savings to licensees with more extensive operations, smaller licensees also can be expected to incur smaller compliance costs.

In order to assist small licensees, the NRC has sought in the proposed rule to eliminate prescriptive requirements wherever possible, and to allow for much greater flexibility in compliance. Such flexibility is particularly helpful to small licensees in reducing their cost of compliance, because it will enable them to avoid the costs of radiation safety measures, such as the detailed requirements for Radiation Safety Committees, that were especially oriented toward larger licensees with numerous modalities and activities in the same institution. NRC has reduced the training and experience requirements applicable to the diagnostic use of byproduct material by focusing those requirements on radiation safety and by reducing the number of hours of training required. NRC has also sought to reduce the prescriptive nature of requirements for testing and calibration, and to reduce reporting and recordkeeping burdens, which can have an especially strong impact on small entities.

Finally, the program for revising Part 35 and the associated guidance documents has involved more interactions and consultations with potentially affected parties (the medical community and the public, including representatives of small licensees) than is provided by the typical notice and comment rulemaking process. Early public input was solicited through several different mechanisms: requesting public input through **Federal Register** notices; holding open meetings of the government groups developing the revised rule language; meeting with medical professional societies and boards; putting background documents, options for the more significant regulatory issues associated with the rulemaking, and a ''strawman'' draft proposed rule on the Internet; and convening public workshops. Participants from the broad spectrum of interests that may be affected by the rulemaking were invited to attend the public workshops in Philadelphia, PA., and Chicago, IL., held in October and November 1997. The public was also welcome to attend these workshops, as well as the Part 35 Workshop that was held in conjunction with the All Agreement States Meeting in October 1997, and the NRC's Advisory Committee on the Medical Uses of Isotopes meetings in September 1997 and March 1998.

As indicated in the Regulatory Flexibility Analysis statement included in the proposed rule, the NRC requests comments from small medical licensees concerning the impacts of the proposed rule and any suggested modifications that may affect the economic impact of the proposed requirements.

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U.S. NUCLEAR REGULATORY COMMISSION

10 CFR Chapter I

Medical Use of Byproduct Material; Draft Policy Statement

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft policy statement.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing, for formal comment, revisions of its 1979 policy statement on the medical use of byproduct material. These proposed revisions are one component of the Commission's overall program, as previously announced in the **Federal Register**, for revising its regulatory framework for medical use, including its regulations that govern the medical use of byproduct material. The overall goals of this program are to focus NRC regulation of medical use on those medical procedures that pose the highest risk and to structure its regulations to be risk-informed and performance-based, where appropriate, consistent with NRC's ''Strategic Plan for Fiscal Year 1997-Fiscal Year 2002.''

DATES: Submit comments by November 13, 1998. Comments received after this date will be considered if it is practical to do so, but the Commission is able only to ensure consideration of comments received on or before this date.

ADDRESSES: Send comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff.

You may also provide comments via NRC's interactive rulemaking web site through the NRC home page (http://www.nrc.gov). From the home page, select ''Rulemaking'' from the tool bar. The interactive rulemaking website can then be accessed by selecting ''New Rulemaking Website.'' This site provides the ability to upload comments as files (any format), if your web browser supports that function. For information about the interactive rulemaking web site, contact Ms. Carol Gallagher, (301) 415–5905; E-mail: cag@nrc.gov.

Deliver comments to: One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 am and 4:15 pm Federal workdays.

Copies of comments received may be examined at: NRC Public Document Room, 120 L Street, NW. (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: Catherine Haney, Office of Nuclear Material Safety and Safeguards, Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–6825, E-Mail: cxh@nrc.gov, or Marjorie U. Rothschild, Office of the General Counsel, Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–1633, E-Mail: mur@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In 1979, the Nuclear Regulatory Commission published a policy statement, ''Regulation of the Medical Uses of Radioisotopes'' (44 FR 8242; February 9, 1979), in which it informed NRC licensees, other Federal and State agencies, and the general public of the Commission's following general intention in regulating the medical use of byproduct material:

1. The NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public.

2. The NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate.

3. The NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine.

NRC activities in the medical area, such as promulgation of regulations and development of regulatory guidance, as well as cooperative relationships with other Federal agencies have been guided by this statement.

A **Federal Register** notice, ''Medical Use of Byproduct Material: Issues and Request for Public Input'' (62 FR 42219–42220; August 6, 1997), describes (as reflected below) NRC's detailed examination of the issues surrounding its medical use program during the last four years. This process started with NRC's 1993 internal senior management review; continued with the 1996 independent external review by the National Academy of Sciences (NAS), Institute of Medicine (IOM); and culminated in NRC's Strategic Assessment and Rebaselining Initiative (SA). In particular, medical oversight was addressed in the SA Direction-Setting Issue Paper Number 7 (DSI 7) (released September 16, 1996). In September 1997, the Commission issued its ''Strategic Plan,'' which stated that its goal in regulating nuclear materials safety is to ''prevent radiation-related deaths or illnesses due to civilian use of source, byproduct, and special nuclear materials' (NUREG–1614, Vol. 1, at 9).

