[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 20, 32, and 35

RIN 3150-AF74

Medical Use of Byproduct Material; Final Rule

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 [insert date 6 months after publication in the Federal Register].

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, "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/NRC/ADAMS/index.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 email to pdr@nrc.gov.

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SUPPLEMENTARY INFORMATION:

I. Background

II. Petition for Rulemaking

III. Summary of Public Comments and Responses to Comments

IV. Summary of Comments on Agreement State Compatibility and Responses to Comments

V. Summary of Changes Made Between the Current Part 35 and the Revised Part 35

VI. Coordination with the Advisory Committee on the Medical Uses of Isotopes

VII. Coordination with NRC Agreement States

VIII. Consistency with Medical Policy Statement

IX. Implementation

X. Issues of Compatibility for Agreement States

XI. Assessment of Federal Regulations and Policies on Families

XII. Final Environmental Assessment: Availability

XIII. Paperwork Reduction Act Statement

XIV. Regulatory Analysis

XV. Regulatory Flexibility Analysis

XVI. Backfit Analysis

XVII. Small Business Regulatory Enforcement Fairness Act

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 is 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 Federal Register Notice for the proposed rule and policy statement (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 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 section 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, 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 section 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 refer to Section IV, Summary of Comments on Agreement State Compatibility and Responses to Comments; Section VII, Coordination with NRC Agreement States; and Section X, Issues of Compatibility for Agreement States, in the SUPPLEMENTARY INFORMATION section in this document.

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 section 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, Pub. L. 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 section in this document.

II. Petition for Rulemaking

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 section 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 can not 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.

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 contains 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 potentially affected parties were provided. These interactions included significant discussions on the risk associated with medical uses of byproduct material.

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 organization 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 lead 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, Pub. L. 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 Radiosugery, 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 section 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 has deleted Subpart J. Only one set of training and experience requirements remains in the final rule. All medical use licensees will have to comply with the new training and experience requirements for AMPs, ANPs, AUs, and RSOs in Subparts B and D through H when the rule becomes effective on [insert date 6 months from publication of the final rule]. All commercial nuclear pharmacy licensees (10 CFR 32.72 licensees) will have to comply with the new training and experience requirements for ANPs in §§ 35.55 and 35.59. Individuals who have status as an AMP, teletherapy physicist, ANP, AU, and RSO at the time

the rule becomes effective will be “grandfathered” under § 35.57, and will not have to satisfy the new training and experience requirements.

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 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 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.

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 was 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, "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." (Proposed §§ 35.920 and 35.930 were deleted in 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. Therefore, annual fees will be rebaselined in FY 2002 unless circumstances warrant rebaselining earlier.

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 14: 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 section 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 was 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 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 §§ 35.190, 35.394, 35.491, and 35.615 and to delete references to §§ 35.633, 35.635, 35.3046, and to the sections in Subpart J that were deleted. 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.

Paragraph (b) 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 (c) 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 (d) 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 2: Were there any other changes made in this section between the proposed and final rule?

Response. Yes. The proposed paragraphs (b) and (c) were deleted because we deleted the training and experience requirements in the proposed Subpart J. Therefore, these paragraphs were no longer needed. As a result, the remaining sections were renumbered. Reference the General Training and Experience discussion in the beginning of this section of the Supplementary Information for more information. The training and experience requirements in the final rule are in Subparts B and D through H.

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 its annual fee rulemaking.

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 speciality 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, 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 was 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) and 35.394(a), and to delete references to the sections in Subpart J that were deleted. 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 was 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 was 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, 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 was 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.

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 section 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 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. 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. 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.

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 paragraph (b) to include AUs 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 was made so that this section is consistent with the revised definition of an AU 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.

Issue 2: Were there any changes made in this section between the proposed and final rule?

Response. Yes. The reference to Subpart J was deleted because that subpart was deleted in its entirety from Part 35. For additional information on the training and experience requirements in the final rule, including the deletion of Subpart J, refer to Section III, Part I, of this document.

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.

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.

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.

Issue 2: What other changes were made in this section between the proposed and final rule?

Response. In paragraph (b), the term “breast feeding infant” was replaced with the term “nursing infant.” This was done to maintain consistency within Part 35. Paragraph (d) was revised to state that records of the instructions provided to breast-feeding females should be made in accordance with § 35.2075(b) rather and § 35.2075(c). This change was needed because of a change in the codified text of § 35.2075. For additional information refer to the discussion of § 35.2075.

Section 35.80, Provision of mobile medical service.

Issue 1: Should mobile medical service licensees be allowed to operate under reciprocity in other regulatory jurisdictions?

Comment. Commenters indicated that mobile medical services are currently operating under reciprocity in some States. Some Agreement States indicated they do not allow medical licensees to operate under reciprocity, while other Agreement States said they permit mobile medical services to come to their State under reciprocity.

Response. Agreement States have the flexibility of determining whether they will issue mobile medical licenses and whether they will allow NRC or other State licensees to operate in their State under reciprocity. Under reciprocity, an Agreement State may allow a specific licensee from another Agreement State (or the NRC) to work within the Agreement State without requiring the licensee to obtain a license in that State. Similarly, under reciprocity, a specific licensee from an Agreement State may work in NRC jurisdictions, provided the requirements in 10 CFR 150.20, Recognition of Agreement State Licensees, are met. Specifically, NRC allows Agreement State mobile medical service licensees to operate in areas under NRC jurisdiction provided they comply with all the requirements in § 150.20, including submittal of the information required in that section.

Issue 2: Should NRC allow byproduct material to be delivered to a client's address of use?

Comment. A commenter recommended that the NRC permit byproduct material to be delivered to the client's address.

Response. Byproduct material may only be transferred to an NRC or Agreement State licensee because the licensee is responsible for the safe handling of the material. In almost all cases, the client is neither an NRC nor an Agreement State licensee. Therefore, the material must only be transferred to the licensed mobile medical service. Byproduct material may be delivered to the mobile medical service licensee at the mobile site (i.e., mobile van) if the byproduct material is secured against unauthorized removal (§§ 20.1801 and 20.1802).

Issue 3: What checks should be performed on instruments used to measure the activity of unsealed byproduct material at a client's address?

Comment. A commenter recommended that the check for instrument operation at the client's address be limited to a constancy check.

Response. Licensees must check the operation of instruments used to measure the activity of unsealed byproduct material to ensure that the instrument is functioning properly. This section was revised to require that licensees check instruments used to measure the activity of unsealed byproduct material for constancy before medical use at each client's address or on each day of use, whichever is more frequent. In the case of a mobile medical service, we believe that a constancy check must be performed to ensure that the instrument is functioning properly. The need for additional testing on the instruments is determined by how the licensee addresses compliance with § 35.60.

Issue 4: Is it necessary to check a survey instrument with a dedicated check source?

Comment. A commenter recommended that the requirement to check the survey instrument with a dedicated check source be deleted because this check was no longer included in § 35.61.

Response. The NRC does not believe that the requirement to check survey instruments with a dedicated check source should be deleted from § 35.80. While we have deleted the requirement from § 35.61, we believe it is needed in § 35.80 because there is a greater

likelihood that a survey instrument in a mobile unit may become damaged or uncalibrated as a result of extensive movement.

Issue 5: Do mobile medical service licensees need to collect contaminated waste generated by patients after administration of the byproduct material?

Comment. A commenter asked that NRC clarify whether mobile medical service licensees need to return to the client's address to collect contaminated waste generated by patients after the administration of the byproduct material.

Response. The mobile medical service licensee does not need to return to the client's address to collect contaminated waste generated by the patient after the administration. The waste is no longer considered under the licensee's control because the patient would have been released from licensee control under § 35.75.

Issue 6: What other changes were made between the proposed and final rule?

Response. The NRC amended this section to use the term "mobile medical service" rather than "mobile service" to indicate clearly that the provisions in this section only apply to medical use. In addition, in paragraphs (a)(1) through (a)(4), "client's address of use" was replaced by "client's address," which is defined in § 35.2. This was done to recognize that mobile medical service may be provided at an area of use or a temporary job site. (*Area of use* is defined as a portion of an address of use that has been set aside for the purpose of receiving, preparing, using, or storing byproduct material.)

Paragraph (a)(1) was also amended by replacing the term “each entity” with the phrase “the licensee and the client.” We believe this more clearly states our intent that the mobile medical service obtain a letter from each client that delineates the authority and responsibility of the licensee and the client.

Paragraph (a)(2) was amended to clarify that the instruments referred to in this paragraph refer to those instruments used to measure the activity of unsealed byproduct material.

In paragraph (b), “the client’s address of use” was replaced by “the client.” This was done to clarify that byproduct material cannot be delivered to the client unless the client has a license allowing possession of the byproduct material.

Section 35.92, Decay-in-storage.

Issue 1: Should this section be moved to Part 20?

Comment. Commenters believed that decay-in-storage should be addressed in Part 20 rather than in Part 35.

Response. Part 20 provides the general requirements for various waste disposal methods, including the decay-in-storage method. Currently, detailed procedures for decay-in-storage are in license conditions. The NRC believes the specific provisions for decay-in-storage that apply to a medical licensee should be codified in Part 35.

Issue 2: Should the rule continue to require that byproduct material be held for 10 half-lives before disposal as nonradioactive material?

Comment. Commenters were divided in response to the NRC's request for specific comment on whether byproduct material should be held for a minimum of 10 half-lives. Commenters in favor of retaining the requirement believed that it would help ensure that the waste is not prematurely disposed of as nonradioactive material due to human error or instrumentation malfunction. They also believed that licensees may not have adequate survey instruments to survey low-energy beta emitters, such as sulfur-35 (S-35).

Commenters supporting the deletion of the requirement indicated that holding the byproduct material for 10 half-lives was in no way a guarantee that the waste could be disposed of as nonradioactive material. They believed that deletion of the requirement to hold the material for 10 half-lives would improve sanitary conditions and provide for more efficient use of storage space. Finally, they indicated that although S-35 is difficult to detect with a survey instrument, S-35 is not a component in any FDA-approved radiopharmaceutical for routine use.

Response. The NRC has not included a requirement in the final rule to hold byproduct material for 10 half-lives before disposing of the material as nonradioactive material. We do not believe this requirement is needed in light of the requirement in paragraph (a)(1) that precludes disposal of byproduct material without regard to its radioactivity until radiation levels adjacent to the material do not exceed background levels.

Issue 3: Does the requirement to obliterate radiation labels only apply to the outermost container, especially if the material will be handled as biohazardous material?

Comment. A commenter questioned whether the obliteration of radiation labels is only required on the outermost container. Specifically, the commenter asked whether labels needed to be defaced on inner containers if the label on the outer container had been defaced and the inner label was not visible.

Response. NRC revised the text in paragraph (a)(2) to require that all radiation labels be removed or obliterated, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee. All radiation labels must be removed or obliterated from outer containers once the radioactivity can not be distinguished from the background level. Radiation labels on biomedical waste (e.g., sharps containers or individual needles and syringes) do not have to be removed or obliterated due to the associated biohazard of retrieving such material from the outer container. Also, in many cases, the waste barrels containing biomedical waste will be incinerated.

Issue 4: What type of byproduct material may be held for decay-in-storage?

Comment. A commenter asked whether radioactive “seeds” can be held for decay-in storage.

Response. The final rule allows a licensee to hold byproduct material with a physical half-life of less than 120 days for decay-in-storage before disposal without regard to its

radioactivity. If a “seed” contains byproduct material with a half-life of less than 120 days, this provision applies.

Issue 5: Were there any other changes made between the proposed and final rule?

Response. Yes. Paragraph (a) was revised to indicate clearly that the provisions in this section pertain only to disposal of the material without regard to its radioactivity. Licensees must continue to comply with any other regulations that pertain to disposal of the material (e.g., Environmental Protection Agency and State biomedical waste regulations).

SUBPART D - Unsealed Byproduct Material - Written Directive Not Required

General comments.

Issue 1: What are the correct titles for Subparts D and E?

Comments. Commenters recommended renaming Subparts D and E to avoid use of the terms “low dose” and “high dose.” A commenter recommended renaming these sections: Subpart D–Unsealed Byproduct Material-Written Directive Not Required and Subpart E–Unsealed Byproduct Material-Written Directive Required.

Response. The NRC agrees that the titles of Subparts D and E should be renamed to avoid use of the terms “low dose” and “high dose.” Subparts D and E in the final rule have been renamed to use the requirement for a "written directive" as the basis for associating the use of the material to radiation risk. The new titles are Subpart D–Unsealed Byproduct Material-Written Directive Not Required and Subpart E–Unsealed Byproduct Material-Written Directive Required.

Issue 2: Are the regulations in Part 35 (except the training and experience requirements) needed?

Comment. Commenters proposed removing the regulations for diagnostic nuclear medicine, except for the training and experience requirements, from Part 35. The commenters believed that properly trained physicians, with the assistance of other associated nuclear

medicine health care providers and the standards of radiation protection in Part 20, are all that are necessary to protect the public health and safety adequately.

Response. During the development of the proposed rule, the NRC 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 need to comply with these requirements, such as the ALARA provisions in Part 20, but we believe there is no need to duplicate requirements.

Part 20 contains general radiation protection requirements applicable to all licensees; Part 35 contains requirements specific to medical use licensees. While some commenters believe that Part 35 should not contain any requirements associated with low risk procedures, certain radiation protection-related requirements specific to medical use are needed in Part 35 because of their contribution to risk reduction. For example, the final rule retains requirements to perform quality control tests on instrumentation used to measure the radioactivity of patient dosages before administration. These regulations are necessary to provide high confidence that the instrumentation used to measure dosages is operating properly.

In other cases, more specific requirements were kept in Part 35 where justified by risk. The majority of those requirements deal with the therapeutic uses of sealed radioactive material. We believe that the requirements in the final rule are necessary, in addition to the requirements in Part 20, to ensure that the dosage administered to a patient is as prescribed by the AU and to ensure protection of workers and the public.

Issue 3: Should the requirements for diagnostic and therapeutic uses of unsealed byproduct materials for medical use be combined?

Comment. A commenter believed that the proposed rule intermingled requirements for diagnostic and therapeutic nuclear medicine and failed to provide a regulatory scheme appropriate to each.

Response. Early in the rulemaking process, the NRC considered structuring the rule to have completely "stand-alone" subparts for each type of medical use. However, under this approach, there would have been significant duplication of the requirements which would make the entire rule unnecessarily voluminous. For example, if we took this approach, each subpart would have had a section that addressed when a license was needed, criteria for amending a license, or RSO qualifications.

We have structured the rule so that Subparts A, B, C, L, M, and N contain the requirements that apply to all licensees. Subparts D, E, F, G, H, and K contain the requirements that apply to a particular modality, e.g., Subpart D provides specific requirements for the use of unsealed byproduct material which does not require a written directive, and Subpart E contains the requirements for the use of unsealed byproduct material which requires a written directive. The subparts for each type of use also contain the specific training and experience requirements for the AU.

Section 35.100, Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.

Issue 1: Why doesn't the NRC eliminate or reduce the regulation of certain § 35.100 materials?

Comment. A commenter recommended eliminating or reducing regulation of materials in § 35.100 with extremely low doses (e.g., 35 μCi of I-125 iothalamate, 10 μCi of iodine-125 (I-125) albumin and 1 μCi of cobalt-57 (Co-57) cyanocobalamin) because medical use of these materials involves minimal risk.

Response. The NRC does not believe that the requirements for the medical use of byproduct material described in § 35.100 should be eliminated. If this material is not handled safely, the public or occupationally exposed individuals could receive an exposure in excess of the Part 20 dose limits. However, we have reduced some regulatory requirements that apply to this type of use, e.g., the requirements in §§ 35.24, 35.61, 35.92, and 35.290 of the final rule. Explanations for these changes can be found in the discussions of the respective sections.

Issue 2: Should §§ 35.100 and 35.200 be combined because the procedures performed in both modalities do not require a written directive?

Comment. A commenter suggested that the two types of studies listed under Subpart D in the proposed rule in §§ 35.100 and 35.200 should be combined into one category, "unsealed byproduct material for which a written directive is not required."

Response. Early in the development of the proposed rule, the NRC considered combining these two categories into one section. We did not do so because we believe that the

training and experience requirements for individuals using byproduct material for imaging and localization should be more rigorous than such requirements for individuals who only use unsealed byproduct material for uptake, dilution, and excretion studies. This is because AUs using unsealed material under § 35.200 are allowed to compound radiopharmaceuticals and, in general, are handling multiple types of radionuclides at higher activity levels than users performing uptake, dilution, and excretion studies.

Issue 3: Is the reference in § 35.100(b) referring to § 35.292 correct?

Comment. A commenter suggested the cross reference in § 35.100(b) to § 35.292 should be § 35.290.

Response. The cross reference in § 35.100(b) of the proposed rule to an individual who meets the criteria to become an AU for use of unsealed byproduct material for imaging and localization is correct. The requirements in the proposed § 35.292 were moved to § 35.290 in the final rule, so § 35.100(b) now references § 35.290. The NRC also added a reference to § 35.390. Sections 35.292 and 35.390 in the final rule give physicians authorization to prepare radioactive drugs using generators and reagent kits. AUs qualified under the final § 35.190 (proposed § 35.290) do not have this type of authorization.

Issue 4: Why aren't FDA-approved IND pharmacokinetic studies addressed in the proposed rule?

Comment. A commenter stated that the proposed rule did not recognize pharmaceutical companies that do not have a 10 CFR Part 35 license but label compounds with byproduct material and transfer them to specific licensees for use in FDA-approved IND pharmacokinetic studies. This commenter proposed addition of a new § 35.100(c) to address this issue.

Response: The final rule addresses this comment and other omissions in the proposed rule. The proposed rule did not recognize pharmaceutical companies who do not have a Part 32 license but who label compounds with byproduct materials and transfer them to a specific licensee for use in FDA-approved IND studies. The proposed rule also did not recognize the use of unsealed byproduct material obtained from an NRC or Agreement State licensee in accordance with an RDRC protocol. Finally, § 35.100 in the proposed rule did not allow specific medical use licensees, who do not have individuals qualified under §§ 35.292, 35.55, 35.920, or 35.980, to prepare unsealed byproduct material in accordance with an RDRC or IND protocol accepted by FDA for use in research. These omissions in the proposed rule unduly restricted labeling and transfer of unsealed byproduct material to Part 35 licensees. New paragraphs (c) and (d) have been added to §§ 35.100 and 35.200 of the final rule to address all of these situations.

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

Issue 1: Is it necessary for physicians using byproduct materials under § 35.100 to be board certified in nuclear medicine?

Comment. A commenter believed that there should be an alternative training and experience pathway for individuals who are not full board certified nuclear medicine physicians, but would like to become an AU for materials authorized under § 35.100.

Response. The final rule contains three pathways for individuals to become AUs for material under § 35.100. The first pathway, § 35.190(a), requires a physician to be certified by a board recognized by NRC. The second pathway, § 35.190(b), allows AUs, qualified under §§ 35.290, 35.390, or equivalent Agreement State requirements, to use byproduct material under § 35.100. The third pathway, § 35.190(c), requires that the physician complete 60 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies. The 60 hours includes classroom and laboratory training and work experience.

Issue 2: Were there any other changes made between the proposed and final rule?

Response: Yes. The training and experience requirements that were in the proposed § 35.290 were moved to § 35.190 in the final rule. This is discussed in greater detail under the general discussion on training and experience located at the beginning of this section of the SUPPLEMENTARY INFORMATION.

Section 35.200, Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.

Issue 1: Were there any changes made in this section between the proposed and final rule?

Response. Yes. Paragraphs (c) and (d) were added to this section in the final rule. These changes are identical to the changes made to § 35.100. The reasons for these additions are in the discussion of § 35.100, Issue 4.

Section 35.204, Permissible molybdenum-99 concentration.

Issue 1: Why is it necessary for NRC regulations to address molybdenum-99 (Mo-99) concentrations?

Comments. Commenters argued for eliminating this section because U.S. Pharmacopeia (USP) and FDA standards already address this area. Another commenter believed that the proposed requirements were excessive and unnecessary. Some commenters supported the change in the requirement from evaluating the Mo-99 concentration for every elution, to evaluating it for only the first elution.

Response. The NRC believes that this requirement is necessary as a means to check generator eluate before medical use to ensure that the generator was not damaged in shipment. This requirement does not preclude more frequent evaluations of the Mo-99 concentrations. We revised paragraph (a) to express the permissible concentration level in SI units: "0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m)." This level is identical to that

used in the U.S. Pharmacopeia (USP) 23 U.S. Pharmacopeial Convention, Inc., 1995, pages 1486-1487.

Issue 2: Were there any changes made in this section between the proposed and final rule?

Response. Yes. The NRC amended paragraph (c) to be more precise. We replaced the phrase “measure molybdenum concentration” with the phrase “measure the molybdenum-99 concentration.”

Section 35.205, Control of aerosols and gases (current rule).

Issue 1: Should the current requirements related to aerosols and gases be deleted?

Comment. The NRC received comments supporting and opposing the deletion of this section in the current rule. A commenter supported the deletion of the requirement because the current requirement is too prescriptive. Another commenter believed that the requirement to control radioactive aerosols and gases should be retained. This commenter stated that the requirement of having a negative pressure environment ensures that there is control over “escaping radioactive gas.”

Response. The NRC does not believe this requirement is needed in Part 35. Part 35 licensees must comply with the occupational and public dose limits of Part 20. Additional

prescriptive requirements for limiting airborne concentrations of radioactive material are not warranted in Part 35.

Section 35.290, Training for imaging and localization studies.

Issue 1: Should all individuals be required to have experience with eluting generators?

Comment. A commenter recommended that the NRC revise the training and experience requirements in the proposed § 35.292 to state: "To be authorized for possession and use of technetium from a generator system, the applicant must obtain supervised practical experience eluting technetium-99m from generator systems." The commenter is drawing a distinction between AUs that plan to limit their use to unit dosages, rather than preparing the dosages themselves. The commenter believed the requirement, as proposed, would be consistent with actual practice and good radiation safety practices. In addition, the commenter recommended that the preceptor not be required to certify that an individual has achieved a level of competency with regards to use of generators. Another commenter believed that we should delete requirements for individuals to receive training in eluting generators, measuring and testing the eluate for radiochemical purity and processing the eluate with reagent kits because unit dosages are obtained from a Part 32 licensee.

