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# Part III

# Nuclear Regulatory Commission

**10 CFR Parts 20, 32, and 35**

**Medical Use of Byproduct Material; Final Rule**

**NUCLEAR REGULATORY COMMISSION**

**10 CFR Parts 20, 32, and 35**

**RIN 3150–AF74**

## Medical Use of Byproduct Material

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Final rule.

**SUMMARY:** The Nuclear Regulatory Commission (NRC) is amending its regulations regarding the medical use of byproduct material. This final rule is one component of the Commission's overall program for revising its regulatory framework for medical use. The overall goals of this program are to focus NRC's regulations on those medical procedures that pose the highest risk to workers, patients, and the public, and to structure its regulations to be more risk-informed and more performance-based, consistent with the NRC's ''Strategic Plan for Fiscal Year 1997–Fiscal Year 2002.''

**EFFECTIVE DATE:** This regulation becomes effective on October 24, 2002.

**ADDRESSES:** Documents related to this rulemaking may be examined at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Room O–1 F23, Rockville, MD 20852. Available documents include the final environmental assessment, regulatory analysis, regulatory flexibility analysis, and NUREG–1556, Vol. 9(draft), ''Consolidated Guidance About Materials Licenses: Program Specific Guidance About Medical Use Licenses.'' Documents created or received at the NRC after November 1, 1999, are also available electronically at the NRC's Public Electronic Reading Room on the Internet at *http://www.nrc.gov/reading-rm.html.* From this site, the public can gain entry into the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. For more information, contact the NRC Public Document Room (PDR) Reference staff at 1–800–397–4209, 301–415–4737 or by E-mail to *pdr@nrc.gov.*

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### I. Background

*Use of Byproduct Material in Medicine*

Since 1946, growth in the medical applications of radioisotopes has been very rapid as their usefulness has become more apparent in diagnosis, therapy, and medical research. Today, approximately eleven million patients undergo medical procedures involving byproduct material annually.

Current medical procedures employ a number of radionuclides in a wide variety of chemical and physical forms. Nuclear medicine procedures for diagnostic and therapeutic applications involve the internal administration of radiolabeled tracers. Administration of the radiolabeled tracers, known as radiopharmaceuticals, may be performed by intravenous injection, inhalation, or oral ingestion. In most cases, diagnostic nuclear medicine involves imaging agents used for the delineation and localization of organ tissues by scintigraphy (e.g., technetium-99m hydroxymethylene diphosphonate used as a bone seeking radiopharmaceutical). Organ function may be determined by quantifying the accumulation of radiopharmaceuticals in organs of interest (e.g., iodine-131 uptake studies used to assess thyroid function). Therapeutic nuclear medicine may use various radiopharmaceuticals for the treatment of disease by selective absorption or concentration (e.g., iodine-131 used to treat thyroid cancer). Other therapeutic applications may involve the use of radiopharmaceuticals in colloidal suspensions for the treatment of malignant tumors (e.g., phosphate-32 infusion for treatment of peritoneal or pleural effusions associated with malignant tumors).

Since the early 1900s, radiation therapy has become one of the major modalities of treatment in the management of neoplastic disease, generally referred to as cancer. Radiation therapy may also be used as a palliative agent in the medical treatment process. The objective of conventional radiation therapy using a teletherapy sealed source is to deliver a precisely measured dose of radiation to a defined tumor volume. This is usually accomplished by delivering a dose in daily increments over several weeks. External beam radiation therapy has evolved using innovative technology that has led to the development of the gamma stereotactic radiosurgery device used for treatment of precisely defined intracranial targets (e.g., brain tumors and arteriovenous malformations).

Brachytherapy uses a variety of smaller sealed sources for localized treatment of cancer. Typically, the sealed sources are either inserted in a cavity (e.g., cesium-137 sources used for intracavitary treatment of cervical cancer) or implanted in tissue (e.g., iodine-125 seeds used for interstitial treatment of prostate cancer). Various remote afterloading devices have been developed for low, medium, and high dose-rate brachytherapy treatments.

*State and Federal Regulations*

Byproduct material and radiation from byproduct material are regulated by either State or Federal laws and regulations. The principal statutory authority for NRC's regulation of the medical use of byproduct material rests in the Atomic Energy Act (AEA) of 1954, as amended, and the Energy Reorganization Act of 1974, as amended. NRC's medical use program includes regulation of the uses of byproduct material in medical diagnosis, therapy, and research. The NRC regulates the administration of byproduct material or radiation from byproduct material in 18 States, the District of Columbia, the Commonwealth of Puerto Rico, and various territories of the United States. There are approximately 1700 NRC licensees authorized for medical use of byproduct material under 10 CFR Part 35, ''Medical Uses of Byproduct Material.''

Thirty-two States have each entered into an agreement with the NRC to regulate the use of byproduct material (as authorized by section 274 of the Atomic Energy Act) within that State. These States issue licenses for certain diagnostic and therapeutic uses of radioactive materials, and currently regulate approximately 4200 institutions, e.g., hospitals, clinics, or physicians in private practice. For additional information on the

Agreement States' regulatory program refer to NRC's Management Directive (M.D.) 5.6, ''Integrated Materials Performance Evaluation Program (IMPEP),'' and M.D. 5.9, ''Adequacy and Compatibility of Agreement States Programs.''

*Revision of NRC's Regulatory Program*

The Commission examined the issues surrounding its medical use program in detail during a 1993 internal senior management review, a 1996 independent external review by the National Academy of Sciences, Institute of Medicine, and the Commission's Strategic Assessment and Rebaselining Project (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'' (NUREG–1614, Vol. 1) 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.''

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 Part 35, associated guidance documents, and, if necessary, the Commission's 1979 Medical Use Policy Statement (MPS) (44 FR 8242; February 9, 1979). The Commission's SRM specifically directed the restructuring of Part 35 into a risk-informed, more performance-based regulation. In addition, the Commission expressed its support for the use of the NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI) and professional medical organizations and societies in the revision of Part 35 and the MPS.

Based on the Commission's direction in this SRM, the process used by the NRC staff to develop the proposed rule and policy statement provided more opportunity for input from potentially affected parties than the normal notice and comment rulemaking process. The process included a number of public meetings and workshops with stakeholders and other affected parties, the ACMUI, Agreement States, and professional medical societies and organizations. See the proposed rule and policy statement published in the **Federal Register** (63 FR 43516; 63 FR 43580; August 13, 1998).

The Commission, in its SRM of June 30, 1997, SECY–97–115—''Program for Revision of 10 CFR Part 35, 'Medical Uses of Byproduct Material' and Associated **Federal Register** Notice,'' approved the NRC staff's proposed plan for the revision of Part 35. In a document published in the **Federal Register**, ''Medical Use of Byproduct Material: Issues and Request for Public Input'' (62 FR 42219–42220; August 6,1997), the Commission solicited early public input on the proposed rulemaking.

The proposed revisions of Part 35 and the MPS that were developed in response to the Commission's SRMs were published for a 90-day public comment period on August 13, 1998 (63 FR 43516 and 63 FR 43580). The comment period was later extended by 30 days (63 FR 64829; November 23, 1998) at the request of stakeholders. The document presenting the contemplated revision of Part 35 solicited public comment on the proposed rule; discussed the issues that were considered during the development of the proposed rule and associated guidance; and summarized the input that was received from the public, potentially affected parties, the ACMUI, and professional medical organizations. These issues included patient notification, precursor events, Radiation Safety Committee, quality management program, and training and experience for authorized users.

In addition to publishing the proposed rule and MPS in the **Federal Register** for comment, the Commission also held facilitated public meetings during the comment period to discuss the Commission's resolution of the major issues. Publicly noticed workshops were held in San Francisco, CA, on August 19–20, 1998, in Kansas City, MO, on September 16–17, 1998, and in Rockville, MD, on October 21–22, 1998. The Commission also held a public workshop in February 1999 to solicit additional comments on implementation issues associated with the proposed revisions to the training and experience requirements. The Commission was specifically interested in information on the process and criteria for approving medical and other specialty boards and examining organizations and entities. The four public workshops are summarized in ''Summary of Public Meeting on Proposed Revisions to Part 35 and the NRC's Medical Policy Statement,'' San Francisco, CA, August 19–20, 1998 (September 11, 1998); ''Summary of Public Meeting on Proposed Revisions to 10 CFR Part 35, ''Medical Use of Byproduct Material'' and the NRC's Medical Policy Statement,'' Kansas City, MO, September 16–17, 1998 (October 12, 1998); ''Summary of Public Meeting on Proposed Revisions to 10 CFR Part 35, ''Medical Use of Byproduct Material'' and the NRC's Medical Policy Statement,'' Rockville, MD, October 21–22, 1998 (November 18, 1998); and ''Summary of Discussion; Facilitated Part 35 Public Meeting with Representatives of the Medical Boards Held in Rockville, Maryland, February 17–18, 1999'' (April 7, 1999). The summary documents are available for inspection at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Room O–1 F23, Rockville, MD 20852. Single copies of the summary documents are available from the persons indicated in the For Further Information Contact section of this document.

The comments received at the workshops and the comments received in response to the proposed rule were all carefully considered by the Part 35 Working and Steering Groups in developing the final rule. Section III, Summary of Public Comments and Responses to Comments, in the **SUPPLEMENTARY INFORMATION** in this document, includes a summary of the comments and the NRC staff's responses to them.

In February 1999, the ACMUI diagnostic and therapeutic subcommittees held public meetings to review the public comments and the NRC staff's first draft of the final rule that addressed the comments. The full ACMUI held a public meeting in March 1999 to discuss specific issues that the Part 35 Working Group wanted the ACMUI to review and comment on before a draft final rule was forwarded for Commission consideration. The ACMUI presented its position on these and other issues at their annual briefing of the Commission in March 1999. In October 1999 and February 2002, the ACMUI briefed the Commission on specific issues that it wanted to bring to the Commission's attention. For additional information on the ACMUI's position on the rulemaking and associated issues refer to Section VI, Coordination with the Advisory Committee on the Medical Uses of Isotopes, in the **SUPPLEMENTARY INFORMATION** in this document.

The Agreement States were involved throughout the rulemaking process. Both the Working Group and Steering Group that developed the revision of Part 35 included representatives of the Agreement States. A draft compatibility chart for Agreement States' regulations

was published for comment with the proposed rule (63 FR 43516; August 13, 1998). The NRC staff discussed the States' rulemaking issues with representatives of the Agreement States at the 1999 annual meeting of the Organization of Agreement States. For additional information refers to Section IV, Summary of Comments on Agreement State Compatibility and Responses to Comments; Section VI, Coordination with NRC Agreement States; and Section X, Issues of Compatibility for Agreement States, in the **SUPPLEMENTARY INFORMATION** in this document.

As the Commission readied the final rule for publication in the **Federal Register**, Congress directed NRC not to implement or enforce certain parts of revised Part 35 relating to diagnostic nuclear medicine until after the NRC submitted a report to Congress explaining why the regulatory burden associated with the rule could not be reduced further without adversely affecting the public health and safety. ''Energy and Water Development Appropriations Act, 2002,'' (Pub. L. 107–66). The NRC transmitted the report to Congress on February 11, 2002. That report concludes that further reduction of regulatory burden beyond that currently proposed in the revised rule has the potential to increase the risk to public health and safety. Although the Act permitted NRC to implement some aspects of the revised rule before submitting the report, NRC chose not to implement any portion of the revised rule until after its report was submitted.

Nevertheless, the NRC acknowledges that stakeholders have identified substantial concerns related to the perceived burden of the implementing guidance and inspection programs. Therefore, the NRC is committed to a program, with public and stakeholder participation, to improve the licensing and inspection guidance to enhance the burden reduction offered by revised Part 35. The NRC noticed the availability of revised draft NUREG–1556, Volume 9, for public comment (67 FR 16467; April 5, 2002); the comment period ends on June 4, 2002. In addition, consideration of future rule changes will remain possible through the NRC's established rulemaking procedures as experience with the new rule is gained by both the NRC and our licensees.

In addition to the revision of Part 35, the Commission published the revision of its policy statement on the Medical Use of Byproduct Material (MPS) (65 FR 47654; August 3, 2000). The revision of the MPS is another component of the Commission's overall program for revising its regulatory framework for medical use. The revision of Part 35 is consistent with the revision of the MPS. Section VIII, Consistency with the Medical Policy Statement, in the **SUPPLEMENTARY INFORMATION** in this document, addresses the consistency of the final rule with each statement in the revised MPS.

The Commission is also concurrently publishing, in a separate document in this **Federal Register**, a modification of ''General Statement of Policy and Procedure for NRC Enforcement Actions,'' NUREG–1600, to revise the examples of severity levels for Part 35 violations to reflect the revised medical use requirements in the final rule. These examples are used in the enforcement process to provide guidance for determining the significance of a particular violation.

*Voluntary Consensus Standards*

The National Technology Transfer and Advancement Act (NTTAA) of 1995, Public Law 104–113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable laws or otherwise impractical. In COMSECY–96–057, ''Materials/Medical Oversight (DSI 7),'' the Commission specifically directed the NRC staff to examine the viability of using or referencing available industry guidance and standards, within Part 35 and related guidance, to the extent that they meet NRC's needs. In addition, Statement 4 in the revised medical use policy statement provides that the NRC regulatory approach consider industry and professional standards that define acceptable approaches of achieving radiation safety.

In developing this final rule, the NRC staff reviewed the technical literature to identify consensus standards and/or protocols that could be used or referenced either in the regulation or associated guidance document. This process included reviewing documents of the official standards consensus bodies that are identified on the National Institutes of Standards and Technology website, e.g., the American National Standards Institute (ANSI). In addition, the NRC staff reviewed protocols developed by technical professional societies that use a consensus process within their own organization, e.g., the American Association of Physicists in Medicine (AAPM). The NRC staff determined that voluntary consensus standards exist that met certain objectives in the final rule. Therefore, the NRC staff did not develop government-unique standards. The requirements in the final rule are, for the most part, performance-based and state the objectives to be achieved. This approach allows the licensee to select among various performance standards to meet the objectives of the regulation. This approach is consistent with the Commission's goal to develop more performance-based regulations. The Commission believes that this approach will provide medical use licensees with significant flexibility in designing their radiation protection programs.

For additional information on how consensus standards were used in the development of the final rule refer to Section III, Summary of Public Comments and Responses to Comments in the **SUPPLEMENTARY INFORMATION** in this document.

## II. Petitions for Rulemaking (PRM)

*PRM–20–24*

The final rule completes action on a Petition for Rulemaking (PRM) filed by the University of Cincinnati, dated April 7,1996 (PRM 20–24), because of its pertinence to Part 35. The petitioner basically requested that the NRC amend 10 CFR 20.1301, ''Dose limits for individual members of the public'' to:

(1) Provide medical use licensees the discretion to permit those visitors determined by the physician to be necessary for the emotional or physical support of the patient to receive up to 5 mSv ( 0.5 rem) (e.g., parents of very young radiation therapy patients, close family members of elderly patients, or other persons who could provide emotional support to the patient);

(2) Exclude pregnant women and individuals younger than 18 years of age from receiving a dose in excess of 1 mSv (0.1 rem);

(3) Document compliance by issuing a radiation dose monitoring device (i.e., pocket dosimeter, film badge, TLD, or electronic dosimeter) to each specified visitor; and

(4) Require licensees to instruct visitors about radiation safety.

On June 21, 1996 (61 FR 31874), the NRC published a notice of receipt and a request for comment on this petition for rulemaking. The comments received in response to that document were discussed in the August 13, 1998, proposed rule (63 FR 43516). Additional comments on the petition were received in response to the request for comments on the proposed rule and are discussed in Section III, Part III of the **SUPPLEMENTARY INFORMATION** of this document.

The NRC reviewed the petitioner's request and comments received on the

petition and believes there is merit in granting the petition in part. The final rule responds to the petition by amending § 20.1301 to allow a licensee the discretion to permit visitors to receive up to 5 mSv (0.5 rem) in a year from exposure to hospitalized radiation patients, i.e., individuals who cannot be released under § 35.75. We believe the emotional benefit to the patient or the visitor outweighs any increase in radiation risk to the visitor. In addition, we believe that the authorized user (AU) is the appropriate individual to evaluate, on a case-by-case basis, the merits of allowing a visitor to potentially receive this additional dose and would do so only when it is warranted by the situation. AUs have the primary responsibility for the health and safety of their patients. They are also responsible for determining, depending on the patient's condition, whether individuals can visit patients and with what limitations. Therefore, we believe the AU should determine whether a visitor is allowed to receive a dose up to 5 mSv (0.5 rem).

The NRC did not grant request (2) of the petition that NRC exclude pregnant women and individuals younger than 18 years of age from receiving a dose in excess of 1 mSv (0.1 rem). Pregnant visitors are not excluded automatically from visiting individuals who cannot be released under § 35.75. The pregnant visitor is subject to the same exposure limits that are applied to any other adult member of the public. The reasons for not excluding pregnant visitors are two-fold. First, as noted in National Council on Radiation Protection and Measurements (NCRP) Commentary No. 11 (Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients, 1995), members of a radionuclide therapy patient's family are likely to perceive that visitors will benefit from providing emotional and physical support to the patient during their treatment, and these visitors are likely to be willing to bear greater risk in order to achieve that benefit. Second, declaration of pregnancy by a prospective visitor is strictly voluntary. If a prospective visitor does not voluntarily declare her pregnant status, the AU is not expected to demand confirmation of the visitor's nonpregnant status.

The NRC also did not grant request (3) of the petition that compliance be documented by use of a radiation dose monitoring device (i.e., pocket dosimeter, film badge, TLD, or electronic dosimeter) by each specified visitor. The Commission does not intend to require monitoring and recording of individual doses to visitors of hospitalized radiation patients. The NRC evaluated the costs associated with monitoring doses to visitors versus the benefits derived and determined that, at these low doses, monitoring is not justified. However, this does not preclude the licensee from monitoring and recording doses to visitors.

The NRC also did not grant request (4) of the petition that licensees be required to instruct visitors about radiation safety. We believe that licensees should have flexibility in determining how they will effectively limit radiation exposure of the visitors to levels that are as low as is reasonably achievable.

This completes action on PRM–20–24.

*PRM–35–16*

On January 11, 2001, the NRC docketed a January 3, 2001, letter from Donald A. Podoloff, MD, of the American College of Nuclear Physicians, and Jonathan M. Links, PhD, of the Society of Nuclear Medicine, to the Office of the Secretary, as a petition for rulemaking under 10 CFR 2.802 (PRM–35–16). The petitioners requested that the Commission: rescind its approval of the NRC staff's proposed revision to 10 CFR Part 35, ''Medical Use of Byproduct Material''; revoke all of 10 CFR Part 35, except for specifically identified requirements; and institute a new rulemaking proceeding to adopt a regulatory scheme for the use of byproduct material in diagnostic nuclear medicine that reflects the discipline's ''unparalleled and undisputed safety record.''

The petitioners believe that the requested changes would benefit the public in two ways. First, substantial requirements for physicians' education, training, and experience, as well as appropriate evidence of mastery by testing would improve the knowledge and abilities of physicians offering diagnostic nuclear medicine. Second, costs to the health care system would decrease without any decrease in safety.

The NRC denied the petition because:

(1) The Commission approved the final rule addressing the issues raised in the petition after an extensive rulemaking process that provided an unprecedented level of enhanced stakeholder and public participation;

(2) The Commission believed that the ACNP/SNM had many opportunities to present their concerns and suggestions as part of that process and did so; and

(3) The petition did not appear to present any significant new information or recommendations that the Commission has not already considered.

This completes action on PRM–35–16.

## III. Summary of Public Comments and Responses to Comments

This section summarizes the written and oral comments that we received on the proposed rule and provides responses to these comments. Part I contain a list of the acronyms used in this section. Part II discusses general issues that were considered during the rulemaking. Part III discusses specific comments on the proposed rule.

*Part I—Acronyms*

The following acronyms are used in the discussion of both the general and specific comments.

AAPM American Association of Physicists in Medicine
ABHP American Board of Health Physics
ABR American Board of Radiology
ABMS American Board of Medical Specialities
ABNM American Board of Nuclear Medicine
ACGME Accreditation Council for Graduate Medical Education
ACMP American College of Medical Physics
ACMUI Advisory Committee on the Medical Uses of Isotopes
ACR American College of Radiology
ALARA As low as is reasonably achievable
AMP Authorized medical physicist
ANP Authorized nuclear pharmacist
ANSI American National Standards Institute, Inc.
AO Abnormal Occurrence
AU Authorized user
FDA Food and Drug Administration
Gy/h Gray per hour
GBq Gigabecquerel
HDR High dose-rate remote afterloader
IDE Investigational Device Exemption
IMPEP Integrated Materials Performance Evaluation Program
IND Investigational New Drug Exemption
INPO Institute for Nuclear Power Operations
IRB Institutional Review Board
JCAHO Joint Commission on the Accreditation of Hospitals Organization
LDR Low dose-rate remote afterloader
MBq Megabecquerel
mCi Millicuries
μCi Microcuries
MDR Medium dose-rate remote afterloader
mSv Millisievert
NAS–IOM National Academy of Sciences-Institute of Medicine
NCRP National Council on Radiation Protection and Measurements
NIST National Institute of Standards and Technology

PDR Pulsed dose-rate remote afterloader
QMP Quality Management Program
SSDR Sealed Source and Device Registry
Sv Sievert
RDRC Radioactive Drug Research Committee
RSC Radiation Safety Committee
RSO Radiation Safety Officer

*Part II—General Issues*

*A. Risk*

Issue 1: What Is the Difference Between a Risk-Informed and a Risk-Based Approach to Rulemaking?

*Comment.* Commenters asked us to explain the difference between a ''risk-based'' rule and a ''risk-informed'' rule.

*Response.* A ''risk-based'' approach to regulatory decisionmaking is one in which a safety decision is solely based on the numerical results of a risk assessment. This places a heavier reliance on risk assessment results than currently may be practicable. A ''risk-informed'' approach to regulatory decisionmaking represents a philosophy that considers risk insights together with other factors to establish requirements that better focus licensee and regulatory attention on design and operational issues commensurate with their importance to health and safety.

The Commission does not endorse risk-based regulation. In revising Part 35, the Commission used risk insights from available risk information. The Commission considered the completeness and reliability of the available risk information and balanced the insights drawn from this information against other factors, such as decades of licensing and inspection experience, the States' perspectives, statutory requirements, and public and stakeholder interests, in formulating policy.

Issue 2: How Was Risk Used in Revising Part 35?

*Comments.* Commenters indicated that the NRC's approach to the Part 35 rulemaking was flawed because a formal risk analysis had not been performed before initiating the rulemaking. Some commenters did not believe that the NRC has the expertise to perform or manage a rigorous risk analysis that is needed before publishing the final rule. Other commenters believed the proposed rule did not explain NRC's perception of the regulatory problem and how the rulemaking would solve that problem. Commenters asked that the NRC start the Part 35 rulemaking over by—

(1) Identifying the problem (perform a formal risk-based analysis);

(2) Revising the Medical Policy Statement;

(3) Completing the rulemaking; and

(4) Developing licensing, inspection, and enforcement policies and procedures to support the rule.

Many of these commenters offered possible ways of evaluating risk and asked that stakeholders be allowed to participate in assessing risk. Some commenters indicated that the NRC should establish a risk-benefit ''filter'' to evaluate this and future rulemakings. They believed that this approach would be useful in dealing with emerging technologies. They also believed that, if the NRC had a structured framework for risk analysis, appropriate regulations could be developed to deal with the real risk to the patient, public, and workers.

Other commenters asked that we consider all types of risk before publishing the final rule, e.g., absolute, relative, comparable, perceived, cost, and ''pseudo risks.'' Commenters discussed these types of risks in the following terms and offered the following comments on each type of risk as they are viewed in the regulation of medicine. While most comments were directed at diagnostic nuclear medicine, many of the statements would also apply to therapeutic uses of byproduct material.

*Absolute risks* are the risks of real health effects (deterministic, stochastic) that include harm to the patient, public, or worker. Commenters indicated that diagnostic nuclear medicine procedures do not present measurable health effects to the patient, public, or workers.

*Relative risks* are the risks of diagnostic nuclear medicine relative to other diagnostic medical procedures that are currently unregulated for the end-user. The side-effects from many non-radiological medical procedures involve higher risks of harm to the patients than microcurie and millicurie amounts of byproduct material that are used for tracer and localization and imaging studies, where there is no observable radiological or pharmaceutical effect.

*Comparable risks* are the risks of diagnostic nuclear medicine as compared to other industrial risks (radiological and non-radiological) and other human activities that are acceptable to the general public.

*Perceived risks* involve the public perception of safe and unsafe uses of radiation that eventually influence the licensee to comply with unnecessary NRC requirements in order to compete in the market place. One commenter noted that most cancer patients are willing to accept higher risks for the benefit of cure. This commenter believed that the large number and prescriptiveness of the current regulations add to the misconception that the public has of radiation. By reducing needless requirements on low risk nuclear medicine, the public perception will adjust accordingly, so that NRC regulatory oversight is less burdensome to licensees.

*Cost risks* result in overspending on low risk activities. This economic imbalance creates a higher risk for other areas that do not receive the resources that would otherwise be available.

*Pseudo risks* are unreal risks in which there is no harm associated with the activity or event, e.g., landfill alarms as a result of disposal of short-lived, low-activity radioactive waste from diagnostic nuclear medicine.

*Response.* In March 1997, the Commission directed the revision and restructuring of Part 35 into a more risk-informed and, where appropriate, more performance-based regulation. This direction was part of the Commission's overall decision to decrease oversight of low-risk activities, such as diagnostic nuclear medicine, while retaining oversight of high-risk activities.

Before initiating the rulemaking, the Commission thoroughly reviewed several extensive assessments, including the external review conducted by the National Academy of Sciences, Institute of Medicine (NAS–IOM), and the related report ''Radiation in Medicine, A Need for Regulatory Reform,'' a 1993 NRC internal senior management review and report, and the Commission's Strategic Assessment and Rebaselining initiative. During the development of the overall revision of Part 35, we considered information on risk provided by members of the public and professional societies, professional medical standards of practice, and event databases maintained by NRC to determine where oversight of lower-risk activities could be decreased and where continuation, or even broadening, of the regulations governing higher-risk activities was needed. In addition, throughout the development of the proposed rule and associated proposed guidance, public workshops were held and early opportunities for comment from the public and other potentially affected parties were provided. These interactions included significant discussions on the risk associated with medical uses of byproduct material. In addition, NRC sought and received comments on the draft guidance document published in August 1998.

In further developing the licensing and inspection guidance, the NRC plans

to seek public comment and hold facilitated public workshops. The NRC expects that the development of the guidance will be completed before the effective date of the rule.

While the NRC did not perform a formal risk assessment, we believe that we have adequately evaluated and considered the risks associated with use of byproduct material in medicine. We have eliminated requirements in the current Part 35 that are contained elsewhere in the Commission's regulations, such as the radiation protection requirements in Part 20. Part 35 licensees will continue to be required to comply with these requirements, such as the ALARA provisions in Part 20, but we do not believe that there is a need to duplicate the requirements in Part 35 unless there are specific, additional radiation protection requirements that are applicable to medical use licensees. We have maintained some prescriptive requirements in the rule that we believe are necessary to ensure adequate protection of the workers, patients, and public. The statements of considerations for the proposed rule and for this final rule and the accompanying Regulatory Analysis explain why we believe changes needed to be made in the regulations.

Issue 3: Is the Risk of Byproduct Material in Diagnostic Nuclear Medicine Low?

*Comment.* Many commenters provided information indicating that risks associated with the use of byproduct material in diagnostic nuclear medicine is low. The commenters provided reasons for the deregulation of low risk nuclear medicine uses altogether. The commenters indicated that the average patient dose from administration of a single unit dose is comparable to the average annual radiation dose from natural background radiation in the United States. They believed that a zero risk tolerance is extremely impractical and the NRC should not attempt to regulate diagnostic nuclear medicine to account for errors that are harmless. Commenters indicated that the NRC should not substitute theoretical risk values for lack of measurable risk values, that ''real risk'' is based on real harms that are measurable, and that there are no measurable risks involved with diagnostic nuclear medicine.

Commenters went on to state that diagnostic nuclear medicine has an outstanding performance history and that there have been zero consequences to the patients, workers, and public. Another commenter stated that in over 300 million applications of radiation for diagnostic purposes, there has been only one death, which occurred over 30 years ago. Commenters believed that, by requiring compliance with regulations where there is no clear hazard or detrimental radiation dose, the NRC is diverting resources away from higher risk activities, e.g., non-radiological risks related to medical practice. This brand of economics for safety programs creates an unjustifiable imbalance of resource allocation for the licensee. They went on to say that an additional risk burden is placed on the higher, non-radiological risk activities because there is competition for finite resources that support NRC requirements for low risk nuclear medicine. In this sense, NRC requirements are overly burdensome for most licensees.

*Response.* The NRC agrees that the risk associated with the use of byproduct material in diagnostic nuclear medicine is low. For this reason, the final rule is much different from the current rule. In consideration of the low radiation risks in the diagnostic area, we have reduced the unnecessary regulatory burden for diagnostic nuclear medicine licensees by either eliminating or decreasing the prescriptiveness of the regulations that apply to them. Instead, we are relying on a performance-based approach that emphasizes the training and experience of the authorized user (AU), authorized nuclear pharmacist (ANP), and Radiation Safety Officer (RSO).

Issue 4: Can Regulation of Diagnostic Nuclear Medicine Be Limited to Part 20 and Training and Experience Requirements?

*Comment.* Commenters stated that the appropriate regulation of diagnostic nuclear medicine should involve only the radiation protection requirements in Part 20 and board certification requirements as an indication of medical competence. Another commenter identified the sections of the proposed rule asserted to perform no useful purpose and to have no risk-based justification. The identified provisions were: §§ 35.6, 35.11(c), 35.13(d), 35.24, 35.27, 35.60, 35.61, 35.62, 35.63, 35.69, 35.204, 35.2024, 35.2060, 35.2061, 35.2063, and 35.2204.

*Response.* The final rule includes requirements that are needed to protect occupationally exposed individuals, patients, and the public. Certain radiation protection-related requirements unique to medical use are needed in Part 35 because of their contribution to risk reduction. For example, the final rule retains requirements to calibrate instrumentation used to measure the radioactivity of patient dosages before they are administered (§ 35.60). For this reason and because the NRC believes that these requirements are essential to the safe handling of byproduct material, we believe the sections cited by the commenter should not be deleted from the rule. (Note, §§ 35.60 and 35.62 were combined in the final rule.)

*B. Licensing*

Issue 1: Should Diagnostic Nuclear Medicine Programs Be Given a General License Rather Than a Specific License?

*Comments.* Many commenters recommended that the NRC issue a general rather than a specific license for diagnostic nuclear medicine programs. The NRC's role would be to establish training and experience requirements for physicians, pharmacists, and RSOs. They indicated that the applicant would provide the NRC with their name, location, and contact information and pay a licensing fee to NRC. Commenters emphasized that, after satisfying the minimum training and experience criteria for low risk nuclear medicine programs, the physician should be authorized to receive and use byproduct material with minimal or no regulatory oversight.

Commenters compared the use of byproduct material in diagnostic nuclear medicine to medical uses of naturally-occurring or accelerator-produced radioactive material (NARM), e.g., thallium-201, gallium-67, and indium-111. Commenters indicated that several states currently have no regulatory authority for NARM. In those states, any physician could receive and use NARM for nuclear medicine procedures without either a registration or a license. There were no training and experience criteria or other radiation safety regulations for medical use of NARM—the medical use of NARM was controlled by current standards for medical care. Commenters believed that the unregulated medical use of NARM products justifies a similar lack of regulations for medical use of byproduct materials that are currently regulated by NRC.

Some commenters suggested that one of the state radiation control agencies should be allowed to establish a pilot program for general licensing of their nuclear medicine licensees. After a period of several years, the NRC could evaluate the pilot program. If the program were found to be successful, the NRC could revise its regulations to issue general licenses for diagnostic nuclear medicine facilities.

Some commenters indicated that it should not be necessary to identify a physician for the medical use program because the focus of the revised Part 35 will be on radiation safety rather than on the physician's (AU's) clinical competence. These commenters recommended that the licensing process be simplified to identify the name and contact information for the management representative responsible for radiation safety and to describe any byproduct material that is normally used and that could become hazardous to public health and safety during a catastrophic event, e.g., an earthquake or a serious fire/explosion. This commenter believed that the NRC should authorize the applicant for broad scope use of byproduct material and should not review the licensee's standard operating procedures before the authorization.