In its Staff Requirements Memorandum (SRM)—COMSECY–96–057,'' Materials/Medical Oversight (DSI 7),'' dated March 20, 1997, the Commission stated that it supported continuation of the ongoing medical use regulatory program with improvements, decreased oversight of low-risk activities, and continued emphasis on high-risk activities. This SRM also directed the NRC staff to revise 10 CFR Part 35, associated guidance documents, and, if necessary, the Commission's 1979 ''Medical Use Policy Statement.'' The Commission SRM specifically directed the restructuring of Part 35 into a risk-informed, more performance-based regulation. In addition, the Commission expressed its support for use of the Advisory Committee on the Medical Use of Isotopes (ACMUI) and professional medical organizations and societies in the revision of Part 35 and the medical policy statement. The Commission specifically directed the NRC staff to ''consider a rulemaking process that provides more opportunity for input from potentially affected parties than is provided by the normal notice and comment rulemaking process, but would be less consumptive of resources and time than the process recently used in the development of NRC's rule on radiological criteria for license termination.''

A June 30, 1997, SRM informed the NRC staff of the Commission's approval, with comments, of the NRC staff's proposed program in SECY–97–131, Supplemental Information on SECY–97–115, ''Program for Revision of 10 CFR Part 35, 'Medical Uses of Byproduct Material,' and Associated Federal Register notice,'' dated June 20, 1997. After Commission approval of the NRC staff's program to revise Part 35 and associated guidance documents, the NRC staff initiated the rulemaking process, which includes revision of the Medical Use Policy Statement, as necessary (62 FR 42219). The Commission directed the NRC staff to consider certain issues, including recommendations on revising the policy statement by focusing regulation of medical use on those procedures that are essential to patient safety and that pose the highest risk, developing regulatory oversight alternatives for diagnostic procedures that are consistent with the lower overall risk of these procedures, and considering the viability of using or referencing available industry guidance and standards to the extent that they meet NRC needs (62 FR at 42219). This notice solicited informal and formal public input during the rulemaking process on the development of proposed rule language and associated documents (62 FR at 42219–4220). At various stages in this process, the Working/Steering Group placed options for a revised Medical Use Policy Statement and major issues associated with 10 CFR Part 35, and a strawman draft of the proposed rule language on the Internet.

In developing a proposed revision of the policy statement, the Commission also has had the benefit of input from the Working/Steering Group, which met publicly in August, September, and December 1997 and in January, February, and March 1998; the ACMUI, at its meetings on September 25–26, 1997, and March 1–2, 1998; ACMUI subcommittee meetings in February 1998; ''stakeholders'' and members of the public at facilitated workshops in October and November 1997; professional medical organization meetings; and State regulators at a publicly noticed workshop at the October 1997, ''All Agreement States'' [1] Meeting. State participants have included representatives of the Organization of Agreement States and the Conference of Radiation Control Program Directors. State participation in this process is intended to further the Commission's strategy to ''work with the Agreement States to assure consistent protection of public health and safety nationwide'' (NUREG–1614, Vol. 1, at 11). Such State involvement also enhances development of corresponding rules in State regulations; provides an opportunity for early State input; and allows State staff to assess potential impacts of NRC draft language on the regulation of non-Atomic Energy Act materials used in medical diagnosis, treatment, or research in the States.

At these meetings and workshops, the NRC staff presented alternatives and/or draft text for the Medical Use Policy Statement and 10 CFR Part 35. Alternatives generated by workshop participants were also discussed. To ensure that all interests were represented, to the degree possible, invited workshop participants included radiation oncologists, nuclear medicine physicians, other physician specialists (*i.e.*, clinical endocrinologists and cardiologists), radiopharmacists, medical physicists, educators, patient rights advocates, oncology nurses, radiation safety officers, medical technologists, hospital administrators, State and Federal Government officials, and radiopharmaceutical manufacturers. Policy statement alternatives ranged from retaining the status quo to various modifications of the current medical policy such as statements limiting NRC's role in the regulation of medical use to ensuring that the physician's prescription is accurately delivered to the correct patient; making clear that NRC will *not* intrude into medical judgments affecting patients; and providing for NRC assessment of risks to the radiation safety of patients that would reference comparable risks, standards, and modes of regulations for other types of medical practice.

The normal pattern for NRC policy statement proposals is the development of a proposed policy statement by the NRC staff for Commission consideration, publication of the proposed statement for public comment, consideration of the comments by the NRC staff, and preparation of a final statement, as appropriate, for Commission approval. As directed and approved by the Commission, the NRC staff has increased participation in the early stages of this development process through meetings and workshops for affected interests and by making documents available on the Internet.