Response. The NRC has not modified the regulatory text to establish separate training and experience requirements for AUs only using unit dosages. We have also not deleted the requirement for "eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and

processing the eluate with reagent kits to prepare labeled radioactive drugs." Physicians who meet all the qualifications in the final § 35.290 are authorized to use generator systems and reagent kits in the preparation of radioactive drugs and must be trained accordingly, even though they may elect to use only unit dosages. If a physician does not have experience in eluting generators he or she will be authorized for unit dosages only. For the same reason, we believe that the preceptor should certify that the individual has achieved a level of competency with regards to use of generators. We would unduly limit where a licensee may obtain unsealed byproduct material if we made any further revisions to the regulatory text.

Issue 2: Were there any other changes made in this section between the proposed and final rule?

Response: Yes. The requirements in the proposed § 35.290 were moved to the final § 35.190. The requirements in the proposed § 35.292 were moved to the final § 35.290. This is discussed in greater detail under the general discussion on training and experience located at the beginning of this section of the SUPPLEMENTARY INFORMATION

SUBPART E - Unsealed Byproduct Material - Written Directive Required

Section 35.300, Use of unsealed byproduct material for which a written directive is required.

Issue 1: Were there any changes made in this section between the proposed and final rule?

Response. Yes. Paragraph (b) was amended by changing the reference to § 35.292 in the proposed rule to § 35.290 in the final rule and adding a reference to § 35.390. The proposed rule would have allowed licensees to use any unsealed byproduct material prepared for medical use by an ANP, a physician who is an AU and who meets the requirements specified in the proposed § 35.292 (§ 35.290 of the final rule), or an individual under the supervision of either as specified in § 35.27. The NRC added the reference to § 35.390 in paragraph (b) of the final rule because a physician who meets the training requirements in § 35.390 also meets the training requirements in § 35.290,.

Paragraphs (c) and (d) were added to this section. This was done because the proposed rule did not recognize pharmaceutical companies who do not have a 10 CFR Part 32 license, but label compounds with byproduct materials and transfer them to a specific licensee for use in FDA-approved IND studies. Also, the proposed rule did not allow specific medical use licensees to prepare unsealed byproduct material in accordance with an IND protocol accepted by FDA for use in research. These omissions in the proposed rule unduly restricted

labeling and transfer of unsealed byproduct material to Part 35 licensees. The final rule addresses these situations.

Sections 35.100 and 35.200 have been revised to address both the RDRC and IND approved material. Note: § 35.300, in contrast to §§ 35.100 and 35.200, does not include reference to RDRC authorizations because FDA's RDRC regulations restrict RDRC approvals to pharmacokinetic and physiological studies. Further, the dose limits for a study that can be approved by an RDRC under 21 CFR 361.1 are as follows:

(1) For a single administration of radioactive drug - whole body, gonads, blood forming organs, and lens--3 rem; all other organs--5 rem; and

(2) For multiple administrations (or annual dose commitment) - whole body, gonads, blood forming organs, and lens--5 rem; all other organs--15 rem.

Section 35.310, Safety instruction.

Issue 1: Who must participate in annual retraining on radiation safety?

Comments. Many commenters questioned the need for the radiation safety instruction required in § 35.310. Some commenters found this requirement to be very burdensome. A commenter suggested that posting radiation safety precautions on a patient's door or in the patient's chart could replace the training requirement. Another commenter believed that annual retraining was not needed for certified radiation therapy technologists and, therefore, recommended that the section specify annual retraining only for "persons without specialized

training in handling radioactive materials." Other commenters thought the requirement was too prescriptive, and that licensees should be given the freedom to decide how to assure compliance with the dose limits in § 35.75 on a case-by-case basis. According to another commenter, annual retraining should be required only for health care personnel who were not directly supervised by trained radiation safety staff. Some commenters argued against placing the radiation safety instruction requirement in Part 35, while other commenters suggested that we make the requirement only applicable to allied health workers who are not nurses. The commenter believed that the need for training should be dependent on whether the licensees needed to provide the individual with dosimetry. These commenters suggested that we revise § 35.310(a) to state: "A licensee shall provide radiation safety instruction, initially and at least annually, to personnel, whose exposure rates may approach the limits in Part 20, caring for patient or human research subjects that have received therapy . . ."

Response. The NRC believes that it is important that personnel caring for patients or human research subjects, who cannot be released in accordance with § 35.75, receive instruction in limiting radiation exposure to the public and workers and in the radiation safety actions to be taken in the case of a medical emergency or death. We believe this provision is needed because exposure in excess of the public dose limits could result unless proper precautions are taken. We also believe this requirement is consistent with ALARA principles. We do not believe that only posting doors or a chart provides adequate information to the licensee's staff, without corresponding instruction.

The rule does not require the licensee to instruct all hospital staff. Instruction must only be provided to personnel caring for patients or human research subjects who cannot be

released in accordance with § 35.75. We considered the comments regarding who should receive the training and whether the requirement should be linked to a dose limit. We decided that it is more appropriate to specify that instruction must be provided to personnel caring for patients or human research subjects, rather than tie the instruction to the dose limits in Part 20. This was done because it is possible for a licensee's staff member to receive a dose that is less than the occupational dose limits in Part 20, but take an action that could result in a dose to a member of the public that exceeds the public dose limit.

We have given the licensee flexibility on the level and detail of instruction that must be provided. The instruction need only be commensurate with the duties of the personnel. In other words, the licensee can determine the appropriate level of radiation safety instruction to be provided, depending on the level of care provided by the personnel. For example, a primary care nurse may receive detailed instructions on patient and visitor control, but the ward clerk may only need to be instructed to observe the caution signs on the patient’s door.

We recognize that certified radiation therapy technologists or other individuals who have received specialized training in handling radioactive materials would have received training in the areas required by this section as part of a training program. However, we believe that refresher training is warranted because of the potential for unnecessary exposure to workers and the public if needed safety precautions are not observed.

Issue 2: Can the AU have a designee?

Comment: A commenter recommended that paragraph (a)(5) be revised to require that personnel be instructed to notify the RSO (or his or her designee) and the AU (or his or her designee) if the patient or the human research subject has a medical emergency or dies.

Response: The final rule provides the RSO flexibility in designating who should be notified to address radiation protection issues. However, the rule does not provide for the AU to have a designee. The AU is the individual who is responsible for the medical use and supervision of other persons using the byproduct material. Therefore, because of the type of dosages that are administered under § 35.300, we believe it is important that an AU be available to be contacted in case of a medical emergency or death.

Issue 3: Should the current requirements in § 35.315(a)(4) related to surveys be deleted?

Comment. A commenter indicated that removal of the current requirements in § 35.315(a)(4) to perform a radiation survey following a therapeutic administration of I-131 would be ill-advised. This commenter also believed that the requirement to perform a careful contamination room survey should not be removed.

Response. The NRC does not believe these survey requirements should be in Part 35. We believe Part 20 contains adequate information regarding radiation surveys. As required in § 20.1501, the licensee must make or cause to be made surveys that are needed to comply with the regulations in Part 20. Part 35 licensees are responsible for ensuring that the occupational and public dose limits in Part 20 are not exceeded.

Issue 4: Were there any other changes made to this section between the proposed and final rule?

Response. Yes. In paragraph (a), the term “radiopharmaceutical therapy” was replaced with the phrase “therapy with unsealed byproduct material.” This change clarifies that this section addresses both drugs and biologics containing byproduct material. The term radiopharmaceutical does not cover both radioactive drugs and radiobiologics containing byproduct material.

Paragraph (b) of the proposed rule (paragraph (a)(5) of the final rule) was restructured to clarify our intent that, for the purpose of this section, only the RSO may have a designee.

Section 35.315, Safety precautions.

Issue 1: Does the rule allow the licensee to quarter patients or human research subjects receiving therapy with unsealed byproduct material together?

Comment. Commenters did not believe that the requirement to quarter a patient or human research subject, who cannot be released in accordance with § 35.75, in a private room with a private bathroom is justifiable. They believed that the requirement should be deleted, citing calculations suggesting that two patients undergoing identical radiation treatments (unsealed byproduct material) and occupying the same room would each have their total radiation dose increased by less than 1 percent due to the presence of the other patient. Others believed that allowing two patients undergoing treatment in the same room would be

helpful as a means of controlling contamination and would, therefore, support ALARA principles.

Commenters also argued that allowing a nontherapy patient to share a room with a patient undergoing radiation therapy (unsealed byproduct material) was unacceptable. They said this would result in unnecessary exposure to a member of the public and would not be ALARA.

Other commenters opposed allowing the sharing of a posted restricted room with a patient who was not undergoing radiation therapy. These commenters were concerned about the radiation exposure to hospital housecleaning staff. Other commenters supported the requirement for a private room because they were concerned that medical institution management and health care insurance companies would not allow patients or human research subjects to be quartered in private rooms or in a double room (with single occupancy) because it was too expensive.

Response. The NRC revised this provision to allow the licensee to quarter a patient or human research subject in either (1) a private room with a private sanitary facility; or (2) a room, with a private sanitary facility, with another individual who also has received therapy with unsealed byproduct material and who also cannot be released under § 35.75. This requirement does not preclude the licensee from quartering the patient in a private room. This change recognizes that the exposure patients could receive from each other is insignificant in light of the exposure the patient is receiving from their administered dosages. Conversely, we do not

believe that it is appropriate to allow a therapy and nontherapy patient to share a room because the nontherapy patient would not receive a radiation exposure under normal conditions.

We believe that contamination control is essential and that two patients could share the same room without negatively affecting the licensee's ability to control contamination. However, licensees should be mindful of the radiation hazards associated with different radionuclides, especially when quartering in the same room individuals who have received different radionuclides. We do not agree that sharing rooms will increase the exposure to housecleaning staff. Assuming that two patients require treatment, the exposure to the housekeeping staff should not be significantly different whether the patients are quartered in the same room or different rooms. In either situation, licensees have the responsibility to maintain the exposures below the Part 20 limits.

Issue 2: Should a patient or human research subject be allowed to take contaminated articles home?

Comment. A commenter asked that this section be revised to permit the licensee to package items contaminated with short-lived material so that the items could be released at the same time as the patient or human research subject. The commenter went on to state that the section should also include a requirement for the licensee to instruct the individual not to unpack the package and use anything in the package until a predetermined date. Finally, the commenter recommended that the date be calculated to ensure the activity remaining in the package is small.

Response. The NRC has not changed the rule because of the potential for unnecessary radiation exposure to the public if the material were not handled properly once it is released from licensee control. Any items contaminated as a result of medical use are the responsibility of the licensee.

Issue 3: Should additional requirements be added to § 35.315 to address hospitalization of patients who can be released under § 35.75, but are still hospitalized because of medical reasons?

Comment. A commenter questioned how a patient, who had been released under § 35.75, but was still hospitalized for another medical condition, should be managed. The commenter was concerned that the nursing staff could be confused by the instructions provided to the patient under § 35.75, because § 35.315 does not address the management of this type of patient. The commenter suggested that § 35.315 be revised to require licensees to implement radiation safety precautions, to include posting warning signs, whenever patients receiving therapy quantities of radiopharmaceuticals are hospitalized.

Response. It is the licensee's responsibility, under § 35.75, to control any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is likely to exceed 5 mSv (0.5 rem).

We do not believe that § 35.315 should be revised to specifically address patients who are released in accordance with § 35.75 but remain hospitalized for other reasons because

compliance with § 35.75 ensures that the maximally exposed individual does not receive a dose in excess of 5 mSv (0.5 rem).

Issue 4: Are the limits in § 35.315 for the release of material and items removed from the patient's or human research subject's room appropriate?

Comment. A commenter was strongly in favor of the revised survey requirements because the previous rules were too prescriptive and not warranted for reasons of health and safety. Another commenter believed that the release limits in § 35.315(a)(3) of the proposed rule are unnecessarily low and are not logical when compared to the annual limit of intake for I-131 and I-125.

Response. Under § 35.315 (a)(4) in the final rule, material and items from the patient's or the human research subject's room cannot be removed until the radiation levels adjacent to the items are not distinguishable from natural background, unless the material and items are managed as radioactive waste. Because this requirement is consistent with the release requirements in § 35.92 for radioactive waste, the NRC does not believe additional modification is needed.

Issue 5: Should the bioassay requirements in the current § 35.325(a)(8) be included in the final rule?

Comment. A commenter asked that the current § 35.315(a)(8) be revised and incorporated in the final rule. The commenter recommended that the following provision be

added: A licensee shall measure the thyroid burden of each individual who helped prepare or administer a dosage of I-131 within 3 days after administering the dosage if there is a likelihood that the individual would receive more than 10 percent of the Annual Limit of Intake in Appendix B of Part 20.

Response. The NRC has not included bioassay requirements in the final rule. Licensees are required to comply with Part 20. As such, they must limit occupational exposure to the limits in Part 20. In addition, they must develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities (§ 20.1101). This would include assessing whether individuals preparing or administering I-131 need bioassays.

Issue 6: Were there any other changes made to this section between the proposed and final rule?

Response. Yes. The NRC restructured paragraph (b) to clarify our intent in the proposed rule that, for the purpose of this section, only the RSO may have a designee. This same change was made in § 35.310. The reasons for this change are under the discussion of § 35.310, Issue 2.

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

Issue 1: Should the training and experience requirements in § 35.390 include instruction in giving radiation safety directions in the event the patient or human research subject dies?

Comment. A commenter recommended that the NRC add a requirement to § 35.390(b)(1) to require that an individual receive instruction on issuing radiation safety directions in the event the patient or human research subject dies.

Response. The NRC does not believe this change is necessary because this issue should be addressed as part of the licensee's overall radiation safety program. Licensees should have flexibility in how they address radiation safety issues associated with the death of a patient or human research subject.

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

Issue 1: Were there any changes made in this subpart between the proposed and final rule?

Response: Yes. The NRC added specific training and experience requirements for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 GBq (33 mCi). This addition is discussed in greater detail under the general

discussion on training and experience located at the beginning of this section of the SUPPLEMENTARY INFORMATION.

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: Were there any changes made in this subpart between the proposed and final rule?

Response: Yes. The NRC added specific training and experience requirements for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 GBq (33 mCi). This addition is discussed in greater detail under the general discussion on training and experience located at the beginning of this section of the SUPPLEMENTARY INFORMATION.

SUBPART F- Manual Brachytherapy

Section 35.400, Use of sources for manual brachytherapy.

Issue 1: Should all therapy sealed sources be required to have National Institute of Standards and Technology (NIST) traceability?

Comment. Some commenters felt that all sources used for therapeutic applications should be required by regulation to have a NIST traceable national standard. Conversely, some commenters felt that it is inconsistent to require licensees to calibrate in the absence of national standards for all clinically used sources.

Response. This comment pertains to all sources used for manual brachytherapy under Section 35.400. Section 35.432 requires that source output be measured with a dosimetry system that has been calibrated using a system or source traceable to NIST. The NRC agrees with the AAPM position that all therapy sealed sources should be calibrated using a system or sources traceable to NIST and published protocols accepted by nationally recognized bodies or by a calibration laboratory accredited by AAPM. In limited cases, a traceable standard identical to the therapy sealed source is not available. In these cases, the requirement allows the licensee the flexibility to use protocols accepted by nationally recognized bodies to meet the calibration requirement. As an example, AAPM Report No. 21 - Specification of Brachytherapy Source Strength, 1987, recommends that sources used in radiation therapy have calibrations with direct or secondary traceability to national standards. AAPM defines direct traceability as "when a source or calibrator has been calibrated either at NIST or an AAPM-Accredited

Dosimetry Calibration Laboratory." AAPM defines secondary traceability as "when the source is calibrated in comparison with a source of the same design and comparable strength which has direct traceability or when the source is calibrated using an instrument with direct traceability." In addition, AAPM TG-56 recommends that, for "sources that do not have a national standard yet, users should develop a constancy check calibrated against the vendor's standard and use this constancy check to verify the source strength. Another option is to develop one's own secondary standard." This allows the licensee flexibility in the event that a direct NIST traceable standard does not exist.

Issue 2. Were there any changes made in this section between the proposed and final rule?

Response. Yes. The NRC added a new paragraph (b) to this section that allows a licensee to use therapy sources in medical research as long as the research is conducted in accordance with an active IDE application accepted by the FDA if the requirements in § 35.49(a) are met. This was done to clarify how research with sealed sources could be conducted if the medical use of the sources differed from the statements found in the SSDR for the sources. With this change, we allow the use of previously registered sources for uses other than those described in the original registration process, as long as the requirements in paragraph (b) are met.

Section 35.404, Surveys after source implant and removal.

Issue 1: Is the requirement for radiation surveys after brachytherapy source implant necessary?

Comment. Commenters felt that a survey of the patient after brachytherapy sources have been implanted for the purpose of looking for misplaced sources would be difficult. The commenters stated that with the sources in the patient, the background around the patient is too high to detect an errant source. Additionally, some commenters believed that radiation surveys should be deleted from Part 35 because this is a Part 20 issue.

Response. The NRC agrees that Part 20 requires surveys and control of licensed material. However, in order to clarify that surveys must be conducted to locate and account for all sources that have not been implanted, the requirements for surveys have been retained in § 35.404(a). Section 20.1501 requires, in part, that each licensee shall make, or cause to be made, surveys that may be necessary for the licensee to comply with the regulations in this part and are reasonable to evaluate: the magnitude and extent of radiation levels; the concentration or quantities of radioactive material; and the potential radiological hazards that could be present. In addition, Subpart I of Part 20 requires that the licensee secure from unauthorized removal or control and maintain constant surveillance of licensed material. Because surveys under § 35.404(a) are not necessarily radiation surveys, the term “radiation” has been removed from the title and the text of paragraph (a) of this section. Depending on the area being surveyed and the ability to distinguish from the radiation background around the patient implanted with brachytherapy sources, these surveys may include radiation surveys of a facility room (e.g., operating room suite) after the patient with implanted sources has been removed

from the room, radiation surveys in and around the patient's room after the implant, and visual surveys of the patient's bed after the implant.

Issue 2: Does adjacent area include contiguous restricted and unrestricted areas?

Comment. A commenter requested that we explicitly indicate that "adjacent area" does not categorically include "contiguous restricted and unrestricted areas." The commenter stated that the latter wording appears in the current § 35.415(a)(4). The commenter indicated there was little rationale for the current requirement and that it has been deservedly removed in the proposed rule.

Response. The NRC deleted the requirement in the current rule (§ 35.415(a)(4)) that required radiation surveys in contiguous restricted and unrestricted areas to demonstrate compliance with the requirements of Part 20. We agree that this requirement is covered by Part 20. Deleting this requirement and relying on Part 20 to ensure that adequate surveys are performed provides the licensee flexibility in performing adequate surveys. For instance, an adequate survey following a brachytherapy implant may include a radiation survey of restricted and unrestricted areas with a maximally loaded patient in a representative patient room. If the circumstances of subsequent brachytherapy patient treatments are equivalent to the initial survey conditions, we believe that the licensee may rely upon the initial survey to show compliance with Part 20.

Section 35.406, Brachytherapy source accountability.

Issue 1: Were there any changes made in this section between the proposed and final rule?

Response: Yes. The NRC changed the title of the section from "Brachytherapy source inventory," to "Brachytherapy source accountability." This title more accurately reflects the regulations in this section. The inventory requirements for sealed sources or brachytherapy sources are in § 35.67 of the final rule.

Section 35.410, Safety instruction.

Issue 1: Who must participate in annual retraining?

Comment. Many commenters questioned the need for the training required in § 35.410. Some commenters found this requirement to be very burdensome. Another commenter believed that annual retraining was not needed for certified radiation therapy technologists and, therefore, recommended that the section only require annual retraining for "persons without specialized training in handling radioactive materials." Additionally, one commenter stated that initial and annual training of all nurses and all hospital staff was not cost effective.

Response. The NRC believes that it is important that personnel caring for patients or human research subjects, who have received a brachytherapy implant and cannot be released in accordance with § 35.75, receive instruction. This instruction should include information on

how to minimize radiation exposures to the public and workers and the radiation safety actions to be taken in the case of a medical emergency or a death. We believe this provision is needed because exposures in excess of public dose limits could result if proper precautions are not taken. We also believe this requirement is consistent with ALARA principles.

We do not require training of all hospital staff. We allow the licensee flexibility in determining the appropriate level of radiation safety instruction to be provided, depending on the level of involvement by various personnel caring for the patient or human research subject. The instruction need only be commensurate with the duties of the personnel. For example, a primary care nurse may receive detailed instructions on patient and visitor control but the ward clerk may only need to be instructed to observe the caution signs on the patient's door.

We recognize that certified radiation therapy technologists, or other individuals who have received specialized training in handling radioactive materials, may have received training in the areas required by this section as part of their training program. However, we believe that refresher training is warranted because of the potential for unnecessary exposure to workers and the public if needed safety precautions are not observed.

Issue 2: When notifying an AU following a patient emergency, can a physician designee be notified if the AU is not available?

Comment. A commenter recommended that for notifications of patient or human research subject medical emergencies, the AU, like the RSO, may not always be readily available and should also have the option to specify a designee, such as another physician.

Response. Sections 35.11 and 35.27 permit an individual to use byproduct material under the supervision of an AU. Nevertheless, an AU, and not a designee, is responsible for the medical use and supervision of the byproduct material. In the event of a medical emergency involving a patient or human research subject implanted with brachytherapy source(s), the NRC believes that, because of the doses administered under § 35.400, an AU must be notified, and this notification cannot be delegated to a designee.

Issue 3. Were there any other changes made in this section between the proposed and final rule?

Response. Yes. The NRC restructured paragraph (a)(5) to clarify our intent that, for the purpose of this section, only the RSO may have a designee.

Section 35.415, Safety precautions.

Issue 1: Is it necessary to list the type and location of emergency response equipment in the regulations?

Comment. Commenters believed that the requirement to list the contents of an emergency pack was too prescriptive and confusing. Additionally, commenters felt that the emergency equipment did not need to be specifically located in the patient's room but could be somewhere accessible in the hospital. Commenters felt that the licensee should have the freedom to adequately stock and locate an emergency pack. One commenter also felt that the

phrase “supplies necessary to surgically remove applicators” kept in the patient’s room implied that surgery should be conducted in a nonsterile environment.

