Kathy Behling has already given a presentation to the Board. We have delivered a matrix to NIOSH and the Board and a working group meeting was held regarding the matrix for the second package. One action item SC&A had as a result of this process was to go back to the matrix for the second package and determine how many of the items can be closed out as a result of our review of the Savannah River workbook. Kathy will resolve those issue and submit the revised matrix to the Board and NIOSH prior to the meeting. Therefore, if NIOSH is in agreement and in a position to submit a written response to the findings, the Board can go through the formal closeout process for the second set of dose reconstruction audit reports, as summarized in the matrix.

- With regard to the 3rd set of cases, we delivered our draft audit reports, and subsequently received several comments on the draft from the Board. We have responded to the comments, and recently submitted a revised audit report for the third set of audits. The matrix for the third set will be sent to the Board and NIOSH by the end of this week. We suggest that Kathy Behling give a brief presentation regarding the findings for the 3rd set, similar to the one she previously gave for the second set of cases. It would probably be appropriate to schedule a working group meeting to begin the issues resolution process for the finding identified in the matrix for the 3rd set of cases.

- With regard to the 4th set of cases, Hans will be prepared to give a status report. The audit of most of the cases has been completed, but we are

finding that some of the realistic dose reconstructions are quite complex. As you may recall, this is the first set of cases that include realistic dose reconstructions, and the Board may be interested in hearing how the audits of realistic dose reconstructions differ from the audits of the min/max dose reconstructions.

5. With respect to the Task 3 procedures review, the matrix for the internal, external, and CATI procedures have been delivered to NIOSH and the Board. Working group meetings were held for external; but due to time constraints, we were not able to discuss issues pertaining to internal dosimetry and the CATI interview process. We suggest that Hans give a brief update on where we are with regard to the closeout of the external dosimetry issues on the Task 3 matrix. I believe most of the external issues were thoroughly discussed and tentatively resolved during an earlier working group meeting, but we have not yet initiated a dialog on internal dose issues and the interview process. We can do that at this Board meeting, if NIOSH concurs.

6. With respect to Task 5, SC&A recently delivered 2 reports to the Board; one is a review of NIOSH procedures for reviewing SEC petitions, and the other is a draft procedure for use by NIOSH and the Board to review SEC petitions. We suggest that Arjun give a presentation summarizing these two deliverables.

Please let me know if my understanding of the agenda is correct and whether we should proceed with making the necessary preparations.

Regards,

John

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No virus found in this outgoing message.
Checked by AVG Free Edition.
Version: 7.1.371 / Virus Database: 267.14.17/227 - Release Date: 1/11/2006

Search 2

From: Nesvet, Jeffrey L - ESA
Sent: Wednesday, April 06, 2005 11:03 AM
To: Turcic, Peter - ESA; Hallmark, Shelby - ESA
Subject: RE: NAS Review of the NIOSH Radiation Dose Reconstruction Program

I agree with Pete that he and I should pitch in at the beginning to try to steer this effort in a direction that will prove useful to us.

JEFFREY L. NESVET
Associate Solicitor for Federal Employees'
and Energy Workers' Compensation
Office of the Solicitor
United States Department of Labor
200 Constitution Avenue, N.W., Room S-4325
Washington, D.C. 20210
(202) 693-5320 693-5360 (fax)

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-----Original Message-----
From: Turcic, Peter - ESA
Sent: Wednesday, April 06, 2005 10:50 AM
To: Hallmark, Shelby - ESA; Nesvet, Jeffrey L - ESA
Subject: RE: NAS Review of the NIOSH Radiation Dose Reconstruction Program
Importance: High

I think on the proposal implementation group I should participate. This is going to get the advocates upset. Once it gets started, Jeff Kotsch could participate on a routine basis. Jeff Nesvet should also be there in the beginning so that we can steer the work plan towards an analysis of making compensation decisions. Also, I think we need to get enough into the work plan so that we can use the results to defend our decisions.

Additionally, this could go a long way to help re-build credibility into the dose reconstruction process.

-----Original Message-----
From: Hallmark, Shelby - ESA
Sent: Wednesday, April 06, 2005 10:28 AM
To: Turcic, Peter - ESA; Nesvet, Jeffrey L - ESA
Subject: FW: NAS Review of the NIOSH Radiation Dose Reconstruction Program

Do you guys think we need a participant on this? My concern is getting interim products as quickly as possible, and keeping the cost within reason. Do we need a person on the team to exercise that kind of influence? If so, who would it be?

-----Original Message-----
From: Howard, John [mailto:zlc1@cdc.gov]
Sent: Wednesday, April 06, 2005 9:38 AM
To: Hallmark, Shelby - ESA; Turcic, Peter - ESA; Nesvet, Jeffrey L - ESA; Elliott, Larry J.; Wade, Lewis; Porter, Diane; Stephens, James W.; Neton, Jim; Homoki-Titus, Zeda (Liz) E.; Durst, Kelley; Sinclair, Raymond C.
Subject: NAS Review of the NIOSH Radiation Dose Reconstruction Program

Gentlepeople:

Thank you for your preliminary comments on the proposed **NAS Review of the NIOSH Radiation Dose Reconstruction Program** by the National Academy of Sciences at yesterday's meeting with OWCP and NIOSH at the DOL. Attached is the revised proposal.

<<OCAS.NAS.Proposal.Revised.doc>>
After our initial discussion of yesterday, we agreed to form a small group to implement the proposal in a more detailed state together with a detailed scope of activities (charge) for the NASA panel, a detailed budget, a detailed timeline and incorporation of a mechanism to receive input from the NAS Panel **during the review timeframe** so that important findings can be utilized quickly by radiation dose reconstruction program (as opposed to waiting until the end of an 18 to 24 month process).

Members of the NAS Radiation Dose Reconstruction Proposal Implementation group will be NIOSH/OD representatives (Lew, Wade, Kelley Durst, Ray Sinclair), an OCAS representative (Larry Elliott); a DOL/OWCP representative (if so designated by DOL/ OWCP); and a NAS representative (TBD).

Ray Sinclair from the NIOSH/OD in Cincinnati, will be secretary of the NAS Implementation Group, and will be notifying participants of the first meeting of the group.

Thank you.

JH

Proposed Review of the NIOSH Radiation Dose Reconstruction by the National Academy of Sciences

Purpose:
Review the scientific aspects of this program with respect to the suitability of current exposure dose reconstruction methods for determining qualification for worker compensation, make recommendations as to enhancing existing methods of OCAS, and identify significant emerging research areas that may impact OCAS in the future.

Steps in the Review:
The National Research Council, through its Division of Earth and Life Studies, and the Institute of Medicine (DELS/IOM) will identify, recruit, and convene a panel of experts for purposes of this evaluation. Those experts will come from relevant fields such as health physics, oncology, epidemiology, risk assessment, and dose reconstruction.

The panel will meet three times under the auspices of the DELS/IOM. The new (March, 2005) Nuclear and Radiation Studies Board (NRSB) will have administrative responsibility for the review. The NRSB replaces the older Board of Radiation Effects Research and the Radioactive Waste Management Board within the NRC.

The panel will develop methods for its review and conduct the review. It will review material provided by (or requested of) OCAS and related organizational units in other agencies. It may gather other evidence from other sources to complete a thorough review. The panel may meet at NAS offices, or travel to other locations if that will enhance the review.

A written evaluation will be prepared by the panel in cooperation with NRC staff. The evaluation will be externally peer-reviewed before its release to the public.

Estimate of Costs:

$800,000 per year (estimated). The NRC informally recommended an 18-24 month time frame for this project. Their final cost estimate would be based on three factors:

a. Complexity of the study
b. Size of the review panel
c. Length of time for the study

Prepared by: Ray Sinclair, NIOSH Senior Scientist, Office of the Director, Cincinnati, 4 April 2005; revised by John Howard, 8 April 2005.

Notes:

1. The NRC will soon release a report on the Radiation Exposure Compensation Act (RECA) for the Health Research and Services Administration (HRSA) of DHHS. They predict it will be released by 4/30/05. Because of that, they feel well-qualified to conduct the study described above.
2. This draft was prepared with the advice of Dr. Evan Douple, Director, Board on Radiation Effects Research (now superseded by the NRSB). He is also project manager of the NIOSH scientific program review.

-----Original Message-----
From: Hallmark, Shelby - ESA
Sent: Friday, April 15, 2005 11:29 AM
To: Krishnamoorti, Mala; Lipnic, Victoria
Cc: Siff, Andrew
Subject: RE: Panel to meet about worker funds
Importance: High

Vicki et al. – in my quick analysis of the impact of declaring SECs for the second half of Mallinckrodt and/or any part of Iowa, I neglected to reiterate that such a declaration, at least based on the criteria currently at play for justifying these SECs, would not only expand the cost of EEOICPA tremendously; it would also expunge the benefit rights of the 40% or so claimants who incur a cancer that is NOT one of the statutorily listed presumptive SEC cancers. Those individuals would have no recourse, as the dose reconstruction process would have been declared invalid by the SEC determination, leaving no basis for any of that 40% of claimants to meet the test of causation. Thus there is an equity issue associated with declaring SEC status in situations where NIOSH would otherwise have sufficient data to conduct dose reconstructions.

Given the likelihood that NIOSH will not present a forceful case for denial of these two petitions, the current make-up of the Board could result in recommendations that are not wise. Such recommendations will be extremely difficult/painful for the HHS Secretary to override.

-----Original Message-----
From: Hallmark, Shelby - ESA
Sent: Thursday, April 14, 2005 2:28 PM
To: Krishnamoorti, Mala
Cc: Siff, Andrew
Subject: RE: Panel to meet about worker funds
Importance: High

Mala – I just sent a couple things down to Vicki – one is a general discussion of the status of our implementation of the October 2004 EEOICPA amendments, and the other covers the imbroglio around NIOSH, dose reconstructions, the Advisory Board, and Special Exposure Cohort petitions. Let me know if you or Andrew have questions. Thanks, sh

Search 1

n:	on behalf of Iverson, Kristine
t:	Wednesday, April 27, 2005 4:53 PM
	Hallmark, Shelby - ESA; Krishnamoorti, Mala; Law, Steven; Lipnic, Victoria; Radzely, Howard
Cc:	Nesvet, Jeffrey L - ESA; Turcic, Peter - ESA; Svenonius, Diane - ESA
Subject:	RE: Update

Shelby - Did you say anything at this Iowa meeting? I would like to be able to tell the Hill that DOL had no comments, just observed.

-----Original Message-----
From: Hallmark, Shelby - ESA
Sent: Wednesday, April 27, 2005 4:05 PM
To: Krishnamoorti, Mala; Law, Steven; Lipnic, Victoria; Iverson, Kristine; Radzely, Howard
Cc: Nesvet, Jeffrey L - ESA; Turcic, Peter - ESA; Svenonius, Diane - ESA
Subject: Re: Update
Importance: High

Mala -- here's the latest.

The Board heard some very demanding and angry presentations from Grassley, Harkin, and Cong. Leach on Monday -- much anger directed at the DOJ opinion on "transparency", many demands for SEC status.

On Tuesday the Board voted to recommend an SEC class for essentially all years, all employees, at Iowa. They carefully avoided using the transparency rationale as a basis for their recommendation. The vote was unanimous. I would speculate that HHS will not overturn this recommendation. It is not clear what the precedential impact of this decision will be -- depends in part on the wording of the recommendation and HHS's finding. But it should be less damaging than an SEC based on the transparency argument.

Today the Board voted to again postpone making a decision on the petition for an SEC for the seond half of Mallinckrodt (St. Louis) -- 1949-1957. NIOSH made an unequivocal statement that it CAN do dose reconstructions for these years -- which should nix a cohort -- but the claimant oriented members of the Board were able to delay a final vote when it looked like they might not prevail on a yea-nay vote.

A final vote is now projected for the Board's next meeting in early July. It may be that at least two current members of the Board will be replaced by new appointees by then, which could significantly change the dynamic of the Board. Such a change is critical, since the Board and "its" contractor seem bent on demanding that NIOSH's processes be far more perfect than is possible -- failing which, SEC's would be demanded everywhere.

The Mallinckrodt delay will continue to tie up very scarce NIOSH resources, and was unnecessary, since it is quite clear that these years do not meet the statutory requirement or NIOSH's regs for declaring a cohort. But at least a very damaging precedent was averted -- for now. Thanks, sh

-----Original Message-----
From: Krishnamoorti, Mala <Krishnamoorti.Mala@dol.gov>
To: Hallmark, Shelby - ESA <Hallmark.Shelby@dol.gov>
Sent: Wed Apr 27 14:08:52 2005
Subject: Update

Shelby - Just thought I'd check in since I hadn't heard from you. Any news/updates from the adv board mtg?

CHAIRMAN

RANKING MINORITY MEMBER

ONE HUNDRED NINTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON THE JUDICIARY
2138 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6216
(202) 225-3951
http://www.house.gov/judiciary

June 9, 2005

Honorable George W. Bush
President of the United States of America
The White House
1600 Pennsylvania Ave, N.W
Washington, DC 20500

Dear Mr. President:

It is the Committee's understanding that changes may be made shortly to the composition of the Advisory Board on Radiation and Worker Health (Board). Members are appointed by your office. New appointments, and the discharging of current members, may negatively affect the Board's balance and independence, thus compromising the Board's ability to fulfill its mandates under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA).

By law, the Board advises the Department of Health and Human Services (HHS) on the validity and quality of the estimates of radiation dose done by the National Institute for Occupational Safety and Health (NIOSH), and designation of groups of workers as Special Exposure cohorts when it isn't feasible to estimate those workers' radiation doses accurately. Board appointments must have "a balance of scientific, medical and worker perspectives."

The House Committee on the Judiciary has jurisdiction over EEOICPA. The Committee has been closely monitoring the activities of this Board. There are perceived conflicts of interest in the interactions of NIOSH's Office of Compensation and Analysis Support (OCAS) with the Board and it's audit contractors as well as alleged inappropriate interference by OCAS with the Board's work. The Committee is examining whether the Board's structure can ensure scientific independence from the program it is auditing. In part, due to the Committee's oversight, some positive changes were implemented by NIOSH, but the structures needed to assure scientific and organizational independence are not resolved. The appointments to the Board and their effect on the overall composition of it are key to the program's continued improvement. As a result, they are of primary concern to the Committee. Consultation with the White House would be welcomed by the Committee with regard to the overall composition and balance of this Board.

Honorable George W. Bush
June 9, 2005
Page 2

Every attempt must be made to assure the Board appointees are independent of NIOSH's program, its contractors, the Department of Energy (DOE) and the Labor Department, inasmuch as the Board is tasked with an independent audit function. Specifically, 42 U.S.C., 7374(n) provides that "the President shall establish and independent review process using the Advisory Board on Radiation and Worker Health" to assess methods used for dose reconstruction and verify dose estimates. If OCAS staff provided the list of candidates to the White House, an appearance of conflict arises, as it is they who will be the subject of the Board's audit. Hopefully, a direct dialogue between the White House and Congress can resolve this problem.

Also, there is concern about the loss of current Board members' institutional memory. It clearly makes sense to retain this memory as the Board is immersed in the numerous audits currently underway.

An effective Board, whose judgment and independence is beyond reproach, is necessary for there to be a public perception that the compensation decisions made, whether approved or denied, are credible. The charter for the Board permits the appointment of up to 20 members. There are presently only 11 members. It may be prudent to add new appointments while keeping the institutional memory of any current members who are willing to stay even if their terms have expired. The additional vacancies should easily allow current Board members to be retained.

It cannot be emphasized enough how crucial it is that Board appointments are unbiased and satisfy the need for "a balance of scientific, medical and worker perspectives." The Board is the entity in the program that must keep the trust of the claimants more than all others.

The Committee looks forward to working with your Administration to take any actions necessary to improve this Board and this compensation program. Should your office have any questions, they may contact the Committee General Counsel, Phil Kiko, at (202) 225-3951.

Sincerely,

F. JAMES SENSENBRENNER, JR.
Chairman

Cc: Hon. Dina Powell, Director, Office of Presidential Personnel

From: Ishak, Laurie D.
Sent: Friday, June 10, 2005 5:01 PM
To: Calhoun, Grady; Rafky, L. Michael; Daniels, Robert D.
Cc: Elliott, Larry J.; Hinnefeld, Stuart L; Homoki-Titus, Zeda (Liz) E.; McGolerick, Robert; 'TooheyR@orau.gov'; Ellison, Chris [NIOSH]
Subject: COI Issues Discussed in ABRWH Meetings

Attachments: COI Memo.doc

This is an abstract of the discussions pertaining to COI issues during ABRWH meetings. I have not had a chance to review the minutes of the Board meetings so this abstract only includes a review of transcripts.

Please let me know if you have any questions.

Thanks,
Laurie

COI Memo.doc (76 KB)

Laurie D. Ishak, JD, MA
Presidential Management Fellow
Office of Compensation Analysis and Support
National Institute for Occupational Safety and Health

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MEMORANDUM

TO: Calhoun, Rafky, Daniels
CC: Elliott, Hinnefeld, Homoki-Titus, McGolerick, Toohey, Ellison
FROM: Ishak
DATE: June 8, 2005

RE: **COI DISCUSSIONS CONTAINED IN ABRWH TRANSCRIPTS**

A key word search was done of all ABRWH transcripts to find discussions concerning conflict of interest (COI) issues with NIOSH and Oak Ridge Associated Universities (ORAU), including the completion of dose reconstructions and site profile documents. This summary of COI issues does not include discussions of individual Board members concerning any COI problems they may have in their role as Board members nor does it look at COI issues that came up regarding procurement issues or SC& A. The search produced the following results:

Transcript Results:

(Listed in order of the earliest Board meeting to the most recent. Meetings with ** indicate that detailed discussion occurred on the COI plan. Shaded areas and ** indicate that there was discussion concerning how the COI plan should apply to individuals working on site profile documents. The shaded sentences on page 3 indicate where Larry stated that a commission would be put together to look at COI issues).

January 22, 2002:

- **Speaker is Mr. Miller.** Discussion centered on the contractors that would be used in the dose reconstruction process. Miller raised concerns about the two contractors and their ties to the DOE. **[p. 230, ln. 16-25 & pp. 231-234]**

February 13, 2002:

- **Speaker is Mr. Elliott.** Elliott is answering a question from Dr. Melius asking how OCAS will handle COI's with the dose reconstruction contractor. Elliott answers by explaining that a COI plan will be included in the RFP. **[p. 36, ln. 8-25 & p. 37, ln. 15]**

- **Speaker is Mr. Alvarez.** Alvarez is proposing an idea for handling COI issues with contractors. Alvarez proposes setting up a subcommittee that would oversee quality assurance of the contractor that is awarded the contract. **[p. 186, ln. 12-25 & p. 187-188]**

- **Speaker is Mr. Miller.** Miller is following up on a question raised by Melius. Miller concerns that the public does not know what the minimum criteria are for

the COI plan that Elliott mentioned would be included in the COI plan. Miller states that transparency in terms of COI's would build public confidence. **[p. 219, ln. 7-25 & pp. 220-221]**

May 2-3, 2002:

- **Speaker is Dr. Melius.** Melius is revisiting the COI plan discussed in the February 13, 2002, meeting. Melius asks if the COI plan has been done satisfactorily. Mr. Elliott cannot comment at that time. **[p. 48, ln. 10-12, & p. 40, ln. 1-2]**

- **Speaker is Dr. Melius.** Melius raises the COI issue and asks how it will be addressed with the contractors. Elliott responds that the issue is a procurement issue and that the contract will contain a COI plan that will be negotiated and agreed upon by the agency, the procurement office and the proposer. Elliott states that the Board will not have the ability to provide advice on the content of the COI plan but that the Board will be able to evaluate and examine the plan and make comments and recommendations. Melius points out that he thinks it's a very critical issue. **[p. 184, ln. 8-12. & pp. 185-187]**

July 1, 2002:

- **Speaker is Mr. Griffon.** Griffon states that the COI issue is important for credibility. He suggests ideas for a panel of experts "outside the box" to review dose reconstructions with Board review. **[p. 49, ln. 19-25, & pp. 50-56]**

- **Speaker is Mr. Miller.** Miller again raises concerns about COI issues with the contractor selected to do dose reconstructions. He also suggests an independent review process of a group of individuals outside of the DOE and who are beyond "reproach." **[p. 238, ln. 18-25, & pp. 239-241]**

August 14-15, 2002:

- **Speaker is Mr. Miller:** Miller states that the COI issue is so broad in terms of potential for conflicts. He suggests disclosure to the claimants about who is doing their dose reconstruction. **[p. 148, ln. 20-25, & pp. 149-150]**

- **Speaker is Dr. Melius.** Melius wants further discussion at the next meeting for COI plans in the contract. **[p. 158, ln. 3-12]**

- **Speaker is Dr. Anderson.** Anderson wants to know if the health physicists name will be on the dose reconstruction or if it will be anonymous. Elliott states that the claimant will know who the dose reconstructionist is and who the reviewers

- **Speaker is Mr. Lada.** Lada expressed concern about COI with ORAU. He believes claimants should know who is working on their claim through the whole process. **[p. 233, ln. 16-24]**

- **Speaker is Mr. Elliott.** Larry clarifies that there are 2 types of COI with the contract. One where someone in a position influences a situation and creates an adverse outcome. Second, there are perceived conflict of interests. **[p. 274, ln. 16-25, & p. 275, ln. 1-24]**

**October 15-16, 2002 (Volume II):

- **Speaker is Dr. Melius.** Melius has suggestions for how NIOSH should implement the proposals in the ORAU proposed COI plan to handle potential or perceived conflicts. Discussion occurs between Melius, Neton, Ziemer, and Elliott. Melius suggests that the biographical information about the health physicist be provided to the claimant once the claim is assigned and allow the claimant the opportunity to contact NIOSH is he/she feels there is a conflict. Additional comments are made by other Board members agreeing to a similar process. Discussion also occurs concerning COI issues with reviewers. Elliott points out that the reviewers are also covered by the COI plan. Some Board members are concerned that the claimant should also be aware beforehand of the reviewers and NIOSH reviewers who will be working on their claim. Dehart raises a question about the COI plan and conflicts with individuals who have testified as an expert witness for DOE or DOE contractors. Some Board members think it is too narrow. **[p. 114, ln. 10-25, & pp. 115-141]**

- **Speaker is Dr. Ziemer.** Ziemer continues earlier discussion about Dehart's comment regarding conflicts with individuals who have testified as an expert witness for the DOE. Dehart felt like his question was answered. Dr. Andrade makes a motion for the Board to recommend that NIOSH create a short letter to be sent to the claimants including the name of the person doing the dose reconstruction, the supervisor and identifying that the entire process will be reviewed by NIOSH staff. Also, the letter should include a statement from NIOSH indicating that no COI is apparent with these individuals. Melius suggests that the Board recommend that NIOSH make biographical information available to claimants as well. Melius also thinks NIOSH should place on its website information on all of the contractor's dose reconstruction and reviewers personnel. The Board then votes on Melius motion and it passes. There is continued discussion about putting information on the web. **[p. 147, ln. 20-25, & pp. 148-166]**

- **Speaker is Larry Elliott.** Discussions concerning a COI plan for technical consultation. The COI plan would need to be evaluated by the evaluation panel. Discussion occurs on weighing technical expertise against potential COI's. **[p. 198, ln. 5-25, pp. 199-204]**

- **Speaker is Larry Elliott.** Elliott points out that the COI issue applies to OCAS staff as well. **[p. 221, ln. 16-22]**

**December 2, 2002:

- **Speaker is Dr. Ziemer:** Ziemer asks Neton clarifications about COI plan. The Board had a discussion regard ng the timeframe from when a COI arises with a contractor working at a DOE facility until the time they are working on a dose reconstruction. The Board also discusses an evaluation panel being set up to select dose reconstructers with a member from the Board on the panel. The Board also discussed the issue of conflicts with individuals involved in previous litigation being prohibited from working on a claim. **[p. 111, ln. 19-25, & pp. 112-140]**

**January 7-8, 2003:

- **Speaker is Dr. Neton.** Neton discusses progress with the COI plan and placing the bio sketches on the web. Melius urges Neton to expedite the release of that information on the web as soon as possible to increase public confidence. Toohey explains that the training of ORAU employees covers COI training. **[p. 49, ln. 12-24; p. 52, ln. 2-8; p. 56, ln. 1-19; p. 57, ln. 12-15]**

- **Speaker is Dr. Roessler.** Roessler asks about possible conflicts with COI and Q clearances. She asks if it is reasonable that the Q cleared individuals would have clearance even if they had not worked at a DOE facility in 2-years (the timeframe as laid out in the COI plan). It is discussed and Q clearances can last longer than 2-years and they can be reinstated. Discussion continues among the Board about how the COI limits can be overly restrictive in terms of Q cleared individuals working on claims. **[p. 230, ln. 1-25; & pp. 231-236]**

- **Speaker is Dr. Ziemer.** Ziemer brings up the wording of the COI plan in regards to pervious employees/contractors of NIOSH and ORAU to discuss. Also discussed the limits on individuals who worked at a site working on a dose reconstruction from that site. Also there was discussion about the use of site experts working on TBD's or site profiles. Dehart also made a motion to change the language dealing with limiting involvement of individuals who testified for DOE to make it more broad to include individuals who make have testified for any part in a suit related to worker compensation or radiation related claims. The motion fails. **[p. 238, ln. 22; & pp. 239-258]**

- **Speaker is Dr. Ziemer.** Ziemer discusses concerns that some Board members have about the 2-year timeframe from an individual working at a DOE facility to

being able to do a dose reconstruction that is listed in the COI plan. Board discussion pursues. **[p. 293, ln. 10-22, pp. 294-297]**

February 5, 2003:

- **Speaker is Dr. Toohey.** Toohey explains the process of communication with claimants and states that the as per the COI plan, information is posted on the web. Toohey is asked about parameters on assigning health physicists. He explains that they want to avoid COI's. **[p. 33, ln. 4-25, & p. 34, ln. 1-9]**

- **Speaker is Mr. Griffon.** Griffon discusses the drafted amendment language to the COI section that was discussed in the January 7-8 meeting. **[p. 341, ln. 16-25, & pp. 342-344]** Discussion was interrupted and resumed again. Board discussed criteria for evaluating COI's without relying totally on the 2 year timeframe. **[p. 353, ln. 1-25, & pp. 354-357]** Discussion again was brought up regarding changes to the COI plan when evaluating individuals doing the dose reconstruction. **[p. 391, ln. 3-25; & pp. 392-413]**

May 20, 2003:

- **Speaker is Mr. Elliott.** Elliott asks the Board to discuss how to balance effective use of resources and appearance of COI's, specifically in light of the Board's auditing process of DR's. Board discussion begins on this issue. Several Board members want to avoid lengthening the process. Discussion around the need to balance and have flexibility. **[p. 412, ln. 10-25, & pp. 413-426]** Miller makes a comment about addressing the COI issue in another meeting. Discusses need to avoid COI's. Miller is not sure that COI screening process is adequate **[p. 426, ln. 6-25, & pp. 427-430]**

**August 19, 2003 (Volume II):

- **Speaker is Dr. Melius.** Melius asks if ORAU posted the information regarding thee biographical sketches on the web yet? Toohey responds that all information is on the web. Melius wanted subcontractors on the web as well? Elliott and Toohey agree to take it under consideration. Gibson asks about site experts from a site working on a site profile document. **[p. 32, ln. 1-25, & pp. 33-35]**

- **Speaker is Dr. Melius.** Melius asks if Larry had proposed relaxing the COI plan for individual DR's. Toohey responds that has not happened because of the consensus of the Board against it. **[p. 48, ln. 14-23]**

- **Speaker is Dr. Melius.** Melius again points out the avoiding COI and increasing transparency is critical to the credibility of the program. **[p. 146, ln. 24-25, & pp. 147-148]**

- **Speaker is Mr. Miller.** Miller brings up the need to ensure that there are no COI's when doing site profiles. He believes that site profile experts should fall into the same COI restraints as DRists and their information should also be on the web. **[p. 277, ln. 6-25, & pp. 278-281]**

**October 28, 2003 (Volume I):

- **Speaker is Mr. Miller.** Miller asks if the Board has decided to hold site experts working on site profile documents to the same COI standards as individual DRists. Elliott answers that biographical sketches for people working on site profiles are also on the web. Miller asks if a person who has worked at a site is barred from doing a site profile from that site? Neton explains that individuals with information about a site because they worked there have not yet been barred from working on a site profile. Miller questions the standards of professional conduct being used to complete the site profile documents. There was also discussion about individuals working on site profile documents that have testified for a site. Elliott explains that that is not acceptable. **[p. 197, ln. 12-25, & pp. 198-203]**

**December 9-10, 2003:

- **Speaker is Mr. Ringen.** Ringen believes that the administrative structure is rifled with potential for COI's. This causes a decrease public confidence in NIOSH's objectivity. Ringen believes that the current policies are not adequate for addressing COI's. Ringen raises issues concerning Savannah River and potential conflicts with the site profile document (he also raises issues regarding methodology). **[p. 199, ln. 5-2, pp. 200-211 (Most COI discussion is on p. 208)]**

- **Speaker is Mr. Miller.** Miller believes the Board needs to discuss COI issues. He believes there needs to be more transparency on the teams for site profile documents. Miller believes that the COI plan for individual dose reconstructions should be extended to individuals working on site profile documents. **[p. 329, ln. 7-2, pp. 330-331]**

**April 20, 2004:

- **Speaker is Dr. Melius.** Melius asks if ORAU has created a COI policy for site profile documents. Neton explains that ORAU is working on a policy for site

are. Elliott again emphasized that the contract will have a COI provision that will be available to the public. **[p. 158, ln. 21-25, & pp. 159-161]**

- **Speaker is Joe Carson.** Carson speaks to the COI discussion raised by Miller and suggests that professional ethics come into play in these situations. **[p. 171, ln. 21-25, & p. 172]**

**October 15-16, 2002 (Volume I):

- **Speaker is Dr. Neton.** Neton discusses the contract that was awarded and the COI plan that was provided. Neton discusses the provisions in the COI plan. **[p. 33, ln. 11-25, & pp. 34-36]**

- **Speaker is Dr. Melius.** Melius raises questions concerning the COI plan as presented by Neton. He also raises questions regarding transparency and biographical sketches on the internet and that will be sent to claimants. Melius also discusses COI with supervisors and contract oversight. [redacted] **[p. 52, ln. 1-14]** Melius agrees that it would be beneficial for the credibility of the program. **[p. 45, ln. 6-25, pp. 46-53]**

- **Speaker is Mr. Gibson.** Gibson asks what happens to a claim when a claimant says that he/she believes that there is a COI. Elliott explained that DOL could remand the claim back to NIOSH if it was found out after the fact. Neton explained that the claimant would get information about the health physicist before the dose reconstruction started so hopefully such a situation would be avoided. But if it happened, it would be dealt with effectively. **[p. 101, ln. 16-25, & pp. 102-103]**

- **Speaker is Mr. Silver.** Silver points out that ORAU has a large number of COI's because of their relationship with DOE. He hopes that individuals like John Till's group are involved because they have a high level of public confidences. He would like to see that group included as auditors. **[p. 220, ln. 15-25, & p. 221]**

- **Speaker is Mr. Miller.** Miller wants everything as transparent and open as possible for claimants. Miller believes the right of claimants to know outweighs privacy act considerations. Miller also asked what recourse individuals had if there was found to be a COI. Elliott explained that there would be points of contact at NIOSH and ORAU for claimants if there are COI problems, or for any other reason. Miller asked if claimants could select their own health physicist. Elliott explained it was not an option. **[p. 224, ln. 21-25, & pp. 225-229]**

- **Speaker is Larry Elliott.** Elliott points out that the COI issue applies to OCAS staff as well. **[p. 221, ln. 16-22]**

****December 2, 2002:**

- **Speaker is Dr. Ziemer:** Ziemer asks Neton clarifications about COI plan. The Board had a discussion regarding the timeframe from when a COI arises with a contractor working at a DOE facility until the time they are working on a dose reconstruction. The Board also discusses an evaluation panel being set up to select dose reconstructers with a member from the Board on the panel. The Board also discussed the issue of conflicts with individuals involved in previous litigation being prohibited from working on a claim. **[p. 111, ln. 19-25, & pp. 112-140]**

[redacted]

[redacted]

February 5, 2003:

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May 20, 2003:

- **Speaker is Mr. Elliott.** Elliott asks the Board to discuss how to balance effective use of resources and appearance of COI's, specifically in light of the Board's auditing process of DR's. Board discussion begins on this issue. Several Board members want to avoid lengthening the process. Discussion around the need to balance and have flexibility. **[p. 412, ln. 10-25, & pp. 413-426]** Miller makes a comment about addressing the COI issue in another meeting. Discusses need to avoid COI's. Miller is not sure that COI screening process is adequate **[p. 426, ln. 6-25, & pp. 427-430]**

[redacted]

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[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

December 15, 2004:

- **Speaker is Mr. Katz.** Katz explains that NIOSH has been vigilant with COI issues and they were in mind when creating the SEC provisions. **[p. 10, ln. 23-25, & pp. 11-13]**

- **Speaker is Mr. Melius.** Melius asks if the COI plan in place for individuals working on dose reconstructions and site profile documents will be the same for SEC petitions. **[p. 28, ln. 2-25, & pp. 29-30]**

- **Speaker is Dr. Toohey.** Toohey adds to the COI issue with SEC petitions explaining that an individual cannot prepare, review or approve SEC petitions if they worked at the site. **[p. 50, ln. 16-25, 51-52]**

are. Elliott again emphasized that the contract will have a COI provision that will be available to the public. **[p. 158, ln. 21-25, & pp. 159-161]**

- **Speaker is Joe Carson.** Carson speaks to the COI discussion raised by Miller and suggests that professional ethics come into play in these situations. **[p. 171, ln. 21-25, & p. 172]**

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Search 4

From: on behalf of Hallmark, Shelby - ESA
Sent: Tuesday, August 30, 2005 10:27 AM
To: Iverson, Kristine - OCIA; Lipnic, Victoria; Wilson, Mark - ESA; Dugas, Peter - OCIA; Krishnamoorti, Mala
Cc: Turcic, Peter - ESA; Nesvet, Jeffrey L - ESA
Subject: Next steps re Mallinckrodt SEC issue
Importance: High

Vicki/Kris, et al. – I just talked with John Howard (NIOSH Director). Strictly inquiries on my part about what NIOSH plans to do with the Board's actions. He indicated, as I expected, that NIOSH will NOT seek to override the Advisory Board's posture on the second half of Mallinckrodt. We talked a bit about the seemingly self-contradictory recommendation the Board made that non-listed cancers (those not covered by the SEC designation) should still be dose reconstructed. John said he was deferring judgment on that until he sees the exact language of the Board's recommendations, but based on NIOSH's desire to be friendly on this issue in the past, I'm sure they will try to support the Board's notion there too. He did acknowledge my request that we see the HHS draft SEC determination language before it's published (as we and OMB have requested before, to no avail), so that hopefully whatever posture they assert on the non-listed cancers can at least not be completely irrational.

John sought to dismiss the fairly obvious precedent implications of the Board recommendation on Mallinckrodt – suggested that their rationale was specific to Mallinckrodt. I didn't argue with him of course, but the document I've seen cites very sweeping issues that would apply to virtually all dose reconstructions, as well as Mallinckrodt-specific issues. HHS may be able to clean that up a little by emphasizing the particularized arguments over the general, but the Board document will be out there and unchallenged, and this action clearly moves the playing field well over to the side of SEC-dom for many more sites.

John did say that now that Mallinckrodt is resolved, he expects that the White House will announce four replacement members for the Board, which may help to slow this train down a bit. But given the history of NIOSH capitulation to date – including allowing the SC&A contractor to directly engage with Congressional staff to pursue their agenda – it's not very likely that any Board, no matter the revised make-up, is going to change this dynamic. Thanks, sh

[Submission for the Record]

From: Calhoun, Grady
Sent: Tuesday, September 20, 2005 8:40 AM
To: Elliott, Larry J.
Cc: Hinnefeld, Stuart L; Neton, Jim
Subject: COI

Larry,

It came up yesterday but you were in a meeting. As expected Mike is having difficulty with the fact that Carol put together most of the document. He is concerned that the transcripts use the term "principal author" or similar and he believes that Carol was this. Since Jay had the ultimate authority to determine what went into the document, I think he is the principal author. Regardless, we don't use that term. Again, I don't believe that ORAU did anything that constitutes a COI. I don't know how we would do it any differently. It only makes sense to have the people who know the most about the site to write the document. We also shouldn't lose sight of the fact that these documents go through extensive review by ORAU and OCAS prior to approval.

Grady Calhoun, CHP
Health Physics Team Leader
Office of Compensation Analysis and Support
(513) 533-6808

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From: Calhoun, Grady
Sent: Thursday, September 22, 2005 4:28 PM
To: Ishak, Laurie D.; Rafky, L. Michael; Sundin, David S.; Hinnefeld, Stuart L
Cc: Elliott, Larry J.; Neton, Jim; Allen, David [NIOSH]
Subject: RE: COI Assessment Review

We seem to be hung up on the term "principal author" that appeared nowhere in the TBD or COI documentation. It is mentioned only out of the mouths of people speaking at the board meetings. Although it needs some tweaking, the revised COI policy does a much better job of defining key roles and responsibilities and limitations.