The meetings and workshops elicited informed discussions of options and approaches for developing a revised Medical Use Policy Statement, and the rationale for such options and approaches. Although these meetings and workshops were not designed to seek ''consensus'' in the sense that there is agreement on how each issue should be resolved, they were conducted at a very early stage of proposed policy statement development to increase participation of interested parties and the public with the following objectives:

(a) To ensure that the relevant issues have been identified;

(b) To exchange information on these issues; and

(c) To identify underlying concerns and areas of disagreement, and, where possible, approaches for resolution.

The Commission hopes that the interactions among the participants in the meetings and workshops also fostered a clearer mutual understanding of the positions and concerns of all participants. Comments made at these workshops and meetings, and related written and electronic comments (as summarized below), were considered by the NRC staff in its preparation of a staff draft proposed policy statement, as described in the paragraphs below. Comments were also used, as

[1] An Agreement State is a State that has signed an agreement with NRC, pursuant to Section 274 of the Atomic Energy Act, allowing the State to regulate the use of radioactive material, other than use in reactor facilities, within the State. During the next 5 years, the total number of Agreement States may increase from 30 to 33. NRC ''Strategic Plan'' (Fiscal year 1997–Fiscal year 2002), NUREG–1614, Vol. 1 (September 1997), at 9.

appropriate, in developing proposed revisions of 10 CFR Part 35. The intent of an informal comment period, in advance of publishing a proposed policy statement in the **Federal Register**, was to provide an opportunity for interested parties to provide input during the development of the draft proposed medical policy statement.

ACMUI

At the ACMUI meetings referenced above, the ACMUI recommended to the NRC staff its versions of a revised medical policy statement. At its meeting in March 1998, a four-part revision of the current policy statement was recommended: the more technically accurate term ''radionuclides'' in Statement 1 is substituted for ''radioisotopes''; the order of Statements 2 and 3 is reversed; former Statement 3 (Statement 2 in the ACMUI version) is revised to make it clear that NRC ''will not intrude into the medical judgments affecting patients'' (rather than the current policy of minimizing such intrusions) and to drop from that statement the phrase ''into other areas traditionally considered to be a part of the practice of medicine''; and to modify Statement 3 primarily to provide that an assessment of risks justifying NRC medical use regulations will reference comparable risks, comparable voluntary standards, and modes of regulation for other types of medical practice.

''All Agreement States'' Meeting Workshop

This workshop, which included State participants in the meeting as well as members of the public, also discussed the issues associated with the revision of 10 CFR Part 35 and the Medical Use Policy Statement. Some participants at the workshop stated that NRC's regulatory framework had been, and in the future could be, properly developed under the existing policy statement. Those participants who found fault with the existing medical regulatory framework did so primarily on the basis that it is too prescriptive and intrudes into the practice of medicine, which they asserted is adequately regulated by existing medical practices, including voluntary standards, within the medical community. Many comments were made about the proposal for a revised policy statement under which NRC assessment of the risks justifying its regulations would reference comparable risks and comparable modes of regulation for other types of medical practice. Some participants questioned the capability of NRC to evaluate those risks and noted that such an evaluation would require some mechanism for judging appropriate risk.

Participants favoring a policy statement limiting NRC's role to ensuring the accurate delivery of the physician's prescription did so mainly on the basis that the statement specified those areas NRC would regulate and that it provided a regulatory role for NRC that would not intrude into the practice of medicine. Several participants drafted an alternative option in addition to those alternatives presented by the Working Group. That alternative primarily modified Statements 2 and 3 of the current policy statement to provide that NRC's role in regulating the radiation safety of patients is to ensure that the physician's prescription is accurately delivered to the correct patient, more strongly state NRC's policy not to intrude into medical judgments affecting patients and into other areas traditionally considered to be part of the practice of medicine, and commit NRC to regulate the radiation safety of patients only where justified by the risk to patients and only where voluntary standards or compliance with such standards are inadequate. Although no clear preference was evident, some States indicated their preference for certain alternatives.

Facilitated Public Workshops

The facilitated workshops considered alternatives for the Medical Use Policy Statement presented by the Working Group, as well as alternatives generated by the workshop participants (which were mainly modeled on the ACMUI or Agreement State recommended statements described above). Certain themes emerged in these workshop discussions, such as ensuring that NRC follows the policy statement in the future, does not interfere in the practice of medicine or medical judgments affecting patients, regulates medical use of byproduct material based on the risk posed by the medical use and only after determining that voluntary medical practice standards are inadequate, and limits its role in regulating the radiation safety of patients to ensuring that the physician's prescription is followed. At the Philadelphia workshop, an alternative with this latter limitation generated the most favorable comments.