Some Agreement State commenters stated that they were opposed to the use of a general license in the medical use area. Commenters believed that, in the past, regulatory difficulties were created by general licenses for other non-medical uses, e.g., fixed gauges containing sealed sources. The Agreement State representatives believed that if this concept could not be supported for non-medical uses, then it was doubtful that it should be endorsed for medical uses. Many also believed a Radiation Safety Committee (RSC) should be retained to review all aspects of the radiation safety program before submitting an application to the regulatory agency and that the regulatory agency should continue to review procedures before the license or amendment was issued.

*Response.* The NRC believes that diagnostic nuclear medicine programs should continue to be specifically licensed rather than generally licensed. A specific license is needed because the potential exists for individuals in the diagnostic nuclear medicine setting to be exposed to radiation levels in excess of the Part 20 dose limits, because of the possession of significant quantities of unsealed material, and because the training and experience of the ANP, AU, and RSO are necessary for the safe handling of byproduct material. However, we have reduced the amount of documentation that must be submitted by an individual or organization that is applying for a specific license to use byproduct material in diagnostic nuclear medicine. When applying for this type of license, the applicant only needs to provide us with information on its facility and the training and experience of the authorized medical physicist (AMP), AMP, ANP, AU, and/or RSO, as appropriate. The applicant no longer needs to provide us with detailed operating and emergency procedures, e.g., dose calibrator calibration procedures, survey meter calibration procedures, or safe handling procedures. In many cases, the final rule gives licensees the flexibility to use either the procedures that have been developed by nationally recognized organizations or the manufacturer's instructions. The final rule also reduces the unnecessary regulatory burden on diagnostic nuclear medicine licensees by eliminating or reducing the prescriptiveness of the regulations concerning diagnostic nuclear medicine.

*C. Inspection*

Issue 1: Could NRC Use an Outside Accrediting Organization for Inspections in Diagnostic Nuclear Medicine?

*Comment.* Some commenters expressed a belief that the inspection program in diagnostic nuclear medicine was not necessary. They believed that the NRC could allow professional accreditation boards and organizations to conduct inspections on behalf of NRC. They state that these organizations are already involved with nationwide monitoring of the quality of nuclear medicine services in a peer review manner that encourages comprehensive improvement of quality and the safe use of radioactive materials. They compared this approach to NRC's recognition of the Institute of Nuclear Power Operations (INPO) for the reactor industry. These commenters went on to state that the low risks to patients, workers, and the public from the use of byproduct material for diagnostic nuclear medicine practices do not warrant the current level of NRC regulatory oversight.

These commenters also provided two examples in which a similar approach has been used in the medical community. One example is where the medical community and the Food and Drug Administration (FDA) worked closely in implementing the ''Mammography Quality Standards Reauthorization Act of 1998'' (Pub. L. 105–248). The FDA partnered with the American College of Radiology (ACR) to establish the ACR accreditation standards as Federally mandated practice standards for personnel, equipment, quality assurance, and other activities involved in mammography. These national standards have led to broad improvements in mammography nationwide. A second example is where the State bureaus for hospital standards recognize the Joint Commission on the Accreditation of Hospitals Organization (JCAHO) accreditation as evidence that State laws have been met by the certified institutions. This approach allows State governments to focus their resources on those facilities that are not certifiable by the JCAHO. This reduces duplication of inspection effort and provides cost savings to the medical institutions.

The commenters thought that the NRC should delegate the inspection program to an accrediting organization by rulemaking or by administrative action after the NRC has reviewed the accreditation organizations. They also indicated that this rulemaking or administrative action should result in a reduction in NRC fees assessed to licensees that voluntarily submit to the accreditation process.

Commenters indicated that the NRC should review the accrediting program to assure that the content of the current monitoring (accrediting) program was adequate and equivalent to the NRC inspection program. Commenters indicated that the site review teams would identify deficiencies, recommend corrective actions, allow time for implementation of improvements, and offer an appeal process to the licensees. They believed that the NRC should then recognize the accreditation organization monitoring programs as adequate to evaluate radiation safety practices of nuclear medicine licensees.

Along with the final rule, commenters recommended that the NRC post a list of approved accreditation boards and organizations. Licensees could voluntarily select the appropriate organization to evaluate their radiation safety programs. Accredited licensees would not be subject to direct inspection by NRC. Licensees that did not voluntarily select an NRC-approved accreditation organization would be subject to direct inspection by the NRC or an Agreement State. Commenters indicated that the NRC could audit the site review teams and randomly accompany them to observe the appropriateness of the evaluation process.

Commenters cautioned that the accreditation organizations should not become the enforcement arm of the NRC and should not be required to report detailed, confidential findings to NRC. Commenters believed a pass/fail list of licensees that voluntarily submitted to the site review team could be made available to NRC. Alternatively, the NRC could condition the nuclear medicine licenses to require the licensees to notify NRC upon certification, re-certification, or change in certification

status (e.g., probation, suspension, termination).

Some commenters did not agree with this approach to inspection. Commenters did not believe there would be a cost savings associated with this approach. They cited increased costs to utilities because of the INPO standards and to medical facilities because the cost of mammography operations were increased by the Mammography Quality Standards Act. These commenters believed that any cost savings associated with JCAHO certification were offset by increased fees from other organizations.

Commenters that did not favor this approach indicated that site review team members would not have the authority of the Federal Government behind them as NRC inspectors do now. Some indicated that the proposed alternative was self-serving and did not account for independent clinics and institutions. These commenters indicated that NRC's endorsement of the accreditation process will set up an unfair advantage and will be used only to increase membership in accrediting organizations.

Representatives from some Agreement States did not think it was likely that Agreement States would relinquish their inspection programs to accrediting organizations.

*Response.* The NRC's inspection program is separate from this rulemaking and may be changed without changing the regulations. The NRC agrees that diagnostic nuclear medicine licensees, as a whole, have operated safely in the past and that the radiation risk to public, patients, and workers is low. The inspection and enforcement history indicates cooperation and successful implementation of radiation protection programs by most licensees.

NRC licensees are encouraged to audit their own activities and discover and correct their own violations. A voluntary program of inspection by an accrediting organization is one method to accomplish this goal. For example, if accrediting organizations were noted to be successful in discovering violations and assuring that those violations are corrected, the frequency of inspections at accredited facilities could be decreased. Under this scenario, some NRC inspections could still be performed to verify the effectiveness of the voluntary program undertaken by the accrediting organization, but the overall number of inspections performed by the NRC would be reduced.

In summary, we believe the proposal for involvement of professional accreditation boards and organizations in the inspection program should be further explored in an ongoing dialogue. In the interim, the NRC will continue to inspect nuclear medicine licensees but will also continue to make improvements to the inspection program, e.g., focusing the inspection program on risk and decreasing the inspection frequency for good performance.

Issue 2: What Changes Should Be Made in the Inspection Process as a Result of the Revised Part 35?

*Comment.* Commenters expressed a concern that NRC inspections were too detailed and focused on records and use of checklists. Some commenters asked that NRC inspectors focus on radiation safety program management. They indicated that, if the program was managed properly, there would be no need to evaluate program records or the written procedures. Commenters believed that inspectors should be satisfied if the big picture does not indicate a violation because the final rule will be less prescriptive, more risk-informed, and performance-based. Other commenters asked that inspectors rely on conversations with licensee staff, and independent measurements to form a basis for inspection findings.

Commenters asked that the NRC provide training on the new rule to inspectors before the final rule is published. They also asked that the period between inspections be increased. Commenters believe that the inspector should be able to recognize the differences between the current and final rule. Agreement State representatives also believe that there will be a critical need to provide training on the final rule to their inspectors. Some commenters also asked that inspectors be encouraged to describe the good practices. They believed this would foster a more positive relationship among NRC, workers, management, and the public.

*Response.* In recent years, the NRC changed the focus of its medical inspections from a detail oriented inspection (check-list) to a more performance-oriented inspection. Under this approach, inspectors are directed to focus more on observations, interviews, and measurements than on record reviews to assess program adequacy. We have also revised our process for documenting inspection results. Before 1998, routine inspections were documented using a checklist format. In 1998 and 1999, we revised our procedures to allow findings to be documented in narrative form. This revision was designed to give the inspectors more flexibility and to promote a more performance-based inspection process.

In recent years, we have also revised our inspection policy to focus on risk. The inspection policy now requires inspectors to extend the time between inspections for good performers, those licensees that have relatively few violations for several inspections in succession and no escalated enforcement actions. The time between inspections is also based on the radiation risks associated with the use of the byproduct material. For example, a licensee using byproduct material for imaging and localization studies in a hospital setting is scheduled to be inspected every 3 years. If this licensee is inspected and demonstrates good performance, the next inspection will be scheduled to be conducted after 5 years, rather than 3 years. A licensee using a high dose-rate remote afterloader (HDR) will be inspected every year. If this licensee is inspected and demonstrates good performance, the next inspection will be scheduled to be conducted after 2 years, rather than 1 year.

The NRC is in the process of implementing the Medical Pilot Inspection Program that was approved by the Commission in SRM–SECY–00–0001 (February 14, 2000), ''Pilot Program for NMSS Initiative on Streamlining Inspection and Enforcement.'' We are conducting inspections under the pilot program for licensees authorized to use unsealed byproduct material under §§ 35.100, 35.200, and 35.300. This 1-year program is intended to streamline the inspection process and to focus inspections on radiation safety performance and more risk-informed outcomes. The intent of the pilot program is to demonstrate that the streamlined approach can—

(1) Maintain, and potentially enhance, safety;

(2) Reduce unnecessary burdens on the licensee;

(3) Increase NRC efficiency and effectiveness; and

(4) Increase public confidence by explicitly addressing more risk-informed outcomes. If successful, the program will be extended to other NRC material licensee inspection programs.

Under this pilot program, inspectors are shifting primary focus away from detailed examination of the licensee's processes, policies, and procedures to an evaluation of the adequacy of outcomes for six radiation safety based and outcome oriented focus elements (FEs). These FEs are:

(1) Adequate program surveillance and corrective actions;

(2) Knowledgeable staff and management;

(3) Occupational and public doses within regulatory limits;

(4) Adequate security and control of licensed material;

(5) Use of licensed material only as authorized; and

(6) Radiopharmaceutical administrations conforming to the physicians written directives.

The extent and depth of the inspection will be guided by the outcomes for the FEs and the potential risk associated with licensed activities. If the desired outcomes are not achieved by the licensee, then a detailed evaluation will follow. It will identify root causes and contributing factors for the licensee's apparent failure to conduct a satisfactory radiation protection program. The detailed evaluation will be similar to the approach that has been used during routine NRC inspections in the past, e.g., review of processes, policies, and procedures, additional observations, and interviews of licensee staff members.

The experience gained from this program will be used to revise all medical inspection procedures. This will help to ensure that the medical inspection procedures incorporate the more risk-informed, more performance-based approach used in the rulemaking.

We will continue to qualify inspectors using NRC Inspection Manual Chapter 1246, ''Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area.'' During the inspector qualification program, the candidate completes self-study exams for the various parts of 10 CFR Chapter I and obtains classroom and practical laboratory experience for each type of medical use. The candidate accompanies other qualified inspectors and the inspection supervisor during inspections of various types of licenses for medical use programs to develop inspection skills necessary to evaluate radiation safety programs independently and to relate inspection findings to the NRC enforcement policy. Finally, individuals must pass an oral qualification board before they become certified to conduct inspections without direct supervision.

The Agreement States also have formal training programs for their inspectors. Agreement State inspector qualification are reviewed during NRC's periodic review of the Agreement State program.

NRC inspectors also participate in ongoing refresher training. This training includes new innovations in the health physics field as well as training in new initiatives underway at the NRC. Individuals performing medical inspections will receive training in the final Part 35 as well as in any guidance documents associated with the rulemaking. Training will focus on the concepts associated with a more risk-informed, more performance-based rule. In addition, inspectors received training on the pilot program for streamlining inspections before the pilot program was introduced.

Issue 3: Will the Agreement State Inspection Program Change as a Result of Changes in the NRC Inspection Program?

*Comment.* Several commenters stated that Agreement States may experience problems with their inspection programs if they follow NRC's lead in moving from a prescriptive to a more performance-based approach to inspecting. Other commenters stated that, if the NRC adopted an approach in which inspections would be deferred or eliminated, States may not be able to, or choose not to, follow NRC's example.

*Response.* Moving from prescriptive to more performance-based inspections will require a period of adjustment for both the NRC and Agreement States, as well as for the licensees. NRC and the Agreement States will address any needed adjustments via their internal training programs. In addition, Agreement States will be provided with copies of guidance documents currently under development by the NRC. Finally, Agreement States are afforded the flexibility to inspect more frequently based on local concerns.

Issue 4: What Changes Will Be Made in the Enforcement Program as a Result of the Revised Part 35?

*Comment.* A commenter agreed with the principal of a performance-based regulation, but questioned whether there would be any changes in the enforcement program.

*Response.* The NRC's enforcement program is separate from this rulemaking and may be changed without changing the regulations. However, as a result of some changes in the rule, the Commission is also publishing, in a separate document in this **Federal Register**, a modification of ''General Statement of Policy and Procedure for NRC Enforcement Actions,'' NUREG–1600 (Enforcement Policy), to revise the examples of severity levels for violations associated with the requirements to: (1) Use written directives for certain medical uses of byproduct material; and (2) develop, implement, and maintain certain procedures for medical uses that require a written directive (10 CFR 35.40 and 35.41). The revised examples reflect the revised requirements in Part 35.

In a broader effort, the NRC is revising its enforcement policy to make that program more risk-informed and performance-based. For example, a number of lesser violations are no longer considered in the aggregate at a higher severity level. This change was introduced in the version of the Enforcement Policy published in the **Federal Register** on November 9, 1999 (64 FR 61142).

Additionally, during the time that this rulemaking was being developed, guidance to the NRC staff was issued on non-escalated enforcement actions (EGM 98–007) in the materials enforcement area to assure that:

(1) Non-cited violations are used for non-repetitive, non-willful Severity Level IV violations;

(2) The use of enforcement discretion not to issue a citation is considered where warranted for Severity Level IV violations in accordance with Sections VII.B.2 through VII.B.6 of the Enforcement Policy;

(3) Responses are not required for cited Severity Level IV violations if the licensee's corrective actions are already available in a docketed report or other correspondence;

(4) RSC meeting minutes and other licensee program audit records are not used to identify violations that the licensee is already aware of unless the corrective action for the violation is not prompt or comprehensive; and

(5) Multiple examples of the same violation are grouped into a single citation when appropriate.

*D. Industry Standards*

Issue 1: Can Standards of Practice Be Used as an Alternative to Regulation?

*Comment.* Some commenters asked whether the NRC would consider replacement of regulations with standards of practice or industry standards that are well understood by medical professionals. For instance, one commenter points out that the American Association of Physicists in Medicine (AAPM) has recently published several excellent reports that relate to radiation safety, including the reports of Task Groups 59, 56, and 40.

Some commenters believed that we could allow a licensee to commit to follow an established standard of practice and thereby limit our regulatory oversight. Commenters also pointed out that many current regulations have become the standard of care and, in instrumentation cases, the

manufacturer's guidance. Conversely, some commenters believed that we, as regulators, had the role of defining the minimum level of practice necessary to directly enhance safety. The commenters indicated that there are some limited cases where those practicing are not following ''voluntary'' standards of practice; therefore regulations were needed. Finally, some commenters questioned our role in regulating an activity that is also regulated by another government agency or by the state.

*Response.* The National Technology Transfer and Advancement Act (NTTAA) of 1995, Public Law 104–113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable laws or is otherwise impractical. The Commission specifically directed the NRC staff to examine the viability of using or referencing available industry guidance and standards within Part 35 and related guidance to the extent that they meet NRC's needs.

In developing the final regulations for therapeutic uses of sealed sources, the NRC consulted several American Association of Physicists in Medicine (AAPM) reports, including AAPM Radiation Therapy Task Group No. 40—Comprehensive QA for Radiation Oncology, 1994 (AAPM TG–40); AAPM Radiation Therapy Committee Task Group No. 56—Code of Practice for Brachytherapy Physics, 1997 (AAPM TG–56); AAPM Radiation Therapy Committee Task Group No. 59—High Dose Rate Brachytherapy Treatment Delivery, 1998 (AAPM TG–59); and AAPM Report No. 54—Stereotactic Radiosurgery, 1995. In developing several other sections of the rule, we also consulted other nationally recognized bodies' reports, including the American National Standards Institute, Inc. (ANSI), ACR, and the American College of Medical Physics (ACMP). We understand that these and other standards of practice are often voluntary and, as such, medical professionals are not required to follow them. The final rule and guidance include statements of the objectives to be achieved and allow the licensee to select among the various performance standards to meet the objectives of the regulation. For example, in § 35.60 we allow a licensee to calibrate instrumentation in accordance with nationally recognized standards or the manufacturer's instructions rather than to submit their specific calibration procedures for our review and approval. We believe that this provides the licensee significant flexibility in designing its radiation protection program.

We agree that, in some cases, the licensed community must comply with several different Federal and state regulations for a single type of use. For instance, in the case of sealed radioactive sources for therapeutic medical uses, the licensed community must comply with FDA regulations for devices and must also comply with NRC regulations on the use of the radioactivity in or on humans. Whenever possible, we reviewed the various state and Federal regulations, including other NRC regulations, to limit duplication of requirements.

For additional information on how consensus standards were used in the development of the final rule refer to Section I, Background in the **SUPPLEMENTARY INFORMATION** in this document.

*E. Training and Experience*

1. Training and Experience—General

Issue 1: Why Are There Two Sets of Training and Experience Requirements in the Final Part 35?

*Comment:* One commenter noted that much of Subpart J is redundant with, but not identical to the training and experience requirements listed in the individual sections of the other subparts. The training and experience requirements should be identical if they are included in two subparts within the same part, or they should only be listed once in the part.

*Response.* The NRC believes that Subpart J should be retained for a 2-year transition period as stated in the proposed rule (63 FR 43516; August 13, 1998 ). The issue of recognition of medical and other specialty boards was discussed during an ACMUI briefing of the Commission on February 19, 2002. In that meeting, two committee members expressed concern that some boards did not qualify for recognition and may not be ready to apply for recognition within 6 months after publication of the final rule. Therefore, implementation of the new Part 35, without Subpart J, could disrupt the current license authorization process for new medical personnel because many license authorizations are granted based on recognition of board certification. The Commission has considered this matter and decided to retain the current training requirements in Subpart J for a 2-year period after the effective date of the final rule. As stated in Section IX, Implementation, during that 2-year period, licensees will have the option of complying with either the requirements of Subpart J or the requirements in Subparts B and D-H. During this transition period, the NRC will continue working with the ACMUI and the medical community to resolve any concerns with the training and experience requirements. The Commission will consider changes to the training and experience requirements, as appropriate.

The training and experience requirements in Subparts B and D through H of the final rule provide alternative pathways for individuals who are not board certified, i.e., the rule specifies the total number of hours of training and experience needed to become an AMP, ANP, AU, or RSO. This was done because we do not believe that we should require that individuals be board certified, but we believe that we should require that they have adequate training to safely handle byproduct material. The primary difference between the ''board certification route'' and the ''alternative pathways'' concerns the regulatory process used for being approved as an AMP, ANP, or AU. For example, if an individual is certified by a board recognized by NRC, a licensee does not need to amend its license before it allows that individual to work as an AU, ANP, or AMP (reference § 35.14(a) and § 35.24(a)). However, if the individual is not board certified, the licensee must apply for and receive an amendment from NRC before it allows that individual to begin work (§ 35.13(b)). In the case of an RSO, a licensee must always amend its license before it allows an individual to work as an RSO unless the individual would be considered a temporary RSO under § 35.24(c).

Issue 2: Would It Be Best for Regulations To Be Developed, Administered, and Monitored by Medical Speciality Organizations?

*Comment.* A commenter believed that the training and experience requirements would be best developed, administered, and monitored by medical speciality organizations with expertise in clinical applications of radiation-related technologies. The commenter cited the Mammography Quality Standards Reauthorization Act as an example of a cooperative public/private partnership that uses the strengths of both established accreditation/certification programs and Federal Government enforcement authority.

*Response.* The NRC acknowledges and values the expertise of medical and other speciality boards involved in

radiation-related technologies. We have met with many of these boards and received valuable information that was used to develop the final rule. However, we believe that the administration of this rule is best performed by the NRC.

Issue 3: Should Speciality Boards Be Listed by Name in the Regulations?

*Comment.* Some commenters recommended that the regulations list the boards, by name, because the boards rarely change. Another set of commenters stated that the cardiology board should be listed by name in the rule. Other commenters expressed concern that NRC would recognize boards that were not recognized by the American Board of Medical Specialities (ABMS).

*Response.* The NRC believes that any reference, by name, to boards should be deleted from the regulation because a rulemaking is needed to add new boards, to change the name of boards, or to delete existing boards. This has been a problem with the current Part 35 on several occasions when individuals requesting AU status have been certified by a board that is not listed in the regulations. In these cases, the NRC evaluated the training of these individuals, in consultation with the Advisory Committee on the Medical Uses of Isotopes (ACMUI), on a case-by-case basis. In the future, without need for a rulemaking, NRC could recognize boards in a more timely manner. (**Note:** We have provisions in §§ 35.50, 35.51, 35.55, 35.190, 35.290, 35.390, 35.392, 35.394, 35.490, 35.491, 35.590, and 35.690 that allow individuals, who are certified by NRC-recognized boards, to function as an ANP, ANP, AU, or RSO.) Under the final rule, the boards must be recognized by the NRC or an Agreement State. The NRC will recognize a board if its certification process requires or will require an individual to meet all of the applicable requirements listed in the alternative pathway of the training and experience requirements in Subparts B and D through H. For example, the individual must complete the required number of hours of training and experience that covers specific topics; obtain a signed preceptor certification; and complete specifically identified patient casework, if required.

We do not believe that the NRC's recognition of boards should be limited to those boards that are recognized by the ABMS. Our recognition is contingent on whether the certification process includes all the requirements listed in the alternative pathway. Before we recognize a board, we will review the board's submittal with ACMUI. We will maintain a list of recognized boards on our website.

Boards that are listed in current Part 35, as well as any other boards that are not listed in the current rule, such as the cardiology boards, will need to apply for recognition under the revised Part 35. We believe it is necessary to obtain a commitment from all of the boards that their certifications meet the criteria in the alternative pathways in the final rule because it has been several years since NRC reviewed many of them.

Issue 4: Should the Board Certification Process Be ''Approved'' or ''Recognized'' by the NRC?

*Comment.* Commenters questioned the phrase ''whose certification process has been approved by the Commission'' because the board will continue to exist regardless of whether the Commission approves the board for Commission purposes.

*Response.* Based on this comment, the NRC changed all training and experience requirements to state that the medical and other specialty board's certification process must be ''recognized'' by the Commission.

Issue 5: What Is the Preceptor's Role?

*Comment.* A commenter stated the proposed regulations place an inappropriate burden on the preceptor to provide written certification that the applicant has satisfactorily completed the didactic instruction in a structured educational program, obtained the required hours of supervised practical experience, and achieved a level of competency to function independently as an AU. The commenter recommended that all didactic training be certified or approved by an independent organization not associated with any society, board, or medical speciality. The commenter stated that the preceptor should not make any judgment regarding competency and should simply attest that an individual completed the training program.

*Response.* The regulations in the final rule do place a high degree of responsibility on the preceptor. Because the preceptor must be an AMP, ANP, AU, or RSO, the NRC believes that the preceptor is in the best position to certify that the individual has achieved a level of competency sufficient to function independently as an AMP, ANP, AU, or RSO. We do not believe this places an undue burden on a preceptor, but rather it demonstrates a high degree of confidence in the preceptor. Further, we believe that these types of judgments of competency in training and experience are consistent with the duties of individuals who direct training programs or provide training.

Issue 6: What Are the Training and Experience Requirements for Physicians Who Perform Research on Human Subjects?

*Comment.* A commenter asked what the training and experience requirements are for physicians who perform research on human subjects.

*Response.* There is no difference between the training and experience requirements for the administration of byproduct material or radiation from byproduct material to a human research subject and the training and experience requirements for an administration to a patient. For example, if the research involves using unsealed byproduct material for imaging and localization studies for which a written directive is required, the physician performing the research must meet the requirements in § 35.390. If the research involves use of sealed byproduct material in a remote afterloader, the physician must meet the requirements in § 35.690.

Issue 7: Should the Training and Experience Requirements Include an Examination?

*Comment.* The NRC received comments both opposed to and in support of a requirement for individual who would like to become an AMP, ANP, AU, or RSO to pass an examination that would assess whether they had sufficient radiation safety knowledge.

Some commenters supported the exam concept. One thought that it would provide an alternative to a requirement for a long training program. Those commenters who supported the examination believe that an examination is an important tool that should be used to assure that individuals have the necessary skill to handle byproduct material safely. Other commenters believed that the examination would be warranted if an individual had not taken an examination as part of a board certification.

Several commenters stressed the practical problems of implementing the requirements for an examination. They noted that establishing an examination program was extremely time-intensive and expensive. According to several commenters, maintaining the confidentiality of questions was a concern. Some commenters said that the examination requirement was unnecessary and should be deleted unless the NRC had information that significant numbers of AMPs, ANPs,

AUs, and RSOs were being inadequately trained.

Other commenters indicated that many training organizations already use testing as part of their educational programs. Therefore, the testing requirement would only increase training costs without adding benefit or value.

Some commenters argued that neither should the NRC give the exam itself, nor should it determine the passing score. Other commenters suggested that examining organizations submit questions to the NRC and that the NRC should develop the exam. Some commenters recommended that the NRC collaborate with one or more boards to develop the radiation safety exam. Others suggested that several boards collaborate to develop a radiation safety examination independent of the NRC. Commenters also recommended that the NRC contract either directly or indirectly with a testing service to administer the exam.

Several commenters stated that the proposed requirement in Appendix A for examining organizations to ensure that examinations are not given to individuals who have also been instructed by the examining organization was too prescriptive. One commenter explained that professional organizations must be trusted to both offer instruction and testing. Another commenter encouraged the NRC to keep the two functions separate.

*Response.* The NRC believes that the training and experience requirements in the final rule for AMPs, ANPs, AUs, and RSOs are sufficient to assure that the radiation safety of the public, patients, human research subjects, and workers is maintained. Therefore, we deleted the requirement for an examination from all the training and experience sections. Instead of an examination, we will rely on the preceptor's certification that an individual has completed the required training and experience and has achieved a level of competency sufficient to function independently as an AMP, ANP, AU, or RSO.

Issue 8: Should Part 35 Contain Training and Experience Requirements for Technologists?

*Comment.* Many commenters suggested that minimum training and experience requirements be established for nuclear medicine technologists. In addition, they suggested that technologists be required to pass an exam. Commenters stated that there is a need for training and experience requirements for those individuals who actually handle radioactive materials.

One commenter felt that health care agencies, rather than the NRC, should mandate licensure requirements for technologists. Commenters opposed NRC requiring specific training and experience for nuclear medicine technologists, but supported mandated licensure requirements by health care agencies.

*Response.* The NRC recognizes that technologists have an important and substantial role in the medical use of byproduct material. However, the licensee is responsible for ensuring that the training and experience of individuals working under the supervision of an AU or ANP are adequate. We will continue to rely on the regulations in § 35.27, Supervision, to assure that individuals working under the supervision of an AU or ANP are provided adequate training. Therefore, we have not established training and experience requirements for technologists or other individuals using byproduct material under the supervision of an AU or ANP.

Issue 9: Will the Training and Experience Requirements for Physicians Affect Training Requirements for Technologists?

*Comment.* Commenters were concerned that the reduction in the duration of some of the physicians' training programs would negatively affect the amount of training that licensees expect technologists to have completed. They were concerned that if NRC reduced the training requirements for AUs that licensees might reduce their training requirements for technologists. The commenters believed that as the technology becomes more sophisticated, a reduction in training could lead to poor quality studies and result in unnecessary radiation exposure to patients.

*Response.* The NRC believes that under the final rule AUs will have sufficient training and experience to assure that byproduct material is handled safely. In addition, an AU is required to be a physician, dentist, or podiatrist. It is the licensee's responsibility to determine the level of training and experience, in addition to the instruction required in § 35.27, needed for individuals working under the supervision of an AU.

2. Training and Experience—Unsealed Byproduct Material.

For the most part, comments received on the following sections related to more than one section. Therefore, the NRC is summarizing comments received on these sections in this portion of the statement of considerations. Comments that pertain only to specific sections are discussed under that particular section heading.

As discussed earlier, the training and experience requirements in proposed § 35.290 were moved to final § 35.190 and the training and experience requirements in proposed § 35.292 were moved to final § 35.290. For purpose of the following discussion, the summary of the comments refers to the sections in the proposed rule and the response refers to the sections in the final rule.

Section 35.190, Training for uptake, dilution, and excretion studies.

Section 35.290, Training for imaging and localization studies.

Section 35.390, Training for use of unsealed byproduct material for which a written directive is required.

Section 35.392, Training for the oral administration of sodium iodide iodine-131 (I–131) requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries).

Section 35.394, Training for the oral administration of sodium iodide I–131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries).

Issue 1: Should NRC's Training and Experience Requirements Focus on Radiation Safety Rather Than Clinical Competency?

*Comment.* Commenters generally supported the NRC focusing training and experience requirements on radiation safety rather than on clinical competency. Some commenters believed that the training and experience requirements for physicians who wish to use unsealed byproduct material should be based on demonstrated competence in nuclear science and radiation safety. These commenters did not believe that the NRC should define the criteria for clinical competence, but rather should allow clinical training to be defined by relevant medical specialty organizations such as the Accreditation Council for Graduate Medical Education (ACGME)-approved training programs or the ABMS-sanctioned certifying boards. However, commenters noted that ''AU status'' was frequently equated with clinical competency. As a result, these commenters encouraged the NRC to clearly state that a license granted under Part 35 only reflects the qualifications of a physician to safely handle radioactive material for medical use and not to practice nuclear medicine.

*Response.* The current training and experience requirements for AUs under §§ 35.100, 35.200, and 35.300 have been revised to focus on radiation safety. The NRC believes that the focus of these

training requirements should not be clinical competency. Clinical competency is best addressed by State Medical Boards, certifying organizations, and hospital credentialing committees. An individual's status as an AU means that the individual has met the requirements to handle byproduct material safely. It does not reflect an assessment of the individual's clinical or professional competency.

Issue 2: Should Training and Experience Be Limited to FDA-Approved Uses of Byproduct Material?

*Comment.* A commenter recommended that training and experience be obtained in those activities that are related to FDA-approved uses of byproduct material, and that all research, drug testing, and related non-FDA approved procedures be excluded from training and experience activities.

*Response.* The training and experience requirements in the final rule focus on radiation safety, not on clinical competency. Therefore, the NRC believes that individuals should have training and experience in the safe handling of all types of byproduct material. Thus, training and experience should not be limited to FDA-approved uses of byproduct material.

Issue 3: Where Should Training Be Obtained?

*Comment.* A commenter recommended that the NRC not recognize training and experience that has been obtained at a facility that is supported by either commercial manufacturers or suppliers. Other commenters recommended that practical training should be in an ACGME-accredited program in nuclear medicine or a graduate level course at an accredited university. Another commenter recommended that only those physicians completing an accredited residency program in an ABMS-approved speciality be allowed to become AUs under § 35.390.

*Response.* The NRC does not believe that the rule should specify where the training should be obtained because this level of prescriptiveness is not warranted by the types and levels of byproduct material that are handled under §§ 35.100, 35.200, and 35.300. We will investigate any allegations regarding inadequate training programs on a case-by-case basis. In addition, we do not believe that the rule should prohibit an individual from obtaining training at locations whose activities are supported by commercial manufacturers, suppliers, or the owners/investors. We will rely on the preceptor's written certification for final assurance that an individual has completed the required training and experience and is competent to function independently as an AU.

Issue 4: Should NRC Provide ''Deemed'' Status to Individuals?

*Comment:* Commenters questioned whether NRC would provide ''deemed'' status to diplomates of the American Board of Nuclear Medicine (ABNM) and whether diplomates of the American Board of Radiology (ABR) or the ABNM should be licensed to use diagnostic radionuclides without additional education or examination requirements.