We cannot lose sight of the implications of saying we screwed up. If you had asked anyone here if Carol was too involved before our friend made these allegations they would have said no. If this level of involvement isn't OK, what are we going to do with future and current TBDs? It is foolish to think that someone without intimate knowledge of a site will write a TBD and interview a "site expert" to add the meat. That is completely inefficient. Jay Maisler, the document owner, said that he had full authority over what went into the document. We need to take credit for the multiple levels of review that take place for every TBD. These are truly intended to be technical reviews that should catch any inaccuracies or bias included in the documents. I believe they do! This is clearly evident in the volumes of comments I have on each and every TBD that comes to us for approval. There is a similar review that takes place on ORAU's side before it ever gets to us.

If we determine that Carol's involvement was a conflict of interest we are going to have to rewrite almost every TBD we have. We won't be able to simply put them out for review and have someone else sign them. They will have to be completely re-written by someone who has had no involvement with the site. This literally puts our program on hold for months if not years. One of the biggest problems that we have in this evaluation is that the critics of what we are doing, both internal and external, do not understand what we are doing and the possible implications of saying we screwed up to placate an outside critic who, by the way, is going to criticize everything we do anyway.

You can only throw your team under the bus so many times to make these outside critics happy. Before long, and its not very long, every aspect of our program becomes a laughing stock because we bend to political forces that are completely indefensible. We know what is right and we should do what is right.

Grady Calhoun, CHP
Health Physics Team Leader
Office of Compensation Analysis and Support
(513) 533-6808

-----Original Message-----
From: Ishak, Laurie D.
Sent: Thursday, September 22, 2005 3:11 PM
To: Calhoun, Grady; Rafky, L. Michael; Sundin, David S.; Hinnefeld, Stuart L
Subject: FW: COI Assessment Review
Importance: High

Larry asked that I share these documents with you all.

Please let me know if you have any questions.

Laurie

Laurie D. Ishak, JD, MA
Presidential Management Fellow

Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health
Office of Compensation Analysis and Support

-----Original Message-----
From: Ishak, Laurie D.
Sent: Thursday, September 22, 2005 10:55 AM
To: Elliott, Larry J.
Subject: COI Assessment Review
Importance: High

Larry,

I have attached a memo and some suggestions regarding the COI assessment. I am also attaching Grady's report with my changes/comments tracked in the document. I also put a hard copy of the documents and the file on your chair.

Please let me know if I can be of any further help.

Laurie

<< File: COI Assessment Memo.doc >> << File: Paducah Combined Assessment with Ishak comments.doc >>

Laurie D. Ishak, JD, MA
Presidential Management Fellow
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health
Office of Compensation Analysis and Support

From: Neton, Jim [mailto:jfn2@CDC.GOV]
Sent: Tuesday, October 25, 2005 10:55 AM
To: Blake, Paul K. CIV
Cc: Elliott, Larry J.; Sundin, David S.; Hinnefeld, Stuart L
Subject: SEC Evaluation Report

Paul,

As we discussed a couple of weeks ago, NIOSH received a Special Exposure Cohort (SEC) petition to add Operation Hardtack to the SEC cohort covered under EEOICPA. We completed our evaluation of this petition on October 20 and forwarded our report to the members of our Advisory Board on Radiation and Worker Health (ABRWH). Based on our review of the information available, we have concluded that NIOSH can not reconstruct doses with sufficient accuracy for DOE and DOE contractor employees who worked at the Pacific Proving Grounds from 1946 to 1962. The basis for this conclusion is contained in the attached PDF copy of the evaluation report, which will be posted on our website in the very near future.

Please keep in mind that this is the first step of the process. Only the Secretary of HHS can officially make an SEC designation, which would come after full deliberation by the ABRWH and a formal recommendation to the Secretary by NIOSH. We expect the Board to deliberate the addition of this SEC class at the next available opportunity, which could be during a conference call at the end of November.

<<SEC 20 PPG Evaluation Report final 10.20.05.pdf>>

If you have any questions, please give me a call.

Jim Neton
OCAS
513-533-6609

41(1)

ORAU TEAM
Dose Reconstruction
Project for NIOSH

November 10, 2005

Mr. Stuart L. Hinnefeld
Project Officer
Office of Compensation Analysis & Support
National Institute for Occupational Safety and Health
4676 Columbia Parkway
MS: R-45
Cincinnati, OH 45226

SUBJ: ORAU Team Corrective Action Plan for OCAS Assessment OCAS-COT-0015

Dear Mr. Hinnefeld:

This letter and its attached document are the ORAU Team Corrective Action Plan for OCAS Assessment OCAS-COT-0015, Assessment of Potential Conflict of Interest Involving ORAUT-TKBS-0019-5, "Technical Basis Document for Paducah Gaseous Diffusion Plant-Occupational Internal Dose."

The NIOSH/OCAS Assessment Report for OCAS-COT-0015 was officially transmitted to Nancy Daugherty, ORAU Team Task 9 Quality Assurance Manager, by electronic mail from Grady Calhoun, NIOSH/OCAS Health Physics Team Leader, on October 28, 2005. In a telephone call between Calhoun and Daugherty on November 1st, the due date to OCAS for the Corrective Action Plan was established as November 10, 2005.

The OCAS-COT-0015 report identified two findings and one recommendation. As documented in the report and confirmed by Calhoun on October 28th, Finding 1 was corrected through the approval and issue of ORAUT-POLICY-0002, Conflict of Interest, Rev 00, on October 11, 2005, and no further action is required for Finding 1. Although the ORAU Team intends to implement the one recommendation, no action is required for assessment recommendations.

The conditions of Finding 2 have been reviewed by the ORAU Team and an External Corrective Action Response is attached. The External Corrective Action Response includes a description of the corrective actions that will be taken by the ORAU Team to rectify the existing condition of the Finding, as well as corrective actions that will be taken to prevent its recurrence. Proposed completion dates have been identified.

Per approved ORAUT-PROC-0069, items 21 and 22 of the External Corrective Action Response are provided for documenting the results of OCAS review of the proposed corrective actions.

The ORAU Team believes that the approval and issue of ORAUT-POLICY-0002, Conflict of Interest, corrects Finding 1 of the OCAS Assessment and that the implementation of the proposed corrective actions for Finding 2 will resolve and close the Findings of the assessment.

If you have any questions regarding this Corrective Action Plan, please contact me (kkimpan@oraucoc.org), or Nancy Daugherty (ndaugherty@oraucoc.org).

Sincerely,

Kate Kimpan
Project Director

KK:nd

Attachments

ORAU	EXTERNAL CORRECTIVE ACTION RESPONSE	ORAU TEAM Dose Reconstruction Project for NIOSH

Assessment/Audit No.: OCAS-COT-0015 Nonconformance No.: Finding 2 Nonconformance Rev. No.: 0

DOCUMENTING THE NONCONFORMANCE
QA SPECIALIST

1	Assessment Title:	Assessment of Potential Conflict of Interest Involving ORAUT-TKBS-0019-5, "Technical Basis Document for Paducah Gaseous Diffusion Plant-Occupational Internal Dose."
2	Scope of Assessment/Audit:	The assessment focused on two specific questions: 1. Did the involvement of an individual who had previously performed health physics work at the Paducah Gaseous Diffusion Plant, and subsequently served as the Subject Expert on ORAUT-TKBS-0019-5, violate existing conflict of interest policies? 2. Does the "Technical Basis Document for Paducah Gaseous Diffusion Plant – Occupational Internal Dose" developed under the circumstance presented in question 1 above take full advantage of and use the best available data for completing dose reconstructions?
3	Issuing External Audit Agency or Organization:	National Institute for Occupational Safety and Health (NIOSH), Office of Compensation, Analysis and Support (OCAS)
4	Dates:	4a. Date Nonconformance identified: 6/07/2005 through 9/28/2005 4b. Date Nonconformance issued: 10/11/2005
5	Type of Nonconformance:	☐ CONCERN ☒ FINDING ☐ OTHER
6	Responsible Task or Project Director:	☐ Task 1 ☐ Task 2 ☒ Task 3 ☐ Task 4 ☐ Task 5 ☐ Task 6 ☐ Task 8 ☐ Task 9 ☐ Task 10 ☐ Project Director ☐ Other
7	Name of Responsible Task Manager or Project Director:	ORAU Team Task 3 Manager, J. Kenoyer
8	Applicable Quality Assurance Criteria:	☒ Program ☒ Work Processes ☐ Management Assessment ☐ Training ☐ Inspection/Test ☐ Independent Assessment ☐ Procurement ☐ Quality Improvement ☐ Other ☐ Documents/Records
9	Requirement Description:	NIOSH/OCAS Assessment Report, OCAS-COT-0015, Assessment of Potential Conflict of Interest Involving ORAUT-TKBS-0019-5, "Technical Basis Document for Paducah Gaseous Diffusion Plant-Occupational Internal Dose," Finding 2, p. 4: *ORAUT-TKBS-0019-5 shall be reviewed and revised as necessary to ensure that the best available data are used. Specifically, the transuranic concentrations documented during operations at the ash receiver and pulverizer, and during the converter salvage line incident, should be evaluated to determine their applicability to the dose reconstruction process.*
10	Nonconformance Description:	<u>Possible inadequate use of available technical information in developing Paducah Gaseous Diffusion Plant Occupational Internal Dose TBD.</u> NIOSH/OCAS Assessment Report, OCAS-COT-0015, Assessment of Potential Conflict of Interest Involving ORAUT-TKBS-0019-5, "Technical Basis Document for Paducah Gaseous Diffusion Plant-Occupational Internal Dose, " pp 2-3: *Does the "Technical Basis Documentation for Paducah Gaseous Diffusion Plant - Occupational Internal Dose," developed under the circumstances presented in question 1 above (item # 2), take full advantage of and use the best available data for completing dose reconstructions? Specifically, does ORAUT-TKBS-0019-5 adequately address the information contained in Paper, Allied Industrial, Chemical and Energy Workers (PACE) International Union document "Exposure assessment projects at the Paducah Gaseous Diffusion Plant?"* *ORAUT-TKBS-0019-5 relies heavily on the same source documents that are used and referenced in the Paper, Allied Industrial, chemical and Energy Workers (PACE) International Union document "Exposure assessment projects at the Paducah Gaseous Diffusion Plant, "as well as the PACE document itself.* *For both documents, the majority of the recommended contributing isotopes and their*

ORAU MJW	EXTERNAL CORRECTIVE ACTION RESPONSE	ORAU TEAM Dose Reconstruction Project for NIOSH

Assessment/Audit No.: OCAS-COT-0015 Nonconformance No.: Finding 2 Nonconformance Rev. No.: 0

		distributions within most work locations were abstracted from a 1987 site exposure assessment report conducted by R.C. Baker. However, for these work locations, more conservative assumptions of ^{241}Am and uranium enrichment, which would result in higher organ doses, are provided in ORAUT-TKBS-0019-5. *Organ doses calculated from the default values in Table 5-4 of ORAUT-TKBS-0019-5 are higher than organ doses calculated using the average or maximum isotopic distribution values in Table 7.9 of the PACE document for all areas except the ash receivers, pulverizer and converter salvage line.* *Organ doses calculated from the default values in Table 5-4 of ORAUT-TKBS-0019-5 are comparable to organ doses calculated using the average isotopic distributions values in Table 7.9 of the PACE document for the ash receivers and pulverizer.* *Organ doses calculated using the default values in Table 5-4 of ORAUT-TKBS-0019-5 are less than the organ calculated using the average or maximum isotopic distributions values in Table 7.9 of the PACE document for the converter salvage line or when using the maximum values cited for the ash receivers and pulverizer.* Also refer to Supporting Discussion, OCAS-COT-0015, "Assessment of Potential Conflict of Interest Involving ORAUT-TKBS-0019-5, "Technical Basis Document for Paducah Gaseous Diffusion Plant-Occupational Internal Dose" Items Numbers 6 and 7 (pages 9, 10 and 11 of 27 respectively)
11	Corrective Action Response Due Date:	November 10, 2005
12	QA Specialist:	Name: Howard D. Milliron Signature: [signature] Date: 11/07/2005

CORRECTIVE ACTION
RESPONSIBLE TASK MANAGER or PROJECT DIRECTOR

13	Basic Cause Category, Near Root Cause, and Root Cause(s):	4-A Product Problem - Inadequate product development. Compressed schedule for development, review and delivery of technical basis documents (TBDs) contributed to the decision making process where the technically acceptable solutions of ORAUT-TKBS-0019-5 were selected and approved by the ORAU Team and OCAS in order to advance toward the goal of implementing the site profile for use by dose reconstructors. A subsequent third-party review of the TBD found and recommended an alternative technically acceptable solution with regard to a specific subset of data in the TBD.
14	Corrective Action(s) to Rectify Existing Condition:	Review and revise, as appropriate, ORAUT-TKBS-0019-5. The ORAU Team will review ORAUT-TKBS-0019-5, evaluating the transuranic concentrations documented during operations at the ash receiver and pulverizer, and during the converter salvage line incident, to determine their applicability to the dose reconstruction process. The ORAU Team will revise as necessary Table 5-4 and related text of ORAUT-TKBS-0019-5 to address concerns identified in Finding 2 and to ensure that the best available data are used.
15	Corrective Action(s) to Prevent Recurrence:	The ORAU Team will submit for review to Stu Hinnefeld a list of proposed site profiles and reasonable submittal dates for FY 2006. A reasonable development and delivery schedule will promote a decision making process that allows more time to consider the implications of a wider range of technically acceptable solutions (e.g. whether or not a third-party needs to review a document). These proposed sites and dates will be proposed for discussion at a meeting of appropriate ORAU Team and OCAS management that currently is being scheduled. Final sites and dates will be incorporated in a revision to ORAUT-PLAN-0019 when concurrence is reached among the ORAU Team and OCAS.
16	Corrective Action Proposed Completion Date:	November 18, 2005 – submittal of proposed FY 2006 site profiles and submittal dates to Stu Hinnefeld. December 16, 2005 - submittal of the revised ORAUT-TKBS-0019-5 to OCAS for review.

ORAU MJW	EXTERNAL CORRECTIVE ACTION RESPONSE	ORAU TEAM Dose Reconstruction Project for NIOSH

Assessment/Audit No.: OCAS-COT-0015 Nonconformance No.: Finding 2 Nonconformance Rev. No.: 0

17	Responsible Task Manager or Project Director Approval:	Name: John M. Byrne as authorized for Judson L. Kenoyer	Signature: John M Byrne for J. L. Kenoyer	Date: 11/10/05
		QA SPECIALIST		
18	QA Specialist Approval:	Name: Howard D. Milliron	Signature: Howard D. Milliron	Date: 11/10/2005
		QA MANAGER		
19	QA Manager Approval:	Name: Nancy M. Daugherty	Signature: Nancy M Daugherty	Date: 11/10/2005
		PROJECT DIRECTOR or BAR DIRECTOR		
20	Project Director (or ORAU Basic and Applied Research [BAR] Director) Approval:	Name: Kate Kimpan	Signature: Kate Kimpan	Date: 11/10/2005
		EXTERNAL AUDITOR		
21	Corrective Action(s) and Corrective Action Proposed Completion Date(s): (Refer to Lines 14-16)	☐ Approved ☐ Rejected Comments:		
22	External Auditor:	Name:	Signature:	Date:
		RESPONSIBLE TASK MANAGER or PROJECT DIRECTOR		
23	Date Corrective Action Complete:	Date:		
24	Responsible Task Manager or Project Director Approval:	Name:	Signature:	Date:
		VERIFICATION OF COMPLETED CORRECTIVE ACTIONS EXTERNAL AUDITOR		
25	Verification Description:			
26	Completion of Corrective Action(s):	☐ Approved ☐ Rejected Comments:		
27	External Auditor:	Name:	Signature:	Date:
		CLOSURE QA MANAGER		
28	QA Manager Approval:	Name:	Signature:	Date:
29	Comments:			

Defense Threat Reduction Agency
8725 John J Kingman Road MS 6201
Ft Belvoir, VA 22060-6201

December 22, 2005

James W. Neton, Ph.D.
Office of Compensation Analysis and Support
The National Institute of Occupational Safety and Health
4676 Columbia Parkway, MS C-46
Cincinnati, OH 45230

Dear Dr. Neton:

This letter responds to your e-mail of October 25, 2005, which included a copy of the National Institute of Occupational Safety and Health (NIOSH) evaluation of Special Exposure Cohort Petition 00020. The proposed class definition includes all Department of Energy (DOE) employees, DOE contractors, or subcontractors employed at the Pacific Proving Ground (PPG) from 1946 through 1962. The evaluation notes that "…the sum of information from the available resources is insufficient to document or estimate the potential maximum internal exposure to members of the class…" and specifically references the Department of Defense (DoD) Nuclear Test Personnel Review (NTPR) Program. After reviewing it, I feel compelled to provide feedback on a number of serious misconceptions, as it appears that the authors were not fully aware of the current operating status of the NTPR Program. Equally concerning are several misrepresentations of a National Research Council (NRC) report in the evaluation.

As you know from previous interactions between our two agencies, the NTPR Program possesses over twenty-five years of experience in supporting veterans and DoD civilian employees and contractors who were potentially exposed to radiation as a result of their participation in U.S. atmospheric nuclear testing or the occupation of Japan. The program has also produced and/or published an extensive body of technical documentation concerning both PPG and Nevada Test Site (NTS) tests and has completed thousands of dose reconstructions for veteran participants. The program has been the subject of numerous external reviews, most recently by the NRC ("A Review of the Dose Reconstruction Program of the Defense Threat Reduction Agency," 2003).

My staff and I have reviewed the NIOSH evaluation report and compiled several comments for your consideration (enclosed), and I would like to highlight a few of them here:

- The technical arguments that support the conclusions of the evaluation appear to be based on a selective citation of factual information from the 2003 NRC report. I'm disappointed that the evaluation cites only the deficiencies identified in section V.C.3.2 of the NRC review (factors tending to underestimate inhalation dose), without any consideration of the countervailing factors in section V.C.3.1. The NRC committee specifically attempted to discourage this practice (p. 210):

"The committee also emphasizes, however, that the discussions of assumptions summarized in Table V.C.7 should not be used to draw conclusions about whether estimates of inhalation dose to atomic veterans in particular scenarios provide credible upper bounds without consideration of the importance of assumptions discussed in the previous section that should tend to result in overestimates of inhalation dose."

Furthermore, there is no discussion of the overall perspective of the NRC findings in regards to methods used by NTPR for estimating upper bounds of internal dose. Neglecting valid and important counterarguments may support your conclusion, but the resulting product fails to meet the stated goal of providing a fair and science-based determination.

- Section 7.1 specifically addresses NTPR dose reconstructions, noting that "In order for NIOSH to consider using the DTRA model for inhalation dose, the model must be able to establish credible upper bounds." In response to the 2003 NRC report, the Defense Threat Reduction Agency (DTRA) issued interim guidance (enclosed) that was intended to establish conservative upper bounds for dose reconstructions. Ongoing efforts to improve methods of uncertainty analysis will likely produce more credible upper bounds, thereby eliminating the need for interim guidance.

- Section 5.0 summarizes available monitoring data, but it appears that several useful DoD publications were not included in the review (enclosed). Some of these documents are publicly available on the DTRA website (http://www.dtra.mil) or at the NTPR reading library in Reston, Virginia. Many others are available through the DTRA Data Archival and Retrieval Enhancement (DARE) Program. Access to DARE is available to Government agencies, their contractors, and other authorized users on a need-to-know basis.

I have also enclosed a review of the NIOSH evaluation report by Dr. David C. Kocher, a member of the 2003 NRC committee. I wholly endorse Dr. Kocher's observations, which address unfortunate distortions of the 2003 NRC findings contained in the NIOSH evaluation report. He raises a number of valid concerns, not the least of which is the NIOSH interpretation that credible upper bounds of PPG internal dose cannot be established. While the NRC report concluded in section V.C.6 (p. 225) that the methods used by the NTPR Program did not consistently provide credible upper bounds, it did not imply that credible upper bounds could not be established.

One could argue that the NIOSH decision to recommend Special Exposure Cohort status for the proposed class may be a proper policy decision. However, the conclusion of this evaluation, namely to treat the proposed cohort presumptively, appears to be insufficiently supported by an incomplete technical analysis despite a search for relevant information. Additionally, I must object to this evaluation on the basis that the NTPR Program has successfully implemented a credible solution for providing defensible dose reconstructions in support of federally-mandated entitlement programs. In this regard, the NTPR Program currently has methods in place that could acceptably assist NIOSH in its support of the EEOICPA.

In conclusion, I believe that DoD could be of significant assistance to your agency in supporting dose reconstructions for individuals involved in atmospheric nuclear testing. I can provide sample post-NRC 2003 dose reconstructions that we have performed for veterans involved in PPG testing. I also can make available to you the NTPR methodology that was developed for atmospheric testing, as well as the supporting data archives. I believe increased collaboration between our two agencies would be of great benefit.

Sincerely,

Paul K. Blake

Paul K. Blake, Ph.D.
Program Manager
Nuclear Test Personnel Review

Enclosures:
1. DTRA comments on the SEC Petition 00020 Evaluation Report
2. DTRA Interim Guidance of July 16, 2003
3. Selected list of publications containing information relevant to the Evaluation Report
4. Dr. Kocher's review of the SEC Petition 00020 Evaluation Report

Copies to:
Chairman, Veterans' Advisory Board on Dose Reconstruction
Chairman, Advisory Board on Radiation and Worker Health

-----Original Message-----
From: Turcic, Peter - ESA
Sent: Tuesday, December 27, 2005 11:52 AM
To: Hallmark, Shelby - ESA; Nesvet, Jeffrey L - ESA; Kotsch, Jeffrey - ESA; Case, Diane; Vance, John - ESA; Turley, Sheldon
Cc: Lelton, Rachel - ESA
Subject: FW: SEC Evaluation Report
Importance: High

We have finally gotten some support for our positions on the NIOSH SEC evaluation approach. Jeff Kotsch and Diane – lets discuss us making comments on the NIOSH evaluation.

-----Original Message-----
From: Elliott, Larry J. [mailto:ljle1@cdc.gov]
Sent: Tuesday, December 27, 2005 11:33 AM
To: Turcic, Peter - ESA
Subject: FW: SEC Evaluation Report

Pete:
FYI, see attached. Now that we have received the formal DTRA response we are making sure the Supplement to the SEC Evaluation Report addresses all technical issues they raise; we will not be reacting to the political turf issues in the Evaluation Report or Supplement. As soon as we have finished revising the supplement I will send it to you. The Board will be given a copy of the supplement as well and take the Evaluation Report up for deliberation at the January 24-28th meeting in Knoxville.
ljle.

From: Blake, Paul K. CIV [mailto:Paul.Blake@dtra.mil]
Sent: Thursday, December 22, 2005 1:09 PM
To: Neton, Jim
Cc: Elliott, Larry J.; Sundin, David S.; Hinnefeld, Stuart L; jzimble1@comcast.net; ziemer@purdue.edu
Subject: RE: SEC Evaluation Report

Jim:

Thank you for forwarding me a copy of your agency's evaluation. I and my staff have reviewed it and feel obligated to provide feedback. Attached is our electronic response – hardcopy to follow. As always, please call or e-mail if you have any questions or thoughts on this issue.

Very respectfully,

Paul K. Blake, PhD, CHP
Nuclear Test Personnel Review Program
Defense Threat Reduction Agency (Code NTDN)
703.767.2407
Paul.Blake@dtra.mil

Buelow, Helen M.

From: kate kimpan [kkimpan@moellerinc.com]
Sent: Monday, January 09, 2006 10:43 AM
To: Hinnefeld, Stuart L
Subject: Re: Questions re: Los Alamos site profile review new message 2

Hi Stu,

Could you please use my kkimpan@oraucoc.org address. The moeller mail goes to a different blackberry. Thanks and sorry for any hassle.

Regarding the message.....do you know when the call might be?

I would like to talk about you and/or Larry and I attending one of these calls to assure the requests SC and A makes, or at least the resulting commitments, are reasonable.

As you probably know, even with our new communications plan between our folks, we also need discipline in how we both proceed.

My team spent hundreds of hours on the most recent firedrill to answer SCA questions. As far as I can discern, the deadlines agreed upon for responses to SCA there were absurdly short for no good reason. Reasonable timeframes could have been proposed for the responses while still being totally cooperative.

If this looks to be the same, we are going to need to discuss what Dr. Wade brought up during the planning session.....we are going to need to work with you to decide whether to do our scheduled dose reconstruction, SEC and TBD work, or apply the same resources to the endless series of undisciplined and unmanaged SCandA requests?

I believe that we absolutely need to answer every one of their questions, but if we are to adhere to other commitments, they can not be offered immediate gratification on every request as it seems to have been happening. I so do not want to seem as though I am not willing to help in any and every way that we can, but as you know, and as is likely true for you at times too, the same folks are needed for a number of different tasks on my team. All of the work we did during the strategic planning-and my ability to successfully manage to it-assumes I have access to the human resources contemplated during the planning. As you can well imagine, these initiatives can have significant impact on those resources, and I would like to help our Teams manage theses sessions and requests more effectively than has been the case until now.

Sorry to babble on about this, but you and I and Larry and I discussed this last week via Y 12.....as you can imagine, it is a huge swing variable in my ability to manage my team more effectively that in its' past.

Let me know your thoughts. As you see, at this point, I sent this only for your consideration.....kk Sent wirelessly via BlackBerry from T-Mobile.

-----Original Message-----
From: "Hinnefeld, Stuart L" <hls8@cdc.gov>
Date: Mon, 9 Jan 2006 09:48:18
To:<kkimpan@moellerinc.com>
Cc:"James P. Griffin" <jgriffin@mjwcorp.com>,<jkenoyer@oraucoc.org>,"Neton, Jim" <JFN2@CDC.GOV>,"Allen, David [NIOSH]" <DKA6@CDC.GOV>,"Calhoun, Grady" <GLC9@CDC.GOV>,"Glover, Sam" <seg3@cdc.gov>
Subject: FW: Questions re: Los Alamos site profile review

Kate,

Attached is a list of questions we have received from SC&A, arising from their review of the LANL Site Profile. ORAU should take the lead in preparing responses to these questions, and should prepare to participate in a subsequent phone conference to discuss them.

Sam Glover (533-6829; seg3@cdc.gov: <mailto:seg3@cdc.gov>) will be the OCAS point of contact for this effort.

Thanks.

ru

From: joef@saliantsolutions.com [mailto:joef@saliantsolutions.com]
Sent: Sunday, January 08, 2006 11:54 AM
To: Hinnefeld, Stuart L
Cc: Neton, Jim; jmauro@scainc.com; mackat116@msn.com; gnrsslr@frontiernet.net; anderha@dhfs.state.wi.us; melius@nysliuna.org; c_owens01@comcast.net; griffonm@comcast.net; Mikehgibson@cinci.rr.com; pl.ziemer@insightbb.com; espoladd@aol.com; RDehart118@aol.com; wimunn@aol.com
Subject: Questions re: Los Alamos site profile review

Dear Stu:

Over the past couple of months, we have reviewed the respective TBDs of the Los Alamos site profile, have conducted initial interviews of site experts, and have begun review of identified onsite records. At this point, I am providing a series of questions compiled by our reviewers and organized by TBD, for response by their counterpart ORAU TBD authors, as preparation for our usual conference call to discuss these and other issues. Please provide responses to these questions and let me know when this call can be set up. Thank you in advance for your assistance on this matter.

JOE FITZGERALD

From: Hinnefeld, Stuart L
Sent: Tuesday, January 17, 2006 1:53 PM
To: Elliott, Larry J.; Wade, Lewis
Cc: Neton, Jim; Sundin, David S.
Subject: RE: Suggested SC&A agenda items

Lew,

Status of procedures review is this:

The Board Working Group (Griffon, Gibson or Espinosa, Munn, and Presley), SC&A and OCAS discussed the findings on external dosimetry procedures at a Working Group meeting in Cincinnati. We are proceeding to implement the recommendations that the Board made as a result of those discussions.

On November 10, OCAS provided to the Working Group and SC&A our initial responses to the findings on internal dosimetry and CATI procedures, anticipating that they might be discussed at the November 16 Working Group meeting. Because of time constraints the Working Group did not get to them on November 16, and there has not yet been a discussion on them.

Rather than review the recommendations from the external dosimetry procedure findings, as SC&A proposes, it might be preferable for OCAS to provide a status report on actions being taken in response to Board recommendations with respect to the external dosimetry procedures.

Stu

-----Original Message-----
From: Elliott, Larry J.
Sent: Tuesday, January 17, 2006 12:04 PM
To: Wade, Lewis
Cc: Neton, Jim; Hinnefeld, Stuart L; Sundin, David S.
Subject: RE: Suggested SC&A agenda items

Lew:
I am concerned that the two SC&A proposals on the SEC procedures are very problematic (Mauro is proposing that Arjun make a presentation to the Board). I hope that we can at least indicate to the Board that we have not yet had time to evaluate these proposals, provide comments to SC&A and the Board; and these should be subject to the 6-step process. I also wonder how these will intersect with the Melius thought paper on sufficient accuracy and as well on timely handling of SEC Evaluation Reports - seems to me the proposals augment and complicate the former and competes against the latter.

I am also concerned with the review of the 4th set of DR reviews. There are three cases in that review that will need to be removed from SC&A's and the Board's review due to DOL recalling the cases for re-work of the dose reconstructions - thus they are not "final adjudicated claims". These three cases were inappropriately completed using an overestimating approach with the PoC finding as compensable. This will be a public relations nightmare - we need to discuss ASAP.

I have not heard from Stu yet but he may or may not have thoughts on the procedures review.

Jim may or may not have heartburn over other items. He and Stu should get to you ASAP if they have any comments.
Lje.

-----Original Message-----
From: Wade, Lewis

Sent: Tuesday, January 17, 2006 10:52 AM
To: Elliott, Larry J.; Neton, Jim
Subject: FW: Suggested SC&A agenda items

Guys:
Let me know if this causes you any gas.
Lew

-----Original Message-----
From: John Mauro [mailto:jmauro@scainc.com]
Sent: Wednesday, January 11, 2006 3:39 PM
To: Arjun Makhijani; Joe Fitzgerald; Kathy Behling; Wade, Lewis
Subject: Suggested SC&A agenda items

Lew,

As a followup to our conversation regarding agenda items for the subcommittee and full Board meeting, the following presents my understanding and some suggestions regarding SC&A's role in the agenda.

1. Y-12 - Joe Fitgerald will be prepared to answer questions and/or give a presentation before the subcommittee and/or full Board regarding on the status of each item in the matrix, as recently discussed at the working group meeting.

2. Rocky Flats - Joe Fitzgerald will be prepared to give a brief overview of the matrix recently delivered to NIOSH and the Board regarding our findings pertaining to the Rocky Flats site profile. We also recognize that a close-out process will be initiated and SC&A will be prepared to participate in working group group meetings that will take place subsequent to the Board meeting.

3. Hanford - A matrix summarizing the major issues resulting from our review of the Hanford site profile is being transmitted to NIOSH and the Board this week. Joe Fitzgerald will be prepared to give a brief presentation on the issues.

4. With respect to the dose reconstruction audit reports, I discussed this matter with Hans and Kathy Behling, and we have the following suggestions:

- Hans can give a brief overview of the status of the 4 packages. In summary, the first set of 20 cases is complete and is on the NIOSH web site. For the second set of audits, Kathy Behling has already given a presentation to the Board. We have delivered a matrix to NIOSH and the Board and a working group meeting was held regarding the matrix for the second package. One action item SC&A had as a result of this process was to go back to the matrix for the second package and determine how many of the items can be closed out as a result of our review of the Savannah River workbook. Kathy will resolve those issue and submit the revised matrix to the Board and NIOSH prior to the meeting. Therefore, if NIOSH is in agreement and in a position to submit a written response to the findings, the Board can go through the formal closeout process for the second set of dose reconstruction audit reports, as summarized in the matrix.

- With regard to the 3rd set of cases, we delivered our draft audit reports, and subsequently received several comments on the draft from the Board. We have responded to the comments, and recently submitted a revised audit report for the third set of audits. The matrix for the third set will be sent to the Board and NIOSH by the end of this week. We suggest that Kathy Behling give a brief presentation regarding the findings for the 3rd set, similar to the one she previously gave for the second set of cases. It would probably be appropriate to schedule a working group meeting to begin the issues resolution process for the finding identified in the matrix for the 3rd set of cases.

- With regard to the 4th set of cases, Hans will be prepared to give a status report. The audit of most of the cases has been completed, but we are

finding that some of the realistic dose reconstructions are quite complex. As you may recall, this is the first set of cases that include realistic dose reconstructions, and the Board may be interested in hearing how the audits of realistic dose reconstructions differ from the audits of the min/max dose reconstructions.

5. With respect to the Task 3 procedures review, the matrix for the internal, external, and CATI procedures have been delivered to NIOSH and the Board. Working group meetings were held for external; but due to time constraints, we were not able to discuss issues pertaining to internal dosimetry and the CATI interview process. We suggest that Hans give a brief update on where we are with regard to the closeout of the external dosimetry issues on the Task 3 matrix. I believe most of the external issues were thoroughly discussed and tentatively resolved during an earlier working group meeting, but we have not yet initiated a dialog on internal dose issues and the interview process. We can do that at this Board meeting, if NIOSH concurs.

6. With respect to Task 5, SC&A recently delivered 2 reports to the Board; one is a review of NIOSH procedures for reviewing SEC petitions, and the other is a draft procedure for use by NIOSH and the Board to review SEC petitions. We suggest that Arjun give a presentation summarizing these two deliverables.

Please let me know if my understanding of the agenda is correct and whether we should proceed with making the necessary preparations.

Regards,

John

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February 22, 2006

Honorable Elaine L. Chao
Secretary
U.S. Department of Labor
Frances Perkins Building
200 Constitution Ave, NW
Washington, DC 202

Dear Secretary Chao:

The Judiciary Committee has been reviewing the implementation of the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) since it's inception. The Subcommittee on Immigration, Border Security and Claims handles this issue as part of its jurisdiction regarding claims against the United States.

The Subcommittee has recently been made aware of an OMB document which credits the DOL's Employment Standards Administration (ESA) with identifying costs associated with the designation of Special Exposure Cohorts (SECs). As you know, you presented the first check in the program yourself in Paducah, Kentucky to a member of the Special Exposure Cohort at that site. The OMB document states:

> **"Energy Employees Occupational Illness Compensation Program Act (EEOICPA) Part B.** ESA[1] is to be commended for identifying the potential for a large expansion of EEOICPA Part B benefits through the designation of Special Exposure Cohorts (SEC). The Administration will convene a White House-led interagency work group including HHS and Energy to develop options for administrative procedures to contain growth in the cost of benefits provided by the program. Discussions are not limited to, but will involve, the following five options.

[1] ESA is the Employment Standards Administration in DOL. The Office of Workers Compensation Programs (OWCP) is in the ESA. ESA Assistant Secretary is Victoria Lipnic. Director of the OWCP is Shelby Hallmark.

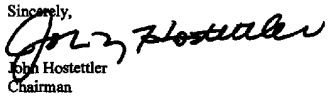
1. Require Administration clearance of SEC determination[s];
2. Address any imbalance in membership of President's Advisory Board on Radiation and Worker Health;
3. Require an expedited review by outside experts of SEC recommendations by NIOSH;
4. Require NIOSH to apply "conflict of interest" rules and constraints to the Advisory Board's contractor; and
5. Require that NIOSH demonstrate that its site profiles and other dose reconstruction guidance are balance[d].

In connections with our review, the Subcommittee seeks documents and communications (as defined in Attachment A) sent or received by ESA employees to any party inside or outside of the Department which:

1) discuss or pertain to approval of any particular SEC petitions by HHS, NIOSH or the Advisory Board on Radiation and Worker Health, changes to the current methods for SEC approvals, evaluations or criticisms of SEC approvals that have been made to date, or recommendations;
2) discuss or pertain to the balance or imbalance in the membership of the Advisory Board on Radiation and Worker Health ("Board"), including mention of or evaluation of any past, current or prospective Board Members, or recommendations for changes to the Board,;
3) discuss or pertain to an expedited review by outside experts of SEC recommendations by NIOSH;
4) discuss or pertain to conflicts of interest involving the Board's audit contractor or any of the audit contractor's staff or associates, and any "constraints" or conflict of interest policy which has or may be considered for application to the contractor;
5) discuss or pertain to the "balance" in NIOSH site profiles or dose reconstruction guidance.

Please provide documents in chronological order for each question. Please provide these documents to the Committee within 7 days, as Subcommittee hearings will be occurring in the coming weeks on this matter. Please contact Cindy Blackston at 225-5727 if you have any questions about this request.

Sincerely,



John Hostettler
Chairman
Subcommittee on Immigration, Border Security
and Claims

Attachment

ATTACHMENT A

DEFINITIONS FOR PURPOSES OF FEBRUARY 22, 2006 SUBCOMMITTEE REQUEST TO THE SECRETARY OF LABOR

1. The term "document" any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to, the following: memoranda, reports, expense reports, books, manuals, instructions, financial reports, working papers, record notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, interoffice and intra office communications, electronic mail (e-mail), contracts, cables, notations of any type of conversation, telephone call, meeting or other communication, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments of any of the foregoing, as well as any attachments or appendices thereto) and graphic or oral records or representations of any kind (including without limitation, photographs, charts, graphs, microfiche, microfilm, videotape, recordings and motions pictures), and electronic, mechanical, and electric records or representations of any kind (including, without limitation, tapes, cassettes, disks, and recordings) and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, disk, videotape or otherwise. A document bearing any notation not a part of the original text is to be considered a separate

document. A draft or non-identical copy is a separate document within the meaning of this term.

2. The term "communication" means each manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, electronic, by document or otherwise, and whether face-to-face, in a meeting, by telephone, mail, telexes, discussions, releases, personal delivery, or otherwise

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February 27, 2006

Honorable Michael Leavitt
Secretary
Department of Health and Human Services
200 Independence Ave., S.W.
Washington, DC 20201

Dear Secretary Leavitt:

The Judiciary Committee has been reviewing the implementation of the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) since it's inception. The Subcommittee on Immigration, Border Security and Claims handles this issue as part of its jurisdiction regarding claims against the United States.