Response. The NRC agrees with these comments because, in a performance-based rule, the essential objectives should be stated in the regulatory text. Therefore, we revised the regulatory text to identify the essential objective of having emergency response equipment available near each treatment room. The list of specific items that are needed for emergency responses has been deleted from this section. The licensee has the flexibility to determine the type of emergency response equipment needed to respond to a source that is either dislodged from the patient or lodged within the patient following removal of the source applicators.

We agree that the emergency equipment does not need to be maintained in the treatment room. However, it should be maintained near each treatment room in order to expeditiously respond to an emergency. The rule allows the licensee some flexibility in locating the emergency response equipment. The issue of whether to conduct surgical removals of applicators or sources within a treatment room that may not be a sterile environment is left to the licensee’s discretion.

Issue 2: Can brachytherapy patients be quartered in the same room with a patient not receiving radiation therapy?

Comment. The NRC solicited specific comment on the current requirement that the licensee not quarter a brachytherapy patient in the same room as an individual who is not receiving radiation therapy. The majority of commenters agreed with the requirement that

would allow more than one brachytherapy patient in a room although a few commenters questioned this requirement. Some commenters believed that the final rule should retain the requirement that the licensee not quarter a patient in the same room as an individual who is not receiving radiation therapy. One commenter pointed out that a posted restricted room should not be shared with a patient not involved in the therapy. Another commenter believed that the requirement to prohibit placing a therapy patient in the same room as a nontherapy patient should apply not only to patients confined under § 35.75, but also to any patient where another individual in the room could receive over 1 mSv (0.1 rem). This commenter believed that limiting the requirement to only patients confined under § 35.75 was not "as low as is reasonably achievable." Conversely, other commenters suggested that the provision for a private room be deleted.

Response. In the current Part 35, the NRC permits the sharing of a brachytherapy patient room with another "individual undergoing radiation therapy." In the final rule, we clarified that the other "individual undergoing radiation therapy" refers to another brachytherapy patient. This is consistent with changes made to § 35.315 to allow therapy patients treated with unsealed material to share a room if they cannot be released under § 35.75.

We did not change the final rule in response to comments on the allowable exposure to the patient sharing the room or to individual members of the public. Section 20.1301 requires the licensee to conduct operations so that, in part, the total effective dose equivalent to individual members of the public from the licensed operation does not exceed 1 mSv (0.1 rem) in a year, exclusive of the dose contributions, in part, from exposure to individuals administered radioactive material and released under § 35.75. Section 35.75 allows release of patients

administered 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). Therefore, if the licensee confines a patient receiving brachytherapy and has not authorized the release of the patient under § 35.75, the licensee must limit the total effective dose equivalent to individual members of the public to less than 1m Sv (0.1 rem) in a year. Concurrent with this Part 35 rulemaking is a new provision in 10 CFR 20.1301(c) that allows a licensee to permit visitors to individuals who cannot be released under § 35.75 to receive a radiation dose not to exceed 5 mSv (0.5 rem), provided the authorized user has determined that it is appropriate. Alternatively, if the licensee authorizes the release of the patient receiving brachytherapy under § 35.75, the licensee must make the determination that the total effective dose equivalent to any other individual is not likely to exceed 5 mSv (0.5 rem). The licensee must also provide the released individual, or the individual's parent or guardian, with instructions on actions recommended to maintain doses to other individuals as low as is reasonably achievable, if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem). In all cases, the licensee is required, under § 20.1101, to conduct operations to achieve doses that are as low as is reasonably achievable.

Issue 3: Where should "Radioactive Materials" signs be posted?

Comment. A commenter suggested that having the option to put "Radioactive Materials" signs in the chart instead of on the door was not a good idea. This commenter felt that signs should be posted on the door and in the chart.

Response. Section 35.415(a) in the current rule specifically states that the patient's door has to be posted. The NRC revised this section to require that the licensee visibly post the patient's or human research subject's room with a "Radioactive Materials" sign. We also revised this section to allow the licensee flexibility in determining where to place the posting so that it is visible. Notations as to where and how long visitors may stay may be placed in the patient's chart or posted on the door.

Issue 4: Why is there a difference in the time periods to notify the AU and the RSO, or his or her designee, if the patient or human research subject dies or has a medical emergency?

Comment. A commenter suggested that the time periods for notification of a medical emergency and death should be the same.

Response. The NRC agrees with the comment. In the final rule, the notification time periods are the same whether the patient or human research subject has a medical emergency or dies. We also modified this section to require that, in the event of a medical emergency, the notification should be as soon as possible, rather than immediately, because the licensee's primary responsibility during a patient's medical emergency is the care of the patient.

Issue 5: Following a patient emergency, when should an AU versus an RSO be notified and can a physician designee be notified if the AU is not available?

Comment. A commenter felt that the AU should be notified and the notification of the RSO should be left to the AU's discretion. Another commenter recommended that for

notifications of medical emergencies, the AU, like the RSO, may not always be readily available and should also have the option to specify a designee, such as another physician.

Response. Sections 35.11 and 35.27 permit an individual to use byproduct material under the supervision of an AU. Nevertheless, an AU, and not a designee, is responsible for the medical use and supervision of the byproduct material. Therefore, under § 35.415(c) an AU and not a designee, must be notified in the event that a patient or human research subject has a medical emergency or dies. Under § 35.24, the RSO is responsible for implementing the radiation protection program. Therefore, we believe that notification of the RSO, or his or her designee, provides additional assurance that appropriate corrective actions to respond to any radiation safety hazard associated with the emergency or death are taken.

Issue 6. Were there any other changes made in this section between the proposed and final rule?

Response. Yes. Paragraph (a) was reworded to make it clear that the requirements in § 35.75 apply to the release of individuals, not to the confinement of individuals. In addition, paragraph (c) was restructured to clarify our intent that, for the purpose of this section, only the RSO may have a designee.

Section 35.432, Calibration of brachytherapy sources.

Issue 1: What does the term “nationally recognized body” mean and what is the policy for taking recommendations from these bodies and making them regulations?

Comment. Commenters questioned what was intended by the term “nationally recognized body” and stated that professional protocols may contain items that are recommended, but that were never intended to be adopted as regulations.

Response. Examples of nationally recognized bodies include ANSI, AAPM, ACR, ACMP, and NIST. Documents issued by nationally recognized bodies include multiple peer-reviews of the reports, protocols, or standards. The requirements in this subpart are based on recommendations found in AAPM TG-40 and TG-56 and are consistent with the calibration requirements for sealed sources and devices for therapy, including those found in ANSI documents. However, the NRC did not include all the recommendations made in these reports because we recognize the prescriptiveness of various reports. Instead, the regulation contains only the essential objectives for the test being required. For additional information on the use of consensus standards in developing the revision of Part 35 refer to Section I, Background.

Issue 2: What is the meaning of the term “intervals consistent with 1 percent physical decay?”

Comment. One commenter requested that we clarify whether the requirement meant 1.0000 percent or allowed rounding down to 1 percent. Some commenters felt that 1 percent was too prescriptive because the calibration requirements are higher. Additionally, a commenter stated that correcting the output/activity at ‘”intervals consistent with 1 percent physical decay” was not feasible for short half-life sources.

Response. This section requires that outputs or activities be corrected for physical decay at intervals consistent with 1 percent physical decay. “Rounding” is a mathematical term. “Consistent with 1 percent” includes from 0.51 percent to 1.49 percent. The 1 percent correction is separate from the calibration. The accuracy of the calibration must be within a given percentage provided by the published protocol used to perform the calibration. This calibration is then used to determine the dose delivered to the patient.

Issue 3: Should the rule contain a requirement to perform calibration measurements of brachytherapy sources and, if so, can the licensee rely on the manufacturer’s or distributor’s calibration?

Comment. In the proposed rule, the NRC solicited specific comment on requirements for brachytherapy source calibrations. Some commenters felt that the vendor’s calibration should be verified by the licensee because use of unverified vendor calibrations poses serious hazards for the patient. Other commenters believed that the calibration of brachytherapy sources should be the manufacturer’s responsibility. They also suggested that we could easily verify procedures at a few manufacturers, rather than at multiple hospitals. Some commenters also requested that we require the manufacturer to guarantee the source activity or output within 3 percent.

Response. The NRC believes that it is good practice to verify the calibration provided by the manufacturer because of the high risk associated with therapy doses to patients. Therefore, § 35.432 requires a licensee to perform calibration measurements before the first medical use of a brachytherapy source. The licensee shall determine the source output or

activity using a dosimetry system that meets the requirements of § 35.630(a); determine source positioning accuracy within applicators; and use published protocols accepted by nationally recognized bodies to meet the previous two requirements.

However, we also believe that licensees should be able to use calibration measurements provided by the source manufacturer or by a calibration laboratory accredited by the AAPM as long as it was done in accordance with a published protocol accepted by a nationally recognized body using appropriately calibrated equipment. In order to ensure the reliability of the outputs or activities reported by the manufacturer, the manufacturer must perform the calibrations in accordance with the same requirements placed on the licensee. This also addresses the issue that the manufacturer guarantee the activity or output because the manufacturer must use at least the same performance standard as the licensee.

Issue 4: What is the meaning of the term “full” in “full calibration?”

Comment. A commenter suggested that the title be changed to “Verification of calibration measurements of brachytherapy sources.” Another commenter requested clarification of the term “full” in “full calibration.” Another commenter suggested that the term “full calibration” be replaced with “spot check” and the phrase “spot check assay” should be added to be consistent with terminology used in AAPM TG-40 and TG-56.

Response. The NRC agrees that the term “full” is confusing in the title because we do not define “full.” Therefore, the title of this section has been changed to “Calibration measurements of brachytherapy sources.” Also, the term “full” has been deleted from the

regulatory text in this section. The terminology, including “calibration,” was selected to be consistent with terminology used in Subpart H of Part 35 and in AAPM and ANSI reports.

Issue 5: When should the brachytherapy sources be calibrated?

Comment. A commenter requested clarification on whether brachytherapy sources should be calibrated before the first medical use period or before the first medical use at a given facility.

Response. As written, the requirement is that each licensee must calibrate its brachytherapy sources before the first medical use at the licensee’s facility. If the licensee is licensed for medical use at more than one facility in a single license, this calibration must only be performed once, before medical use, at any of the facilities listed in the license.

Issue 6: Does the rule allow calibration of a sampling of sources when a batch of sources is received?

Comment. Some commenters suggested that for short half-life sources and pure beta-emitting sources [e.g., I-125 and palladium-103 (Pd-103)], a sampling of the sources should be allowed.

Response. The NRC does not preclude a sampling of short half-life sources when received in a large batch. The rule requires that the calibration be performed using published protocols accepted by nationally recognized bodies, such as AAPM. The AAPM, in the report

from TG-40, recommends for short half-life sources that “for groupings with a large number of loose seeds, a random sample containing at least 10 percent of the seeds be calibrated” and “for a large number of seeds in ribbons, a minimum of 10 percent or 2 ribbons (whichever is larger) should be calibrated.” However, this recommendation is made to the end user and as a verification of the source strength measurement performed by the manufacturer. The licensee must ensure that the published protocol allows for sampling of sources that have not been previously calibrated.

Issue 7: Are sources currently in the possession of the licensee exempt from the calibration requirement?

Comment. A commenter suggested that we include an exemption for sources in inventory before the requirement becomes effective.

Response. Because calibration standards and methods have varied over the years, the NRC believes that to ensure that the correct dose is given to the patient, in accordance with § 35.41, the brachytherapy source output or activity must be calibrated in accordance with published protocols currently accepted by nationally recognized bodies. Therefore, we did not revise this section to include the requested exemption for sources in inventory before the effective date of the rule. Instead, we revised this section to clarify that all brachytherapy sources must be appropriately calibrated before the first medical use after the effective date of this rule. By including this date, the rule now clearly indicates that sources currently possessed by the licensee must be calibrated before the first medical use after the effective date of this rule and in accordance with a published protocol accepted by a nationally recognized body. If

the source was previously calibrated in accordance with a currently accepted published protocol and using a dosimetry system that meets the requirements of § 35.630(a), the calibration would not need to be repeated after the final rule becomes effective.

Issue 8: Are the calibration requirements for high-dose versus low-dose sources the same?

Comment. A commenter requested that the calibration requirements make a distinction between high-dose and low-dose brachytherapy sources.

Response. The NRC does not believe that such a distinction is needed. We believe that when a therapeutic dose is delivered to a patient or human research subject, the licensee is responsible for ensuring that the correct dose is administered, regardless of the source strength.

Issue 9: Do the manufacturer's measurements need to be performed consistent with those required by the licensee?

Comment. A commenter suggested that for the manufacturer's accepted measurements, the phrase "that are made in accordance with the requirements of this section" be deleted.

Response. This phrase has been retained in the final rule. To ensure the same level of calibration, the NRC believes that unverified calibrations performed by the manufacturer must meet the same calibration standard as the calibrations required of the licensee.

Issue 10: Is the requirement for source positioning accuracy necessary?

Comment. Some commenters felt that the requirement for source positioning accuracy within applicators was vague and may be irrelevant or impossible to comply with.

Response. The NRC believes that, in order for the licensee to ensure further that the correct dose is delivered, the applicators used to help deliver the dose must be appropriately tested. We reviewed several standards currently available for calibration of brachytherapy sources. For example, AAPM TG-40 recommends, at a minimum, that initial tests be performed on brachytherapy applicators. TG-40 states that "of major concern is that the applicators position the source where they are intended to be localized, and that any part of the structures which are used to attenuate the radiation (e.g., rectal and bladder shields) have not shifted."

Issue 11: Should the accuracy of source activity or output determination be stated in the rule?

Comment. A commenter suggested that the accuracy for I-125 be changed to 10 percent because a 5 percent accuracy is not possible.

Response. The NRC deleted the reference to +/- 5 percent from § 35.432(c)(1) of the proposed rule. We do not believe that the accuracy of the source activity or output measurement needs to be stated in the rule because the published protocol addresses the accuracy requirement.

Issue 12: Is new equipment required by licensees to perform calibrations?

Comment. Several commenters indicated that the new requirement to calibrate brachytherapy sources would require licensees not currently involved in teletherapy or remote afterloader therapy to procure equipment. Additionally, a commenter requested clarification on whether a well ionization chamber (e.g., dose calibrator) was adequate for calibrating low dose rate brachytherapy sources because farmer chambers have historically been associated with § 35.630.

Response. As represented in the Regulatory Analysis accompanying this final rule, the NRC recognizes that licensees may need to procure additional equipment to meet this requirement. We believe that the additional expenditure is warranted for the licensee administering brachytherapy doses to ensure that the correct dose is administered to patients. We agree that a well ionization chamber could meet the requirement if the chamber, or source used to calibrate the chamber, is traceable to NIST or an AAPM-accredited calibration laboratory, and a published protocol accepted by a nationally recognized body is used.

Section 35.433, Decay of strontium-90 sources for ophthalmic uses.

Issue 1: Were there any other changes made to this subpart between the proposed and final rule?

Response: Yes. The NRC added this new section that requires an AMP to calculate the activity of a strontium-90 (Sr-90) source that will be used in determining the treatment time for ophthalmic uses. It also requires that the activity be calculated using the source activity determined under § 35.432.

We added this section because we are aware of numerous misadministrations involving Sr-90 for opthalmic use that were caused by individuals improperly calculating the decay of sealed sources. Given the risks associated with use of Sr-90 and the numerous misadministrations in this area, a more prescriptive requirement is warranted.

Section 35.457, Therapy-related computer systems.

Issue: Were there any other changes made to this subpart between the proposed and final rule?

Response. Yes. The NRC added this new section that is consistent with the requirement found in § 35.657 for therapy-related computer systems. The new section requires brachytherapy licensees who use treatment planning systems to perform acceptance testing on the system in accordance with published protocols accepted by nationally recognized bodies.

Section 35.490, Training for use of manual brachytherapy sources.

General comments on this section are summarized under the General Training topic found at the beginning of this section of the Federal Register notice.

Issue 1: Should training include ordering and inventory of byproduct material?

Comment. A commenter requested that we delete the following from work experience requirements: "ordering" material safely and "maintaining running inventories of material on hand." The commenter believed that there was no risk associated with these procedures.

Response. Because the AU is responsible for use of byproduct material under the license, the NRC believes that experience in ordering and maintaining inventories of radioactive materials is an important component of a training program for an AU.

Section 35.491, Training for ophthalmic use of strontium-90.

Issue 1: Were there any other changes made in this subpart between the proposed and final rule?

Response: Yes. The NRC added this new section. The proposed rule had deleted specific training and experience requirements for individuals who wanted to use Sr-90 for ophthalmic use. Under the proposed rule, these individuals would need to meet the training and experience requirements in the proposed § 35.490 or § 35.940. This change was proposed because, at that time, we believed it was warranted in view of the similarities between the use of Sr-90 eye applicators and the use of sealed byproduct material in medical devices,

and recent misadministrations involving Sr-90 eye applicators. Upon further review of the misadministrations, we believe that the majority of the misadministration events could have been prevented if an AMP had calculated the decay of the sources, rather than if NRC required additional training and experience for AUs who want to use Sr-90 for ophthalmic use. Therefore, we added a requirement for an AMP to calculate the activity of the source (§ 35.433) and have included a specific section that provides the training and experience requirements for an individual who would like to use Sr-90 sources for ophthalmic treatments.

This section is identical to § 35.941, Training for ophthalmic use of Sr-90 in the current rule with minor exceptions. We have deleted the phrase "who is in the active practice of therapeutic radiology or ophthalmology." We believe it is important that the individual is a physician and therefore this additional level of prescriptive regulation is not warranted. We have also added a requirement for a written statement, signed by a preceptor AU, stating that the individual has satisfactorily completed the training requirements and has achieved a level of competency sufficient to function independently as an AU for use of Sr-90 for ophthalmic treatments. This change is consistent with the other training and experience sections within the revised rule. The preceptor statement is discussed in more detail under the General Training topic found at the beginning of this section. Additionally, we have added a provision that a physician who meets the requirements in § 35.490 or equivalent Agreement State requirements would automatically meet the requirements to become an AU under § 35.491.

SUBPART G - Sealed Sources for Diagnosis

The NRC received comments on only three areas in Subpart G. They are: (1) SSDR; (2) availability of survey instruments; and (3) training and experience requirements. The first two topics are summarized under the “Global Changes” topic in the beginning of this section because the same comments pertain to multiple sections in the rule. Comments on the training and experience requirements are summarized under the “General Training” topic found at the beginning of this section.

SUBPART H - Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Units

General Comments.

Issue 1: Can this subpart be revised to eliminate redundant and overly prescriptive requirements?

Comment. A commenter suggested that Subpart H should be rewritten to eliminate redundancy and overprescriptive procedures that the NRC expects licensees to follow. The commenter felt that the licensees should have the ability to develop their own procedures instead of the NRC dictating each step.

Response. The NRC agrees that the rule should not be redundant and we have combined sections whenever possible. For example, in the final rule, we combined § 35.644, Periodic spot-checks for low dose-rate remote afterloaders, with § 35.643, Periodic spot-checks for high dose-rate and pulse dose-rate remote afterloader units. However, the full calibration requirements for all therapy units have been retained in separate sections for each type of unit to avoid confusion on the applicability of certain tests for a given therapy unit.

Subpart H contains requirements for emergency response and operating procedures, including full calibration and spot-check tests. Where warranted by risk, we maintained the prescriptive requirements in the rule. We identified the performance objectives for full calibrations and spot-checks in the rule. This decision was based on various AAPM and ANSI

reports. However, the exact content of these procedures has not been specified. These procedures are required to be developed by the licensee and the AMP. Where applicable, the procedures must use published protocols accepted by a nationally recognized body. We believe that this provides the licensee more flexibility in developing its procedures.

Issue 2: How have national standards been incorporated into the rule?

Comment. Commenters were concerned that we are transforming recommended "practice standards" into excessively prescriptive and unnecessarily burdensome regulatory requirements.

Response. In many sections, the rule allows licensees to develop their own procedures in accordance with multiple peer-reviewed reports, protocols, or standards. Examples include following recommendations published by the AAPM, ACR, ANSI, and ACMP. The NRC believes this provides licensees with the flexibility needed to develop their own procedures as long as they meet the minimum regulatory requirements in this subpart.

For additional information on the use of consensus standards in the final rule refer to I, Background, in the SUPPLEMENTARY INFORMATION section.

Issue 3: Were there any other changes made in this section between the proposed and final rule?

Response. Yes. The NRC changed the title of this subpart and the language in

§ 35.600 to make it clear that the requirements in this section refer to only photon-emitting remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

Section 35.600, Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.

Issue 1: Should all therapy sealed sources be required to have NIST traceability?

Comment. Some commenters said that all sources used for therapeutic applications should be required by regulation to have a NIST traceable national standard. Conversely, some commenters said that it is inconsistent to require licensees to calibrate such sources in the absence of national standards for all clinically used sources.

Response. Sections 35.632, 35.633, and 35.635 require that sealed source output be measured with a dosimetry system that has been calibrated using a system or source traceable to NIST and published protocols accepted by nationally recognized bodies or by calibration laboratory accredited by AAPM. The NRC agrees with the AAPM position that all therapy sealed sources should be calibrated in accordance with a traceable standard. In limited cases, a traceable standard identical to the therapy sealed source is not available. In these cases, §§ 35.632, 35.633, and 35.635 allow the licensee the flexibility to use protocols accepted by nationally recognized bodies to meet the calibration requirement. As an example, AAPM Report Number 21 recommends that sources used in radiation therapy have calibrations with direct or secondary traceability to national standards. AAPM defines direct traceability as “when a source or calibrator has been calibrated either at NIST or an AAPM-Accredited Dosimetry

Calibration Laboratory." AAPM defines secondary traceability as "when the source is calibrated in comparison with a source of the same design and comparable strength which has direct traceability or when the source is calibrated using an instrument with direct traceability." In addition, AAPM TG-56 recommends that for "sources that do not have a national standard yet, users should develop a constancy check calibrated against the vendor's standard and use this constancy check to verify the source strength. Another option is to develop one's own secondary standard." This allows the licensee flexibility in the event that a direct NIST traceable standard does not exist.

Issue 2: Were there any other changes made in this section between the proposed and final rule?

Response. Yes. The NRC added a new paragraph (b) to this section that allows a licensee to use therapy sources in medical research if the research is conducted in accordance with an active IDE application accepted by the FDA and if the requirements in § 35.49(a) are met. This was done to clarify how research with sealed sources could be conducted if the medical use of the sources differed from the statements found in the SSDR for the sources. With this change, we allow previously registered sources to be used for uses other than those described in the original registration process as long as the requirements in paragraph (b) are met.