*Response.* Any individual who is an AMP, teletherapy physicist, ANP, AU, or RSO on a license issued by the Commission or Agreement State, a permit issued by a Commission master material licensee, a permit issued by a Commission or Agreement State broad scope licensee, or a permit issued by a Commission master material license broad scope permittee before the effective date of the final rule will continue to be considered such by NRC. After the rule becomes effective, these individuals will have ''deemed'' status as an AMP, ANP, AU, or RSO on licenses that authorize similar type(s) of use(s) of byproduct material, i.e., there will be no change in what an individual is ''authorized'' to do. For example, an individual currently recognized as a ''teletherapy physicist'' would be recognized as an AMP for teletherapy units under the final Part 35. However, the individual could not be listed as an AMP on a license only authorizing use of gamma stereotactic radiosurgery, unless he or she also satisfied the requirements in the new § 35.51(b)(1) for experience with the tasks that are applicable to those units (§§ 35.635, 35.645 and 35.652). The teletherapy physicist could not be listed as an AMP on a license that only included gamma stereotactic radiosurgery units and remote afterloaders, unless the individual obtained written certification, signed by a preceptor AMP, that he or she had satisfactorily completed the applicable requirements and had achieved a level of competency to function independently as an AMP for those types of uses.

The same criteria would apply in determining if AUs have ''deemed status'' under the final rule. They would only continue to be recognized as AUs for the type(s) of use(s) of byproduct material for which they already have AU status. An AU under the current § 35.932, Training for treatment of hyperthyroidism, would continue to be recognized as an AU for the use of I–131 for diagnosis of thyroid function under the new § 35.390, Training for use of unsealed byproduct material for which a written directive is required. However, if the individual would also like AU status for parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV, the individual would have to satisfy the applicable training and experience requirements for this use in § 35.390.

Once the final rule becomes effective, diplomates of boards, such as the ABNM and ABR, will be considered to have met the training and experience requirements if the boards have been recognized by NRC. Recognition of a board will be contingent on whether the board's certification process includes all the requirements listed in the alternative pathways for satisfying the training and experience requirements. However, as stated previously, the Commission is retaining the current training requirements in Subpart J for a 2-year period after the effective date of the final rule. During that 2-year period, licensees will have the option of meeting either the requirements of Subpart J or the requirements in Subparts B and D–H.

Issue 5: Why Are There Different Requirements for Training of AUs Under §§ 35.100, 35.200, and 35.300?

*Comment.* Commenters questioned why the training and experience requirements for using byproduct material under §§ 35.100, 35.200, and 35.300 are different. They indicated that the basic radiation safety practices and knowledge of radiation science should be the same regardless of the quantity of byproduct material and how it is used.

*Response.* The NRC recognizes that there is a certain degree of basic radiation safety knowledge that is common among all the types of use, e.g., use of the decay formula and decontamination techniques. However, we also believe that there are some basic differences between the uses of byproduct material under §§ 35.100, 35.200, and 35.300 that warrant additional training and experience, e.g., increased potential for exposures in excess of Part 20 limits and the potential for adverse biological effects. For example, AUs handling byproduct material for imaging and localization studies, as compared to uptake, dilution, and excretion studies, are generally handling larger quantities and many different radionuclides. Also, AUs meeting the training and experience requirements in § 35.190 are not authorized to prepare radioactive drugs

using generators and reagent kits, but AUs under § 35.290 are authorized to prepare drugs using generators and reagent kits. Finally, AUs under § 35.390 are handling material in quantities that can cause deterministic effects.

Issue 6: How Long Should the Training Programs Be for Individuals Who Would Like To Become AUs Under §§ 35.190, 35.290, and 35.390?

*Comment.* Numerous comments both supported and opposed the duration of the proposed training and experience requirements for individuals who would like to become an AU for unsealed byproduct material.

Some commenters strongly supported the proposed reduction of the training and experience requirements for use of unsealed byproduct material in diagnostic nuclear cardiology because of the minimal risk to patients and public safety.

Some commenters believed that NRC should not establish an ''arbitrary'' number of training and experience hours. They indicated that it may take some individuals more time to master needed information. They believe that classroom training should focus on radiation safety and that there should be a requirement to show evidence of mastery in comprehensive nuclear and radiation science through an exam. In addition, they believe that the rule should clearly identify what knowledge and skills an individual should have.

A commenter suggested that the proposed requirements for an individual who would like to use material under § 35.100 be changed from 20 hours of classroom and laboratory experience to 40 hours of supervised practical experience.

A commenter recommended that the proposed requirement for an individual who would like to use material under § 35.200 should be a minimum of 240 hours of supervised practical experience. For the same type of use, another commenter suggested that an individual complete a 6-month/1200 hour training program in an ACGME-accredited or equivalent training program. Finally, a commenter recommended that individuals certified by the ABR or ABNM should automatically qualify as AUs. These commenters also indicated that as an alternative pathway to board certification, an individual who would like to use material under § 35.200 should be required to complete a dedicated 4-month nuclear medicine/radiology training program that integrates radiation safety training with clinical training and experience. This integrated experience should be obtained in an ACGME-approved residency program in diagnostic radiology or nuclear medicine.

A commenter stated that the current training and experience requirements for physicians authorized for nuclear medicine therapy (§ 35.390) are minimal to a fault. The commenter cited the 1996 NAS–IOM analysis of NRC's medical program that recommended increasing the requirements for a nuclear medicine therapy AU. Another commenter found it inconsistent that the use of unsealed byproduct material for therapy requires far less training than the use of sealed byproduct material. Another position is that therapeutic nuclear medicine represents a higher risk for patients. Therefore, the training and experience requirements to become an AU for therapy should be greater than those for diagnostic nuclear medicine.

A commenter recommended that the current requirements for an individual who would like to use unsealed byproduct material under § 35.300 should be revised to be at least equal to or greater than the requirements to use material under § 35.200. Another commenter suggested that an individual have 100 hours, rather than 40 hours, of supervised practical experience under the supervision of an AU. The commenter went on to state that this additional time would be used to cover the requirements that pertain to dosages requiring a written directive.

Another commenter stressed the importance of remembering that, under § 35.300, byproduct material is used for therapeutic treatments and that the possibility of injury to the patient and others is very real. This commenter stated that he had personally seen both significant bone marrow suppression after using strontium for bone pain and life-threatening pulmonary edema after treatment of a patient with iodine-131 (I–131) for metastatic thyroid cancer of the lungs.

*Response.* The NRC believes that the regulatory text should contain a list of the subject areas to be addressed in a training program. In the final rule, we have not included a requirement for an examination to demonstrate that an individual has sufficient knowledge in radiation safety. Instead, we will rely on the duration of the training program and the preceptor's written certification that a physician has completed the required training and experience and is competent to function independently as an AU.

The following discussion summarizes the training and experience requirements for use of unsealed byproduct material under §§ 35.100, 35.200, and 35.300. We believe the specified training periods will provide individuals with sufficient knowledge to handle byproduct material safely. We also believe that it is sufficient to specify the overall period for training. We do not believe that any further breakdown is needed in terms of the hours devoted to classroom/laboratory training and work experience. Note, this same approach is used in the current rule for the training and experience requirements for an ANP. In addition, this approach will provide needed flexibility in designing and implementing training programs.

In § 35.190, Training for uptake dilution and excretion studies, the total number of hours (i.e., 60 hours) in the final rule is the same as the total number of hours in the current rule and in the proposed rule. AUs, qualified under § 35.290, § 35.390, or equivalent Agreement State requirements, may use byproduct material under § 35.100. AUs qualified under § 35.190 are not authorized to prepare unsealed byproduct material using generators and reagent kits.

In § 35.290, Training for imaging and localization studies, we agree with the public comments that the proposed 120 hours is not sufficient. AUs in this category are authorized to prepare unsealed byproduct material for medical use using generators and reagent kits. Therefore, we have increased the period of training in § 35.290 from 120 hours in the proposed rule to 700 hours (essentially 4 months) in the final rule. This change was necessary to assure that physicians spend an adequate amount of time in an environment in which radioactive drugs are routinely being prepared and/or administered for medical use. Note that the 700 hours in the final rule is a reduction from the current 1200 hours of training required for imaging and localization studies.

As stated earlier, we have not specified a breakdown between the number of hours of didactic (i.e., classroom and laboratory) and work experience to allow flexibility in designing and implementing training programs. Therefore, the number of hours of classroom and laboratory training needed to address the required subject areas in § 35.290(c)(1)(i) may vary with individual training programs. The remainder of the required 700 hours would be devoted to supervised work experience to include, but not be limited to, the subject areas in § 35.290(c)(1)(ii).

We recognize that physicians in training will not dedicate all of their time specifically to the subject areas in § 35.290(c)(1)(ii) and will be attending

to other clinical matters involving the diagnostic use of the material under the supervision of an AU (e.g., reviewing case histories or interpreting scans). Even though these clinical matters are not specifically required by the NRC, this type of supervised work experience may be counted toward the supervised work experience to obtain the required 700 hours.

We agree that the training and experience requirements should be increased for individuals who would like to use byproduct material for which a written directive is required. The hours have been increased from 80 hours in the current rule to 700 hours in the revised § 35.390, Training for use of unsealed byproduct material that requires a written directive. We believe this increase is needed because these physicians would be authorized to elute generators and prepare radioactive drugs, as well as to administer a wide variety of radionuclides requiring written directives. Thus, the associated radiation risks of the use could be greater. In addition, the work experience in the administration of such dosages to patients must specifically include at least three cases in each of the following categories for which the individual is requesting AU status:

1. Oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I–131;
2. Oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I–131;
3. Parenteral administration of any beta-emitter or a photon-emitting radionuclide with a photon energy less than 150 keV; and/or
4. Parenteral administration of any other radionuclide.

Physicians who are authorized under § 35.390 for all of these types of administrations also meet the requirements in §§ 35.190, 35.290, 35.392, and 35.394.

Issue 7: What Are the Appropriate Training Requirements for an Individual Who Would Like To Use I–131 for Treatment of Hyperthyroidism and Thyroid Cancer?

*Comment.* Commenters were strongly opposed to the proposed changes to the requirements for the administration of I–131 for treatment of hyperthyroidism and thyroid cancer. Commenters felt that there was no justification for revising the current § 35.932, Training for treatment of hyperthyroidism, and to do so would conflict with NRC's guidelines of ''minimizing intrusion into medical judgments affecting patients and into other areas considered to be a part of the practice of medicine.'' These commenters indicated that the increased training was not warranted in light of endocrinologists' impeccable safety record with the use of I–131 and the fact that there have been no records of therapeutic misadministrations of any byproduct material by endocrinologists. In addition, commenters stated that, in reality, most of the practical aspects of handling I–131 that would be covered in the proposed 40 hours of additional training is already covered in the 80 hours of didactic training and in the supervised clinical training that is currently required by § 35.932, Training for treatment of hyperthyroidism, and § 35.934, Training for treatment of thyroid carcinoma.

Commenters stated that the clinical endocrinologist is the physician best qualified to take care of patients with thyroid disease and part of their responsibility is to protect their patients from unnecessary burdens. Commenters stated that the practical effect of increasing the basic radiation physics and safety training from 80 hours to 120 hours would be to exclude endocrinologists from administering I–131 to patients with hyperthyroidism and thyroid cancer. Some commenters went on to state that increasing the requirement for licensure would actually result in fewer endocrinologists being able to take care of their own patients and would ultimately place increased and undue strain on the patients such as:

1. Increased costs to the patient. The cost to patients receiving treatment in a hospital setting are double or triple the cost of an endocrinologist administering I–131 in his/her own office.
2. Increased potential safety hazards for the patient. There is much more personal and focused attention given to the patient in the endocrinologist's office. In other settings, the patient is one of dozens of people waiting to be treated with a variety of doses for a variety of diseases. Thus, the possibility of error in communications and for the misadministration of I–131 is greatly increased.
3. Increased emotional trauma during treatment. Patient anxiety and fear will be increased as a result of patients being required to go to nuclear medicine departments where other patients are being treated for all manner of disease, including cancer. This is an unnecessary exposure of the patient to psychological trauma and can be a deterrent to a patient seeking appropriate care.
4. Increased need to visit additional specialists. With fewer endocrinologists administering I–131, patients will have to endure another layer of specialty consultation, resulting in delays in treatment, inconvenience and loss of time from work, significant increase in the cost of treatment, and exposure to unfamiliar settings and personnel.

Commenters were also concerned that the proposed rule required that the 40 hours of supervised practical experience be obtained at a medical institution. They thought this is a prescriptive requirement which is not warranted because acceptable training could be provided in other clinical settings. Other commenters noted that this requirement would make it more difficult for endocrinologists to receive supervised practical experience from mentors or preceptors who practice and administer radioiodine in their offices, rather than in medical institutions.

A commenter thought it paradoxical that the proposed rule would actually decrease the amount of clinical experience needed for licensure. The commenter indicated that currently, under § 35.932, physicians are required to have supervised clinical experience with 10 patients with hyperthyroidism and, under § 35.934, they are required to have supervised clinical experience with 3 patients with thyroid cancer. The commenter indicated that, in the proposed rule, an individual must have experience with 5 cases. This commenter believed that this was a step backward from the current regulations because the clinical experience and practical aspects of the use of radioiodine are obtained during clinical experience, rather than obtained in a classroom setting. According to another commenter, the blanket requirement for 5 cases for each procedure may not always be appropriate. This commenter thought that it might be better to list the procedures and the number of required cases in the regulations.

*Response.* In the final rule, §§ 35.392 and 35.394 have been added to specifically address oral administrations of sodium iodide I–131. These sections do not increase the duration of training for an endocrinologist over the current requirements in §§ 35.932 and 35.934.

In the final rule, § 35.392 was added to provide the training and experience requirements for physicians who only seek authorization for the oral administration of sodium iodide I–131 in dosages less than or equal to 1.22 gigabecquerels (GBq) (33 millicuries (mCi)) and do not seek authorization to prepare radioactive drugs using generators and reagent kits. To qualify as an AU under this limited authorization, an individual must have 80 hours of classroom and laboratory training and supervised work experience that includes 3 cases

involving the oral administration of sodium iodide I–131 in dosages less than or equal to 1.22 GBq (33 mCi). The NRC has not specified a breakdown between the number of hours of didactic (i.e., classroom and laboratory) and supervised work experience to allow licensees flexibility in designing and implementing training programs. Therefore, the number of hours of classroom and laboratory training and supervised work experience needed to adequately address the required subject areas can vary with individual training programs. These individuals may not prepare unsealed byproduct materials using generators and reagent kits.

Also, § 35.394 was added in the final rule to provide training and experience requirements for physicians who only seek authorization for the oral administration of sodium iodide I–131 in dosages greater than 1.22 GBq (33 mCi) and do not seek authorization to prepare radioactive drugs using generators and reagent kits. To qualify as an AU under this limited authorization, an individual must have 80 hours of classroom and laboratory training and work experience that includes 3 cases involving the oral administration of sodium iodide I–131 in quantities greater than 1.22 GBq (33 mCi). Physicians authorized under § 35.394 would also meet the training and experience criteria in § 35.392. These individuals may not prepare unsealed byproduct materials using generators and reagent kits.

We agree that it is not necessary for the supervised work experience required by §§ 35.392 and 35.394 to be obtained at a medical institution. The essential element of this requirement is who is supervising the individual rather than where the experience is obtained. The final rule allows an individual to obtain work experience at any type of medical facility (e.g., medical institution, clinic, or private practice office), if the experience is under the supervision of an AU who meets the applicable requirements.

Issue 8: Should There Be a Difference Between the Training and Experience Requirements for Use of Sodium Iodide I–131 Liquid and Capsules?

*Comment.* A commenter indicated that an individual who only planned on using iodine in a capsule should not be required to have as much training as someone who planned on using liquid iodine. The commenter recommended that only 40 hours of training was needed to learn how to handle I–131 capsules.

*Response.* The final training and experience requirements do not differentiate between the different forms of I–131. The NRC believes that AUs should have the flexibility to prescribe whatever form of I–131 they believe appropriate. Although there are differences between handling iodine in capsule form and liquid form (e.g., decontamination procedures), we do not believe that the differences are significant enough to warrant a separate category for training.

Issue 9: Should Diagnostic Use of I–131 Be Authorized Under § 35.200 or § 35.300?

*Comment.* A commenter noted that the proposed rule would move requirements for whole body imaging using sodium iodide I–131 from § 35.200 to § 35.300. The commenter argued that this would prevent physicians who are imaging specialists from performing the procedure and allow therapy specialists to do the procedure. This commenter suggested that the procedure not be included in either, but instead be listed as a line item authorization and that specified training and experience requirements be adopted for it.

*Response.* The NRC does not believe that training and experience criteria for the use of sodium iodide I–131 for whole body imaging should be excluded from the regulations. The radiation safety considerations associated with the diagnostic use of millicurie quantities of sodium iodide I–131 more closely resemble the therapeutic use of sodium iodide I–131 than most diagnostic imaging and localization studies using technetium-99m. Therefore, the training and experience requirements for the use of sodium iodide I–131 in quantities greater than 1.11 Megabecquerels (MBq) (30 microcuries (μCi)), regardless of how it will be used, requires additional experience in the administration of these types of dosages.

The final rule reduces the required number of cases, as stated in the proposed rule, from 5 to 3 for each type of use for which authorization is requested. We believe that a physician's involvement in 3 cases will provide him or her with adequate training and experience. In addition, we do not believe that requiring physicians to obtain administration experience or demonstrate they have such experience for three cases of sodium iodide I–131 represents an unwarranted burden, nor would it discourage such physicians from becoming authorized to use I–131.

Issue 10: Should Both §§ 35.190 and 35.290 in the Final Rule Refer to Reagent Kits?

*Comment.* A commenter stated that the proposed § 35.292 (final § 35.290) does not refer to ''reagent kits,'' although proposed § 35.290 (final § 35.190) does, and questioned whether this was an error.

*Response.* The training and experience requirements to become an AU for imaging and localization require a physician to have experience with generators and reagent kits because physicians authorized under the final § 35.290 (proposed § 35.292) may prepare unsealed byproduct material using generator systems and reagent kits. Under the final § 35.190 (proposed § 35.290), physicians are not authorized to prepare byproduct material using generator systems and reagent kits. Therefore, it is appropriate that final § 35.290, and not final § 35.190, requires experience with eluting generator systems appropriate for preparing unsealed byproduct material for imaging and localization studies, measuring and testing the eluate for radiochemical purity, and processing the eluate with reagent kits.

Issue 11: Is It Necessary To Require Training in Calibrating Dose Calibrators and in Calculating and Measuring Dosages?

*Comment.* A commenter stated that there was an inconsistency between the training and experience requirements in the proposed §§ 35.292 and 35.390 and the requirement to calibrate dose calibrators in § 35.60 and the requirement to measure unit dosages in § 35.63. The commenter recommended that we replace the phrase ''Calculating, measuring, and safely preparing patient or human research subject dosages,'' with the phrase ''Determining and safely preparing patient or human research subject dosages.''

*Response.* The NRC believes that physicians who plan to use unsealed byproduct material must have training in calibrating instruments used to measure the activity of unsealed byproduct materials, in calculating and measuring dosages, and in eluting generators even though, in practice, an AU may choose to only use unit dosages. We believe that this training is important because AUs who meet the qualifications in the final §§ 35.290 and 35.390 are not restricted to using unit dosages. The training requirements do not interfere with the practice of medicine or pharmacy because the rule provides sufficient flexibility for

procuring and preparing unsealed byproduct material.

We have not replaced the words ''calculating and measuring'' with the word ''determining.'' Use of the words ''calculating and measuring'' clearly states our intent that an individual receive training in calculating (perform radioactive decay calculations) and measuring (use instrumentation to determine the activity) the activity of unsealed byproduct material.

Issue 12: Were There Any Other Changes Made to These Sections Between the Proposed and Final Rule?

*Response.* Yes. The NRC revised the requirement for individuals to have experience administering dosages to patients or human research subjects to state: ''Administering dosages of radioactive drugs to patients or human research subjects.'' This was done to state clearly that experience administering radioactive drugs need not be limited to radioactive drugs containing byproduct material because there is no difference between the safety precautions that must be exercised when administering byproduct or nonbyproduct material.

We revised the requirement for individuals to have experience using procedures to contain spilled byproduct material safely and using proper decontamination procedures to state: ''Using procedures to contain spilled radioactive material safely and using proper decontamination procedures.'' This was done to state clearly that experience with containing spilled radioactive material and decontaminating areas need not be limited to byproduct material because there is no difference between the safety precautions that must be exercised when handling byproduct or nonbyproduct material.

We revised §§ 35.290(c)(ii)(G) and 35.390(b)(ii)(F) to state: ''* * * measuring and testing the eluate for radionuclidic purity* * *'' rather than ''* * * measuring and testing the eluate for radiochemical purity.'' This change has been made because it more accurately reflects the testing that licensees actually perform for quality control testing on generator eluates, e.g., determining the molybdenum-99 concentration in the eluate from a molybdenum-99/technetium-99m generator.

We added a reference to § 35.390 in paragraph (b) of §§ 35.100, 35.200, and 35.300. This was done to recognize that an individual who meets the requirements in § 35.390 has sufficient training and experience to handle material safely under §§ 35.100, 35.200, and 35.300.

3. Training and Experience—Sealed Byproduct Material.

For the most part, comments received on the following two sections related to more than one section. Therefore, the NRC is summarizing the comments received on these two sections in this discussion. Comments that pertain only to specific sections are discussed under that particular section heading.

Section 35.490, Training for use of manual brachytherapy sources.

Section 35.690, Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

Issue 1: What Is the Appropriate Level of Training To Require?

*Comment.* Some commenters felt that the current training requirements should be retained and that lessening of the current training requirements could have a tremendous detrimental effect on patient care. Many of these same commenters believed that the training for coronary artery therapy should be of the same level as for all other sealed source therapy. Conversely, some commenters supported lessening the training requirements to a level that considers only radiation safety and not clinical competence.

*Response.* The NRC did not change the training levels required by these sections. We believe that individuals should complete a structured educational program that includes both classroom and laboratory training and work experience. We recognize that radiation safety training and clinical competency may be intertwined, especially for therapeutic uses of sealed sources. Therefore, we agree that significant changes should not be made in the current training requirements for AUs in this area.

Issue 2: Can This Section Be Revised To Refer to the Appropriate Review Committee and the Appropriate Time Division Reviewed by the Committee?

*Comment.* A commenter suggested that §§ 35.490(b)(2) and 35.690(b)(2) should refer to the Residency Review Committee for Radiation Oncology (since 1993). The commenter also stated that the phrase ''that includes one year in a formal training program'' should be replaced with ''in radiation oncology as part of a formal training program.''

*Response.* The NRC agrees with the suggested changes because the changes reflect the changes in the certification process since 1993. We have incorporated the requested changes in the rule.

Issue 3: Is Concurrent Training Allowed for Clinical and Work Experience?

*Comment.* A commenter pointed out that, as written in the proposed rule, 6 years of training is required unless concurrent training is allowed. The commenter felt that the proposed rule would require 500 hours of supervised practical experience plus 3 years of supervised clinical experience. The commenter also felt that the proposed rule would require 3 years of training with, for instance, iridium-192 sources, and an additional 3 years of training in order to use gamma stereotactic radiosurgery sources.

*Response.* The NRC agrees that concurrent training should be allowed for the clinical and work (practical) experience requirements in §§ 35.490 and 35.690. Therefore, we revised the regulatory text in §§ 35.490(b)(2) and 35.690(b)(2) to allow for concurrent work and clinical experience.

Issue 4: Were There Any Other Changes Made in These Sections Between the Proposed and Final Rule?

*Response.* Yes. The NRC deleted the phrase ''or equivalent program approved by the NRC'' from §§ 35.490(b)(2) and 35.690(b)(2) because a program equivalent to the ACGME program does not exist.

*F. Global Changes in the Rule.*

Issue 1: What Is the Sealed Source and Device Registry and How Do I Access the Registry?

*Comment.* A commenter noted that the proposed revision would be strengthened if there were an indication as to the nature of the Sealed Source and Device Registry and how to obtain a copy.

*Response.* The Sealed Source and Device Registry (SSDR), as defined in § 35.2, is the national registry containing all the registration certificates, generated by both NRC and the Agreement States, that summarize the radiation safety information for sealed sources and devices and describe the licensing and use conditions approved for these products. The information contained in the registry is summarized from information provided during registration of the source or device in accordance with § 32.210, Registration of product information. The Commission or Agreement State evaluates the information submitted to register a source (or device) and, if acceptable, issues a ''Safety Evaluation of Sealed Source (or Device).'' A

compilation of these evaluations can be found electronically at the following address: *http://www.hsrd.ornl.gov/nrc/ssdr/ssdrindx.htm*.

Issue 2: Should the Requirements in the Current Rule Related to Possession of Survey Instruments Be Deleted?

*Comment.* A commenter stated that the requirements in the current Part 35 concerning possession of survey instruments are very useful and should not be deleted from the rule (§§ 35.120, 35.220, 35.320, 35.420, 35.520, and 35.620 in the current Part 35). This commenter believed that the Part 20 requirements are not specific enough on this point.

*Response.* The NRC does not believe specific requirements relating to possession of survey instruments are needed in Part 35. Section 20.1501 requires that the licensee make, or cause to be made, surveys to demonstrate compliance with 10 CFR Part 20. This provision requires, in part, the licensee to ensure that instruments and equipment used to show compliance with Part 20 are periodically calibrated. In addition, § 30.33(a)(2) of this chapter requires licensees to have adequate instrumentation. Information on the types of instruments is available in NUREG–1556, Vol. 9 (draft), ''Consolidated Guidance About Materials Licenses: Program-Specific Guidance about Medical Use Licenses.''

Issue 3: Should the Term ''Dose Calibrator'' Be Replaced With the Term ''Radionuclide Calibrator'' in the Training and Experience Requirements for Unsealed Byproduct Material?

*Comment.* Commenters suggested that we replace the term ''dose calibrator'' with the term ''radionuclide calibrator'' in proposed §§ 35.50, 35.55, 35.290, 35.292, 35.390, 35.920 and 35.930.

*Response.* The reference to ''dose calibrators'' in §§ 35.50, 35.55, 35.190, 35.290, and 35.390 has been deleted in the final rule and replaced with ''instruments used to determine the activity of dosages.'' (§§ 35.920 and 35.930 will be retained 2 years after the effective date of the final rule.) As stated in the discussion of § 35.60, this change recognizes that there are various types of instruments that can be used to measure the activity of unsealed byproduct material. Therefore, the NRC believes that individuals should have experience with the different types of instruments and not be limited only to experience with dose calibrators.

Issue 4: Were There Any Other Changes Made to the Rule Between the Proposed and Final Rule?

*Response.* Yes. References in the proposed rule to § 35.290 have been changed to § 35.190 and references to § 35.292 have been changed to § 35.290. This was done because the training and experience requirements in proposed §§ 35.290 and 35.292 were moved to §§ 35.190 and 35.290, respectively. This change groups the sections that specify the requirements for an individual who would like to become an AU for a specific type of use with the section that provides information on that specific type of use. For example, § 35.100 provides authorization for use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required and § 35.190 contains the training and experience requirements for someone who would like to use material under § 35.100.

Throughout the final rule, the NRC has replaced the word ''promptly'' with the phrase ''as-soon-as-possible.'' In the proposed rule, we used both ''promptly'' and ''as-soon-as-possible.'' For the purpose of this rule, both could be used interchangeably. Therefore, we have chosen to use the phrase ''as-soon-as-possible'' to maintain consistency within the rule. The phrase ''as-soon-as-possible'' is used to indicate that the required action should be taken immediately considering the circumstances. The term ''as soon as possible'' adds a degree of reasonableness to ''immediate.'' For example, a notification might be made the next morning rather than in the middle of the night.

*G. Costs of the Revision*

Issue 1: How Will Less Prescriptive Requirements in the Proposed Rule Affect Regulatory Compliance and Implementation Costs?

*Comment.* Some commenters suggested that a shift from a more prescriptive to a less prescriptive and more performance-based regulatory system could lead to overall cost increases for regulatory compliance. For example, they said that if licensees are not required to submit procedures as part of their licensing application, and if NRC does not review their procedures at the time of licensing, the burden of reviewing the procedures may shift to inspections in the field. Therefore, these commenters believed that inspections might be more time-consuming and costly for both licensees and NRC. In addition, the frequency of review might increase because inspection cycles are shorter than licensing review cycles. Furthermore, the qualifications of inspectors might need to be increased, thus increasing the costs of implementing the rule. However, other commenters thought that less prescriptive regulatory requirements were desirable because, among other advantages, they would lower regulatory compliance costs.

*Response.* The NRC estimates that licensees will incur lower compliance costs under less prescriptive regulatory requirements. Certain requirements have been eliminated and other requirements have been revised to allow licensees greater flexibility in compliance. For example, licensees will have greater flexibility in setting up Radiation Safety Committees and some licensees will not be required to form such committees. We plan to revise our licensing and inspection procedures and criteria to reflect the less prescriptive regulatory approach. Under the new performance-based approach, as long as licensees do not experience safety-related problems or medical events, they will be able to select the most efficient method of achieving regulatory compliance. It should not be necessary for NRC to incur implementation costs for inspections to review the approach licensees have selected, unless performance-related information suggests that a review is needed. For example, the NRC does not expect to review licensees' procedures unless a problem occurs that indicates the procedures may be inadequate and should be reviewed.

Issue 2: How Will the Cost and Availability of Health Care Involving Radionuclides Be Impacted by the Revised Regulations?

*Comment.* Commenters argued that the costs of regulatory compliance could have the effect of reducing the availability of certain medical procedures by making them more expensive to the patient or by creating an incentive for physicians to substitute other procedures that have lower regulatory costs for diagnostic or therapeutic procedures involving radionuclides. Others stated that in their opinion the proposed rule was a positive step toward reducing compliance costs and creating concise and pertinent radiation safety standards.

*Response.* The NRC believes that physicians act in the best interest of their patients. Therefore, the NRC expects that physicians will continue to select procedures that will result in the best diagnostic or therapeutic outcome for their patients.

Issue 3: How Will the Revised Regulations Affect Fees to Medical Licensees?

*Comment.* Commenters suggested that if the revised Part 35 regulations result in lower implementation costs to NRC and the Agreement States, there should be a reduction of licensing fees for medical use licensees.

*Response.* Lower implementation costs that might result from this revision of Part 35 may not necessarily result in lower fees assessed to Part 35 licensees. Although budgeted costs are a major factor affecting the annual fees that individual NRC materials licensees are assessed, there are many other contributing factors. For example, a decrease in total costs to be assessed to materials licensees may not result in a decrease in the annual fee each licensee pays if there is also a significant decrease in the number of licensees available to pay the budgeted costs. Similarly, a decrease in costs associated with the implementation of Part 35 might be offset by increased costs for other activities.

Most NRC materials licensees are subject to Part 171 annual fees only. The annual fees are established to recover NRC's budgeted costs allocated to this class of licensees, including the costs for inspections, license amendments, license renewals, and generic activities such as rulemaking and development of regulatory guides. The new license and inspection costs, which are indicative of the complexity of the various types of materials licenses, are used as a proxy for allocating the budgeted costs for the license fee categories within the materials license class.

In FY 1999, the Commission determined that it would continue its policy to streamline and stabilize fees by adjusting the annual fees based on the percent change in the NRC's total budget each year, with additional adjustments for the number of licensees paying fees, changes in Part 170 collections, and other adjustments that may be required, unless there is a substantial change in the total NRC budget or the magnitude of the budget allocated to a specific class of licensees, in which case the annual fee base would be reestablished. The Commission established new baseline annual fees in FY 1999, and determined at that time that future annual fees should be rebaselined every three years, or earlier if warranted. After carefully considering all factors, including the changes to the amount of the budget allocated to classes of licensees, and weighing the complex issues related to both fairness and stability of fees, the Commission determined that it was appropriate to rebaseline the annual fees in FY 2001. A final rule revising the fee schedules was published on June 14, 2001 (66 FR 32452).

Issue 4: Will Part 35 Create a Net Hazard by Imposing Costs for Regulatory Compliance That Could Be Better Spent Addressing Some Other Societal Risk?

*Comment.* Commenters argued that for every approximately $9 to $12 million spent on regulatory compliance and, therefore, not available for spending on some other aspect of safety, a life will be lost. They suggested that NRC has not demonstrated that the impact of the Part 35 regulations in terms of patients saved from harm outweighs the costs imposed.

*Response.* The NRC agrees that Part 35 should not impose costs that do not correspond to the risks being addressed. We have developed a rule that is intended to be more risk-informed, in which risk insights are considered together with other factors to establish requirements that better focus licensee and regulatory attention on design and operational issues commensurate with their importance to public health and safety. We have also made the final rule less prescriptive and more performance-based to help ensure that it does not create unnecessary compliance or implementation costs. Therefore, we believe that the final rule properly balances the risks and costs involved.

Issue 5: What Is the Total Cost of Regulating the Medical Uses of Radionuclides?