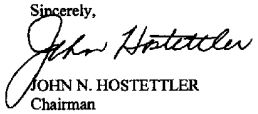
In November 2004, the Committee made a request for extensive materials from the Department with regard to EEOICPA due to several real and perceived internal problems with that program. To date, while improvements have been made in some areas, several problems remain or have worsened and new significant issues have arisen. After 5 years, for example, 38% of EEOICPA claims are still awaiting dose reconstruction, while the National Institute for Occupational Safety and Health's (NIOSH) contractor costs have risen from $74 million to an estimated $200 million. Based on observations at the recent Advisory Board on Radiation and Worker Health (ABRWH) meeting, their work is still less than satisfactory. New concerns have arisen about potential conflicts of interest (COI) involving NIOSH contractors, in particular, Oak Ridge Associated Universities (ORAU) and proposed changes to their COI policies. Recent membership changes to the ABRWH require review of the ABRWH's composition and new potential COIs involving the latest Board members. Balance in the composition of the ABRWH is essential to this program. The independence of the ABRWH's audit contractor is a primary concern due to past problems. There is also concerned about any Department of Labor (DOL) interference with NIOSH's scientific assessments, and any possible outside interference with your department's evaluations and decisions on the approval of Special Exposure Cohort petitions. Finally, there is a need to review NIOSH's implementation of all ABRWH recommendations. These issues compel the continued review and in depth monitoring continue to ensure this program is being carried out as intended when it was enacted into law.

The Department's response to the Committee's November 19, 2004, information request (Attachment A) contained documents through November 2004.

Please provide all documents and communications created from November 1, 2004 to date relative to items 9-17 from that letter. The definition of the term "document" and "communication" applicable to the Subcommittee's information requests is included in the original request. Also attached is a list of information requested for the current review (Attachment B) that was not pertinent to the prior request.

The Subcommittee requests receipt of this information not later than March 24, 2006, and welcomes receipt of individual documents and information as soon as they become available. Please contact Cindy Blackston at 202-225-5727 with any questions concerning this request. Thank you for your assistance.

Sincerely,



JOHN N. HOSTETTLER
Chairman
Subcommittee on Immigration, Border Security
and Claims

Cc: Honorable Julie E. Gerberding, Director
Centers for Disease Control
Honorable John Howard, MD, Director
National Institute for Occupational Safety and Health

List of To Date Updates for Information Previously Requested and Received per November , 2004 Information Request:

1. Any and all documents and communications (including internal Department of Health and Human Services ("HHS"), Centers for Disease Control ("CDC") and National Institute for Occupational Safety and Health ("NIOSH") communications), sent by any HHS, CDC, or NIOSH employee to any person which discuss or pertain to the audit contract with Sanford Cohen and Associates ("SCA"), the award of the audit contract, the award of task orders, expenditures made by the audit contractor, the performance of the audit contractor, and the release of documents prepared by the audit contractor to the public or Congress.

2. Any and all documents and communications (including internal HHS, CDC and NIOSH communications), sent by any HHS, CDC, or NIOSH employee to any person which discuss or pertain to the contract between CDC and Oak Ridge Associated Universities (ORAU), including all contract modifications. A copy of the contract and all contract modifications.

3. Any and all documents and communications (including internal HHS, CDC and NIOSH communications), sent by any HHS, CDC, or NIOSH employee to any person which discuss or pertain to performance evaluations, award fee evaluations, and award fees of ORAU. A copy of all the performance evaluations, award fee evaluations, and award fees.

4. Any and all documents and communications (including internal HHS, CDC and NIOSH communications), sent by any HHS, CDC, or NIOSH employee to any person which discuss or pertain to all invoices and payments issued to ORAU. A copy of the invoices and payments issued.

5. Any and all documents and communications (including internal HHS, CDC and NIOSH communications), sent by any HHS, CDC, or NIOSH employee to any person which discuss or pertain to the amounts authorized under the ORAU contract, amounts expended each year, and amounts of each modification to that contract. A list of the amounts authorized under the ORAU contract, amounts expended each year, and amounts of each modification.

6. Any and all documents and communications (including internal HHS, CDC and NIOSH communications), sent by any HHS, CDC, or NIOSH employee to any person which discuss or pertain to ORAU performance history. A list of the number of completed dose reconstructions per month completed by ORAU since contract was awarded, number of site profiles completed by ORAU, and number of Special Cohort petition reviews.

7. Any and all documents and communications (including internal HHS, CDC and NIOSH communications), sent by any HHS, CDC, or NIOSH employee to any person which discuss or pertain to all meetings held with workers on site profiles. A list of all of those meetings by date and location.

ATTACHMENT A

DEFINITIONS FOR PURPOSES OF FEBRUARY 24, 2006 SUBCOMMITTEE REQUEST TO THE SECRETARY OF HEALTH AND HUMAN SERVICES

1. The term "document" any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to, the following: memoranda, reports, expense reports, books, manuals, instructions, financial reports, working papers, record notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, interoffice and intra office communications, electronic mail (e-mail), contracts, cables, notations of any type of conversation, telephone call, meeting or other communication, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments of any of the foregoing, as well as any attachments or appendices thereto) and graphic or oral records or representations of any kind (including without limitation, photographs, charts, graphs, microfiche, microfilm, videotape, recordings and motions pictures), and electronic, mechanical, and electric records or representations of any kind (including, without limitation, tapes, cassettes, disks, and recordings) and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, disk, videotape or otherwise. A document bearing any notation not a part of the original text is to be considered a separate document. A draft or non-identical copy is a separate document within the meaning of this term.

2. The term "communication" means each manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, electronic, by document or otherwise, and whether face-to-face, in a meeting, by telephone, mail, telexes, discussions, releases, personal delivery, or otherwise

ATTACHMENT B

DOCUMENTS, COMMUNICATIONS, AND INFORMATION FROM THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, THE CENTERS FOR DISEASE CONTROL AND NIOSH PERTAINING TO THEIR ROLE AND THE ROLE OF THEIR CONTRACTORS IN IMPLEMENTING EEOICPA

1. Please provide the contract awarded to Battelle for dose reconstruction (including request for proposal), award fee plans and determinationsNovember 1, 2004, and all related communications. Please indicate if there is a ceiling on this contract.
2. Please provide all documents and communications pertaining to conflict of interest involving the ORAU or Battelle team and subcontractors since November 1, 2004, including: copies of each individual's Individual Conflict of Interest Disclosure and Agreement; each contractor's Corporate Conflict of Interest Disclosure and Agreement; evaluation of contractor conflicts of interest, and any changes to contractor conflict of interest plans or policies.
3. Please provide a copy of the ORAU report (including all drafts) which identifies sites and classes of workers which could qualify for membership in the Special Exposure Cohort (SEC). NIOSH required such report be submitted by December 31, 2004. Please provide all communications pertaining to this report.
4. Please provide all documents and communications between NIOSH and the Department of Labor, excluding individual case files, since November 1, 2004. Please provide current interagency agreement between NIOSH and DOL regarding EEOICPA.
5. Please provide all documents and communications within the NIOSH Office of Compensation and Analysis Support, between NIOSH and DOL, NIOSH and ORAU, or between NIOSH and the White House Office of Presidential Personnel pertaining to appointments to the Advisory Board on Radiation and Worker Health since January 1, 2003.
6. Please provide all documents and communications involving Foxfire Scientific or IEM, including contracts, bid proposals, qualifications and list of key personnel. Please provide copies of task orders, invoices, and communications between NIOSH or the ORAU Team and Foxfire Scientific or IEM.
7. Please provide progress reports regarding the completion of residual radiation and residual beryllium reports that were required in the FY 2005 Defense Authorization Act. Please provide copies of contracts for such report updates.
8. Please provide all communications and documents pertaining to Congressional oversight or proposed legislation affecting EEOICPA since November 1, 2004.
9. Please provide documents pertaining to the development of the Interim Final Rule regarding Special Exposure Cohorts.
10. Please provide any documents and communications pertaining to any policy or legal analysis of the "passback" document from OMB to the Department of Labor concerning SEC petition consideration and the creation of an intergency working group to coordinate efforts to contain costs associated with SEC petitions.

DOCUMENTS PERTAINING TO THE ADVISORY BOARD ON RADIATION AND WORKER HEALTH (ABRWH) AND IT'S AUDIT CONTRACTOR, SANFORD COHEN & ASSOCIATES

1. Please provide the names and addresses of the three recently appointed members to the Advisory Board on Radiation and Worker Health, their Curriculum Vitae/Resume, their phone numbers and e-mail, their financial disclosure forms, their conflict of interest disclosures, and if applicable, their conflict of interest waiver letters. Please provide the current waiver letters and financial disclosures for the incumbent members of the Advisory Board (excluding those who ceased to serve as Board members after the January 26, 2006 Board meeting).
2. Please provide a copy of all communications and documents pertaining to conflict of interest involving the audit contractor, SC&A since November 2004. Please provide copies of NIOSH/CDC's assessments of the audit contractor's performance for 2004 and 2005. 13)Please provide the actual outlays for the Board and its audit contractor the actual outlays for the Advisory Board and its audit for FY 04 and FY 05. Please provide the projected budget for the Advisory Board and its audit contractor for FY 06.
3. Please provide a copy of all recommendations made by the Advisory Board on Radiation and Worker Health to the Secretary since November 1, 2004, and the status of NIOSH implementation on each of these recommendations.

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March 9, 2006

Honorable David M. Walker
Comptroller General
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Mr. Walker:

The Judiciary Committee has reviewed the General Accountability Office's (GAO) February 10, 2006, report ENERGY EMPLOYEES COMPENSATION: Adjustments Made to Contracted Review Process, But Additional Oversight and Planning Would Aid the Advisory Board in Meeting Its Statutory Responsibilities (GAO-06-177).

GAO's report regarding implementation of the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) focused on the accounting, planning and the need for independence in administering the small support contract for the Advisory Board on Radiation and Worker Health, but did not address the National Institute for Occupational Safety and Health's (NIOSH) substantially larger contracts for radiation dose reconstruction.

GAO identified "conflict of roles" involving NIOSH Program staff interference with the work of the Advisory Board and its audit contractor, and stated that in response to concerns about the "independence of certain federal officials," NIOSH removed certain officials, and this had mitigated the actual and perceived conflicts of interest.

GAO noted that "Credibility is essential to the work of the Advisory Board and the contractor." However, the report contains no recommendations for prevention of future "conflict of roles," and only states, that the Department of Health and Human Services (HHS) should be "diligent in avoiding actual or perceived conflicts of roles as new candidates are considered for certain positions [Project Officer and Designated Federal Official] over the life of the Advisory Board." Due to recent events, it appears changes in the structure of this program management at all levels may be necessary.

An Office of Management and Budget (OMB) Passback memo to the Department of Labor (DOL) was the subject of a March 1, 2006, hearing of the Subcommittee on Immigration, Border Security, and Claims. That document outlines a plan to contain the growth in benefits from new Special Exposure Cohort designations by requiring "administration clearance" before the HHS Secretary can make a decision, and calls for a White House led interagency task force to "address any imbalance" in the Advisory Board's membership. In this context, this appears to intend a tilt in the Advisory Board's composition against approval of Special Exposure Cohorts.

OMB/DOL options also include a plan to impose "constraints" on the Advisory Board's audit contractor, which DOL testified had, in their view, a bias due to previous work on behalf of claimants in proceedings. Other witnesses noted that NIOSH contractors had a bias because some had served as experts defending the government or its contractors against workers' claims, and that in order for a critical review to take place this bias required the Advisory Board to retain scientists whose work was beyond reproach. The audit contractor has stringent conflict of interest restrictions, and it is the Board, not the contractor, which decides on scientific recommendations— so DOL's concern seems misplaced.

Assuring Balance on the Advisory Board and Independence of the Audit Contractor

While looking at options for actions need to protect the independence and credibility of the Advisory Board and its audit contractor, the Committee would be interested in GAO's views on possible options: 1) continuing the action taken in the FY 06 Labor, HHS Appropriations Act (P.L. 109-149), directing specific funding for the work of the Advisory Board and its audit contractor and 2) amending EEOICPA to include Congress in the appointment process for members of the Advisory Board. The Committee requests a report outlining legislative and policy options which will ensure balance in perspectives in the composition of the Advisory Board and preserve independence from the adjudicative agency or from the program being audited.

Costs Associated with Oak Ridge Associated Universities (ORAU)

GAO's report also states that:

> "There is another contractor -Oak Ridge Associated Universities (ORAU)-that also plays an important role in the Energy Employees Occupational Illness Compensation Program. In September 2002, NIOSH awarded a 5-year contract to ORAU to support NIOSH in performing its responsibilities related to the program, such as developing site profiles and performing dose reconstructions. About $70 million was originally allocated to this contract, but this figure had increased to over $200 million by 2004."

The Director of NIOSH testified on March 1 that another contractor, Battelle, has been hired to support NIOSH's dose reconstruction. The Committee is now starting to look into the cause for the tripling of ORAU's costs and what additional costs will be associated with the added contract with Battelle. Please review the total administrative costs for dose reconstruction claims attributable to NIOSH, DOL, and the Department of Energy (DOE) individually and collectively (through June 2006), and compare those amounts with the amount of benefits paid to claimants for dose reconstruction claims. How much of the ORAU increase is attributable to added work not included in the original scope of the ORAU contract? How much of this is due to an increase in claims activity beyond that specified in the Request for Proposals? How much is attributable to ORAU inability to meet the expectations that they complete 200 dose reconstructions per week by July 2003? Were all cost increases appropriate and justified?

What is the cost per dose reconstruction? Has ORAU had to revise many of its site profiles? How much of ORAU's cost growth is tied to site profile revisions or individual dose reconstruction revisions? Are the costs of reworks and revisions deemed allowable costs under the contract?

What is the average hourly rate charged to the government by ORAU, MJW and Dade Moeller for dose reconstructors? What is the hourly rate charged for ORAU, MJW and Dade Moeller's senior managers? What is the average hourly rate charged to the Government for individuals evaluating Special Exposure Cohort petitions? What have been the costs for evaluating each specific Special Exposure Cohort? Who sets the amount expended for each SEC evaluation? Is it capped, or open ended? What criteria is used to decide the amount of resources that will be assigned to evaluate an individual SEC?

What is included in ORAU's award fee evaluations? Does it consider the quality or just the quantity of the site profiles and dose reconstructions? What performance ratings has ORAU received, and are these warranted? Are award fees motivating the contractor to control costs adequately? Is NIOSH management satisfied with ORAU's performance? Has NIOSH effectively managed ORAU's growth in expenditures? If not, what were the causes?

ORAU has indicated its site profiles are to be reviewed and if the profile's author has conflicts of interest (COI), as defined by a revised ORAU COI policy, the profile will be reworked. Who is responsible for these costs? Will ORAU collect an award fee for this work?

Delays in Dose Reconstruction

Five and a half years since enactment, NIOSH still has over 7,000 dose reconstructions to complete. Would additional dose reconstructors and health physicists significantly reduce the delays in completing the backlog of claims? NIOSH has stated there is a scarcity of health physicists and dose reconstructors. Have they taken steps to increase the pool of dose

reconstructors and health physicists to help speed claims processing? If not, would doing so reduce the costs of the program? Were there options available to NIOSH since enactment to increase the supply? Was this problem foreseeable at any point since this law was enacted?

ORAU Conflict of Interest

The ORAU Team has numerous organizational and professional conflicts of interest. For example, Battelle, which runs the radiation dosimetry program at Hanford, also had its staff lead the development of the NIOSH site profiles at Hanford. At Idaho National Labs, former managers of the health physics programs prepared Site Profiles for NIOSH, even though at least one individual served as an expert witness defending workers' compensation claims for a contractor at that site. At Rocky Flats, a manager of health physics programs prepared NIOSH's site profiles, Technical Information Bulletins, is actively involved in the evaluation of a Special Exposure Cohort Petition, which includes validation of results used in his previous work.

The NIOSH director testified on March 1st that they are developing a "state-of-the-art" conflict of interest policy. Is the ORAU Team conflict of interest policy that has been in effect sufficient to ensure that conflicts or biases do not taint the credibility and quality of the science produced to date? Does it have loopholes that need to be closed? Has ORAU or NIOSH taken appropriate steps to validate the accuracy of individual's Conflict of Interest Disclosure Statements, particularly with respect to past involvement in litigation or the identification of those sites where ORAU Team members may have conflicts of interest? Was the ORAU data base which was required in its initial COI policy ever established to deal with individual or corporate conflicts of interest? Has this data base ever been used? If so, has it been effective?

Has ORAU management overlooked conflicts of interest or interpreted its guidance in a way that allowed it to evade COI restrictions. What motivated this? Has ORAU managed COI rigorously, or has this been treated as a low priority? Has NIOSH audited the ORAU Team for organizational or professional conflicts of interest or conflict of roles, as previously committed? How effective has NIOSH been in overseeing ORAU's management of its conflicts of interest?

NIOSH Staff Conflicts of Interest

A number of the NIOSH program staff in the Office of Compensation and Analysis Support (OCAS) formerly managed health physics programs for the DOE and its contractors, and are now reviewing and approving dose reconstructions, site profiles and Special Exposure Cohort Evaluations for these same sites. Is there a written COI policy for NIOSH federal staff working in the OCAS program? What does it provide, is it a public document, and is it adequately monitored and enforced? Are NIOSH staff conflicts of interest publically disclosed, and who is responsible for day-to-day management of NIOSH staff conflicts of interest?

U.S. House of Representatives
Committee on the Judiciary
F. James Sensenbrenner, Jr., Chairman

http://judiciary.house.gov/

News Advisory

For immediate release
June 14, 2006

Contact: Jeff Lungren/Terry Shawn
202-225-2492

Hostettler Statement on Subcommittee's Oversight Efforts Regarding EEOICPA

WASHINGTON, D.C. – Contrary to legislative intent, an internal Office of Management and Budget (OMB) memo sent to the Department of Labor (DOL) in late 2005 outlined five policy options to be developed by a "White House led interagency work group" to reduce the number of Special Exposure Cohorts (SECs) as a way to "contain the growth in benefits under the program."

House Judiciary Immigration, Border Security and Claims Subcommittee Chairman John N. Hostettler (R-Ind.) made document requests to DOL and the Department of Health and Human Services (HHS) over three months ago in order to review agency actions with regard to this "passback" memo and the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) program. Chairman Hostettler also planned to request that OMB produce a witness to testify on the OMB plan at a congressional oversight hearing. Those attempts at performing oversight of the EEOICPA have been resisted and have added to the concern that the administration of the program may not be consistent with congressional intent.

On May 31, 2006, OMB issued a letter to certain Members of Congress. It stated in relevant parts:

> "There will be no steps taken by the Administration to reduce the amount of SEC approvals in order to minimize benefit payments" . . . the "Administration will work to ensure that scientific decisions and the law govern which workers receive compensation under this program and will not allow budgetary concerns to override those determinations" . . . "the Administration will continue to meet the statutory requirement that the Advisory Board reflect a balance of scientific, medical and worker perspectives."

Chairman Hostettler stated, "While we appreciate that OMB has responded in a general way, the substance of the Administration's response is thin and lacks meaningful clarification or steps to

reverse actions already taken that coincide with the passback. Until significant steps are taken to clarify the Administration's position, a cloud will remain over this program."

"This Subcommittee tried for more than three months to reach an agreement with the Administration on providing a meaningful declaration by OMB which would reject each of the five options in its passback memo, but it appears that the Administration is unwilling, at this time, to repudiate in its entirety the five passback options, or to take steps to restore the balance to the Advisory Board on Radiation and Worker Health," added Chairman Hostettler.

"I had hoped to come to a satisfactory resolution of this controversy through negotiation. After three months, sadly that hope is all but gone. Absent an expeditious improvement in cooperation by these agencies with the Subcommittee's mission to reinstate the program's integrity, I will be compelled to request that Chairman Sensenbrenner authorize subpoenas to be issued to OMB for a witness to testify before the Subcommittee on the passback document, and to DOL and HHS for the documents in their possession pertinent to the Subcommittee's oversight."

The May 31 letter to congressional offices from OMB leaves open the following passback issues:

1) The only Administration actions that could be potentially limited under the terms of the May 31 letter are decisions to block SECs based purely on budgetary grounds. This leaves the door open to other manipulations by OMB officials who may otherwise justify their actions.

2) Members of the Advisory Board on Radiation and Worker Health, who are tasked with independent review of the basis for approval of SECs, have been selectively removed by the White House without apparent cause and now only two of 11 members represent workers. No effort has been made to re-balance that advisory board consistent with the legal requirement for a balance of "scientific, medical and worker perspectives."

3) The letter does not reject the option for the OMB or DOL to commission additional scientific reviews beyond those reviews assigned by statute to the Advisory Board.

4) The letter does not assure the independence and singular role of the Advisory Board and their audit contractor in reviewing and recommending approval or denial of Special Exposure Cohorts for groups of sick workers where radiation dose records are limited.

While OMB's letter acknowledges the need for a "fair and open process," it contains no specific measures to increase transparency so the public and the claimants are reassured. The loss of credibility in decision making must be addressed so that claimants are assured that secret processes are not in place that would lead to unfair benefit denials.

"Claimants are expressing growing concern with not so much what was said in the letter, but with what was glaringly absent from it. Having been deceived by their government while working on national defense programs, these workers need much clearer assurances that they will be well served by the government before they can once again place their trust in statements by the Administration," concluded Chairman Hostettler.

United States Government Accountability Office
Washington, DC 20548

September 26, 2006

The Honorable John N. Hostettler
Chairman
Subcommittee on Immigration,
Border Security and Claims
Committee on the Judiciary
House of Representatives

Subject: Contractor Costs in Energy Employees Program

Dear Mr. Chairman:

This letter confirms our commitment to study Subtitle B of the Energy Employees Occupational Illness Compensation Program Act based on your letter to the Comptroller General. In our August 3, 2006, letter to you, we outlined our approach to designing the study. Based on that design and discussions with your staff on August 1, 2006, we will complete our work and issue a report to you by July 23, 2007. The enclosure to this letter sets forth the key aspects of the study.

We look forward to working with you and your staff on this assignment. Should you have any questions, please contact me on (202) 512-5988 or bertonid@gao.gov or, Andrew Sherrill, Assistant Director, on (202) 512-7252 or sherrilla@gao.gov.

Sincerely,

Daniel Bertoni, Director
Education, Workforce, and
Income Security Issues

Enclosure

Terms of the Work

Objectives/Key Questions

This review will examine various issues regarding the implementation of Subtitle B of the Energy Employees Occupational Illness Compensation Program Act. Our key questions are as follows:

1) What have been the total administrative costs incurred by the Department of Labor, National Institute for Occupational Safety and Health (NIOSH), and the Department of Energy, and total benefits paid out for Subtitle B dose reconstruction claims?

2) What are the reasons for any increases in costs for NIOSH's contractors—Oak Ridge Associated Universities (ORAU), Battelle, and their subcontractors—and how effectively has NIOSH managed contractor costs?

3) What are the conflict of interest policies pertaining to Subtitle B for NIOSH and its contractors—ORAU and Battelle—and to what extent have these organizations established procedures to ensure that the policies are adequately implemented?

4) What roles do Labor and NIOSH play in funding the work initiated by the Advisory Board on Radiation and Worker Health and conducted by the contractor assisting the Board (S. Cohen and Associates), and to what extent, if at all, does Labor perform activities related to Subtitle B that have been tasked to other organizations by statute, regulation, or contract?

5) What procedures are in place to ensure the independence of the Advisory Board and the contractor assisting the Board, and what options could further strengthen their independence?

Scope and Methodology

To address question 1, we will obtain data on administrative costs and benefits paid out from Labor, NIOSH, and Energy from the beginning of fiscal year 2001 through June 2006, focusing on Subtitle B claims that require dose reconstruction. We will assess the reliability of these data for the purposes of our study.

Enclosure
Terms of the Work

To address question 2, we will interview agency and contractor officials, and analyze the ORAU and Battelle contracts and modifications to identify cost increases and reasons for the increases. In addition, we will assess how effectively NIOSH has overseen these contracts. To this end, we will analyze key contract-related documents and examine NIOSH"s internal control procedures and actions taken to monitor and manage these two contracts. Relevant criteria for our assessment are contained in sources such as the *Federal Acquisition Regulation, Health and Human Services Project Officers' Contracting Handbook, and Standards for Internal Control in the Federal Government.* Our work will address the various sub-questions in your request letter pertaining to question 2, on topics including

- administrative costs per output (e.g., dose reconstruction, site profile, and Special Exposure Cohort petition evaluation),
- hourly rates charged by various types of contractor staff, and
- agency ratings of contractor performance and criteria for contractor award fees.

Another aspect of our work related to question 2 will involve examining the actions NIOSH has taken to expedite the processing of claims that require dose reconstructions and what progress has been made. In particular, we will determine the extent to which NIOSH has used strategies to perform dose reconstructions more efficiently or obtain additional staff resources for performing dose reconstructions.

To address question 3, we will examine conflict of interest policies pertaining to contractor and NIOSH staff who develop dose reconstructions or site profiles. Specifically, we will examine how the policies' provisions have changed over time. We will also examine the adequacy of NIOSH and contractor procedures and actions for implementing, monitoring, and enforcing these conflict of interest policies. Our work will involve reviewing minutes of relevant Advisory Board meetings, examining conflict of interest policies for similar compensation programs, and interviewing NIOSH, contracting officials, advocates, and subject matter experts. Given our broad focus on the adequacy of organizations' internal controls, our work will not be designed to investigate the merits of specific allegations of conflicts of interest.

To address question 4, we will review relevant documents and interview agency officials to establish Labor and NIOSH's current roles in funding the work initiated by the Advisory Board and conducted by S. Cohen and Associates. To determine whether Labor is performing activities that have been tasked to other organizations in its administration of Subtitle B, we will interview agency and other officials and

review pertinent documents, including the extensive documentation and correspondence that Labor and NIOSH recently provided to the Subcommittee.

To address question 5, we will examine the Advisory Board's requirements, membership, and functions as specified in *Executive Order 13179* and *Federal Advisory Committee Regulations*. We will also review how similar federal advisory boards are structured, such as the advisory board created jointly by the Departments of Veterans Affairs and Defense to oversee dose reconstruction claims filed by veterans. To assist us in identifying options for enhancing the independence of the Advisory Board and the contractor assisting the board, we will also interview members of the Advisory Board, advocates, and subject matter experts. We will then identify key factors that should be considered in assessing these options and use these factors to identify the pros and cons of the various options.

Our work will be done in accordance with Generally Accepted Government Auditing Standards.

Product Type and Delivery Date

We will provide this information in one or more written products to be issued by July 23, 2007. We will obtain comments from the Departments of Labor, Health and Human Services, and Energy on a written draft of this product(s) prior to issuance.

Reporting on Job Status

We will update your staff periodically as our work progresses.

Documents Excerpted or Referenced in the Testimony of Richard Miller at 11/15/06 Subcommittee Hearing

1) Judiciary Committee notes of e-mails reviewed by Judiciary Committee staff at the Department of Labor (DOL) related to Special Exposure Cohorts (SEC) and OMB Passback, including an e-mail prepared on 10/5/05 by DOL staff which outlined the 5 options that were included in the OMB Passback, and an e-mail sent 10/5/05 by OMB official (MW) to SH and VL (Shelby Hallmark and Assistant Secretary Victoria Lipnic). (8 pages)

2) OMB Passback to the DOL for FY 07 Budget (1 page)

3) Notes from DOL/HHS/DOE Deputy Secretary Conference Call of 7/2/2002 which discuss how NIOSH adopted provisions requested by the DOL to be included in the NIOSH proposed Special Exposure Cohort Rule. (3 pages)

4) E-mail from Shelby Hallmark of 5/7/03 discussing DOL's views urging that NIOSH limit cancers covered under the Special Exposure Cohort to as few as 1 cancer, instead of the 22 cancers specified in the law. (2 pages)

5) E-mail from Shelby Hallmark of 8/2/05 opposing legislation introduced by Senators Clinton and Schumer (S.1506) setting new SEC criteria. (9 pages)

6) E-mail from Shelby Hallmark of 6/18/04 urging DOL opposition to an amendment to the Defense Authorization Act which would designate the Iowa and Mallinckrodt facilities as part of the Special Exposure Cohort. (2 pages)

7) E-mail from Jeff Nesvet of 4/6/05 urging that DOL "steer" a National Academy of Sciences review of the NIOSH program. Similar memo from Pete Turcic. (3 pages)

8) Judiciary Committee notes of a February 2006 e-mail from Shelby Hallmark to Melissa Bomberger at the OMB regarding his EEOICPA briefing paper, and his concern that NIOSH not "know where the verbiage came from." (1 page)

9) E-mail from LuAnn Kressley, Chief of the DOL Final Adjudication Branch, of 11/21/05 urging that claimants not be told that their case is being remanded to NIOSH because "they're part of a management plan." E-mail from Diane Case, DOL Health Physicist, to LuAnn Kressley of 11/18/05 indicating that DOL is reviewing infrequently compensated cases which are compensable (>50% POC) based on "increasing management concern." (4 pages)

10) E-mail from Larry Elliott (NIOSH) to Pete Turcic (DOL) of 12/9/05 regarding Agenda for joint NIOSH-DOL meeting to be held on 1/4/06. Agenda item for meeting includes OMB "Passback Report calling for WH Panel to discuss program/cost containment."

(1)

Judiciary Committee notes of e-mails reviewed at the Department of Labor related to Special Exposure Cohorts and the OMB passback

(Note: some words were abbreviated by the Judiciary Committee in the process of taking notes on the original e-mails; however, the words were not abbreviated in the original. The Judiciary Committee was allowed to review 8 binders of documents at DOL, but was not allowed to obtain xerox copies of the originals.)

Fr: SH
To: MK, KI
1/31/05 5:37 PM
Alts. To NIOSH FR Not. On SECs

Mala, Kris, et al. - as requested, we've spent sev hours pouring over NIOSH Fed Reg Notice, attempting to devise alt lang that might reduce the precedent'l impact of SEC approvals it rec's for Iowa Army Ammunition Plant and Mallinckrodt.

As discussed, the rationale prov'd in doc for add'g 1949-1957 at Mallinckrodt is that, while NIOSH has all the data needed to reconstr doses during those years, pet'rs and others have cast doubt on the accuracy of some of the expos. Data and hence claimants would be skeptical about any dose estimate results. The rationale for making the entire period of work at Iowa an SEC class is that while NIOSH has the data to do dose reconstructions, it believes it is constrained from doing so b/c the data is class'd and dose estimate assumptions could therefore not be fully and transparently revealed to the claimant.

W/ respect to Mallinckrodt, we have sugg'd revised lang (see attachment) that would simplify the eval and recommend a single SEC class covering the years 1942-1948. This SEC is justified in terms of the lack of data upon which to make credible dose reconstr'ns at that site based on the specific fact pattern there, and does not (as revised) open the door to direct application of the finding to other sites. By adding the years 1946-48 to the earlier period, roughly half of the claims DOL has rec'd from Mallinckrodt emps or their survivors would be incl'd in the SEC cohort.

However, the per 1949-1957 at Mallinckrodt ca't, in our view, be justf'd for incl'n as an SEC. The NIOSH doc openly acknowledges that dose reconstructions can be done for that per, and the only reason cited for asserting that an SEC shld be decl'd is that claimants and advocates have alleged that espos/monitoring data is missing, inaccurate, or corrupted. As noted in our formal cts last week, that same alleg'n has been made for virtually every DOE site, and in most cases has been acknowledged to one degree or another, and NIOSH's dose reconstr'n process was specifically designed to overcome those data weaknesses where possible. Therefore, the use of that rationale for Mall't will absolutely imply its enthusiastic applicat'n all around the complex. Further, there is no basis in the statute or NIOSH rules to approve an SEC appl'n in

circumstances in which NIOSH has annonced that in CAN do dose reconstr'ns, which it announces in the very Notice at issue. (Note: NIOSH has compl'd several dozen dose reconstr'ns at Mall't, making their recomm'n of SEC status for these years even more mysterious.)

For these compelling reasons, and b/c we have no info whatever with which to constr an alt justf'n for this per, we have revised the attached version of the notice to eliminate the extralegal and broadly applicable "credibility cloud" rationale, and thus to require that NIOSH DENY the SEC class petition with respect to employees who worked at Mall't during 1949-57, but who had less than 250 days emplmt during the 1943-48 per. We recognize that this outcome will not be will-rec'd by those w/ whom HHS apparently shared the draft Notice, but we know of no way to assert that an SEC for these years is justf'd, and the use of the proffered rationale would essentially signal acceptance of SECs at all DOE sites. As noted, the early years SEC approval will result in about half the Mall't claims being adjudt'd under the SEC presumption, which is an appropriate outcome given the deferring situations in terms of data availability (and, as we understand it, real risk of expos) during the 2 diff time periods.

With respect to the Iowa eval, we have been unable to ID any chgs to the rationale for an SEC approval that would limit its applicability to other sites, or make it more defensible. We considered hanging the rationale on a NIOSH regulatory provision that allows SEC status to be decl'd if NIOSH is unable to obtain the data it need to conduct dose reconstr'ns in a timely fashion. However, that provision is not applicable here, since NIOSH freely admits that it has all the (presumably classf'd) data needed to estimate doses. We have exhausted our knowledge of the issues at Iowa and can present no alt or impr'd or narrowed rationale for an SEC approval that isn't flatly contradicted by NIOSH's own admissions. Therefore, the attachment simply leaves the Iowa eval unchgd.

If NIOSH and DOE have any specific knowledge about the type of materials, and especially the degreean sensitivity of the classf'n of data surrounding those materials, perhaps they could insert that specificity into the revised Notice and limit its precedent-setting impact, at least to the 5 or 6 sites that performed essentially similar work - e.g., assembly and disassembly of warheads. Please note, however that by adding such specific rationale, NIOSH would very clearly be inviting SEC pet'ns from the obviously similar sites. And our experience with DOE complex is that functions that are thought to be segregated in a few sites tend to have spread in a somewhat surprising manner, such that it can be expected that warhead work will be "discov'd" in many places where it was not supposed to have happened. Finally, claimants an their reps will assert the argument that classified data abounds in the DOE complex, even if the classification issues at their own particular site are different and less significant than at Iowa-like sites.

All that said, it remains our firm conviction that the "transparency" criterion adduced by NIOSH for accepting the SEC petition for Iowa is not spelled out or supported by the statute or their regs. Even if they could add more refined descriptions of the type of classf'd info and the reason why it is especially important that discussion about dose estimation involving that info be curtailed, there is no legal basis for the SEC approval of the Iowa class. Claimants whose cases

are subsequently denied b/c the site has become an SEC via this process (i.e. thos with non-RECA cancer) will be able to sue to overturn the SEC decision, whether the rationale is couched in its current extremely broad lang, or is circumscribed as much as can be done given the parallels betw several DOE sites that did the same kind of work as Iowa. The NIOSH proposal for Iowa is not a good policy outcome.

In sum, we found a partial compromise that broadens the Mall't SEC to encompass about half of that work force in a way that is defensible, but we were unable to find any way to narrow or strengthen the Iowa eval. Since we were asked to improve the notice rather than simply reach a completely opposite outcome, we left the Iowa portion unchgd. We continue to believe that it is neither legally sound nor supportable as policy.

Let me know if we shld do more on this. Thx, sh

10/05/05 1:30 PM
Fr: PT
To: SH

Shelby,
Here my recommend's for policy actions. I talked to Larry Elliott. He was not sure what the Mall't designation will say. Particular note, John, Lew Wade and Diane Porter were at OCAS today. Larry asked about refreshing the Board and Diane informed him that it has been decided not to make any chgs to the Board membership!

10/05/05 12:25 PM
Fr: MW
To: SH,VL, MW
cc: PT, JN

Thx Shelby. We share concerns.

If there are any programmatic reforms – leg., admin, reg'y, you name it – that we could potentially tee up for our policy officials, we're all ears. At this point nothing should be ruled out. These would be OMB ideas, not DOL ideas.

My bosses typically expect the id of a problem to be accompanied by options to solve it. Legis solutions are not a 1st option, b/c they are hard to get enacted.

MW

10/05/05 9AM
Fr: SH
To: MW, VL, MW
Cc: PT, JN

FYI, Apropos of our brief discussion about EE.. Costs, see the Cantwell news release and letter to NIOSH and the EE Advis. Brd. Chair attached. As I sugg'd, the criteria the Board has advanced (and NIOSH and HHS have endorsed) for adding to the SEC for the the 1st 5 apprv'd pet'ns are so fuzzy and some cases so clearly related to pol. press., they almost beg for this kind of "me too" response.

You'll note that Cantwell is quoting from a report of the Brd's (really NOSH's) support contractor SC&A, an outfit that has basically driven NIOSH toward more and more lopsided and extreme exaggerations of dose on the grounds that every decision point must be as "claimant favorable" as conceivably possible. The Brd has allowed, even encouraged SC&A to pursue this unbalanced course, and NIOSH has shown no willingness to stand up to it, and recently doesn't even try to refute SC&A's more outlandish assertions. This is not a slippery slope, it's the expert downhill chute.