Section 35.604, Surveys of patients and human research subjects treated with a remote afterloader unit.

Issue 1: What is the purpose of the survey required by this section?

Comment. A commenter requested clarification of the requirement to survey the patient or human research subject and the remote afterloader with a portable radiation detection survey instrument to confirm that the source(s) have been removed from the patient or human research subject and returned to the safe shielded position.

Response. The radiation surveys are needed to ensure that a source does not remain within the patient or outside of the source shield following completion of each treatment with the unit.

Issue 2: Who may perform the survey?

Comment. A commenter requested that the rule be revised to allow the medical physicist to train an assistant to do the radiation surveys, required by § 35.604, when the physicist is not available.

Response. The rule does not specify who must perform the surveys required by § 35.604. The NRC believes that the licensee should have the flexibility to decide who should perform the surveys. However, the record of the survey must include the name of the individual who performed the survey, in accordance with § 35.2404.

Section 35.605, Installation, maintenance, adjustment, and repair.

Issue 1: Who may repair a LDR unit?

Comment. The NRC solicited comments on whether the restrictions in this section on who may work on a device containing a sealed source should apply to LDR units. Some commenters said that the restrictions should apply to LDR units. Other commenters believed that the restrictions should only apply to LDR units if the device manufacturer recommends the restriction for the particular device. Conversely, some commenters said that the restrictions should not apply to LDR units because the risk from these low dose-rate units is minimal enough that a trained individual knowledgeable of the unit's operation could install, perform maintenance, adjust, or repair the device. They believed that we should not "over-regulate" these units. Some commenters also believed that users of nonmedical devices who perform these types of services must submit procedures that show they have had appropriate training in performing these services on the specific devices. They stated that persons who perform installation, maintenance, and repair of other NRC-regulated devices (that do not apply radiation to humans) are routinely limited to services on the specific devices for which they have training and experience, e.g., fixed gauges, radiography cameras, etc. In addition, repairs of therapy devices are not just an issue of source or cable replacement, but could also include electronics and software modifications. Consequently, they believed that none of the training and experience requirements identified in the proposed regulations provide for this kind of training. Therefore, the service provider's specific training must be evaluated by the NRC.

Response. Because of the risk associated with therapy devices, the final rule only allows an NRC or Agreement State licensed entity to install, maintain, adjust, or repair a therapy device that involves work on the source(s) shielding, the source(s) driving unit, or other

electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the therapy unit or the source(s). Additionally, these regulations limit the installation, replacement, relocation, or removal of the sealed source(s) or source(s) in a teletherapy unit, gamma stereotactic radiosurgery unit, HDR, MDR, and PDR, to an entity specifically licensed by the NRC or an Agreement State for these activities. For LDR source(s), the NRC allows an AMP or a specifically licensed entity to perform these functions. This provides relief for licensees possessing LDRs when replacing decayed sources or removing and installing sources to render each individualized treatment plan. However, for work on the LDR source(s) safe, the source(s) driving unit, or other electronic or mechanical components that may expose the source(s) or compromise the radiation safety of the unit, we believe that specialized training, in addition to the training required to meet AMP status, is necessary to perform these activities. Therefore, only personnel specifically licensed by the NRC or an Agreement State may perform these activities.

Issue 2: Does install, maintain, adjust, or repair include assembly?

Comment. A commenter suggested that the word "assembly" be added to the list of activities that must be performed by a specifically licensed person.

Response. The NRC believes that “assembly” is included within the meaning of installation and repair. Therefore, we made no change in the regulatory text.

Section 35.610, Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

Issue 1: Does the rule allow individuals other than the patient to be present in the treatment room?

Comment. Commenters indicated that therapy administrations in cardiac catheterization suites require the presence of other persons for the safety of the patient during the treatment, and may require that individuals have access to the patient through the treatment room doors without interruption of the treatment. In such cases, the commenters believed that the exposures to personnel were already limited by Part 20 requirements. A commenter also questioned the term “contraindicated” in the phrase "ensuring that only the patient . . . is in the treatment room before initiating treatment with the source(s), unless contraindicated . . .”

Response. The NRC agrees that, in limited cases, the licensee may need to allow other individuals in the treatment room during treatment. We also agree that the scope of “unless contraindicated” needs to be defined. Therefore, we modified the final rule to permit individuals approved by the AU, AMP, or RSO to be present in the treatment room, during treatment with the source(s). These individuals are in the best position to determine if an individual may be present in the treatment room during a treatment. However, licensees are still required to control the exposures of workers and members of the public in accordance with Part 20.

Issue 2: Must the console and the console keys be secured?

Comment. A commenter suggested that securing both the console and the console keys was redundant. The commenter went on to state that securing a teletherapy or a gamma stereotactic radiosurgery treatment room is unnecessary if the console or console keys are

secured because it would be highly unlikely that unauthorized individuals would remove the devices given their bulk and weight. The commenter felt that, in keeping with a performance-based rule, this section should be revised to read “prevention of unauthorized use or removal of the device when not in use or unattended.”

Response. Paragraph (a)(1) of this section specifies the mechanism for ensuring that the licensed material in therapy treatment devices is controlled when the devices are not attended or are not in use. In keeping with a performance-based rule, the NRC removed the proposed requirement for written security procedures. This allows the licensee flexibility in determining the appropriate method for meeting this requirement. General requirements for security of byproduct material are addressed in Part 20, Subpart I. However, because of the high risk posed by these sources, we believe that a more prescriptive requirement is warranted.

Issue 3: Where should emergency procedures and instructions be posted?

Comment. Some commenters said that requiring a copy of instructions and procedures to be posted only at the device console was too prescriptive. They suggested that the language should be revised to read “in the immediate vicinity of the device console.” A commenter also suggested that paragraph (c) of this section was unnecessary because it requires posting the location of the procedures, and paragraph (b) requires the procedures be posted. Another commenter suggested that, in some cases, a console may not exist.

Response. The NRC has not changed either paragraph (b) or (c) in the final rule. Paragraph (b) requires that a copy of the emergency procedures required by paragraph (a)(4)

be physically located at the unit console. Paragraph (c) requires posting the location of emergency procedures and the names and telephone numbers of the emergency contacts. Because the emergency procedures for some devices (e.g., HDR units) may consist of several volumes of error codes and their meaning, we do not require that these procedures be posted. However, the actual location (e.g., specific drawer in the console) where these procedures are stored must be posted at the unit console to alert individuals about where to find the detailed emergency procedures in the event of an emergency. We agree that this does not specifically require posting the procedures on the console, but may allow, for instance, posting them on the wall in front of the console. We also believe that a console exists for "remotely" delivered sources because the sources must be removed from the source shielding from outside of the treatment room. For cardiac units, this may be an infusion console.

Issue 4: Should device operators be listed in the license?

Comment. A commenter felt that operator knowledge was vital to prevent a medical event, but the requirements do not address operator education, training, or experience. The commenter suggested that the operator be named in the license.

Response. It is the licensee's responsibility to ensure that operators are trained. In accordance with § 35.27, operators use licensed material and operate licensed devices, depending on the activity being conducted, under the supervision of the AU. Therefore, the NRC does not believe that NRC's prior review of a specific operator's training is necessary.

Issue 5 : What is the appropriate frequency and scope of instruction?

Comment. Some commenters suggested that we clarify that persons not receiving annual refresher training are simply prohibited from operating the unit until the training is provided and that the individuals need not be removed from authorization in the institutional license. A commenter also felt that the instruction requirements were too prescriptive for the variety of devices. In addition, while it may be possible to perform a drill simulating the removal of a patient from a teletherapy unit, such a drill is not practical for an HDR unit. The commenter requested that the regulatory text be revised to read "a licensee shall provide instruction and practice drills or demonstrations, initially and at least annually . . ." Conversely, some commenters suggested that retraining was not necessary at all because the AMP and the operator routinely perform the procedures.

Response. The NRC amended the regulatory text to clarify the requirements for instruction. We believe that initial instruction and annual retraining are needed to ensure that the correct dose is administered to the patient or human research subject and to ensure that responsible individuals appropriately respond to emergencies. We also believe that emergency drills are appropriate for all devices. The requirement for training on emergency and operating procedures has been revised to clarify that the training provided is “as appropriate to the individual’s assigned duties.” We believe that the revised rule allows the licensee flexibility in determining the appropriate level of instruction to be provided depending on the level of involvement of personnel in the operation of and emergency response for the therapy unit.

Issue 6: Were there any other changes made in this section between the proposed and final rule?

Response. Yes. In keeping with a more performance-based rule, the NRC removed the requirement for a written procedure for preventing dual operation of radiation producing devices,. This allows the licensee flexibility in determining the appropriate method for meeting this requirement.

Paragraph (g) of this section was added to refer licensees to the record keeping requirements in § 35.2610.

Section 35.615, Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

Issue 1: Is it necessary to list the type and location of emergency response equipment in the regulations?

Comment. Commenters believed that the requirement to list the contents of an emergency pack was too prescriptive and confusing. Additionally, commenters believed that the emergency equipment did not need to be specifically located in the patient's room but could be somewhere accessible in the hospital. Commenters felt that the licensee should have the freedom to adequately stock and locate an emergency pack. One commenter also felt that the phrase "supplies necessary to surgically remove applicators" kept in the patient's room implied that surgery should be conducted in a nonsterile environment.

Response. The NRC agrees with these comments because, in a performance-based rule, the essential objectives should be stated in the regulation. Therefore, we revised the

regulatory text to identify the essential objective of having emergency response equipment available near each treatment room. The list of specific items that are needed for emergency responses has been deleted from this section. The licensee has the flexibility to determine the type of emergency response equipment needed to respond to a source that remains in the unshielded position or is lodged within the patient following completion of the treatment.

We agree that the emergency equipment does not need to be maintained in the treatment room. However, it should be maintained near each treatment room in order to expeditiously respond to an emergency. The final rule allows the licensee some flexibility in locating the emergency response equipment but does not preclude the licensee from placing the equipment in the room. This is especially important in the situation where heavy source shields are needed. The issue of whether to conduct surgical removals of applicators or sources within a treatment room that may not be a sterile environment is left to the licensee's discretion.

Issue 2: Is this section applicable to remote afterloader units with beta-emitting sources?

Comment. The NRC solicited specific response on whether the safety precautions in this section should apply to beta-emitting sources. Some commenters felt that the requirements in this section should not apply to remote afterloader beta-emitting sources, since the lower doses from the beta-emitting sources present a very low risk. For example, some commenters felt that paragraphs (b), (c), (d), and (g) could be waived. Other commenters did

not believe that we should waive the requirements in this section for remote afterloader beta-emitting sources in keeping with ALARA.

Response. The NRC amended the title of this subpart to make it clear that it only applies to photon-emitting units. We agree that when requirements for beta-emitting remote afterloader units are subsequently added to the regulations, many of the types of requirements described in this section may be appropriate. However, until the use and safety issues of beta-emitting remote afterloader units are fully understood, specific requirements for these units have not been incorporated into this subpart.

Issue 3: Who may generate a treatment plan?

Comment. A commenter suggested adding a requirement that only an AMP may generate an HDR treatment plan. The commenter believed that the level of complexity and the chance for error in this area certainly warranted a requirement in this area.

Response. The NRC has not changed the final rule to state who should generate a treatment plan. We believe that licensees should determine who will generate the treatment plan. Additionally, we remind licensees that under § 35.41, Procedures for administrations requiring a written directive, the licensee must develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directives, including providing the correct dose to the patient.

Issue 4: Is an intercom system necessary?

Comment. A commenter requested that the requirement for an intercom system be deleted because voice communication with the patient is not necessary during treatment. The commenter also suggested that the requirement to have an intercom system restricts treatments given by a deaf employee.

Response. Based on ANSI and AAPM recommendations and to help ensure patient and worker safety, the NRC retained the requirement for an intercom system in the final rule. This does not preclude additional use of another voice activated system that can be used by a deaf operator.

Issue 5: Should the word “expeditious” be used in the rule?

Comment. A commenter suggested that the term “expeditious” in paragraph (e) implies that, if the source is difficult to remove, the licensee will be cited. The commenter also felt that this requirement could interfere with what the physician considers to be in the best interest of the patient.

Response. The potential dose to the patient from a decoupled or jammed therapy source remaining within the patient is significant. Therefore, the NRC has retained the requirement for a licensee to only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

Issue 6: Who needs to be present during LDR treatments?

Comment. A commenter felt that treatments with an LDR unit should allow for trained individuals, working under the supervision of an AU, who have been trained in the operation of the device to be physically present during treatment initiation and an AU and AMP immediately available. Another commenter felt that the AU and the AMP should be physically present during the initiation of patient treatments involving LDR devices. This commenter also asked whether the reference to a radiation oncology physician includes a resident in training. Still another commenter requested that the NRC delete the requirement for an AU and AMP to be present for continuation of LDR treatments because the treatment may last 48-72 hours and it is not possible to have someone continually available.

Response. In response to public comments, the requirements for the presence of trained personnel during LDR, MDR, and PDR treatments were amended. The final rule does not contain any requirements for the presence of trained personnel for LDR treatments. The risk associated with use of byproduct material in an LDR and manual brachytherapy are similar. Therefore, the NRC does not believe that regulatory text is needed in this area.

For MDR and PDR units, an AMP must be physically present during the initiation of patient treatments and must be immediately available during continuation of the treatments. The final rule allows an AU to permit a physician, working under his/her supervision and with training specific to operation and emergency response for the unit, to be physically present in place of the AU during initiation of patient treatment involving an MDR or PDR unit. The final rule also allows the AU to permit an individual, working under his/her supervision and with training in removing source applicator(s), to be “immediately available” in place of the AU during continuation of patient treatment involving an MDR or PDR unit. Because the treatment times

for pulsed dose-rate treatments are significantly longer than those for high dose-rate treatments and the activities of pulsed dose-rate sources are approximately one-tenth of the activities of high dose-rate sources, the change in physician attendance during pulsed dose-rate treatments is warranted. Additionally, for normal resumption of treatment controlled by the pulsed dose-rate device during the normal continuation of the treatment, the presence of a medical professional is not required. This revision allows the licensee flexibility in determining the appropriate personnel to have physically present or "immediately available" for medical response to patients treated with these units.

Issue 7: Who needs to be present during HDR treatments?

Comment. Some commenters believed that a physician and a properly trained radiation therapy technologist should be present for HDR treatments. The commenters believed that the responsibility for the device is the AU's, since this is an FDA-approved device. Another commenter believed that the physical presence of an AMP is sufficient if an AU, or a physician trained to respond to an emergency, could be summoned to the HDR unit console within 2 minutes. Some commenters also requested that all remote afterloader requirements be combined because the present requirements are repetitive.

Response. The NRC believes that the requirements for HDR units should differ from the requirements for LDR, MDR, and PDR treatments because the treatment times and the source activities differ significantly. We believe that the requirements appropriately address emergency situations.

An AMP is required to be physically present during the initiation and continuation of all patient treatments involving the unit. The final rule allows an AU to permit a physician, working under his or her supervision, to be physically present in place of the AU during continuation of patient treatment as long as the physician has received operating and emergency response training for the device and as long as the AU is physically present during initiation of the patient treatment. We believe that this revision is appropriate because it allows the licensee flexibility in determining who should be physically present during treatments involving HDR units.

Issue 8: Who needs to be present during gamma stereotactic radiosurgery treatments?

Comment. A commenter requested that for gamma stereotactic radiosurgery treatments, an AU or anyone trained in the setting of the coordinates and emergency procedures should be present. Another commenter suggested that emergency response could be limited to requiring the presence of a physician capable of dealing with the patient's medical needs and two individuals trained in emergency procedures particular to the unit. Still another commenter suggested that we require continuous monitoring by one trained individual and monitoring by an AU during the start and the end of the treatment.

Response. The NRC requires the physical presence of an AU and an AMP throughout all patient gamma stereotactic radiosurgery treatments to ensure appropriate response to an emergency and to ensure that the correct dose is delivered to the patient.

Issue 9: Were there any other changes made in this section between the proposed and final rule?

Response. Yes. The NRC amended paragraph (b)(2) to delete the word " immediately." We did not believe the word was needed because the text clearly indicates that the interlock system must cause the sources to be shielded when an entrance door is opened.

We also added a requirement to § 35.615 (f) that an AU and an RSO, or his or her designee, must be notified in the event the patient or human research subject has a medical emergency or dies. This notification requirement is similar to § 35.415(c) and provides consistency in the requirements for therapy devices and manual brachytherapy. In cases where an AU is physically present during the patient treatment, the notification need only be made to the RSO.

Section 35.630, Dosimetry equipment.

Issue: Is calibrated dosimetry equipment needed for low dose-rate therapy?

Comment. A commenter suggested that licensees routinely do not have or have available, other than through a source provider, calibrated dosimetry equipment that is applicable to the lower dose-rates used in standard brachytherapy. Therefore, the commenter requested that dosimetry equipment only be required for higher dose-rate procedures.

Response. As noted in the Regulatory Analysis accompanying this final rule, the NRC recognizes that licensees may need to procure additional equipment to meet this requirement. We believe that the additional expenditure is warranted for the licensee administering therapeutic doses to ensure that the correct dose is administered to patients. However, we

added regulatory text on the use of the source output or activity determined by the manufacturer so that this section is consistent with the requirements in Subpart F, Manual Brachytherapy. In the final rule, a licensee using an LDR source(s) may rely on the manufacturer's calibration, and hence the manufacturer's calibration equipment, as long as the equipment and source calibration is performed in accordance with protocols accepted by nationally recognized bodies.

Section 35.632, Full calibration measurements on teletherapy units.

Issue 1: What does the term "nationally recognized body" mean and what is the policy for making recommendations from these bodies into regulations?

Comment. Commenters questioned what was intended by the term "nationally recognized body" and stated that professional protocols may contain items that are recommended but that were never intended to be adopted as regulations.

Response. "Nationally recognized bodies," as used in Part 35, refers both to official standards consensus bodies that are identified on the NIST website and to those professional organizations that develop their reports, protocols, or standards using a consensus process and multiple peer-reviews. Examples of nationally recognized bodies include ANSI, AAPM, ACR, and ACMP. The requirements in this subpart are based on recommendations found in ANSI and AAPM reports and are consistent with the calibration requirements for other sealed sources and devices for therapy. However, the NRC did not include all the recommendations made in the ANSI and AAPM reports nor did we adopt them as regulations because we recognize the

prescriptiveness of various reports. Instead, the regulation only contains the essential objectives for the test being required are listed in the rule.

For additional information on the use of consensus standards from nationally recognized bodies, refer to Section I, Background, and the discussion of industry standards in the beginning of this section.

Issue 2: What is the meaning of the term “intervals consistent with 1 percent physical decay"?

Comment. One commenter requested that we clarify whether the requirement meant 1.0000 percent or allowed rounding down to 1 percent. Some commenters felt that 1 percent was too prescriptive because the calibration requirements are higher. Additionally, a commenter requested that the posted values be within 1 percent of the mathematically corrected values.

Response. This section in the final rule requires that outputs be corrected for physical decay at intervals not exceeding 1 month for cobalt-60, 6 months for cesium-137, or at intervals consistent with 1 percent decay for all other nuclides. “Rounding” is a mathematical term. “Consistent with 1 percent” includes from 0.51 percent to 1.49 percent. The 1 percent correction is separate from the output full calibration. The accuracy of the output full calibration must be within +/- 3 percent in accordance with paragraph (b)(1) of this section. This calibration is then used to determine the dose delivered to the patient.

Issue 3: What is the meaning of the term “calibrate” when referring to timer accuracy and linearity?

Comment. Commenters requested the meaning of “calibrate” when referencing timer accuracy and linearity. The commenters suggested that, if the purpose is to measure these items to assure they are within some tolerance, this purpose should be stated in the regulation.

Response. Procedures for calibrating the timer are provided in various protocols, which include tolerances. Examples include ANSI N449 and N449-1, “Procedures for Periodic Inspection of Cobalt-60 and Cesium-137 Teletherapy Equipment”; and AAPM TG-40. As stated in this regulation, the calibration must be performed in accordance with published protocols accepted by nationally recognized bodies. The term calibrate, as used in this context, means to perform measurements to assure that the timer is operating appropriately within a given tolerance. The tolerances may be found in reports such as AAPM TG-40. Therefore, the licensee is given flexibility in developing its calibration methods.

Issue 4: Why are repetitive output measurements necessary?

Comment. A commenter agreed with the requirement for full calibration of sources. However, the commenter suggested that repetitive output checks of long-lived sources, such as cesium, was unnecessary because the output is not going to change as long as the source is not leaking.

Response. When delivering a therapeutic dose to a patient or human research subject, the NRC believes that the licensee is responsible for ensuring that the correct dose is administered. Additionally, in accordance with § 35.41, the licensee must implement procedures to ensure that the dose is administered in accordance with the written directive. As part of ensuring that the correct dose is administered, we believe that the source output for all sources used to administer a therapeutic dose must be calibrated and verified. We also agree with published protocols, such as ANSI and AAPM recommendations, that include periodic recalibration of source activity when delivering therapeutic doses. Therefore, we retained the proposed calibration requirements in the final rule.

Section 35.633, Full calibration measurements on remote afterloader units.

Issue 1: Why are repetitive output measurements necessary and shouldn't the output test requirements reference the equipment calibration requirements?

Comment. A commenter agreed with the requirement for full calibration of sources. However, the commenter suggested that repetitive output checks of long-lived sources, such as cesium, was unnecessary, because the output is not going to change as long as the source(s) is not leaking. Another commenter suggested that the output calibration requirement should reference the requirement for dosimetry equipment in § 35.630.

Response. When delivering a therapeutic dose to a patient or human research subject, the NRC believes that the licensee is responsible for ensuring that the correct dose is administered. Additionally, in accordance with § 35.41, the licensee must implement

procedures to ensure that the dose is administered in accordance with the written directive. As part of ensuring that the correct dose is administered, we believe that the source output for all sources used to administer a therapeutic dose must be calibrated and verified. We also agree with published protocols, such as AAPM recommendations, that include periodic recalibration of source activity when delivering therapeutic doses. Therefore, we retained the proposed calibration requirements in the final rule. However, for consistency with manual brachytherapy, which is traditionally low dose-rate, we included an allowance for LDR sources in the final rule. Paragraph (f) allows licensees using LDRs to accept the manufacturer's calibration of the unit and source as long as the manufacturer conducted the calibration in accordance with this section and with a published protocol accepted by a nationally recognized body and used a dosimetry system as described in § 35.630(a) to measure the output.