*Comment.* Several commenters stated that it would be useful to know the total cost of regulating the medical uses of radionuclides. Knowledge of the full costs, in the view of some commenters, would allow the selection of the least costly and least restrictive regulations and would allow a more rational allocation of resources than the current system. Some commenters reported that their estimates indicated that the annual cost of regulatory compliance exceeded $100 million; others reported that their estimate indicated the annual cost exceeded $130 million just for paperwork; still others reported that their estimate indicated the annual cost exceeded $500 million to $1 billion the first year and hundreds of millions per year thereafter. In contrast, other commenters stated that developing an estimate of the total cost of compliance was probably very difficult or impossible.

*Response.* In evaluating the costs of regulatory compliance and implementation, the NRC has used detailed information whenever it is available. We have sought data from a number of sources, including medical speciality groups, manufacturers, members of the ACMUI, the National Institutes of Health, and various published sources. However, certain necessary data are treated as proprietary. Other data are not collected or are available only in a disaggregated form. Many of the compliance costs will vary substantially from licensee to licensee, depending on the number and type of modalities and procedures that they use and perform. Other compliance costs will be dependent on numerous interrelated variables. We believe that an effort to collect the necessary data and/or develop necessary models to provide substitutes for missing or unavailable data would require very considerable time and expense. We are concerned that at the conclusion of such an effort, because of many remaining gaps and uncertainties in the underlying data, an estimate of the total cost of the regulations would still fall within such broad confidence bounds that it would be fundamentally flawed. In this regard, we note that commenters' estimates of the total costs of the regulations vary by at least one order of magnitude and provide little or no underlying basis for their conclusions. Therefore, we prepared an estimate of the regulatory costs for a typical single practitioner licensee in order to satisfy the requirements of the Regulatory Flexibility Act. We have not prepared an estimate of the kind called for by the commenters because of the reasons discussed above.

Issue 6: Is NRC Aware That Certain Costs Are Not Reimbursable by the Health Care Financing Agency (HCFA)?

*Comment.* Several commenters noted that HCFA does not reimburse certain regulatory costs. Therefore, they asserted that either unnecessary regulations should be eliminated, or that NRC should intercede with HCFA to change the reimbursement policy. Estimates of the impact of HCFA's policy varied. A commenter suggested that at least 35 percent of medicine is practiced in the public sector (Medicare, Medicaid, and State health care programs); that in nuclear medicine a larger percentage of costs are being paid by Federal agencies; and that absence of reimbursement can reduce a physician's revenues by 15 to 30 percent. Another commenter estimated that regulatory compliance costs an estimated $30 to $40 per patient for a diagnostic procedure involving radionuclide materials. However, another commenter noted that for a procedure for which

reimbursement was $750 to $1,500, an estimated unpaid cost of compliance of $35 to $40 was not particularly significant.

*Response.* The NRC believes that involvement by NRC in HCFA's development of policy on reimbursement is outside the scope of this rulemaking and NRC's jurisdiction.

Issue 7: Will Testing Requirements for New Authorized Users, Authorized Nuclear Pharmacists, etc., Cause an Unnecessary Increase in Cost Without Commensurate Benefit?

*Comment.* Commenters argued that the testing requirements in the proposed rule were not necessary. Providers of didactic training already make use of testing as a validation system. In addition, testing would substantially increase the costs of implementing the rule. Development, administration, and maintenance of a separate testing system would not be cost effective. Unless testing were offered frequently, the requirement could create an obstacle to adequate staffing of medical institutions or nuclear pharmacies and actually negatively impact compliance and safety.

*Response.* The NRC agrees with the commenters and have removed the testing requirement that was in the proposed rule.

Issue 8: Does the OMB Estimate Accurately Summarize the Paperwork Burden of the Proposed Rule?

*Comment.* Commenters suggested that the OMB estimate of the Part 35 recordkeeping and reporting requirements is too low, listing several items that in their opinion were not properly included. Some commenters argued that NRC's suggested procedures are ''useless'' and, therefore, licensees will need to write numerous procedures. In addition, increased legal costs, amendment costs, and costs from discarded doses needed to be included. Commenters also suggested that hundreds of millions of dollars in paperwork costs were missing from the estimate, or that such costs are ''staggering,'' without providing a more specific description of the sources of the missing costs.

*Response.* The estimates for the information collection burden of many of the reporting and recordkeeping requirements in the proposed rule were based on previous estimates that were made available for public comment and submitted to the Office of Management and Budget (OMB). In a number of cases, the reporting and recordkeeping requirements in the final rule have been reduced from the requirements in the current rule. Therefore, the total information collection burden is lower than previously submitted to OMB for the current Part 35. In addition to information from previous burden estimates, we also obtained updated data from other sources such as NRC licensees, NRC regional licensing and inspection staff, NRC data bases, Agreement States, and stakeholders.

We agree that the estimates for the information collection burden associated with the testing requirements in the proposed rule were uncertain and may have been too low. However, the testing requirements are not included in the final rule.

Issue 9: Do the Potential Health and Safety Benefits of Requiring All Licensees to Possess Dose Calibrators Outweigh the Cost of the Calibrators?

*Comment.* Commenters suggested that the NRC should not require all licensees to possess a dose calibrator. They noted that certain categories of licensees only use unit dosages, and, therefore, obtaining a dose calibrator would create an unnecessary expense for them.

*Response.* The NRC has revised § 35.63 to require a licensee to determine and record the activity of each dosage before medical use. For a unit dosage, this determination could be made by a decay correction, based on the activity or activity concentration determined by (1) a manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements, or (2) an NRC or Agreement State licensee in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA for use in research. Therefore, a licensee who uses only unit dosages would not be required to incur the cost of a dose calibrator. However, the requirements also allow a licensee to use a dose calibrator to determine the activity of the unit dosage by direct measurement of radioactivity if he or she chooses to do so.

Issue 10: Do the Potential Health and Safety Benefits of Requiring Licensees To Conduct an Annual Retrospective Review of a Sample of Records of Administrations That Require a Written Directive Outweigh the Costs of the Reviews?

*Comment.* Commenters on a ''strawman'' version of the rule stated that the review that would be required by § 35.24(c) of the proposed rule, under which licensees would have been required to review a representative sample of records of administrations that require a written directive, would be an expensive requirement that would not reduce the rate of medical events. Furthermore, they said that a licensee would be forced to review 100 percent of the records to ensure that an inspection does not uncover a problem that was not reported.

*Response.* The NRC agrees that the proposed requirement was too prescriptive and, therefore, we deleted it from the final rule.

Issue 11: Do the Potential Health and Safety Benefits of Requiring Licensees To Establish Procedures To Provide Reasonable Assurance That a Radiopharmaceutical Will Not Be Unintentionally Administered to a Pregnant or Breast-Feeding Woman Outweigh the Costs of Compliance?

*Comment.* Commenters argued that a requirement to provide reasonable assurance that a radiopharmaceutical will not be unintentionally administered to a pregnant or breast-feeding woman could result in the administration of pregnancy tests for nearly all patients of child-bearing age, and this will increase costs.

*Response.* The NRC recognizes that the standard of practice for authorized users is to assess the pregnancy or nursing status of their female patients (see ACR ''Standard for the Performance of Therapy with Unsealed Radionuclide Sources,'' 1996, and ''Society of Nuclear Medicine General Procedure Guidelines for Imaging with Radionuclides,'' 1997). As a result, we do not believe that it is necessary for the NRC to require a licensee to assess the pregnancy or nursing status of patients before a medical treatment involving byproduct material.

Issue 12: Should Costs of Regulatory Implementation and Compliance by Licensees of Agreement States Be Included in the Regulatory Analysis?

*Comment.* A commenter argued that the regulatory analysis should reflect the possibility that Agreement States may not adopt all of the regulatory provisions included in the proposed rule.

*Response.* The NRC agrees with the commenter that, depending on the compatibility level assigned to particular regulatory requirements, Agreement States may not adopt all of the provisions in the proposed rule. However, in order to estimate the full impact of the regulatory changes in Part 35, we have assumed in developing the Regulatory Analysis that the Agreement States will adopt and implement all the provisions. However, we have provided sufficient details concerning estimated numbers of Agreement State licensees. Therefore, anyone who wishes to do so can estimate the effects of different

assumptions concerning Agreement State adoption and implementation of the requirements in the final rule.

Issue 13: Does the Regulatory Analysis Properly Estimate the Costs of Compliance With Particular Sections of the Proposed Rule?

*Comment.* Commenters criticized the estimates in the Regulatory Analysis for particular sections of the proposed rule. In particular, they suggested that the time necessary to prepare a license amendment could be greater than estimated for § 35.6, that the number of license amendments likely to be submitted under § 35.13 could be estimated more precisely, and that the time required for a meeting of a Radiation Safety Committee could be greater than estimated. Commenters also suggested that the interaction of §§ 35.400, 35.500, and 35.590 with § 35.12 was unclear, and additional license amendments might need to be costed under § 35.12. Commenters questioned whether the intent of the rule was to require calibration of every brachytherapy source under § 35.432, and, if so, said that additional costs should be estimated. Commenters also asked for substantiation for the $1000 estimate for calibrating brachytherapy sources and asked for clarification regarding the number of affected licensees. When no incremental cost was indicated for a particular section of the proposed rule (e.g., §§ 35.610, 35.3045, and 35.3067), a commenter requested that a cost estimate be provided.

*Response.* The NRC reviewed the Regulatory Analysis and provided additional clarification when possible for the points raised by the commenters. We concluded that the estimated time for preparation of an application for a license amendment under § 35.6 would not differ significantly from the time necessary to prepare any other license amendment application.

We also concluded that because the changes to the requirements concerning when a license amendment is required reflect changes to other sections of the rule (e.g., revisions to the requirements concerning changes to the areas of use under §§ 35.100 and 35.200) a count of former license amendment applications would not provide useful data. We agree that the time required for Radiation Safety Committee meetings can vary, but concluded that the elimination of prescriptive requirements for the Radiation Safety Committee, including the number of required attendees and procedural requirements concerning the meetings, would result in an average reduction in the duration of meetings. We concluded that the commenter had not correctly interpreted the interaction of §§ 35.400, 35.500 and 35.590 with § 35.12, particularly because the commenter appeared to be referring to the strawman proposed rule. Therefore, we did not provide the estimate called for. The estimate of $1000 per licensee for calibration of brachytherapy sources was based on information from NRC staff and members of the ACMUI concerning the number of calibrations that would be performed by an average licensee and the time necessary to perform each calibration. With respect to the commenter's request for a total cost estimate, see the response to Issue 5.

*Part III—Specific Comments on the Proposed Rule*

*Part 20—Standards for Protection Against Radiation*

*Section 20.1002, Scope*

Issue 1: Were Any Changes Made to This Section Between the Proposed and Final Rule?

*Response.* Yes. The NRC amended this section to replace the phrase ''to exposure from individuals administered radioactive material and released in accordance with § 35.75'' with the phrase ''to exposure from individuals administered radioactive material and released under § 35.75.'' This change clarifies that the dose to individual members of the public from a licensed operation does not include doses received by individuals exposed to patients who were released by the licensee under the provisions of § 35.75.

In 1997, we amended the regulations for the release of patients administered radioactive material to base the criteria for patient release on the potential dose to other individuals exposed to the patient (62 FR 4120; January 29, 1997). As part of that rulemaking, we also amended the regulatory text in §§ 20.1002, 20.1003 and 21.1301 to reflect the Commission's policy that patient release is governed by § 35.75, not § 20.1301 (62 FR 4120; January 29, 1997, see page 4122).

Current §§ 20.1002, 20.1003, and 20.1301(a)(1) indicate that the dose limits for individual members of the public or for an occupationally exposed individual from a licensed operation do not include doses received by individuals exposed to patients who were released in accordance with § 35.75. Upon further review, we believe that changes needed to be made to the current regulatory text in §§ 20.1002, 20.1003, and 20.1301, to further clarify that the dose limits do not apply to the maximally exposed individual from a patient or human research subject who has been administered unsealed byproduct material or implant containing byproduct material (reference § 35.75) and has been released from the licensee's control.

Under § 35.75, a licensee may release an individual from its control if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisievert (mSv)(0.5 rem). The licensee is required to comply with all the requirements in § 35.75. Failure to comply with any of the provisions in § 35.75 may result in enforcement action. This change in § 20.1002 makes it clear that any violations will be cited against § 35.75 and not Part 20.

*Section 20.1003, Definitions*

Issue 1: Were Any Changes Made to This Section Between the Proposed and Final Rule?

*Response.* Yes. The NRC made corresponding changes to the definitions for occupational dose and public dose to clarify that these doses do not include doses received by individuals exposed to patients who were released by the licensee under the provisions of § 35.75. Specifically, we amended these definitions to replace the phrase ''from exposure to individuals administered radioactive material and released in accordance with § 35.75'' with the phrase ''from exposure to individuals administered radioactive material and released under § 35.75.'' The rationale for these changes is discussed in depth under § 20.1002, above.

*Section 20.1301, Dose Limits for Individual Members of the Public*

Issue 1: Who Should Approve Whether a Visitor Is Allowed To Receive a Dose Up to 5 mSv (0.5 rem)?

*Comment.* A commenter suggested that the RSO, not the AU, should be the appropriate individual to approve the merits of allowing a visitor to receive up to 5 mSv (0.5 rem).

Response. AUs have the primary responsibility for the health and safety of their patients. They are also responsible for determining, depending on the patient's condition, whether individuals can visit patients and with what limitations. Therefore, the NRC believes that the AU should approve whether a visitor is allowed to receive a dose up to 5 mSv (0.5 rem). However, the AU may consult with the RSO at any time regarding visitor control.

Issue 2: Should Visitors be Allowed To Receive a Dose Up to 5 mSv (0.5 rem)?

*Comment.* The commenter stated that the proposed rule did not meet any standard for justifying an increased exposure to someone visiting a hospitalized (confined) patient. The commenter indicated that one of the reasons for the increased dose limit in § 35.75 was the economic benefit of allowing the patient or human research subject to be released from control earlier. He went on to state that in the case of the proposed revision to § 20.1301, there was no economic benefit to the licensee and that NRC was basing this change on an emotional benefit to the patient rather than an economic benefit.

Response. The justification for this change was discussed in detail in the Statements of Consideration for the proposed rule (63 FR 43516; August 13, 1998) and in the associated draft Regulatory Analysis. It is restated in Section III, Part III of the **SUPPLEMENTARY INFORMATION** in this document and in the final Regulatory Analysis. Overall, the NRC believes that the emotional benefit to the patient or the visitor outweighs the increase in radiation risk to the visitor. AUs should have the flexibility to make a determination, based on their judgment, as to whether a patient or human research subject would benefit from allowing a visitor to receive a dose up to 5 mSv (0.5 rem). The AU must consider the patient's condition when determining whether it is appropriate to allow a visitor to receive a dose up to 5 mSv (0.5 rem). We changed the regulatory text in § 20.1301(c)(2) to clarify that the authorized user must make the determination whether the visit is appropriate before the visit occurs.

Issue 3: Were Any Changes Made to This Section Between the Proposed and Final Rule?

Response. Yes. The NRC changed the regulatory text in § 20.1301(a)(1) to indicate that the dose to individual members of the public from a licensed operation does not include doses received by individuals exposed to patients who were released by the licensed operation under the provisions of § 35.75. Specifically, we replaced the phrase ''from exposure to individuals administered radioactive material and released in accordance with § 35.75'' with the phrase ''from exposure to individuals administered radioactive material and released under § 35.75.'' The rationale for this change is discussed under § 20.1002.

*Part 32—Specific Domestic Licenses of Broad Scope for Byproduct Material*

*Section 32.72, Manufacture, Preparation, or Transfer for Commercial Distribution of Radioactive Drugs Containing Byproduct Material for Medical Use Under Part 35*

Issue 1: Were There Any Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. The NRC corrected the reference to ''paragraph (b)(2) and (b)(3)'' in § 32.72(b)(1) to read ''paragraphs (b)(2) and (b)(4).''

*Part 35—Medical Use of ByProduct Material*

*Subpart A—General Information*

*Section 35.1, Purpose and scope.*

Issue 1: How Does This Rule Provide for the Radiation Safety of Patients?

*Comment.* Commenters did not believe that Part 35 should address the radiation safety of patients because it would necessitate NRC making medical judgments. Commenters noted that physicians are trained to make informed decisions on behalf of patients. They believed that the NRC should ensure that those practicing nuclear medicine are adequately trained in nuclear science, thus ensuring that the radiation safety of patients is provided for.

*Response.* The NRC made no changes to the regulatory text in this section. We believe that the NRC should provide for the radiation safety of the public, workers, and patients. The Commission's goal in regulating nuclear material safety, as stated in its September 1997 ''Strategic Plan'' (NUREG–1614, Vol. 1), is to ''prevent radiation-related deaths or illnesses due to civilian use of source, byproduct material, and special nuclear material.'' The radiation safety of the public, workers, and the patient is central to the fulfillment of the Commission's statutory mandate to ''protect health and minimize danger to life.''

The Commission has decided to retain its long-standing medical use regulatory program. However, it is doing so with improvements, including decreased oversight of low-risk activities and continued emphasis on high-risk activities. The Commission has long recognized 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 interest of their patients. However, the NRC has a secondary, but necessary, role with respect to the radiation safety of patients. The NRC will, when justified by the risk to patients, regulate their radiation safety, primarily to ensure that the use of radionuclides is in accordance with the physician's directions.

Issue 2: Were There Any Changes Made in This Section Between the Proposed and Final Rule?

*Response.* Yes. The NRC replaced the word ''prescribes'' with the phrase ''contains the'' in the first sentence of the section because Part 35 contains the requirements and provisions for the medical use of byproduct material and for issuance of specific licenses authorizing medical use.

*Section 35.2, Definitions*

The NRC received numerous comments on the definitions. Commenters asked us to revise, delete, or add definitions for terms used in the rule. We also added some new terms in this section because of changes made in other sections of the rule. Public comments and our response to the comments, as well as the reasons for other changes to this section, are presented below, in alphabetical order of the terms.

Address of use.

Issue 1: Were There Any Changes Made in This Definition Between the Proposed and Final Rule?

*Response.* Yes. The NRC added the word ''preparing'' to the definition to recognize that licensees not only receive, use, and store byproduct material but, in the case of a medical licensee, they may also prepare the material for use.

Area of use.

Issue 1: Were There Any Changes Made in this Definition Between the Proposed and Final Rule?

*Response.* Yes. The NRC added the word ''preparing'' to the definition to recognize that licensees not only receive, use, and store byproduct material but, in the case of a medical licensee, they may also prepare the material for use.

Authorized Medical Physicist.

Issue 1: Should the Term ''Medical Physicist'' Be Used in the Rule?

*Comment.* Commenters believed that a ''medical physicist'' would better be defined by a unique term, similar to ''Authorized User,'' which has no meaning outside the regulations. They stated that use of the term ''authorized physicist'' would be consistent with ''authorized user.''

*Response.* The NRC retained the term ''authorized medical physicist'' in the final rule. This was done to maintain consistency with other terms used in Part 35 (AU and ANP). We also believe the term ''authorized physicist'' may be too broad, and we would like to make it clear that this individual has experience as a medical physicist.

Issue 2: Can an AMP Be an AU?

*Comment.* Commenters questioned whether a medical physicist could be the AU and, if so, whether there would be a need to have a physician listed on a nuclear medicine license?

*Response.* It is always necessary to name an AU on the Part 35 license because only an AU can prescribe dosages or doses of byproduct material for medical use under Part 35. An AU for medical use under §§ 35.100, 35.200, 35.300, 35.400, and 35.600 must be a physician. An AU for medical use under § 35.500 may be a physician, dentist, or podiatrist. An AMP could only be an AU, named in the license, if the AMP meets the criteria in the definition of AU in § 35.2, including the training and experience criteria cited in that section.

Issue 3: Were There Any Changes Made in This Definition Between the Proposed and Final Rule?

*Response.* Yes. In addition to restructuring the definition, to make it more readable, the NRC substituted the word ''individual'' for the word ''physicist.'' This change has been made so that the definition of the term would be similar to the definition for an RSO.

We also amended the definition for the AMP to include individuals identified as an AMP on a medical use permit issued by a Commission master material licensee, or a permit issued by a Commission master material license broad scope medical use permittee. This change, which was also made to the definitions of ''ANP,'' and ''AU,'' accounts for the fact that an AMP may be named on a permit issued by a master material licensee. For example, in the first case identified above, if a master material licensee has issued a permit that recognizes a particular individual as an AMP, under the revised definition the individual would continue to meet the requirements for an AMP under an NRC license. In the second case, if a master material licensee chooses to issue a broad scope permit to a hospital and that hospital has authorization to issue permits designating AMPs, under the revised definition an AMP on the permit would also meet the requirements for an AMP under an NRC license. For a definition and description of master materials licenses refer to NUREG–1556, Vol. 10, ''Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Master Materials Licenses.''

Authorized Nuclear Pharmacist.

Issue 1: What Are the Duties of an ANP?

*Comment.* A commenter stated that the responsibilities and duties of the ANP were not codified.

*Response.* The NRC did not change the regulatory text in response to this comment. We have used the definitions section to provide an understanding of what we mean by a term. We do not believe it is appropriate to list the responsibilities and duties of the ANP either in the definitions section or elsewhere in the rule. In most cases, we have not specified who must perform a particular duty. This was done to give the licensee flexibility in how it implements its radiation protection program. However, where justified by risk, we have specified who must perform specific duties in a limited number of cases. For example, the full calibration measurements on remote afterloader must be performed by an AMP (§ 35.633(h)).

Issue 2: Why Do Nuclear Pharmacies Have the Authority To Approve ANPs?

*Comment.* A commenter did not believe that nuclear pharmacies should be authorized to approve ANPs.

*Response.* This commenter objected to one way by which an individual may be qualified to be an ANP, i.e., approval by a nuclear pharmacy authorized to approve ANPs. This pathway to be a qualified ANP was added to the final rule for two reasons. One, the current definition needs to recognize that § 32.72(b)(4) allows nuclear pharmacies to designate a pharmacist as an ANP if the individual meets certain requirements. Specifically, § 32.72(b)(4) contains a ''grandfathering'' provision permitting certain Part 32 nuclear pharmacy licensees to designate a pharmacist as an ANP, if the individual is identified, as of December 2, 1994, as an AU on a nuclear pharmacy license issued by the Commission. [If you would like additional information on § 32.72, refer to the regulatory history of the radiopharmacy rule (58 FR 33396; December 2, 1994, see page 33400).] Second, this change is needed because some nuclear pharmacies have a license amendment that allows them to approve ANPs if the individual meets the training and experience requirements in Part 35. Without this corresponding change in Part 35, the individual would not be allowed to function as an ANP regardless of the nuclear pharmacy's approval.

Issue 3: Were There Any Changes Made in This Definition Between the Proposed and Final Rule?

*Response.* Yes. The definition was restructured to make it more readable. The NRC also amended the definition for the ANP to include pharmacists identified as ANPs on a permit issued by a Commission master material licensee that authorizes medical use or the practice of nuclear pharmacy or a permit issued by a Commission master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy, or designated as an ANP in accordance with § 32.72(b)(4). This change, which parallels changes made to the definitions of ''AMP'' and ''AU,'' accounts for the fact that an ANP may be named on a permit issued by a master material licensee. In addition, the definition was amended to include ANPs that have been identified by a commercial nuclear pharmacy which has been given authorization to identify ANPs. In the first case identified above, if a master material licensee has issued a permit that recognizes a particular individual as an ANP, under the revised definition the individual would continue to meet the requirements for an ANP under an NRC license. In the second case, if a master material licensee chooses to issue a broad scope permit to a hospital and that hospital has authorization to issue permits designating ANPs, under the revised definition an ANP on the permit would also meet the requirements for an ANP under an NRC license.

Authorized User.

Issue 1: What Does an AU Do?

*Comment.* A commenter recommended that the definition of ''Authorized user'' include the duties of an AU.

*Response.* The NRC did not change the regulatory text to include the duties of the AU in the definition. We have used the definitions section to provide an understanding of what we mean by a term, as it is used in Part 35. Duties that must be performed by the AU are stated in regulatory text, where appropriate. The issue of whether the duties of a licensed individual belong in the definition section is discussed in more detail under the term ''authorized nuclear pharmacist.''

Issue 2: Does the Rule Distinguish Between Different Types of AUs?

*Comment.* A commenter recommended we clarify each type of

AU, or distinguish between AUs involved in diagnostic versus therapeutic medical uses.

*Response.* The NRC does not believe the definition of AU should be modified in this way. Other requirements in this part address the safety requirements for the different types of medical uses and the AU's actual duties. For example, the training and experience requirements for AUs, as well as other requirements in the regulations, differentiate between diagnostic and therapeutic medical uses of byproduct material. The training and experience requirements for an AU who would like to use unsealed byproduct material for uptake, dilution, and excretion studies (§ 35.290) differ from the training and experience requirements for an AU who would like to use unsealed byproduct material for therapy (§ 35.390). Also, radiation safety requirements are not the same for diagnostic medical uses as compared to therapeutic medical uses. Finally, the medical use license indicates what materials can be used by an AU.

Issue 3: Can Non-Physicians Be AUs?

*Comment.* A commenter noted that although the definition of ''AU'' refers to ''any prescriber,'' (i.e., physician, dentist, or podiatrist),'' the proposed rule language (in §§ 35.100, 35.200, and 35.300) refers only to a physician. The commenter indicated that if dentists and podiatrists cannot be AUs, the regulations should state this.

*Response.* Section 35.2 contains a general definition of an AU. Specific training and experience requirements for AUs are contained elsewhere within the regulatory text of Part 35. Where appropriate, the rule does specify when an AU must be a physician. An AU of materials authorized in §§ 35.100, 35.200, 35.300, 35.400, and 35.600 must be a physician. An AU using materials authorized under § 35.500 can be a physician, dentist, or podiatrist, if that individual meets all of the training and experience requirements for this type of use.

Issue 4: Were There Any Changes Made in This Definition Between the Proposed and Final Rule?

*Response.* Yes. The NRC also amended the definition for the AU to include physicians, dentists, or podiatrists identified as AUs on a permit issued by a Commission master material licensee that is authorized to permit the medical use of byproduct material, or a permit issued by a Commission master material license broad scope medical use permittee that is authorized to permit the medical use of byproduct material. This change, which was also made to the definitions of ''ANP,'' and ''AMP,'' accounts for the fact that an AU may be named on a permit issued by a master material licensee. For example, in the first case identified above, if a master material licensee has issued a permit that recognizes a particular individual as an AU, under the revised definition the individual would continue to meet the requirements for an AU under an NRC license. In the second case, if a master material licensee chooses to issue a broad scope permit to a hospital and that hospital has authorization to issue permits designating AUs, under the revised definition, an AU on the permit would also meet the requirements for an AU under an NRC license.

We also added a reference to new sections in the final rule that list the training and experience requirements for individuals using only I–131 in quantities that would require a written directive (§§ 35.392 and 35.394) and for individuals using strontium-90 for ophthalmic treatments (§ 35.491).

*Brachytherapy.*

Issue 1: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

*Response.* Yes. The NRC added a definition for brachytherapy. We believe it is important to define such a term as it is used in Part 35 so that the regulated community and regulatory agencies have a clear understanding of what we mean when we use the term in the rule.

Brachytherapy source.

Issue 1: Were There Any Changes Made in This Definition Between the Proposed and Final Rule?

*Response.* The NRC did not receive any public comment on this definition. However, we did delete the word ''sealed'' in the definition. This was done in order to include sources which do not meet the definition of ''sealed source'' (i.e., ''radioactive plated, embedded, and activated'' sources).

Client's address.

Issue 1: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

*Response.* Yes. The NRC added a definition for client's address because we now use it in § 35.80, ''Provision of mobile medical service.'' The term ''client's address'' encompasses an area of use, as well as a temporary job site. Use of this term in the rule is explained in greater depth under the discussion of § 35.80.

Diagnostic clinical procedures manual.

Issue 1: Is This Term Needed?

*Comment.* Commenters recommended this term be deleted because it is too prescriptive and should be replaced with the term ''radiopharmaceutical prescription/order.'' A radiopharmaceutical prescription/order can either be written for an individual patient (e.g., a written directive for therapeutic radiopharmaceuticals) or be in the form of specific standing orders. The commenter was concerned that use of the term ''clinical procedures manual'' may limit a licensee's ability to compound radioactive drugs. As such, according to the commenter, the term raises a clinical medical practice issue under state law regarding the practice of medicine and pharmacy. The commenter believed that it would be more appropriate for the NRC to require a general description of the radiation safety procedures used to protect workers, the public, and other patients from unintentional exposures. The commenter indicated the procedure manuals are written by physicians and should only be considered as informational or guidance documents for technologists.

*Response.* In response to this comment, the NRC deleted ''diagnostic procedures manual'' both as a defined term in § 35.2 and from the definition of ''prescribed dosage'' in § 35.2. Also, because this term is not used in the regulatory text, we no longer need to define it.

As modified, the rule is less prescriptive and does not limit a licensee's ability to compound certain radioactive drugs. Sections 35.100, 35.200, and 35.300 permit certain uses of unsealed byproduct material which are prepared by an ANP, a physician who is an AU (meeting certain requirements), or an individual under their supervision.

Health physicist.

*Comment.* A commenter asked that we add a definition for ''health physicist.'' This individual would be defined as ''a person qualified in the art, science, and professional practice of radiation safety as evidenced by current certification by the American Board of Health Physics (ABHP) or an equivalent certifying body with substantially the same requirements.'' The commenter believed that NRC, when identifying physicists, was defining a specific position too narrowly, with delineated duties and responsibilities that represent only a portion of the duties and responsibilities of physicists who are involved in radiation safety.

*Response.* The NRC has not defined the term in Part 35 because it is not used

in Part 35. Physicists meeting the requirements for an ''authorized medical physicist'' or ''Radiation Safety Officer'' would be recognized on the license as either an AMP or RSO, respectively.

High dose-rate remote afterloader and low dose-rate remote afterloader.

Issue 1: Should There Be Another Category of ''Afterloader,'' Such as a ''Non-Remote'' or ''Beta-Only'' Afterloader?

*Comment.* A commenter stated that the proposed afterloader definitions don't distinguish between the beta device that delivers more than 2 Gray/hour (Gy/h) to a target tissue and less than 0.002 Gy/h to the remainder of the body from the afterloader capable of delivering a lethal whole body dose. The proposed definitions will result in confusion for licensees and inspectors. The commenter recommended that another category of afterloaders, such as ''non-remote'' or ''beta-only'' afterloaders, be developed.

*Response.* The NRC has not distinguished between beta and photon-emitting remote afterloaders in the definition. The purpose of the definition is to categorize afterloaders into different groups based on the dose rate (i.e. high, medium, or low) of the remote afterloader. Requirements for the devices are found in Subpart H. The final rule only addresses use of photon-emitting afterloaders. Use of beta-emitting afterloaders is being addressed on a case-by-case basis at this time because use of these types of afterloaders is relatively new and both regulators and licensees continue to identify elements of safe operation.

Issue 2: Were There Any Other Changes Made in This Definition Between the Proposed and Final Rule?

*Response.* Yes. The definition for a high dose-rate remote afterloader (HDR) was amended to state that it means a brachytherapy device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed, rather than a dose rate in excess of 2 gray (200 rads) per hour. The definition for a low dose-rate remote afterloader (LDR) was also amended to state that it means a brachytherapy device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the point or surface where the dose is prescribed, rather than a dose rate of less than 2 gray (200 rads) per hour. These changes were needed because the final rule includes a definition for medium dose-rate remote afterloader (MDR).

Licensee.

Issue 1: Should This Term Be Defined?

*Comment.* A commenter asked that this term be defined.

*Response.* The NRC did not define the term in Part 35 because ''licensee'' is defined in 10 CFR 20.1003, ''Definitions,'' as the holder of a license. Wherever possible, we have tried to rely on the definitions in other parts of 10 CFR Chapter I that apply to medical licensees, rather than duplicate the definitions in Part 35.

Management.

Issue 1: Who Is ''Management''?

*Comment.* A commenter asked that we clarify what we mean when we use the term ''management.'' The commenter wanted to know whether management could be the chief executive officer or the head of one or all departments?

*Response.* The NRC clarified the regulatory text to define management as the Chief Executive Officer (CEO) or other individual having the authority to manage, direct, or administer the licensee's activities, or those persons' delegate or delegates. If the head of one or all departments is a delegate(s) of the CEO or if the individual has the authority to manage, direct, or administer the licensee's activities, that person(s) would be considered to be part of ''management.''