SH

NIOSH Dose Reconstr'n Policy Actions

1. **Nat'l Acad of Sci Revw** - The review of NIOSH site profiles procedures, and dose reconstructions conducted by SC&A thus that of the Advisory Board has not addressed the accuracy of the process concerning potential over estimation of exposures. The stand. for comp is 50 potential over estimation of expos's. The standard for comp is 50% or more Prob of Caus (POC) at the 99% confidence level, however, the Brd's "audits" only look at potential under estimation. An independent review of the process is needed to determine if the NIOSH dose reconstr'ns are either over or under compensatinng deserving claimants. An expedited review by a group such as the NAS could accomplish this if the review was structured to review the resulting compensation results along with the dose reconstr's. This review shld also focus on the findings and recomm's of SC&A and the Brd to determine if the recomm's are resulting in either under or over comp. It hld also look at conformance w/ the statutory and reg'y req's concerning accuracy and use of reasonable and plausible assumptions.

2. **Refresh the Advisory Brd(AB)** - A # of the AB members' terms have expired. Replacing these members could bring significantly more balance to the Board.

3. **Add Ex-officio Brd Membs** – A # of gov agencies have a direct or indirect interest in the deliberations of the AB and the impact it has on the resulting dose reonstr's. Any agency w/ responsibilities for rad'n safety and health can be significantly impacted by the outcome

of this AB's actions. These incl but are not limited to DOL, DOE, DOJ, NRC, Naval Nuclear Propulsion Prog, and VA. Significant benefit could come by having ex-officio members on the Board (they could be non-voting members) from several of these agencies.

These SC&A and AB reviews that are resulting in determ'ns that create add'l class designations have significant and direct impact on DOJ in administering RECA and VA in administering their comp progs. Dose reconstr's are done by the Defense Threat Reduction Agency for these progs at the Nevada Test Site and the Pacific Proving Grounds. The Brd will review a petition for the Pacific Proving Grounds in the near future and they will also review the NIOSH site profile for the Nevada Test Site.

4. **Apply Conflict of Int. Criteria to the Brd's Contractor** – NIOSH contractors conducting dose reconstr'ns or working on site profiles have conflict of interest lims. Dose reconstructionists are prohibited from working on dose reconstructions at sites where they were previosuly employed or where they did professional work and could have a conflict interest. No such reqmt exists for SC&A and as a result, inds conducting the reviews for the Brd are also involved in tort claims at the very sites where they are reviewing the NIOSH results. Since the SC&A contract is a NIOSH contract, NIOSH could place a prohibition on SC&A for involvement of SC&A employees in cases where they have such conflicts of interest. Add'lly, NIOSH contract emps conducting dose reconst'n were req'd to file conflict of int stmts which were and are public. A similar provision should also be applied to SC&A.

5. **Admin Review of New Class Determination** – Early review of SEC class determ's and def's would be of significant benefit. Recent designations were issued before there was any review by DOL or OMB. There have been significant probs encountered with the specific class def's that caused considerable probs in admin'g the new SEC and in the case of Oak Ridge Y-12, req'd the significant expansion of the class due to vague def'n of the class. This could have been mitigated had the adjudicators been given the opportunity to review the designation. The scope of cov'd emps in the class could have been def'd in a way that limited incl'n to those ind who the eval and desig'n intended to cover.

6. **Strict Application of the Statutory Stands. Of Causation** – NIOSH dose reconstr'ns are more freq'y applying assumptions that are systematically and dramatically increasing over estimations under the premise of "claimant friendly" assumptions or even for reasons of "calculational convenience." This is trending to ever increasing POCs. A strict applictn of the stand of causation comp would have a dramatic impact. This impact could be significantly enhanced if the AB was also charged to not only look at under comp but also over comp in their deliberations and recomms.

10/06/05 5:24PM
Fr: JN

To: SH
Cc: PT, RM, OP, ST, JC

Attached is redraft of Pete's sugg's. Essentially I put a front piece on and then just re-arranged and edited Pete's sugg's. I did leave one out, about Ex-Officio membs, since I think that would req legis and also they would not have a vote and they probably wouldn't have any effect on the rush to judgment advocates anyways. I think I incorporated all his other suggs.

E-mails from previous doc

Energy Emps Occupat'l Illness Comp Prog Act

DOL has grown increasingly concerned over HHS's rapidly diminishing coordination of activities and decision concerning the Energy Emps Occupat'l Illness Comp Prog Act (EEOICPA (EE..)). Recent actions, particularly those relating to adding add'l classes of emps the EE.. SEC, which grants those emps EE.. benefits if they have incurred any of 22 cancers and have worked in any SEC facilities a total of 250 days, have the potential to vastly increase the cost of the prog and decrease its sci validity. HHS's inability or unwillingness to reasonably construe the Cong criteria for such add's, particularly the reqmt that dose reconstruction (estimating emp's expos. to rad'n at the facility) be infeasible for the add'l class, appears to be leading to an all-encompassing expansion of theSEC resulting in costs approaching $7billion.

DOL has attempted to raise this issue and a # of others also threatening to result in an excessive, unjustified and inequitable increase in claims accepted under EE. w/ little success. At this pt it is clear that only intervention by the OMB is likely to stem this trend.

DOL has a # of concrete sugg's concerning how this might be accomp'd.

- **Clearance of SEC determ's by OMB** - The single most effective way to prevent of billions of dollars is by req'g HHS to clear its determ'n to add add'l emps to the SEC w/ the OMB after an opportunity for int'd agencies such as DOL to comment on the analysis and the determin'n. DOL has unsuccessfully requested an opportunity to review the HHS analysis and determination of SEC petitions. While recognizing that Cong has imposed an unreasonably short deadline of 30 days from receipt of the recomm'n of the AB on Rad'n and Worker Health (AB) for HHS to act, we still believe OMB clearance is crucial to preventing unjustified admissions to the several of the recent SEC petitions considered by the AB. DOL has also experienced problems in several cases w/ the description of the class adopted by the Nat'l Inst for Occup'n Safety and Health (NIOSH). In view of the effect and costs of an over-expansive def'n, we sugg that such determ's also be subject to OMB clearance.

- **Impartial Review** –Cong intended AB provide impartial analysis of sci validity

and qual of dose reconstr'n efforts by NIOSH and of other matters related to rad'n and worker health and to make impartial recomm's on add's to the SEC. So far AB has totally failed to take a bal'd approach to examining NIOSH activities. Nearly have its membs have operated as unwavering advocates of any action that would expand benefits, while the remaining membs occassionally raise dissenting views but are unwilling to forcefully advocate any positions likely to disturb the claimant community. This unwillingness to fulfill their responsibility by carefully examine issues such as whether the so-called "claimant-friendly" devices increasingly adopted by NIOSh are overestimating and over-compensating claimants has been magnified by NIOSH's decision to provide technical support for the AB through a contractor Sanford Cohen & Associates (SC&A) rather than through its own staff. SC&A has relentlessly pursued an agenda that appears to be designed to result in max pmts to claimants regardless of scientific validity. DOL sugg's the following in an to attempt to provide the impartial review not currently being undertaken.

- **Nat'l Acad of Sci Review** – HHS previously indicated that it was considering requesting a review of its dose reconstr'n prog by the Nat'l Acad of Sci (NAS). Our understanding is that this idea has since been abandoned. We believe that this would supply the kind of outside eval'n not being provided by the AB and would serve as a val benchmark in assessing the activities of both the AB and of SC&A.

- **Refresh the AB** – A # of the AB membs' terms have expired. We were previously informed that a # of new membs would be apptd. More recently we were informed that the AB would remain as currently constituted. We believe that replacing these membs could provide an opportunity to add Brd membs willing and able to advocate a scientifically valid approach to carrying out NIOSH's responsibilities under EE.

- **Apply Conflict of Int Criteria to SC&A** – NIOSH contractors conduct in dose reconstr'ns or working on site profiles have conflict of int. lims that prohibit them from working on dose reconstr'ns at sites where they were previously employed or where they did professional work and could have a conf of int. They are also req'd to file pub conflict of interest stmts. No such req't has been imposed on SC&A by NIOSH and as a result, inds conducting the reviews for the AB are also involved attempts by various indvs to seek damages as a result of rad'n expos at the sites where they are reviewing the NIOSH results. This is an obvious and considerable incentive for those individuals to seek to magnify to the greatest extent possible rad'n exposure at those facilities. NIOSH should be req'd to impose the same conflict of int provision it applies to its other contractors on SC&S.

- **Operational Concerns** – In addition to the other concerns expressed above, DOL has serious concerns about the operational conduct of dose reconstruction and of the creation of site profiles (facility-specific guidance docs detailing how a dose reconstr'n shld be performed) by NIOSH. To the extent that OMB is in a position to review the conduct of NIOSH, particularly its recent and increasingly problematic use of assumptions about the amount of rad'n exposure incurred by emps at cov'd facilities that are systematically and dramatically increasing over estimations under the premise of providing "claimant friendly" assumptions or for reasons of "calculational convenience," this could prevent a substantial amount of overcompensation of claimants and a substantial undermining of the sci validity of the EE. Comp prog.

As noted above absent a major chg of direction by HHS or substantial oversight by OMB, the EE.. Prog is rapidly heading in the direction of an expansion of benefits in an amount orders of magnitude beyond what Cong, at its most generous, ever contemplated when this prog was enacted.

2

- **Legislative proposals.** The 2007 Budget assumes DOL will continue to work with Congress regarding legislation to deter repeat violations of child labor and union financial integrity laws; and reforms to improve the efficiency, fairness, and fiscal integrity of the FECA and Black Lung programs.

  - **FECA benefit reforms.** The 2007 Budget will again include changes to FECA to improve benefit fairness, deter frivolous claims, and update and rationalize the benefit structure. No later than December 9th, DOL should provide final savings estimates for this package for inclusion in the 2007 Budget.

  - **Black Lung Disability Trust Fund Refinancing.** The 2007 Budget will re-propose legislation to restructure the Black Lung Disability Trust Fund debt. The Department is recognized for its efforts to gain Congressional support for this reform, and should continue its work to enact H.R. 3915 - Black Lung Disability Trust Fund Debt Restructuring Act.

Program Management. The 2007 estimate assumes the following with respect to major components of ESA programs.

- **Central bill processing contract.** While ESA is working to address cost and implementation issues related to the central medical bill processing contract, concerns remain, and ESA is requested to provide periodic status reports on its status.

- **Energy Employees Occupational Illness Compensation Program Act (EEOICPA) Part B.** ESA is to be commended for identifying the potential for a large expansion of EEOICPA Part B benefits through the designation of Special Exposure Cohorts (SEC). The Administration will convene a White House-led interagency workgroup including HHS, and Energy to develop options for administrative procedures to contain growth in the costs of benefits provided by the program. Discussions are not limited to, but will involve, the following five options:
  1. Require Administration clearance of SEC determination;
  2. Address any imbalance in membership of President's Advisory Board on Radiation and Worker Health;
  3. Require an expedited review by outside experts of SEC recommendations by NIOSH;
  4. Require NIOSH to apply "conflict of interest" rules and constraints to the Advisory Board's contractor; and
  5. Require that NIOSH demonstrate that its site profiles and other dose reconstruction guidance are balance.

- **PART assessments.** ESA is encouraged to implement quickly and deliberately recommendations made in PART assessments for each of its activities. We look forward to working with DOL on each of these reforms.

3

Notes for DOL/HHS/DOE Deputy Secretary Conference Call
July 2, 2002

Coordination of EEOICPA activities with HHS/NIOSH continues to be excellent and very productive. The NIOSH regulations on Probability of Causation (POC) and Dose Reconstruction are fully implemented by both NIOSH and DOL. The first claim processed under these regulations for a claimant who worked at Oak Ridge Y12 Plant has received a Final Decision awarding benefits. This individual was involved in a "criticality" accident receiving extremely high doses of radiation. Eleven additional dose reconstruction reports are under final processing by NIOSH and will be sent to DOL shortly.

Coordination of activities with DOE has not been as smooth. While the utilization of the ORISE database has been very successful and continues to be improved, employment verification by DOE continues to be very problematic and in a number of situations appears to have deteriorated.

Other activities with NIOSH involve the NIOSH Notice of Proposed Rulemaking (NPRM) on Guidelines for Additions to Special Exposure Cohorts (SEC) published on June 25, 2002. DOL reviewed this NPRM and appreciates the cooperation by NIOSH in addressing our concerns. The initial reaction to this NPRM appears to involve issues with which DOL concurs with the NIOSH approach. These are:

- Stakeholders expressed concern regarding the methodology for determining the most radiogenic cancer to be used in determining whether to include a class of employees in the SEC. The approach taken by NIOSH in the NPRM was adopted in response to DOL suggestions in this area in order to more accurately reflect the actual possibility that members of the proposed class suffered cancers caused by their exposure to radiation.

- Objections were raised that the NPRM process would be limited to facilities or classes of workers where NIOSH could not perform a dose reconstruction.

- Concerns were expressed relating to the process for DOL adjudicating claims after a SEC was added. Stakeholders raised the possibility that DOL's SEC determination of claims of employees added to the SEC would be biased if DOL had previously rejected the claimant's non-SEC cancer claim. DOL will attend the four proposed NIOSH public meetings to explain the NPRM to address the integration of the process into the DOL claims process.

NOTE: Senator Harkin has written to DOL (and perhaps HHS?) raising concerns regarding delays in implementing the dose reconstruction process. We were

advised this week that NIOSH now believes its contract for mass processing of dose reconstructions – to address the more than 5000 cases DOL has already referred to NIOSH for this process and the thousands more expected – will not be let until late August. Given a built-in 90 transition/start-up period, this means that a significant number of dose reconstructions will not begin to flow back to DOL until December at the earliest.

The DOE Employment Verification process continues to be problematic. An interagency records working group has been actively working for several months, however DOE's response to DOL's concerns has consisted primarily of responding to problems that arise from unilateral process changes at the DOE Records Centers. **[These process changes cause significant delays and quality problems in the employment verification process, which could have been averted if DOE had coordinated operational changes with DOL prior to implementation by the DOE Records Center. These problems often arise after implementation of Directives issued by DOE Office of Workers Advocacy.]** These on-going record issues include:

- Timeliness of DOE responses to employment verification requests has not improved and in many instances has deteriorated. The only exceptions are cases where the ORISE database is sufficient to verify employment.
- A number of DOE Records Centers have become extremely lax and inconsistent in the extent of their record searches resulting in very serious problems with the quality of the DOE verification.
    - Some Records Centers are requiring DOL to provide them with a contract number for subcontractors before they will search the records, even though the subcontract was a DOE contract.
    - Some Centers will only search by employee SSN even though the necessary records may be included in records that are filed by date or by employee name. **[This issue was raised to the working group with the DOE resolution being that they will address this type of situation on a case by case basis when DOL finds out that the Center is using a process such as this.]**
    - Some Centers are merely scanning hundreds of pages of records – most of which are not employment records – and then sending them to DOL on a CD with no verification, or explanation.
    - The Oak Ridge Records Center recently had over 500 employment verification requests pending for over 60 days.

During the May 31st conference call preparing for the June 3rd public hearing in Oak Ridge, the DOE Records manager reported that about 500 verifications were sent to the District Office the previous evening. We modified our presentation based on this information. We have not yet received these verifications.

In early March 2002, it was agreed in a Deputy Secretaries conference call discussion about records problems that DOL District Directors and staff should meet with the individual DOE Records Centers to establish an efficient and effective process for the individual situations. The Office of Worker Advocacy was assigned responsibility to make arrangements for such visits – DOL has requested the status of these arrangements on a weekly basis. The first such visit was recently set up, but then cancelled by DOL because the primary DOE records contact person was not going to be available for the meeting.

- The FY 2003 Defense Authorization bill passed the Senate without any EEOICPA amendments. A number of amendments were discussed with DOL that caused serious concern, including a proposal to move all or part of the state workers' compensation assistance program for other occupational diseases from DOE to DOL. Apparently, a decision was made by interested members of the Senate to postpone any further amendments, but to hold hearings in the very near future on various EEOICPA issues.

(4)

Reinhalter, Mark A - ESA

From: Hallmark, Shelby - ESA
Sent: Wednesday, May 07, 2003 4:11 PM
To: Turcic, Peter - ESA; Nesvet, Jeffrey L - ESA
Cc: Mosler, Roberta - ESA; Reinhalter, Mark A - ESA
Subject: RE: Notes Form NIOSH Advisory Board Telephone Meeting on May 1, 2003

That could be true if they're holding a public hearing aimed at gathering input, but the deliberations of the Board require some management if they're not to be left with a fait accompli – otherwise Rick Miller is in effect running things without opposition.

-----Original Message-----
From: Turcic, Peter - ESA
Sent: Wednesday, May 07, 2003 3:35 PM
To: Nesvet, Jeffrey L - ESA; Hallmark, Shelby - ESA; Kotsch, Jeffrey - ESA
Cc: Mosler, Roberta - ESA; Reinhalter, Mark A - ESA
Subject: RE: Notes Form NIOSH Advisory Board Telephone Meeting on May 1, 2003
Importance: High

That was well understood. NIOSH was very low keyed on the whole thing – they didn't defend the position. I think NIOSH feels that they can only listen and cannot appear to defend the policy choice in a proposed rule.

-----Original Message-----
From: Nesvet, Jeffrey L - ESA
Sent: Wednesday, May 07, 2003 2:57 PM
To: Turcic, Peter - ESA; Hallmark, Shelby - ESA; Kotsch, Jeffrey - ESA
Cc: Mosler, Roberta - ESA; Reinhalter, Mark A - ESA
Subject: RE: Notes Form NIOSH Advisory Board Telephone Meeting on May 1, 2003

Did anybody from NIOSH explain the somewhat quirky way that this would work, i.e. that they were not (and could not since it is established by the Act) limiting the cancers for which any SEC class member could be compensated, but only providing that you have to have a specific cancer to be included in the class.

Since you can only collect one $150k payment that might not be a significant point if you are already in because the one cancer was listed (though it makes medical payments for any other listed cancer simple to pay). The rule does not require that the cancer you are required to have be a listed cancer. You could, however, have a class requiring a non-listed cancer, of course you would have to have a listed cancer as well to get coverage through the SEC.

Originally, we commented on their draft language by noting we did not think that a one cancer class was prohibited by the Act, which was what the draft said. They later decided that it made scientific sense since different exposures triggered different cancers. Are they backing off that position?

-----Original Message-----
From: Turcic, Peter - ESA
Sent: Wednesday, May 07, 2003 2:08 PM
To: Hallmark, Shelby - ESA; Kotsch, Jeffrey - ESA
Cc: Turcic, Peter - ESA; Mosler, Roberta - ESA; Nesvet, Jeffrey L - ESA
Subject: RE: Notes Form NIOSH Advisory Board Telephone Meeting on May 1, 2003
Importance: High

What I got from the discussion was that the Board, decided this issue solely on the issue of being equitable. The advocates made the pitch that the intent of Congress was to have a uniform and equitable program and no one countered that the limitation of cancers to only those that could reasonably come from the specific situation, i.e. lung cancer when the risk was limited to inhalation, is in fact the uniform and equitable approach.

-----Original Message-----
From: Hallmark, Shelby - ESA
Sent: Wednesday, May 07, 2003 1:58 PM
To: Kotsch, Jeffrey - ESA
Cc: turcic pete; mosier roberta; nesvet jeff
Subject: RE: Notes Form NIOSH Advisory Board Telephone Meeting on May 1, 2003

Did NIOSH not do any selling on this? I know the Millers and worker advocates wailed about it, but there's good scientific reason for limiting the cancers, I was told, and surely some of the Board would have been supportive of that. Allowing the Board to go so strongly against this makes for a steep climb in the final rule.

-----Original Message-----
From: Kotsch, Jeffrey - ESA
Sent: Wednesday, May 07, 2003 1:47 PM
To: Hallmark, Shelby - ESA
Subject: RE: Notes Form NIOSH Advisory Board Telephone Meeting on May 1, 2003

Shelby, the vote on the 22 cancers was totally in favor of deleting the language, except for an abstention by Wanda Munn. The Board's comments, along with all of the other public comments received, will be posted on the NIOSH-OCAS website; probably in the next two weeks.

Jeff

-----Original Message-----
From: Hallmark, Shelby - ESA
Sent: Wednesday, May 07, 2003 1:41 PM
To: Kotsch, Jeffrey - ESA; Turcic, Peter - ESA; Mosier, Roberta - ESA; Lelton, Rachel - ESA
Cc: Hallmark, Shelby - ESA; Reinhalter, Mark A - ESA; Rose Toufexis
Subject: RE: Notes Form NIOSH Advisory Board Telephone Meeting on May 1, 2003

Jeff, was the Board's vote on the issue of less than 22 cancers recorded – that is, do you know how many and who voted which way? Will we be able to see the actual comment the Board submits?

-----Original Message-----
From: Kotsch, Jeffrey - ESA
Sent: Tuesday, May 06, 2003 7:40 AM
To: Pete Turcic; Roberta Mosier; Rachel Lelton
Cc: Shelby Hallmark; Mark Reinhalter; Rose Toufexis
Subject: Notes Form NIOSH Advisory Board Telephone Meeting on May 1, 2003

Attached are the brief notes from the NIOSH Advisory Board's

5

-----Original Message-----
From: Hallmark, Shelby - ESA
Sent: Tuesday, August 02, 2005 12:02 PM
To: Dugas, Peter - OCIA
Cc: Lipnic, Victoria; Wilson, Mark - ESA
Subject: FW: Special expsoure cohort bill introduced 7/27

Peter – can you contact your counterpart at HHS and see what if anything they plan to say about this bill? Clearly this is squarely in their ballpark, and they should take the lead, but as Jeff notes below, there's no history of them being willing to step to the plate. DOL shouldn't have to be the flak-catcher on this, but if nobody else is..... This would be a massive SEC expansion. Hopefully it has no chance of moving, but given the recent Senators' letter and other wacky happenings, I'm not sure we can afford to simply ignore it. Thanks, sh

-----Original Message-----
From: Nesvet, Jeffrey L - ESA
Sent: Monday, August 01, 2005 11:04 AM
To: Hallmark, Shelby - ESA; Turcic, Peter - ESA; Mosier, Roberta - ESA; Dugas, Peter - OCIA
Cc: Pannocchia, Orlando; Turley, Sheldon G - ESA
Subject: FW: Special expsoure cohort bill introduced 7/27

This bill would really open the floodgates for the SEC. I am not quite sure how to read the last part "(B)" of section 2 but the bill seems to lower the SEC bar enormously by letting in facilities based on radiation and lack of monitoring of a majority of workers. Hard to imagine how many facilities would qualify including just about every AWE I bet.

Requiring HHS to amend the SEC regs and to provide a list of facilities that will qualify for the SEC in 90 days is also a nice touch.

From the tenor of Larry's email I do not detect much confidence that HHS will step up to the plate.

JEFFREY L. NESVET
Associate Solicitor for Federal Employees'
and Energy Workers' Compensation
Office of the Solicitor
United States Department of Labor
200 Constitution Avenue, N.W., Room S-4325
Washington, D.C. 20210
(202) 693-5320 693-5360 (fax)

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-----Original Message-----
From: Elliott, Larry J. [mailto:lje1@cdc.gov]
Sent: Monday, August 01, 2005 10:15 AM

To: Turcic, Peter - ESA; Mosier, Roberta - ESA; Nesvet, Jeffrey L - ESA
Subject: FW: Special expsoure cohort bill introduced 7/27

FYI, see below. Will DOL be commenting on this? Will DOL encourage HHS to comment?
-----Original Message-----
From: Chang, Chia-Chia
Sent: Monday, August 01, 2005 9:56 AM
To: Brand, Anstice M.; Howard, John; Porter, Diane; Wade, Lewis; Durst, Kelley; Hearl, Frank J.; Elliott, Larry J.; Homoki-Titus, Zeda (Liz) E.; Katz, Ted
Cc: Broehm, Jason E.
Subject: RE: Special expsoure cohort bill introduced 7/27

Here is the text of the bill. Haven't seen the House bill, but it'll probably be identical.

BILL TEXT
S 1506
VERSION: INTRODUCED IN SENATE
July 27, 2005

109th CONGRESS

1st Session

S. 1506

To amend the Energy Employees Occupational Illness Compensation Program Act of 2000 to include certain former nuclear weapons program workers in the Special Exposure Cohort under the energy employees occupational illness compensation program.

IN THE SENATE OF THE UNITED STATES

JULY 27, 2005

Mrs. CLINTON (for herself and Mr. SCHUMER) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

---

A BILL

To amend the Energy Employees Occupational Illness Compensation Program Act of 2000 to include certain former nuclear weapons program workers in the Special Exposure Cohort under the energy employees occupational illness compensation program.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. FINDINGS.

Congress finds that—

(1) employees working on Cold War-era nuclear weapons were employed in hundreds of facilities owned by the Federal Government and private sector producing and processing radioactive materials for use in the nuclear weapons program of the United States beginning in the mid-1940's;

(2) those atomic workers helped to build the nuclear arsenal that served as a deterrent to the Soviet Union during the Cold War, but many paid a high price in terms of their health;

(3) during the Cold War, many atomic workers were exposed to radiation and placed in harm's way by the Department of Energy and contractors, subcontractors, and vendors of the Department—

(A) without the knowledge and consent of the workers;

(B) without adequate radiation monitoring; and

(C) without necessary protections from internal or external occupational radiation exposures;

(4) due to the inequities posed by the factors described in paragraph (3) and the resulting potential harm, Congress legislatively designated classes of Cold War-era workers at the Paducah, Kentucky, Portsmouth, Ohio, Oak Ridge K-25, and the Amchitka Island test sites as members of the Special Exposure Cohort under the Energy Employees Occupational Illness Compensation Program Act of 2000 (42 U.S.C. 7384 et seq.);

(5)(A) the contribution of the State of New York to the security of the United States throughout the Cold War was very significant; and

(B) New York is home to 36 former atomic weapons employer facilities and sites of the Department of Energy that produced and processed radioactive materials, carried out classified research, operated nuclear reactors, and processed high level nuclear waste, 14 of which are located in the western region of New York;

(6) research by the Department of Energy, the National Institute for Occupational Safety and Health, the Advisory Board on Radiation and Worker Health, and congressional committees indicates that—

(A) workers at certain facilities were not adequately monitored for internal or external exposures to ionizing radiation to which the workers were exposed during the 1940's to 1960's; and

(B) at other facilities, records were not maintained, are not reliable, or fail to measure the radioactive isotopes to which workers were exposed;

(7) at Bethlehem Steel in Lackawanna, New York, an atomic weapons employer facility (as defined in section 3621 of the Energy Employees Occupational Illness Compensation Program Act of 2000 (42 U.S.C. 7384*l*)), no personal radiation dosimetry monitoring records are available;

(8) if it is determined that it is not feasible to estimate radiation dose with sufficient accuracy and there is a reasonable likelihood that a class of workers may have been endangered, the Secretary of Health and Human Services is authorized, after receiving advice from the Advisory Board on Radiation and Worker Health, to designate additional classes of workers as members of the Special Exposure Cohort under section 3626 of the Energy Employees Occupational Illness Compensation Program Act of 2000 (42 U.S.C. 7384q);

(9) the Secretary of Health and Human Services promulgated regulations on May 28, 2004, to establish procedures for classes of individuals to petition for membership

in the Special Exposure Cohort;

(10) section 3626(b) of the Energy Employees Occupational Illness Compensation Program Act of 2000 (42 U.S.C. 7384q(b)) provides for the designation of an additional class of employees in the Special Exposure Cohort if it is not feasible to estimate with sufficient accuracy the radiation dose that the class received and there is a reasonable likelihood that the radiation dose may have endangered the health of members of the class; and

(11) legislation is needed to provide additional parameters to the Secretary of Health and Human Services and the Advisory Board on Radiation and Worker Health for evaluating petitions for the Special Exposure Cohort in cases in which there is limited or nonexistent individual radiation exposure monitoring or an absence of records.

SEC. 2. ADDITION OF CLASSES OF FORMER NUCLEAR WEAPONS PROGRAM WORKERS IN THE SPECIAL EXPOSURE COHORT UNDER ENERGY EMPLOYEES OCCUPATIONAL ILLNESS COMPENSATION PROGRAM.

Section 3626(b) of the Energy Employees Occupational Illness Compensation Program Act of 2000 (42 U.S.C. 7384q(b)) is amended—

(1) by inserting "(A)" after "(1)";

(2) by redesignating paragraph (2) as subparagraph (B);

(3) by striking the period at the end and inserting "; or"; and

(4) by adding at the end the following:

"(2)(A) subject to subparagraph (B), in the case of a class of employees employed at an atomic weapons employer facility or a Department of Energy facility during a period (in the aggregate) of at least 250 days (or a shorter duration connected to discrete events, as determined by the Secretary) during which—

"(i) the employees in the class had the potential for exposure to occupational ionizing radiation from production or processing materials related to atomic weapons, or engaged in research, development, testing, assembly, disassembly,

decontamination, decommissioning, or waste management, or work related to such activities; and

"(ii)(I) fewer than 50 percent of the employees in the class were individually monitored on a regular basis (using reliable methods and procedures) under a formal health physics program for exposure to internal and external ionizing radiation for the types of radiation and specific radioactive isotopes to which the employees had the potential for exposure during the period when the employees were exposed;

"(II) individual internal and external exposure records for the types of radiation and specific radioactive isotopes to which the employees in the class were potentially exposed at the facility during the period when the employees were exposed are nonexistent or are not available; or

"(III) to the extent that a portion of individual internal or external records are available for the period from the facility, individual radiation doses cannot be reliably determined for greater than 2/3 of the employees in the class using the individual internal and external monitoring records from the facility; and

"(B) in the case of a class of employees employed at a facility for which the National Institute for Occupational Safety and Health has updated the report and made the determination described in section 3169(b)(4) of the Ronald W. Reagan National Defense Authorization Act for Fiscal Year 2005 (Public Law 108-375; 42 U.S.C. 7384 note) during a period determined under the report, during which (as determined by the Secretary) the employees at the facility met the criteria described in clauses (i) and (ii) of subparagraph (A).".

SEC. 3. REGULATIONS.

(a) In General.—Not later than 90 days after the date of enactment of this Act, the Secretary of Health and Human Services shall modify the regulations and procedures of the Secretary relating to the Special Exposure Cohort under the Energy Employees Occupational Illness Compensation Program Act of 2000 (42 U.S.C. 7384 et seq.) to conform the regulations and procedures to section 3626(b)(2) of the Energy Employees Occupational Illness Compensation Program Act of 2000 (as amended by section 2).

(b) Bethlehem Steel Site.—

(1) INITIATION OF PETITION.—Not later than 90 days after the date of

enactment of this Act, the Secretary of Health and Human Services shall initiate a petition to include workers employed at the Bethlehem Steel site in Lackawanna, New York as a class to be included in the Special Exposure Cohort in accordance with section 3626(b)(2) of the Energy Employees Occupational Illness Compensation Program Act of 2000 (as amended by section 2).

(2) EVALUATION.—The evaluation of the petition shall be conducted in accordance with section 3626 of the Energy Employees Occupational Illness Compensation Program Act of 2000 (42 U.S.C. 7384q).

(c) Report.—Not later than 90 days after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to Congress a report that identifies the facilities, classes, and the number of claimants in each class who meet the criteria established under section 3626(b)(2) of the Energy Employees Occupational Illness Compensation Program Act of 2000 (as amended by section 2) for membership in the Special Exposure Cohort.

Source: Government Printing Office
From CQ Bill Text Service
Providing government documents on demand, in context.
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From: Brand, Anstice M.
Sent: Wednesday, July 27, 2005 2:08 PM
To: Howard, John; Porter, Diane; Wade, Lewis; Durst, Kelley; Hearl, Frank J.; Chang, Chia-Chia; Elliott, Larry J.; Homoki-Titus, Zeda (Liz) E.; Katz, Ted
Cc: Broehm, Jason E.
Subject: FW: Special expsoure cohort bill introduced 7/27

FYI...

Clinton press release:
http://clinton.senate.gov/news/statements/details.cfm?id=241555&&

July 27, 2005

Senators Clinton, Schumer and Representatives Reynolds, Slaughter, Higgins Introduce Legislation To Compensate Nuclear Workers

Washington, DC — Senators Hillary Rodham Clinton and Charles E. Schumer joined Representatives Thomas Reynolds, Louise Slaughter and Brian Higgins in introducing

legislation to reform the compensation program for nuclear workers at Bethlehem Steel and other former New York atomic weapons production facilities. The bill would enable employees to be added to a "special exposure cohort" and receive compensation under the Energy Employees Occupational Illness Compensation Program if exposure records do not enable case-by-case decisions to be made.

"It is time to right the wrong that has been done to our state's nuclear workers and their families who have not received the compensation they deserve," said Senator Clinton. "This bill will ensure that nuclear workers are not penalized because, through no fault of their own, exposure records are inadequate."

"Our bill would correct years of injustice for Western New York's nuclear workers," Schumer said. "After the sacrifice these Cold War Heroes made for our country, they have waited far too long. This bill would finally put them on the path to getting the recognition and compensation they deserve."

"No one who deserves compensation should have it denied, period," said U.S. Representative Thomas M. Reynolds, R- Clarence, the lead sponsor of the House bill. "This legislation will fulfill a national commitment we made to these 'Veterans of the Cold War,' by providing them with compensation that is long overdue. It is the right thing to do for these victims and their families, and I look forward to working with my colleagues in both the House and the Senate to help make it happen."

"The workers of Bethlehem Steel, Linde Ceramics, and many other Department of Energy facilities deserve immediate compensation. Despite many incidences of work-related illnesses and deaths, employees across this country have not found relief because of insufficient records that not only delay site profiles, but also make dose reconstruction virtually impossible," said Rep. Slaughter. "This bill, by allowing Special Exposure Cohort status designation to specific facilities, will help employees receive the benefits promised to them in a timely manner."

"This bill frees suffering workers and their families from a process that has failed them for too long. I am pleased to support this bipartisan bill, and sincerely hope that justice will finally be carried out for all those affected," said Congressman Higgins.

Congress passed the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) in 2000 to compensate workers who contracted radioactive cancer, beryllium disease or chronic silicosis after working at sites that performed nuclear weapons work during World War II and the Cold War. Under EEOICPA, former nuclear workers or their survivors were eligible to file claims with the US Department of Labor (DOL) for individual payments of $150,000, as well as medical benefits. To file a claim, patients or their surviving families needed to provide proper documentation of their illness and employment history.

Claims are decided by the DOL and the National Institute for Occupational Safety and Health (NIOSH) by using available records about work conditions and employment history. Using these records, NIOSH estimates the radiation doses received by each worker and then determines whether that radiation exposure was likely to have caused the worker's illness. This "dose reconstruction" process has been time-consuming and controversial, particularly at facilities like Bethlehem Steel in Lackawanna, New York, where workers did not wear individual radiation monitors, and there was minimal monitoring of ambient radiation. For Bethlehem Steel workers, compensation decisions have been made using a radiation exposure model that relies on data from another facility—the Simonds Saw facility in Lockport, New York.

The bill introduced today would amend the criteria by which employees can be added to a "special exposure cohort." Being added to a cohort means that employees do not have to go through a "dose reconstruction" process. Instead, if a person has an eligible cancer and worked at a facility when weapons work was performed, their cancer is presumed to have been caused by workplace exposure and the person's claim is paid. Under the legislation, workers would be added to a special cohort if:

• they worked at an eligible facility for an aggregate of at least 250 days, and;

• fewer than 50 percent of the total number of the workers at the facility were individually monitored on a regular basis for exposure to internal and external ionizing radiation using reliable methods under a formal health physics program or;

• individual internal and external exposure records for radiation are non existent or are not available, or;

• to the extent that a portion of individual internal or external records are available for that period from such facility, the exposure to radiation at such facility cannot be reliably determined for greater than 2/3 percent of workers.

The bill also directs the Secretary of Labor to apply these criteria to the Bethlehem Steel facility within 90 days of enactment. Because individual records are not available at Bethlehem Steel, workers would qualify for inclusion in a special cohort under the legislation if they worked at the facility for an aggregate of 250 days during 1949-1952. Based on draft site profiles prepared by NIOSH for the Linde Ceramics and Simonds Saw facilities, it appears that many workers from these facilities would qualify under the legislation as well. Because these and other New York facilities are not as far along in the claims process as Bethlehem Steel, it is impossible to determine exactly how the legislation would apply. However, it could assist workers across New York. Click here to view the list of facilities with more than 20 claims filed.

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6) Our estimate of costs at the Iowa and Mallinkrodt sites, based on current claims in hand and a conservative estimate of new claims after SEC status is declared, is roughly $120 million over the expectation should dose reconstruction continue to be applied.

Shelby Hallmark

Please note new email address:
hallmark.shelby@dol.gov

-----Original Message-----
From: Keelan, Elizabeth
Sent: Monday, June 21, 2004 12:03 PM
To: Hallmark, Shelby - ESA
Cc: Nesvet, Jeffrey L - ESA; Turcic, Peter - ESA
Subject: RE: Bond/Harkin amdt on EEOICPA SECs

Can you put together some brief TPs on this issue for me? This afternoon, if possible? I am hearing that now the NY and AK folks want to add their facilities in with IA and MO...so the list is expanding. And if there's anything you have on hand about why their cost estimates are too low, that would be great too...thank you!!!