Some participants expressed the view that the objectives described above could be achieved by revisions to the current statement, whereas others asserted that mechanisms such as tort law or ''physician practice review procedures'' could substitute for NRC regulatory control in certain areas. On the other hand, participants expressed concern that certain policy statement alternatives could so limit NRC's role that its regulation would not encompass either high-risk diagnostic or ''emerging'' medical use technologies. Another concern was that NRC regulation of only the administration of the byproduct material would not provide an adequate level of protection to the patient.

According to certain participants, there is an absence of data supporting the necessity of NRC regulation to ensure that the correct patient receives the correct dose. In view of the perception that NRC is not qualified to assess the risks associated with medical practice, the workshop participants voted in favor of a policy statement providing that in any assessment of such risks, NRC, as a matter of policy, will rely on the determinations of the ACMUI and representatives of major professional medical organizations and Government agencies (to include stakeholder participation). Supporters of this statement pointed out that one of its advantages is that it would provide for stakeholder participation in risk assessment decisions. However, other participants expressed concern that certain professional organizations might not necessarily have the best interests of patients in mind when developing a risk assessment.

Overview of Written and Electronic Comments

The Commission also received written comments in response to the above notice, some of which addressed the Commission's Medical Use Policy Statement. Commenters on the policy statement include a State, professional medical organizations, an industry trade group, universities, and members of the public. The Commission has provided an overview of comments below.

An Agreement State recommended that the Commission continue the status quo with respect to the Medical Use Policy Statement, but more strictly adhere to that policy. According to that State, any intrusion into medical judgments affecting patients should be based solely on radiation protection considerations.

A number of professional societies, *e.g.*, the American Brachytherapy Society (ABS), the Society of Nuclear Medicine/American College of Nuclear Physicians (SNM/ACNP), and the American Association of Physicists in Medicine (AAPM) also provided comments on the Medical Use Policy Statement. ABS agrees with current Medical Use Policy Statements 1 and 3, but believes that Statement 3 needs revision to provide that NRC will regulate the radiation safety of patients

only where justified by the risk to patients and only where voluntary standards or compliance with these standards are inadequate. According to ABS, Statement 2 should also make clear that ''[t]he risk threshold justifying patient safety risks will be comparable to those of other types of medical practice.'' ABS believes that the NRC concept of acceptable patient risk is zero.

The SNM/ACNP asserts that contrary to the clear language in the current policy statement, NRC has steadily increased its involvement in the regulation of nuclear medicine despite minimal changes in this area of medicine over the years and a lack of significant problems with this medical modality. The AAPM supports NRC's efforts to revise the Medical Use Policy Statement to focus on radiation safety and not on the practice of medicine or medical physics. However, the AAPM urged NRC to publish its risk data so that the regulated community can understand the NRC's actions in regulating the medical uses of radiation. AAPM supports the concept of risk-based regulations, although noting that the licensees' response to regulatory actions will require the expenditure of health care funds.

A university of health sciences commented that NRC's current Medical Use Policy Statement is appropriate. This commenter believes that NRC should continue to regulate medical use to provide for the radiation safety of workers, patients, and the general public and that there is no need for changes to the particular statement of general policy. Another university's comments were very similar to those of the AAPM, described above.

Comments were also submitted on behalf of the Council on Radionuclides and Radiopharmaceuticals, Inc. (CORAR). According to CORAR, any revision of the Medical Use Policy Statement is futile unless NRC takes direction from that statement. As to the first statement of the medical policy, CORAR believes that 10 CFR Part 35 is unnecessary because 10 CFR Part 20 is adequate for regulation of all other uses of radioactive material and could be expanded to ensure the safety of medical use. CORAR commented on the second and third statements of medical policy by asserting that regulation of the radiation safety of patients is neither justified nor inadequate. In support of this contention, CORAR cited several factors, including regulation by other bodies such as the Food and Drug Administration and State Boards of Medicine, the responsibility of physicians to adhere to standards and codes of medical practice, and the exemplary performance record of nuclear medicine. CORAR concludes that the current medical policy statement provides argument against perceived prescriptive regulation.

One member of the public questioned what constitutes ''other areas traditionally considered to be part of the practice of medicine,'' within the meaning of the policy statement. This commenter agreed that although the ACMUI should be the primary source of ''risk judgments,'' it can't be the only source of such judgments, and consideration should be given to other groups and individuals. Another member of the public commented that the policy statement should not limit NRC's role to protection of workers and the general public. This commenter stated that the policy statement assumes there is some entity to ensure that clinical nuclear medicine physicians are qualified to protect those groups. According to the commenter, it is of considerable concern that the policy statement does not account for the fact that many private practice offices and outpatient centers are not components of hospitals.