Manual brachytherapy.

Issue 1: Should the Term ''Manual Brachytherapy'' Be Defined?

*Comment.* A commenter asked that we define this term because it is not a common or standard term and it is used as a subpart title.

*Response.* The NRC added a definition for manual brachytherapy. As used in this part, manual brachytherapy has been defined to be a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed topically on or inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume.

Medical use.

Issue 1: Should the Definition of the Term ''Medical Use'' Include the Term ''Byproduct Material''?

*Comment.* A commenter recommended that the term ''byproduct material'' be deleted from the definition of the term ''medical use'' because the regulations use the phrase ''byproduct material for medical use,'' which is redundant. The commenter did not believe it necessary to include the term ''byproduct material'' in the definition of ''medical use'' and then to modify the term ''medical use'' with the phrase ''byproduct material'' in the regulations. The commenter stated that deleting the term ''byproduct material'' from the definition ''requires the least amount of correction and simplifies compatibility by Agreement States.''

*Response.* The NRC recognizes that there is some redundancy in using the phrase ''Medical use of byproduct material.'' However, we believe that this level of redundancy in some requirements is not objectionable, if it helps to clarify NRC's implementation of specific requirements of the AEA.

Medium dose-rate remote afterloader.

Issue 1: Is There a Need for a Definition of the Term ''Medium Dose-Rate Remote Afterloader''?

*Comment.* Commenters were divided in response to our request for comment on whether the rule should define the term ''medium dose-rate remote afterloader.'' Some commenters recommended that the term be defined because, although the regulatory requirements for ''high'' and ''medium'' dose-rate afterloaders are very similar, the radiation safety precautions are different and, thus, these terms require different definitions. Commenters who did not support a definition for an MDR cited various reasons for their position. Some commenters believed that the regulatory requirements for HDR and MDR should be identical, and, therefore, there was no need to define an MDR. This position is based on the opinion that the risks to patients from high, medium, pulsed and low dose-remote afterloaders, capable of whole body irradiation, are indistinguishable. Other commenters were concerned that the definition for an MDR could lead to confusion because the definition would overlap with the current definition of ''high dose-rate remote afterloader.''

*Response.* The NRC included a definition for an MDR in the final rule because the final rule contains requirements that apply to MDRs. The definitions of an HDR and an LDR were revised so there is no overlap between the definitions.

Mobile medical service.

Issue 1: Were There Any Changes Made in This Definition Between the Proposed and Final Rule?

*Response.* The NRC did not receive any public comment on this definition. However, we did change the term from ''mobile service'' to ''mobile medical service.'' This was done because we wanted to state clearly that the mobile service provisions apply only to medical

use. The final rule defines ''mobile medical service'' as the transportation of byproduct material and its medical use at the ''client's address,'' which includes the ''area of use'' or a ''temporary job site.'' In addition, the definition of this term no longer contains the phrase ''by the same licensee'' because that phrase unduly limited the transportation and medical use of the byproduct material to one licensee.

Output.

Issue 1. Were There Any Changes Made in This Definition Between the Proposed and Final Rule?

*Response.* The definition for output was amended to also refer to the exposure rate or dose rate from a brachytherapy source, remote afterloader, or gamma stereotactic radiosurgery unit. The proposed rule only addressed the output from a teletherapy unit. This was done because various sections in Subpart H reference output from these other units.

Patient intervention.

Issue 1: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

*Response.* Yes. The NRC added a definition for patient intervention. We believe this definition is needed to state clearly what we mean when we use the term in § 35.3045. Discussion of patient intervention is found in the section of this document responding to comments on § 35.3045.

Preceptor.

Issue: Should the Term ''Preceptor'' Be Defined?

*Comment.* Commenters recommended that the term be defined and that the definition distinguish between low-dose radiopharmaceuticals (diagnostic) and high-dose radiopharmaceuticals (therapeutic). The former would include ''persons designated as authorized physician users of low-dose radiopharmaceuticals.'' Preceptors of ''high-dose radiopharmaceuticals'' must be ''program directors of structured educational programs in medical teaching institutions that consist of didactic training and practical experience.'' Commenters believed that the ''preceptor'' should not be limited to someone in the medical, dental, or podiatry profession.

Commenters believe the term ''preceptor'' should be defined as an individual who is listed on a license, such as an AU or RSO, or is appointed by licensee management to act in the capacity of a preceptor for the purpose of documenting that an individual has completed a structured educational program and/or practical experience. The preceptor must have demonstrated training and experience that is at least equal to the training and experience of the individuals being trained.

*Response.* The NRC agrees the term ''preceptor'' should be defined because the term is used throughout the training and experience requirements in the revised Part 35. A preceptor is defined as someone who provides or directs the training and experience required for an individual to become an AU, AMP, ANP, or RSO. In addition, we agree that the preceptor must have training and experience that is at least equal to the training and experience required by the AU, AMP, ANP, or RSO, as appropriate. This is reflected in the paragraphs that require the preceptor certification in the training and experience requirements in Subparts B and D through H.

Prescribed dosage.

Issue 1. Were There Any Changes Made in This Definition Between the Proposed and Final Rule?

*Response.* Yes. The NRC amended the definition for ''prescribed dosage'' to allow the AU to direct the administration of a range of activity and to delete the reference to the ''diagnostic clinical procedures manual.''

Prescribed dose.

Issue 1. Were There Any Changes Made in This Definition Between the Proposed and Final Rule?

*Response.* Yes. The NRC amended the definition for ''prescribed dose'' to clarify that item (3) refers to manual brachytherapy and item (4) refers to remote brachytherapy afterloaders.

Pulsed dose-rate remote afterloader.

Issue 1. Were There Any Changes Made in This Definition Between the Proposed and Final Rule?

*Response.* Yes. The NRC restructured the definition of pulsed dose-rate remote afterloader (PDR) to make it easier to read and clarified that it refers to a remote afterloading brachytherapy device. We also added a statement that the device uses a single source that is capable of delivering dose rates in the ''high dose-rate'' range, but is approximately one-tenth of the activity of typical HDR sources.

Radiation Safety Officer.

Issue 1: Were There Any Changes Made in This Definition Between the Proposed and Final Rule?

*Response.* Yes. The NRC restructured the definition to make it more readable. We also amended the definition for the RSO to include individuals identified as an RSO on a medical use permit issued by a Commission master material licensee. This change, which was also made to the definitions of ''ANP,'' ''AMP,'' and ''AU,'' accounts for the fact that an RSO may be named on a medical use permit issued by a master material licensee. If a master material licensee has issued a permit that recognizes a particular individual as an RSO, under the revised definition the individual would continue to meet the requirements for an RSO under an NRC license.

Radionuclide or radiopharmaceutical.

*Comment.* Commenters opposed the use of terms like ''radionuclide,'' or ''radiopharmaceutical'' in Part 35 because these terms are not defined as specifically containing byproduct material. They indicated that this was very important because NRC's statutory authority for regulating medical use under Part 35 is limited to byproduct material. They recommended that the regulation should use terms that have been defined to mean ''byproduct material radionuclide'' or ''byproduct material radiopharmaceutical.''

*Response.* Section 35.1, Scope, specifies that ''this part contains the requirements and provisions for the medical use of byproduct material and for the issuance of specific licenses authorizing the medical use of this material.'' In addition, medical use is defined in § 35.2, to mean the intentional internal or external administration of byproduct material or the radiation from byproduct material to patients or human research subjects under the supervision of an AU.

The word ''radiopharmaceutical'' is only used in §§ 35.204 and in 35.2063. In both cases, it is clear that the requirement applies to radiopharmaceuticals containing byproduct material. The word ''radionuclide'' is used in §§ 35.13, 35.40, 35.2067, and 35.3067 and is also used in the training and experience sections in Subparts B and D through H. Again, it is clear that the requirements in §§ 35.13, 35.40, 35.2067, and 35.3067 apply to radionuclides containing byproduct material, and it would be redundant for the rule text to restate the phrase ''containing byproduct material.'' In the case of the training and experience sections, we have chosen to allow an individual ''to take credit for'' experience obtained with handling nonbyproduct and byproduct material in meeting the training and experience requirements because there is very little difference between how byproduct and nonbyproduct materials are handled.

Sealed source.

Issue 1: Are Epoxy Vials Used for Testing Dose Calibrators ''Sealed Sources''?

*Comment.* A commenter asked that we clarify whether the epoxy vials used for testing dose calibrators are ''sealed sources.'' The commenter stated that epoxy vials are more correctly characterized as monoliths and should not be subject to leak testing.

*Response.* A ''sealed source'' is defined in § 35.2 as ''any byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material.'' Under this definition, epoxy vials used for testing dose calibrators are typically considered sealed sources. However, it is the licensee's responsibility to verify that a particular manufacturer's vial is considered by the relevant regulatory agencies to be a sealed source. This can be done by referencing the SSDR.

Stereotactic radiosurgery.

Issue 1: Were There Any Changes Made in This Section Between the Proposed and Final Rule?

*Response.* Yes. The definition was amended to clarify that stereotactic radiosurgery devices deliver therapeutic doses.

Teletherapy.

Issue 1: Were There Any Changes Made in This Section Between the Proposed and Final Rule?

*Response.* The NRC added a definition for teletherapy. This was done because we believed it is important to define this term as it is used in Part 35 so that the regulated community and the regulatory agencies have a clear understanding of how we have used a term within the rule.

Therapeutic dosage and therapeutic dose.

Issue 1: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

*Response.* The NRC added definitions for the terms ''therapeutic dosage'' and ''therapeutic dose'' because both terms are used in § 35.40, ''Written directives.'' In addition, we believe these definitions are needed to eliminate any confusion about when a written directive is needed.

Type of use.

Issue 1: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule.

*Response.* Yes. The NRC added a definition for the term ''type of use.'' This term replaced the term ''clinical procedure'' in § 35.13(a). We believe this term makes it clear that we are discussing ''uses'' in Part 35 (e.g., a use of byproduct material as specified in §§ 35.100, 35.200, 35.300, 35.400, 35.500, 35.600, and 35.1000), rather than ''clinical procedures'' (e.g., a bone scan, liver scan, or whole body scan).

Unit dosage.

Issue 1: Is Manipulation of ''Unit Dosages'' Permitted Under the Definition of This Term?

*Comment.* A commenter asked to what extent the ''end user'' would be allowed to manipulate a ''unit dosage.'' The commenter indicated that the greater the manipulation of the dosage, the greater the chance of an error being made in calculating the activity.

*Response.* The NRC amended the definition of unit dosage to make it clear that unit dosages cannot be manipulated after being initially prepared because any manipulation could change the activity in the dosage.

Issue 2: Were There Any Other Changes Made in This Definition Between the Proposed and Final Rule?

*Response.* Yes. The NRC amended the definition to stipulate that unit dosages must be prepared for medical use for administration as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared. This change acknowledges that preparation of a unit dosage is not limited to a manufacturer or preparer licensed under § 32.72 or equivalent Agreement State requirement. It also highlights that a unit dosage is intended for administration to a patient or human research subject without any further manipulation.

Written directive.

Issue 1: Does the Definition of ''Written Directive'' Recognize ''Computerized Directives''?

*Comment.* A commenter asked that the definition of written directive be revised to recognize that many facilities are using computerized systems and are not relying on written documents.

*Response.* The NRC did not change the definition. The intent of the definition of ''written directive'' and the requirements in § 35.40 are to distinguish between an AU's written versus oral direction for the administration of byproduct material, rather than between written (hard copy) and electronic directions. As used in Part 35, ''written'' includes information recorded in a computerized system. If a written directive is generated or stored in a computerized system, the licensee must have a method of authenticating the AU's signature. Refer to the discussion of § 35.5 for additional information on maintenance of records.

**Section 35.5, Maintenance of records**

Issue 1: Can Required Records, Other Than Originals, Be Authenticated?

*Comment.* A commenter asked how a copy or microform is authenticated by authorized personnel. The commenter indicated there is no requirement to authenticate records stored in electronic media. The commenter believed that all records should be required to be authenticated in writing when provided for legal purposes, or verbally when being reviewed during an inspection.

*Response.* Any record required by Part 35 must be maintained in accordance with § 35.5. These records must be authenticated regardless of the storage media. The issue of authenticating records was addressed by the NRC under a separate rulemaking, published in the **Federal Register** on May 27, 1988 (53 FR 19240). The following explanation of ''authenticated,'' as stated in that final rule, applies to all records retained under NRC's regulatory authority: '''Authenticated' denotes that the data has been verified for completeness and accuracy by an authorized individual and that it is a true representation of the original data'' (see page 19243).

Issue 2: Were There Any Changes Made in This Section Between the Proposed and Final Rule?

*Response.* Yes. The NRC made an editorial change in the second sentence to replace the phrase ''original, or a reproduced copy or a microform,'' with the phrase ''original, reproduced copy, or microform.''

*Section 35.6, Provisions for Research Involving Human Subjects.*

Issue 1: Should § 35.6 Include a Requirement That Licensees Develop, Implement, and Maintain Procedures for Evaluating When a Medical Procedure Would be Considered To Be a Research Procedure?

*Comment.* The NRC received a comment in support of the requirement, as well as comments opposed to the requirement. The commenter who wrote in favor of requiring such procedures stated there are occasions when a clear definition of what constitutes research would be useful in deciding which procedures must be approved by the Institutional Review Board (IRB) or RSC.

Commenters opposed to a requirement for procedures indicated that FDA regulates research through IRBs. They believed that existing regulations and guidelines provided

adequate oversight of research and that decisions regarding research should be left to the individual licensee and the licensee's IRB. They noted that the IRB must follow the Federal Policy for the Protection of Human Research Subjects. As a result, they believed that research that is approved by an IRB and is within the scope of the authorized inventory should be permitted. Commenters also noted that similar procedures are not required in other areas of medicine. Finally, commenters indicated that a requirement for procedures would not increase public health and safety.

*Response.* The NRC does not believe it is necessary to include a separate definition of the term ''research'' in Part 35 because Section 102 of the Federal Policy for the Protection of Human Research Subjects defines the term ''research.'' (Further information on this can be found in the **Federal Register** (56 FR 28003; June 18, 1991, see page 28013). In addition, we consider research conducted by NRC medical use licensees involving human subjects, which is also regulated by FDA, to be within the scope of § 35.6(b). Therefore, it is not necessary for such a licensee, prior to conducting such research, to apply for and receive a specific amendment to its NRC license. However, under §§ 35.6 and 35.7, the licensee is not relieved from complying with FDA or other requirements applicable to such research.

We agree with the comment that the NRC should not add a requirement in Part 35 for licensees to develop, implement, and maintain procedures for evaluating when a medical procedure would be considered to be research. We believe that the issue of ensuring that all medical procedures and studies that should be subject to the policy are recognized as ''research'' and are reviewed by an IRB should be resolved as a matter of common policy, rather than in any separate effort by NRC. However, in reaching this conclusion, we do not believe that we must be guided by whether, for any given Commission requirement, there is a comparable requirement for other areas of medicine. The regulatory history of Part 35 shows that the Commission has operated under the assumption that Congress intended a disproportionate degree of Federal regulatory control be exercised over the medical use of nuclear materials, as compared to the medical use of other sources of radiation (e.g., x-rays or accelerator-produced isotopes) (44 FR 31701; May 14, 1980, see page 31702). The issue of why similar procedures are not required in other areas of medicine is outside the scope of this rulemaking.

Issue 2: Do Broad Scope Licensees Need a License Amendment Before Conducting Research?

*Comment.* A commenter recommended that broad scope licensees be exempted from the requirement to amend their licenses before conducting research involving human subjects using byproduct material.

*Response.* The NRC believes that broad scope medical use licensees should be required to comply with § 35.6. This section is designed to protect the rights of human research subjects by requiring all licensees to obtain the informed consent of the subjects and by requiring an IRB to give prior review and approval of the research.

Issue 3: Were There Any Changes Made in This Section Between the Proposed and Final Rule?

*Response.* Yes. The NRC restructured the section to make it easier to read. We also added an introductory paragraph to make it clear that research permitted under § 35.6 may only be performed using byproduct material that is already authorized for medical use by the license. For example, if a licensee is authorized to use byproduct material under §§ 35.100, 35.200, and 35.300, it could not conduct research using a remote afterloader. However, the same licensee could conduct research using materials authorized in §§ 35.100, 35.200, or 35.300.

We also added a new paragraph (d). This paragraph codifies the Commission's intent that § 35.6 does not relieve licensees from complying with other provisions in Part 35. In other words, as stated in the regulatory history of § 35.6, the relevant radiation safety provisions of Part 35 are applicable to research involving human subjects. For further information on this issue, you may want to refer to the December 2, 1994, **Federal Register** (59 FR 61767).

*Section 35.8, Information Collection Requirements: OMB Approval*

Issue 1: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

*Response.* Yes. Paragraph (b) was amended to add references to §§ 35.19, 35.190, 35.392, 35.394, 35.433, 35.491, 35.615, 35.1000, 35.2041, 35.2433, and 35.2610 and to delete references to §§ 35.62, 35.292, 35.644, and Appendix A. These were conforming changes needed because of changes made in the regulatory text between the proposed and final rule.

*Section 35.10, Implementation*

Issue 1: Should the Time Period for Implementation of the Final Rule Be Extended?

*Comment.* Commenters asked that the implementation period for the new rule be extended up to 1 year from its publication to allow licensees and applicants sufficient time to adjust their budgets for any increased expenditures needed to implement the rule.

*Response.* The NRC has maintained a 6-month implementation period for all sections of the final rule. We believe that 6 months provides adequate time for licensees to develop and implement any changes in their radiation safety programs.

Issue 2: Should the Rule Provide Relief From Restrictive Requirements in the Rule or License?

*Comment.* A commenter recommended that § 35.10(e) be revised because otherwise it will maintain the most restrictive requirements of either the revisions of Part 35 or the licensee's current license conditions. The commenter was concerned if a license condition cites a deleted requirement in Part 35, the license condition remains in effect unless the license is amended in order to remove the needless requirements. The need for a license amendment would diminish the projected cost saving of the rule.

Commenters also raised the issue of whether there is a ''duality'' of the new Part 35 and existing license conditions, thus raising a concern about inspection and enforcement. Licensees will have to make significant amendments comparable to submitting a license renewal. Commenters believed that, if feasible and upon written request, licensees should be permitted to comply with the ''new'' Part 35 without regard to the restrictive nature of the license and without requiring a license amendment. If NRC believes that a regulation can be relaxed or eliminated without a reduction in radiation safety, the NRC should allow licensees to change their programs accordingly.

*Response.* The NRC modified the text of § 35.10 to allow for relief from the current rule and, in some cases, license conditions. The following discussion explains and summarizes the changes made in this section.

Paragraph (a) requires licensees to implement the provisions in the rule 6 months after the final rule is published in the **Federal Register**, except as stated in paragraph (b) of this section.

Paragraph (b) allows certain training and experience requirements to be

implemented on or before 2 years after the effective date of the final rule.

Paragraph (c) allows, prior to the date 2 years after the effective date of the final rule, licensees to have the option of complying either with Subpart J or Subparts B and D–H.

Paragraph (d) states if a license condition exempted a licensee from a provision in the current Part 35, that license condition continues to exempt the licensee from the requirements in the corresponding provision in §§ 35.1–35.4002 of Part 35. As shown in the following example, a corresponding provision may not always have the same numerical section reference. For example, if a licensee is exempted from the requirements in current § 35.57(c), Authorization for calibration and reference sources, the licensee will be exempted from the corresponding requirements in the final § 35.65(c), Authorization for calibration, transmission, and reference sources.

Paragraph (e) states that when a regulatory requirement in Part 35 differs from the requirement in an existing license condition, the requirement in Part 35 governs. This paragraph primarily applies to those licensees that committed to follow the procedures in Regulatory Guide 10.8, ''Guide for the Preparation of Applications for Medical Use Programs.'' When the final rule becomes effective, licensees will follow the requirement in Part 35 if it differs from the requirement that the licensee committed to by referencing the Regulatory Guide. For example, most licensees have committed to calibrate their dose calibrators using the procedures in Regulatory Guide 10.8, Appendix C, ''Model Procedure for Calibrating Dose Calibrator.'' These procedures are very prescriptive. The final Part 35 only requires licensees to calibrate instruments used to measure the activity of unsealed byproduct materials in accordance with nationally recognized standards or the manufacturer's instructions. Therefore, after the effective date of the final rule, a licensee must calibrate its dose calibrators in accordance with nationally recognized standards or the manufacturer's instructions, rather than being tied to using the procedures in Regulatory Guide 10.8.

Paragraph (f) states that the licensee shall continue to comply with any license condition that requires it to implement procedures for spot-checks on teletherapy, photon-emitting remote afterloaders, or gamma stereotactic radiosurgery units and to implement emergency procedures for photon-emitting remote afterloaders, teletherapy units, or gamma stereotactic radiosurgery units until there is a license amendment or renewal that modifies or removes the condition. Specifically, licensees must continue to follow any emergency response and spot-check procedures for teletherapy, remote afterloaders, and gamma stereotactic radiosurgery units that were submitted to NRC in support of a licensing action because of the high radiation risk associated with this type of use of byproduct material.

Issue 3: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

*Response.* Yes. Paragraph (b) was amended to add references to §§ 35.190(a), 35.392(a), and 35.394(a), and to delete reference to § 35.292(a). Paragraph (g) was deleted. Reference the General Training and Experience discussion in the beginning of this section of the **SUPPLEMENTARY INFORMATION** for more information.

*Section 35.11, License Required*

Issue 1: Should the Term ''Person'' Be Used in Lieu of ''Individual''?

*Comment.* A commenter noted that the word ''person'' was used in paragraph (a), while in paragraphs (b) and (c), the word ''individual'' was used. They recommended that the word ''person'' in paragraph (a) be changed to ''individual.''

*Response.* The NRC did not change the regulatory text of § 35.11. The term ''person'' is used in § 35.11(a) because licenses are issued to ''persons'' as defined in 10 CFR 30.4. Section 30.4 states that a person includes not only individuals (defined in 10 CFR 20.1003 as ''any human being''), but also corporations, government agencies other than the Commission, and States. Paragraphs (b) and (c) of § 35.11 use the term ''individual'' because the activities authorized by those sections are performed by ''individuals'' (under the supervision of an ''authorized user'' or ''authorized nuclear pharmacist''), but not necessarily by all of the entities which constitute ''persons.''

Issue 2: Can There Be Transfer of Sources Among Licensees?

*Comment.* A commenter indicated that changes in the health care environment have created affiliations between hospital groups which may or may not be under a single NRC license. The commenter believed that this regulation could prohibit the cost savings created by these affiliations. The commenter believed that if sources are received from a licensed distributor and handled properly, there should be some flexibility in transferring the sources between licensees.

*Response.* The NRC did not change the regulatory text in this section. However, we did change the regulatory text of § 35.49 to address this comment. Section 35.11 references conditions of a specific license issued by the Commission or an Agreement State. This license would require the licensee to comply with all provisions of Part 35. Section 35.49 has been modified to state that a licensee may use sealed sources or devices for medical use which are non-commercially transferred from a Part 35 licensee, i.e., if two licensees are authorized to possess sealed sources for medical use, they may transfer the sources from one to the other.

Issue 3: Were There Any Other Changes Made in this Section Between the Proposed and Final Rule?

*Response.* Yes. ''Prepare'' was added to paragraph (a) in recognition that medical licensees may also prepare byproduct material for medical use and need a license to do so. In addition, the section was restructured to make it easier to use. Paragraphs (b) and (c) were combined into one paragraph because they both provide information on when a specific license is not needed.

*Section 35.12, Application for License, Amendment, or Renewal*

Issue 1: Who May Apply for a License?

*Comment.* The commenter believed that the requirements in the current § 35.12(a) are inconsistent. According to the commenter, under the current rule, any person may apply for a license for medical use not sited in a medical institution, while only a medical institution's management may apply for a license for medical use sited in a ''medical institution.'' The commenter recommended that the NRC issue the license to a ''responsible person'' no matter what the license type. The commenter further recommended that the text of the rule be changed to reflect that the NRC will only accept a license application from a financially and/or legally responsible person.

*Response.* The NRC did not make any changes between the proposed rule and the final rule in response to this comment. Section 35.12(a) of the final rule requires that the license application be signed by the applicant's or licensee's management, regardless of the types of use applied for or authorized. For a sole practitioner, the ''management'' could be the same as the AU. This paragraph clarifies that ''management,'' by signing the

application, is responsible for the license, regardless of the size of the licensee.

Issue 2: Is There a Need for a Separate License for Medical Uses Covered by § 35.600?

*Comment.* Commenters stated that license applicants should be permitted to submit one license application covering several uses of radioactive material, as long as the activity is under both the same management and a qualified RSO. Commenters asked that we justify the inconsistent and separate licensing of a medical device such as a cobalt-60 machine because neither the administrative nor the technical requirements of the radiation safety program are going to be unique for the cobalt-60 unit. Commenters believed that a licensee should not be assessed a separate annual fee just for a medical device. The additional cost will only place a greater burden on the health care delivery system.

*Response.* NRC agrees with the commenter that licensees should be permitted to submit one application covering all medical uses. We have amended the regulatory text to require only one application for a Part 35 license, regardless of which medical use modalities the licensee will be performing. It will not be necessary for a licensee or applicant to file a separate application for each medical use of byproduct material, as described in §§ 35.600 or 35.1000. Licensees who currently hold separate licenses may request that the licenses be combined.

The commenter's suggestion that a single fee be assessed for all medical uses covered by a license would require a revision to Parts 170 and 171. The NRC will address this issue in an annual fee rulemaking subsequent to the issuance of this revision to 10 CFR Part 35.

Issue 3: Can Licenses Be Combined at Facilities?

*Comment:* Commenters believed that it would be advantageous for larger licensees that employ a full-time RSO and that have several existing licenses to unify all specific licenses into a single license. Commenters believed that the RSO should have the freedom and flexibility to manage resources to control all types of use without describing all the individual radiation safety procedures for the NRC. The RSO could appoint specialty RSOs, if needed, to manage the daily radiation safety program in specialty areas, *e.g.,* nuclear medicine, cardiology, radiation therapy, or individual campuses. For example, universities or large hospitals with several campuses could issue sub-licenses under a unified license. The RSO could authorize individual users who qualified under the training and experience criteria, without notifying NRC. This would be appropriate for authorizing physicians for emerging technologies, as well.

*Response.* The NRC agrees that licensees should have the flexibility of combining several licenses into one license. This will help to foster a more unified radiation protection program at the licensee's facility. Section 35.12 has been amended to allow applicants to apply for one license for all types of medical uses. For example, it is no longer necessary to have separate licenses for medical uses such as teletherapy, gamma stereotactic radiosurgery, or diagnostic nuclear medicine. Licensees have flexibility in structuring their radiation protection program to include specialty RSOs but the Commission holds the RSO named on the license responsible for the radiation protection program. Licensees do not have authority to issue any type of license. Under § 35.24, only licensee management can approve AUs.

Issue 4: Should Licensees Be Required To Submit Operating Procedures to NRC for Review and Approval as Part of the License Application?

*Comment.* The NRC received comments recommending that we review operating procedures as part of the license application. We also received comments indicating that we did not need to review procedures and that licensees should have flexibility in program management.

Some commenters recommended that we should not abandon our practice of reviewing a licensee's or applicant's procedures before issuing a license. These commenters believed it is important for NRC to review procedures as part of the licensing process. This is important because licensee management, AUs, workers, and NRC staff must have a common understanding of what is in the procedures. They believed that this would avoid enforcement problems during subsequent inspections.

Commenters believed licensees should have the flexibility to change certain procedures, even if the procedures had been submitted to the NRC, as long as the spirit of the rule is met. Once the procedure is incorporated into the license, the regulatory agency and the licensee know what to expect. NRC review of procedures during the license application or renewal process is a good way to see if the licensee has established procedures in compliance with NRC requirements. Other commenters asked that this section be changed to include the requirement that applicants either (1) commit to adopting the model procedures contained in NUREG–1556, Volume 9(draft), or (2) submit with the application the procedures they wish to use for review and approval by the Commission. These commenters did not believe inspectors have the time or resources during an inspection to both conduct the inspection and determine the adequacy of the licensee's procedures.

Other commenters suggested that the NRC review procedures only at the time of the initial application or when the license is periodically renewed. Procedures would not need to be submitted for license amendments. They believed that this approach would be helpful for smaller licensees that do not employ a full-time RSO and who usually rely on a consultant to write their standard operating procedures.

We also received comments that did not support NRC review of procedures. These commenters indicated that the NRC must recognize that there are many acceptable procedures to accomplish a specified goal. A licensee should be able to use any one of a large number of procedures as long as the performance standard is met. No written procedures of any kind need to be submitted to the NRC for review or be required as license conditions. Commenters also indicated that because the level of radioactivity involved in diagnostic medical uses of byproduct material is so low, compliance with the requirement for licensees to develop, maintain, and implement procedures provides no additional safety. Such a requirement would only increase the cost to the patients without any corresponding increase in the safety of the patient, hospital worker, or physician. Finally, commenters stated that this licensing approach should be extended to other uses outside Part 35, such as radiography (Part 34) and irradiator (Part 36) licenses.

*Response.* The NRC has amended the various provisions in the rule to delete, with one exception, the requirement for licensees to develop, implement, and maintain procedures (*e.g.,* § 35.24). We have also modified § 35.12 to state that only procedures required under §§ 35.610, 35.642, 35.643, and 35.645, as applicable, must be submitted to NRC for review as part of the license or amendment application. We agree that submittal of a licensee's operating procedures for NRC review and approval is necessary for certain higher risk medical uses such as those authorized in Subpart H, but is not

necessary for low risk uses, such as in diagnostic nuclear medicine. The lack of a procedure for the high risk modalities could result in situations where the public, workers, or patients could be exposed to unnecessary radiation. Overall, the final rule reduces the amount of documentation, including operating procedures, that an applicant must submit for either a license or amendment.

Issue 5: What Are the Information and Licensing Requirements for ''Emerging Technology''?

*Comment.* Commenters were concerned that significant resources may be expended by companies for clinical research for ''emerging technologies,'' without knowing what the actual regulatory requirements will be. Commenters asked that provisions be made for protection of confidential and proprietary information which licensees are required to submit in accordance with § 35.12(d)(1). Commenters also asked whether NRC would be open to a petition for rulemaking proposing an appropriate way to license an ''emerging technology,'' such as brachytherapy.

*Response.* The NRC clarified the regulatory text in § 35.12(d) to make it clear that the information in paragraph (d)(1) must be submitted in addition to the information required by other paragraphs in this section. Paragraph (d) was added because the current rule does not provide for the efficient licensing of ''emerging technologies'' (*i.e.,* those medical uses that are not specifically included in Subparts D through H). Paragraph (d)(1) provides a generic list of all the information needed by NRC to approve a medical use that is not specifically addressed in those Subparts. The specified information is needed because we must verify that the byproduct material will be handled safely. At this time, and because of the evolving nature of ''emerging technologies,'' it is not possible to be more specific about the necessary information. Applicants for ''emerging technology'' licenses are encouraged to consult with the NRC staff about the required information during the application process. Of course, licensees for these technologies would also be required to comply with all the applicable sections in Part 35 and 10 CFR Chapter I (*e.g.,* Parts 30 and 71).

Provisions are already in place for the protection of trade secrets or privileged or confidential information. Section 2.790(b)(1) contains procedures under which any person who proposes to withhold a document (or a part of it) from public disclosure on the ground that it contains trade secrets or privileged or confidential information may file an application for withholding accompanied by an affidavit.

Any ''interested person'' may file a petition for rulemaking under 10 CFR 2.802. During the NRC review of the petition, the NRC staff will review the interested person's request and determine whether a rulemaking is needed to address the issue. In some cases, there may be existing regulatory requirements that adequately address the petitioner's request; in other areas, the petitioner's request may result in development of a new rule or revision of an existing rule.

Although any ''interested person'' may file a petition for rulemaking in accordance with 10 CFR 2.802, such a petition should not be necessary for licensing ''brachytherapy.'' Licensing medical use involving brachytherapy is covered in the final rule in Subpart F, ''Manual Brachytherapy,'' and Subpart H, ''Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.'' If an applicant believes that the use is not covered in either Subparts F or H, the applicant may request use under § 35.12(d) and Subpart K, ''Other Medical Uses of Byproduct Material or Radiation from Byproduct Material.'' Subpart K provides a means for licensing medical use of an ''emerging technology.''

Issue 6: Does a Broad Scope Licensee Need To Amend Its License for Medical Use of an Emerging Technology?