-----Original Message-----
From: Hallmark, Shelby - ESA
Sent: Friday, June 18, 2004 10:50 AM
To: Wolpers, Stephanie - OCIA; Keelan, Elizabeth; Iverson, Kristine; Lipnic, Victoria; Krishnamoorti, Maia; Sullivan, Adam
Cc: Wilson, Mark; Turcic, Peter - ESA; Nesvet, Jeffrey L - ESA
Subject: RE: Bond/Harkin amdt on EEOICPA SECs

Just in case there was any question, it's my strong belief that we should do everything possible to oppose these SEC amendments. It's quite possible that NIOSH may accept petitions creating SEC status for some time periods at both the Iowa plant and Mallinkrodt, but that process should be allowed to proceed as outlined in the HHS regulations, not be short-circuited (and extensively broadened) by ill-considered legislation which will only inflame other Congressional delegations to join that parade. Although it's complicated, we also think the $61 million being discussed as the 10 year cost of the amendments is far too low. But the real issue is, this would be a terrible precedent. Thanks, sh

-----Original Message-----
From: Wolpers, Stephanie - OCIA
Sent: Friday, June 18, 2004 9:45 AM

To: Keelan, Elizabeth; Iverson, Kristine; Lipnic, Victoria; Krishnamoorti, Mala; Sullivan, Adam; Hallmark, Shelby - ESA
Subject: RE: Bond/Harkin amdt on EEOICPA SECs

No further action was taken on the amendment yesterday. It is still pending.

-----Original Message-----
From: Keelan, Elizabeth
Sent: Thursday, June 17, 2004 11:36 AM
To: Iverson, Kristine; Lipnic, Victoria; Krishnamoorti, Mala; Sullivan, Adam; Hallmark, Shelby - ESA
Cc: Wolpers, Stephanie - OCIA
Subject: Bond/Harkin amdt on EEOICPA SECs

FYI, earlier this AM, Harkin, Bond and Talent were discussing their amdt to expand the list of facilities designated as Special Exposure Cohorts (SECs) to include Mallinkrodt in MO and the IAP facility in Iowa. Initially we did not know if they would be able to work something out with Warner to be allowed to offer the amdt, have talked to HELP cmte, and believe that Bond negotiated this with Warner. They pulled the amdt earlier this AM though because they are fighting over the offset -- approx. $61M, Bond had come up with something that Warner and budget cmte folks were ok with, and then Harkin said that he wanted it to come from the customs user fees. Several Republicans have raised objections - citing that this is too often used as an offset. So, hold up is currently over the offset. If they work this out, likely the amdt will be agreed to by voice vote like yesterday.

We will be meeting with House folks on the Bunning amdt and will raise this as well this afternoon, so I have asked Stephanie to keep an eye on the floor should this come up again.

Thanks, EK

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Search 2

From: Nesvet, Jeffrey L - ESA
Sent: Wednesday, April 06, 2005 11:03 AM
To: Turcic, Peter - ESA; Hallmark, Shelby - ESA
Subject: RE: NAS Review of the NIOSH Radiation Dose Reconstruction Program

I agree with Pete that he and I should pitch in at the beginning to try to steer this effort in a direction that will prove useful to us.

JEFFREY L. NESVET
Associate Solicitor for Federal Employees'
and Energy Workers' Compensation
Office of the Solicitor
United States Department of Labor
200 Constitution Avenue, N.W., Room S-4325
Washington, D.C. 20210
(202) 693-5320 693-5360 (fax)

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-----Original Message-----
From: Turcic, Peter - ESA
Sent: Wednesday, April 06, 2005 10:50 AM
To: Hallmark, Shelby - ESA; Nesvet, Jeffrey L - ESA
Subject: RE: NAS Review of the NIOSH Radiation Dose Reconstruction Program
Importance: High

I think on the proposal implementation group I should participate. This is going to get the advocates upset. Once it gets started, Jeff Kotsch could participate on a routine basis. Jeff Nesvet should also be there in the beginning so that we can steer the work plan towards an analysis of making compensation decisions. Also, I think we need to get enough into the work plan so that we can use the results to defend our decisions.

Additionally, this could go a long way to help re-build credibility into the dose reconstruction process.

-----Original Message-----
From: Hallmark, Shelby - ESA
Sent: Wednesday, April 06, 2005 10:28 AM
To: Turcic, Peter - ESA; Nesvet, Jeffrey L - ESA
Subject: FW: NAS Review of the NIOSH Radiation Dose Reconstruction Program

Do you guys think we need a participant on this? My concern is getting interim products as quickly as possible, and keeping the cost within reason. Do we need a person on the team to exercise that kind of influence? If so, who would it be?

-----Original Message-----
From: Howard, John [mailto:zkz1@cdc.gov]
Sent: Wednesday, April 06, 2005 9:38 AM
To: Hallmark, Shelby - ESA; Turcic, Peter - ESA; Nesvet, Jeffrey L - ESA; Elliott, Larry J.; Wade, Lewis; Porter, Diane; Stephens, James W.; Neton, Jim; Homoki-Titus, Zeda (Liz) E.; Durst, Kelley; Sinclair, Raymond C.
Subject: NAS Review of the NIOSH Radiation Dose Reconstruction Program

Gentlepeople:

Thank you for your preliminary comments on the proposed **NAS Review of the NIOSH Radiation Dose Reconstruction Program** by the National Academy of Sciences at yesterday's meeting with OWCP and NIOSH at the DOL. Attached is the revised proposal.

<<OCAS.NAS.Proposal.Revised.doc>>
After our initial discussion of yesterday, we agreed to form a small group to implement the proposal in a more detailed state together with a detailed scope of activities (charge) for the NASA panel, a detailed budget, a detailed timeline and incorporation of a mechanism to receive input from the NAS Panel **during the review timeframe** so that important findings can be utilized quickly by radiation dose reconstruction program (as opposed to waiting until the end of an 18 to 24 month process).

Members of the NAS Radiation Dose Reconstruction Proposal Implementation group will be NIOSH/OD representatives (Lew, Wade, Kelley Durst, Ray Sinclair), an OCAS representative (Larry Elliott); a DOL/OWCP representative (if so designated by DOL/ OWCP); and a NAS representative (TBD).

Ray Sinclair from the NIOSH/OD in Cincinnati, will be secretary of the NAS Implementation Group, and will be notifying participants of the first meeting of the group.

Thank you.

JH

Proposed Review of the NIOSH Radiation Dose Reconstruction by the National Academy of Sciences

Purpose:
Review the scientific aspects of this program with respect to the suitability of current exposure dose reconstruction methods for determining qualification for worker compensation, make recommendations as to enhancing existing methods of OCAS, and identify significant emerging research areas that may impact OCAS in the future.

Steps in the Review:
The National Research Council, through its Division of Earth and Life Studies, and the Institute of Medicine (DELS/IOM) will identify, recruit, and convene a panel of experts for purposes of this evaluation. Those experts will come from relevant fields such as health physics, oncology, epidemiology, risk assessment, and dose reconstruction.

The panel will meet three times under the auspices of the DELS/IOM. The new (March, 2005) Nuclear and Radiation Studies Board (NRSB) will have administrative responsibility for the review. The NRSB replaces the older Board of Radiation Effects Research and the Radioactive Waste Management Board within the NRC.

The panel will develop methods for its review and conduct the review. It will review material provided by (or requested of) OCAS and related organizational units in other agencies. It may gather other evidence from other sources to complete a thorough review. The panel may meet at NAS offices, or travel to other locations if that will enhance the review.

A written evaluation will be prepared by the panel in cooperation with NRC staff. The evaluation will be externally peer-reviewed before its release to the public.

Estimate of Costs:

~~$800,000 per year~~ (estimated). The NRC informally recommended an 18-24 month time frame for this project. Their final cost estimate would be based on three factors:

a. Complexity of the study
b. Size of the review panel
c. Length of time for the study

Prepared by: Ray Sinclair, NIOSH Senior Scientist, Office of the Director, Cincinnati, 4 April 2005; revised by John Howard, 6 April 2005.

Notes:
1. The NRC will soon release a report on the Radiation Exposure Compensation Act (RECA) for the Health Research and Services Administration (HRSA) of DHHS. They predict it will be released by 4/30/05. Because of that, they feel well-qualified to conduct the study described above.
2. This draft was prepared with the advice of Dr. Evan Douple, Director, Board on Radiation Effects Research (now superseded by the NRSB). He is also project manager of the NIOSH scientific program review.

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A February 2006 e-mail communication from the head of OWCP to OMB states in part:

_____,

I am uncomfortable with even an unofficial sharing of my briefing piece for today's meeting with my second floor people since I am not at all convinced they will be willing to argue directly for any or all the actions it proposes, and I know they are very reluctant to be on the cutting edge of this argument. I feel pretty sure their response is going to be "OMB such [sic] be holding HHS accountable here – DOL isn't in any position to try to do that". But if you promise not to spread it, and if you don't use the language in your documents such that NIOSH will know where the verbiage came from, I'll share it (I'm still smarting from your (probably _____'s since you weren't back?) citation of the ideas in the budget passback as having been suggested by ESA Is that agreeable?

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Search 4

From: Kressley, Luann - ESA
Sent: Monday, November 21, 2005 9:57 AM
To: Case, Diane
Subject: RE: DR Remand for [redacted] (NIOSH 8017)

That message was meant for Sidne. When we send remand orders to claimants, I don't want them to know they're part of a management plan. Let's have lunch sometime soon.

LuAnn Kressley
Chief, Final Adjudication Branch
DEEOIC
Suite 565
800 N. Capitol St.
Washington, DC
(202) 513-6400

-----Original Message-----
From: Case, Diane L - ESA
Sent: Monday, November 21, 2005 8:13 AM
To: Kressley, Luann - ESA
Subject: RE: DR Remand for [redacted] (NIOSH 8017)

LuAnn,

Welcome back (?)

Regarding the [redacted] case, I thought my response (below) was provided as justification for a rework of the recommended decision. With regard to "don't put the first paragraph in your "decision,"" – I thought that this case will go back to the DO for a rework to NIOSH, therefore a final decision will not be issued by Sidne (at least not for now). Do you mean don't include that in the future decision (i.e., later on when it comes back?). Please tell me if I am misunderstanding the process.

Now that I think about it – most of the DRs for the "special cancers" we are reviewing that result in PoC>50% are appropriately performed by NIOSH (no rework required). I've just been sending a one-liner back to the DOs/FAB saying so. I hope no one is mentioning the fact that we took another look at these DRs and said it was fine - in the recommended or final decisions.

I am glad we caught this [redacted] case in particular, because the dose reconstruction assumed he worked in glove boxes, and there is no evidence that he did. I subsequently called NIOSH, and they agreed that it needed to go back for a rework.

Anyway, I don't want to take your time, as I am sure you have another meeeaattttinnnnggggggg to go to soon!! ☺

Regards,

DLC

-----Original Message-----
From: Kressley, Luann - ESA
Sent: Sunday, November 20, 2005 8:21 PM
To: Case, Diane L - ESA; Valdivieso, Sidne M - ESA
Cc: LaRock, Jeana F - ESA; Hill, Thomasyne - ESA; Kotsch, Jeffrey - ESA
Subject: RE: DR Remand for [redacted], (NIOSH 8017)

And Sidne, please don't put Diane's first paragraph in your decision.

-----Original Message-----
From: Case, Diane L - ESA
Sent: Friday, November 18, 2005 1:09 PM
To: Valdivieso, Sidne M - ESA
Cc: Kressley, Luann - ESA; LaRock, Jeana F - ESA; Hill, Thomasyne - ESA; Kotsch, Jeffrey - ESA
Subject: DR Remand for [redacted] (NIOSH 8017)

Based on increasing management concern over a potential increase in compensable claims for cancers perceived as normally/previously non-compensable, I reviewed the NIOSH dose reconstruction report (DR) for [redacted] 8340 (NIOSH 8017), and identified several issues that merit further consideration by NIOSH.

Mr. [redacted] worked at the Savannah River Site (SRS) from 06/51 through 06/80, and he was diagnosed with prostate cancer in 1985 (at age 67) and colon cancer in 1996 (at age 72). In addition, Mr. [redacted] worked at the Oak Ridge National Laboratory (X-10) from 03/44 through 07/44, and at the Hanford Site from 08/44 through 03/45. The estimated dose to the prostate was 23.7994 rem (PoC 35.02%), and the estimated dose to the colon was 18.880 rem (PoC 40.49%). The resultant PoC was 61.33%.

ISSUES:

1. We ask NIOSH to identify the years for which Mr. [redacted] was monitored for external photon exposure, and Mr. [redacted]'s DOE whole body deep dose of record, in the DR report.

2. We ask NIOSH to identify the surrogate organ used (bladder) to determine the external dose to the prostate.

3. In the *Missed Dose* section, The DR states: "A potential missed dose was assigned to each actual or potential dosimeter cycle to maximize the potential external doses received by Mr. [redacted]. Based on information provided in the Savannah River Site Technical Basis Document, the total number of dosimeter cycles assigned was 537 for photons. This number was based on a claimant-favorable assumption of varying badge exchanges each full or partial year of employment and was chosen to ensure that all possible instances of a zero badge reading were accounted for in this dose reconstruction."

   We request NIOSH to identify the change-out frequencies used in the DR throughout Mr. [redacted]'s employment. We further request that NIOSH use Mr. [redacted]'s employee-specific dosimeter change-out frequency, as available, to calculate his missed doses. This seems to be the appropriate application for a compensable case.

4. NIOSH states that "The majority of Mr. [redacted]'s radiation exposure was received during employment as an observer, health physicist, and a superintendent of planning and analysis. He worked in the 300M, 773A (plutonium), and 700A areas. According to the telephone interview, Mr. [redacted]'s work required him to perform duties in glove boxes. This could cause the recorded does could be underestimated. The photon correction factors of 2 for penetrating photons and 2.8 for non-penetrating photons..."

   I reviewed the CATI, and I could not find any indication that Mr. [redacted] provided the interviewer with any information about working in glove boxes, except on page 3; per the question: "What exposure/contamination control measures were used to protect you?" The interviewer checked the box "sometimes" for fume hoods, glove boxes, shielding, remote control devices, and local ventilation.

   Without access to any other records used by NIOSH, and basing Mr. [redacted]'s work environment and duties on the information provided in the CATI, there is no indication that Mr. [redacted] routinely worked using glove boxes, or that he was specifically located in the following areas for the following employment periods:

   300M: (1951-1958) and (1970-1973)
   773A (plutonium): (1959-1969)

700A areas (736A, 1974-1980)

We are therefore requesting NIOSH to reevaluate Mr. [redacted]'s glove box use, and his locations on site for the years as indicated above.

5. If NIOSH can verify that Mr. [redacted] used a glove box for any given period, the application of the glove box correction factor to each recorded dosimeter dose within that period assumes that the employee worked at a glove box constantly, i.e., whenever the dosimeter was worn. Therefore, all recorded dose, regardless of various other potential exposure origins, is assumed to be solely associated with glove box use. It seems unreasonable that an employee would work in a glove box for 8 hours a day, every day, over an extended number of years. We therefore ask NIOSH to review this assumption in terms of the fraction of time Mr. [redacted] was reasonably working in glove boxes, for example, in any given day.

7. The DR does not state whether or not the glove box correction factors were applied to the assigned missed doses. If so, we request NIOSH provide the rationale for doing so.

6. The glove box correction factor assumes a simple, generic glove box configuration that results in a high exposure yield (minimal shielding, maximum viewing area, etc.). This constant factor is applied for all years of employment and is not modified by information specific to the employee, the site, or to the era.

As stated in TIB-27,

> A review of the literature indicates that the design of glove boxes varied widely. Since the actual glove box design is not known for each dose reconstruction scenario, a claimant favorable approach is used by assuming the glove box had a large viewing face with relatively little difference in photon attenuation between the external source and the organ of interest and between the external source and the dosimeter. This is considered a reasonable but necessary claimant favorable assumption, since identifying the actual glove box design at each facility (DOE site, building, room, etc.) would be time consuming. In addition, during the course of an energy employee's employment, it is likely that they conducted work in many different types of glove boxes, thus a time dependent work location correction factor for each glove box design would be necessary to account for such differences. The tendency of this assumption is toward an overestimate of the dose rather than an underestimate.

It is not reasonable or necessary to assume that each glove box employee worked at glove box with a large viewing face with relatively little difference in photon attenuation between the external source and the organ of interest and between the external source and the dosimeter, for all years of employment.

It is reasonable to assume that an employee who used glove boxes all day for multiple years, especially an individual who was employed as a "health physicist" at some time, would be able to provide reasonable detail as to what type of work was performed in the glove boxes, and/or the basic glove box design including the relative size of the viewing area. In addition to, or alternatively, in lieu of "identifying the actual glove ox design at each facility, (DOE site, building, room, etc.)," the types and design of glove boxes used at many sites within a given decade, at the very least, should be reasonable to identify, or to assume based on knowledge of the specific site and based on era-specific technology and radiation safety practices and procedures

If NIOSH can verify that Mr. [redacted] used a glove box for any given period, we ask NIOSH to reconsider the reasonableness of assuming a generic, high-exposure potential glove box design for this employee for all years worked. Since this dose reconstruction resulted in a compensable prostate claim, and because TIB-27 states that "The tendency of this assumption [basic, open-view glove box design] is toward an overestimate of the dose rather than an underestimate," we request that NIOSH determine the characteristics of the actual glove boxes Mr. [redacted] used. If this is indeterminable, we ask NIOSH to develop and use the characteristics of the most likely type(s) of glove box(es) Mr. [redacted] actually used at SRS, based on scientific and technological evidence and using sound professional knowledge and judgment. We ask NIOSH to use this information to determine a more employee-specific

external photon dose assignment for Mr[redacted].

We recommend that this dose reconstruction be remanded to the District Office for a rework by NIOSH to address the concerns expressed above. Please ask the DO to include these issues in the rework request.

Thanks,

Diane

Diane L. Case, Ph.D., CHP
Health Physicist
U. S. Department of Labor
Division of Energy Employees Occupational Illness Compensation
Phone: (202) 693-0277
Fax: (202) 693-1465
case.diane@dol.gov

HHS 51(2)

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Buelow, Helen M.

From: Elliott, Larry J.
Sent: Friday, December 09, 2005 2:39 PM
To: Pete Turcic (Turcic.Peter@dol.gov)
Cc: Mosier, Roberta - ESA
Subject: Jan. 4th agenda items proposal

Pete:
To get us started toward finalizing an agenda for the January 4th meeting, please modify and/or add to the draft category list of agenda items below:

Claims Processing:
- SEC claims process protocol
- Employment verification for non-claimant SEC petitioners
- Notification of affected and non-affected claimants after a modification in DR approach/IREP method
- DOL DO implementation of 30-IREP run for cases >45%<50%
- NIOSH Project Management Plan for completing oldest claims

Science/Technical Issues
- Lymphomas and site of origin vs site of DR
- CLL
- Smoking Risk Adjustment
- Age at time of exposure and other temporal risk factors

External Oversight/Influences
- ABRWH new member status
- Status of SEC Rulemaking to codify Amendment Language changes
- Amendment Language seeking report of cancers to be added to the SEC-specified cancer list
- Passback Report calling for WH Panel to discuss program/cost containment

HEALTH HAZARDS IN NYCO FACILITIES PRODUCING AND PROCESSING URANIUM

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[redacted]

HEALTH HAZARDS IN NYOO FACILITIES PRODUCING AND PROCESSING URANIUM

Abstract

The findings of the NYOO Medical Division are given in identifying and evaluating the health problems associated with the NYOO facilities that process and produce uranium and certain of its compounds. Detailed information is given on principal occupational health hazards, transportation of materials, and liquid and solid waste disposal. Plant changes required to correct unsatisfactory conditions are indicated, and the need for continued studies is discussed.

The appendices describe the plant processes as background for understanding the health problems and explain the computation of individual dust exposures and "tolerance" levels for insoluble uranium compounds in inhaled air.

[redacted]

file #577

This report consists of ii + 73 pages and 21 figures. Copy no. 7 of 7 copies, series A.

Note: This Doc. may be declassified if the items marked in yellow on pp. 3, 11, 12, 19, 36, 44, 48, 49, 58 are deleted. See memor. dtd 3/2/66, Carroll to Cooper

67749

U. S. Atomic Energy Commission

New York Operations Office

HEALTH HAZARDS IN NYOO FACILITIES PRODUCING AND PROCESSING URANIUM

(A Status Report - April 1, 1949)

Prepared By

NYOO Medical Division

Special Review Final Determination Unclassified By: K. A. Walter Date: Aug. 6, 1980 T. F. Davis

~~RESTRICTED DATA~~

~~This document contains restricted data as defined in the Atomic Energy Act of 1954. Its contents in any manner to unauthorized persons is prohibited.~~

Issued: April 18, 1949

08016[illegible]52

R2331

[illegible] the transportation of [illegible] from Africa to Middlesex is not clear.

Subsequent processing of the ore yields a sludge (K-65) which contains the radium and the acid insolubles from the ore in concentrated form. [illegible] this sludge. It is stored by NYOO until requisitioned by the vendor, at which time overseas transfer of the materials is arranged. This sludge contains approximately 750-900 milligrams of radium per ton.

At Middlesex, the ore is dried, crushed, sampled, stored, and shipped as needed to the processing plants. Carload shipments of the material are made periodically to Plant 6, Mallinckrodt Chemical Works, which produces brown oxide (UO_2). This oxide is shipped 1) by truck to the nearby Plant 4 of the same company, 2) by rail to Harshaw Chemical Company (Cleveland) and 3) by rail to Linde Air Products (Buffalo). The radium bearing sludge mentioned above is derived from the extraction process at Plant 6 and has until recently been shipped by rail to Middlesex. Future shipments of the sludge will be to the Lake Ontario Ordnance Works.

Harshaw Chemical Company converts the brown oxide to green salt (UF_4) by hydrofluorination and then to UF_6 by fluorination. The UF_6 is transported from Harshaw to K-25 by Government truck at the current rate of approximately 90 tons per month. This operation is under the jurisdiction of ORO but the feasibility and economy of railroad transportation is now under discussion. If the latter form of transportation is adopted, the operation will be transferred to the jurisdiction of NYOO.

Linde Air Products Division of Union Carbide and Carbon Company converts the brown oxide to green salt which is then delivered by truck to the Electro Metallurgical Division at Niagara Falls. This plant,

MALLINCKRODT CHEMICAL COMPANY

This plant employs approximately 90 people in the conversion of brown oxide to green salt, and green salt to UF_6. Severe exposures to [illegible] dust containing [illegible] are [illegible]. A description of this plant process is given in Appendix I.

Beta Radiation. A thousand fold concentration of the beta activity of natural uranium occurs in the fluorination of green salt when the UF_6 volatilizes, leaving an "ash" having about 0.1% (one tenth per cent) of the original mass, but containing all of the UI_1-UI_2. The exposure record of this plant for the 200 weeks of its operation is summarized in Figure 8. The number of weeks of employment and the total reps as measured by film badges is indicated. It will be noted that more than half of the employees are exposed to a dosage rate of 500 millireps per week or greater. Eight of the employees have had total exposures in excess of 100 reps. The cumulative dose which is shown as total beta-gamma is largely beta (more than 95%). The exposure record for a representative 13 week period is shown in Figures 9 and 10.

The beta active ash is removed from the furnaces in trays which are handled manually with leather gloves for protection. Good quantitative information on hand exposure rates is not available but it can certainly be stated that beta irradiation of the hands, at the rate of several r per week, is occurring regularly among the 8 reactor furnace operators.

Alpha Dust. This plant has been thoroughly surveyed using the technique adopted for evaluation of dust hazards. The results of this study are summarized in Figure 11 which shows the estimated exposure by

compositions. Readings are reported in multiples of the preferred levels of 70 alpha disintegrations per minute per cubic meter. In this chart, [illegible] of employees [illegible] is noted in parentheses within each bar. It will be noted that [illegible] employees, except [illegible] are exposed to excessive dust levels. Thirty three of the 86 employees of this plant are exposed to dust concentrations which range from 140 to 570 times the preferred level. Table 5 shows the distribution of employees having varying periods of exposure, against the levels of dust exposure. It will be noted that many of the employees have had from 2 to more than 4 years of exposure to high levels of atmospheric contamination.

Prospects for Improvement

The nature of these processes is such that both the high levels of external beta radiation and atmospheric contamination are the result of a lack of proper mechanization. A very substantial improvement from the medical point of view is expected in about a year when drastic modification of the present process will be completed. "Continuous" reactors will replace the present batch processes, thereby eliminating manual handling which is the cause of most of the present high exposures to dust and beta radiation.

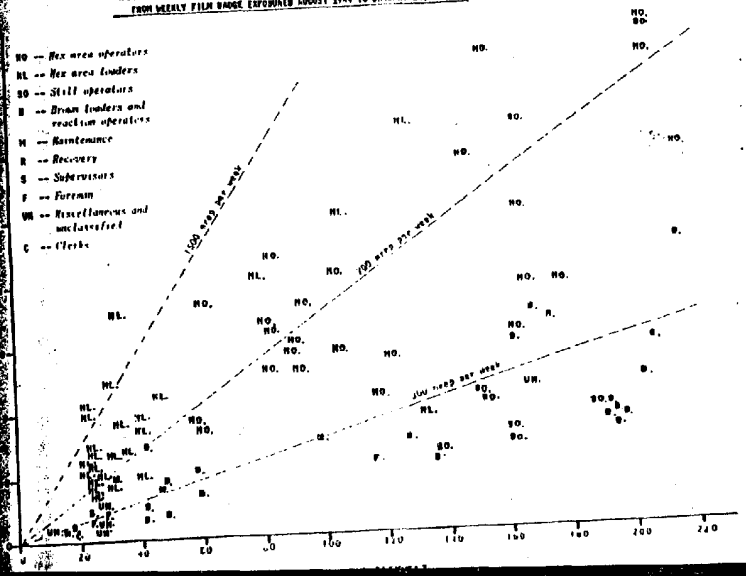
The morale in this plant has been low at both the employee and supervisory level. This has been reflected in careless working procedures and sloppy housekeeping. In January of this year, the plant management was reorganized and there has been a very substantial improvement in housekeeping and maintenance during the past month. Exposures of certain

FIG. 4

HARSHAW CHEMICAL COMPANY

ACCUMULATED DOSE AND DOSE RATE FOR PRESENT EMPLOYEES

FROM WEEKLY FILM BADGE EXPOSURES AUGUST 1944 TO JANUARY 24, 1949



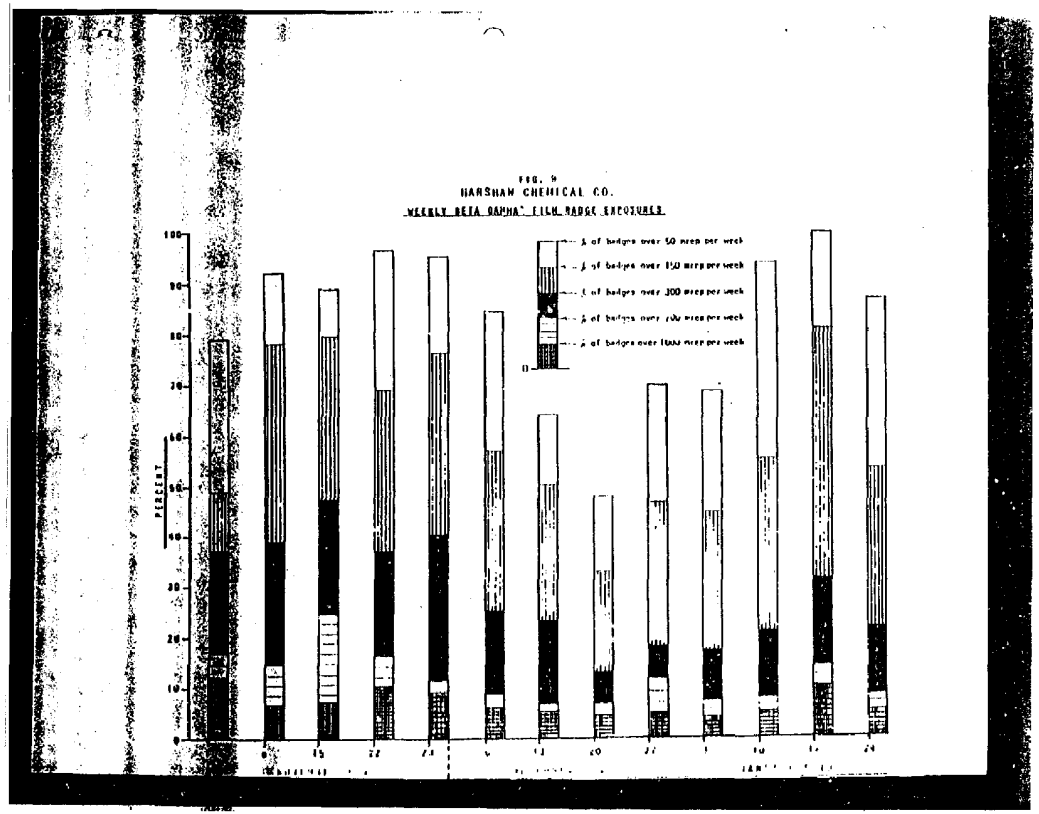


FIG. 9
HARSHAW CHEMICAL CO.
WEEKLY BETA GAMMA FILM BADGE EXPOSURES
% of badges over 50 mrem per week
% of badges over 150 mrem per week
% of badges over 300 mrem per week
% of badges over 500 mrem per week
% of badges over 1000 mrem per week
PERCENT
100
90
80
70
60
50
40
30
20
10
0
0
15
22
24
6
13
20
27
3
10
17
24

FIG. 19
HARSHAW CHEMICAL CO.
AVERAGE FILM BADGE EXPOSURES
APRIL 1954 TO JANUARY 23, 1956

MULTIPLES OF THE PREFERRED ALPHA LEVEL
LABORATORY
CLERKS (2)
MAINT. & REPAIR (2)
SUPERINTENDENT AND GENERAL FOREMAN (2)
FOREMEN & SUPERVISORS (3)
CLEANER (1)
HEX AREA OPERATOR (8)
REACTOR FURNACE OPERATOR (8)
STILL OPERATOR (8)
BROWN OXIDE LOADER #2 (8)
BROWN OXIDE LOADER #1 (8)
FUME RECOVERY ROOM OPERATOR (1)
HEX AREA LOADERS (24)
Number inside bars represents total Personnel of Occupation.
P.L. - Preferred Level
FIG. 11
HARSHAW CHEMICAL COMPANY
DISTRIBUTION OF OCCUPATIONS BY DUST CONCENTRATION LEVELS IN AREA "C"
SEPTEMBER 21-30, 1948

Table 5

HASSHAT CHEMICAL COMPANY

DISTRIBUTION OF EMPLOYEES BY LENGTH OF EMPLOYMENT AND LEVEL OF DUST EXPOSED

Mult. of Prof. Alpha Level	Number of Months of Exposure 0-6	6-12	12-24	24-36	36-48	>48	Total
0-1	1	2	2	0	1	1	7
1-5	1	1	0	0	2	0	4
5-25	0	5	5	12	10	11	43
25-125	0	0	0	0	0	0	0
>125	0	17	10	3	4	0	34
Total Personnel	2	25	17	15	17	12	88

operators have been restricted recently. Compared with previous data, considerable improvement has been noted. The results of this comparison are as follows:

Operator	Exposure (multiples of tolerance levels)	
	Sept. 1948	Feb. 1949
Brown oxide loader #1	185	100
Brown oxide loader #2	160	68
Reactor Furnace Operator	17	1.4

Process ventilation is grossly inadequate and industrial hygienists of the Medical Division have designed an improved ventilation system for which bids are now being prepared.

LINDE AIR PRODUCTS

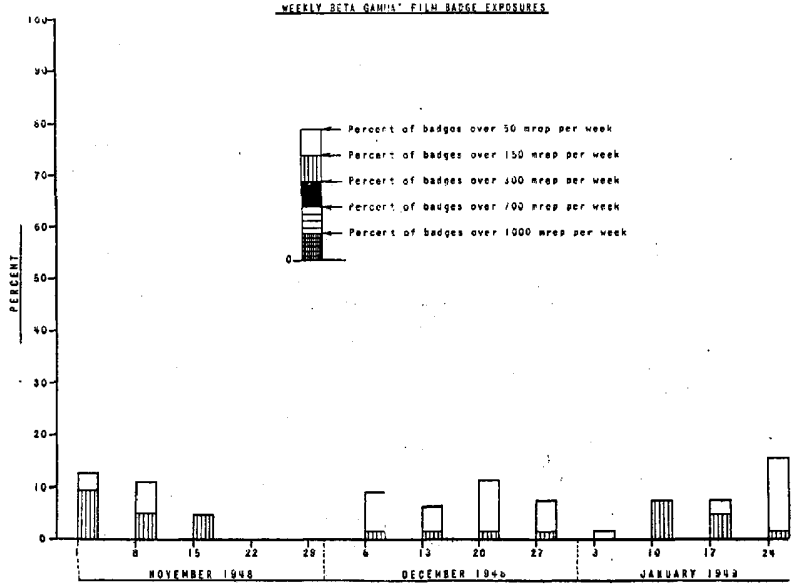
In this plant, which employs 85 men in the process area, there is low level exposure to beta radiation and a moderately severe uranium dust exposure. The plant process is described in Appendix I.

Exposure Data

Beta Radiation. The weekly film badge exposures at this plant are summarized in Figure 12. It will be noted that except for one badge, none were over 300 mrep/wk and most of the badges in this plant are consistently less than 50 mrep/wk. The whole body exposure to radiation in this plant is considered to be satisfactory.

Uranium Dust. This plant has been surveyed by the Industrial Hygiene Section and the findings are given in Figure 13. Fifteen employees are shown to be exposed to 33 times the preferred level of 70 alpha d/m per cubic meter of air. This dust is dispersed in operations such as the transfer of brown oxide to weighing drums, scooping the oxide onto trays, transfer of the trays to and from the green salt reactor, and other manual operations involving powdered uranium compounds. Recommendations giving means for reducing the dust concentrations have been submitted to the Production Division but uncertainties as to the future of this plant make it doubtful that any major plant improvements will be made. Minor changes are being made in the process area as a result of the recommendations. Although no definitive figures are available, the few results received to date indicate some improvement. It is expected that in 18 months or less this plant will be shut down and maintained in a stand-by condition. We have discussed with the Production Division the policy

FIG. 12
LINDE AIR PRODUCTS CO.
WEEKLY BETA GAMMA* FILM BADGE EXPOSURES



* over on percent Beta

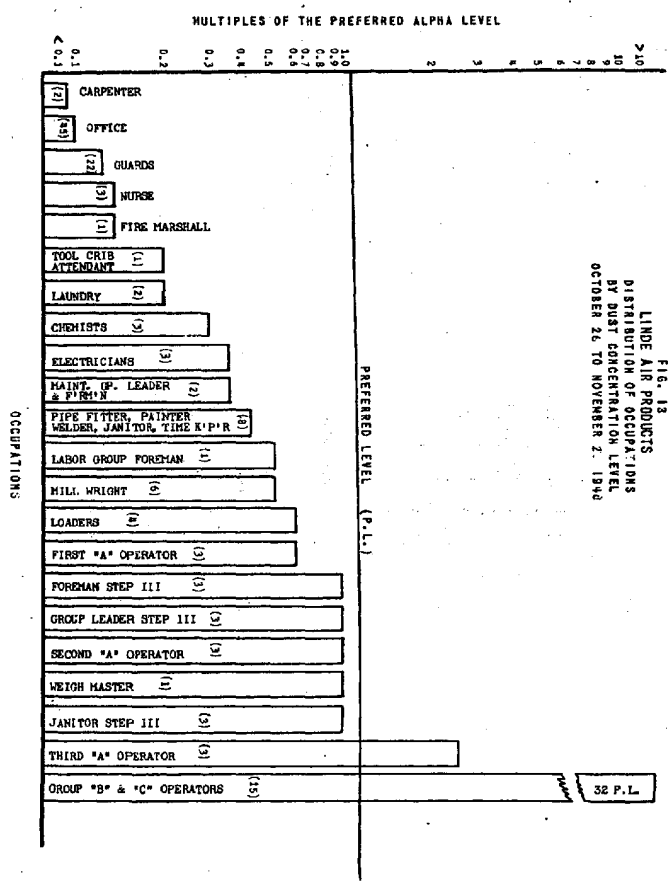


FIG. 13
LINDE AIR PRODUCTS
DISTRIBUTION OF OCCUPATIONS
BY DUST CONCENTRATION LEVEL
OCTOBER 26 TO NOVEMBER 2, 1940

question of whether sufficient changes should be made in facilities which are to be in stand-by status so that satisfactory standards of plant hygiene can be achieved if and when operations are resumed. No conclusion has been reached on this question.

ELECTRO METALLURGICAL COMPANY, DIVISION OF UNION CARBIDE & CARBON CO.

In this plant which employs approximately 50 men in the process area, there is a severe exposure to uranium dust and a moderately severe exposure to beta radiation. The plant process is described in Appendix I.

Exposure Data

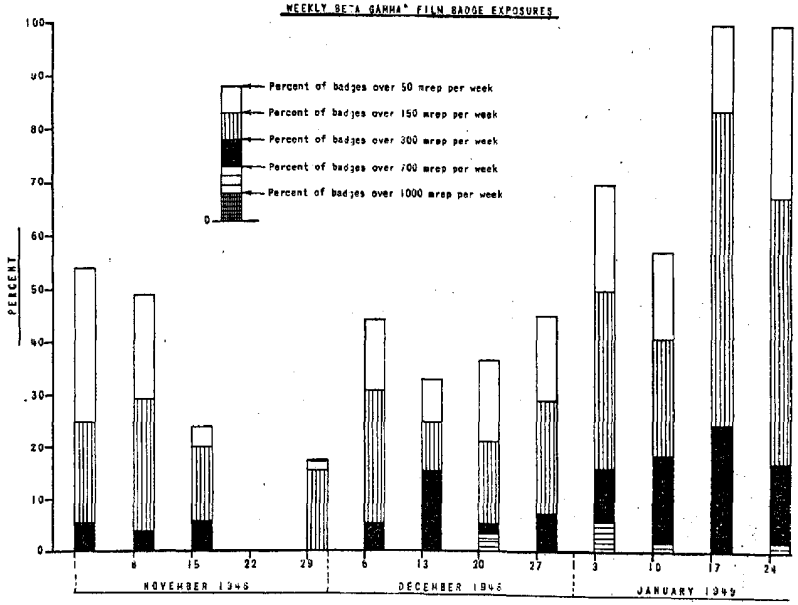
Beta Radiation. The beta activity of natural uranium is markedly concentrated in a way similar to that described at Mallinckrodt plant #6. The vacuum furnace in this plant is of a better design from a contamination control standpoint than those which have been in use at Mallinckrodt, because it has a condensing chamber which retains much of the volatilized impurities of the metal. In Figure 14, we have summarized the film badge data for a 13 week period. Occasional badges over 700 mrep will be noted. We have summarized the film badge data for 30 weeks from June 1948 through January 1949. These data indicate that 6 employees averaged 350 mrep/wk.