Although the Commission has considered all of the comments provided, it is specifically responding to comments that raised major issues associated with revision of the Medical Use Policy Statement. At the outset, the Commission notes that its nationwide ''performance goals'' for measuring results toward meeting NRC's nuclear materials safety goal include ''[z]ero radiation-related deaths due to civilian use of source, byproduct, and special nuclear materials'' and for ''no increase in the number of misadministration events which cause significant radiation exposures'' (NUREG–1614, Vol. 1, at 9–10).[2] In response to comments, the Commission is proposing revisions of its policy statement (see Section IV., below) that make clear its intent to avoid intrusion into medical judgments affecting patients, rather than the current policy of minimizing such intrusions. The Commission rejects regulation of the medical use of byproduct material on the basis of ''comparable risk,'' as the ACMUI and ABS have proposed. The Commission doubts that such an approach would meet the statutory standard in Section 161b. of the Atomic Energy Act of 1954, as amended (AEA), to regulate all uses of byproduct material ''to protect health and minimize danger to life.'' The Commission (as well as others, such as NAS and the ACMUI) has recognized the lack of acceptable data to compare the risks from medical use of byproduct material with risks in other medical modalities. In the absence of acceptable data, regulation on the basis of ''comparable risk'' would be regulation to an inadequately understood level of risk. In addition, there is not an expressed authorization in the AEA to regulate any use of byproduct material on the basis of an insufficiently known ''comparable risk.'' Without acceptable data or an express statutory authorization, justifying the significant departure from the Commission's established policy with respect to risk to patients would be, at a minimum, problematic.

[2] The Commission is proposing to amend its regulations to substitute the term ''medical event'' for ''misadministration.'' However, in historical discussions, the term ''misadministration'' is still used.

II. Rationale

NRC's principal statutory authority for regulating medical use of byproduct material rests on sections 81, 161, 182, and 183 of the AEA. See 42 U.S.C. 2111, 2201, 2232, and 2233. Section 81 of the Act prohibits, without NRC authorization, the manufacture, production, transfer, receipt in interstate commerce, acquisition, ownership, possession, import, and export of byproduct material (42 U.S.C. 2111).

Section 81 of the AEA directs that:

> The Commission shall not permit the distribution of any byproduct material to any licensee, and shall recall or order the recall of any distributed material from any licensee, who is not equipped to observe or who fails to observe such safety standards to protect health as may be established by the Commission or who uses such material in violation of law or regulation of the Commission or in a manner other than as disclosed in the application therefor or approved by the Commission.

Id. (emphasis added).

By virtue of section 161 of the Act, the Commission is authorized to undertake a variety of measures ''[in] the performance of its functions'' (42 U.S.C. § 2201). As stated in subsection b, the Commission may ''establish by rule, regulation, or order, such standards and instructions to govern the possession and use of special nuclear material, source material, and byproduct material as the Commission may deem necessary or desirable * * * *to protect health or to minimize danger to life* or property'' [42 U.S.C. § 2201(b) (emphasis added)]. Similarly, section 161i. authorizes the Commission to ''prescribe such regulations or orders as it may deem necessary'' to ''(3) govern any activity authorized pursuant to this Act, including standards and restrictions governing the design, location, and

operation of facilities used in the conduct of such activities, in order *to protect health and minimize danger to life* or property'' [42 U.S.C. § 2201(I) (emphasis added)].

The Commission is bound by statute to regulate byproduct material (as well as source and special nuclear material) to ''protect health and minimize danger to life.'' This statutory standard applies to the myriad of uses of byproduct material, including, not only medical use, but also, for example, radiography and irradiators. However, the Commission is not bound by the limitation in section 104a, of the AEA, which is often mistakenly cited for the proposition that, in regulating medical use of byproduct material, the AEA requires that the Commission ''impose the minimum amount of regulation consistent with its obligations under this Act to promote the common defense and security and to protect health and safety of the public'' [(42 U.S.C § 2134(a)]. This ''minimum regulation'' limitation does not apply to the medical use of byproduct material which falls within NRC's broad standard-setting authority in sections 81 and 161. Section 104a, on its face, applies only to medical therapy licenses for ''utilization facilities'' (*e.g.*, reactors) and ''special nuclear material.'' This ''minimum regulation'' directive does not govern the Commission's regulation of the medical use of byproduct material.

For the most part, the regulations to carry out the broad statutory scheme for byproduct materials are set forth in 10 CFR Parts 30 through 36. In addition, the public and occupational dose limits in 10 CFR Part 20, ''Standards for Protection Against Radiation,'' apply whether the use of byproduct material is for medical or other purposes. However, the scope of Part 20 in § 20.1002 states that, ''[t]he limits in this part do not apply to doses due * * * to any medical administration the individual has received or due to voluntary participation in medical research programs.'' The Commission has clarified that ''the medical administration of radiation or radioactive materials to any individual, even an individual not supposed to receive a medical administration, is regulated by the NRC's provisions governing the medical use of byproduct material rather than by the dose limits in the NRC's regulations concerning standards for protection against radiation'' (''Medical Administration of Radiation and Radioactive Materials,'' 60 FR 48623; September 20, 1995). Thus, the Commission believes that ''an administration to any individual is and should be subject to the regulations in Part 35'' (60 FR 48623).