*Comment.* A commenter stated that broad scope licensees should not be required to amend their licenses simply for medical use of emerging technologies. The commenter asked that this section be clarified or added to the list of exemptions for broad scope licenses in § 35.15.

*Response.* The NRC agrees with the commenter's recommendation. We amended § 35.15 to relieve a broad scope licensee from the requirement to file a request for a license or amendment for medical use of byproduct material, as described in § 35.1000. This regulatory relief only applies if the broad scope licensee is already authorized to possess the type and form of byproduct material used in the emerging technology.

Issue 7. Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

*Response.* Yes. Section 35.12(a) was amended to delete the phrase ''of the facility.'' The proposed rule required that the application be signed by the management of the facility. The final rule requires that the application be signed by the applicant's or licensee's management. The addition of the words ''applicant's or licensee's'' is discussed under Issue 1 of this section. The NRC deleted the phrase ''of the facility'' because the word ''management'' clearly ties the requirement to activities performed by the licensee. (Refer to the definition of ''management'' in § 35.2.)

Paragraph (c) was amended to recognize that the application may be either in a letter format or on NRC Form 313, consistent with the current regulations.

Paragraph (d) was amended to delete the requirement to submit information on the training and experience of proposed users of an emerging technology. This requirement was redundant of the requirement in paragraph (b) for applicants to submit the training and experience qualifications of AUs.

*Section 35.13, License Amendments*

Issue 1: Why Would a License Amendment Be Necessary for a Type of Use Not Authorized in the License?

*Comment.* A commenter was concerned that this section implies the NRC will be regulating medical procedures through the licensing process, *i.e.,* NRC will use license conditions to prevent the clinical use of certain isotopes. According to the commenters, physicians should not have to wait for the NRC to grant an amendment in order to practice medicine.

*Response.* The NRC has not made any changes in the regulatory text as a result of these comments. Requiring a licensee to obtain a license amendment for a type of use permitted under Part 35, but not authorized on the licensee's current license, is not intended to prevent the medical use of certain radionuclides. A licensee must apply for and receive an amendment for such a type of use because it may change the licensee's byproduct material program and might increase the potential for radiation exposure to workers and the general public. For example, a licensee would need to amend its license if it is only authorized to use byproduct material for imaging and localization studies and it would like to use a remote afterloader. These types of changes in the byproduct material program are potentially significant and require a license amendment because:

(1) The NRC must be assured that the licensee has adequate training and experience and facilities before authorizing a change in the type of

medical use or the amount of byproduct material used; and

(2) Such a change might also indicate a need for increased inspection frequency.

Issue 2: Should There Be a Provision for a Temporary RSO?

*Comment.* A commenter asked if we planned to add language to this section to codify the discussion in the Statements of Consideration for the proposed rule on § 35.13(c) (53 FR 43516; August 13, 1998) regarding using an AU to fill the RSO position, if the RSO leaves with little or no warning. This commenter recommended that we add the following phrase to § 35.13(c): ''changes permanent Radiation Safety Officer.'' Commenters recommended that we allow an ANP or AMP to function as the RSO because either of these individuals would meet the qualifications of an RSO in § 35.50.

*Response.* The NRC addressed these comments by adding a provision for a ''temporary RSO'' in § 35.24(c). As stated in § 35.24(c), and discussed in greater detail under the Statements of Consideration for § 35.24, an AU or an individual qualified to be an RSO may function as the temporary RSO. The broader issue of who can be an RSO is discussed in greater detail in the response to comments on § 35.50. A licensee would not need to amend its license for a temporary RSO.

Issue 3: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

*Response.* Yes. Paragraph (a) was amended to clarify that a licensee must apply for a license amendment before it ''prepares'' byproduct material for a type of use that is not authorized on the licensee's current license.

The NRC amended paragraph (b) to include ANPs identified on a permit issued by a Commission master material licensee that is authorized to permit the use of byproduct material in medical use or in the practice of nuclear pharmacy, or identified by a commercial nuclear pharmacy that has been given authorization to identify authorized nuclear pharmacists. This change has been made so that this section is consistent with the revised definition of ANPs in the final rule.

We also made minor editorial changes to the regulatory text in paragraph (b) to make the rule easier to read. For example, we started each requirement by stating to whom the requirement applies, *e.g.,* we replaced the phrase ''An authorized user who meets the requirements in * * * '' with ''For an authorized user, an individual who meets the requirements in * * * ''

In addition, paragraph (b) was amended to add references to §§ 35.190(a), 35.392(a), and 35.394(a); and to delete § 35.292(a). These actions are considered conforming changes needed for other changes made to the regulatory text between the proposed and final rule. In addition, paragraphs (b)(4) and (5) were combined to make the rule easier to use.

We also amended paragraph (d) requiring the licensee to apply for and receive a license amendment before it receives byproduct material in excess of the amount, in a different form, or a different radionuclide than is authorized in the license. This change makes the regulatory text clearer.

A new paragraph (g) was added that requires a licensee to apply for a license amendment if it revises the procedures that must be submitted in accordance with § 35.12(b)(2), where such revision reduces radiation safety. This applies to procedures required by §§ 35.610, 35.642, 35.643, and 35.645, as applicable.

*Section 35.14, Notifications*

Issue 1: Is the Purpose of Notification To Initiate a License Amendment?

*Comment.* A commenter recommended the title of this section be changed to ''Thirty-day Notifications for Amendments.'' In addition, the commenter stated that an introductory sentence should be added to the section indicating that the notifications should be made to initiate license amendments. Without this sentence, it is not clear that the purpose of the notification is to initiate an amendment.

*Response.* The NRC has not changed the regulatory text. The purpose of § 35.14 is to identify when a licensee must notify NRC of changes in its program for which it does not need to apply for a license amendment. For example, if an AU, AMP, or ANP is certified by a specialty board recognized by NRC, the licensee may allow that individual to begin work immediately (without first seeking and obtaining a license amendment). All the licensee must do is notify the NRC, within 30 days, that the individual has begun working.

Issue 2: Is There a Conflict Between the Requirements in §§ 35.13(b)(1) and 35.14(b)(1)?

*Comment.* A commenter indicated that this section was confusing because it was not clear whether the board certifications mentioned in § 35.14(a)(1) meant only those boards ''adopted by regulation'' or those certifying organizations listed in Appendix A. The commenter also believed the section conflicted with § 35.13(b)(1), which permits persons to act as an AU if they meet the training and experience requirements in §§ 35.290(a), 35.292(a), 35.390(a), 35.490(a), 35.590(a), or 35.690(a) and § 35.59 and §§ 35.910, 35.920, 35.930, 35.932, 35.934, 35.940, 35.941, 35.950, 35.960 and § 35.49.

*Response.* Section 35.13 provides information on when a licensee must apply for a license amendment. Section 35.14 provides information on when a licensee must notify NRC of a change in its program. In order to provide some regulatory relief to licensees and to allow individuals to begin work immediately, the NRC structured these provisions as two parts that address two different groups of people—those who are certified by a board recognized by NRC and those who are not certified by a board recognized by NRC. In the case of an AU, a licensee would not need to amend its license before allowing an individual to begin work if the individual is certified by a board whose certification process has been recognized by NRC. However, the licensee would need to notify us within 30 days of having allowed that individual to work as an AU. Conversely, a licensee would need to amend its license if the individual is NOT certified by a board that has been recognized by NRC.

We have deleted any references to boards by name in the final rule. In addition, Appendix A to the proposed rule was not included in the final rule. More detailed information on these changes can be found under the discussion of ''General training and experience,'' in Part II, General Issues, at the beginning of this section.

Issue 3: Is It Necessary To Name an AMP on a License?

*Comment.* A commenter recommended that NRC need only allow individuals who meet the training and experience requirements for an AMP to function as an AMP.

*Response.* The NRC believes that the requirements for naming an AMP and AU in the license should be the same. In order to be considered an AMP, the individual must meet the training and experience qualifications in § 35.51. If the individual is certified by a board whose certification process has been recognized by NRC, the licensee may allow that individual to begin work immediately and notify us within 30 days that the individual has begun work. If the individual is not certified by a board whose certification process

has been recognized by NRC, the licensee must apply for and obtain an amendment of its license before it allows that individual to begin work as an AMP.

Issue 4: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

*Response.* Yes. The NRC revised paragraph (a) to include AUs, AMPs, and ANPs that are identified on a permit issued by a Commission master material licensee or a permit issued by a Commission master material license broad scope permittee. This change has been made so that this section is consistent with the revised definition of AUs, AMPs, and ANPs in the final rule. Paragraph (b)(4) was amended to state that the licensee must notify NRC when it adds to or otherwise changes the areas where byproduct material is used in accordance with §§ 35.100 and 35.200. This change has been made to clarify the regulatory text.

*Section 35.15, Exemptions Regarding Type A Specific Licenses of Broad Scope*

Issue 1: Were There Any Changes Made in This Section Between the Proposed and Final Rule?

*Response.* Yes. A new paragraph (f) was added that exempts broad scope licensees from the requirement to notify NRC when there are additions to or changes in the areas of use identified in the application or on the license where byproduct material is used in accordance with §§ 35.100 and 35.200. This exemption is consistent with the current exemption that these licensees have from the requirement to apply for a license amendment when there are additions to or changes in the areas of use only at the addresses specified on the license. The exemption was inadvertently omitted from the proposed rule.

*Section 35.19, Specific Exemptions*

Issue: Shouldn't This Section Provide an Exemption for Diagnostic Nuclear Medicine?

*Comment* Some commenters believed that essentially all diagnostic nuclear medicine procedures should be exempted from regulation because they would not endanger life or property or the common defense or security and are otherwise in the public interest.

*Response.* The NRC did not make any changes in this section. Section 35.19 recognizes that an applicant for a license or licensee filing an amendment request may seek to be exempted from a specific requirement in this part (50 FR 30616; July 26, 1985, see page 30624). However, this provision does not provide the basis for a ''blanket'' exemption of an entire category of medical use such as ''diagnostic nuclear medicine procedures'' from Part 35. Nevertheless, consistent with making Part 35 more risk-informed, we have decreased the regulatory burden on licensees administering or preparing byproduct material for most diagnostic uses by decreasing the requirements imposed on them in Part 35.

*Subpart B—General Administrative Requirements*

*Section 35.20, ALARA Program*

Issue 1: Should the Current Part 35 Requirements Related to ALARA Programs Be Deleted?

*Comment* A commenter supported the deletion of the current Part 35 requirements related to the ALARA program. However, another commenter believed that the requirements in Part 35 related to the ALARA program should be retained. This commenter stated that keeping this regulation in Part 35 is appropriate because Part 20 regulations are not specific enough.

*Response.* The NRC deleted § 35.20, which includes prescriptive requirements related to the ALARA program, in its entirety from the revised Part 35. Medical use licensees will continue to be required to comply with § 20.1101 that includes a requirement to implement an ALARA program designed to keep doses as low as reasonably achievable. We believe that deletion of the prescriptive ALARA requirements that are in the current § 35.20 will provide licensees flexibility in developing and implementing their ALARA programs.

*Section 35.24, Authority and Responsibilities for the Radiation Protection Program*

Issue 1: Can Licensee Management Delegate Its Responsibility To Approve Individuals Before Allowing Them To Work as an AU, ANP, or AMP?

*Comment* Several commenters said that mandating that licensee management approve individuals before allowing them to work as AUs, ANPs, or AMPs is excessive. Normally, management does not approve other individuals to work in non-NRC licensed areas. The approval to work generally comes from the department chief or the hospital credentialing committee. Therefore, the commenters suggested inserting ''or management designee'' after ''management'' in paragraph (a)(2) of this section to allow management to delegate the responsibility for approving individuals to either a responsible individual in the department or the hospital credentialing committee.

*Response.* In the current Part 35, the RSC has the responsibility to approve AUs, ANPs, and teletherapy physicists before allowing them to work. In the new § 35.24(a)(2), licensee management is given this responsibility for several reasons. First, licensee management has the ultimate responsibility for the radiation protection program in the revised rule. Second, not all licensees are required to have an RSC. Therefore, giving licensee management the responsibility for approval of individuals makes the requirement uniform for all medical licensees, i.e., the authority for approving individuals is not dependent on whether or not a licensee has an RSC.

As defined in § 35.2, management means the chief executive officer or other individual having the authority to manage, direct, or administer the licensee's activities, or those persons' delegate or delegates. Thus, licensee management could delegate the task of approving individuals before allowing them to work.

Issue 2: Is There a Need for a Requirement for the RSO To Acknowledge Responsibility for Implementing the Radiation Protection Program in Writing?

*Comment* The NRC received comments in response to the Commission's question as to whether a requirement for the RSO to acknowledge in writing responsibility for implementing the radiation protection program would impact the licensee's effectiveness in carrying out its radiation protection program. These comments both agreed and disagreed with the requirement in paragraph (b) of this section that an RSO agree in writing to be responsible for implementing the radiation protection program. One commenter supported this requirement, especially in cases where the RSO position is assigned to a junior medical staff member who has significantly more pressing obligations. Another commenter supported the requirement because it enhances the visibility of the RSO position. Several commenters noted that National Council on Radiation Protection and Measurements (NCRP) Report No. 127, Operational Radiation Safety Program (1998), Section 3 on Organization and Administration, includes recommendations for the RSO's responsibilities for the radiation safety program.

Other commenters questioned why the RSO should be required to sign off on his or her duties when the AU, AMP, and ANP are not required to do so. One commenter said that a written agreement seems more appropriate between management and the AUs, or between the AUs and NRC. Increasing the responsibilities of the AUs would provide more incentive for them to become familiar with the details of the radiation safety aspects of the licensed activities. Another suggestion was that there be a requirement for the licensee and AUs to commit in writing to follow the radiation protection program, instructions, and procedures, as formalized/approved by the RSO.

Other commenters questioned why there needs to be a paper trail of the RSO's agreement to be responsible for implementing the radiation safety program. They questioned whether there is a concern that management may assign the RSO duties to someone who is unaware of their responsibilities or there is a concern because unqualified, uncommitted RSOs have been named in the past. A commenter believes that if an individual agrees to assume the RSO's duties and his or her name is on the license as the RSO, a written statement from the RSO is redundant and unnecessary. Instead, the Commission should require that the individual appointed to be the RSO sign the license amendment naming him or her as RSO, which would not only provide documentation of their acceptance of the RSO duties, but would also provide the licensing staff with a copy of the RSO's signature for future reference.

Another commenter was concerned that the written agreement seems to be more of a legal, contractual matter than it is a radiation safety matter, and it could be later used by management against the RSO.

*Response.* After reviewing and evaluating the public comments, the NRC retained the requirement in paragraph (b) of this section for the RSO to acknowledge, in writing, responsibility for implementing the radiation protection program. We believe that future confusion over the responsibilities for the radiation protection program can be prevented by having a clear, written agreement between licensee management and the RSO. The final rule explicitly gives the RSO the responsibility for implementing the radiation protection program. Therefore, we believe it is more appropriate for that individual, rather than the AU, ANP, or AMP, to agree to that responsibility in writing.

Issue 3: Why Does the Rule Increase Management Oversight of, and Consequently Limit the RSO's Authority Over, the Radiation Safety Program?

*Comment.* Commenters believe that the proposed rule is very prescriptive about the relationship between the RSO and licensee management. The rule implies that licensee management gives the responsibility for maintaining the radiation safety program to the RSO, but does not allow the RSO the authority needed to manage the program. No other radiation protection program in 10 CFR Chapter I has as much management oversight as the medical use program. The NRC should also stipulate that the RSO report directly to senior management.

*Response.* The requirements in paragraphs (e) and (g) of § 35.24 that are associated with the RSO's authority are also in the current § 35.23. The revised rule retains all of the RSO's current authority, plus provides the RSO with additional authority to stop unsafe operations. The NRC did not address whether there is the same level of management oversight of other NRC licensees' radiation protection programs because that issue is beyond the scope of this rulemaking. We believe that the requirements for both the RSO's authority and for management oversight are more risk-informed and, therefore, appropriate for the risk associated with the medical use of byproduct material.

Issue 4: Should There Be a Provision for a Temporary RSO?

*Comment.* As noted in Issue 2 under § 35.13, License amendments, a commenter asked if we planned to add regulatory text to allow a licensee to use an AU to fill the RSO position when the RSO leaves a facility with little or no advance warning. Commenters also recommended that we allow an ANP to function as the RSO if the individual meets the qualifications for an RSO in § 35.50.

*Response.* The NRC added a new provision in paragraph (c) of § 35.24 that allows a licensee to have a temporary RSO for up to 60 days a year if the licensee meets the requirements for RSOs in paragraphs (b), (e), (g), and (h) of this section and notifies the Commission in accordance with § 35.14(b). The temporary RSO must meet the training and experience requirements in §§ 35.50 and 35.59. This new provision was added so that licensees can appoint someone in a timely manner to fulfill the duties and responsibilities of the RSO following the sudden departure of the permanent RSO named on the license. We also added a new paragraph (d) that allows a licensee to simultaneously appoint more than one temporary RSO, if needed, to ensure that the licensee has an individual that is qualified to be an RSO for each of the different types and uses of byproduct material permitted by the license. Even though we have added a provision for a temporary RSO, a licensee is expected to fill the position of permanent RSO as soon as possible.

Issue 5: Would the Proposed Deletion of the Requirement for a Radiation Safety Committee (RSC) Impact the Licensee's Effectiveness in Carrying Out Its Radiation Protection Program?

*Comment.* The NRC received a substantial number of comments on whether the proposed deletion of the RSC would impact the licensee's effectiveness in carrying out its radiation protection program. The majority of the comments supported retaining the current requirement for an RSC at medical institutions because the RSC is a valuable resource in this case. The decision to eliminate the RSC could be detrimental to the institution's radiation safety program, especially with the proposed reduction in the training and experience hours for some AUs. Commenters noted that, in a medical institution, the RSC provides a valuable forum with expertise from all aspects of the licensee's medical use operations. The RSC performs many functions, such as developing and mandating the implementation of radiation protection policies and procedures, peer reviewing the radiation safety aspects of research protocols, and responding to enforcement or infractions of radiation safety practices. In addition, it provides the RSO support, authority, and access to management. It is incorrect to assume that other hospital committees will encompass the area of radiation safety compliance. An accountable RSC, and documentation of its activities, will assure that decisions are made in the interest of radiation safety and regulatory compliance.

Several commenters noted that NCRP Report No. 127, Operational Radiation Safety Program, clearly supports the RSC, especially in the formulation of policies, review and audit of program effectiveness, and guidance of the RSO.

Other commenters supported retaining the requirement for an RSC, but not specifically tying the requirement to medical institution licensees. One recommendation was to retain the RSC for complex, multiple discipline, multi-department, and multi-use licensees. Another recommendation was for eliminating the requirement for

small operations authorized under §§ 35.100 and 35.500, and possibly under § 35.200, but making the requirement mandatory for activities under §§ 35.300, 35.400, and 35.600 and for larger operations involving imaging. Other recommendations included modifying the definition of medical institution to only include those facilities that perform more than one radioactive material modality; and requiring an RSC for facilities with inpatients. Commenters also said that any requirement for facilities with multiple modalities should be qualified by ''within the same speciality'' because there is no benefit to having physicians who use completely separate modalities communicating regularly.

Some commenters supported deletion of the RSC. According to one commenter, there is no evidence that the absence of an RSC jeopardizes public and occupational health and safety. Another commenter noted that, in some cases, other Federal agencies, such as the FDA, have committee requirements that meet radiation safety objectives. Also, facilities comply with Occupational Health and Safety Administration or Environmental Protection Agency regulations without a requirement for a committee. Therefore, deletion of the RSC would not reduce the effectiveness of the program, but would allow the licensee flexibility in meeting radiation safety objectives and in organizing its operations in the most efficient manner. However, another commenter said that removing the RSC may increase the burden on licensees, especially in conjunction with not requiring procedures to be submitted for review by licensing staff.

Another commenter suggested that rather than eliminating the entire requirement for an RSC, it might be more appropriate to reduce the more prescriptive requirements, such as the meeting, quorum, recordkeeping, and membership requirements.

*Response.* Based on public comments, the NRC retained the current requirement, with modifications, for certain medical licensees to have an RSC to oversee all the uses of byproduct material permitted by the license. In the final rule, only licensees that are authorized for two or more different types of uses of byproduct material under Subparts E, F, and H, or two or more types of therapy units under Subpart H, are required to establish an RSC. Examples of such licensees are those authorized to use therapeutic quantities of unsealed byproduct material (§ 35.300) and manual brachytherapy (§ 35.400), or manual brachytherapy (§ 35.400) and LDR units (§ 35.600), or teletherapy units (§ 35.600) and gamma stereotactic radiosurgery units (§ 35.600). An example where an RSC would not be required would be a licensee authorized for use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required (§ 35.100) and for use of unsealed byproduct material for imaging and localization studies for which a written directive is not required (§ 35.200). However, we believe that, based on public comments, many other medical use licensees will also continue to use an RSC to oversee the use of byproduct material, even if they are no longer required to do so. Licensees should note that the requirement for an RSC is no longer tied to medical institutions, which means that it now also applies to ''free-standing clinics.''

We have deleted most of the prescriptive list of administrative requirements and committee tasks that are specified in the current rule. For example, the final rule does not include specific requirements for the frequency of meetings, the content of the meeting minutes, or the tasks that the RSC must perform to oversee the use of licensed material. However, based on public comment, we have specified the membership of the committee, as discussed in Issue 6.

Issue 6: If an RSC Is Required, Who Should Be Members of the Committee?

*Comment.* The Commission asked whether the regulatory text should explicitly require that the RSO be a member of the RSC, if a requirement for a committee to oversee the radiation safety program was included in the final rule. Several commenters said that the membership of the RSC is best left to the licensee. While most licensees would make their RSO a member, there is no obvious reason to require this action. Some commenters said that the RSO should be allowed to decide the committee membership, and then submit the specialties of the membership to the NRC.

Most commenters agreed that both the RSO and a representative of the licensee's upper management should be explicitly named as members. Commenters also recommended that representatives of the different users and the nursing staff be on the committee, if the facility is licensed for inpatient therapies. While the RSO is responsible for implementing the radiation safety program, a successful committee requires both management backing and resources, and user support.

*Response.* As discussed in Issue 4, the final rule includes a requirement for certain medical licensees to have an RSC. We essentially agree with the commenters' recommendations for the membership of the RSC. We have included a requirement in the final rule that the membership of the RSC must include an AU for each type of use authorized by the license, the RSO, a representative of the nursing service, a representative of management, and other members the licensee considers appropriate.

Issue 7: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

*Response.* Yes. Paragraph (b) was amended to delete the phrase ''in the daily operation of the licensee's radiation protection program.'' This phrase did not add anything to the requirement and was awkwardly worded.

*Section 35.26, Radiation Protection Program Changes*

Issue 1: What Is Meant by Changes in a Licensee's Radiation Protection Program That ''Do Not Reduce Radiation Safety?'

*Comment.* Several commenters said that the provision in the proposed § 35.26(a)(2), that radiation protection program changes can be made if the revisions ''do not reduce radiation safety,'' was ambiguous and subjective and would invite second-guessing by NRC inspectors. There should be objective measures for acceptable changes, such as changes that do not result in a licensee exceeding the limits in Part 20 or only changes that comply with all applicable regulations and license conditions.

*Response.* The NRC intended for this provision to provide licensees with as much flexibility as possible in making changes in their radiation protection program, without seeking Commission approval. However, in response to comments that the proposed wording was not clear when applied to minor (ministerial) changes to the licensee's radiation protection program, we revised the rule to allow licensees to make revisions in their radiation protection program that are ''in compliance with the regulations and the license.''

Issue 2: Why Is There a Requirement To Instruct Individuals on Changes in the Radiation Protection Program?

*Comment.* Commenters said that the requirement to instruct individuals on changes in the radiation protection program should be removed. This

requirement only adds work for licensees, with no resultant increase in safety, and is not consistent with the Commission's philosophy of more risk-informed regulations.

*Response.* This requirement has been retained in the final rule because the NRC believes that it is important to instruct individuals on radiation protection program changes before they are implemented, so that individuals have a clear understanding of those changes in the radiation protection program that may affect them. This instruction may be provided in writing, or orally, and may be conducted on either an informal or formal basis. For example, the instruction could be provided at an informal staff meeting.

*Section 35.27, Supervision*

Issue 1: Why Does This Section Include Requirements for Supervising Individuals?

*Comment.* Commenters had a number of concerns about the requirements for supervising individuals in this section. One concern was that there is no requirement for a licensee to notify the NRC that it operates in the manner permitted by this section, i.e., a licensee does not have to inform NRC when it allows supervised individuals to use byproduct material. Therefore, this section is not consistent with other sections in the regulations that only allow licensees to conduct activities that are permitted by their licenses. This section should be deleted or changed to require licensees to apply for a supervised user program within their license applications. In addition, commenters noted that if NRC is not made aware of this type of activity, it is not conducive to inspection activities.

Another concern was that this section permits individuals, including physicians, to use byproduct material without completing the training and experience requirements for AU status. This also allows a physician who does not meet the training and experience requirements for an AU to perform the duties of the AU without the AU being present. If the training and experience required to become an AU is necessary, the supervising AU should be required to be present (e.g., during the administration and reading of films), and the supervised physician should be required to attain licensure in a specified period of time.

Another commenter also said that this section should be deleted, but said that if the section is retained it should be revised to meet minimal ACGME teaching requirements for physicians. Recommended changes relate to whether: the supervising physician and the supervised physician must be within the same city (and preferably in the same building); the number of physicians supervised at one time should be limited; the duration of a physician working under the supervision of an AU should be limited; the NRC should verify the ability of the supervising individual to teach; the supervised program should have a curriculum, goals, objectives, handouts, and testing; and the NRC should be notified that a supervised physician program is in effect.

Some commenters said that there was no need for this section because its provisions are covered in other sections of Part 35. For example, proposed § 35.11 (b) and (c) state that a specific license is not needed for individuals receiving, possessing, using, transferring, and preparing byproduct material under the supervision of an AU or ANP, respectively. In addition, commenters said that paragraphs (a) and (b) of this section, that contain requirements for supervised individuals to follow the instructions of the supervising AU or ANP, should be deleted. If there is a failure to properly supervise, the licensee, not the supervisor, will ultimately be responsible because paragraph (d) of this section holds the licensee responsible for the acts and omissions of supervised individuals.

In addition, one commenter said that the ANP should be added to paragraph (a) because, in order to prepare material, the material must first be received, possessed, and used.

*Response.* Under part 35, only AUs and ANPs identified on a medical use license are allowed to use or prepare, respectively, byproduct material in the practice of medicine. It is frequently necessary for an AU or an ANP to delegate specific tasks associated with using or preparing byproduct material to other individuals who do not have the same training in the use or preparation of the byproduct material for medical use. This section allows for that delegation, if the individuals are properly supervised and instructed. The supervised individuals must also be required to follow the instructions of the supervisor for medical uses of radioactive material or for preparation of byproduct material for medical uses, the licensee's written radiation protection program procedures and written directive procedures, the license conditions, and the regulations of this chapter. These provisions do not require prior notification of the NRC that a licensee has delegated tasks associated with the medical use of byproduct material, e.g., tasks such as package receipt, administration, and disposal of the radioactive waste. Such a requirement would be an unnecessary burden and negate the flexibility afforded to licensees in conducting their medical use programs.

The AUs and ANPs are best suited to determine what tasks supervised individuals are capable of performing and the degree of supervision that each needs. Consequently, this section does not include prescriptive requirements for training or list delegatable tasks. The NRC believes that the requirements in this section provide the best balance between NRC's responsibility to assure the public health and safety and the licensee's responsibility for the safe use of byproduct material.

We have not added ANP to paragraph (a) of this section because this requirement is tied to § 35.11(b)(1), which only allows individuals to receive, possess, use, or transfer material under the supervision of an AU. Section 35.11(b)(2) permits the preparation of byproduct material for medical use under the supervision of an AU or ANP, unless prohibited by license condition.

Issue 2: Is There a Need for Licensees To Have a Policy for Supervised Individuals To Request Clarification From AUs or ANPs About Procedures or Instructions (proposed § 35.27(c))?

*Comment.* Commenters said that the requirement for licensees to have a policy for supervised individuals to request clarification if they do not understand procedures or instructions should be deleted. This requirement will not stop a misadministration which may be caused by other factors, such as human error or poor management. One commenter said that there were no data demonstrating that the failure to ask clarifying questions had resulted in a misadministration associated with either nuclear medicine or radiation oncology. If misadministration data are being used to justify the requirement, then it should not apply to diagnostic nuclear medicine because there has probably never been an instance where a diagnostic misadministration was the result of someone not understanding procedures or instructions.

*Response.* The NRC deleted the proposed paragraph (c) of this section that required licensees to have a policy for supervised individuals to request clarification if they do not understand procedures or instructions. Licensees should have flexibility in establishing communication programs that are tailored to their facilities. Appendix S, in NUREG–1556, Vol. 9 (draft),

discusses the importance of instructions being clearly communicated to professional team members, with constant attention devoted to detail during the treatment process. The guidance document states that licensees should instruct all workers to seek guidance if they do not understand how to carry out a written directive. Based upon actual case histories, the NRC believes that some types of medical events can be prevented if workers ask questions about what to do or how it should be done, before administering a dose or dosage, rather than continuing the procedure when there is any doubt.

Issue 3: What Is the Purpose and Intent of the Statement in the Proposed § 35.27(d) That Licensees Are Responsible for the Acts and Omissions of Supervised Individuals?

*Comment.* Commenters raised a number of concerns about the statement in paragraph (d) of the proposed rule that licensees that permit supervised activities are responsible for the acts and omissions of supervised individuals. By explicitly stating that the licensee is responsible for the acts and omissions of supervised individuals, the implication is that the licensee is not responsible for the acts and omissions of AUs, ANPs, AMPs, or the RSO. State laws hold the supervising physicians and pharmacists responsible for the actions of all health professionals working under their supervision. Another concern was that licensees would be held responsible for willful actions and omissions of supervised individuals against established policies and/or procedures. One commenter requested a definition of the term ''supervising AU.'' This term appears to imply that the ''AU'' is responsible for supervision, while other statements in Part 35 give the authority for supervision to management. In addition, some commenters suggested that this requirement be deleted because it states the obvious and is unnecessary.

*Response.* This statement of the licensee's responsibility for the acts and omissions of supervised individuals is in the current § 35.25(c). According to the Statements of Consideration for this provision, it was added to make it clear that a ''licensee can not delegate responsibility to supervised individuals. If a supervised individual, through misunderstanding, negligence, or commission, acts contrary to the requirements of the license, the regulations, or an order, the licensee remains responsible'' (51 FR 36932; October 16, 1986). This is still an accurate statement of the Commission's intent in retaining this provision for supervision by an AU or ANP.

As used in this section, a ''supervising AU'' is simply an AU who supervises an individual using byproduct material. Even though an individual may be supervised by an AU, the licensee is ultimately responsible for the acts and omissions of supervised individuals.

Issue 4: Should ''Telesupervision'' Be Allowed for Part 35 Licensees?

*Comment.* One commenter said that the Part 35 rulemaking should address the issue of ''telesupervision.'' With present technology, AUs can stay in their offices and supervise medical procedures at facilities that are miles away. Due to all of the upcoming challenges of emerging technologies, the NRC should address this issue to ensure protection of public health and continued radiation safety.

*Response.* The NRC has not addressed ''telesupervision'' during the revision of Part 35 because the need for the AU or a medical physicist to be present during the medical use of byproduct material is dependent on the risk associated with the particular modality. For example, the use of remote afterloader units requires onsite supervision by individuals who are knowledgeable of the radiological hazards associated with the use of that material.

Issue 5: Were There Any Other Changes Made in This Section Between the Proposed and Final Rules?

*Response.* Yes. The phrase ''in addition to the requirements in § 19.12'' was added to both paragraphs (a)(1) and (b)(1) of this section. This addition to § 35.27 has been made as a reminder to licensees that they must also comply with the requirements for supervision in § 19.12, Instructions to workers.

The phrase ''written directive procedures'' was added to paragraph (a)(2) because it is important that supervised individuals follow the licensee's procedures for written directives.

Paragraph (b)(1) of this section was amended to read ''individual's involvement with byproduct material,'' rather than ''use of byproduct material,'' because the requirement also applies to individuals who prepare byproduct material for medical use under the supervision of an ANP.

*Section 35.40, Written directives*

Issue 1: Why Does Part 35 Need To Include Requirements for Written Directives?