Uranium Dust. In November 1948, a thorough dust survey of this plant was done. Findings are given in Figure 15. It was found that the exposure of 70% of the plant was to concentrations less than 5 times the preferred level. Of these, 20 employees (30%) were exposed to less than the preferred level. Of the remaining personnel, 17 men were found to have exposures to radioactive dusts which ranged between 10 and 30 times the preferred level of 70 $d/m/m^3$. One group however was found to have an extreme exposure. This was the group comprising 3 men (4% of the plant total) engaged in the bomb loading operation. Concentrations at this location when weighted for an 8 hour exposure per day, revealed that

FIG. 14

ELECTRO METALLURGICAL CO.

WEEKLY BETA GAMMA* FILM BADGE EXPOSURES



* Approximately 75 percent Beta

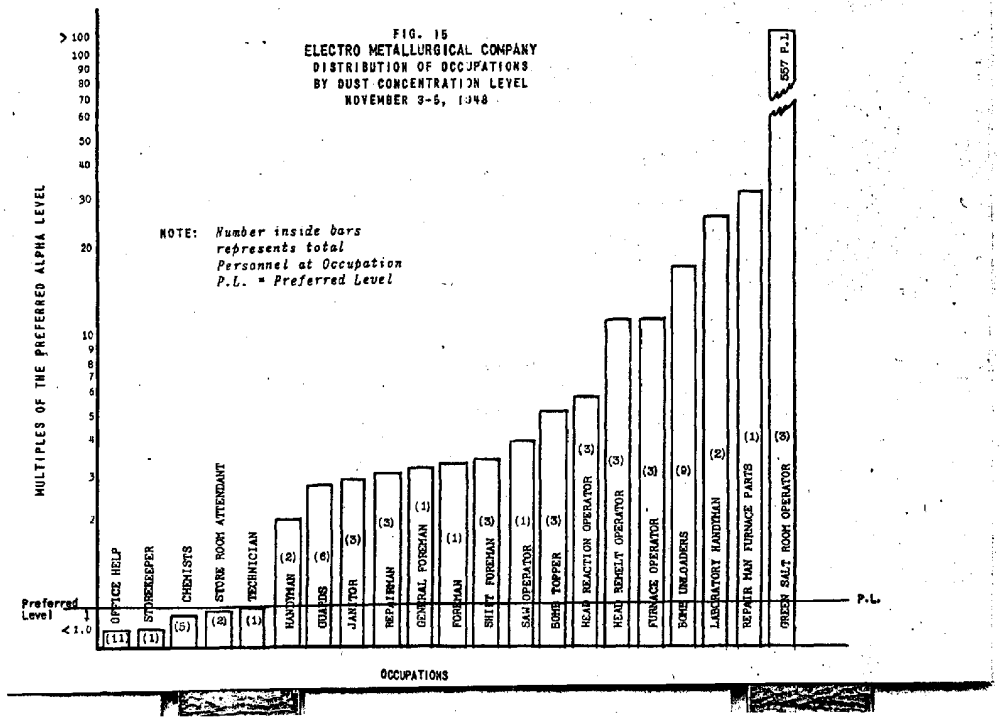


FIG. 15
ELECTRO METALLURGICAL COMPANY
DISTRIBUTION OF OCCUPATIONS
BY DUST CONCENTRATION LEVEL
NOVEMBER 3-5, 1948
NOTE: Number inside bars represents total Personnel at Occupation
P.L. = Preferred Level
MULTIPLES OF THE PREFERRED ALPHA LEVEL
> 100
100
90
80
70
60
50
40
30
20
10
9
8
7
6
5
4
3
2
Preferred Level
< 1.0
P.L.
557 P.L.
OFFICE HELP (11)
STOREKEEPER (1)
CHEMISTS (5)
STORE ROOM ATTENDANT (2)
TECHNICIAN (1)
HANDYMAN (2)
GUARDS (6)
JANITOR (3)
REPAIRMAN (3)
GENERAL FOREMAN (1)
FOREMAN (1)
SHIFT FOREMAN (3)
SAW OPERATOR (1)
BOMB TOPPER (3)
HEAD REACTION OPERATOR (3)
HEAD REHELT OPERATOR (3)
FURNACE OPERATOR (3)
BOMB UNLOADERS (9)
LABORATORY HANDYMAN (2)
REPAIR MAN FURNACE PARTS (1)
GREEN SALT ROOM OPERATOR (3)
OCCUPATIONS

these operators are exposed to almost 600 times the preferred alpha dust level. Although only 30% of the operating personnel are exposed to dust concentrations greater than 5 times the preferred level, this 30% includes almost the entire group of process workers. Of these, only the reactor operators and the bomb toppers are found to have less than 8 times the acceptable dust concentration. The rest of those exposed to the lower concentrations are technicians, storekeepers, office employees, guards, etc. This reflects one significant fact as opposed to conditions at some of the other plants. The areas in which operations are not being carried out are relatively clean, and a reasonably good maintenance and clean-up schedule is maintained.

As in the case of Linde, this plant is not expected to be in operation longer than another 13 months. In order to provide for adequate dust control, a substantial sum of money ($50,000 to $100,000) would have to be spent. As before, whether or not extensive dust exposures are corrected will depend on policy decision as to the advisability of spending funds for the purpose of placing stand-by plants in satisfactory medical condition.

During the next few months, minor changes in process ventilation can be expected to alleviate the dust exposure to some extent.

SIMONDS SAW & STEEL CO. AND VULCAN CRUCIBLE STEEL CO.

These plants are commercial steel mills which have contracted for the rolling of uranium metal from Mallinckrodt and Electro Metallurgical. Rolling is performed in the plants about 5-7 days a month.

The processes are described in Appendix I. Because of the pyrophoric character of uranium, this operation results in profuse atmospheric contamination. In addition to the fuming of the cherry-hot billets, continuous oxidation produces a scale which consistently spalls from the billets. This material after falling to the floor is ground to dust by the heavy foot traffic incidental to the rolling operation.

In order to satisfy Hanford's urgent need for rolled metal, it was necessary to begin operations before suitable controls could be installed.

Exposure Data

Operations at Simonds Saw and Steel Company have been in progress since March 1948. Several surveys to determine the effectiveness of control procedures have been completed, as summarized in the following table:

Table 6

SUMMARY OF WEIGHTED DAILY EXPOSURES

Operator	No. of Employees	Multiples Prof. Level for Continuous Exposure 10/27/48*	12/1/48**	1/10/49***
Foreman	2	25	13	5
West Rollers	8	17	13	4
East Rollers	8	155	28	13
Quench and Scarp	6	25	10	28
Furnace Operator	4	8	4	1.4
Drag-down	2	9	10	1.6

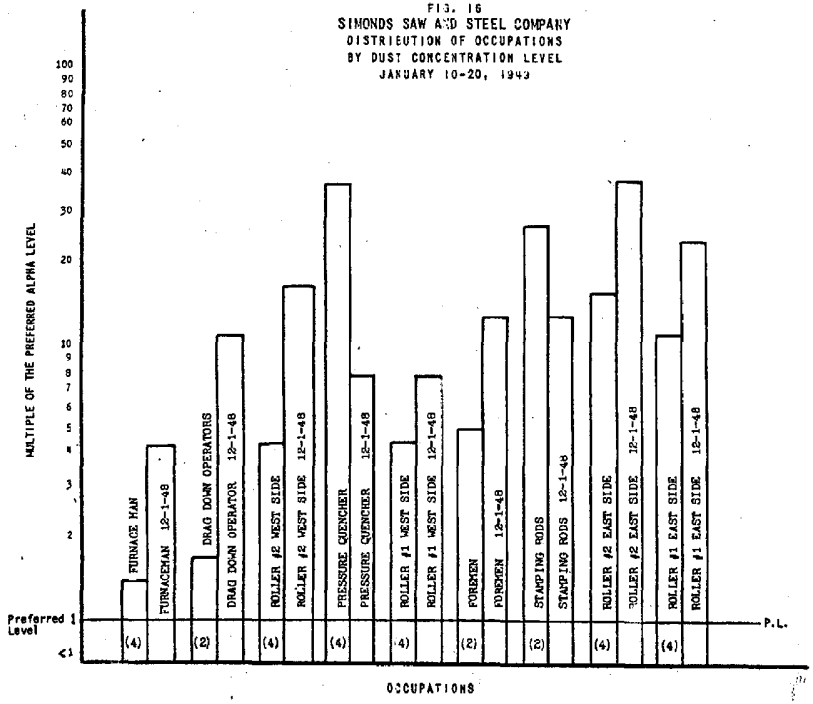
(The preferred level for continuous exposure is 70 alpha d/m/m3)

* No dust control measures.

** Vacuum cleaner, and exhausts for rolls installed.

*** Exhaust for descaler installed.

FIG. 16
SIMONDS SAW AND STEEL COMPANY
DISTRIBUTION OF OCCUPATIONS
BY DUST CONCENTRATION LEVEL
JANUARY 10-20, 1949



The improvement demonstrated by the above data is a result of the control measures indicated by the footnotes to Table 6. The most recent exposure data are shown on Figure 16.

Vulcan Crucible Steel Company has been rolling uranium since September 1948. Dust levels in this past have been found to be somewhat higher in general than those at Simonds, and the rollers are exposed to concentrations markedly in excess of similar operators at the former plant. (Figure 17.)

The question of closing out this contract is being discussed at present.

THE TRANSPORTATION OF MATERIAL BETWEEN PLANTS

The interplant transportation of radioactive materials is of considerable concern to us. The biggest problem is the shipment of ore from Middlesex to St. Louis and return shipments of K-65. In the past, shipments of K-65 containing as much as 200 grams of radium have been transported by railroad from St. Louis to Jersey City, thence by barge across New York Harbor to Brooklyn. In the future, shipments will be made between St. Louis and Lake Ontario Ordnance Works at the rate of approximately 60 grams of radium per month.

Until six months ago, these shipments were made in cattle cars but within the past year the New York Office has purchased 10 freight cars which are used exclusively for the transportation of ore and K-65. The material is shipped in drums but the possibility exists that a major train wreck would distribute large amounts of radium bearing materials along the right of way, possibly contaminating water supplies.

Radiation levels from carloads of K-65 are shown in Figures 20 and 21. These levels are in excess of those permitted under existing regulations and shipments are currently being made under special permits granted by the I. C. C.

Contact has been established between this office and the American Association of Railroads for the purpose of establishing emergency procedures in the event of a train wreck.

By special arrangements with the American Association of Railroads, carload shipments of film are transported by routes different from those used by us in shipping ore and radium bearing sludge.

deposition of this material in the lungs, and its subsequent distribution and excretion. One is not necessarily related to the other, because of large physiological differences in breathing rates, alveolar retention, lymphatic drainage and other factors. We believe our estimates of exposure would have more meaning if our observations could be made on the man rather than on his environment. To this end, we have embarked on an intensive effort to use urinary excretion of uranium as an indication of exposure. We have begun to collect urine samples under controlled conditions and are correlating the urinary excretion with levels of dust exposure. The various uranium compounds of project significance are being studied in this way.

We have not as yet seen clinical evidence of either chemical intoxication or radiological injury from uranium. However, should symptoms appear in the future it will be important to correlate such findings with levels of exposure as measured by both air analyses and urinary excretion.

3. Record of Exposure to Radioactive Dust:

Our methods of compiling estimates of exposure to radioactive dust are such that it will be possible to include a record of cumulative dust exposure as part of the medical history of the employee.

In reviewing the present records of the various plants we find, in most cases, insufficient information as to the

NEED FOR FURTHER INFORMATION

A number of aspects of the health and safety problems in these plants require further study.

1. Local Radiation Exposure:

The considerable amount of manual handling in these plants makes it likely that local exposure to the hands is in many cases several times greater than the estimate of whole body radiation provided by film badges. Such is probably the case, for example, at Harshaw Chemical Company, where much of the 1r. or so of whole body beta exposure to the reactor operators originates in the manual handling of trays of ash having high specific beta activity. Similarly, at Mallinckrodt Chemical Works and Electro-Metallurgical Company, manual contact with beta active residue of the vacuum furnaces provides opportunity for hand irradiation of a greater magnitude than whole body. Film rings have been made available during the past three weeks and are now being worn by selected groups for estimation of hand exposure.

2. Validity of Dust Exposure Estimates:

Our estimates of exposure to radioactive dust are based on data collected by experienced industrial hygienists on the staff of the Medical Division and represent the best available technique for obtaining data of this kind. However, we do recognize the fact that we are estimating the dust concentration in air, whereas our real interest is in the

Table 7 - continued

Plant	Waste	Quantity of Waste	Radioactive Contamination	Disposal
Simonds Saw (continued)	Water from quenching rods	Unknown	Unknown	To sewer, ultimate disposal unknown.
Vitro Manufacturing Company	Liquid wastes from U recovery	Unknown	Unknown	Part through waste pipe to swampy area east of plant and on the bank of Chartiers Creek. Part through open ditch to same area.
	Solid wastes from recovery process and from former radium manufacture	Unknown	Unknown	Stored on east side of plant property.

Table 7 - continued

Plant	Waste	Quantity of Waste	Radioactive Contamination	Disposal
Harshaw (cont'd)	Condenser water	Unknown	Normally none	Through drain pipe to Cuyahoga River.
	Residue from hexa-fluoride process	2000 gal/day	High in UX_1-UX_2	Stored at Lake Ontario Ordnance Works.
	Scrap metal	Small	Unknown	Past disposal not known. Will be stored pending establishment of disposal procedure and standards.
Linde Air Products Company	Floor drainage	Small Floors washed weekly	Unknown amt. U from green salt process	To Dorr thickener. Effluent to Tonawanda sewer system. No sludge yet removed from thickener.
	Laundry wastes	16500 gal/day	5ppm or less of U	To same Dorr thickener.
	Condenser water from HF recovery	Unknown	Normally none	Direct to Tonawanda sewer.
	Scrap	Unknown	Unknown	Stored at Lake Ontario Ordnance Works.
Electro-Metallurgical Co.	Waste from floor drains, toilets and laboratory sinks	Small. Floors not washed	Unknown	To Niagara Falls Sewer.
	Slag	OK 1/8/21 ~~70000 lbs/mo.~~	Unknown	Stored at Lake Ontario Ordnance Works.
	Graphite	~~3500 lbs/mo.~~	Unknown	Stored at Lake Ontario Ordnance Works.
Simonds Saw & Steel Co.	Scale from rolling of billets	Few lbs per billet	High. Waste is mainly uranium oxide	Removed from floor by vacuum and treated for uranium recovery.

(Continued)

Table [illegible]

LIQUID AND SOLID WASTES

Plant	Waste	Quantity of Waste	Radioactive Contamination	Disposal
Ferry Warehouse	Floor flushing and laundry wastes	Unknown	Unknown	Through drainage system and ditch to small tributary of Raritan River. Floor flushing wastes will be treated by sedimentation and laundry wastes by chemical coagulation and sedimentation. Sludges will be barged to sea.
	Open paved area drainage	Unknown	Unknown	Part to drainage collection system. Part flows direct to adjacent property. It is believed this portion should also be collected in drainage systems.
	Ash from burning trash	Small	Unknown	Barged to sea.
Mallinckrodt Chemical Works	Alkaline filtrate	3,000,000 gal/day	0.0020% U	Through drain pipe to Mississippi River.
	Acid Waste	Small	Unknown	Through drain pipe to Mississippi River.
	Solid K-65	6000-12000 lbs/day	0.2% U, 750 mg/ton Ra	Stored in drums at airport storage site (St. Louis).
	Solid AJ-4	6800 lbs/day	0.1% U, 1 mg/ton Ra	Open storage at airport.
	Solid AM-7	13000 lbs/day	0.2% U	Open storage at airport.
	Scrap metal	Unknown	Unknown	Stored at airport.
	Trash	Unknown	Unknown	Stored at airport.
Harshaw Chemical Company	Filtered floor drainage	150 gal/day	Unknown - probably low	Through drain pipe to Cuyahoga River a few miles above Lake Erie.

(Continued)

- 49 -

542

survey showed some spread of contamination. When study of the analytical results is completed, it may reveal the necessity for further sampling.

presumed to be of the order of background. (A control sample from a point 25 miles from New York City contained 4.97×10^{-11} grams per gram.) A mud sample from Four Mile Creek, which receives drainage from the storage area, contained 4.11×10^{-11} grams per gram. Two mud samples from the main drainage ditch, at the point where it leaves government property contained 3.22×10^{-11} and 3.4×10^{-11} grams of radium per gram of mud.

A sample of silt from the bank of Four Mile Creek contained 0.07 micrograms of uranium per gram. Three mud samples from the main drainage ditch inside the property contained 0.12, 0.10 and 0.04 micrograms per gram. Of sixteen soil samples taken between the boundary and five miles outside of it, four contained 0.13, 0.11, 0.08 and 0.06 micrograms per gram, respectively, and the other eleven results were 0.03 or less. (It was reported that 0.03 was the limit of sensitivity of the analytical method.)

Although tests made so far have not demonstrated contamination outside the government owned area, it is proposed to take enough additional samples so that the spread of contamination can be mapped and monitored. We also hope to be able to refine the method for determining uranium in soils to the point where background quantities can be detected.

Haiste Property

This is an area in Tonawanda which was used for the storage of solid wastes arising from previous Linde operations with Colorado feed materials. Only minute amounts of radium plus uranium and vanadium should be present in these wastes stored in piles on the ground. A soil sampling

pass through a waste pipe and part through an open ditch to a swampy area east of the plant property and on the bank of Chartiers Creek. Surface drainage from a storage yard also flows to this area. There are old piles of sludge from former radium manufacture in the storage yard. We made a preliminary survey of this area and found gamma radiation levels up to 3 mr/hr. A preliminary investigation was also made by Dr. Bruce Wallace of the Long Island Biological Association to determine whether a study of biological accumulation of radioactive materials and the effect of radiation on the life of the area would be feasible. This may be followed up in more detail if consultants so advise. It is further proposed to make a uranium-radium survey of the soil and the surface water and to extend it far enough from the plant to determine fall-off to background. The possibility of making a geological and ground water study is also being considered.

Lake Ontario Ordnance Works

Scrap, slag from uranium metal manufacture and other solid wastes are stored at this site. In the future, all of the Mallinckrodt Chemical Works E-35 will be stored here. The Geological Survey performed a ground water survey of this area but their report has not been received as yet. A survey conducted by this Division shows some ground contamination within the site.

Fifteen soil samples taken outside the grounds, from the boundary to a distance of five miles, ranged in radium content from 1×10^{-12} to 9.56×10^{-11} grams per gram. The average was 2.35×10^{-11}. The results did not show any significant relation to distance and are therefore

indicate the need for a survey of ground and ground water contamination.

Electro-Metallurgical Company

Floor drains, toilets and laboratory sinks are connected to the Niagara Falls sewer, but floors are not washed and clothing is laundered at the Linde plant. Consequently, there is little liquid waste.

Solid wastes and by-products include:

1500 pounds a month of ash containing about 40% uranium, from burning of sweepings, chippings and trash. This is shipped to the Vitro Manufacturing Company in drums.

35,000 pounds a month of rich slag containing 2% uranium is shipped to the Vitro Manufacturing Company in drums.

70,000 pounds a month of lean slag is stored at Lake Ontario Ordnance Works.

5000 pounds a month of crucible dross and other oxide scrap is shipped to the Mallinckrodt Chemical Works in drums.

About 3500 pounds a month of contaminated graphite is stored at Lake Ontario Ordnance Works.

Tests have been made confined to monitoring of scrap. No other tests are planned.

Simonds Saw & Steel Company and Vulcan Crucible Steel Company

Scale from the rolling of billets is recovered by a vacuum system. Water from quenching the rods and a small amount of contaminated scrap stored at Lake Ontario Ordnance Works are believed to be the only other contaminated wastes. The water goes to a sewer. It is planned to determine the uranium content and the point of disposal of this waste water. No work along these lines as yet has been done.

Vitro Manufacturing Company

Liquid wastes arise from uranium recovery processes. Part of these

concentrations in the water were from 0.000 to 0.006 micrograms per c.c. Both water and soil samples were too few for accurate determination. Samples from the drain pipe contained 1.2, 2.5 and 0.5 micrograms of uranium per c.c.

It is proposed to take enough samples for an accurate determination and to explore farther upstream to obtain background data. Monitoring the condenser water is also being considered.

Linde Air Products

Floors are vacuumed to recover uranium oxide and green salt. They are washed about once a week. Floor drainage and laundry wastes go to a Dorr thickener and thence to the Tonawanda sewer system. The effluent amounts to about 16,500 gallons a day, mostly from the laundry, and contains 5 ppm or less of uranium, according to tests made over a seven month period in the Linde laboratory. The sludge has never been removed from the thickener.

Condenser water from an HF recovery process goes direct to the sewer. It is not monitored but the recovered HF was found free of detectable contamination. The chance of serious contamination of the HF coinciding with condenser leakage and remaining undiscovered long enough to introduce considerable contamination to the sewer appears remote. The hydrous HF recovered is shipped to the HF vendor.

Contaminated scrap is stored at Lake Ontario Ordnance Works.

It is proposed to monitor the effluent from the Dorr thickener periodically. The Geological Survey has included the neighborhood of the Linde plant in a ground water study and their report may or may not

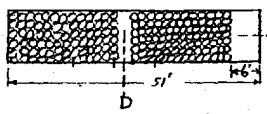
In the shipping of brown oxide and uranium metal, AEC owned cars are not used. Although each of the sites makes an effort to decontaminate the cars before returning them to the railroad, the cars are invariably returned with residual contamination. This subject is one which has not been investigated thoroughly by us. However, decontamination does not usually succeed in reducing the car interiors to below 2500 d/m/100 cm^2. We are of the opinion that it will be necessary to apply strippable coatings to the interiors of railroad cars which are used for the transportation of such material.

FIG. 21

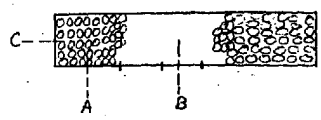
RADIATION FROM K-65 AND Q-11 BOXCARS

Taken 12/28/48

96 Drums of K-65
Car 206 - Shipment 63



87 Drums of Q-11
Lot 63



Distance From Car in Feet	mr/hr Perpendicular To Center of Load
1 4.1' up	85
3	72.5
5	50
8	37.5
12	27
18	19
24	12.5
30	9.4

3 ft. Under Center of Car
L & W = 96 mr/hr
Zeus = 105 mr/hr
3.5' from Floor To rail

3 ft. From empty end
L & W = 5 mr/hr

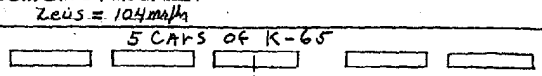
Center of Roof
Zeus = 104 mr/hr

Distance From Car in Feet	mr/hr Along A	mr/hr Along B	mr/hr Along C
2	37	7.75	24
4	24	8.75	
6	18	9.	9.5
8	16	9.5	
10	14	9.7	6.6
12	12	9.7	
14	10.5	9.5	5.5
16	9	8.5	

3 ft. Under center of Car
L & W = 4.5 mr/hr
3 ft. Under center of Load
L & W = 25 mr/hr

Readings on roof - Zeus
Center of Car = 11
End of Car = 21

5 CARS OF K-65

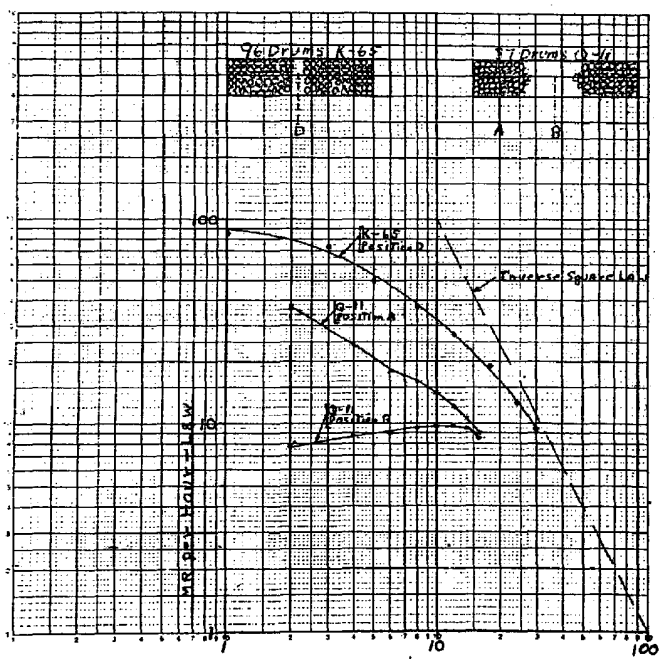


Distance From Car in Feet	mr/hr ⊥ To middle car
10	50
25	22
43	13
50	10.2

FIG. 20

RADIATION FROM K-65 AND G-11 BOXCAR

Taken 12/28/48



DISTANCE FROM SURFACE OF CAR IN FEET

specific job histories of the employees. The men were transferred from one department to another and no record made of the fact. It will, therefore, be impossible, without relying on the memory of the individual employees and their foremen, to reconstruct the dust exposure records of many present employees.

4. Educational Program:

It is important that an educational program, at the workers' level, be designed around the special problems in radiological safety which exists in these plants. Except for one location, no effort has been made to explain the nature of the special problems which exist. There appears to be no insurmountable security problem involved in establishing such a program but there has been considerable hesitation in obtaining general agreement that such a program should be actually pursued under present conditions.

DISCUSSION

It is clear that the activities of the producing plants within the New York Operations office have produced a reservoir of individuals who have had considerable exposure to uranium dust, both soluble and insoluble. This large reservoir of potential damage should, if at all possible, be followed carefully in the future. This raises considerable difficulty, since the bulk of these employees will not be employed by present contractors indefinitely and the mechanism for establishing such a follow-up is not clear. Unless this is done, however, there could be a considerable lag between the appearance of disease conditions and the recognition of their etiology.

The expectation held during the war that pressure of production requirements would be diminished with the cessation of hostilities has not materialized. The decision must therefore be made to provide satisfactory operating conditions despite existing operational pressures. If this is not done, it will be necessary to classify at least some of the operations within these plants as being extra-hazardous in nature. This of course means numerous concomitant complications, such as difficulty in securing individuals for the job if full recognition is given to its extra-hazardous nature, and insurance difficulties. It is particularly important to make these changes as rapidly as possible if it is anticipated that reclaimed metal will be used as feed material.

The design recommendations of the Medical Division are based on operating experience and an effort has been made to keep costs to a

minimum. It therefore must be anticipated that the original designs will require some modification after operating experience is obtained. This method of procedure appears more logical to us than assuring safe results by overdesigning ventilation systems, enclosure of operations, remote control, etc.

Since, in animal experimentation, it has been demonstrated that kidney pathological changes may exist without clinical evidence and since radiation damage is delayed in appearance, it is necessary to base criteria of potential danger for a particular individual on either (1) knowledge of his exposure or better, (2) uranium analyses on urine (and perhaps blood and feces). One of the chief tasks of this office will be that of trying to understand such uranium analyses in biological material so that "levels" of danger may be established on a logical basis.

SUMMARY

1. This report summarizes our knowledge to date of the medical problems associated with the operation of eight chemical plants which, under contract with MDC, produce uranium compounds from pitchblende.

2. Approximately 660 people are presently employed in these plants. The total number of people who have been employed in these plants now and in the past for periods 1) longer than two months is 3,018 and 2) longer than 1 year is 1,585.

3. The most serious health hazard, common in more or less degree to all of the plants, is that of over-exposure to radioactive dust. Our estimates of exposure are based on detailed studies which provided weighted average daily exposure. In Table 6, the dust exposures in these plants are summarized. The average daily exposure of 60 people is more than 125 times the preferred level of 70 alpha disintegrations per minute per cubic meter of air.

4. Excessive radiation exposures exist in process steps where there is marked separation and concentration of activities in the uranium series. Specifically,

a). Mallinckrodt Chemical Works processes pitchblende having a radium content of about 100 grams per month. This radium is concentrated in a sludge containing about 750 milligrams of radium per ton. The handling and storage of this sludge involves a radon hazard and a severe gamma radiation hazard.

b). The fluorination of green salt at Harshaw Chemical Company produces a residue of approximately 2000 grams per day having

Table 8

SUMMARY OF AVERAGE DAILY EXPOSURE TO ALPHA EMITTING DUST AT SEVEN URANIUM PLANTS

Uranium Plants	(Multiples of P.L.)* 0-1	1-5	5-25	25-125	125	Total
Mallinckrodt Chemical Works						
Plant # 6	53 (31%)**	73 (43%)	24 (14%)	2 (1%)	18 (11%)	170
Plant # 4	11 (14%)	7 (9%)	27 (35%)	30 (39%)	2 (3%)	77
Harshaw Chemical Company	9 (9%)	11 (11%)	45 (46%)	0	33 (34%)	98
Linde Air Products	119 (87%)	3 (2%)	0	15 (11%)	0	137
Electro-Metallurgical	19 (28%)	21 (31%)	21 (31%)	3 (5%)	3 (5%)	67
Simonds Saw & Steel (Jan.'48)	0	16 (53%)	8 (27%)	6 (20%)	0	30
Vulcan Crucible Steel	0	4 (16%)	17 (68%)	0	4 (16%)	25
Vitro Manufacturing Company	23 (52%)	16 (36%)	4 (9%)	1 (3%)	0	44
Totals	234 (36%)	151 (23%)	146 (23%)	57 (9%)	60 (9%)	648

*P.L. = Preferred level for alpha emitting dust = 50 μg of uranium/m^3 = 70 d/m/m^3 on the average for an 8 hour work day.

** The first figure denotes number of personnel. The second, in parenthesis, expresses the first as a percentage of total in the last column.

[redacted]. Employees in the vicinity of this operation are exposed to whole body beta radiation, approximating 1r. per week, and have been for as long as three years. A summary of film badge results, for a typical 13 week period, is given in Table 9.

c) Recasting of metal at both Mallinckrodt Chemical Works (plant #4) and Electro Metallurgical produces a separation of UX_1+UX_2 causing excessive beta exposure to personnel at these operations.

5. The transportation of large quantities of radium bearing sludges (as much as 150 grams of radium per shipment) presents the possibility of dangerous contamination of water ways in the event of a major transportation wreck.

6. It is contemplated that in the next two years, at least 2000 grams of radium will be contained in the sludges being stored in drums at Lake Ontario Ordnance Works. The storage of this sludge appears to be the major disposal problem existing in the uranium processing chain.

7. Recommendations, intended to correct conditions found to be unsatisfactory, have been submitted by the Medical Division, NYOO. The Medical Division, has had excellent cooperation from other divisions and contractors in implementation of these recommendations, but in several cases, necessary improvements have been postponed or delayed 1) by policy problems, such as whether a plant will continue in operation, 2) by awaiting contemplated basic changes in process methods, 3) by lack of knowledge of the extent and type of future operations, 4) by budgetary limitations and 5) by the pressure on the New York Operations Office to

Table 9

NUMBER OF WEEKLY FILM BADGE EXPOSURES AT HYOO SITES

(based on 13 weeks from Nov. 1, 1948 to Jan. 24, 1949)

Plant	No. Badges worn/wk	No. over 50 mrep/wk	No. over 150 mrep/wk	No. over 300 mrep/wk	No. over 700 mrep/wk	No. over 1000 mrep/wk	No. over 1500 mrep/wk	Remarks
Middlesex	59	52	40	19	4	1	-	65% Gamma
Mallinckrodt								
Plant 4:								
Beta	91	83	35	17	8	5	2	Beta only
Gamma	91	8	2	-	-	-	-	Gamma only
Plant 6:								
Beta	267	124	16	1	-	-	-	Beta only
Gamma	267	103	47	17	-	-	-	Gamma only
Harshaw	91	75	54	26	10	6	3	Over 95% beta
Linde	65	5	2	-	-	-	-	" " "
Electro Mat	50	26	18	5	1	-	-	75% beta
Vitro	50	37	19	1	-	-	-	60% gamma

Total No. of Film Badges: 673
No. over 150 mr/week (beta and gamma): 252 (37.5%)
No. over 300 mr/week (beta and gamma): 105 (15.6%)

take on short-term jobs without delay (rolling operation). The status of the major plant revisions is given in Table 10.

Table 10

SUMMARY OF PRINCIPAL CHANGES BEING CONTEMPLATED

(UYOO URANIUM PRODUCING AND PROCESSING FACILITIES)

Plant	Types of Exposure	Proposed Change	Expected Completion	Remarks
Middlesex	1. Radioactive dust (alpha emitting)	Vent. and encls. for a. conveyor b. crushing pit c. sampler	July 1, 1949	Recs. submitted. Held up pending decision as to approval of site.
	2. Beta, gamma radiation	a. Elimination of K65 handling b. Shield for hopper & conveyor c. Revised drum handling	May 1, 1949 July 1, 1949 Under discussion	
	3. Radon	Vent. of freight cars	Completed	
Mallinckrodt Chem. Works Plant # 4:				
a. Metal Plant	1. Radioactive dust	a. Vent. of bomb stop & burnout	June 1	New metal plant to replace present unit about Jan. 1950.
	2. Beta radiation			Vent. for recasting furnaces will markedly improve beta exposure at this operation.
b. Green Step	1. Radioactive dust	a. Redesign green handling b. " brown loading c. Central vacuum system	June 15 July 1 Under discussion	Green step to be discontinued in about 18 mos.

(Continued)

Table 10 continued

Plant	Types of Exposure	Proposed Change	Expected Completion	Remarks
Plant # 6:	1. Beta, gamma radiation	a. Ore room shielding	Completed 2/19/49	
		b. Remote control for filters	April 1949	Almost completed
		c. K65 centrifuge shielding	" "	" "
		d. Shield tanks	In progress	75% completed
		e. C-3 cell block shielding	April 1949	Almost completed
		f. Revise ore house weighing	Completed	
	2. Radioactive dust	a. Ore room dust control	Completed 3/15/49	
		b. Brown oxide handling	7/1/49	
		c. Orange handling	4/15/49	
		d. Central vacuum system	Under discussion	
	3. Radon	a. Ore car ventilation	Completed	
		b. Ventilate ore drying oven		Steel delivery delayed
Harshaw Chemical Co.	1. Radioactive dust	a. Central vacuum system		Recs. submitted
		b. Continuous green salt reactor	1/1/50	Designs complete
		c. Improve present vent system	Completed	Recs. submitted 6/48
		d. Stack gas decontamination	July 1, 1949	" " "
		e. Mechanization of present green salt reactor	No action expected	Req. made 4/30/48
	2. Beta radiation			The continuous green salt reactor will reduce beta exposure markedly
Linde Air Products Div. Union Carbide & Carbon Co.	1. Radioactive dust	a. Modify brown & green hoods	Under discussion	This plant will probably not operate for more than 18 mos.
		b. Enclose & ventilate blender	" "	
		c. Central vacuum system		

(Continued)

Table 10 continued

Plant	Types of Exposure	Proposed Change	Expected Completion	Remarks
Electrometallurgical Div. U.C. & C. Co.	1. Radioactive dust	a. Revise vent. in green room	Under discussion	This plant will probably not operate for more than 18 mos.
		b. Revise burnout hood	Completed	
		c. Central vacuum cleaner	Under discussion	
		d. Exhaust sampling lab.	" "	
	2. Beta radiation	a. Pneumatic foot cover for furnaces	Almost complete	
		b. Shielding for crucibles, etc.	" "	
Simonds Saw & Steel Co.	1. Radioactive dust	a. Hood & ventilating rolls	Complete	Resurvey with controls completed
		b. Install central vacuum	"	
		c. Lay floor grating	"	
		d. Ventilate descaling	"	
		e. Install dust collector in hoods	May 1	Contract let
Vitro Mfg. Co.	1. Radioactive dust			Plant process now being revised

green uranium tetrafluoride which is produced in this process is then dumped into drums which are transported to another location for loading into the "hex" reactors. The reactor trays are loaded manually and placed within the reactors for fluorination. This converts the uranium tetrafluoride into the hexafluoride which is condensed in water cooled receivers. The tail gas from these receivers is passed through a dry ice trap to remove residual UF_6. A residual ash remains in the trays and is vacuum conveyed to a dust collector. The ice traps are removed to a still room where the impure hexafluoride is distilled into cylinders for shipment by government truck to K-25.

7. Linde Air Products - Ceramics Plant

Carload shipments of brown oxide are received in fibre containers from the Mallinckrodt Chemical Works. This material is transferred to a weighing drum and is manually loaded into magnesium trays for hydrofluorination. The trays are transferred to movable racks and loaded directly into the reaction furnaces. After hydrofluorination, the trays of UF_4 are removed from the furnace, replaced in the movable racks and transported to another location where they are dumped into a portable hopper. After the hopper has been filled, it is elevated mechanically to the top of a micro-pulverizer from which the material feeds into a blender and is tumbled. Following this, the material is discharged into small steel drums and sealed for shipment to Electro-Metallurgical Company.