The provisions of Part 30, ''Rules of General Applicability to Domestic Licensing of Byproduct Material'' ''are in addition to * * * other requirements in this chapter'' (Section 30.2). This section requires that ''any conflict between the general requirements in Part 30 and the specific requirements in another part'' are governed by those specific requirements (Section 30.2). The regulations in Part 35 that are designed ''to provide for the protection of the public health and safety'' reflect the broad statutory standard in the AEA, discussed above (Section 35.1). The Commission has determined that, as a matter of policy, ''the patient * * * as well as the general public * * * are all members of the public to be protected by NRC'' (44 FR 8242, at 8244). (See discussion following.)

The NRC and the Food and Drug Administration (FDA) have regulatory responsibilities concerning medical devices, drugs, and biological products utilizing byproduct, source, and special nuclear material. NRC has responsibility, as described above, for regulating the actual medical use of byproduct material from the standpoint of reducing unnecessary radiation exposures to the public, patients, and occupational workers. In general, the FDA is responsible for assuring the safety, effectiveness, and proper labeling of medical products, *i.e.*, drugs, devices, and biologics. NRC routinely relies on prior FDA approval of medical devices as an essential component of NRC's sealed source and device safety evaluations. In a ''Memorandum of Understanding'' (MOU), effective August 26, 1993, NRC and FDA coordinated existing NRC and FDA regulatory programs for these devices, drugs, and products (58 FR 47300; September 8, 1993). These regulatory programs include activities for evaluating and authorizing the manufacture, sale, distribution, licensing, and labeled intended use of these products. The specific ''elements of coordination'' cover notification of product complaints, medical events, and emergency situations; coordination of investigations; investigation information exchange; NRC and Agreement State notifications; product pre-marketing and pre-licensing information exchange, and sharing of other information such as special notifications to manufacturers, operators, licensees, or patients (58 FR at 47302).

III. The Proposed Commission Policy

Based on the comments and advice of all the participants in the process described previously, as well as members of the public on the ''Internet'' (via the NRC ''s Technical Conference Forum), the Commission is proposing the following as a revised Medical Use Policy Statement to guide its future regulation of the medical use of byproduct material:

1. NRC will continue to regulate the uses of radionuclides in medicine as necessary to provide for the radiation safety of workers and the general public.
2. NRC will not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public.
3. NRC will, when justified by the risk to patients, regulate the radiation safety of patients primarily to assure the use of radionuclides is in accordance with the physician's directions.
4. NRC, in developing a specific regulatory approach, will consider industry and professional standards that define acceptable approaches of achieving radiation safety.

Statement 1

The first portion of the proposed policy statement restates the first part of the current policy statement with the substitution of the phrase ''uses of radionuclides in medicine'' for the phrase ''medical uses of radioisotopes.'' As rephrased, this is a more accurate technical statement of the scope of NRC regulation in this area. Statement 1 conveys the traditional regulatory function of NRC for all uses of byproduct, source, and special nuclear material. Protection of the radiation safety of members of the public and workers is central to fulfillment of the Commission's statutory mandate to ''protect health and minimize danger to life.'' This protection is provided for, in part, in the public and occupational dose limits in 10 CFR Part 20 cited previously. Those limits apply whether the use of byproduct material is for medical use or other purposes. The Commission has determined to retain its long-standing regulatory framework as necessary in the medical uses of byproduct material. As stated in the **Federal Register** notice initiating the Commission's request for public comment, the Commission ''was not persuaded by the National Academy of Sciences (NAS), Institute of Medicine (IOM) report that recommends that the NRC should not be the Federal agency involved in the regulation of ionizing radiation in medicine'' [62 FR at 42219 (quoting SRM of March 20, 1997)].

Statement 2

The second portion of the proposed policy statement is based on the third part of the current statement. The modifications explicitly state the Commission's proposed policy not to intrude into medical judgments affecting patients except to provide for the radiation safety of workers and the general public. Given the significance of this change, the Commission is soliciting specific public comment on whether the wording in the current statement should be revised to read ''not intrude into medical judgments,'' rather than ''to minimize intrusion into medical judgments.'' These comments will be especially useful in evaluating the consistency between the proposed MPS and the Commission's preliminary intent to continue to require patient notification following medical events (the proposed revision to 10 CFR Part 35 would replace the term ''misadministration'' with ''medical event''). Specifically, some would argue that continued regulatory requirements for patient notification would be inconsistent with the proposed revision to Statement 2 of the MPS. Others would argue that notification requirements would be consistent with Statement 3 of the proposed policy statement since a medical event represents a situation where the physician's directions for the administration of byproduct material were not followed and, thus, patient notification should be made.