Issue 2: What system tests and tolerances should be included in calibration requirements?

Comment. Commenters requested the meaning of "calibrate" when referencing source guide tubes, connectors, and timer accuracy and linearity. If the purpose is to measure these items to assure they are within some tolerance, the commenters suggested that this purpose be stated in the regulation. Another commenter suggested that timer accuracy is irrelevant to dosimetry as long as the timer functions the same at the time of treatment as at the time of calibration (i.e., consistency), and responds linearly. Some commenters requested deletion of: (1) timer accuracy and linearity for LDR and PDR units; (2) guide tube calibrations; (3) connector length calibrations; (4) autoradiograph of LDR sources to verify inventory (because sources are difficult to remove from the unit); and (5) battery backup checks (should only be

performed at preventative maintenance inspection conducted by the manufacturer). Additionally, a commenter suggested that a reasonable positioning accuracy was 2 millimeters for an HDR stepping source and 5 millimeters for an LDR source (reference AAPM TG-59). A commenter also requested that the NRC clarify that tests for tubes and connectors apply to tubes and connectors in use, and that no tests are required if the unit is not in use.

Response. Various professional reports provide suggested protocols for quality assurance tests on remote afterloaders. The NRC based the performance objectives for various tests in this section on recommendations made by AAPM TG-56. For instance, AAPM TG-56 suggests 1 millimeter positional accuracy for HDR, LDR, and PDR units; initial, annual, and quarterly battery backup checks; timer accuracy tests for LDR units; and autoradiograph of LDR sources. We agree with the recommendations made in AAPM reports and believe that the calibration requirements in this section are warranted to ensure that the correct dose is administered to the patient.

The terminology used in this section was chosen to reflect the current language used in practice. AAPM reports use “timer accuracy and linearity, applicators, transfer tubes, and transfer tube-applicator interfaces.” We noted small discrepancies in the terminology used in the proposed requirements versus in AAPM reports. Therefore, we revised the term “source guide tube” to “source transfer tube” and the term “connector” to "transfer tube-applicator interface” in the final rule. The tests apply only to units and accessories in use.

Issue 3: How frequently should recalibrations be performed?

Comment. A commenter stated that a full calibration is always performed immediately after the source exchange. However, it is probable that the source exchange for an iridium-192 HDR source may take more than 120 days. The commenter suggested that a full calibration on the source after 120 days was not necessary if the source was not yet exchanged for a new source. Another commenter agreed with the proposed requirement that HDR units should be calibrated within 120 days and that LDR units should be calibrated annually, within 1 year. A commenter also requested clarification of the phrase "not exceeding one quarter."

Response. The NRC believes that, for iridium-192 (Ir-192) HDR sources, the source calibration frequency can be changed to "at source exchange" to allow for source exchanges that slightly exceed the 120-day period. Therefore, the frequency for full recalibration of HDR, MDR, and PDR units has been revised to quarterly for sources whose half-lives exceed 75 days. We believe that this revision will facilitate the use of sources with short half-lives. We also believe that this revision will not reduce safe use of sources whose half-lives are less than 75 days (e.g., Ir-192), because these sources are exchanged at the end of their useful life, which is approximately quarterly for Ir-192. The requirement to perform a full calibration at source exchange has been retained. The phrase "not exceeding one quarter" can be equated to a 3-month period.

Issue 4: Who is required to perform the decay corrections for source output?

Comment. A commenter requested that dosimetrists be allowed to perform decay corrections.

Response. The AMP remains responsible for performing decay corrections because of the high consequence associated with errors in these corrections.

Issue 5: Were there any other changes made in this section between the proposed and final rule.

Response. Yes. The NRC deleted the requirement to repeat the full calibration of the remote afterloader unit and source, whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration. We deleted this requirement because the requirement to perform output spot-checks on remote afterloader units was deleted from § 35.643.

We also revised § 35.633(b) to include patient dose delivery components for LDR units that are detailed in AAPM TG-56. Specifically, the requirements in paragraphs (b)(4), (b)(5), (b)(6), and (b)(7) were moved in the final rule so that they apply to all remote afterloaders, including LDRs. The items in these paragraphs are measurement of the length of the source transfer tubes and applicators; measurement of the timer accuracy and linearity over the typical range of use; and function tests of the source transfer tubes, applicators, and transfer tube-applicator interfaces. We believe that these changes are necessary to ensure that, during acceptance testing of the units, including LDR units, and after source replacement, these additional tests that increase patient radiation safety are performed.

Section 35.635, Full calibration measurements on gamma stereotactic radiosurgery units.

Issue 1: What is the meaning of the term “calibrate” when referring to timer accuracy and linearity?

Comment. Commenters requested the meaning of “calibrate” when referencing timer accuracy and linearity. The commenters suggested that, if the purpose is to measure these items to assure they are within some tolerance, this purpose should be stated in the regulation.

Response. The terminology used in this section reflects the current language used in practice. AAPM reports use “timer accuracy and linearity.” As stated in this regulation, calibrations must be performed in accordance with published protocols accepted by nationally recognized bodies. The term calibrate, as used in this context, means to perform measurements to assure that the timer is operating appropriately within a given tolerance. The tolerances may be found in reports such as AAPM TG-40. Therefore, the licensee is given flexibility in developing its calibration methods.

Issue 2: Can the licensee adopt the manufacturer’s measurements for relative helmet factors?

Comment. A commenter suggested that many users currently adopt the manufacturer’s recommended relative helmet factors rather than measure them directly. The commenter stated that this was preferable because: (1) there are inherent difficulties in measuring these factors; (2) requiring users to measure their own factors could result in large errors in some situations; and (3) using the manufacturer’s factors aids in sharing information among facilities conducting research protocols.

Response. The NRC believes that measurement of helmet factors is inherent in patient dosimetry. Various professional reports provide suggested protocols for quality assurance tests on gamma stereotactic radiosurgery units. The performance objectives for various tests in this section are based on recommendations in AAPM Report No. 54. For example, AAPM Report No. 54 recommends that helmet factors be measured by the end user. However, in the final rule we changed the proposed requirement for annual measurements of relative helmet factors to require only measurements before the first medical use of the helmet and following any damage to the helmet.

Issue 3: Were there any other changes made in this section between the proposed and final rule?

Response. Yes. The NRC added the components related to the delivery of the dose to the patient that are in § 35.645, Periodic spot-checks for gamma stereotactic radiosurgery, because all patient dose delivery components detailed in the periodic spot-check section, § 35.645, were not included in the proposed full calibration requirements, and, therefore, were not required during initial quality assurance testing on the unit or after source replacement. The new paragraphs (b)(7) through (b)(10) in the final rule include tests of the treatment table retraction mechanism, helmet microswitches, emergency timing circuits, and stereotactic frames and localizing devices (trunnions). We believe that these changes are necessary to ensure that these additional tests involving patient radiation safety are performed during acceptance testing of the unit and after source replacement. These additions are consistent with the approach used in the teletherapy unit requirements for full calibration and spot-checks.

Section 35.642, Periodic spot-checks for teletherapy units.

Issue 1: What is the meaning of the term “calibrate” when referring to timer accuracy and linearity?

Comment. Commenters requested the meaning of “calibrate” when referencing timer accuracy and linearity. The commenters suggested that, if the purpose is to measure these items to assure they are within some tolerance, this purpose should be stated in the regulation.

Response. Procedures for calibrating the timer are provided in various protocols, which include tolerances. Examples include ANSI N449 and N449-1, and AAPM TG-40. The term calibrate, as used in this context, means to perform measurements to assure that the timer is operating appropriately within a given tolerance. The tolerances may be found in reports such as AAPM TG-40. As stated in this regulation, the measurements must be performed in accordance with procedures established by the AMP. The licensee is therefore given flexibility in developing its spot-check methods.

Issue 2: Were there any changes made in this section between the proposed and final rule?

Response. Yes. Paragraph (f) was revised to add a reference to the procedures required by paragraph (b).

Section 35.643, Periodic spot-checks for remote afterloader units.

Issue 1: Is an output spot-check necessary?

Comment. Commenters requested deletion of the output spot-check because output is calibrated at installation and by the manufacturer, thereby satisfying all the requirements for assuring correct dosimetry and administration. A commenter also suggested that a requirement to determine the output with a dosimetry system described in § 35.630(b) be included.

Response. The NRC agrees that the full calibration output measurements are adequate. Therefore, we have deleted the proposed output spot-check requirement. We believe that a quarterly test for HDR, MDR, and PDR source output and an annual test of LDR source output are sufficient to ensure that the correct dose is delivered to the patient. In the place of the output check, we have included a requirement to check the computer decayed source activity against a precalculated decay chart to confirm that the unit has decayed the source activity properly. The output checks done in accordance with § 35.633 continue to require the use of an appropriate dosimetry system, described in § 35.630, when performing the output calibration.

Issue 2: How frequently should spot-checks be performed?

Comment. Some commenters suggested that the spot-checks be done each day of use, thereby insuring patient safety and not duplicating weekly checks. A commenter requested that the term “beginning of each day of use” be revised to “prior to the use of the device on a given day.” Another commenter suggested that the frequencies provided in

NUREG/CR-6276, “Quality Management in Remote Afterloading Brachytherapy”, should be used. With regard to timer constancy, a commenter felt that a monthly check was adequate for LDR units.

Response. The regulation has been amended to state “before the first use of an HDR, MDR, or PDR unit on a given day.” The NRC developed the frequency of the spot-checks from recommendations of AAPM TG-40 and TG-56, meetings with medical physicists, input from the Therapy Subcommittee of the ACMUI, and NUREG/CR-6276. Therefore, we believe that the frequencies of the spot-checks are appropriate.

Issue 3: What is the meaning of the term “calibrate” when referring to timer constancy/accuracy and linearity?

Comment. A commenter requested that timer constancy be deleted because it is not a credible source of risk to the patient with the current timer technology. The commenter stated that this is verified at installation and needs no further monitoring. Commenters also requested the meaning of “calibrate” when referencing timer accuracy and linearity. The commenters suggested that, if the purpose is to measure these items to assure they are within some tolerance, this purpose should be stated in the regulation.

Response. The terminology used in this section was chosen to reflect the current language used in practice. AAPM reports use the terminology “timer accuracy and linearity.” The term calibrate, as used in this context, means to perform measurements to assure that the timer is operating appropriately within a given tolerance. The tolerances may be found in

reports such as AAPM TG-40. As stated in this regulation, the measurements must be performed in accordance with procedures established by the AMP. The licensee is given flexibility in developing its spot-check methods. The NRC has also retained timer checks because they are recommended by the AAPM and are similar to ANSI requirements for teletherapy units. Spot-checks of timer linearity are not required by this section because we believe that timer linearity for remote afterloaders needs only to be measured during full calibration measurements.

Issue 4: Why must nonexistent source exposure indicator lights be checked?

Comment. A commenter suggested that checks of source exposure indicator lights be deleted because these lights do not exist on a remote afterloader unit.

Response. The NRC is unaware of any remote afterloader units that do not have source exposure indicator lights. Source position indicator light checks are recommended by the AAPM and are similar to ANSI requirements for teletherapy units. Therefore, these requirements have been retained in the final rule.

Issue 5: Is it necessary to perform a simulated cycle of treatment?

Comment. A commenter suggested that the requirement to conduct a simulated cycle of treatment should be deleted because it is vague and will not necessarily provide any higher level of assurance that the remote afterloader unit is working properly than the daily and monthly checks already performed.

Response. The NRC agrees with this comment and has deleted this requirement.

Issue 6: Does a treatment system have to be locked-out if the system fails safety tests, but a backup system is available?

Comment. A commenter suggested that the NRC change the wording in this section to be more flexible. The commenter stated that, in some instances, a backup device may be available that will allow patient treatments to continue without compromising patient safety.

Response. This section does not prohibit the use of the unit if the licensee replaces the malfunctioning system before using the unit for treatment. Additionally, the requirement to arrange for prompt repair of a system has been deleted from this section. The NRC believes that the requirement to lock the control console in the off position and not use the unit until repaired is sufficient.

Issue 7: Should door interlocks and audiovisual systems apply to LDR units?

Comment. The NRC solicited specific comment as to whether the requirements for electrical interlocks and audiovisual systems should apply to low dose-rate remote afterloader units. Some commenters felt that LDR units may not require interlocks or audiovisual systems, depending on the dose rate and whether sources are gamma-emitters only. One commenter suggested that we always require interlocks, but require an audiovisual system only when direct visual contact is not available. Another commenter felt that we should always require interlocks and an audiovisual system for LDR units.

Response. The NRC amended the title of this subpart to clarify that it only applies to photon-emitting units. We have retained the requirements for interlocks for LDR units because they are consistent with recommendations in AAPM reports. We have not included a requirement for an audiovisual system for an LDR.

Issue 8: Were there any changes made in this section between the proposed and final rule?

Response. Yes. Paragraph (f) was revised to add a reference to the procedures required by paragraph (b).

Section 35.645, Periodic spot-checks for gamma stereotactic radiosurgery units.

Issue 1: How frequently should spot-checks be performed?

Comment. A commenter suggested that the requirement for monthly checks be deleted if spot-checks are performed daily. A commenter specified that the term “beginning of each day of use” be revised to “prior to the use of the device on a given day.” Another commenter suggested that the frequencies provided in NUREG/CR-6324 should be used. Other commenters said that: (1) a daily output measurement was not necessary as long as the user checks the mechanical integrity of the system through a standard run; and (2) the manufacturer recommends that the battery backup system only be tested on a monthly basis.

Response. The regulation has been amended to state “before first use of the unit on a given day.” The NRC developed the frequency of the spot-checks from recommendations of AAPM Report No. 54, meetings with medical physicists, input from the Therapy Subcommittee of the ACMUI, and NUREG/CR-6324, “Quality Assurance for Gamma Knives.” We believe that the final rule distinguishes between the checks that must be done daily or monthly. Additionally, the final rule only requires output checks and battery backup checks monthly. Therefore, we believe that the frequencies of the spot-checks are appropriate.

Issue 2: Define “assure proper operation of stereotactic frames and localizing devices?"

Comment. A commenter requested that we clarify what is meant by “assure proper operation of stereotactic frames and localizing devices.”

Response. Various professional reports provide suggested protocols for quality assurance tests on gamma stereotactic radiosurgery units. For instance, reports from AAPM, ACR, ACMP, and ANSI may be used by the licensee in performance of these tests. The phrase “assure proper operation of stereotactic frames and localizing devices” means to perform quality assurance tests on these devices to assure that they operate appropriately when used to deliver a dose to a patient. The measurements must be performed in accordance with procedures established by the AMP. The licensee is, therefore, given flexibility in developing its spot-check methods.

Issue 3: What is the meaning of the term “calibrate” when referring to timer accuracy and linearity?

Comment. Commenters requested the meaning of “calibrate” when referencing timer accuracy and linearity. The commenters suggested that, if the purpose is to measure these items to assure they are within some tolerance, this purpose should be stated in the regulation.

Response. The terminology used in this section reflects the current language used in practice. AAPM reports use “timer accuracy and linearity.” The term calibrate, as used in this context, means to perform measurements to assure that the timer is operating appropriately within a given tolerance. The tolerances may be found in reports such as AAPM TG-40 The measurements must be performed in accordance with procedures established by the AMP. Therefore, the licensee is given flexibility in developing its spot-check methods.

Issue 4: Were there any other changes made in this section between the proposed and final rule?

Response. Yes. The NRC deleted the requirement to check the hydraulic cutoff mechanism because we believe that checking the hydraulic backup system monthly is sufficient.

We revised the regulatory text to make the spot-checks, and associated corrective actions, consistent with the requirements in §§35.642 and 35.643. Paragraph (b)(1) requires that licensees perform spot-checks in accordance with written procedures established by the AMP. Paragraph (b)(2) requires that the AMP review the results of the spot-checks within 15 days and notify the licensee as soon as possible in writing of the results of the spot-checks.

Paragraph (g) was revised to add a reference to the procedures required by paragraph (b).

Section 35.647, Additional technical requirements for mobile remote afterloader units.

Issue 1: What are the requirements for discontinuing use of a malfunctioning unit?

Comment. A commenter noted that this section did not contain a requirement for discontinuation of use of a malfunctioning unit and questioned whether this was an oversight.

Response. The NRC agrees with this comment. We believe that a licensee using a mobile unit must also meet the requirements described in other sections of this subpart applicable to the particular device in use. However, for clarification, we added language that prohibits the use of the unit if a safety check is failed. Paragraph (d) now reads: "If the results of the checks required in paragraph (b) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system."

Issue 2: Were there any other changes made in this section between the proposed and final rule?

Response. Yes. Consistent with the terminology used in § 35.633, "connectors" was revised to "source transfer tubes, and transfer tube-applicator interfaces."

Section 35.652, Radiation surveys.

Issue 1: Are these surveys limited to therapy units?

Comment. A commenter questioned whether the surveys required by this section were only for therapy devices or if they included other instruments or devices used at medical facilities.

Response. The requirements of Part 35 apply only to medical uses of byproduct material. The requirements in this section apply to licenses issued for uses in this subpart. Therefore, these requirements do not include sealed sources covered by other subparts (e.g., Subparts F and G). The NRC added the phrase “licensed under this subpart” to this section to clarify this issue.

Issue 2: Why do radiation levels around devices differ?

Comment. Commenters suggested that the maximum radiation levels and average radiation levels around devices could be made a generic number, as with radiography cameras and source changers. They also suggested that it may make sense to put in the average acceptable reading for each type of afterloader unit (i.e., high dose-rate, low dose-rate, and pulsed dose-rate units).

Response. The radiation levels referenced in the SSDR differ greatly by device manufacturer. Therefore, the NRC retained the requirement in paragraph (a) of this section “to

ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry."

Section 35.657, Therapy-related computer systems.

Issue 1: What is the purpose of acceptance testing on computer operating systems?

Comment. Commenters felt that acceptance testing of computer operating systems should be deleted because no method could guarantee that software would always operate appropriately. A commenter also said that this requirement should be deleted because it appears to be a year 2000 concern with operating systems.

Response. The NRC agrees with these concerns and has deleted the requirement to verify operability of computerized operating systems. This concern is addressed by the FDA's regulations of medical devices, which require reliability testing on computerized operating systems.

Issue 2: Should acceptance testing of treatment planning systems be a requirement?

Comment. Commenters believed that the requirement for treatment planning system acceptance testing was warranted. However, they suggested that the methodology for acceptance testing should be left to the licensee. The commenters also questioned the ability

to guarantee that the systems are operating appropriately and questioned our interest in the device operating system that is reviewed by the FDA.

Response. Paragraph (a) of this section in the proposed rule would have required the licensee to verify that the computerized operating system and treatment planning system are operating appropriately. Based on these comments, FDA's review of reliability testing on medical devices, and the device's associated computer operating systems, the NRC deleted these requirements from the final rule.

We agree with commenters that treatment planning system acceptance testing is warranted. Therefore, the requirement to perform acceptance testing on treatment planning systems has been retained. We believe that this requirement is appropriate and still provides the licensee flexibility in designing its acceptance testing program. We amended the regulation to incorporate the components of acceptance testing addressed in AAPM TG-56. The licensee is provided flexibility in performing acceptance testing of treatment planning systems as long as a published protocol accepted by a nationally recognized body is used and as long as the minimum testing requirements are met.

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

Issue 1: Were there any changes made in this section between the proposed and final rules?

Response. Yes. The NRC revised paragraph (b)(3) to read " an authorized user of *each* type of therapeutic unit for which the individual is requesting authorized user status." This change clarifies that the preceptor authorized user must certify that the individual has achieved a level of competency sufficient to function independently as an authorized user for *each* type of unit for which the individual would like authorized user status. However, this does not mean that the individual has to satisfy paragraphs (b)(1) and (b)(2) in their entirety for each type of unit, e.g., an individual does not need 1400 hours in a structured educational program if he or she wants to be an AU for two types of units under § 35.690.

In paragraph (b)(3) we also clarified that the preceptor AU must be an AU for *each* type of unit for which he or she is a preceptor.

General comments on this section are summarized under the General Training topic found at the beginning of this section.

SUBPART J - Training and Experience Requirements

Issue 1: Why are there two sets of training and experience requirements in the revised 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 2 subparts within the same part, or they should only be listed once in the part.

Response. The NRC has deleted Subpart J, so there is only one set of training and experience requirements in the final rule. All medical use licensees will have to comply with the new training and experience requirements for AUs, AMPs, ANPs, and RSOs in Subparts B and D through H when the rule becomes effective on [insert date 6 months from publication of the Final Rule].

Individuals who have status as AUs, AMPs, ANPs, and RSOs at the time the rule becomes effective will be “grandfathered” under § 35.57, and will not have to satisfy the new training and experience requirements. For additional information on the “deemed status” of individuals when the final rule becomes effective refer to the general discussion of the training and experience requirements at the beginning of this section.

Issue 2: Why were the lists of certifying medical boards in Subpart J of the current Part 35 not updated during the rulemaking to include other medical specialty boards and other subspecialties?

Comment. Several commenters noted that there are other medical specialty boards and other subspecialties that should be added to the lists of certifying boards in Subpart J.

Response. The suggested updates were not made in the final rule because Subpart J was deleted and there are no lists of certifying specialty boards in the new training and experience requirements in Subparts B and D through H of Part 35. Under the new regulations, the NRC will continue to review the appropriate training and experience requirements of the boards and recognize the boards that satisfy these requirements. However, we will provide the lists of recognized boards in a public document (e.g., on NRC's Internet site <www.nrc.gov>), rather than in the regulations. Before the effective date of the final rule, we encourage the certifying boards to submit their applications for recognition under the new regulations. For additional information on the recognition of specialty boards refer to the general discussion of the training and experience requirements at the beginning of this section.

Issue 3: Why have the references to ACGME programs been retained in Subpart J?

Comment. Several commenters said that all references to ACGME programs of less than 2 years should be deleted.

Response. The NRC deleted Subpart J, including the references to ACGME programs of less than 2 years.

Issue 4: Why are there no training requirements for endovascular brachytherapy in Subpart J?