*Comment.* Several commenters agreed that the NRC should require licensees to prepare written directives, especially for those procedures that create the greatest risk to the patient from errors and those procedures that are performed by supervised individuals. However, if the written directive is really meant to be a tool for communication between the AU and other health care staff, the proposed requirements for written directives should be revised to allow licensees more flexibility in defining what information must be included in written directives. For example, an AU should be allowed to determine what information is necessary for a supervised individual to administer the byproduct material. One commenter said that the NRC should only require that a written directive be prepared before a treatment to a patient is delivered and should not define even the essential elements of the directive.

Another group of commenters opposed both the use of the term ''written directive'' and the need for written directives for administrations of unsealed byproduct material in medicine. Written directives, as described in the proposed rule, are ''prescriptions,'' which are the standard of practice in medicine and pharmacy. Prescriptions are already controlled by the State Board of Medicine and Pharmacy and the Attorney General of each state. Licensees should be allowed to create records that are consistent with other requirements for medical practice and pharmacy, rather than duplicating a ''prescription.'' The NRC should cite data demonstrating that the traditional method of prescribing medicine is not adequate. If the requirement for a written directive is retained, ''radiopharmaceutical'' in § 35.40(a) should be qualified by adding ''containing byproduct material'' because no other radiopharmaceuticals fall under NRC's jurisdiction.

*Response.* The NRC believes that the requirements for written directives in this section only include what is essential to provide high confidence that the byproduct material will be administered as directed by the AU. Licensees have the flexibility to include additional information that they feel is necessary for a supervised individual to perform a procedure according to the directions of the AU. Records that include the information specified in § 35.40 and are used to demonstrate compliance with other requirements are acceptable.

During the Quality Management and Misadministrations rulemaking (56 FR 34104; July 25, 1991), several medical societies recommended that NRC use the term ''written directive'' to avoid confusion with the term ''prescription''

in medical and pharmacy practices. We have retained the use of the term ''written directive'' so that there continues to be a clear distinction between NRC's requirements and other requirements for a ''prescription.''

This section neither prevents licensees from keeping or creating other pharmacy or medical records, nor requires licensees to create records that duplicate prescriptions. Written directives are not duplicative of prescriptions. They must include information necessary to ensure that byproduct material is administered as directed by the AU. This may require different or more detailed information than is in a prescription.

Most diagnostic procedures are low risk. Therefore, licensees are not required to prepare written directives for most administrations of unsealed byproduct material. This section only requires written directives for the higher-risk administrations, such as sodium iodide I–131 in quantities greater than 1.11 MBq (30 μCi). We also agree that the NRC's jurisdiction only covers radioactive drugs containing byproduct material, so we have replaced the word ''radiopharmaceutical'' with ''radioactive drug containing byproduct material'' throughout Part 35.

Issue 2: Does a Written Directive Need To Be Prepared If the AU Physician Performs or Is Present During the Administration?

*Comment.* Several commenters questioned the need for a written directive when the AU physician performs or is present during the medical use of the byproduct material. In particular, they questioned the benefit of a physician in such a situation having to prepare a written directive, if the primary purpose of written directives is to prevent misadministrations in carrying out the physician's directions. Commenters also questioned whether physicians were expected to prepare or revise written directives while simultaneously performing administrations.

*Response.* Written directives must be prepared in accordance with § 35.40 whether or not the AU physician performs or is present during the procedure that involves the medical use of byproduct material. The NRC does not expect physicians to either prepare or revise written directives while performing medical procedures. We agree with the commenter that the main reason for requiring written directives is to provide high confidence that the administration is according to the directions of the AU physician, i.e., that there is no misinterpretation of the physician's directions by another physician, pharmacist, or supervised individual.

Licensees are required to retain copies of written directives for 3 years. These copies provide documentation that the actual administrations were according to the written directives prepared before the administrations. Licensees are required to report medical events, in accordance with § 35.3045, based on the differences between the information in the written directives and the actual administrations. Therefore, if written directives, or copies of them, are not available for all administrations for which they are required (e.g., if written directives were not prepared when physicians were present during the administrations) licensees will not be able to demonstrate compliance with either § 35.40 or § 35.3045.

Issue 3: What Are the Requirements for the AU's Signature on Written Directives?

*Comment.* One commenter agreed that the requirement for the AU to sign the written directive should be retained. The AU checks the written directive for ''appropriateness of study'' before signing the document before treatment. This practice is part of the Quality Assurance Program developed by the Joint Review on Accreditation of Hospital Organizations.

Several commenters requested clarification of the requirements and policies associated with signatures on written directives. One commenter said that the requirement for preparing, signing, and dating written directives has been interpreted differently by regulators in the past. The regulations should explicitly state whether a written directive must be signed by an AU, or whether a physician under the supervision of the AU may sign the written directive. Another commenter questioned whether ''electronic signatures'' or ''signatures on file'' would be accepted on written directives.

*Response.* This section allows an individual under the supervision of an AU to prepare a written directive, but requires an AU to sign and date it. The NRC requires the signature of the AU on a written directive so that there is a record that the AU has reviewed and approved the information on the written directive.

Section 35.5 allows records to be maintained electronically. Therefore, AUs may use their own electronic signatures if they are signing an electronic version of a written directive. However, licensees may not use the ''signature on file'' notation on written directives because another individual may add it to a written directive and, therefore, it may or may not mean that the AU has reviewed and approved the written directive.

Issue 4: How Soon Should Oral Directives or Oral Revisions to Written Directives Be Documented in Writing?

*Comment.* One commenter recommended that written documentation of oral directives or oral revisions to written directives should be made the next working day. The current requirement for written documentation within 48 hours is unnecessarily restrictive in some cases (e.g., over a weekend) and too lenient in other cases (e.g., during the week).

*Response.* In situations where a delay in order to revise a written directive or to prepare a written directive would jeopardize the patient's health, the current requirements in § 35.32(a)(1) allow for revisions of written directives to be signed by the AU within 48 hours of the oral revision and for written directives to be prepared within 24 hours of oral directives. In both the proposed and final requirements, NRC has decreased the regulatory burden on licensees by allowing licensees to document both oral directives and oral revisions to written directives within 48 hours. The 48-hour requirement provides more flexibility for AU physicians and also allows them to prepare any written documentation during the workweek, unless they choose to do otherwise.

Written directives are essential to providing high confidence that the byproduct material is administered as directed by the AU. Therefore, we do not believe that the requirement should allow for written documentation of the administration ''the next working day.'' This could potentially result in a delay of over 80 hours before an error in the administration is identified, if the administration is made early Friday and the written directive is not prepared until late Monday.

Issue 5: Do the Requirements for Written Directives Allow for Prescribing Doses or Dosages in a Range?

*Comment.* Several commenters said that the NRC should allow AU physicians to prescribe a range of doses and dosages in a written directive. At the time that written directives are prepared, physicians are not always aware of how much radioactive drug will be taken up or how many seeds will actually be implanted. One commenter suggested that an alternative to a dose range in manual brachytherapy is not to specify a dose. This allows the

physician to make a guess at the number of seeds of a certain strength to implant and when the implant is completed to document the number of seeds actually implanted. If this is acceptable, the dosimetry could be done later.

*Response.* The regulations allow for AU physicians to prescribe a range of dosages, but not doses, in written directives. Section 35.2 states that prescribed dosage means the specified activity or range of activity of unsealed byproduct material. The definition of prescribed dose in § 35.2 is dependent on the modality.

In addition, paragraph (b)(6)(ii) of this section allows the physician to change the written directive after the brachytherapy sources (other than HDR) are implanted, but before completion of the procedure, to more accurately reflect what actually took place (e.g., number of sources used, total source strength, exposure time, etc.).

Issue 6: What Is the Basis for Requiring Written Directives for Administrations of Greater Than 1.11 MBq (30 μCi) of Sodium Iodide I–131?

*Comment.* One commenter questioned why the threshold for preparing a written directive for administrations of sodium iodide I–131 is set at greater than 1.11 MBq (30 μCi) when the patient release criteria in § 35.75 indicates that hundreds of millicuries in a patient do not pose undue harm. Another commenter said that the threshold for I–131 should be increased.

*Response.* The threshold for preparing a written directive for administrations of sodium iodide I–131 was set at 1.11 MBq (30 μCi) because it results in a 0.5 sievert (Sv) (50 rem) dose to the thyroid. The Commission, with the recommendation of the ACMUI, adopted an organ dose of 0.5 Sv (50 rem) as one threshold for identifying medical events (previously ''misadministrations'') during the Quality Management Program and Misadministrations rulemaking (56 FR 34104; July 25, 1991). We cited NCRP Commentary No. 7, Misadministrations of Radioactive Byproduct Material-Scientific Background (July 1991), as stating that this threshold was considered to be well below the onset of acute, clinically detectable adverse effects that may be caused by ionizing radiation. We believe that the current threshold for preparing a written directive for sodium iodide I–131 is appropriate. Therefore, we have retained it in the final rule.

The criteria for licensees to authorize the release of patients in § 35.75 are based on the potential dose to the maximally exposed individual, not on the quantity of byproduct material associated with the administration to the patient. Under § 35.75, a licensee may authorize the release of any individual from its control who has been administered radioactive drugs or implants containing byproduct material, if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).

Issue 7: Should There Be Any Changes to the Proposed List of Information That Is Required To Be Included in Written Directives?

*Comment.* For any administrations of quantities greater that 1.11 MBq (30 μCi) of sodium iodide I–131, the name of the radiopharmaceutical and the route of administration should be provided so that the requirements for written directives for all unsealed byproduct material are consistent.

*Response.* The requirements are not consistent because there is no need to specify either the name of radiopharmaceutical or the route of administration when sodium iodide is used. Sodium iodide is the name of the radioactive drug administered and it concentrates in the thyroid regardless of the route of administration.

*Comment.* For gamma stereotactic radiosurgery, the total treatment volume should be deleted because there is no way of determining it numerically.

*Response.* The NRC agrees with the comment and has deleted the requirement in paragraph (b)(3) of this section to include the total treatment volume in written directives for gamma stereotactic radiosurgery.

*Comment.* For teletherapy, the inclusion of the overall treatment period is not necessary. Extending the treatment time for one or two missed fractions has no impact on the overall effectiveness of the treatment.

*Response.* The NRC agrees that it is not necessary to include the overall treatment period in written directives for teletherapy. The requirement for overall treatment period has been deleted from paragraph (b)(4) of this section.

*Comment.* For HDR brachytherapy, the number of fractions and dose per fraction can be used to calculate the total dose. The requirement for total dose should be deleted so that there is no confusion if two different doses (dose per fraction and total dose) are required on the written directive.

*Response.* The NRC retained the requirement for the written directive for HDR brachytherapy to specify the total dose because the treatment time is very short compared to other types of brachytherapy.

*Comment.* For all other brachytherapy, several commenters suggested revision of the requirements for written directives for brachytherapy. One commenter said there was no need to require the dose to be stated if the number and source strengths were included, while another commenter said the opposite. Another commenter suggested separate requirements for permanent and temporary brachytherapy implants.

*Response.* Following discussion of the comments with the ACMUI, the NRC deleted the requirement in paragraph (b)(6)(i) of this section to provide the number of sources and source strengths before implantation. We do not believe that there needs to be different requirements for permanent and temporary brachytherapy because the rule allows the AU to document certain information after implantation, but before the procedure is completed.

Issue 8: Can the Footnote Be Incorporated Into the Regulatory Text of This Section?

*Comment.* One commenter suggested that the footnote in this section be incorporated into the body of the rule text.

*Response.* The NRC agrees and has incorporated the footnote, in its entirety, into the body of the text. That footnote contains important information about preparing written directives when a patient's health could be jeopardized by any delay in providing medical care. The requirements for written documentation of an oral directive and documentation of a revision to a written directive now appear in paragraphs (a)(1) and (c)(1) of this section, respectively.

Issue 9: Were Any Other Changes Made to This Section Between the Proposed and Final Rules?

*Response.* Yes. Paragraph (a) was amended to delete the requirement for an AU to prepare a written directive. The change recognizes the fact that written directives are often prepared by supervised individuals.

Paragraph (b)(2) was revised to make it clear that the requirements in this paragraph apply to an administration of a *therapeutic* dosage of unsealed byproduct material.

The requirements for written directives for gamma stereotactic radiosurgery in paragraph (b)(3) were amended to delete ''the target coordinates (including gamma angle), collimator size, plug pattern, total dose for the treatment, and the total treatment

volume'' and to add ''the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site.'' These changes were made to ensure that written directives for gamma stereotactic radiosurgery include the essential information.

Paragraph (b)(5) was revised to make it clear that the requirements in this paragraph apply only to high dose-rate brachytherapy.

Paragraph (b)(6) was revised to make it clear that the requirements in this paragraph apply to all other brachytherapy, including low, medium, and pulsed dose-rate remote afterloaders.

Paragraph (b)(6)(i) was amended to delete the requirement for written directives for brachytherapy, before implantation, to include the number of sources and source strengths. The number of sources used is often not known until the procedure is performed.

Paragraph (b)(6)(ii) was revised to include a requirement for written directives for brachytherapy, after implantation but before completion of the procedure, to document the number of sources. The number of sources used is determined during the procedure.

Paragraph (d) was amended to include the words ''a copy of'' the written directive to conform with the text of § 35.2040.

*Section 35.41, Procedures for Administrations Requiring a Written Directive*

Issue 1: Is There a Need for Medical Licensees to Have a Quality Management Program (QMP)?

*Comment.* Most of the commenters favored deletion of the QMP, as it appears in the current Part 35. The commenters felt that the provisions of the QMP were redundant with requirements that are already in place because of State pharmacy laws or with regulations codifying the routine ''standard of care'' in medicine. They also noted that the data collected on misadministrations do not show that QMPs have any impact. In particular, there were no data that showed patient identification is a problem. Therefore, the issue of incorrect patients being administered dosages of byproduct material has been exaggerated. Several commenters noted that regulations cannot prevent misadministrations (medical events) that are due to human error, purposeful misconduct, or failure of a supervised individual to ask questions. In addition, commenters welcomed the paperwork relief provided by deletion of some of the QMP review and reporting requirements.

Several commenters favored retention of the current QMP requirements. One commenter said that the requirement for a QMP reinforces the need for a quality improvement committee (QIC) in his institution. The QIC reviews patient records and plans, investigates, checks, and acts on issues of quality improvement. In addition, the QIC periodically reviews compliance with all aspects of the QMP, prepares a report that summarizes the findings of the review and identifies the corrective actions taken, and then submits it to the RSO. Therefore, the QMP can be important in assisting licensees to maintain good radiation protection programs. Another individual supported retention of the QMP for the following reasons: licensees have already developed QMPs that meet the regulations; the annual reviews of the QMPs evaluate the effectiveness of the therapy programs; QMP program reviews are documented and distributed to management; and they provide a mechanism to identify precursor events.

Several commenters favored a more balanced approach. They would delete some of the prescriptive QMP requirements, such as submittal of the QMP plans to NRC for review, but retain some essential requirements, such as identifying the patient and ensuring that each administration is in accordance with the written directive.

*Response.* The NRC has not retained the current § 35.32, Quality management program, in the final rule. We have decided that only certain essential requirements are necessary to provide high confidence that byproduct material will be administered as directed by the AU. For any administration that requires a written directive to be prepared in accordance with § 35.40, licensees must develop, implement, and maintain written procedures to assure that the patient's or human research subject's identity is verified before each administration and that each administration is in accordance with the written directive. These procedures must address certain items applicable to the licensee's use of byproduct material. Beyond these requirements, the final rule allows licensees the flexibility to develop procedures to meet their needs. In addition, there is no requirement for submission of these procedures to NRC for its approval, as was previously required by the quality management rule.

Issue 2: What Is the Commission's Intent in Requiring Procedures for Administrations Requiring a Written Directive in § 35.41(a)?

*Comment.* One commenter noted that the emphasis in § 35.41 seems to be on development of the procedures, rather than on what the Commission is trying to accomplish with the procedures. Another commenter was in favor of the proposed requirements in paragraph (a) if the intent is to permit licensees to develop their own policies and procedures to prevent patient misadministration, rather than submitting QMP programs requiring prior approval by the NRC.

*Response.* The NRC's intent in requiring procedures to provide high confidence that the administration will be as directed by an AU is to avoid burdening licensees with an absolute requirement that this objective be met. We do not intend to imply that all errors in the administration of byproduct material can be prevented. For additional information refer to the regulatory history of Part 35 (56 FR 34104; July 25, 1991, page 34115). Paragraph (a) provides licensees with some flexibility to develop procedures that are appropriate for their uses of byproduct material. We recognize that there is no ''absolute'' way to achieve the objectives of these procedures, e.g., verifying the patient's or human research subject's identity. However, NRC does require that these procedures be sufficient to provide high confidence that the patient's or human research subject's identity is verified. For example, just asking an individual his name may not provide high confidence that the administration was given to the correct individual. Although the procedures do not have to be submitted for NRC review and approval, licensees may be requested to make them available for review during an inspection or, following a medical event, to demonstrate that they provide the requisite high degree of confidence.

Issue 3: Does § 35.41(b) Include the Appropriate Items That Should Be Addressed in Procedures for Written Directives?

*Comment.* Commenters differed on whether the list of items that must, at a minimum, be addressed in the written procedures was too prescriptive or too vague. Commenters noted that if a licensee has procedures that provide high confidence that the patient's identification is verified and that the administration is in accordance with the written directive, the procedures will have to include the appropriate

information in paragraph (b). Another commenter said that not all of the items to be addressed in paragraph (b) are applicable to all of the uses of byproduct material that require a written directive.

A commenter said that the requirement in paragraph (b) to have procedures for checking the manual and computer-generated dose calculations and verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units is vague and does not state how these should be done. Another commenter recommended adding an ''/or'' after the word ''and'' in paragraph (b)(3) to acknowledge that there could be either manual or computer-generated dose calculations.

*Response.* Paragraph (b) has been retained in the final rule because the Commission believes that these are the minimum items that should be addressed in procedures to provide high confidence that the patient's identification is verified and that the administration is in accordance with the written directive. The commenter correctly noted that not all of the items in paragraph (b) are applicable to all of the uses of byproduct material that require a written directive. Therefore, paragraph (b) of this section was revised to read that the procedures ''must address the following items that are applicable to the licensee's use of byproduct material.'' Paragraph (b)(2) of this section was revised to read ''treatment plan, if applicable.'' Both of these changes were made because all of the items listed in paragraph (b) may not be applicable to the licensee's use of byproduct material. The NRC amended paragraph (b)(3) to state more correctly that ''both manual and/or computer-generated dose calculations'' should be checked. We have not been more specific in order to provide the licensee flexibility in determining how these items should be addressed in the procedures for his or her modality or unit.

Issue 4: Were There Any Other Changes Made in This Section Between the Proposed and Final Rules?

*Response.* Yes. Paragraph (b)(2) of this section was amended to read ''verifying that the administration is in accordance with the treatment plan.'' The phrase ''the specific details'' was deleted because they are not provided in the regulations.

Paragraph (b)(4) of this section was amended to read ''therapeutic medical units'' to correspond to the use of ''units'' in Subpart H.

Paragraph (c) of this section was added to refer licensees to the record keeping requirements in § 35.2041.

*Section 35.49, Suppliers for Sealed Sources or Devices for Medical Use*

Issue 1: Are the Sealed Sources and Devices Covered by This Section Only Supposed to Be for Medical Uses?

*Comment.* As worded, one commenter said that the proposed regulation could be interpreted to mean that the sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a Part 30 and § 32.74 license may be used only for medical use. If the latter interpretation is used, cesium-137 (Cs-137) brachytherapy sources could not be used for shielding evaluations because this is not a medical use.

*Response.* The intent of the regulatory text is for licensees to use only the sealed sources and devices listed in paragraphs (a), (b), and (c) for medical use. Other sealed sources and devices may not be used for medical use. Therefore, the NRC revised the regulatory text to make it clearer that licensees shall use only the sealed sources and devices that are listed in paragraphs (a), (b), and (c) of this section for medical use. This paragraph does not address what sources may be used for non-medical uses. For example, Cs-137 brachytherapy sources may be used for shielding evaluations.

Issue 2: Are iridium-192 Seeds and Ribbons Considered to Be Sealed Sources Under Part 35?

*Comment.* A commenter indicated that iridium-192 seeds and ribbons are not ''sealed'' sources. Are they included in the reference to sealed sources in this section?

*Response.* The NRC considers iridium-192 seeds and ribbons to be sealed sources, as defined in § 35.2.

Issue 3: Under What Circumstances Can Limited-Scope Licensees Participate in Medical Device Trials Conducted Under FDA-Approved Investigational Device Exemptions (IDE)?

*Comment.* One commenter said that § 35.49, under both the current and proposed regulations, has the effect of prohibiting medical facilities with specific licenses from participating in certain manufacturer-sponsored trials of medical devices conducted under FDA-approved IDE. The commenter recommended that § 35.49 be modified to permit the participation of limited-scope licensees in multi-site manufacturer-sponsored medical device trials conducted under FDA-approved IDEs.

*Response.* A specific licensee may have to amend its license before it participates in a trial with a source with an IDE in the following situations: (1) the sealed source/device design or use is changed from that documented in the SSDR; or (2) the sealed source or device was not initially distributed by a § 32.74 supplier. There are other situations where a specific licensee may use a sealed source under an IDE and not have to amend its license. For example, when the sealed source is the same as the description in the SSDR and the sealed source was originally distributed by a § 32.74 supplier, but the FDA requires an IDE because the description of the sealed source or device differs from that originally described to the FDA.

There are additional regulatory requirements for broad scope medical licensees beyond the requirements for specific licensees. Because the broad scope licensees must comply with additional requirements to ensure the safe use of byproduct material, they have more flexibility than specific licensees in the activities that may be conducted under their licenses.

Issue 4: Should This Section Also Address Distribution by § 32.72 Licensees?

*Comment.* One commenter questioned whether § 35.49(a) should include § 32.72 licensees as distributors of the sources.

*Response.* Section 32.72 applies to unsealed byproduct material distributors. Therefore, these licensees should not be included in § 35.49(a), which applies to sealed sources.

Issue 5: What Are the Regulations for the Use and Distribution of Sealed Sources and Devices From International Manufacturers?

*Comment.* A commenter questioned whether the rules prohibit the use of sources and devices from international manufacturers that may not have an NRC or Agreement State license to manufacture, package, and distribute these sources and devices.

*Response.* In order for an international manufacturer of sealed sources to distribute these sources in the United States, the manufacturer must have both a distribution license and a manufacturing license. The manufacturing license does not have to be from the US. The distribution license must be from NRC or an Agreement State and the sources to be distributed must go through the SSDR process.

Issue 6: What Other Comments Were Made on This Section in the Proposed Rule?

*Comment.* One commenter said that ''assembled'' needed to be added to § 35.49(a).

*Response.* As used in § 35.49(a), the word ''manufactured'' includes ''assembly'' of the sealed sources or devices.

Issue 7: Were There any Other Changes Made in This Section Between the Proposed and Final Rule?

The NRC added a new paragraph (b) to allow for medical use of sealed sources and devices that have been noncommercially transferred from a Part 35 licensee. ''Noncommercially transferred,'' as used in this part, means that the sources and devices are not being transferred for profit in the open market. Subsequent distribution of the sealed source or device is not subject to the requirements of this paragraph, if the source or device is distributed to licensees that have a license to possess the source or device. However, the source and device cannot be altered from the description and intended use documented in the SSDR. Currently, licensees must obtain an amendment exempting them from the requirements in this section following the initial distribution of the sealed source or device.

*Section 35.50, Training for Radiation Safety Officer*

Issue 1: Due to the Large Variation in Authorized Uses of Byproduct Material Under Medical Licenses, What Are Appropriate Training and Experience Requirements for RSOs Listed on Such Licenses?

*Comment.* Commenters expressed concern that, due to the large variation in the authorized uses of byproduct material under medical licenses, it is difficult to have one set of requirements for RSOs. Other commenters believe that the qualifications of the RSO should be specified in competencies that are commensurate with the scope and complexity of the radiation safety program that the RSO must implement. For example, the required experience in paragraph (b) should be tied to the specific medical uses that are authorized on the license. It is neither necessary nor practical to require a certified health physicist to be the RSO at a small clinical program that only involves low risk modalities, such as routine nuclear medicine procedures. Alternatively, it is inappropriate for an AU to function as the RSO at a large complex program or one which may involve a broad scope license. A related comment was that certification by the ABHP does not mean that an individual is qualified to be an RSO for a medical licensee because he or she may have no experience in a medical environment.

One commenter said that the issue of acceptable qualifications for an RSO should be dealt with both through the regulations and the licensing process. A license reviewer should be able to place additional qualifications on an RSO for a more complex byproduct material program.

Another concern was the perceived inconsistencies in the requirements. For example, board certification in paragraph (a) requires many more hours of training and experience than is listed in paragraph (b). In addition, AUs, AMPs, and ANPs are not required to obtain written certification that they have achieved a level of radiation safety knowledge sufficient to independently function as an RSO.

*Response.* The NRC agrees that it is very difficult to have a single set of training and experience requirements for RSOs named on medical licenses because of the wide variation in medical uses of byproduct material. Therefore, we made several changes to the current requirements for RSOs to ensure that the RSO has adequate training for the types of uses for which he or she has RSO responsibilities. The final rule requires that an RSO must have one year of full-time radiation safety experience involving similar types of uses of byproduct material and a signed preceptor statement that the individual can function as an RSO for a medical use licensee. If an AU, AMP, or ANP is named RSO, he or she must have the required experience with *similar types of uses* of byproduct material for which the individual has RSO responsibilities.

The NRC reviews the training and experience of the RSO as part of the licensing process to determine if the individual has the qualifications to be named as RSO for the medical uses authorized on that license. A major focus during the rulemaking has been to incorporate all of the requirements for medical licensees in Part 35 so that there is no need for additional requirements (via license conditions) to be placed on licensees during the licensing review.

Issue 2: What Will Be the Status of an RSO Who Satisfies the Current Training and Experience Requirements, But Not the New Training and Experience Requirements, When the Rule Becomes Effective?

*Comment.* One commenter said that the regulations need to accommodate older, valuable professionals with years of experience as health physicists and medical health physicists. The preceptor of such an individual may no longer be available (retired or deceased) to provide the written certification. In addition, it serves no purpose for these individuals to satisfy 200 hours of didactic training when they might well be the instructors for such programs.

*Response.* An individual who is currently listed on a license as an RSO will be ''grandfathered'' under § 35.57 when the rulemaking becomes final and will not have to satisfy the requirements in § 35.50. The individual will be able to continue as an RSO, including being named as an RSO on a new license application at a future date.

Issue 3: Can a Technologist Be the RSO for a Medical Licensee?

*Comment.* The NRC received comments that both supported and opposed technologists being RSOs for medical licensees. Some commenters think that nuclear medicine technologists are often the individuals who are most familiar with radiation safety requirements and are in the best position to carry them out. Other commenters think that technologists are more involved in clinical procedures. Therefore, technologists are not as totally oriented to radiation safety as either medical physicists or health physicists. One commenter said that certified or registered technologists would many times be better choices for RSOs than AUs. Another commenter said that one year of full-time experience as a radiation safety technologist does not provide enough opportunity to address all the issues that confront an RSO.

*Response.* The current Part 35 allows a technologist to be an RSO if the requirements in § 35.900, Radiation safety officer, are met. The NRC continues to believe that a technologist can be an RSO if he or she successfully completes all of the training and experience requirements in the new § 35.50, Training for Radiation Safety Officer.

Issue 4: Is the Requirement in § 35.50(b) for an RSO To Have 1 Year of Full-Time Supervised Radiation Safety Experience Involving Similar Types(s) of Use(s) of Byproduct Material Adequate?

*Comment.* One commenter said that 1 year of full-time experience is not adequate for an RSO to cover both nuclear medicine and therapy or to cover all aspects of a broad scope licensee's radiation safety program.

*Response.* The NRC has retained the requirement for 1 year of full-time

supervised experience because that requirement is in the current § 35.900(b)(2) for radiation safety technologists, and we have no evidence that the 1 year requirement has resulted in inadequate experience using byproduct material. This requirement is important because it must involve similar type(s) of use(s) of byproduct material for which the individual will have RSO responsibilities. In addition to the 1 year of full-time experience, the individual must also satisfy the other training and experience requirements in § 35.50 in order to be named as an RSO on a license.

Issue 5: Why Is There a Requirement for an RSO To Obtain a Preceptor Statement?

*Comment.* Several commenters questioned the need for a preceptor statement for RSOs and noted the difficulty of obtaining these statements. One commenter said that preceptors are not common in the health physics profession. RSOs often obtain their training and experience at multiple institutions. Therefore, no single individual would be able to attest to satisfactory completion of all of the training and experience requirements. Several commenters said that the requirement for a preceptor statement should allow for submission of documents such as resumes or college transcripts that are comparable to a preceptor statement. Another suggestion was that licensee management be able to sign the preceptor statement.

*Response.* The NRC has retained the requirement for an RSO to obtain written certification that he or she has completed the training and experience requirements in paragraph (b)(1) of § 35.50. We consider such a statement to be an important component of the overall training requirements. The requirement for a preceptor statement for an ANP is in the current Part 35. We are not aware of any difficulties an ANP may have experienced in getting the required written certification. We recognize that professionals very often get their training and experience at multiple locations and there may not be one individual who can attest to completion of all of the training and experience requirements. In that case, the preceptor would be expected to look at the transcripts or possibly check some references for the individual for whom they are preceptoring in order to certify that the individual has satisfied the requirements in paragraph (b)(1) of this section. We have required that the preceptors be RSOs because they are most qualified to judge whether the individual has achieved a level of radiation safety knowledge sufficient to independently function as an RSO for medical uses of byproduct material. Licensee management may not have the same knowledge. Therefore, the licensee may not be in the best position to judge another individual's level of radiation safety knowledge and experience. We discuss the training and experience requirements in the final rule, including the preceptor, in Section III, Part I, of the **SUPPLEMENTARY INFORMATION** of this document.

Issue 6: Should AUs, AMPs, and ANPs Be RSOs?

*Comment.* The NRC received a number of comments that did not agree with the provision in paragraph (c) of this section that allows AUs, AMPs, or ANPs to be RSOs. Commenters felt that there was an inconsistency between the requirements for an RSO to complete 200 hours of didactic training, and allowing AUs, with as little as 40 hours of didactic training and 20 hours of supervised training, to be RSOs.

There were no comments that recommended that the hours required for RSOs be reduced. Rather, commenters recommended that if AUs, AMPs, and ANPs are allowed to be RSOs, they should be required to satisfy the same requirements as RSOs, including 200 hours of didactic training and supervised experience in the activities listed in paragraph (b)(1)(ii). Another suggestion was to revise the training requirements for AUs to focus on requirements associated with being an RSO. One commenter said that paragraph (c) should be deleted because training and experience requirements for RSOs should be independent of AU, AMP, and ANP status.

Another concern was that physicians typically have AU status for one type, or similar types, of medical use and may not be qualified to be the RSO for other types of medical uses. For example, a physician with AU status in nuclear medicine may be qualified to be an RSO for a licensee that only provides nuclear medicine services, but he or she should not be named as RSO for a brachytherapy device licensee or a broad scope licensee.

Several commenters said that only AUs for § 35.100 and § 35.200 uses should be allowed to be RSOs, while another commenter suggested that an AU for § 35.600 uses could be an RSO for all other uses. One commenter said that, in small practices, an AU should be allowed to serve as the RSO for the modality in which they have AU status, while in broad scope institutions a ''dedicated'' RSO is necessary. One commenter said that the regulations should allow licensees to have more than one RSO, or the regulations should emphasize that an RSO must have training and experience in all of the types of uses for which he or she has RSO responsibilities.

*Response.* Following a review and evaluation of the public comments, the NRC retained the provision in paragraph (c) that allows AUs, AMPs, and ANPs to be RSOs. The current rule allows AUs that are identified on the licensee's license to be RSOs. Retention of this provision is important for a licensee that is a sole practitioner and must be both the AU and RSO. Not allowing such a licensee to be an RSO would result in unnecessary regulatory burden on that licensee.

The final rule also allows for AMPs and ANPs to be RSOs. This provides medical licensees even more flexibility in whom they name as their RSO. We believe that AMPs are well aware of the radiation safety issues associated with therapeutic units. In addition, we believe that the 700 hours of training and experience required for ANPs provides them with extensive knowledge of the radiation safety issues associated with the medical use of unsealed byproduct material.

Note that AUs, AMPs, and ANPs may be named as RSO only if they have experience with the radiation safety aspects of similar type(s) of use(s) of byproduct material for which the individual will have RSO responsibilities. For example, an AU of unsealed byproduct material cannot be named an RSO for therapeutic medical units, or vice versa, unless he or she has additional training and experience with these types of units.