As set forth above, providing for the radiation safety of the public and workers is essential for the Commission to carry out its statutory mandate. When this protection necessitates a degree of regulation of medical judgments affecting patients, the Commission may find it necessary to intrude, to a certain extent, into medical judgments to protect the public and workers. For example, release of patients administered radioactive materials has long been considered a matter of regulatory concern to protect members of the public, not just a matter of medical judgment (''Criteria for the Release of Individuals Administered Radioactive Material,'' 62 FR 4120; January 29, 1997). Thus, from a strictly medical point of view, it may be appropriate for a physician to release a patient administered radioactive materials from the hospital. However, patient release criteria in NRC regulations (10 CFR 35.75) may require confinement of that patient if release of that patient could result in a dose to other individuals that exceeds the dose-based limit stated in 10 CFR 35.75(a).

In the current policy statement, the Commission stated its intent to ''minimize intrusions into medical judgments affecting patients and into other areas traditionally considered to be part of the practice of medicine.'' The modifications in this part of the proposed policy statement more strongly reflect the Commission's long-standing recognition that physicians have the primary responsibility for the diagnosis and treatment of their patients. NRC regulations are predicated on the assumption that properly trained and adequately informed physicians will make decisions that are in the best interests of their patients. Therefore, in recent years, the Commission has moved away from a more rigid scheme of medical use regulation, which at one time, for example, restricted the uses of therapeutic and certain diagnostic radioactive drugs to the indicated procedures that had been approved by the FDA (44 FR 8242, at 8243).

NRC regulations no longer prohibit authorized user physicians from using diagnostic or therapeutic radioactive drugs containing byproduct material for indications or methods of administration not listed in the FDA-approved package insert. Further, NRC regulations now permit medical use licensees and commercial nuclear pharmacies to depart from the manufacturer's instructions for preparing radioactive drugs using radionuclide generators and reagent kits. In addition, the recent amendment of 10 CFR 35.75, cited above, substituting a dose-based limit for patient release (rather than an activity-based limit), may provide medical use licensees greater flexibility in determining when such patients may be released from their control.

The Commission's proposed policy to avoid (rather than minimize) intrusion into medical judgments affecting patients is consistent with recent Federal legislation (specifically applicable to FDA), which is to be construed so as not to ''limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship.'' (There are certain exceptions to this mandate, which do not change any existing prohibition on the promotion of unapproved uses of legally marketed devices.) ''Food and Drug Administration Modernization Act of 1997,'' Pub. L. No. 105–115, § 906, 111 Stat. 2296 (1997).

Statement 3

Neither the AEA sections cited above nor the regulations in 10 CFR Part 35 use the term ''risk.'' The Commission's current policy statement on medical use, quoted above, makes specific reference to ''risk'' to patients. As there stated and reaffirmed here, the Commission specifically rejects the notion that it should not regulate patient radiation safety (44 FR at 8243). The Commission will continue to regulate radiation safety of patients where justified by the risk to patients. However, proposed Statement 3 makes clear that the focus of NRC regulation to protect the patient's health and safety is primarily to ensure that the authorized user physician's directions are followed. The NRC goal in this aspect of medical use regulation is tied to the physician's directions as they pertain to the application of the radiation or radionuclide, rather than to other, non-radiation related aspects of the administration. Consistent with the Commission's statutory authority, if a situation should arise in the future which identifies an additional risk to the patient's health and safety, the Commission will consider adopting an additional limitation or control on a particular radiation or radionuclide modality as necessary. ''Prescription'' is not being used for this purpose because it might typically include aspects of the administration that are outside NRC's purview. Either the ''written directive'' or ''clinical procedures manual'' (as those terms are defined in Part 35) would contain the physician's directions (*i.e.,* the procedure to be performed and the dose) . This regulatory objective is currently reflected in certain provisions of Part 35 (*e.g.,* 10 CFR 35.32(a) (requiring ''high confidence'' that byproduct material or radiation therefrom will be administered as directed by an authorized user physician) and as part of the rationale of the current policy statement. In the proposed revision of 10 CFR Part 35 and as explicitly stated above, NRC is emphasizing that protection of patient radiation safety is an overall NRC goal in regulating the medical use of byproduct material. Although the Commission recognizes that physicians have primary responsibility for the protection of their patients, NRC has a secondary, but necessary, role with respect to the radiation safety of patients.

The Commission is attempting to make its medical use regulatory framework more ''risk-informed,'' based on its regulatory strategy of regulating ''material uses consistent with the level

of risk involved, by decreasing oversight of those materials that pose the lowest radiological risk to the public and continuing emphasis on high-risk activities' (NUREG–1614, Vol. 1, at 11). In addition, this portion of the proposed policy statement reflects the Commission strategy of identifying those regulations and processes that are now or can be made risk-informed (NUREG–1614, Vol. 1, at 11. SRM of March 20, 1997, at 2).