F. Electro-Metallurgical Company

This plant receives its material by truck from Linde, which is located almost 20 miles away. Green salt is received at this plant and is converted into uranium metal billets using a process which is identical to that used at the Mallinckrodt metal plant.

G. Simonds Saw & Steel Company and Vulcan Crucible Steel Company

The uranium billets from the Mallinckrodt Chemical Works and the Electro-Metallurgical Company are shipped by rail to these plants for rolling. The billets are heated to the proper temperature in a soaking furnace and manually transported to the rolls. Here they are passed through roughing and finishing rolls for a sufficient number of passes to reduce the diameter of the billets to form rods of a size which is desirable for the fabrication of slugs. These rods are then shipped by rail to Hanford.

H. Vitro Manufacturing Company

Scrap material packed in drums is brought into the plant on electric trucks, weighed and dumped into a wet ball mill. After milling for an hour, the slurry which is formed is digested, treated with acid and pumped to outside storage tanks for cooling. The cooled acid slurry is pumped to a neutralizing tank, where it is treated with sodium carbonate to precipitate the impurities. These impurities are filtered out in a filter press and the cake, called "iron cake", is repulped and refiltered. This residue, after sampling and assaying, is discarded to a stockpile outside of the fenced area.

The filtrate liquors are treated with caustic to precipitate

APPENDIX II

METHOD OF ESTIMATING EXPOSURE TO RADIOACTIVE DUST

Because of the severity of our dust exposures, we have deemed it advisable to establish special procedures for the evaluation of atmospheric dust concentrations. In general, we follow the customary technique of collecting our samples on filter paper at a known rate of flow. The samples are then assayed for alpha activity in a parallel plate chamber.

In all of our plants, except one (Middlesex Warehouse), we have preceded our dust surveys with time studies which give us an operational breakdown for each job in the plant. Dust samples are then collected from the workers breathing zone, and the general workroom air in such a way as to provide an estimate of the exposure for each job component. By properly weighting the samples with respect to time, we are then able to obtain the average daily concentration to which the various employees are exposed. An example of the method is given in Table 11.

The validity of this technique was demonstrated recently when two of our contractors, (Mallinckrodt Chemical Works) performed an independent survey of their plant in order to check on the results reported by our Industrial Hygiene Section. The results of the two surveys agree to an extent which we consider excellent. This comparison is shown in Table 3, page 21. This method of estimating average daily exposure is useful, not only in judging the hazard to employees and in following the progress of plant improvements, but also for correlating exposures with levels of urinary excretion, body content, and clinical findings.

Table II 2

METHOD OF ESTIMATING AVERAGE DAILY EXPOSURE TO DUST

(Top furnace man, recasting area: 2 men shift, total 6 men)

Operation	No. of Min.	No. of times per shift	Total time (min	Alpha Concentration d/m/m³	Alpha Concentration times total time*	Beta Concentration d/m/m³	Beta Concentration times total time*
Operator opens lids of recast furnace and removes crucible.	2.5	8	20	7,000	140,000	26,000	520,000
Operator cleans out furnace.	4	8	32	41,000	1,300,000	240,000	7,700,000
Operator puts in crucible with new load of "derbies"; places lid on furnace.	8	8	64	2,700	170,000	7,900	510,000
Gen. air sample recast furnace area.	-	-	289	1,500	430,000	2,000	580,000
Cafeteria	30	1	30	57	1,700	160	5,000
Rest room	15	2	30	57	1,700	160	5,000
Locker room	15	1	15	62	930	130	2,000
			480		2,000,000		9,300,000

Average alpha concentration = $\frac{2,000,000}{480}$ = 4200 d/m/m³ Average beta concentration = $\frac{9,300,000}{480}$ = 19,000 d/m/m³

*All data (including totals) in this column are adjusted to two significant figures.

APPENDIX III

Note on Calculation of "Tolerance" Level for Insoluble Uranium Compounds in Inhaled Air.

Assumptions:

0.1 R/day

1) "Tolerance" alpha radiation level to lung is 30 mrep/week or 4.3 mrep/day.
2) Fraction of inhaled material retained in the lungs and pulmonary lymphatic tissue is 0.25.
3) "Biological half-life" of insoluble uranium compounds in the lung is 90 days.
4) Weight of pair of lungs = 1000 gms.
5) An individual inhales 10 m^3 per 8 hour working day.

(1) $\frac{\mu c}{gm}$ of lung required to deliver 4.3 mrep/day

$$= \frac{(5.2 \times 10^7)\ (.0043)}{2.2 \times 10^6 \times 60 \times 24 \times 8.86}$$

$$= 8 \times 10^{-6}$$

where 5.2×10^7 is the number of Mev/gm equivalent to 1 rep.
.0043 rep/day is the assumed daily acceptable dose rate.
2.2×10^6 is the number of disintegrations per minute per microcurie.
60 x 24 is the number of minutes per day.
8.86 is the sum of the energies of the alpha radiation from 238 and 234 in equilibrium, in Mev.

(2) Total μc in lungs for 4.3 mrep/day to lungs

$$= 1000 \times 8 \times 10^{-6}$$

$$= 8 \times 10^{-3}\ \mu c$$

(3) Number of microcuries per 10 cubic meters (inhaled in 8 hrs.) which will give 8×10^{-3} μc in the lung at equilibrium (assuming exposure every day)

$$= \frac{8 \times 10^{-3}}{.25 \times 90 \times 1.4}$$

[redacted]

where 8×10^{-3} is the number of μc in the lungs at equilibrium,
.125 is the fraction of inhaled material deposited in the lung
90 is the assumed biological half-life in the lungs in days
1.4 is the factor to convert half-life to mean life.

$$= 2.54 \times 10^{-4}$$

(4) $$\frac{\mu c}{1\ m^3} = 2.54 \times 10^{-5}$$

$$= 56\ d/m/m^3$$

(5) Since exposure every day was assumed, this can be increased to about 70 d/m/m3 or approximately 50 μg/m3.

No factor has been introduced into this calculation for the fact that the uranium is not distributed uniformly in the lungs or lymphatic tissue. Also, there appears to be some question whether the weekly acceptable dose rate for alpha radiation will be 30 mrep/week or 15 mrep/week. If the lower value is finally adopted, the calculated figure would have to be decreased by a factor of 2.

[redacted]

Simonds Saw & Steel Co.
Lockport, N. Y.

October 27, 1948

Occupation	No. of Employees	Approx. % of Total Personnel	Multiples of the Preferred Level
Foreman *	2	6.8	25
Roller #1, west side	4	13.6	23
Roller #1, east side	4	13.6	190
Roller #2, west side	4	13.6	11
Roller #2, east side	4	13.6	120
Pressure quencher	4	13.6	21
Stamping rods	2	6.8	28
Furnace man *	4	13.6	8
Drag-down operator	2	6.8	9

December 1, 1948

Foreman *	2	6.8	13
Roller #1, west side	4	13.6	12
Roller #1, east side	4	13.6	21
Roller #2, west side	4	13.6	15
Roller #2, east side	4	13.6	36
Pressure quencher	4	13.6	7
Stamping rods	2	6.8	12
Furnace man *	4	13.6	4.
Drag-down operator	2	6.8	10

January 10-20, 1949

Foreman *	2	6.8	4.6
Roller #1, west side	4	13.6	3.6
Roller #1, east side	4	13.6	9.9
Roller #2, west side	4	13.6	4.1
Roller #2, east side	4	13.6	15.7
Pressure quencher	6	13.6	37
Stamping rods	2	6.8	26.7
Furnace man	4	13.8	1.4
Drag-down operator	2	6.8	1.6

Oct. 27, 1948 - Feb. 15, 1949

Foreman	2	5
West Rollers	8	4
East Rollers	8	13
Quench & Stamp	6	28
Furnace Operator	4	1.4
Drag-down	2	1.6

Simonds Saw & Steel Co.
Lockport, N. Y.

April 5, 1949

Occupation	No. of Employees	Approx. % of Total Personnel	Multiples of the Preferred Level
Foreman *	2	6.2	4.6
Roller #1, west side	4	12.5	3.6
Roller #1, east side	4	12.5	9.9
Roller #2, west side	4	12.5	4.1
Roller #2, east side	4	12.5	15.7
Pressure quencher	6	18.8	37
Stamping rods	2	6.2	26.7
Furnace man *	4	12.5	1.4
Drag-down operator	2	6.2	1.6

January 6, 9 and 10, 1950

Foreman	2		1.8
Roller #1 West	4		1.8
Roller #1 East	4		7.7
Roller #2 West	4		1.9
Roller #2 East	4		4.3
Pressure Quencher	4		4.0
Rod Stamper	2		2.1
Drag Down	2		6.2
Furnace Man	6		2.7
Shearman	8		1.1

August 21, 1951

Foremen	2		2.1
Roller #1 West	4		1.88
Roller #1 East	4		1.77
Roller #2 West	4		1.63
Roller #2 East	4		2.5
Pressure Quencher	2		1.3
Rod Stamper	2		1.07
Drag Down	2		1.67
Billet Loader	2		1.13
Heater (Furnace man)	2		1.03
Heater Helper	2		1.8
Shearman	8		0193
Weighers	4		0.81

Simonds Saw & Steel Co.
Lockport, N. Y.

May, 1950

Occupation	No. of Employees	Approx. % of Total Personnel	Multiples of the Preferred Level
Foremen	2		2.2
Weighup	10		0.3
Furnace			
Dragdown	2		2.6
Roll #1 - East	4		3.9
Roll #2 - East	4		4.6
Roll #1 - West	4		0.6
Roll #2 - West	4		2.4
Shearmen (Straighteners)	4		0.9
Quenchers	2		0.8
Dippers	4		1.1
Stampers	2		2.2
Shippers	3		0.2

August, 1950

Foremen	2		1.18
Furnace	6		1.16
Dragdown	2		1.11
Roll #1 East Side	4		2.26
Roll #2 East Side	4		1.76
Roll #1 West Side	4		1.24
Roll #2 West Side	4		1.45
Straighteners	4		.22
Quenchers	2		.72
Dippers	4		2.49
Rod Stampers	2		0.68

January, 1950

Foremen	2		1.63
Furnace Operators	6		1.63
Dragdown	2		1.80
Roll #1 East	4		12.40
Roll #2 East	4		18.90
Roll #1 West	4		0.97
Roll #2 West	4		1.07
Straighteners	4		1.15
Dippers	6		1.83
Rod Stampers	2		1.65

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Office Memorandum • UNITED STATES GOVERNMENT

TO : W. E. Kelley, Manager DATE: January 31, 1951

FROM : Merril Eisenbud, Director, Health and Safety Division

SUBJECT: REPORT ON MALLINCKRODT EMPLOYEES

SYMBOL: HS:ME:mg

About a year ago, you asked if it would be possible for us to estimate our "potential liability" among the long term Mallinckrodt employees. As I explained at that time, you presented a rather knotty problem, one which, in the state of our present knowledge, would probably not be answered even to a first approximation.

Stimulated by the question you asked, we have since prepared the attached report, "An Estimate of Cumulative Multiple Exposures to Radioactive Materials". This report gives, by extrapolation of the best available laboratory and human data, estimates of the doses to the critical organs of all Mallinckrodt employees during the period July 1942 to October 1949. The report shows that there are 17 employees whose lungs have had more than 1000 rem of exposure.

I have purposely withheld distribution of this report for some two months in order to give us a little more time to consider the validity of our estimates. I am now satisfied that these estimates are reasonably sound, again only to a first approximation, and we plan to present our approach to the problem at the forthcoming meeting of the Medical Laboratory Directors. Perhaps some of the visitors will be willing to venture an opinion as to the value of this approach and the meaning of our estimates in terms of "potential liability".

My own judgment is that if these estimates are in error, we err on the side of safety, and that although the possibility of tumor development among the Mallinckrodt employees must be recognized, we can rule out the possibility of a widespread incidence of disease in this group.

Specifically, Warren, Dunn, Morgan, Fiala. ME

Attachment:
"An Estimate of Cumulative Multiple Exposures to Radioactive Materials"

Tom, this is the cover letter.

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MALLINCKRODT - 5

This document consists of 19 pages
No. 7 of copies, series A

AN ESTIMATE OF CUMULATIVE MULTIPLE EXPOSURES

TO

RADIOACTIVE MATERIALS

MALLINCKRODT CHEMICAL WORKS

PLANTS 4 and 6

July 1942 to October 1949

46396

CLASSIFICATION CANCELLED
Date 3-12-54
For The Atomic Energy Commission
William A. Fitzner
Chief, Declassification Branch

by

Hanson Blatz
and
Merril Eisenbud

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[redacted]

ABSTRACT

An attempt has been made to estimate the cumulative radiation dose to the "critical" organs of all employees of Mallinckrodt plants 4 and 6, who have had more than six months of exposure to radioactive materials. These workers have been exposed to several types of radiation from both internal and external sources.

From the outset, the difficulties involved in such a study were known, but the effort was believed to have been worthwhile. The mechanics required for the dose approximations have now been established, and the data can be adjusted from time to time as new information becomes available. The gaps in our knowledge have been emphasized, and it is to be hoped that this will stimulate further laboratory and field investigations that are required in order to provide data that are not now available. For the present, dose estimates to a first approximation are presented that can serve as a basis of correlation with the clinical history of these employees.

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The Mallinckrodt Chemical Works has been engaged in the refining and processing of uranium under contract with MTOO (formerly Manhattan District) since July 1942. Their operations are conducted in two plants constructed relatively early in the program of the Manhattan District at a time when it was not expected that the processing of uranium ores and compounds would involve potential occupational risks of radiation injury. This point of view was in part originated by the low specific activity of uranium, and in part because it was believed that the plants would operate for only a short period of time.

For the first few years of operation, there were neither radiation measurements nor evaluations of the dust exposure made in these plants. No personnel monitoring procedures were in effect.

Early in 1947, the MTOO evaluated the potential hazards in these plants and, after finding them to be considerable, recommended the necessary corrective actions. In addition, steps were taken by the MTOO in cooperation with the contractor to institute procedures for effective environmental and personnel monitoring. It was recognized that pending elimination of excessive exposures, here was an unique opportunity to conduct clinical studies on a fairly large size population whose radiation exposure for several years had been considerably in excess of any group for which data are available.

This report summarizes our estimates of cumulative radiation exposure to the employees in this plant. As we will see, the exposures were several in type, both external and internal. We believe our estimates of exposure are the best that can be made in our present state of knowledge, but our principal exposure was to radium and uranium dust and the calculated tissue doses must be accepted as only tentative, to be revised as more abundant information about the fate of these dusts in man becomes available. The clinical history of these employees is currently being evaluated and will shortly be correlated with the data of this report.

Types of Exposure:

The process in these plants begins with the receipt of uranium ore and ends in the shipment of metallic uranium and the brown oxide of uranium (UO_2). In this process, the following sources of exposure exist:

1. Gamma radiation, primarily from the radium daughters.

2. Beta radiation from UX_1 and UX_2, the short-lived daughters of uranium. Highly active beta emitting residues occur at steps in the process which concentrate these daughters.

3. Radon from the ore and process sludges which contain radium.

4. Alpha emitting dusts from the processing of uranium and radium bearing materials.

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Availability of Personnel and Area Monitoring Records

Although some of the employees have been exposed since 1942, no film badges were worn until 1946. No breath radon determinations were made until 1947, and dust measurements were not made until 1948. We are thus handicapped at the start by a lack of data for most of the period of exposure.

It is proper to assume that exposures prior to the dates when information became available were at least as severe as they were found to be at the time of our initial studies. The exposures may have been moderately more severe, but there is no reason to believe that conditions had been more favorable in the past. Our estimates of cumulative exposure are thus based on the premise that the exposures found to exist at the time of our initial surveys could be extrapolated back through the period for which no data were available. Exposures in the past may have been more severe and our estimates may, therefore, be conservative.

The estimates of cumulative exposure are based on air analyses for alpha emitting dusts (radium and uranium), film badges for external beta and gamma radiation, and breath radon analyses for estimates of fixed radium burden.

The breath radon is collected by obtaining one liter samples of exhaled breath after two days of non-exposure (usually on a Monday morning) and measured by an automatically recording pulse counting device described elsewhere. (1) Since many of the early breath radon samples undoubtedly represent transient as well as fixed burden, estimates of alpha radiation to the bone based on breath radon measurements would in most cases be higher than actual. It has been found that background level at the point of sampling, which in general has been ignored, is a significant influencing factor in the total radon measured. Here again, any such error would result in observations being higher than actual exposures.

The use of film badges was routine except that more particular attention was paid to the quantitative evaluation of beta exposure than is customary because of the relative importance of this type of exposure.

The alpha emitting dusts are collected on a 1-1/8" diameter Whatman No. 41 filter disc by means of a hand held air sampler with a collection rate of from 15 to 20 l.f.m. Our method of estimating exposure to alpha emitting dust, however, is unusual and will be described in brief.

The operations from which the dust exposures originate are, as is the case of many industrial operations, highly repetitive. Prior to the collection of atmospheric samples, each job in the plant is studied

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and the individual operational components of the job listed together with the length of time spent on each particular job component. Air samples are then collected for each component of the job and a weighted daily average exposure was calculated. A sample worksheet showing a typical calculation is given in Table I. It should be noted that the bulk of the air samples are taken in the breathing zone.

Weighted daily averages prepared in this manner are reproducible within a factor of 2. This is not a precise measurement, but it is a quite satisfactory estimate which is in all probability within the range of variability due to other factors, such as differences in breathing rates, upper respiratory retention, lung clearance and metabolic rate.

Method of Estimating Cumulative Dose:

The organs we have considered in attempting to estimate the cumulative radiation dose from these exposures are the skin, bone and lung. The significant contributions to the dose received by these organs are shown in Table II.

We have not considered the bronchial tree per se because we have no means by which we can estimate the dose which the alpha emitting dusts contribute to this structure.

Estimate of Skin Dose:

The dose delivered to the skin by external radiation was estimated from the film badge measurements. Standard practice dictates the use of gamma radiation measured in air as the criterion of skin exposure with a factor of safety estimated to account for backscatter. In the case of external beta radiation to the skin, the known beta emission from metallic uranium is used as a standard of comparison. This measurement includes backscatter by the definition of the rep. These two types of radiation are added to give total skin exposure from external sources. The alpha radiations with which we are concerned are not considered a hazard because of their inability to penetrate the stratum corneum due to their relatively low energies.

Estimate of Lung Dose:

We are conscious of the fact that in calculating the dose from the internal emitters we are on very tenuous ground. As shown in Appendix A, we have calculated that tissue containing 1k parts per million of natural uranium, evenly distributed, is being irradiated at a rate of 300 millirems per week.

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TABLE I

SAMPLE WORKSHEET FOR COMPUTING DAILY WEIGHTED AVERAGE EXPOSURE

OPERATOR: PROCESS HELPER - BIRD FILTER 1 man/shift; 3 shifts/day; 4 man/day

Operation or Operating Area	Time per Opera. (Min)	Opera. per Shift	Time per Shift (Min) (T)	No. of Samples	Concentration ug/m³ Low	High	(C) Aver.	Cum'a. Times Total time (T X C)
Building bird filter cake	8	3	24	4	60	125	83	2,000
Flowing off cake	6.5	3	19	3	110	530	232	4,400
Bird centrifuge area	--	-	121	2	20	175	97	11,700
Digester and recovery tanks	--	-	80	5	5	38	19	1,500
Denitration pot area	--	-	90	12	5	85	31	2,800
Filter press room	--	-	60	4	20	45	30	1,800
Cleaning press	11	1	11	4	190	615	376	4,100
Lunch and breaks	--	-	60	4	6	56	31	1,900
Locker room	--	-	15	4	4	72	39	600
	ΣT		480			$\Sigma(T \times C)$		31,800

$$\Sigma \frac{(T \times C)}{T} = 67 \text{ ug/m}^3$$

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TABLE II

ORGAN	CONTRIBUTING EXPOSURE
Skin	External beta and gamma radiation
Lung	External gamma radiation and internal alpha radiation from uranium and radium
Bone	External gamma radiation, internal alpha irradiation from uranium, radium and radium decay products

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In order to provide a basis for calculating the lung dose in individuals exposed to uranium and radium dusts, we have made the following assumptions:

1. The build-up of the relatively insoluble dusts in the human lung is comparable to the data reported in the University of Rochester dog exposures to an uranium compound UO_2 of low solubility. (2) In Figure 1, we present a curve showing the equilibrium lung concentrations versus exposure. This curve is taken from UR-67. It is used as the basis for our estimate of human exposure because it is, at the present time, the only basis for making such an estimate. The University of Rochester found that at any given exposure level, the equilibrium lung concentration is reached in from 1 to 2 years. Their data show that from 70 to 75% of equilibrium is reached at the end of one year and our estimations of lung uranium concentration are based on the assumption that this is likewise true in man.

   We have had an opportunity to study the concentration of uranium in the lung of one individual having a known exposure to the dust of uranium compounds. He was exposed for 24 months to an average concentration which we estimate at 17,000 micrograms uranium per cubic meter of air. His exposure was to UF_4 and to UF_6 in the ratio of 3:1. Assuming lung retention from the latter compound to be negligible because of its high solubility, we may limit our consideration to his UF_4 exposure, which was, therefore, of the order of 12,000 ug uranium per cubic meter of air. He died of pulmonary tuberculosis approximately ten months after his last exposure and following autopsy, his lungs were assayed for uranium. A concentration of 0.34 micrograms of uranium per gram of wet tissue was reported. There is animal evidence that the biological half life of UF_4 in the lung is approximately 30 days. Assuming this to be valid in man, one can calculate that the pulmonary concentration just prior to the cessation of exposure was 350 ug per gram.

   This is lower by a factor of 4 than the concentration which would be estimated on the basis of the Rochester UO_2 experiments. A limited amount of animal studies involving exposure to UF_4 have in fact shown that the equilibrium lung concentrations are somewhat lower than those found in the case of UO_2 exposure. This factor may be partially explained on the basis of the somewhat higher solubility of UF_4.

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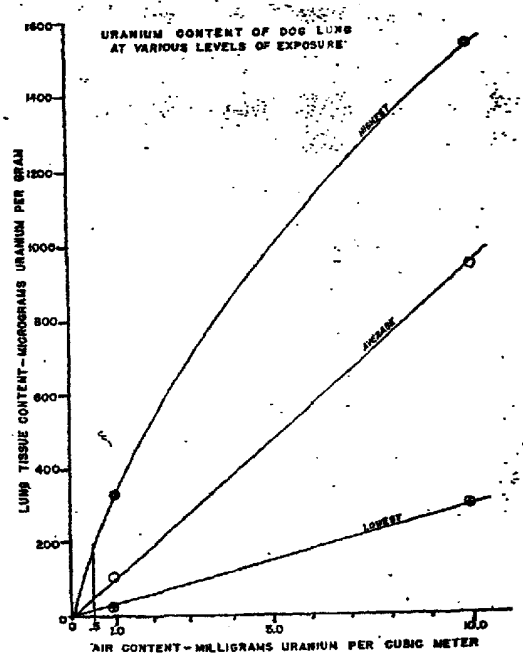
URANIUM CONTENT OF DOG LUNG
AT VARIOUS LEVELS OF EXPOSURE
LUNG TISSUE CONTENT—MICROGRAMS URANIUM PER GRAM
1600
1400
1200
1000
800
600
400
200
0
HIGHEST
INTERM
LOWEST
0
.5
1.0
5.0
10.0
AIR CONTENT—MILLIGRAMS URANIUM PER CUBIC METER

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Estimate of Bone Dose:

The skeletal dose originates from external radiation and uranium and radium deposited in the bone.

There are no good animal data by which one can approximate the uranium skeletal burden of an individual having known exposure. For this study, we have taken advantage of the availability of two autopsies and one biopsy from individuals having known uranium exposure.

One individual (J.H.) was employed 3 months in an operation involving exposure to UF_6 at an average estimated level of 1000 ug/m^3. For the next 40 months, he was employed at an operation with an estimated 150 ug/m^3, predominantly UF_6. He died of carcinoma of the stomach 9 weeks after the termination of employment. A post mortem showed uranium concentration in the bone of 0.40, 0.43 and 0.67 ug/g from three samples.

Another case (J.B.) was employed for 24 months at an operation involving an estimated exposure of 17,000 ug/m^3 (80% UO_2 and UF_4 and 20% UF_6). This man died of tuberculosis 10 months after termination of employment and an autopsy showed an uranium concentration in the bone of an average of 16.5 ug/g from five samples.

One biopsy was obtained from an individual (R.R.), still employed, whose work record indicated a variety of exposures to UO_2 and UF_4, as follows:

Length of Time	Estimated Exposure
2 months	4500 ug/m^3
3½ "	None
7½ "	4500 ug/m^3
19 "	850 "
5 "	None
46 "	850 "

From the above figures, an estimated average exposure level of 1200 ug/m^3 for a total period of 81 months was used. The biopsy indicated a uranium concentration in a specimen of bone from the knee of 4.9 micrograms per gram of bone.

These data have been plotted (Figure 2) in order to arrive at a tentative working relationship between exposure and bone burden. In plotting, it was assumed that there is a direct relationship

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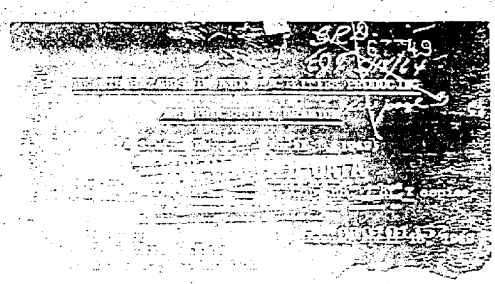

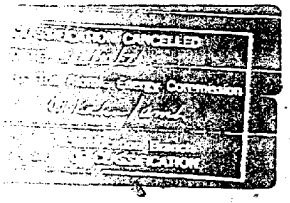

SUMMARY OF POTENTIAL CONFLICTS OF INTEREST
S. COHEN & ASSOCIATES

S. Cohen and Associates (SC&A) was issued a contract by the National Institute for Occupational Safety and Health (NISOH) to provide technical support for the Advisory Board on Radiation and Worker Health (Board) in advising the Secretary of Health and Human Services (HHS) on the science utilized by the NIOSH in conducting dose reconstructions, and on proposed additions of classes of employees to Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA). There are a significant number of questionable activities that create organizational and individual conflicts that have not been identified by SC&A in their Conflict of Interest declarations. The following information includes a more detailed explanation of these activities as well as supporting documentation. Examples included are:

- SC&A was retained by inhabitants of the Republic of the Marshall Islands (located within the Pacific Proving Grounds – a DOE facility covered by EEOICPA) in their efforts to obtain additional compensation exceeding $3.3 billion from the U.S. Government for radiation-related claims due to nuclear weapons testing.

- Dr. Makhijani, and his associate at SC&A and the Institute for Energy and Environmental Research (IEER) Mr. Bernd Franke, were retained by the Concerned Citizens for Nuclear Safety (CCNS) in *CCNS v. DOE* (D.N.M. Civ. No. 94-1039-M), a case involving the Los Alamos National Laboratory, which is a DOE facility. In a 2003 supplemental report involving this case, Mr. Franke erroneously noted that a dose reconstruction study had yet to be conducted at LANL to be used to support their EEOICPA claims.

- Dr. Makhijani is also involved as an expert witness for the plaintiffs in *Laurence O'Connor, et al. v. Boeing N.A., et al.*, a civil case in the U.S. District Court for the Central District of California involving the Boeing-Rocketdyne Nuclear facility, a DOE facility covered by EEOICPA.

- Dr. Makhijani was a key expert witness for the plaintiffs in a Pennsylvania class action case (*Hall, et al. v. Babcock and Wilcox Company, et al.*, Case No. 94-095 in the U.S. District Court in Pittsburgh, PA). This case involved the NUMEC facility, an AWE covered by EEOICPA.

- Dr. Makhijani preformed work for the Rocky Mountain Peace and Justice Center (RMPJC) relating to the Rocky Flats nuclear weapons plant dated December 2001, a DOE facility covered by EEOICPA. Supplementing the 2001 IEER report is a December 2003 report, Supporting a Conservative Approach to Cleanup at Rocky Flats; also prepared by IEER for RMPJC.

- Dr. Makhijani authored a report issued by the IEER and Snake River Alliance involving the Idaho Falls National Laboratory, a DOE facility covered by EEOICPA.

- Mr. Fitzgerald, former DOE Deputy Assistant Secretary for Health and Safety, exercised management control over a significant portion of the DOE activities at sites that included Hanford, Rocky Flats, and Oak Ridge. Although Mr. Fitzgerald's conflict of interest declaration indicates that he would be "precluded from performing work on projects directly related to his work at DOE, he now serves as the SC&A assistant Project Manager and lead site profile reviewer for the Hanford, Rocky Flats, and Y-12 DOE facilities. Dr. Mauro's March 1, 2006 statement for Congress stresses that, "no SC&A team member that has worked in the past at a Federal facility can serve in a lead capacity on any task issued under this contract dealing with that facility." Mr. Fitzgerald's responsibilities clearly included management of safety and health activities at all these facilities.

ADVISORY BOARD ON RADIATION AND WORKER HEALTH
Potential Conflicts of Interest of S. COHEN & ASSOCIATES

Background: The President's Advisory Board on Radiation and Worker Health (Board) advises the Secretary of Health and Human Services (HHS) on the science utilized by the National Institute for Occupational Safety and Health (NIOSH) in conducting dose reconstructions, and on proposed additions of classes of employees to Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA). The Board also conducts reviews of individual NIOSH dose reconstructions. NIOSH, as administrator of Board activities, issued CDC Contract Number 200-2004-03805 to S. Cohen and Associates (SC&A) to provide technical support for the Board. As a requirement of the contract, SC&A implemented a conflict of interest plan on December 15, 2004 (Attachment 1).

Recently, it has been alleged in a number of venues that the SC&A conflict of interest plan is extremely stringent. For example, this allegation was emphasized in the March 1, 2006 statement that was prepared for the House Judiciary Subcommittee on Immigration, Border Security and Claims Oversight Hearing on EEOICPA by Dr. John Mauro, Project Manager for the SC&A contract (Attachment 2). The above-noted conflict of interest plan addresses both organizational conflicts and individual conflicts of SC&A staff members. Exhibit A of the SC&A plan is an example of the conflict of interest certification that is completed by individual SC&A staff members. Although questions II, III and IV of the certification are clearly one-sided by limiting their inquiry to activities "on behalf of" (emphasis in original) the Department of Energy (DOE), a DOE contractor, an Atomic Weapons Employer (AWE), or an AWE contractor pursuant to a contract or in litigation, question V is broader and specifically asks for "any current or past history of contracts or financial relationships that would result in an actual or perceived conflict of interest with respect to potential work performed under CDC Contract No. 200-2004-03805."

There are a significant number of questionable activities by various SC&A staff members that create organizational as well as individual conflicts that have not been identified by SC&A in their Conflict of Interest declarations. While most of these questionable activities may not trigger the one-sided test for excluding activities related to defending DOE or its contractors in radiation-related claims, many raise obvious potential conflicts due to current and past relationships that have a direct bearing on the work SC&A performed to assist the Board's evaluation of NIOSH dose reconstruction program activities. Examples of these activities are presented below.

Activities of SC&A and Drs. Mauro and Behling:

Attachments 3 and 4 are the SC&A Disclosure Statements of Drs. Mauro and Behling, respectively. Note that Dr. Mauro only lists the Savannah River Site as a DOE/AWE site where a conflict of interest exists and Dr. Behling lists none. However, SC&A was retained by inhabitants of the Republic of the Marshall Islands (located within the Pacific

Proving Grounds – a DOE facility covered by EEOICPA) in their efforts to obtain additional compensation from the U.S. Government for radiation-related claims due to nuclear weapons testing. SC&A, particularly Drs. Mauro and Behling, did this work and represented claimants in both compensation claims under the Nuclear Claims Tribunal established by the U.S. Government with the Republic of the Marshall Islands and in their "Changed Circumstances" petition with the U.S. Government in 2005 (prior to and after SC&A began working for the Board). Attachment 5 is a copy of the Congressional Research Service report on the "Changed Circumstance" petition. Pages CSR-14 and CSR-15 reference Dr. Mauro's work in which Dr. Behling also participated. The petition was based, in large part, on SC&A's representational work. Attachment 6 is the report of a 1999 House Committee on Resources hearing entitled, "The Status of Nuclear Claims, Relocation and Resettlement in the Marshall Islands." This example demonstrates that SC&A organizationally, and Dr. Mauro and Dr. Behling individually, conducted work to support claims against the United States in excess of $3.3 billion at the Pacific Proving Grounds. These activities raise significant conflicts at this particular DOE site. Dr. Mauro is the Project Manager for SC&A and Dr. Behling is the SC&A lead on individual dose reconstruction reviews as well as on the NIOSH/ORAU Procedure Review.

Activities of Dr. Arjun Makhijani:

Dr. Makhijani is the lead on the SC&A review of SEC evaluations by NIOSH, as well as a SC&A reviewer of site profiles. Attachment 7 is his conflict of interest declaration indicating no conflicts at any DOE or AWE site. Dr. Makhijani has done significant work for groups that have been or are currently involved in litigation with DOE (or its contractors) and AWEs. He has served as an expert witness in this litigation and has done significant work that is attributed as being done under contract to such groups. Much of this work is directly related to radiation-related claims and his work in these cases is directly related to the NIOSH work that he is reviewing under the Board's contract.

Examples of cases where Dr. Makhijani served as an expert witness for plaintiffs include:

- Dr. Makhijani, and his associate at SC&A Mr. Bernd Franke, are involved in a consultative role to the Concerned Citizens for Nuclear Safety (CCNS) in *CCNS v. DOE* (D.N.M. Civ. No. 94-1039-M), a case involving the Los Alamos National Laboratory, which is a DOE facility. Attachment 8 is a CCNS press release describing the litigation and Dr. Makhijani's and Mr. Franke's roles on an ongoing basis (a November 2005 report cover and acknowledgement by Dr. Makhijani of this activity is also included). Mr. Franke's SC&A disclosure statement, Attachment 9, indicates no conflicts at any DOE or AWE sites. Also included in Attachment 8 is the Executive Summary of a supplemental report, New Mexico's Right to Know: The Impact of Los Alamos National Laboratory Operations On Public Health and the Environment, authored by Mr. Franke and others in August 2003. **Note in document that Mr. Franke states, "LANL [Los Alamos National Laboratory] was the first site to develop atomic weapons.**

Yet a complete dose reconstruction study has not been conducted at LANL...Workers at other DOE sites have utilized these dose reconstruction studies to support their claims under the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA). To their detriment, LANL retirees and workers do not have a dose reconstruction to rely on for their EEOICPA claims." NIOSH has in fact completed over 300 dose reconstructions for cases from LANL, nearly half the cases sent to NIOSH by DOL from this facility. Also note that SC&A has not begun their evaluation of the LANL site profiles at the time Mr. Franke drew this conclusion and reported it as a deficiency in a report done for the plaintiffs in this lawsuit.

- Dr. Makhijani is also involved as an expert witness for the plaintiffs in *Laurence O'Connor, et al. v. Boeing N.A., et al.*, a civil case in the U.S. District Court for the Central District of California involving the Boeing-Rocketdyne Nuclear facility, a DOE facility covered by EEOICPA. Attachment 10 is a motion in the case which lists Dr. Makhijani as an expert witness for the plaintiffs. Attachment 11 gives Dr. Makhijani's description of his role as the plaintiffs' expert.

- Dr. Makhijani was a key expert witness for the plaintiffs in a Pennsylvania class action case (*Hall, et al. v. Babcock and Wilcox Company, et al.*, Case No. 94-095 in the U.S. District Court in Pittsburgh, PA). This case involved the NUMEC facility, an AWE covered by EEOICPA.

These examples raise significant conflicts for both Dr. Makhijani and Mr. Franke at these DOE and AWE sites. There are a number of other groups opposing DOE or its contractors that Dr. Makhijani had relationships with that cause direct conflicts with his work for the Board. Significant work was performed by the Institute for Energy and Environmental Research (IEER), an organization where Dr. Makhijani serves as President and Mr. Franke is a staff member as well as on SC&A staff, for groups involved in a lawsuit against DOE. Much of this work is done for a number of the 39 plaintiff groups involved in Natural Resources Defense Council v. Richardson, Civ. No. 97-936 (SS). This work was often funded as part of this litigation through a "Citizens Monitoring and Technical Assistance" Fund. Documentation of this Fund and a list of awards under the Fund are in Attachment 12. Examples of such relationships and work include:

- Attachment 12 also includes a press release concerning work Dr. Makhijani preformed for the Rocky Mountain Peace and Justice Center (RMPJC) relating to the Rocky Flats nuclear weapons plant dated December 2001, a DOE facility covered by EEOICPA. Supplementing the 2001 IEER report is a December 2003 report, Supporting a Conservative Approach to Cleanup at Rocky Flats; also prepared by IEER for RMPJC (Attachment 12 also includes the Executive Summary of this report).

- Attachment 13 is a report issued by the IEER and Snake River Alliance authored by Dr. Makhijani involving the Idaho Falls National Laboratory, a DOE facility covered by EEOICPA.