Comment. One commenter noted that Subpart J includes no training requirements for endovascular brachytherapy.

Response. The NRC has deleted Subpart J. When the research on endovascular brachytherapy is completed, the standard protocol for this technology will be evaluated to determine if it is similar to the modalities currently licensed under Part 35 or if it should be licensed as an emerging technology under § 35.1000. Following this determination, the training and experience requirements for this modality will be evaluated to see if new requirements are needed for this use or if it should continue to be regulated as a sealed source therapy.

Section 35.981, Training for experienced nuclear pharmacists.

Issue 1: What is the impact of deleting this section?

Comment. All of the commenters that responded to this question, which the NRC asked in the proposed rule, said that this section could be deleted because the requirements in § 35.57 for an experienced nuclear pharmacist are adequate.

Response. Because neither the commenters nor the NRC staff and the ACMUI could identify a current scenario in which an individual would need to use this section to become an ANP, this section was deleted, along with the other sections of Subpart J.

SUBPART K - Other Medical Uses of Byproduct Material or Radiation from Byproduct Material

Section 35.1000, Other medical uses of byproduct material or radiation from byproduct material.

Issue 1: What is the purpose and scope of this section?

Comment. There were a number of general comments on this section. Comments ranged from an endorsement of the need for this section to concerns that NRC's regulations for emerging technologies will limit the use of new technologies and radiopharmaceuticals and, consequently, affect the delivery of high quality health care.

Some commenters believed that the purpose of this section is vague, undefined, and confusing, and that there needs to be a clearer definition of an emerging technology. One suggestion was that the definition be tied to whether an IND/IRB approval is required. Another commenter said that this section should specifically exempt radiopharmaceuticals because they are regulated by the FDA under RDRC, new drug applications (NDA), biologic product license applications (PLA), and INDs. Thus, all radiopharmaceuticals should fit under Subpart D or E.

One commenter said that emerging technology uses should be reviewed on a case-by-case basis to determine their proper location in the regulations. The commenter proposed a process to determine how an emerging technology should be regulated: propose performance-based regulations for a 90-day comment period; locate the regulations in a separate subpart;

and establish that any technology placed in this subpart would have a 5-7 year sunset period at which time the regulations for this technology would be relocated in another appropriate subpart. This process would provide the opportunity for the technology to establish itself and allow the regulations to be amended, based on observed risk.

Response. The NRC added Subpart K to Part 35 so that there would be codified regulatory requirements and a more clearly defined process to obtain a license, or a license amendment, for a new medical use of byproduct material or radiation from byproduct material, i.e., an emerging technology. By adding requirements for emerging technologies to the regulations in §§ 35.12(d) and 35.1000, an applicant for a medical use that does not fit the regulatory requirements for another subpart knows the type of information to submit to NRC.

The scope of this subpart includes all new medical uses of byproduct material or radiation from byproduct material. We have not attempted to define what is included in this subpart or what is excluded from this subpart more clearly because there is no way to predict what types of medical technologies will be developed in the future. The Commission, with input from the ACMUI, as requested, will determine if the emerging technology is truly a new technology and is covered by Subpart K, or if the “new” technology is actually a type of use regulated under Subparts D through H.

Issue 2: What process will be used to establish regulatory requirements and evaluate applications for emerging technologies?

Comment. Commenters stated that it is important to have a reasonable regulatory scheme and time frame for approving applications for new technologies. Some commenters expressed concerns about placing so much regulatory burden (e.g., too many safety constraints) on new technologies that there is an impact on the development of new products.

Emerging technologies have an undefined risk. Once the risk becomes clear, the degree of regulation that is needed to minimize the risks to the public can be defined. The NRC might be interested in the design of trials involving emerging technologies, and what kind of data are collected, in order to define the risks from emerging technologies.

A model was suggested for establishing the requirements for emerging technologies. Under the suggested model, appropriate professional societies would establish task forces to examine the issues (e.g., the training requirements) associated with the emerging technology. This model was successful in defining the standards for gamma stereotactic radiosurgery in the late 1980's when it was considered an emerging technology.

Response. The NRC agrees with these comments and will take them into consideration in setting up the process for establishing regulatory requirements and for approving applications for emerging technologies. We intend to evaluate each technology on a case-by-case basis and to work with the ACMUI, the medical community, the public, and the developers of the new technology, as appropriate, to determine the specific risks associated with the technology and any additional regulatory requirements for the medical use of the technology.

Issue 3. Will the NRC coordinate its regulations for emerging technologies with the FDA's regulations?

Comment. One commenter has observed that the FDA process works well in addressing patient safety for investigational new drugs and devices. This commenter suggested that the NRC communicate its concerns to the FDA to assure that any radiation safety issues will be included and documented in the investigational research process.

Response. The NRC does not intend to develop requirements that are redundant with those of the FDA. FDA and NRC have different authorities and responsibilities for protection of public health and safety; FDA has the authority to approve investigational new drugs and devices; and NRC has the authority to protect the public, workers, and patients from the medical use of byproduct material. However, we have a "Memorandum of Understanding" with FDA under which we coordinate certain agency functions and share information (58 FR 47300; September 8, 1993 and 62 FR 15740; April 2, 1997, renewal).

Issue 4: Why does this section not include training and experience requirements for AUs of emerging technologies?

Comment. Several commenters said that this section should provide the minimum criteria and training requirements for AUs of these new medical uses. The qualifications of individuals to use emerging technologies are pretty well established by the developers of the emerging technology, and they are aware of the radiation safety problems associated with the new technology. Whether it is an emerging technology or not, there is a need to understand

the properties and hazards of the radioactive material being used, the radiobiological issues, and the measures to be taken in the event of a spill, and to demonstrate the ability to safely handle the radioactive material.

Response. Section 35.1000 does not include any training and experience requirements for AUs of emerging technologies because there is no way of knowing what training requirements will be necessary for the safe use of byproduct material in new technologies. Applicants are required by § 35.12(b) to provide the training and experience for the AU, ANP, or AMP, as appropriate, to the NRC. The training and experience will be evaluated on a case-by-case basis with input from the ACMUI and individuals who have been involved with development of the technology, as needed, and other input, as appropriate.

Issue 5: Will cost issues be considered during the development of requirements for emerging technologies?

Comment. Comments were provided on several different cost issues. One commenter said that it is very difficult to spend millions of dollars on clinical research on new technologies and have no idea what the regulatory requirements are going to be. Another commenter said that cost effectiveness needs to be considered during the development of requirements for new technologies. For example, a requirement to have multiple professionals present during a procedure would not only increase the cost of the procedure, but would also limit its availability to patients.

Response. Licensing requirements for emerging technologies will be based on the risk posed by the specific modality and when possible licensing requirements will be modeled on other medical uses with similar risk. In order for new or revised requirements to be codified in Part 35, a public rulemaking process under the administrative procedure act must be followed including the development of a cost-benefit analysis made available for public comment.

Issue 6: Will intravascular brachytherapy be considered an emerging technology in the revised Part 35?

Comment. Some commenters believe that intravascular brachytherapy is still experimental and covered by § 35.6 and need not be considered in § 35.1000. Other commenters believe that intravascular brachytherapy should be categorized, or specifically mentioned, as an emerging technology under the provisions described in § 35.1000.

One commenter stated that in the proposed rule the standard use of radioisotopes in patients in the field of cardiology was reclassified as experimental and cardiologists had become radiation oncologists.

Response. Section 35.6 contains some specific provisions for protection of human research subjects and does not permit the use of byproduct material for medical uses that are not authorized on the licensee's medical use license. Intravascular brachytherapy is a very complex field with a number of methodologies and radionuclides being evaluated for use. Currently, the NRC is regulating intravascular brachytherapy as a sealed source therapy. Because no single standard protocol for intravascular brachytherapy has been established, the

Commission, with input from the ACMUI, the medical community, and the public, will review the technology in light of that protocol to determine if new regulatory requirements are needed for this use. Pending development of those regulatory requirements, an applicant will be able to submit a license application or amendment request, under the provisions of §§ 35.12 and 35.1000, to incorporate the new modality into their licensed program.

Issue 7. What are the training and experience and radiation safety requirements for intravascular brachytherapy?

Comment. Some commenters felt that intravascular brachytherapy should have the same training and radiation safety requirements as the rest of radiation oncology. Other commenters felt that the training and radiation safety requirements for nuclear cardiology should be reserved until the technology advances enough to develop standard protocols with the assistance of a group of experts. Still other commenters stated that the NRC should develop the training and safety requirements for intravascular brachytherapy.

Response. As we noted in Issue 6, intravascular brachytherapy is currently an evolving medical treatment composed of diverse technologies. Currently, the NRC is regulating intravascular brachytherapy as a sealed source therapy with the associated training and experience requirements for that therapy. The types of sources used vary widely in terms of the type of radiation emitted, the activity, and the level of encapsulation. In fact, intravascular brachytherapy may not evolve into either a standard protocol or a single modality. Pending receipt of additional information, we believe that it is too early to make changes in the level of training and experience for the use of intravascular brachytherapy.

Issue 8: Were there any other changes made in this section between the proposed and final rules?

Response: Yes. The NRC corrected the wording in paragraph (a) to state that the information that is required to be submitted by an applicant for use of byproduct material under § 35.1000 is in § 35.12(b) through (d), not only in paragraphs (b) and (c).

We amended the wording in paragraph (b) to reflect a change in § 35.12(d) that allows licensees to submit an application for a license amendment, rather than an application for a separate license, for use of byproduct material under § 35.1000. This change is discussed under § 35.12.

SUBPART L - Records

Issue 1: Should all the recordkeeping requirements be grouped into one subpart or should they be incorporated into the section requiring the record?

Comment. Commenters provided a wide range of responses to the Commission's question on whether all of the recordkeeping requirements should be grouped into one subpart, or whether they should be incorporated into the individual sections requiring the records. Some commenters favored having all of the recordkeeping requirements in one subpart because this format provides for easy reference, simplifies licensing, assists licensees in meeting their obligations for the radiation safety program, and simplifies compliance. Other commenters favored having the recordkeeping requirements in the individual sections because this format would place all of the requirements pertaining to a particular area of interest in one section. Therefore, licensees would know exactly what was expected of them in a particular area. They also find the similar separation in 10 CFR Part 20 to be confusing. Several commenters preferred a "balanced approach" in which the recordkeeping requirements would be in the individual sections and then all of the requirements would be summarized in a separate subpart.

Response. After reviewing all of the responses to this question, the NRC concluded that having all of the recordkeeping requirements in one subpart makes it easier for licensees to reference these requirements. However, the final rule is consistent with the "balanced approach" because each section in the final rule that is associated with a recordkeeping

requirement includes a cross-reference to the specific recordkeeping requirements in Subpart L.

Issue 2: Are all of the recordkeeping requirements in Part 35 needed?

Comment. Comments on the need for the recordkeeping requirements in Part 35 ranged from all of the records are needed; to the only records that are needed are those that document overexposures, exceeding environmental limits, and leaking sources; to the only records that should be required are those that have a documented history of improving radiation safety; to none of the records are needed.

Response. During preparation of the final rule, each specific recordkeeping requirement was reviewed in light of these comments and changes were made, where appropriate. These changes are noted in the discussions of the individual recordkeeping sections.

Issue 3: Are the recordkeeping requirements too prescriptive?

Comment. The recordkeeping requirements in the proposed revision maintain the detailed, prescriptive elements that are in the current Part 35.

Response. All of the elements in the recordkeeping requirements in the proposed rule were considered important for documenting radiation safety issues associated with a more risk-informed regulation. During preparation of the final rule, the NRC reviewed each recordkeeping requirement in light of this comment and made appropriate changes.

Issue 4: Why are there different retention periods for the records required by this subpart?

Comment. One commenter said that compliance with NRC's recordkeeping requirements would be simplified if all of the record retention periods were the same. Another commenter suggested that because most of the records have a retention period of 3 years, it would make more sense to include a separate section that states that all of the records in this subpart are to be maintained for 3 years, unless otherwise stated, than to restate the retention period in each section.

Response. The record retention periods in Part 35 were set according to either the safety significance of the action being recorded or the inspection frequency. As a result, there are several different retention periods for records in Subpart L. Because record retention periods are tied to safety considerations, the NRC believes that the regulations should specifically state the retention period for each recordkeeping requirement even if it means repeating regulatory text.

Issue 5: How can a patient's privacy and confidentiality be protected in records required by NRC?

Comment. A comment received stated that the patient's privacy and confidentiality are "ignored" with NRC recordkeeping requirements for records of the patient's name, social security number, and other personal information.

Response. Any records that must include the patient's name or personal information relating to the patient are to be retained by the licensee. Reports relating to medical events, which licensees provide to the NRC, explicitly must not contain the individual's name or any other information that could lead to identification of the individual.

Issue 6: Can initials be used on a record to identify the individual who performs an activity or an operation?

Comment. The requirement to record the "name of the individual" that performed a certain activity appears throughout this subpart. Several commenters said that because it is common practice to utilize initials as identifiers of individuals, the words "name of the individual" should be replaced with "identification of the individual."

Response. The NRC requires that the full name of an individual appear on a record to better ensure future identification of the individual who performed the activity or operation. It is not uncommon for several individuals to have different names, but the same initials. Also, initials are more likely to be illegibly scribbled.

Issue 7: Why do some records require a signature, rather than the name of the individual?

Comment. Several commenters said that requiring a signature on a record is prescriptive, not performance based, and does not necessarily mean that an individual has actually read or reviewed a record.

Response. The NRC has required signatures only on those records where we feel it is important to the radiation safety program to document who approved the action, reviewed the report, performed the calibration, etc. If an individual signs a record saying, for example, that he or she performed an action, we assume that the individual actually did perform whatever action was required and is in compliance with the recordkeeping requirements in this part. Note that most of the recordkeeping requirements in Subpart L require the name of the individual, rather than a signature.

Issue 8: Do the recordkeeping requirements in Part 35 allow for the use of electronic signatures?

Comment. Some commenters were concerned that the requirements for signatures preclude maintaining records electronically.

Response. Section 35.5, Maintenance of records, allows records to be maintained electronically. Therefore, electronic signatures are permitted.

Section 35.2024, Records of authority and responsibilities for radiation protection programs.

Issue 1: Can the requirements in this section be made less prescriptive and therefore less burdensome on licensees?

Comment. Several commenters felt that the requirements in this section are too prescriptive and burdensome, especially for private practices with one physician who is also the owner/president and RSO.

Response. The NRC has retained the requirements in this section because we believe that records associated with the authority and responsibilities of the radiation protection program are fundamental to the safe use of byproduct material by all medical licensees, regardless of their size. Even single practice physicians, who may also serve as RSOs, need to be well aware of and to document their authority, duties, and responsibilities associated with being the RSO named on either an NRC or Agreement State license.

Issue 2: Why is it necessary for licensees to retain records of the licensee's management's written approval of actions associated with the radiation protection program for 5 years?

Comment. One commenter said that the requirement in paragraph (a) of this section to retain records for 5 years is excessive.

Response. The NRC considers the records required by paragraph (a) of this section to be important in documenting actions taken by the licensee's management that affect its radiation protection program. These records include requests for a license application, renewal, or amendment; approval of AUs, AMPs, and ANPs; and radiation protection program changes that do not require a license amendment. The 5-year retention period will ensure that the records that are key to a licensee's radiation protection program are available for review during

inspection of medical use licensees. During the development of the proposed rule, we evaluated the retention period for this requirement and changed the retention period from the duration of the license to 5 years. Therefore, the recordkeeping burden for licensees to comply with the requirements in this paragraph is less than the burden to comply with the current rule.

Issue 3: Why is it necessary for both licensee management and the RSO to sign the authorities, duties, and responsibilities of the RSO?

Comment. Several commenters said that the requirement in paragraph (b) of this section for both licensee management and the RSO to sign the authorities, duties, and responsibilities of the RSO was too prescriptive. They felt that it was unnecessary to require the signature of both of them because other sections only require one signature or name. One commenter was also concerned that, if a problem occurred, the written agreement could be used by licensee management against the RSO.

Response. The NRC retained the requirement for signatures of both licensee management and the RSO because we believe it is important that there is a signed record of what the licensee management and the RSO agree are the authorities, duties, and responsibilities of the RSO. If both the licensee management and the RSO have a clear understanding of the responsibilities of the RSO for the licensee's radiation protection program, problems such as that referred to in the comment could be avoided. We explicitly state in this section that the signed document, as required by § 35.24 (b), and the responsibilities of the Radiation Safety Officer, as required by § 35.24 (e), must be retained for the duration of the license. This retention period is identical to the retention period specified in § 30.51(b), which

would otherwise apply. However, without this explicit statement in Part 35, the licensee would have to reference the general recordkeeping provisions in § 30.51 for the record retention period.

Section 35.2026, Records of radiation protection program changes.

Issue 1: Why is there a requirement for retaining records of changes to a licensee's radiation protection program that "do not reduce safety," and why must these records be signed by licensee management?

Comment. Commenters said that it is excessive and unnecessary to retain records of radiation protection program changes that do not reduce safety. In addition, the commenters believed that it is unnecessary to have licensee management sign the records of radiation protection program changes that had already been reviewed and signed by the RSO, the licensee's radiation safety expert.

Response. Licensees are required to obtain Commission approval for changes in their radiation protection program, except for the revisions authorized by § 35.26. Because licensees are not required to submit these latter changes to NRC for approval, the records of the changes made in accordance with § 35.26 provide the Commission an opportunity to evaluate these changes during the inspection process. The NRC believes that this approach is warranted in light of the importance of changes in a licensee's radiation protection program.

The reference in proposed § 35.26(a)(2) to changes that “do not reduce radiation safety” resulted in many comments that this phrase was “ambiguous” and “subjective.” The proposed wording was intended to provide the licensee with as much flexibility as possible in making changes in its radiation protection program, without seeking Commission approval. However, because commenters felt that the proposed wording was not clear, we revised the text of paragraph (a)(2) to state the more objective parameter of changes that are “in compliance with the regulations and the license.”

We have deleted the requirement in § 35.2026 for the RSO to sign the records of radiation protection program changes because licensee management is ultimately responsible for the radiation protection program. Therefore, the final rule includes a requirement for licensee management to sign these records.

Issue 2: Can the requirements in this section be made less prescriptive and therefore less burdensome on licensees?

Comment. Several commenters noted that the recordkeeping requirements in this section are quite prescriptive and suggested that the sentence with the list of items that must be included in the records be deleted or revised to be less prescriptive.

Response. The NRC believes that the recordkeeping requirements in this section are needed to document what changes have been made in the licensee’s radiation protection program. We considered the burden on licensees during development of the final requirements for this section and believe that the requirements for radiation protection changes, and the

associated records, provide the licensee more flexibility to manage its radiation protection program than in the current rule and reduce the recordkeeping burden on licensees. For example, licensees must currently retain a record of each radiation protection change until the license has been renewed or terminated. Under the final rule, licensees are only required to retain these records for 5 years.

Issue 3: Why are licensees required to retain a copy of the old radiation protection procedures?

Comment. One commenter questioned the need to retain a copy of the old radiation protection procedures because they are immaterial to the current procedures and could be confusing to workers.

Response. The NRC believes that licensees should retain a copy of their old radiation protection procedures for 5 years so that they are available during the licensee's next inspection after the procedures were changed. If a "problem" or "event" is discovered during an inspection, the radiation protection procedures that were in place at the time of the event may be very useful in determining the cause of the event.

We suggest retaining the copy of the old radiation protection procedures in the licensee's filing system so that they are not readily available for workers to refer to by mistake.

Issue 4. Were there any other changes made in this section between the proposed and final rules?

Response. Yes. The word “safety” was removed from the title of this section. This change was made to correct an inconsistency between the regulatory text in this recordkeeping section and the corresponding § 35.26, Radiation protection program changes.

Section 35.2040, Records of written directives.

Issue 1: Is there a need for an NRC requirement to retain a copy of written directives for therapeutic administrations of unsealed byproduct material?

Comment. One commenter said that the requirement for retaining a copy of written directives should exempt radiopharmaceuticals because state laws already require retention of prescription records.

Response. Section 35.40, Written directives, contains a list of items that must be included in a written directive and requires that an AU sign and date the written directive before administration of sodium iodide I-131 greater than 1.11 MBq (30 μCi) or any therapeutic dosage of unsealed byproduct material. In other words, this section includes specific requirements for preparing written directives before administering higher dosages of unsealed byproduct material. Prescriptions for radiopharmaceuticals may or may not be signed by AUs and may or may not include all of the items that are required by § 35.40 for written directives for administrations of therapeutic dosages of unsealed byproduct material. The NRC believes that retaining copies of written directives will help ensure that administrations of therapeutic dosages of unsealed byproduct material are in accordance with the written directives. In addition, a copy of the written directive may be useful in evaluating whether a medical event was a result of a generic problem that may also affect other licensees.

Section 35.2041, Records for procedures for administrations requiring a written directive.

Issue 1: Were there any changes made in this section between the proposed and final rule?

Response. Yes. This section was added to the final rule. We explicitly state in this section that the procedures required in § 35.41 (a) must be retained for the duration of the license. This retention period is identical to the retention period specified in § 30.51(b), which would otherwise apply. However, without this explicit statement in Part 35, the licensee would have to reference the general recordkeeping provisions in § 30.51 for the record retention period.

Section 35.2045, Records of medical events.

Issue 1: Can the requirements in this recordkeeping section be made less prescriptive and therefore less burdensome on licensees?

Comment. One commenter noted that the recordkeeping requirements in this section are quite prescriptive and suggested that the list of items that must be included in the records be deleted.

Response. Section 35.2045 has been deleted in the final rule. Since licensees are required to report information about medical events to the NRC under §35.3045, we believe that it is not necessary to require licensees to retain a record of this information under § 35.2045.

Issue 2: Should there be a requirement for maintaining records of significant precursor events?

Comment. One commenter opposed the recordkeeping requirement for significant precursor events.

Response. There are no recordkeeping requirements for significant precursor events in the final rule because there are no requirements for reporting precursor events.

Issue 3. Were there any other changes made in this section between the proposed and final rules?

Response. Yes. The NRC reworded paragraph (a) to read ”reported in accordance with” instead of “reported pursuant to” to make the language more consistent with the other sections of Part 35.