Part 35 does not allow licensees to have more than one permanent RSO. The RSO named on the license must have training and experience with the radiation safety aspects of all types of uses of byproduct material for which the individual will have RSO responsibilities. However, § 35.24(c) in the final rule does allow licensees to name multiple temporary RSOs, if necessary. For additional information, refer to the discussion of the provision for temporary RSOs in § 35.24.

Issue 7: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

*Response.* Yes. The NRC added a phrase, ''or permit issued by a Commission master material licensee,'' in paragraph (b)(1)(ii). This phrase was added to conform with the change in the definition of Radiation safety officer, in which the phrase ''a medical use permit issued by a Commission master material

licensee was added as one way to identify a Radiation Safety Officer.

The NRC added a new paragraph (b)(1)(ii)(F) that states that the RSO's experience should include the use of emergency procedures to control byproduct material. The list of RSO duties in the current Part 35 includes ''taking emergency action if control of byproduct material is lost,'' but this area was omitted in the proposed rule.

We also reworded paragraph (b)(2) of this section to state more clearly that the preceptor must certify in writing that the individual has both completed the structured educational program in paragraph (b)(1) and achieved a level of radiation safety knowledge sufficient to function independently as an RSO for a medical use licensee.

*Section 35.51, Training for an Authorized Medical Physicist*

Issue 1: What Is the Distinction Between a Physicist, Health Physicist, and a Medical Physicist in Part 35?

*Comment.* One commenter was concerned about the lack of differentiation between a physicist, a health physicist, and a medical physicist in the proposed rule. Health physics is radiation detection and radiation safety. Medical physics involves radiation detection and health physics, but with additional emphasis on treatment planning, therapy, and dosimetry. Under the new regulations, it appears that a solid state physicist with a masters degree, who had never had a course in medical physics or dosimetry, could work for 2 years on the radiation safety aspects of the tasks listed in § 35.51(b)(1), learn to calibrate an HDR, take a test on radiation safety, and be an AMP.

*Response.* The term ''authorized medical physicist,'' as used in Part 35, is defined in § 35.2. The NRC uses the term AMP in the new Part 35, rather than ''teletherapy physicist'' as in the current Part 35, because the regulations now include requirements for photon-emitting remote afterloader units and gamma stereotactic radiosurgery units in addition to teletherapy units. The terms ''physicist'' and ''health physicist'' are not defined in § 35.2 because they are not used in Part 35. Physicists and health physicists that meet the requirements for an AMP or RSO would be recognized on the license as an AMP or RSO, respectively.

The requirements for an AMP in this section are similar to the requirements for a teletherapy physicist in the current § 35.961, Training for teletherapy physicist. As in the current Part 35, a physicist who wants to be an AMP would have to have a master's or doctor's degree in physics, biophysics, radiological physics, or health physics; and complete 1 year of full-time training in therapeutic radiological physics and an additional year of full-time work experience under the supervision of a medical physicist at a medical institution performing the tasks in the sections listed in § 35.51(b)(1). The only new requirement is for an AMP to obtain a preceptor statement that he or she has obtained a level of competency sufficient to function independently as an AMP. We have deleted the proposed requirement for an AMP to demonstrate sufficient knowledge in radiation safety by passing an examination. We discuss the training and experience requirements in the final rule, including the deletion of the examination, in Section III, Part I, of this document.

Issue 2: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

*Response.* Yes. In the lead-in sentence, a phrase ''Except as provided in § 35.57'' was added. This phrase was inadvertently left out in the proposed rule.

The phrase ''or an equivalent training program approved by the NRC'' was deleted from paragraph (b)(1) of this section because the NRC is not going to approve training programs under the revised training and experience requirements. For a more detailed discussion of the new training and experience requirements refer to Section III, Part I, of this document.

Paragraph (b)(1) was amended to include a reference to the new § 35.433, Decay of strontium-90 sources for ophthalmic use. Section § 35.433 requires that only an AMP shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments.

In addition, we reworded paragraph (b)(2) to state more clearly that the preceptor must certify in writing that the individual both has completed the requirements in paragraph (b)(1) and has achieved a level of competency sufficient to function independently as an AMP. We also reworded paragraph (b)(2) to clarify that the preceptor has to be an AMP who meets the requirements in § 35.51 or equivalent Agreement State requirements for an AMP for each type of therapeutic medical device for which the individual is requesting AMP status. For example, an individual who is an AMP for only remote afterloaders can not be a preceptor for an individual who wants to be an AMP for gamma stereotactic radiosurgery units.

*Section 35.55, Training for an Authorized Nuclear Pharmacist.*

Issue 1: Should the Current Requirement for ANPs To Complete 700 Hours in a Structured Educational Program Be Retained?

*Comment.* Most commenters supported the proposal to maintain the current 700 hours of training and experience for ANPs because they believe that this training is necessary to assure the quality of nuclear pharmacy practitioners. One commenter recommended that the 700 hours of training and experience should specifically include 200 hours of didactic training.

*Response.* Throughout this rulemaking, the NRC reviewed and discussed the training and experience requirements in Part 35 at facilitated public meetings held both during the development of the proposed rule and during the public comment period on the proposed rule. Based on these discussions and on a review of the written comments received on the proposed rule, we made no changes to the current requirements for an ANP to complete 700 hours in a structured educational program. The current requirements are considered appropriate for the duties and responsibilities of an ANP, as defined in § 35.2.

Issue 2: Were There Any Changes Made in This Section Between the Proposed and Final Rule?

*Response.* Yes. In the lead-in sentence, a phrase ''Except as provided in § 35.57'' was added. This phrase was inadvertently left out in the proposed rule.

The NRC reworded paragraph (b)(2) of this section to state more clearly that the preceptor must certify, in writing, that the individual both has completed the structured educational program in paragraph (b)(1) and has achieved a level of competency sufficient to function independently as an ANP. We also reworded this section to state more correctly that the preceptor is certifying that the individual has achieved a level of competency sufficient to function independently as an ANP, rather than to independently operate a nuclear pharmacy. The amended text is consistent with the text used in the other training and experience sections.

*Section 35.57, Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized User, and Nuclear Pharmacist.*

Issue 1: Why Doesn't § 35.57 Include a Reference to § 35.55, Training for an Authorized Nuclear Pharmacist?

*Comment.* One commenter noted that § 35.57(a) in the proposed rule referred to experienced RSOs, physicists, and nuclear pharmacists, but only referenced the training requirements for RSOs and physicists.

*Response.* The NRC corrected § 35.57(a) to include the reference to § 35.55, Training for an authorized nuclear pharmacist.

Issue 2: Why Did § 35.57(b) in the Proposed Rule Reference Training Requirements for AUs in Subparts C-H, When There Are No Training Requirements for AUs in Subpart C?

*Comment.* One commenter noted that § 35.57(b) in the proposed rule referenced training requirements for AUs in Subparts C-H, but there are no training requirements for AUs in Subpart C.

*Response.* The NRC corrected § 35.57(b) to delete the reference to Subpart C, which does not include training requirements for AUs.

Issue 3: Were There Any Changes Made in This Section Between the Proposed and Final Rule?

*Response.* Yes. The NRC revised paragraphs (a) and (b) to include AUs and other authorized persons that are identified on a permit issued by a Commission master material licensee, a permit issued by a Commission or Agreement State broad scope licensee, or a permit issued by a Commission master material license broad scope permittee. This change has been made so that this section is consistent with the revised definition of AUs and other authorized persons in the final rule.

*Section 35.59, Recentness of Training*

Issue 1: How Much Related Continuing Education and Experience Does an Individual Need To Have if Their Training and Experience Has Not Been Obtained Within 7 Years Preceding the Date of the Application?

*Comment.* A commenter questioned that if the training and experience have not been obtained within the 7 years preceding the date of application, how much related continuing education and experience would the individual need to have, and would this be a case-by-case evaluation with input from the ACMUI.

*Response.* If the training and experience was not obtained within 7 years preceding the date of the application, the continuing education and experience requirements for an individual would be reviewed on a case-by-case basis, with input from the ACMUI, as necessary.

*Subpart C—General Technical Requirements*

*Section 35.60, Possession, Use, and Calibration of Instruments To Measure the Activity of Unsealed Byproduct Materials*

Issue 1: Can All Requirements for Calibration of Instruments Used To Measure the Activity of Unsealed Byproduct Material Be Combined? Is it Necessary to Have Prescriptive Calibration Requirements for these Instruments?

*Comment.* Commenters proposed that §§ 35.60 and 35.62 be combined into one section because both sections address calibration of instruments used to measure the activity of unsealed byproduct material. They also recommended that the prescriptive calibration requirements be deleted so that licensees have the flexibility to develop a calibration program that meets their needs.

*Response.* The NRC agrees that §§ 35.60 and 35.62 should be combined because both sections address instrument calibration. We also agree that the prescriptive requirements should be deleted from the section. Therefore, the regulatory text was amended to delete prescriptive calibration requirements. The section now requires that licensees calibrate instrumentation in accordance with nationally recognized standards (e.g., voluntary consensus standards, such as ANSI N42.13–1986 (R 1993), ''Calibration and Usage of Dose Calibrator Ionization Chambers for the Assay of Radionuclides.'') or with the manufacturer's instructions. This change makes the requirements for instrument calibration more flexible, more adaptable to new technology, and more performance-based.

Issue 2: Does This Section Apply To Licensees That Use Brachytherapy Sources?

*Comment.* A commenter asked that we revise the section to state that the section does not apply to use of brachytherapy sources.

*Response.* The title of this section has been amended to clarify that it only pertains to instruments used to measure the activity of unsealed byproduct material. The calibration of brachytherapy sources is addressed in § 35.432.

Issue 3: Should Licensees That Only Use Unit Dosages Be Required To Possess, Use, and Calibrate Instruments To Measure the Activity of Unsealed Byproduct Material?

*Comment.* Some commenters agreed that the NRC should not require unit dosages to be assayed. As a result, they did not believe that it was necessary to require licensees that only use unit dosages to possess, use or calibrate instruments to measure the activity of unsealed byproduct material. Other commenters disagreed with the proposed provision that did not require direct measurement of unit dosages prior to administration. They believed that all dosages should be assayed. Therefore, all licensees should be required to comply with this section.

*Response.* The NRC amended the regulatory text to state clearly that this section only applies to direct measurements that are made in accordance with § 35.63, which requires licensees to assay (measurement of radioactivity) nonunit dosages except when volumetric measurements and mathematical calculations are used.

As stated in the Statements of Consideration for the proposed rule (63 FR 43533; August 13, 1998), if a licensee administers only unit dosages from manufacturers (or preparers) and uses decay methods to determine the dosages, the licensee is not required to have a measurement instrument and, thus, is exempt from the calibration requirements of this section. However, if a licensee administers unit dosages but chooses to reassay a unit dosage, the licensee must comply with this section. If an instrument is used to measure dosages, it is extremely important that it is calibrated.

Issue 4: Is It Necessary To Keep a Record of Instrument Calibrations?

*Comment.* Some commenters did not believe that it was necessary to keep a record of the instrument calibrations.

Response. The NRC retained the requirement to maintain calibration records because they are needed to document that the instruments have been calibrated. However, we have simplified the recordkeeping requirements in § 35.2060 of the final rule by requiring that the licensee record the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration. These changes are further discussed in § 35.2060.

*Section 35.61, Calibration of Survey Instruments*

Issue 1: Is This Section Needed in Part 35?

*Comment.* A commenter believed that this section should be deleted from Part 35 because survey instrument calibration is addressed in 10 CFR 20.1501.

*Response.* The NRC has not deleted this section. Section 20.1501 requires that licensees calibrate survey instruments periodically, but it does not provide specific requirements for calibrations of survey instruments. Specific requirements are needed for Part 35 licensees to ensure that their radiation survey instruments are properly calibrated. An accurate survey instrument is important because individuals rely on the instrument output to assess radiation levels in areas in or adjacent to nuclear medicine or radiation therapy departments where patients or the public may have access.

Issue 2: Is It Necessary To Require That Survey Instrument Operability Be Determined With a Check Source?

*Comment.* A commenter stated that the NRC should retain the requirement in the current rule that requires licensees to check survey instrument operability with a dedicated check source. Another commenter indicated that the word ''check'' should be deleted in the section title because the regulatory text did not include a requirement for an instrument ''check.''

*Response.* The requirement to check survey instrument operability with a dedicated check source was not included in the proposed or final rule because the NRC believes that licensees should have flexibility in how they determine that instruments are operating properly. We deleted the word ''check'' from the title because the section does not include a requirement for an instrument ''check.''

Issue 3: How Often Should a Survey Instrument Be Calibrated?

*Comment.* Commenters suggested various frequencies for instrument calibrations. Some commenters suggested that instruments be calibrated every 6 months. Others agreed with the 1-year interval in the proposed rule and still others suggested a 2-year interval.

*Response.* The NRC believes that survey instruments should be calibrated before first use, annually, and following any repair that affects the calibration of the instrument. A 1-year calibration frequency is consistent with nationally recognized standards, such as ANSI (ANSI–N323A–1997).

Issue 4: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

*Response.* Yes. In paragraph (a), the NRC added the phrase ''that affects the calibration.'' This was done to clarify that the licensee does not need to recalibrate an instrument if the repair did not affect the calibration. For example, if the licensee replaced the batteries in the instrument, the licensee would not need to calibrate it. In paragraph (a)(2), we added the word ''decade'' to account for instruments with digital readouts.

Proposed paragraph (b) was deleted from the final rule. We believe the licensee should have flexibility in how it documents information on the status of survey instrument calibrations. Our primary concern is that the instrument is reading accurately. Proposed paragraph (c) stated that a licensee may not use a survey instrument if the difference between the indicated exposure rate and the calculated exposure rate exceeds 20 percent. Therefore, we do not believe the requirement in the proposed paragraph (b) for a licensee to attach a correction chart is needed. A statement regarding when a licensee shall consider a point calibrated is unnecessary. Because of the deletion of proposed paragraph (b), proposed paragraphs (c) and (d) have been redesignated as paragraphs (b) and (c) in the final rule.

*Section 35.62, Possession, Use, Calibration, and Check of Instruments To Measure Dosages of Alpha- or Beta-Emitting Radionuclides*

Issue 1: Can This Section Be Combined With § 35.60?

*Comment.* Commenters proposed that this section be combined with § 35.60.

*Response.* The NRC agreed that §§ 35.60 and 35.62 could be combined because Part 35 requirements for instrument calibrations are the same for all types of instruments. (See the response to similar comments under § 35.60.)

*Section 35.63, Determination of Dosages of Unsealed Byproduct Material for Medical Use*

Issue 1: Can This Section Be Combined With § 35.60?

*Comment.* A commenter proposed that this section be combined with § 35.60.

*Response.* The NRC did not combine § 35.60 with § 35.63 because these sections have different purposes. Section 35.60 contains the requirements for calibrating instruments used to determine the activity of a dosage. Section 35.63 contains the requirements for determining the activity of a dosage.

Issue 2: Should Unit Dosages Be Reassayed Before Administration?

*Comment.* Some commenters supported the lack of a proposed requirement for the licensee to reassay unit dosages. These commenters believed that the administered activity could be based on the activity reported by the nuclear pharmacy. Other commenters did not support the proposed rule. They believed that all dosages should be assayed by the licensee before administration.

*Response.* The NRC believes that a licensee should determine and record the activity of each dosage before medical use. For unit dosages, this determination must be made by direct measurement of radioactivity or by a decay correction based on the activity or activity concentration. The provision for licensees to determine the activity of the unit dosage by direct measurement of radioactivity was added to the final rule. The activity or activity concentration must have been determined by a manufacturer or preparer licensed under § 32.72 or equivalent Agreement State requirement or by an NRC or Agreement State licensee for use in research in accordance with an RDRC-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA. Because the unit dosages have been assayed by the Part 32 licensee or by a licensee for use in research in accordance with an RDRC-approved protocol or an IND protocol accepted by FDA, we do not believe the Part 35 licensee should be required to reassay the dosage. Licensees should note that, if a unit dosage has been changed or manipulated in any way, it is no longer considered to be a unit dosage and will need to be reassayed before it is administered.

Issue 3: Can Volumetric Measurements Be Used To Determine the Activity of a Dosage?

*Comment.* Commenters asked that we clarify whether the phrase ''combination of measurements and calculations'' would allow a licensee to base the administered activity on the radioactivity measurement made by a manufacturer (or a preparer), with volume measurement and calculation by a licensee. Commenters also asked that we clarify whether the term ''direct measurement'' means that the activity of the dosage must be based on a measurement of the radioactivity.

*Response.* The NRC agrees that the terms ''direct measurement'' and

''combination of measurements and calculations'' in the proposed rule text needed to be clarified. In the final rule, we made two changes:

1. We replaced the term ''direct measurement'' by ''direct measurement of radioactivity,'' and
2. We added an alternate method for determining dosage by using the radioactivity measured by a manufacturer or a preparer, with volume measurement and calculation by a licensee.

Issue 4: Should the Administered Dosage Be Allowed To Deviate From the Prescribed Dosage?

*Comment.* Commenters recommended that we delete the requirement in § 35.63(d) that states: ''a licensee shall not use a dosage if the dosage differs from the prescribed dosage by more than 20 percent.'' Many commenters believed that this was an overly prescriptive requirement. They stated that it is the AU's responsibility to determine the proper dosage or dosage range for patients.

*Response.* The NRC believes that the requirement should be maintained in the final rule with some modification to address prescribed dosage ranges. AUs are responsible for prescribing the dosage or dosage range. AUs may prescribe a dosage range greater than 20 percent. This range can be case specific or can be a ''blanket'' range that would cover all administrations of unsealed byproduct material. For example, the AU could establish a policy where all administered dosages may deviate from the prescribed dosage by plus or minus ''xx'' percent.

In cases where the AU has not prescribed a dosage range, we believe that the regulation should allow for some deviation from the prescribed dosage. Without this 20 percent ''default'' range, all administered dosages would need to exactly match the prescribed dosage at the time of administration. We believe that a 20 percent deviation is reasonable in consideration of current technology. We have not allowed a deviation outside of the prescribed range because the AU has the flexibility of establishing the acceptable range under this provision.

Issue 5: Is It Necessary To Perform a Decay Correction for Long-Lived Radionuclides?

*Comment.* Commenters asked that the rule be modified so that licensees are not required to perform a decay correction for long-lived radionuclides.

*Response.* The NRC does not believe that the rule should specify when, based on half life, a decay correction should be performed. We believe the rule addresses this issue by permitting a licensee to administer a dosage if the dosage activity is within 20 percent of the prescribed dosage or is within the prescribed dosage range. This requirement gives the licensee responsibility for determining when it is appropriate to perform a decay correction. In the case of a long-lived radionuclide, the licensee may make a determination that a decay correction is not needed to verify that the dosage is within 20 percent of the prescribed dosage or is within the prescribed range because of the long half life of the byproduct material.

*Section 35.65, Authorization for Calibration, Transmission, and Reference Sources*

Issue 1: Are Medical Licensees Authorized To Receive Calibration Sources From Licensees That Are Licensed Under §§ 32.72 and 32.74?

*Comment.* A commenter asked that this section be revised to allow licensees to receive calibration and reference sources from licensees that are licensed under § 32.72, Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under Part 35, and § 32.74, Manufacture and distribution of sources or devices containing byproduct material for medical use.

*Response.* NRC has added a new paragraph (b) to address the issue of whether medical use licensees can receive calibration, transmission, and reference sources from § 35.72 and/or § 32.74 licensees. Paragraph (a) of the current regulations has been reworded to state more clearly that licensees can receive sealed sources, not exceeding 1.11 GBq (30 mCi) each, manufactured and distributed by a person licensed under § 32.74 of this chapter or equivalent Agreement State regulations. A new paragraph (b) has been added to allow medical use licensees to receive sealed sources, not exceeding 1.11 GBq (30 mCi) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under § 32.74 of this chapter, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions. This permits the sources to be received from any licensee with redistribution authorization, which codifies current practice.

Issue 2: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

*Response.* Yes. The NRC inserted the word ''transmission'' in the section title. This was done to clarify that licensees may receive, possess and use transmission sources that do not exceed the quantity limits in this section.

We corrected an error in paragraphs (a) and (b). Paragraph (a) should have referred to ''1.11 GBq (30 mCi)'' rather than ''1.11 kilobecquerel (kBq) (30 mCi)'' and paragraph (b) (final rule paragraph (c)) should have referred to ''0.56 GBq (15 mCi)'' rather than ''0.56 MBq (15 mCi).'' In addition, paragraph (c) (final rule paragraph (d)) was clarified. Our intent is to allow the licensee to receive, possess, and use byproduct material with a half-life longer than 120 days provided individual amounts do not exceed the smaller of 7.4 MBq (200 μCi) or 1000 times the quantities in Appendix B of 10 CFR Part 30.

*Section 35.67, Requirements for Possession of Sealed Sources and Brachytherapy Sources*

Issue 1: When Are Leak Tests Required?

*Comment.* Some commenters believed that leak tests should only be required if a radioactive source has been abused, misused, or retrieved after being lost. Other commenters questioned whether the rule requires leak testing of small check sources. In addition, some commenters believed that sources should be leak tested annually. Others supported semiannual leak testing. Finally, some commenters believed the rule should not require a licensee to leak test certain sources, such as dry radionuclides embedded in acrylic.

*Response.* Section 35.67(b) contains the leak test requirements for sealed sources. The NRC believes that sealed sources should be leak tested semiannually or in accordance with the interval approved by the Commission or an Agreement State in the SSDR. A semiannual leak testing requirement is consistent with recommendations in ANSI–N542. If licensees are unsure whether a source meets the definition of a sealed source, they should reference the SSDR. This registry may be accessed at *http://www.hsrd.ornl.gov/nrc/ssdr/ssdrindx.htm.*

We have not included a requirement for a source to be leak tested if it has been ''abused, misused, or retrieved after being lost'' because the licensee is responsible for assuring that the dose limits in Part 20 are not exceeded. If the licensee suspects that a source may be leaking or could have been damaged, it

should evaluate whether a survey (leak test) should be performed.

Paragraph (f) lists the sources that do not need to be leak tested. In particular § 35.67(f)(3) states sources containing 3.7 MBq (100 μCi) or less of beta or gamma-emitting material or 0.37 MBq (10 μCi) or less of alpha-emitting material need not be leak tested. If a source contains less than this quantity of material, a leak test is not needed.

We believe leak tests are needed for sources such as dry radionuclides embedded in acrylic because removable contamination could exist due to:

1. Radioactivity contained at the surface of the acrylic;
2. Interaction between any chemicals or solvents that may accidently come into contact with the acrylic;
3. Aging of the acrylic; or
4. Radiation damage to the acrylic.

(Note: if the radioactivity of the acrylic source is less than the quantities in § 35.67(f)(3), leak testing would not be necessary.)

For example, a common dose calibrator source which is embedded in cast epoxy resin matrix, sometimes referred to as an ''E Vial,'' meets the definition of a sealed source and would have to be leak tested in accordance with the requirements in this section. However, E vials containing no more than 3.7 MBq (100 μCi) of a gamma-emitting material are exempt from leak testing under § 35.67(f)(3).

*Issue 2: When Should an Inventory of Sealed Sources and Brachytherapy Sources Be Performed?*

*Comment.* Commenters suggested that inventories of sealed sources should be performed quarterly, others suggested semiannually, as in the proposed rule. Other commenters believed that sealed sources that are exempt from leak testing should not be subject to inventory requirements. Another commenter questioned whether extra brachytherapy seeds should be subject to inventory requirements.

*Response.* Sealed source inventories should be performed semiannually. A review of events where sources have been lost or stolen in the past 10 years indicated that quarterly inventories would not have had a significant impact on preventing the incidents. The change from a quarterly frequency to a semiannual frequency would reduce unnecessary regulatory burden and radiation exposure for individuals performing the inventories.

The NRC believes sealed sources that are not required to be leak tested should be inventoried because handling sources listed in paragraph (f) would not necessarily be considered low risk. For the same reason, extra brachytherapy sources should be inventoried. If one of these sources were lost and were picked up by an individual, the radiation dose received by the individual may exceed the Part 20 limits.

Issue 3: What Is the Appropriate Time Period for Reporting a Leaking Source?

*Comment.* A commenter suggested that the time period for reporting a leaking source should be changed from ''within 5 days'' to ''within 15 days.''

*Response.* The NRC has not changed the time period for reporting a leaking source. We continue to believe that it is important to inform NRC promptly when a licensee discovers that a source is leaking.

Issue 4: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

*Response.* Yes. The NRC amended paragraph (a) to delete the requirement to maintain a copy of the radiation safety and handling instructions supplied by the manufacturer for the duration of source use because it was overly prescriptive. We believe that this change makes the regulation more performance-based. However, deletion of the requirement does not prohibit the licensee from maintaining the instructions.

Paragraphs (d) through (f) were amended by replacing the term ''leakage test'' with the phrase ''leak test.'' This change reflects common use of the term ''leak test.''

Paragraph (f) was revised to indicate clearly that a stored source is exempt from the leak testing requirements in this section, regardless of the length of time that it has been in storage. The current rule does not contain a requirement to leak test stored sources after 10 years. The provision for leak testing after 10 years was added to the proposed rule because, at that time, we believed that leak testing was appropriate given the time of storage and the potential for contamination. At this time, we do not think this prescriptive requirement is warranted because the licensee must test each stored source for leakage before any use or transfer unless it has been leak tested within 6 months before the date of use or transfer.

*Section 35.69, Labeling of Vials and Syringes*

Issue 1: Can This Section Be Deleted?

*Comment.* Commenters suggested that this section should be deleted because appropriate labeling is the standard of medical and pharmacy practice and is adequately regulated by the FDA, the State Boards of medicine and pharmacy, and the US Pharmacopeia. Syringe shields can be used to maintain exposures ALARA. Under certain circumstances, syringe shields can be hazardous to patients because they could obscure subtle visualization of the syringe content.

*Response.* The NRC does not think this section should be deleted in its entirety. In addition, we do not believe that this requirement duplicates the requirements of the FDA, State Boards of Medicine and Pharmacy, and the U.S. Pharmacopeia. The labeling requirements in Part 35 are limited to two very specific purposes: to provide information to physicians or technologists that indicates the contents of the syringe to ensure that the administration is in accordance with the written directive; and to warn workers that the syringe contains byproduct material, i.e, radiation protection from the medical use of byproduct material. Labeling requirements of the other organizations have different purposes and, consequently, may result in different information on the labels. Any other labeling that contains the same information required by this section is acceptable. If another labeling requirement does not specify all of the information required by § 35.69, the additional information may be included on that label.

We deleted the requirement for the licensee to develop, implement, and maintain written procedures for labeling each syringe, syringe shield, or vial shield that contains a radiopharmaceutical and for shielding vials and syringes. We also deleted the requirement to provide individuals with instructions on these procedures. Both requirements have been deleted because we believe the rule should focus on labeling the vial or syringe, rather than on procedures.

Syringe or vial shields can be used to maintain exposures ALARA. However, we believe licensees should have flexibility to determine whether syringe or vial shields should be used. Thus, we have deleted the requirements to shield the syringe or vial. However, deletion of the requirement does not prohibit the licensee from using syringe or vial shields. When syringe shields or vial shields are used by a licensee, the final rule requires the licensee to label the shields, if the label on the syringe or vial is not visible.

*Section 35.70, Surveys for Ambient Radiation Exposure Rate*

Issue 1: Is This Section Needed?

*Comment.* Some commenters did not believe this section was needed because it was up to the licensee, through the RSO, to ensure radiation safety. Some commenters agreed that surveys should only be required when byproduct material requiring a written directive is used. Other commenters believed that the rule should require surveys of all areas where byproduct material is used.

*Response.* This section is needed to ensure that a radiation survey is conducted in areas where unsealed byproduct material that requires a written directive was prepared or administered. The NRC believes that a radiation survey, at the end of each day, should be required in Part 35 because patients and other individuals could be present near a nuclear medicine or radiation therapy department. Without surveying ambient radiation levels, it is possible for patients or other individuals to receive unnecessary or excessive radiation exposures.

In order to make the rule more risk-informed, we do not believe all areas need to be surveyed. However, licensees must be prepared to show compliance with the public and occupational dose limits in Part 20.

Issue 2: When Should Surveys Be Performed?

*Comment.* Some commenters believed that surveys should be performed after preparation or administration of byproduct material, rather than at the end of the day. Some opposed removing the existing requirements to survey areas where radiopharmaceuticals or waste is stored and to survey for removable contamination. Finally, one commenter asked that the NRC clarify whether the requirement for surveys in paragraph (b) applies only to patients' rooms or whether it also applies to the area where the patient's dosage was prepared.

*Response.* The general survey requirements are in Part 20. In addition to these requirements, the NRC believes that medical use licensees should be required to perform radiation surveys at the end of the day in areas where unsealed byproduct material requiring a written directive was prepared for use or administered. A medical use licensee, such as a hospital, prepares and administers byproduct material to multiple patients or human research subjects throughout the day. If a survey were required after each preparation or administration of byproduct material, there would be a significant increase in the licensee's burden to comply with this requirement without an associated safety benefit. We believe that a survey at the end of each day of use is sufficient to detect elevated radiation levels. If elevated levels are detected, corrective action, if warranted, could be taken. However, licensees always have the flexibility of performing more frequent surveys.

We do not believe a requirement for weekly surveys for removable contamination is needed because licensees are required to show compliance with public and occupational dose limits in Part 20 of this chapter. In addition, the licensee will need to be able to show compliance with Part 20, Subpart F, Surveys and Monitoring.

We have clarified paragraph (b) to indicate that the licensee does not need to perform the surveys required by paragraph (a) of this section in areas where patients or human research subjects are confined when they cannot be released under § 35.75. In this case, the licensee must be prepared to show compliance with the Part 20 requirements.

*Section 35.75, Release of Individuals Containing Radiopharmaceuticals or Implants*

Issue 1: Should Any Changes Be Made to the Criteria for Release of Individuals Containing Pharmaceuticals or Implants?

*Comment.* Some commenters supported the dose-based release criteria in the proposed rule, while others asked that the criteria be revised. Those commenters that supported the 5 mSv (0.5 rem) release limit believed that § 35.75 provided regulatory relief to the medical profession without an associated increase in radiation risk to the public. These commenters recognized that one of the major obstacles to allowing the release of individuals in accordance with § 35.75 is a possible increase in radiation alarms at landfills. However, they believed the issue of landfill alarms should be addressed in other ways, such as raising the threshold for the alarms to a ''more practical'' level, rather than revising the release criteria in § 35.75. Commenters also indicated that several studies had been conducted that indicated that radiation exposures to family members from released patients were less than the 5 mSv (0.5 rem) limit. As a result, they asked that NRC reevaluate information provided in the guidance associated with this requirement.

Other commenters asked that the release criteria be revised because they believed that the criteria were based solely on economics and not on radiation risk. They were also concerned that household waste from an individual who had been released from the hospital could be contaminated and could trigger radiation alarms at landfills. This situation would affect State radiation protection programs because the States would have to investigate incidents in which the alarms had been activated.

*Response.* The NRC does not believe that any changes are needed to this section as a result of the public comments. We acknowledge that some States have reported an increase in the number of alarms at landfills. However, we have no documentation indicating that the exposure rates to the maximally exposed individuals have exceeded the dose limit in § 35.75. The NRC does not have regulatory jurisdiction over the landfill operators, nor over the alarm set points for radiation detectors at landfills. However, we do encourage continued communication between regulatory bodies and landfill operators to resolve this issue.

We believe that the release criteria provide licensees with needed flexibility in program management. A dose limit of 5 mSv (0.5 rem) to individuals knowingly exposed while voluntarily helping in the care, support, and comfort of patients provides adequate protection of these individuals. In addition, licensees are required to provide instructions to the released individual, or the individual's parent or guardian, on actions recommended to maintain doses to other individuals as low as reasonably achievable (ALARA) if the total effective dose equivalent to any other individual is likely to exceed 1mSv (0.1 rem). Licensees should consider this latter provision regarding instructions on maintaining exposures ALARA in situations where the individual has been released under § 35.75 but remains hospitalized for other reasons. In this case, the maximally exposed individual may be a member of the licensee's staff. The dose limit of 5 mSv (0.5 rem) to individuals comforting patients is consistent with the recommendations of the NCRP and the International Commission on Radiological Protection (ICRP). For additional information on the background of this section, refer to 62 FR 4120 (January 29, 1997).

Finally, we recognize that the values presented in NUREG–1556, Volume 9, for release of patients are based on some conservative values. The licensee may use case-specific information in place of the values used in the guidance document.