Statement 4

According to Statement 2 of the current policy statement, NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate. In its SRM of March 20, 1997, the Commission repeated its continued support of professional medical organizations and societies (as well as the ACMUI) in developing regulatory guides and standards (SRM, at 1). Proposed Statement 4 commits NRC to an approach for regulation of medical use which ''will consider industry *and* professional standards that define acceptable levels of achieving radiation safety.'' Such consideration, however, does not involve, as a prerequisite for regulation, the problematic determination of licensee compliance with a voluntary standard (as implied in current Statement 2). At a minimum, such an undertaking leaves NRC with the dilemma of how to deal with licensees that may not comply with voluntary standards. For this reason, the Commission's proposed policy statement does not retain that aspect of the current policy statement.

The Statement of Consideration for the proposed 10 CFR Part 35 rulemakings specifically addresses NRC's current policy of consideration of ''voluntary standards and compliance with such standards.'' Affirming consideration of industry and professional standards as part of the NRC policy in achieving radiation safety in medical use conforms to the Commission's Strategic Plan. The relevant strategy there stated is to increase the involvement of licensees and others in the NRC regulatory development process, based on the concepts in the ''National Technology Transfer and Advancement Act of 1995'' (the NTTAA), Pub. L. No. 104–113, 110 Stat. 775 (1995). Section 12(d) of the NTTAA requires ''all Federal agencies and departments to use technical standards that are developed or adopted by voluntary consensus bodies * * * as a means to carry out policy objectives or activities,'' except when use of such standards ''is inconsistent with applicable law or otherwise impractical.''

It is not clear that all ''medical industry and professional standards'' would meet the definition of ''technical standards'' in Section 12(d)(4) of the NTTAA (''performance-based or design-specific technical specifications and related management systems practices).'' Nevertheless, as indicated above, the Commission endorses, in regulating medical use of byproduct material, the concept in Section 12(a) of the NTTAA, of ''emphasizing, where possible, the use of standards developed by private, consensus organizations.'' As also stated in the Strategic Plan, the Commission encourages ''industry to develop codes, standards, and guides that can be endorsed by the NRC and carried out by industry.''

IV. Policy Implications

This proposed policy statement affirms the Commission determination that it shall continue its role in regulating the medical use of byproduct material, but with emphasis on the goal of protecting the radiation safety of occupational workers, the public, and patients, while avoiding intrusion into medical judgments affecting patients. Ensuring that the authorized user physician's directions for the administration of byproduct material are followed is the primary means of achieving this regulatory goal. Moreover, the Commission is renewing the objective of utilizing industry and professional standards that define acceptable levels of achieving radiation safety.

Reference Information

1. Strategic Assessment Direction-Setting Issues Paper Number 7 is available by writing to the U.S. Nuclear Regulatory Commission, Attention: NRC Public Document Room, Washington, DC 20555–0001, telephone: (202) 634–3273; fax: (202) 634–3343.

2. The memorandum ''Management Review of Existing Medical Use Regulatory Program (COMIS–92–026)'' (dated June 16, 1993) is available by writing to the U.S. Nuclear Regulatory Commission, Attention: NRC Public Document Room, Washington, DC 20555–0001, telephone: (202) 634–3273; fax: (202) 634–3343.

3. ''Radiation in Medicine: A Need for Regulatory Reform'' (1996) is available from the National Academy Press at 2101 Constitution Avenue, NW, Box 285, Washington, DC 20555.

4. Summary minutes and transcripts of the ACMUI March 1998 meeting or transcripts of the May 8, 1997, Commission briefing are available by writing to the U.S. Nuclear Regulatory Commission, Attention: NRC Public Document Room, Washington, DC 20555–0001, telephone: (202) 634–3273; fax: (202) 634–3343. Transcripts of the May 8, 1997, briefing are also available by Internet at http://www.nrc.gov.

5. The NRC Medical Policy Act Statement of 1979 was published in the **Federal Register**, Volume 44, page 8242, on February 9, 1979.

6. SECY–97–115, Program for Revision of 10 CFR Part 35, ''Medical Uses of Byproduct Material'' and Associated Federal Register notice; SECY–97–131, Supplemental Information on SECY–97–131, Supplemental Information on SECY–97–115, ''Program for Revision of 10 CFR Part 35, ''Medical Uses of Byproduct Material,'' and Associated Federal Register notice; and the associated SRM (dated June 30, 1997) are available by writing to the U.S. Nuclear Regulatory Commission, Attention: NRC Public Document Room, Washington, DC 20555–0001, telephone: (202) 634–3273; fax: (202) 634–3343. Copies are also available on the NRC Technical Conference Forum at http://techconf.llnl.gov/noframe.html.

Dated at Rockville, Maryland, this 5th day of August, 1998.

For the Nuclear Regulatory Commission.

John C. Hoyle,

Secretary of the Commission.

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