Several changes were made in the list of items that must be included in the record. We reworded paragraphs (b)(2)-(b)(4) to state the requirements more clearly. Paragraph (b)(2) was reworded to read “Names of the individuals involved.” Paragraph (b)(3) was reworded to read “The social security number or other identification number, if one has been assigned, of the individual who is the subject of the medical event.” Paragraph (b)(4) was reworded to read “A brief description of the event...” Paragraphs (b)(5) and (b)(6) were also reworded to read “the effect, if any, on the individual; and the actions, if any, taken or planned to prevent recurrence”, respectively. The words “if any” and “planned” were added because there might

not be any effect on the individual or any actions taken at the time the record is made. A new paragraph (b)(7) was added so that there would be a record of whether the licensee notified the individual (or the individual's responsible relative or guardian) and, if the individual was not notified, whether that decision was based on guidance from the referring physician.

Section 35.2060, Records of calibrations of instruments used to measure the activity of unsealed byproduct material.

Issue 1: Does this section address "calibrations" or "performance checks"?

Comment. A commenter recommended that the word "calibrations" be replaced with the term "performance checks" because the commenter believes that the tests required by the section are more accurately defined as performance checks.

Response. The NRC did not adopt this comment because this section addresses calibration of all instruments used to measure the activity of unsealed byproduct material, including dose calibrators. We believe this is the appropriate term because the term "calibration" is commonly used within the radiation protection profession.

Issue 2: Were there any other changes made in this section between the proposed and final rules?

Response. Yes. The NRC changed the title of this section to state more accurately that it addresses the calibration of instruments used to measure the activity of unsealed byproduct

material. In addition, we deleted prescriptive requirements from § 35.2060. This change is consistent with the revisions made to § 35.60. The licensee is only required to 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. We believe that this information will provide adequate documentation of calibrations of instruments used to measure the activity of unsealed byproduct material.

Section 35.2061, Records of radiation survey instrument calibrations.

Issue 1: Is it necessary to keep instrument calibration records?

Comment. Commenters suggested that the requirement to retain records of radiation survey instruments be deleted. Some commenters stated that because the current calibration status and expiration date must be displayed on the instrument, they did not see a benefit to radiation safety by maintaining certificates of calibration. Other commenters stated that this section is already covered in 10 CFR 20.2103.

Response. The NRC believes records of calibration should be kept because they can be used to document that the instrument has been calibrated. This is particularly important when the calibration sticker is unreadable, missing, or in error or when an instrument that was used in a required survey cannot be located. Section 20.2103 requires that licensees maintain records of calibrations but it does not provide specific recordkeeping requirements. Therefore, this section is needed to provide medical use licensees with specific information on what items must be maintained in this record.

Issue 2: Were there any other changes made in this section between the proposed and final rules?

Response. Yes. The NRC amended § 35.2061 to delete the requirements to include the description of the calibration procedure and the source used in calibrating the meter; the certified exposure rates from the source; the rates indicated by the instrument being calibrated; and the correction factors deduced from the calibration data. These changes are consistent with the revisions made to § 35.61. In the final rule, the licensee is required to 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. We believe this information will provide adequate documentation of calibrations of radiation survey instruments.

Section 35.2063, Records of dosages of unsealed byproduct material for medical use.

Issue 1: Are records of administered dosages of unsealed byproduct material needed?

Comment. Commenters did not believe this recordkeeping section was needed because prescribing and dispensing records are required by state medical and pharmacy laws. Other commenters did not believe that the recordkeeping requirements should apply to byproduct material administered under §§ 35.100 and 35.200.

Response. The NRC believes that it is important to keep records of the dosages administered. These records are needed to document that the byproduct material was

administered to a patient or human research subject in accordance with the written directive and to document the amount of byproduct material that was administered. However, if a licensee keeps the same records under state law, the licensee need not retain duplicate records.

Issue 2: Should the expiration date of a radioactive drug be deleted from the regulations?

Comment. A commenter indicated that the current requirement in § 35.53 to record the expiration date of a radioactive drug should not be deleted from the regulations. The commenter believed the expiration date is important because it can be used, for example, to establish time limits on sterility, dosage, and effectiveness of tagging. The commenter also believed the paperwork burden for including the expiration date is minimal.

Response. The NRC agrees that the expiration date of a radioactive drug is important. However, we believe that licensees have to comply with other regulations governing the use of drugs that include noting the expiration date because it is related to stability and sterility. Therefore, we do not believe that it is necessary to have a requirement in Part 35 for licensees to record the expiration date of a radioactive drug.

Issue 3: Should the terms “prescribed dosage” be removed from the requirement?

Comment. A commenter asked that the term “prescribed dosage” be deleted from

§ 35.2063 because there is no requirement for the AU to prescribe the dosage and, in the case of therapeutic administrations, only a written directive is needed.

Response. The NRC has not deleted the term "prescribed dosage." The term is defined in § 35.2. In Part 35, only an AU may direct the administration of sealed or unsealed byproduct material for medical use.

Issue 4: Were there any other changes made in this section between the proposed and final rules?

Response. Yes. The NRC restructured § 35.2063 to match the format used in other recordkeeping sections. We also deleted the requirements for the record to include the radionuclide, generic name, trade name, or abbreviation of the radiopharmaceutical and its lot number. These items were deleted to make the rule less prescriptive. The final rule requires that the licensee record the radiopharmaceutical; patient or human research subject's name, or identification number, if one has been assigned; the prescribed dosage, the determined dosage, or a notation that the total activity is less than 1.1 MBq (30 μCi); the date and time of the dosage determination; and the name of the individual who determined the dosage. This information will provide adequate documentation of dosage administrations.

Section 35.2067, Records of leak tests and inventory of sealed sources and brachytherapy sources.

Issue 1: Why should licensees maintain records of negative leak tests?

Comment. A commenter agreed with retention of positive leak test records, but not with the requirement to maintain records of negative tests.

Response. The rule requires records of all leak tests required by § 35.67(b) to show that leak tests were performed. The NRC changed the final rule to require records of the test results, but a licensee has flexibility in how it records the test results. For negative leak tests, a licensee may simply document that the measured activity is “negative.”

Issue 2: Should this section make a reference to § 35.2406, Records of brachytherapy source inventory?

Comment. A commenter asked that we add a reference which states that additional brachytherapy records may be required by § 35.2406.

Response. The NRC does not believe this reference is needed. We have tried to eliminate redundancy and cross referencing in the rule unless it is needed to make the rule more understandable.

Issue 3: Were there any other changes made in this section between the proposed and final rules?

Response. Yes. The NRC amended the title of this section to state more clearly what type of records are required by this section.

We also deleted the requirements to record the measured activity of each test sample and a description of the method used to measure each test sample in the record. These items were deleted to make the rule less prescriptive.

Section 35.2070, Records of surveys for ambient radiation exposure rate.

Issue 1: Are contamination surveys included in this section?

Comment. A commenter indicated that the requirement for records of removable contamination should be deleted because § 35.70 does not require removable contamination surveys.

Response. The commenter is correct. The NRC deleted the requirement for the licensee to record removable contamination in each area (expressed in disintegrations per minute per 100 square centimeters) and the instrument used to analyze the samples. However, the licensee must maintain records to show compliance with ALARA.

Issue 2: Are the requirements in this section already covered by § 20.2103, Records of surveys?

Comment. Commenters did not believe this section was needed because radiation surveys are addressed in § 20.2103.

Response. 10 CFR Part 20 contains general provisions on records. Section 20.2103 requires that licensees maintain records of surveys, but it does not provide specific recordkeeping requirements. This section is needed to specify what Part 35 licensees must document in the record required by this section.

Issue 3: Were there any other changes made in this section between the proposed and final rules?

Response. Yes. The NRC deleted the requirements to record a plan of each area surveyed; the trigger level established for each area; and the detected dose rate at several points in each area expressed in millirem per hour or the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters. These items were deleted to make the rule less prescriptive. The final rule requires the licensee to record the date of the survey; the results of the survey; the instrument used to make the survey; and the name of the individual who performed the survey.

Section 35.2075, Records of the release of individuals containing unsealed byproduct material or implants containing byproduct material.

Issue 1: Should paragraph (b) of this section that requires that a record be kept that instructions were provided to a breast-feeding woman be deleted?

Comment. A commenter stated that the requirements in paragraph (b) [proposed paragraph (c)] are intrusive into medical practice. The commenter believed that instructions should be left to the physician's judgment.

Response. The NRC did not make any changes in paragraph (b) of the proposed rule which requires licensees to keep a record that instructions, including written instructions, were provided to a breast-feeding female if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 mSv (0.5 rem). This requirement is also in the current Part 35. We believe that providing written instructions to patients or human research subjects is necessary because they may not remember all the oral instructions. In addition, written instructions provide needed information to other family members or individuals who are caring for the patient or human research subject.

The requirement for a licensee to retain a record to demonstrate that instructions were provided to a breast-feeding female is more risk-informed. These records are associated with higher risk administrations of radiopharmaceuticals, e.g., therapeutic administrations of iodine-131.

Issue 2: Were there any other changes made in this section between the proposed and final rules?

Response. Yes. The NRC corrected paragraph (a) of this section because it inadvertently required that licensees maintain records of all releases. This recordkeeping requirement was more restrictive than the current rule. We modified the rule to require records of the release of individuals only when the total effective dose equivalent is calculated by using

the retained activity rather than the administered activity; using an occupancy factor less than 0.25 at 1 meter (3.3 feet); using the biological or effective half-life; or considering the shielding by tissue. We also amended paragraph (c) to specify that the records required by both paragraphs (a) and (b) of this section must be maintained for 3 years.

Section 35.2080, Records of mobile medical services.

Issue 1: Were there any changes made in this section between the proposed and final rules?

Response. Yes. The NRC amended the title of this section to state more clearly what type of records are required by this section.

We also deleted the requirement to record a plan of each area surveyed and the measured dose rate at several points in each area of use expressed in millirem per hour. These items were deleted to make the rule less prescriptive. The final rule requires the licensee to record the date of the survey; the results of the survey; the instrument used to make the survey; and the name of the individual who performed the survey. In addition, we clarified that the letter that permits the use of byproduct material must delineate the authority and responsibility of the licensee and the client.

Section 35.2092, Records of decay-in-storage.

Issue 1: Are the requirements in this section already covered by § 20.2103, Records of surveys?

Comment. Commenters did not believe this section was needed because radiation surveys are addressed in § 20.2103.

Response. 10 CFR Part 20 contains general provisions on records. It does not provide specific recordkeeping requirements for disposal of waste through decay-in-storage. Section 35.2092 is needed to specify what Part 35 licensees must document in the records required by § 35.92.

Issue 2: Were there any other changes made in this section between the proposed and final rules?

Response. Yes. The NRC amended the first sentence to replace the term “made in accordance with” with the phrase “as required by.” We believe this makes the sentence more readable. We also deleted the requirement to document the name of the radionuclide that was disposed. We do not believe it is necessary for the licensee to document what material was disposed of because § 35.92 no longer requires that the material be held for 10 half-lives. However, this does not preclude the licensee from including this information in the record.

We also amended the requirement so that the record includes the name of the individual who performed the survey, rather than the name of the individual who performed the disposal.

We believe that it is important to have a record of the individual who actually surveyed the material and determined that it could be disposed of without regard to its radioactivity.

Section 35.2204, Records of molybdenum-99 concentration.

Issue 1: Can this record be deleted?

Comment. Commenters suggested that this section, as well as § 35.204, be deleted. They did not believe the rule should require licensees to measure molybdenum-99 concentrations. (See comments on § 35.204.)

Response. The NRC did not delete the requirement for licensees to measure molybdenum-99 concentrations, nor have we deleted the requirement for licensees to maintain a record of the molybdenum-99 concentration tests required by § 35.204. We believe the record is needed to document that the test has been performed and that the results of the test do not exceed the levels specified in § 35.204.

Section 35.2310, Records of safety instruction.

Issue 1: Is it necessary to maintain records of safety instruction given to non-film badged workers?

Comment. According to commenters, it is excessive to require licensees to maintain records of training given to non-film badged allied health care workers, who receive instruction in accordance with §§ 35.310, 35.410 or 35.610.

Response. Records of all individuals receiving safety instruction in accordance with §§ 35.310, 35.410 or 35.610 are needed to document that the instruction was provided by the licensee. The NRC believes it is important that the personnel caring for patients or human research subjects who have received radiopharmaceutical therapy (and cannot be released in accordance with § 35.75) receive instruction in limiting radiation exposure to the public or workers and what actions should be taken in the case of a medical emergency or death.

Issue 4: Were there any other changes made in this section between the proposed and final rules?

Response. Yes. The title of this section was changed to correspond to the title of § 35.310, Safety instruction. That section includes the requirement for licensees to retain a record of individuals receiving safety instruction.

Section 35.2404, Records of surveys after source implant and removal.

Issue 1: Is it necessary to maintain records of negative surveys? Also, can the record retention requirement be changed from 3 years to 1 year?

Comment. Some commenters felt that maintenance of negative surveys for 3 years was excessive and suggested that the survey record include only an indication of the survey being performed and the results of any positive surveys. These same commenters also suggested that the record need only be kept for 1 year.

Response. The NRC simplified the recordkeeping requirements in this section by deleting the requirement to record the location of the survey and the patient identifier. These items were deleted to make the rule less prescriptive. We added a requirement to record "the results of the survey" because we do not believe that a requirement to record the results of the survey is excessive, even if the results are that all sources are accounted for. We have also retained the 3-year recordkeeping period to be consistent with the 3-year inspection period for most medical use licensees.

Issue 2: Could the recordkeeping requirements of this section be less prescriptive, consistent with providing more flexibility in running a radiation protection program?

Comment. A commenter suggested that the contents of the record for radiation surveys be deleted, consistent with providing the licensee flexibility in developing, maintaining, and implementing its radiation protection program. If this cannot be done, the commenter suggested that the "name of the individual" be changed to "the identity of the individual."

Response. The NRC simplified the recordkeeping requirements in this section by deleting the requirement to record the location of the survey and the patient identifier. As discussed in Issue 6 of the general comments on this subpart, we believe that the full name of

an individual must appear on a record to better ensure future identification of the individual who performed the survey.

Issue 3: Were there any other changes made in this section between the proposed and final rules?

Response. Yes. The NRC changed both the title and regulatory text of this section to accommodate changes made in § 35.404, Surveys after source implant and removal. For example, the term “radiation” was struck from the section, recognizing that the survey may not necessarily be a radiation survey. The licensee may also perform a visual survey to locate and account for all sources. Other changes are discussed in the comments on § 35.404.

Section 35.2406, Records of brachytherapy source accountability.

Issue 1: Is it necessary to retain a record of permanent implant sources returned to storage if all sources were used during the implant?

Comment. A commenter suggested that, in some permanent implant cases, all of the sources will be utilized. The commenter proposed that the word “unused” be added to item (c)(2) immediately before “sources.”

Response. The NRC changed the regulatory text in this section to require that the record include “the number and activity of sources not implanted.” Therefore, if all of the

sources were used, the licensee would have to note that all of the sources were implanted and, consequently, none were returned to storage.

Issue 2: Were there any other changes made in this section between the proposed and final rules?

Response. Yes. The title of this section was changed to correspond to the revised title of § 35.406, Brachytherapy source accountability. That section requires licensees to maintain accountability at all times for all brachytherapy sources in storage or use.

Section 35.2432, Records of calibration measurements of brachytherapy sources.

Issue 1: Were there any changes made in this section between the proposed and final rules?

Response. Yes. The title of this section was changed to correspond to the title of § 35.432, Calibration measurements of brachytherapy sources. That section requires licensees to retain records of calibrations performed before the first medical use of brachytherapy sealed sources. Several changes were also made in this section to accommodate changes made in § 35.432. For example, the proposed rule said that the full calibration measurements must include determination of the output or activity within +/- 5 percent, and the final rule says that a licensee must determine the source output or activity using a dosimetry system that meets the requirements in § 35.630(a). Other changes are discussed in the comments on § 35.432.

Section 35.2433, Records of decay of strontium-90 sources for ophthalmic treatments.

Issue 1: Were there any other changes made in this subpart between the proposed and final rules?

Response. Yes. The NRC added this section to correspond with the new § 35.433, Decay of strontium-90 sources for ophthalmic treatments. That section includes a requirement that a record be made of the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. For additional information, see the discussion for § 35.433.

Section 35.2605, Records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

Issue 1: Were there any other changes made in this section between the proposed and final rules?

Response. Yes. The NRC amended the title of this section to state more clearly what type of records are required by this section.

We also added the word “adjustment” to the title and text of this section to conform them with the regulatory text. In addition, the phrase “remote afterloader unit, teletherapy unit, or gamma stereotactic unit” was added. This list of units was added because Subpart H in the

final rule includes requirements for these types of devices, in addition to the requirements for teletherapy units which are in the current Part 35.

Section 35.2610, Records of safety procedures.

Issue 1: Were there any changes made in this section between the proposed and final rule?

Response. Yes. This section was added to the final rule. We explicitly state in this section that the procedures required in §§ 35.610 (a)(4) and (d)(2) must be retained until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit. Without this explicit statement, the licensees would have to reference the general recordkeeping provisions in § 30.51 for the record retention period and therefore, would have had to retain the procedures for the duration of the license.

Section 35.2630, Records of dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

Issue 1: Can the record retention period for this section be changed from “for the duration of the license” to 3 years?

Comment. A commenter suggested that the record retention period could be changed to “3 years after the last calibration.”

Response. The NRC has not changed the record retention period in this section. The dosimetry equipment calibrations, intercomparisons, and comparisons performed to show compliance with § 35.630 are necessary to document that the correct radiation dose is delivered to the patient or human research subject. If there is a future question about whether the correct radiation dose was delivered to a patient or human research subject, we believe that these records should be available to document that calibration of the therapy unit was made with properly calibrated instruments.

Issue 2: Were there any other changes made in this section between the proposed and final rules?

Response. Yes. The NRC amended the title of this section to state more clearly what type of records are required by this section.

We also amended paragraph (b)(2) to require that licensees include the manufacturer's name for the instruments that are calibrated, intercompared, or compared in accordance with § 35.630. This change is consistent with requirements in other sections to include the manufacturer's name of other types of equipment.

Section 35.2632, Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations.

Issue 1: Were there any changes made in this section between the proposed and final rules?

Response. Yes. Changes were made in this section to incorporate the requirements that were in the proposed §§ 35.2633 and 35.2635, which were deleted. Section 35.2632 in the final rule includes the recordkeeping requirements for full calibrations of teletherapy, remote afterloader, and gamma stereotactic radiosurgery units. Licensees can refer to this section for all of the recordkeeping requirements for full calibrations of the therapy units covered by Subpart H.

Section 35.2633, Records of remote afterloader full calibrations.

Issue 1: Were there any changes made in this section between the proposed and final rules?

Response. Yes. This section was deleted in the final rule because the requirements were moved to § 35.2632, Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations. This change was made so that all of the recordkeeping requirements for full calibrations of therapy units in Subpart H would be in one place for easier reference for licensees.

Section 35.2635, Records of gamma stereotactic radiosurgery unit full calibrations.

Issue 1: Were there any changes made in this section between the proposed and final rules?

Response. Yes. This section was deleted in the final rule because the requirements were moved to § 35.2632, Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations. This change was made so that all of the recordkeeping requirements for full calibrations of the therapy units covered by Subpart H would be in one place for easier reference for licensees.

Section 35.2642, Records of periodic spot-checks for teletherapy units.

Issue 1: Were there any changes made in this section between the proposed and final rules?

Response. Yes. Paragraph (c) was added to the final rule. We explicitly state in this section that the procedures required in § 35.642 (b) must be retained until the licensee no longer possesses the teletherapy unit. Without this explicit statement, the licensees would have to reference the general recordkeeping provisions in § 30.51(b) for the record retention period and therefore, would have had to retain the procedures for the duration of the license.

Section 35.2643, Records of periodic spot-checks for remote afterloader units.

Issue 1: Were there any changes made in this section between the proposed and final rules?

Response. Yes. Several changes were made to accommodate changes made in § 35.643.

Paragraph (c) was added to the final rule. We explicitly state in this section that the procedures required in § 35.643 (b) must be retained until the licensee no longer possesses the remote afterloader unit. Without this explicit statement, the licensees would have to reference the general recordkeeping provisions in § 30.51(b) for the record retention period and therefore, would have had to retain the procedures for the duration of the license.

Section 35.2645, Records of periodic spot-checks for gamma stereotactic radiosurgery units.

Issue 1: Were there any changes made in this section between the proposed and final rules?

Response. Yes. Several changes were made to accommodate changes made in § 35.645. These changes are discussed in the comments on § 35.645.

Paragraph (c) was added to the final rule. We explicitly state in this section that the procedures required in § 35.645 (b) must be retained until the licensee no longer possesses the gamma stereotactic radiosurgery unit. Without this explicit statement, the licensees would have to reference the general recordkeeping provisions in § 30.51(b) for the record retention period and therefore, would have had to retain the procedures for the duration of the license.

Section 35.2647, Records of additional technical requirements for mobile remote afterloader units.

Issue 1: Were there any changes made in this section between the proposed and final rules?

Response. Yes. Other changes are discussed in the comments on § 35.647.

Section 35.2652, Records of surveys of therapeutic treatment units.

Issue: Can the record retention period be changed to 3 years, instead of "for the duration of use of the unit?"

Comment. A commenter suggested that the record retention period could be changed to 3 years.

Response. The NRC has not changed the record retention period in this section. The surveys performed to show compliance with §35.652 are necessary to ensure that the source/device radiation level limits stated in the SSDR are not exceeded. We believe that these surveys should be retained for the duration of use of the device because of the potential radiation risks associated with these devices.

SUBPART M - Reports

Issue 1: Should all the reporting requirements be grouped into one subpart or should they be incorporated into the section requiring the report?

Comment. Commenters provided diverse responses to the Commission's question on whether all of the reporting requirements should be grouped into one subpart, or whether they should be incorporated into the individual sections requiring the reports. Commenters favored having all of the reporting requirements in one subpart because this format provides for easy reference, simplifies licensing, and assists licensees in determining their reporting requirements, which makes it easier to maintain compliance. Other commenters favored having the reporting requirements in the individual sections because this format is more orderly and informative. They find the similar separation of the actual reporting requirements and the requirements for what needs to be in the reports in Part 20 to be confusing. A number of individuals have misinterpreted sections of Part 20 simply because of the separation. Several commenters preferred a balanced approach where the reporting requirements would be in the individual sections and all of the requirements summarized in a separate subpart.