CCNS

Chronology of CCNS's Clean Air Act citizen's suit

Consent Decree between CCNS and DOE

Settlement Agreement between CCNS and DOE

CCNS's comments on proposed the Environmental Protection Agency (EPA) rule for National Emission Standards for Hazardous Air Pollutants (NESHAP): Site Remediation. 40 CFR 63, Subpart GGGGG CCNS's letter to the Department of Justice to begin the CAA dispute resolution process(.pdf) (March 31, 2003)

Audits:

First Audit:

Monitoring Report for the Institute for Energy and Environmental Research on the First Independent Technical Audit of the Los Alamos National Laboratory Compliance Status with Respect to the Clean Air Act by Arjun Makhijani and Bernd Franke *April 2000*

Independent Technical Audit of Los Alamos National Laboratory Compliance with the Clean Air Act, Subpart H, in 1999 by the Risk Assessment Corporation *2000*

Facts About the Consent Decree Settling the Clean Air Act Lawsuit Brought by CCNS Against the Department of Energy

In 1994, Concerned Citizens for Nuclear Safety (CCNS) filed a citizens' lawsuit against the Department of Energy, CCNS v. DOE, (D.N.M. Civ. No. 94-1039-M) for Clean Air Act violations at Los Alamos National Laboratory (LANL). 40 CFR 61, Subpart H.

The federal district judge found for CCNS, based upon DOE's admission that 31 of 33 "major" stacks and associated quality assurance programs were not in compliance with the Subpart H regulation. In January 1997, facing $2.5 billion in possible penalties and the potential shutdown of many of its facilities, the Department of Energy (DOE) settled the landmark Clean Air Act citizens' lawsuit with CCNS.

Under the settlement provisions of the Consent Decree, up to four comprehensive independent audits will be performed to verify whether LANL is in full compliance with the Clean Air Act (Subpart H).

The parties agreed that Dr. John Till, of the Risk Assessment Corporation, and his Independent Technical Audit Team (ITAT) would perform the audits. The ITAT is comprised of Dr. John Till, Risk Assessment Corporation; Jill W. Aanenson, Scientific Consulting, Inc.; H. Justin Mohler, Independent Consultant; Arthur S. Rood, K-Spar, Inc.; and Helen A. Grogan, Cascade Scientific Inc. Dr. Till determines the scope of depth of the technical audits.

CCNS's consultants in the audit process are Dr. Arjun Makhijani and Bernd Franke, of the Institute for Energy and Environmental Research. DOE must pay for CCNS's technical consultants to monitor the ITAT in order to safeguard the independence of the audit process.

The audit schedule:

- The first audit was to verify LANL's 1998 Subpart H compliance. During the first audit, the ITAT found that LANL "did not meet certain regulatory and technical requirements and was not in compliance with 40 CFR 61, Subpart H, for 1998."
- The second audit was to verify LANL's 1999 Subpart H compliance. The ITAT concluded that LANL was in compliance with Subpart H. CCNS and IEER replied that the statement of compliance should have been conditional because LANL did not perform uncertainty calculations and that the relatively low dose estimate for 1999 (0.32 mrem) was partly the result of the fact that the main beam at the Los Alamos Neutron Science Center (LANSCE) did not operate during 1999.

STATEMENT OF DR. JOHN MAURO, SANFORD COHEN AND ASSOCIATES

Dr. **MAURO.** Thank you for inviting me here today and thank you to the people of Enewetak for asking me to come. I work for Sanford Cohen and Associates. This is a small company in McLean, Virginia, that specializes in risk assessment.

My background is specifically in the area of health, physics, and radioecology. This is the study of radioactivity in the environment and its effects on people. I have been performing analyses of the type that I will be summarizing here for about the past 25 years at hundreds of different sites throughout the United States.

This past September the people of Enewetak retained SC&A to peform an independent evaluation of the radiological conditions on Enewetak atoll, specifically, and to assess what needs to be done to remediate the atoll so that it would comply with the clearance criteria, or the acceptance criteria, for cleanup that was summarized by Mr. Richardson.

We started our investigations in October, and we completed them in April. In April we appeared before the tribunal presenting testimony on our findings. The 12-page summary that I provided you with there summarizes this, but I also have a full copy of our report that I would like to leave with the Committee. It details our findings.

What we basically did was collect all of the data that the Department of Energy has collected since the 1970s, literally tens of thousands of measurements. We did not perform any measurements of our own. We used that data to perform mathematical modeling of if the people of Enewetak were to return to the northern islands—by the way, some of the questions that were raised earlier, as I proceed I would like to respond to some of those questions because I think they are important.

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The people of Enewetak are currently living on the southern islands, Enewetak island. But the northern islands such as Enjebi, homeland for many of the Enewetak people, are currently not being occupied because of radiologic concerns.

What we did—what I did as part of a team of people at SC&A was to gather all of the data and evaluate the radiation doses that might occur to people who would relocate to the northern islands tomorrow and assess what kind of radiation doses they would receive and what needs to be done to correct the problem.

What we found out is that the radiation doses, if the people of Enewetak should return to Enjebi, for example, one of the many islands north, in the year 2000, the doses would be 10 to 100 to 500 times higher than the current radiation protection standards we are using in the United States, an unacceptable situation.

We then proceeded to ask what could be done about that. We evaluated a broad range of alternative remediation strategies. We actually costed out 30 different approaches to remediate the problem. And in doing so, we used five criteria to sort of score or evaluate the merits of all of the alternatives to fix the problem.

First, whatever the remedy, it should allow the people of Enewetak to return to their homes in the northern islands as soon as possible. If you were to wait for the radioactivity to decay, it turns out the important radionuclide, the cesium 137 with a 30 year half life, it would take over 100 years to decay down to levels that were acceptable.

Second, the cleanup has to be protective. That means achieve the cleanup criteria of 15 millirem per year. Third and very important, whatever strategies that are adopted it minimizes the ecological damage and incorporates measures that restores the ecosystem to a self-sustaining condition.

Fourth, cost effective; and finally, permanent, that is, whatever solution or remedy strategy is selected, it should be a permanent solution. Based on our investigations, we identified a strategy to recommend, and it consists of five elements.

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NOTES FROM READING ROOM

Fr: JN
To: JC, ST\
1/31/05 5:39PM

This is where we are - wherever that is!

Fr: SH
To: MK, KI
1/31/05 5:37 PM
Alts. To NIOSH FR Not. On SECs

Mala, Kris, et al. - as requested, we've spent sev hours pouring over NIOSH Fed Reg Notice, attempting to devise alt lang that might reduce the precedent'l impact of SEC approvals it rec's for Iowa Army Ammun Plant and Mallinckrodt.

As discussed, the rationale prov'd in doc for add'g 1949-1957 at Mallinckrodt is that, while NIOSH has all the data needed to reconstr doses during those years, pet'rs and others have cast douby on the accuracy of someof the expos. Data and hence claimants would be skeptical about any dose estimate results. The rationale for making the entire period of work at Iowa an SEC class is that while NIOSH has the data to do dose reconstructions, it believes it is constrained from doing so b/c the data is class'd and dose estimate assumptions could therefore not be fully and transparently revealed to the claimant.

W/ respect to Mallinckrodt, we have sugg'd revised lang (see attachment) that would simplify the eval and recommend a single SEC class covering the years 1942-1948. This SEC is justified in terms of the lack of data upon which to make credible dose reconstr'ns at that site based on the specific fact pattern there, and does not (as revised) open the door to direct application of the finding to other sites. By adding the years 1946-48 to the earlier period, roughly half of the claims DOL has rec'd from Mallinckrodt emps or their survivors would be incl'd in the SEC cohort.

However, the per 1949-1957 at Mallinckrodt ca't, in our view, be justf'd for incl'n as an SEC. The NioSH doc openly acknowledges that dose reconstr'ns can be done for that per, and the only reason cited for asserting that an SEC shld be decl'd is that claimants and advocates have alleged that espos/monitoring data is missing, inaccurate, or corrupted. As noted in our formal cts last week, that samealleg'n has been made for virtually every DOE site, and in most cases has been achknowledged to one degree or another, and NIOSH's dose reconstr'n process was specifically designedto overcomethose data weaknesses where possible. Therefore, the use of that rationale for Mall't will absolutely imply its enthusiastic applicat'n all around the complex. Further, there is no basis in the statute or NIOSH rules to approve an SEC appl'n in circumstances in which NIOSH has annonced that in CAN do dose reconstr'ns, which it announces in the very Notice at issue. (Note: NIOSH has compl'd several dozen dose reconstr'ns at Mall't, making their recomm'n of SEC status for these years even more mysterious.)

For these compelling reasons, and b/c we have no info whatever with which to constr an alt justf'n for this per, we have revised the attached version of the notice to eliminate the extralegal and broadly applicable "credibility cloud" rationale, and thus to require that NIOSH DENY the SEC class petition with respect to employees who worked at Mall't during 1949-57, but who had less than 250 days emplmt during the 1943-48 per. We recognize that this outcome will not be will-rec'd by those w/ whom HHS apparently shared the draft Notice, but we know of no way to assert that an SEC for these years is justf'd, and the use of the proffered rationale would essentially signal acceptance of SECs at all DOE sites. As noted, the early years SEC approval will result in about half the Mall't claims being adjudt'd under the SEC presumption, which is an appropriate outcome given the deferring situations in terms of data availability (and, as we understand it, real risk of expos) during the 2 diff time periods.

With respect to the Iowa eval, we have been unable to id any chgs to the rationale for an SEC approval that would limit its applicability to other sites, or make it more defensible. We considered hanging the rationale on a NIOSH regulatory provision that allows SEC status to be decl'd if NIOSH is unable to obtain the data it need to conduct dose reconstr'ns in a timely fashion. However, that provisionis not applicablehere, since NIOSH freely admits that it has all the (presumably classf'd) data needed to estimate doses. We have exhausted our knowledge of the issues at Iowa and can present no alt or impr'd or narrowed rationale for an SEC approval that isn't flatly contradicted by NIOSH's own admissions. Therefore, the attachment simply leaves the Iowa eval unchgd.

If NIOSH and DOE have any specific knowledge about the type of materials, and especially the degreean sensitivity of the classf'n of data surrounding those materials, perhaps they could insert that specificity into the revised Notice and limit its precedent-setting impact, at least to the 5 or 6 sites that performed essentially similar work - e.g., assembly and disassembly of warheads. Please note, however that by adding such specific rationale, NIOSH would very clearly be inviting SEC pet'ns from the obviously similar sites. And our experience with DOE complex is that functions that are thought to be segregated in a few sites tend to have spread in a somewhat surprising manner, such that it can be expected that warhead work will be "discov'd" in many places where it was not supposed to have happened. Finally, claimants an their reps will assert the argument that classified data abounds inthe DOE complex, even if the classification issues at their own particular site are different and less significant than at Iowa-like sites.

All that said, it remains our firm conviction that the "transparency" criterion adduced by NIOSH for accepting the SEC petition for Iowa is not spelled out or supported by the statute or their regs. Even if they could add more refined descriptions of the type of classf'd info and the reason why it is especially important that discussion about dose estimation involving that info be curtailed, there is no legal basis for the SEC approval of the Iowa class. Claimants whose cases are subsequently denied b/c the site has become an SEC via this process (i.e. thos with non-RECA cancer) will be able to sue to overturn the SEC decision, whether the rationale is couched in its current extremely broad lang, or is circumscribed as much as can be done given the parallels betw several DOE sites that did the same kind of work as Iowa. The NIOSH proposal for Iowa is not a good policy outcome.

In sum, we found a partial compromise that broadens the Mall't SEC to encompass about half of that work force in a way that is defensible, but we were unable to find any way to narrow or strengthen the Iowa eval. Since we were asked to improve the notice rather than simply reach a completely opposite outcome, we left the Iowa portion unchgd. We continue to believe that it is neither legally sound nor supportable as policy.

Let me know if we shld do more on this. Thx, sh

10/05/05 1:30 PM
Fr: PT
To: SH

Shelby,
Here my recommend's for policy actions. , I talked to Larry Elliot. He was not sure what the Mall't designation will say. Particular note, John, Lew Wade and Diane Porter were at OCAS today. Larry asked about refreshing the Board and Diane informed him that it has been decided not to make any chgs to the Board membshp!

10/05/05 12:25 PM
Fr: MW
To: SH,VL, MW
cc: PT, JN

Thx Shelby. We share concerns.

If there are any programmatic reforms – leg., admin, reg'y, you name it – that we could potentiallly tee up for our policy officials, we're all ears. Atthis pt., nothing should be ruled out. These would be OMG ideas, not DOL ideas.

My bosses typically expect the id of a problem to be accompanied by options to solve it. Legis solutions are not a 1st option, b/c they are hard to get enacted.

MW

10/05/05 9AM
Fr: SH
To: MW, VL, MW
Cc: PT, JN

FYI, Apropos of our brief discussion about EE.. Costs, see the Cantwell news release and letter to NIOSH and the EE.. Advis. Brd. Chair attached. As I sugg'd, the criteria the Brd has advanced (and NIOSH and HHS have endorsed) for adding to the SEC for the the 1st 5 apprv'd

pet'ns are so fuzzy and some cases so clearly related to pol. press., they almost beg for this kind of "me too" response.

You'll note that Cantwell is quoting from a report of the Brd's (really NOSH's) support contractor SC&A, an outfit that has basically driven NIOSH toward more and more lopsided and extreme exaggerations of dose on the grounds that every decision point must be as "claimant favorable" as conceivably possible. The Brd has allowed, even encouraged SC&A to pursue this unbalanced course, and NIOSH has shown no willingness to stand up to it, and recently doesn't even try to refute SC&A's more outlandish assertions. This is not a slippery slope, it's the expert downhill chute.

SH

NIOSH Dose Reconstr'n Policy Actions

1. **Nat'l Acad of Sci Revw** - The review of NIOSH site profiles procedures, and dose reconstructions coducted by SC&A thus that of the Advisory Brd has not addressedthe accuracy of the process concerning potential over estimation of exposures. The stand. for comp is 50 potential over estimation of expos's. The statndard for comp is 50% or more Prob of Caus (POC) at the 99% confidence level, however, the Brd's "audits" only look at potential under estimation. An independent review of the process is needed to determine if the NIOSH dose reconstr'ns are either over or under compensatinng deserving claimants. An expedited review by a group such as the NAS could accomplish this if the review was structured to review the resulting compensation results along with the dose reconstr's. This review shld also focuson the findings and recomm's of SC&A and the Brd to determine if the recomm's are resulting in either under or over comp. It hld also look at conformance w/ the statutory and reg'y req'ss concerning accuracy and use of reasonable and plausible assumptions.

2. **Refresh the Advisory Brd(AB)** - A # of the AB membs' terms have expired. Replacing these membs could bring sginificantly more balance to the Brd.

3. **Add Ex-officio Brd Membs** – A # of gov agencies have a direct or indirect interest in the deliberations of the AB and the impact it has on the resulting dose reonstr's. Any agency w/ responsibilities for rad'n safety and health can be significantly impacted by the outcome of this AB's actions. These incl but are not limited to DOL, DOE, DOJ, NRC, Naval Buclear Propulsion Prog, and VA. Significant benefit could come by having ex-officio membs on the Brd (they could be non-voting membs) from several of these agencies.

   These SC&A and AB reviews that are resulting in determ'ns taht create add'l class designations have significant and direct impact on DOJ in administering RECA and VA in administering their comp progs. Dose reconstr's are done by the Defense Threat Reduction Agency for these progs at the Nevada Test Site and the Pacific Proving Grounds. The Brd will review a petition for the Pacific Proving Grounds in the near

future and they will also review the NIOSH site profile for the Nevada Test Site.

4. **Apply Conflict of Int. Criteria to the Brd's Contractor** – NIOSH contractors conducting dose reconstr'ns or working on site profiles have conflict of int lims. Dose reconstructionists are prohibited from working on dose reconstructions at sites where they were previosuly employed or where they did professional work and could have a conflict interest. No such reqmt exists for SC&A and as a result, inds conducting the reviews for the Brd are also involved in tort claims at the very sites where they are reviewing the NIOSh results. Since the SC&A contractis a NIOSH contract, NIOSH could place a prohibition on SC&A for involvement of SC&A employees in cases where they have such conflicts of interest. Add'lly, NIOSH contract emps conducting dose reconst'n were req'd to file conflict of int stmts which were and are public. A similar provision shld also be applied to SC&A.

5. **Admin Review of New Class Determination** – Early review of SEC class determ's and def's would be of significant benefit. Recent designations were issued before there was any review by DOL or OMB. There have been significant probs encountered with the specific class def's that caused considerable probs in admin'g the new SEC and in the case of Oak Ridge Y-12, req'd the significant expansion of the class due to vague def'n of the class. This could have been mitigated had the adjudicators been given the opportunity to review the designation. The scope of cov'd emps in the class could have been def'd in a way that limited incl'n to those ind who the eval and desig'n intended to cover.

6. **Strict Application of the Statutory Stands. Of Causation** – NIOSH dose reconstr'ns are more freq'y applying assumptions that are systematically and dramatically increasing over estimations under the premise of "claimant friendly" assumptions or even for reasons of "calculational convince." This is trending to ever increasing POCs. A strict applictn of the stand of causation comp would have a dramatic impact. This impact could be significantly enhanced if the AB was also charged to not only look at under comp but also over comp in their deliberations and recomms.

10/06/05 5:24PM
Fr: JN
To: SH
Cc: PT, RM, OP, ST, JC

Attached is redraft of Pete's sugg's. Essentially I put a front piece on and then just re-arranged and edited Pete's sugg's. I did leave one out, about Ex-Officio membs, since I think that would req legis and also they would not have a vote and they probably wouldn't have any effect on the rush to judgment advocates anyways. I think I incorporated all his other suggs.

E-mails from previous doc

Energy Emps Occupat'l Illness Comp Prog Act

DOL has grown increasingly concerned over HHS's rapidly diminishing coordination of activities and decision concerning the Energy Emps Occupat'l Illness Comp Prog Act (EEOICPA (EE..)). Recent actions, particularly those relating to adding add'l classes of emps the EE.. SEC, which grants those emps EE.. benefits if they have incurred any of 22 cancers and have worked in any SEC facilities a total of 250 days, have the potential to vastly increase the cost of the prog and decrease its sci validity. HHS's inability or unwillingness to reasonably construe the Cong criteria for such add's, particularly the reqmt that dose reconstruction (estimating emp's expos. to rad'n at the facility) be infeasible for the add'l class, appears to be leading to an all-encompassing expansion of theSEC resulting in costs approaching $7billion.

DOL has attempted to raise this issue and a # of others also threatening to result in an excessive, unjustified and inequitable increase in claimsaccepted under EE.. w/ little success. At this pt it is clear that only intervention by the OMB is likely to stem this trend.

DOL has a # of concrete sugg's concerning how this might be accomp'd.

- **Clearance of SEC determ's by OMB** - The single most effective way to prevent of billions of dollars is by req'g HHS to clear its determ'n to add add'l emps to the SEC w/ the OMB after an opportunity for int'd agencies such as DOL to comment on the analysis andthe determin'n. DOL has unsuccessfully requested an opportunity to review the HHS analysis and determination of SEC petitions. While recognizing that Cong has imposed an unreasonably short deadline of 30 days from receipt of the recomm'n of the AB on Rad'n and Worker Health (AB) for HHS to act, we still believe OMB clearance is crucial to preventing unjustified admissions to the several of the recent SEC petitions considered by the AB. DOL has also experienced problems in several cases w/ the description of the class adopted by the Nat'l Inst for Occup'n Safety and Health (NIOSH). In view of the effect and costs of an over-expansive def'n, we sugg that such determ's also be subject to OMB clearance.

- **Impartial Review** –Cong intended AB provide impartial analysis of sci validity and qual of dose reconstr'n efforts by NIOSH and of other matters related to rad'n and worker health and to make impartial recomm's on add's to the SEC. So far AB has totally failed to take a bal'd approach to examining NIOSH activities. Nearly have its membs have operated as unwavering advocates of any action that would expand benefits, while the remaining membs occassionally raise dissenting views but are unwilling to forcefully advocate any positions likely to disturb the claimant community. This unwillingness to fulfill their responsibility by carefully examine issues such as whether the so-called "claimant-friendly" devices increasingly adopted by NIOSh are overestimating and over-compensating claimants has been magnified by NIOSH's decision to provide technical support for the AB through a contractor Sanford Cohen & Associates (SC&A) rather than through its own staff. SC&A has relentlessly pursued an agenda that appears to be designed to result in max pmts to claimants regardless of sci valididty. DOL sugg's the following in an to attempt to provide the impartial review not currently

being undertaken.

- **Nat'l Acad of Sci Review** – HHS previously indicated that it was considering requesting a review of its dose reconstr'n prog by the Nat'l Acad of Sci (NAS). Our understanding is that this idea has since been abandoned. We believe that this would supply the kind of outside eval'n not being provided by the AB and would serve as a val benchmark in assessing the activities of both the AB and of SC&A.

- **Refresh the AB** – A # of the AB membs' terms haveexpired. We were previously informed that a # of newmembs would be apptd. More recently we were informedthat the AB would remain as currently constituted. We believe that replacing these membs could provide an opportunity to add Brd membs willing and able to advocate a scientifically valid approach to carring out NIOSH's responsibilities under EE..

- **Apply Conflict of Int Criteria to SC&A** – NIOSH contractors conduct in dose reconstr'ns or working on site profiles have conflict of int. lims that prohibit them from working on dose reconstr'ns at sites where they were previously employed or where they did professional work and could have a conf of int. They are also req'd to file pub conflict of int stmts. Nos uch req't has been imposed on SC&A by NIOSH and as a result, inds conducting the reviews for the AB are also involved attempts by various indvs to seek damages as a result of rad'n expos at the sites where they are reviewing the NIOSH results. This is an obvious and considerable incentive for those individuals to seek to magnify to the greatest extent possible rad'n exposure at those facilities. NIOSH should be req'd to impose the same conflict of int provision it applies to its other contractors on SC&S.

- **Operational Concerns** – In addition to the other concerns expressed above, DOL has serious concerns about the operational conduct of dose reconstruction and of the creation of site profiles (facility-specific guidance docs detailing how a dose reconstr'n shld be performed) by NIOSH. To the extent that OMB is in a position to review the conduct of NIOSH, particularly its recent and increasingly problematic use of assumptions about the amount of rad'n exposure incurred by emps at cov'd facilities that are systematically and dramatically increasing over estimations under the premise of providing "claimant friendly" assumptions or for reasons of "calculational convenience," this could prevent a substantial amount of overcompensation of claimants and a substantial undermining of the sci validity of the EE.. Comp prog.

As noted above absent a major chg of direction by HHS or substantial oversight by OMB, the EE.. Prog is rapidly heading in the direction of an expansion of benefits in an amount orders of magnitude beyond what Cong, at its most generous, ever contemplated when this prog was enacted.

United States General Accounting Office

GAO

Testimony

Before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

For Release on Delivery
Expected at
10:00 a.m. EST
Wednesday
March 17, 1994

HEALTH AND SAFETY

Protecting Department of Energy Workers' Health and Safety

Statement of Jim Wells, Associate Director,
Energy and Science Issues,
Resources, Community, and Economic
Development Division

GAO/T-RCED-94-143

059101 152992

Mr. Chairman and Members of the Subcommittee:

We are pleased to participate in this hearing on the Department of Energy's (DOE) efforts to protect the health and safety of its workers. Over the past five decades, the weapons complex produced tens of thousands of nuclear weapons. In the process, it also produced huge volumes of radioactive and other toxic substances. These included the radionuclides uranium, plutonium, and cesium; toxic metals such as mercury, beryllium, and lead; organic solvents and chlorinated hydrocarbons. All of these represent potential threats to the over 600,000 men and women who have worked at the complex over the last 50 years, as well as to the people who have lived in communities surrounding the weapons sites. Over the last decade, we have reported on DOE's problems with health and safety issues throughout the complex, and we recently reviewed DOE's management of its Health Surveillance Program.

On the basis of our work, I would like to discuss the following issues.

-- Worker health and safety has been and continues to be a problem for DOE. Historically, DOE's overemphasis on weapons production has meant limited attention to the potentially adverse health effects of working within the weapons complex. In the future, problems in protecting workers from radiation and other hazardous substances at DOE sites will remain, and the cleanup program will expose workers to additional dangers. Recently, the Secretary has taken actions to strengthen DOE's organization for ensuring worker health and safety.

-- Last year, when we evaluated DOE's Health Surveillance Program, one of the programs managed by the Office of Environment, Safety and Health, we found that the program is still at least 4 years away from being fully implemented, that the coverage of workers is limited, and that some data on workers' health are not included in the program's analyses.[1] As a result, we recommended that DOE (1) develop an implementation plan for the program that outlines the tasks to be performed, as well as specific milestones, and (2) correct the problems with data collection in the current program before expanding it to additional sites. DOE has not officially indicated what action it intends to take on our report.

-- You asked us to provide information about the quality of the data collected at DOE sites on workers' exposures to

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[1] Health and Safety: DOE's Implementation of a Comprehensive Health Surveillance Program is Slow (GAO/RCED-94-47, Dec. 16, 1993).

toxic substances. While we have not systematically studied the issue, evidence from our previous work and the work of others suggests that problems have occurred with the monitoring of exposures and the collection of exposure data within the complex. For example, DOE's internal appraisals, such as the Tiger Teams, have found problems with radioactive monitoring practices at DOE's sites. These problems raise questions about DOE's ability to accurately determine the health risks to workers in the complex.

I would now like to discuss each issue in greater detail.

HEALTH AND SAFETY CONCERNS HAVE BEEN A PROBLEM FOR DOE

Workers within DOE's industrial complex face hazards from being exposed to radiation and toxic chemicals, cleaning up the complex, and repairing and maintaining aging facilities. Historically, the overemphasis on weapons production, along with complacency about workers' safety, has meant that DOE management has given limited attention to the potentially adverse health effects of working at DOE sites. Beginning in the early 1980s, we have repeatedly reported on problems with DOE's oversight of health and safety issues within the complex.[2] In addition, DOE's own technical safety appraisals, implemented in 1985, have identified the extent of the Department's health and safety problems. We reviewed these appraisals in 1990 and reported that 18 of the sites appraised had over 1,700 health and safety problems.[3] Of these, 113 represented a clear and present danger to workers or the public and 160 represented a significant risk or substantial noncompliance with DOE orders.

Inadequate radiological protection programs and procedures were a major deficiency throughout DOE, according to the safety appraisals. For example, a 1988 appraisal at the Rocky Flats plant in Colorado found inadequate capabilities for monitoring and sampling air to detect radiation releases. In addition, a 1988 followup appraisal at the Fernald site in Ohio found that

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[2]See, for example, Better Oversight Needed for Safety and Health Activities at DOE's Nuclear Facilities (EMD-82-36, Jan. 27, 1982); DOE's Safety and Health Oversight Program at Nuclear Facilities Could Be Strengthened (GAO/RCED-84-50, Nov. 30, 1983); Nuclear Health and Safety: Oversight of DOE's Nuclear Facilities Can Be Strengthened (GAO/RCED-88-137, July 8, 1988); Safety and Health: Key Independent Oversight Program at DOE Needs Strengthening (GAO/RCED-93-85, May 17, 1993).

[3]Nuclear Health and Safety: Need for Improved Responsiveness to Problems at DOE Sites (GAO/RCED-90-101, Mar. 28, 1990).

the site's contamination control program did not adequately ensure that personnel and material leaving the site were free of contamination.

Protection from chemical hazards has also been given less than adequate emphasis at DOE sites. According to a 1989 review by the National Research Council, DOE's contractors lacked stringent controls for conventional, as opposed to nuclear, hazards.[4] For example, at the Y-12 Plant at Oak Ridge, Tennessee, Council reviewers found that cyanide solutions in the plating shop were handled with potentially inadequate ventilation. They also found cartons and bags of chemicals, some toxic and some leaking onto the floor, stored on pallets in work areas and near high-traffic routes.

In November 1991, the Department's Advisory Committee on Nuclear Facility Safety issued its final report on safety issues throughout the complex. The committee's report noted that its work had confirmed the negative findings on radiation protection of the technical safety appraisals, as well as the more recent Tiger Team assessments. The committee recommended that DOE address the root causes of the deficiencies it and others had identified, noting that increasing management attention and committing more resources--such as qualified personnel--to these issues would be necessary.

In addition to the hazards faced by workers during the weapons production era, other dangers at DOE sites will exist for workers in the cleanup program. As we noted in our June 1993 report, a major component of the cleanup will be the decommissioning and decontamination of as many as 7,000 inactive facilities throughout the complex.[5] Much of the weapons complex is old, presenting serious risks to individuals who work in and around the aging facilities. For example, at the Hanford site, years of inadequate maintenance and deteriorating conditions contributed to an April 1992 fatality at an inactive reactor building when a worker fell through the roof.

In addition to posing safety problems because of their poor physical condition, inactive facilities can contain known and unknown contaminants that increase the dangers for workers in and around these facilities. For example, in August 1992, during decommissioning and decontamination, nuclear research equipment at the Hanford site exploded spreading caustic lithium acetate

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[4]The Nuclear Weapons Complex: Management for Health, Safety, and the Environment, National Research Council (National Academy Press, Dec. 1989).

[5]Department of Energy: Cleaning Up Inactive Facilities Will Be Difficult (GAO/RCED-93-149, June 25, 1993).

throughout the building. DOE's contractors contributed to this explosion by eliminating, part way through the project, an interim work step that was intended to remove any remaining lithium; they eliminated this work step in an effort to complete the long-delayed project without determining how much lithium remained or considering the likelihood of chemical reactions.

In a similar vein, the Office of Technology Assessment's February 1993 report stated that the number and variety of toxic chemicals present at many of the hazardous waste sites and the potential interaction of contaminants make it difficult to accurately assess all potential chemical or radiological hazards.[4] The Office noted that in the weapons complex, work situations may therefore include numerous and varied hazards possibly posing an immediate danger to life or health.

Secretary O'Leary has introduced a number of initiatives aimed at addressing health and safety problems. Specifically, in April 1993, the Secretary announced a major restructuring of DOE, which included consolidating headquarters' health and safety policy and oversight functions within the Office of Environment, Safety and Health and elevating the position of the Assistant Secretary for Environment, Safety and Health to report directly to the Secretary. Furthermore, in May 1993, the Secretary announced a set of health and safety initiatives that included issuing a health and safety policy statement that defines the principles the Department will use and strengthening the authority of the Office of Environment, Safety and Health.

DOE'S HEALTH SURVEILLANCE PROGRAM
HAS HAD PROBLEMS

Because DOE workers are often exposed on a daily basis to hazardous conditions that can seriously affect workers' health, it is essential that DOE evaluate its health and safety procedures to determine their effectiveness and to identify areas for improvement. The Office of Environment, Safety and Health is responsible for managing programs to protect workers' health and safety. As I have noted, we and others have expressed concerns over the past few years about the adequacy of this office's programs.

One key program we recently reviewed, the Health Surveillance Program, is designed to systematically collect and analyze data about workers' health and workplace exposures to toxic substances. The goal of this program is to limit workers' exposures, identify the causes of adverse health effects,

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[4]Hazards Ahead: Managing Cleanup Worker Health and Safety at the Nuclear Weapons Complex, Office of Technology Assessment (Feb. 1993).

intervene to minimize or eliminate the causes of the adverse effects and institute policies and procedures to prevent reoccurrences. Our review of the Health Surveillance Program found that, although DOE intended to fully implement the program by March 1992, the Department currently projects that it will take until 1998 before the program is fully implemented. As a result, DOE cannot systematically determine if hazardous conditions at the sites affect workers' health.

The Health Surveillance Program is intended to consist of four modules, each of which is designed for specific data from DOE sites. The four modules are the Health Events Module, the Demographic Module, the Exposure Module, and the Clinical Module. The Health Events Module contains data on workers' illnesses and injuries, while the Demographic Module contains descriptive and occupational information about each worker, such as a coded identification number, birth date, sex, race, job title, and work location. The Exposure Module, which is currently under development, is designed to contain exposure data for each worker, while the Clinical Module, also under development, is intended to contain information from workers' physical examinations and laboratory tests. Because of the number and variety of potential hazards to workers at DOE sites, it is critical that this program provide regular and timely analysis and feedback about workplace conditions to DOE headquarters and site management.

DOE is currently operating a program that is limited to analyzing patterns of injuries and illnesses on the basis of information provided by the sites. The program does not routinely correlate exposure data with health data because the Exposure and Clinical Modules are not yet functioning. Thus, DOE cannot systematically determine if hazardous conditions at the sites affect workers' health. DOE told us it plans to test these modules at four sites during 1994 and 1995 using currently available data on workers' physical examinations and radiation exposure. However, because many sites lack exposure data--on exposures to chemicals, gases, and other hazardous substances--that can be linked to individual workers, a fully functioning Exposure Module is still years away.

Moreover, we found that the coverage provided under this program is limited. Currently, only 7 of DOE's 33 facilities are participating in the program, covering about 40 percent of DOE's 150,000 contract workers. DOE plans to expand the program to six more sites in 1994. During our review, we also found that some information on grave illnesses among these workers may not be provided to the program. For example, the primary source of data on injuries and illnesses for the Health Events Module is the "return-to-work medical clearance." After a worker's absence, this form is completed by a physician in the site's medical department, certifying that the employee is physically able to

return to work. The form reports identification information, the number of days absent, and, most importantly, the type of illness or injury. But we found that an employee with a major illness or injury who does not return to his or her job is not issued this clearance. Thus, major illnesses and injuries are not reported in the Health Events Module, as the following example shows. In 1991, a University of Washington contractor compared Hanford's cancer data in the Health Events Module with national cancer data over the period 1985 to 1990. Among Hanford's 60 to 64 age group, he found only 39 percent of the cases expected. The most plausible explanation, according to the contractor, is that people who become sick and have cancer diagnosed often simply retire and do not report back through the site's medical departments.

As a result of the weaknesses found in the Health Surveillance Program during our review, our December 1993 report recommended that DOE (1) develop an implementation plan that outlines the tasks to be performed, as well as specific milestones, and (2) correct the problems with data collection in the current program before expanding it to additional DOE sites. DOE has not indicated what action it intends to take.

QUALITY OF EXPOSURE DATA RAISES QUESTIONS ABOUT DOE'S ABILITY TO DETERMINE RISK TO WORKERS

Mr. Chairman, you asked us to provide information about the quality of the exposure data that DOE collects and maintains. While we have not systematically reviewed this issue in our work to date, we have found during previous audits, and others have also noted, that problems exist with monitoring workers' exposures and collecting exposure data at DOE sites. Accurate data are important for two reasons. First, as I just noted, accurate data are needed to ensure that current workers' exposures are not leading to adverse health effects. Second, an accurate historical record of exposures is vital to answer questions about the long-term health effects of continuous exposure to radiation and hazardous substances and to establish standards for workplace exposures.

According to DOE's technical safety appraisals, to ensure the accuracy of exposure data, the instruments used to obtain measurements of radioactivity, or personnel dosimetry, should be calibrated and maintained, but at Rocky Flats in 1987, for example, the appraisers found that the plant did not have an instrumentation calibration program meeting DOE's standards and that instruments were often not adequately calibrated.

The issue of accuracy of exposure data was also addressed in

a 1991 report by the Office of Technology Assessment.[7] The report noted that a review of six weapons facilities by DOE's own Tiger Teams through December 1989 revealed many problems with the practices for monitoring radiation and assessing doses. For example, air sampling techniques were inadequate at 83 percent of the facilities assessed and shortages of personnel trained in radiation measurements were found at several sites.

We also found information in the technical safety appraisals regarding problems with the completeness of the exposure data collected at the sites. For example, at Rocky Flats, some dosimeters were not returned to the contractor prior to final processing. Yet in these instances, the contractor did not require an estimate of exposure. This situation can result in errors in the data reported to DOE and to the employees in their exposure report cards.

During our review of the Health Surveillance Program, we interviewed the Pacific Northwest Labs staff scientist who chairs a DOE group working on issues concerning the radiation dosimetry data to be included in a comprehensive data base. He noted problems with the comparability and accessibility of exposure data. Specifically, he pointed out that for most DOE facilities, the methods used to calculate recorded radiation doses for workers varied considerably over the years and that the documentation of historical dosimetry practices is fragmented. The documentation for workers employed in the early periods of DOE's operations is particularly uncertain and individuals with direct knowledge about workers' exposure are rapidly retiring and leaving DOE. He also noted that the status of radiation protection records is highly variable among DOE facilities. In many cases, electronic files of dosimetry information do not exist, and manual retrieval is difficult, expensive, and time-consuming.

Finally, the National Research Council addressed the issue of data quality in its 1989 review of workers' health and safety in the weapons complex. The council stated that the data collected at DOE sites during ongoing monitoring and surveillance programs are useful in assessing risks to workers' health only to the extent the data are accurate, comprehensive, accessible and comparable. The data collected in the past, the Council concluded, are inadequate--because of both the kinds of data collected and the means in which they are stored.

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[7] Complex Cleanup: The Environmental Legacy of Nuclear Weapons Production, Office of Technology Assessment (Feb. 1991).

SUMMARY

In summary, Mr. Chairman, health and safety problems continue to exist at DOE sites. GAO and other external organizations continue to report problems at DOE sites in protecting workers against radiation and hazardous chemicals. The cleanup program will expose workers to additional dangers. As a result, DOE needs a vigorous health and safety program that can accurately determine and minimize the risks to workers. The Secretary has recognized the need for improvement, and has moved to strengthen the Office of Environment, Safety and Health. However, our examination of a key program, the Health Surveillance Program, has found many problems. Moreover, important issues such as data quality have been raised by this Subcommittee and others--and evidence suggests that DOE's data on workers' exposures to hazardous substances may not be reliable. Without reliable data, DOE cannot accurately determine the risks to workers in the weapons complex.

We look forward to working with this Subcommittee to further its goal of protecting DOE's workers.

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Mr. Chairman, this completes my prepared statement. I will be glad to respond to any questions you may have.

(302116)