Response. After reviewing all of the comments responding to this question, the NRC concluded that having all of the reporting requirements in one subpart makes it easier for licensees to reference those requirements. However, the final rule is consistent with the "balanced approach" because each section in the final rule that is associated with a reporting requirement includes a cross-reference to the specific reporting requirements in Subpart M.

Section 35.3045, Report and notification of a medical event.

Issue 1: Do stakeholders think that the term "medical event" is an improvement over the use of the term "misadministration" in the current Part 35?

Comment. Commenters supported the use of the term “medical event.” One commenter agreed with the change, but could see no reason for “candy coating” the term “misadministration.”

Response. The NRC used the term “medical event” in the final rule because some believe the term “misadministration” has a negative connotation that implies negligence on the part of the physician or other hospital workers. The term “medical event” more correctly and simply conveys that the byproduct material or radiation from byproduct material was not administered as directed by the AU.

Issue 2: Are the reporting requirements for medical events necessary?

Comment. Several commenters said that there was no need for the requirements in this section. Events that result from poor radiation protection practices are covered in the primary regulations for the use of radioactive material, e.g., inadequate survey of a patient following an HDR treatment. If such problem areas in licensees’ programs are brought to their attention, licensees can correct the problems before they result in medical events.

Other commenters expressed concern that the overall wording in this section is subject to a great deal of interpretation and debate over whether specific actions are appropriate for a particular patient and whether an event is a reportable medical event. Therefore, the NRC should develop more specific language describing a medical event in order to avoid intrusion into medical judgments. It should be made clear that medical events are major deviations from a planned treatment that have or could have significant effects on the patient. These effects

include either a reduction in the possibility of tumor control or an increase in the possibility of complications. In addition, licensees should be able to appeal to medical experts if NRC staff determines that an incident is a reportable medical event.

Response. The NRC believes that the reporting and notification requirements in this section are necessary so that the NRC is aware of events that trigger the thresholds for medical events to determine what actions, if any, need to be taken to prevent recurrence; so that other licensees can be made aware of generic problems that result in medical events; and so that patients can make timely decisions regarding remedial and prospective health care. The requirements throughout Part 35 are more specific for medical use than the general requirements for the use of radioactive material in the other parts, e.g., Part 20 requirements.

During the development of the final rule, we revisited the proposed wording of all sections, including § 35.3045, to see if we could clarify the regulatory text to avoid future misinterpretations and debates about the meaning of the regulatory text. This type of clarifying change was made to exclude reporting medical events that are due to “patient intervention.”

Issue 3: Are the threshold dose levels for reporting medical events set at appropriate levels?

Comment. Some commenters said that the reporting levels for medical events in the proposed § 35.3045(a)(1) cannot be justified on the basis of any real risk to either patients or the public. Reporting at these levels implies that these events result in harm to the patient, when they often result in no effect on the patient. Therefore, this is an example of a low risk

requirement that the 1997 NAS-IOM Report (Radiation in Medicine: A Need for Regulatory Reform, Institute of Medicine, National Academy Press, Washington, DC, 1997) recommended be deleted. In addition, inherent risks do not justify intrusion by NRC into professional activities and the doctor-patient relationship.

Commenters said that the action level criteria for the total dose delivered from brachytherapy procedures or gamma stereotactic radiosurgery procedures should be revised from the prescribed dose to a level at which harm to patients has been demonstrated. Another commenter questioned why the threshold was not similar to FDA's requirements for reporting morbidity and mortality.

One commenter said that the reporting thresholds of 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) to an organ or tissue were reasonable levels because they are "reasonably significant radiation exposures." Five rem is the annual limit for a radiation worker, and 50 rem to an organ is the level when one might start seeing organ effects. For example, 50 rem to the testicles will result in a decreased sperm count.

Response. The NRC made no change in the proposed threshold reporting levels for medical events. These reporting levels correspond to the annual occupational dose limits in Part 20 and the level for reporting overexposures of workers to NRC. We believe that applying these same thresholds to reporting exposures to patients is reasonable.

The NRC uses the information from the reports of medical events that exceed the dose thresholds to reduce the likelihood of other medical events. For example, information from a

report may indicate a breakdown in the licensee's program for ensuring that byproduct material or radiation from byproduct material is administered as directed by the AU or may indicate a generic issue that should be reported to other licensees.

Issue 4: Should licensees be required to report events in which the administration of byproduct material or radiation from byproduct material results in a total dose that differs from the prescribed dose by 20 percent or more?

Comment. Commenters said that the 20 percent difference is arbitrary, and that exceeding this limit presents little or no risk to the patient. The limit should be examined and justified. Recommendations ranged from the limit should be 100 percent, to maybe there should not be a limit and the physician can decide when to report harm to a patient, to it is inappropriate to have a single criterion for all procedures.

Commenters believe that the 20 percent limit is reasonable for external beam therapy and unsealed therapeutic radiopharmaceuticals, but that it is too restrictive for brachytherapy, gamma stereotactic radiosurgery, and unsealed diagnostic dosages. Commenters said that they were aware of clinical data that supported the 20 percent level for external beam therapy. However, they were unaware of any brachytherapy or gamma stereotactic radiosurgery data demonstrating that a 20 percent difference between the prescribed dose and delivered dose would result in harm to the patient. In addition, a few millimeters in brachytherapy can make a tremendous difference in the dose. Some provision should be made to exempt brachytherapy, or to change the 20 percent limit up to 100-120 percent.

Several commenters questioned the applicability of the 20 percent limit to uses of unsealed byproduct material. Exceeding a radiotherapy dosage by 20 percent may be significant, but reporting an administration of a diagnostic dosage that exceeds the prescribed dosage by 20 percent is overregulation.

Response. The NRC has retained the 20 percent difference that is in the current rule. According to the Statements of Consideration for the Quality Management Program and Misadministrations rulemaking (56 FR 34104; July 25, 1991), a 20 percent difference between the prescribed dose and the total dose delivered is required to be reported because it could possibly indicate a deficiency in the licensee's program, not because it necessarily indicates a significant risk to the patient. We agree with this rationale and see no reason to change the threshold.

Licensees should note that they do not have to report an event in which the total dose or dosage delivered differs from the prescribed dose or dosage by 20 percent or more unless the dose also differs from the prescribed dose or from the dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin.

The NRC uses the information from the reports of medical events where the administration of byproduct material or radiation from byproduct material results in a total dose that differs from the prescribed dose by 20 percent or more to reduce the likelihood of other medical events. For example, the difference between the prescribed and administered doses

may indicate a breakdown in the licensee's program for ensuring that byproduct material or radiation from byproduct material is administered as directed by the AU.

Issue 5: Does the proposed rule adequately address wrong treatment site?

Comment. Commenters both agreed and disagreed on whether the proposed rule adequately addressed wrong treatment site. Two commenters said that it was unclear how wrong treatment site will be handled for therapy, especially for brachytherapy where a medical event can occur if the patient moves even a small distance. In addition, commenters questioned how the wrong treatment site criteria will be applied to permanent seed implants that migrate from the prescribed site.

Another comment was that the criteria for a medical event involving the wrong treatment site must be justified. The criteria of a 0.5 Sv (50 rem) tissue/organ dose and difference of 20 percent from the expected dose defined in the written directive are excessively restrictive. Justification can be provided that the percentage deviation could be 100 percent. At a minimum, radiobiological justification can be made for 1 Sv (100 rem) as a significant threshold. The FDA uses this threshold criteria for evaluating lengthy fluoroscopy studies that could result in skin injury.

Response. In § 35.3045(a)(3) of the proposed rule, the NRC attempted to define more clearly when exposure of a wrong treatment site is considered a medical event by including both a 0.5 Sv (50 rem) tissue/organ dose limit and a 20 percent deviation from the expected dose defined in the written directive. We believe that the proposed 0.5 Sv (50 rem)

tissue/organ dose limit should be retained, but the allowable deviation from the dose in the written directive should be increased to 50 percent. Therefore, we amended paragraph (a)(3) of this section in the final rule to read “50 percent of the dose expected ...” We believe that this change allows for some variation in doses to the wrong treatment site during administrations of radiation from byproduct material, and requires licensees to only report significant doses to the wrong treatment site due to the movement of the patient or source, e.g., during brachytherapy treatments. In addition, we added a statement that is in the current rule, which was inadvertently not included in the proposed rule, that excludes permanent implants of seeds that were implanted in the correct site but migrated outside the treatment site.

Issue 6: Does the proposed rule adequately address patient intervention?

Comments. The NRC received a range of responses to the Commission’s question on whether the proposed rule adequately addressed patient intervention, i.e., actions by the patient such as dislodging or removing treatment devices or prematurely terminating treatment. Several commenters said that this issue was adequately addressed in the rule. Other commenters said that any patient intervention should not result in a medical event. One commenter said that an exemption should be provided to the licensee when the cause of a medical event is patient intervention.

A number of commenters said that the phrase in the proposed rule “that could have been prevented by the licensee” was ambiguous and subjective, and should be deleted because it would result in varying interpretations between NRC and licensees. In addition, decisions on what are considered “reasonable medical practices” for patient control infringe on

the practice of medicine and should be left to the physician's professional judgment. Therefore, this requirement is in violation of Statement 2 of the proposed revision of the Medical Policy Statement: NRC will not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public.

Response. As part of the medical use rulemaking, the Commission is codifying a common-sense approach to the reporting requirements for medical events that excludes incidents involving patient intervention. In the proposed rule, the phrase "that could not have been reasonably prevented by the licensee" was added to § 35.3045(a) in an attempt to avoid further expenditure of resources by licensees and NRC in trying to determine what constitutes patient intervention, which is not specifically addressed in the current rule. The issue has involved whether or not a licensee did everything it should to prevent patient intervention during a treatment that resulted in a medical event. Following our evaluation of the comments on patient intervention, the NRC deleted the proposed phrase from § 35.3045(a) because it did not seem to clarify when an event caused by patient intervention must be reported to NRC as a medical event.

In the final § 35.3045(b), we addressed the issue of when an event caused by patient intervention must be reported to NRC as a medical event. In addition, we added a definition of patient intervention to § 35.2. As defined, patient intervention means "actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration." We believe licensees should only be required to report serious medical events due to patient intervention. Paragraph (b) of this section in the final rule requires licensees to report any event resulting from intervention of

a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician. As a result of the significantly higher threshold, the NRC will only receive reports involving patient intervention for events with serious consequences, e.g., unintentional permanent functional damage.

This reporting requirement should result in decreased regulatory burden on licensees because in most situations where patients intervene in their treatment, either voluntarily or involuntarily, there is no permanent functional damage. Therefore, the revised reporting requirement should significantly reduce the resources expended by the NRC and licensees in debating what are considered reasonable medical practices for patient control because the NRC will no longer require most of the reports it currently receives involving patient intervention. In addition, it should avoid intrusion into medical judgments by the NRC because the decision on whether the administration resulted in permanent functional damage to an organ or a physiological system is to be determined by a physician.

Issue 7: Why do licensees need to notify the NRC by telephone no later than the next calendar day after discovery of a medical event?

Comment. Two commenters questioned the need for licensees to notify the NRC no later than the next calendar day after discovery of a medical event because this requirement implies that these events are harmful or hazardous. There are some medical events with serious consequences that should be reported right away but there is no benefit in reporting events with no medical significance so promptly.

Response. According to the Statements of Consideration for the Quality Management Program and Misadministration final rule [56 FR 34104; July 25, 1991], misadministrations (medical events) warrant telephone notification of the NRC no later than the next calendar day because these events require that a threshold of either 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) dose equivalent be exceeded. The early telephone notification allows the NRC to promptly take any necessary actions based on the circumstances, e.g., dispatch an inspector or medical consultant or notify other licensees of potential generic problems. The NRC continues to believe that licensees should promptly notify the NRC of medical events that trigger these thresholds because the circumstances of the medical events need to be evaluated as soon as possible to determine if any immediate follow-up or corrective actions are necessary.

All medical events may not be associated with serious consequences. However, we believe that a requirement that allows for different reporting periods, depending on the initial assessment of the event, would lead to differing interpretations and confusion as to whether the magnitude of the event requires notification of the NRC no later than the next calendar day. In addition, there may be a medical event where the seriousness of the consequences would not be immediately apparent and which, therefore, would not be reported.

Issue 8: Should licensees be required to notify the individual (affected by the medical event) about a medical event?

Comment. The NRC received a range of comments on the requirement in § 35.3045(e) to notify the individual affected by the medical event. These ranged from the licensee should always notify the patient or guardian to this requirement should be deleted.

Some commenters suggested modification of the requirement. For example, a licensee should be allowed not to notify an individual if the rationale for withholding the information is noted in the written report to the NRC. Other suggestions were that notification of the patient should not be required unless the medical event results in a detrimental effect to the patient, or it is necessary to ensure patient safety.

Other commenters said that the requirement should depend on the risk of the procedure. In cases of diagnostic and low-risk therapeutic procedures, notification should not be mandatory. For high-risk therapeutic applications, a patient should only be notified if an adverse outcome is probable and only if the patient's mental state would not be adversely affected.

Commenters provided a number of reasons why they felt that this requirement should be deleted: it overlaps with existing medical practice standards; it intrudes into the practice of medicine; it interferes with the physician-patient relationship; there are no data that patients are not being notified; it presents the appearance of much greater harm than there may actually be; there is no precedent in other areas of medicine; and it is in contradiction to NRC's Medical Policy Statement.

Response. The NRC retained the proposed requirements for notifying individuals following a medical event in the final rule. As stated in the proposed rule (63 FR 43516; August 13, 1998), this position reaffirms statements made by the Commission during the misadministration rulemaking, that patient notification ". . . recognizes the right of individuals to know information about themselves which is contained in records both inside and outside the Federal sector" ["Human Uses of Byproduct Material, Misadministration Reporting Requirements," (43 FR 2927; May 7, 1978)]. We continue to believe that patient notification enables patients, in consultation with their personal physicians, to make timely decisions regarding any remedial and prospective medical care. This approach also codifies existing medical ethical standards obligating physicians to provide complete and accurate information to their patients.

This approach is consistent with aspects of another Federal patient notification requirement specifically in "The Mammography Quality Standards Reauthorization Act of 1998," Pub. L. 105-248, under which notification of a patient may be required for certain events (e.g., when a patient has received mammography from a facility whose quality is found to be "so inconsistent with quality standards as to present a risk to individual or public health"). [42 U.S.C. 263b(h)(2)(1999)]. By statute, as well as FDA regulations, a summary of the written report of the patient's mammography results must be sent directly to the patient if the patient's physician is not available or if there is no such physician. [42 U.S.C. 263b(f)(1)(G)(ii)(III); 21 CFR 900.12(e)(1)(2)(ii)(a) and (iii) (1999).]

Issue 9: Should licensees be required to notify the referring physician about a medical event?

Comment. Several commenters disagreed with the need for a regulation requiring licensees to notify referring physicians about a medical event. Nuclear medicine physicians and referring physicians have a professional relationship that would be negatively impacted if the nuclear medicine physician provided inaccurate information or withheld information from the referring physician. Therefore, the NRC does not need to mandate notification of the referring physician.

Response. It is important that a referring physician is aware of medical events involving individuals. The referring physician knows the individual and his or her medical history and is likely to be in the best position to make a decision about whether informing the individual about the medical event would be harmful. That physician may also need to evaluate any follow-up actions relative to the individual's overall health history. Although notification of referring physicians may represent the "standard of care," that practice may not be uniformly followed. Therefore, the NRC retained the current requirement for a licensee to notify the referring physician about a medical event. The final rule includes a requirement that licensees annotate a copy of their report to the NRC about the medical event and provide it to the referring physician, if other than the licensee, within 15 days after discovery of the medical event. We believe that it is important for the referring physician to have all the available documentation about the medical event to support any decision about remedial or prospective health care. The 15-day time period to provide the referring physician with a copy of the record is based on paragraph (d) which requires a licensee to submit a report to the NRC within 15 days. Consistency, where possible, between the requirements in Subparts L and M will simplify compliance with the recordkeeping and reporting requirements.

The issue of notifying the referring physician was addressed in the Statements of Consideration for the 1995 rulemaking that amended the medical misadministration requirements ("Medical Misadministration of Radiation and Radioactive Material," 60 FR 48623; September 20, 1995). The Commission noted that "If a misadministration occurs because the material was administered to the wrong individual, there may be no referring physician. If there is no referring physician, the licensee is relieved of the responsibility of notifying the referring physician, but must comply with all other requirements of § 35.33."

Issue 10: Why is there a requirement for a licensee to provide a written report to the individual affected by a medical event?

Comment. The NRC received several comments on the need for a licensee to provide a written report to the individual affected by a medical event. Commenters were concerned that providing a written report to the individual may lead to a misunderstanding of the consequences for the patient (i.e., the individual may be unduly alarmed that a report had to be submitted to NRC) and jeopardize the individual's confidence in the ability of the physician providing medical care. Another commenter noted that there is no precedent for providing a written report to a patient about a misadministration of other diagnostic agents.

Response. The NRC deleted the current requirement to furnish an individual affected by a medical event with a written report. Instead, in the final rule licensees are required to inform the individual, or responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. Licensees are required to provide such a written description to the individual, if requested. We believe that a written report would be

especially useful to an individual who needs to make decisions about any follow-up medical care, and provides the individual a permanent record to refer to for information about the event.

Issue 11: What other changes were made as a result of comments?

Comment. It is not clear whether the thresholds in paragraph (a)(1) and either (a)(1)(i) or (ii) need to occur simultaneously for the event to be reported.

Response. The NRC made editorial changes in the text of paragraph (a) to make it clearer that an event is only classified as a reportable medical event if *both* the threshold in paragraph (a)(1) *and* the threshold for the difference between the total dose and prescribed dose in paragraph (a)(1)(i) *or* the difference between the total dosage and prescribed dosage in paragraph (a)(1)(ii) *or* the difference between the fractionated dose delivered and the prescribed dose in paragraph (a)(1)(iii) have been exceeded.

Comment. The word “of” is missing between “20 percent” (50 percent in the final rule) and “the dose expected” in paragraph (a)(3) of this section that addresses the threshold for determining when a dose to a “wrong treatment site” is a reportable medical event.

Response. The text of paragraph (a)(3) of this section has been corrected to read “50 percent *of* the dose expected from the administration defined in a written directive.”

Comment. Paragraphs (c)(1)(vi) and (vii) could be combined into one paragraph because they both address actions or improvements that have been taken, or are planned, to prevent recurrence of a medical event.

Response. We combined the requirements in the proposed paragraphs into paragraph (d)(1)(vi) in the final rule.

Issue 12: Were there any other changes made in this section between the proposed and final rule?

Response. Yes. The NRC amended the title of this section to state more correctly that this section includes *both* reporting *and* notification requirements for medical events.

The phrase "results from intervention by a patient or human research subject" in paragraph (a) of the proposed rule was deleted and replaced by "an event that results from patient intervention" in the final rule. We made this change because the definition of patient intervention in § 35.2 includes actions by either a patient or human research subject, so paragraph (a) of the proposed rule contained duplicative language.

We added the phrase "administration of byproduct material or radiation from byproduct material" in paragraph (a) of the final rule because the requirements in Part 35 are limited to the medical use of byproduct material.

Paragraph (a)(1) was clarified to add the phrase “dose that would have resulted from the prescribed dosage.” This change was needed to clarify that this provision applies to the medical use of sealed and unsealed byproduct material as evidenced by the reference to “total dosage” in paragraph (a)(1)(ii).

Paragraph (a)(1)(i) of the proposed rule that contained the threshold for the difference between the delivered dose or dosage and the prescribed dose or dosage was split into paragraphs (a)(1)(i) and (ii) in the final rule. We made this change to reflect the fact that physicians can prescribe a range of dosages, but not doses, in written directives.

We replaced the word “pharmaceutical” in paragraph (a)(2)(i) with “radioactive drug containing byproduct material” because the requirements in Part 35 are limited to the medical use of byproduct material.

We amended paragraph (a)(3) to read “50 percent or more” (20 percent in the proposed rule) to make it clearer that the dose to a wrong treatment site has to *exceed* 50 percent or more of the dose expected from the administration defined in the written directive before a licensee is required to report the event to NRC as a medical event.

Paragraphs (d)(1)(v)and (vi) [paragraphs (c)(1)(v) and (vii) of the proposed rule] require that information on the effects of the medical event on the individual who received the administration and on the actions to prevent recurrence be included in the written report to the NRC. We reworded these paragraphs in the final rule to read “the effect, if any, on the individual;” and “what actions, if any, have been taken, or are planned, to prevent recurrence.”

The words “if any” and “are planned” were added because there might not be any effect or any actions taken at the time the event is reported.

We revised paragraph (d)(1)(vii) [paragraph (c)(1)(viii) in the proposed rule] to require that the written report include a certification that the licensee notified the individual (or the individual’s responsible relative or guardian), and if not, why not. We made this revision because notifying these individuals is important enough to warrant documentation that the individual(s) was notified. In addition, we believe that it is important that the licensee notify the patient so that he or she can be actively involved in any decision about remedial or prospective health care following the event.

We deleted paragraph (c)(1)(ix) in the proposed rule because the referring physician, and not the licensee, may have notified the individual. Therefore, the licensee may not know what information the referring physician provided to the individual.

We amended paragraph (e) [paragraph (d) of the proposed rule] in the final rule. The words “when appropriate” were deleted from the last sentence in paragraph (d) of the proposed rule because the intent was covered by the phrase “may be made” in the same sentence.

We added paragraph (g) to the final rule to require that licensees annotate a copy of their report to the NRC about the medical event and provide it to the referring physician, if other than the licensee, within 15 days after discovery of the medical event. We believe that it is important for the referring physician to have all the available documentation about the medical event to support any decision about remedial or prospective health care.

Section 35.3047, Report and notification of a dose to an embryo/fetus or a nursing child.

Issue 1: Should the Abnormal Occurrence Policy Statement criteria for reporting of unintended exposures to an embryo/fetus or nursing child be modified?

Comment. Numerous commenters recommended that § 35.3047 be deleted and the Abnormal Occurrence (AO) Criteria be revised to reflect the deletion of this section.

Response. The information required by this section is needed so that NRC can comply with Section 208 of the Energy Reorganization Act of 1974 (Pub. L. 93-438, 5848, 42 U.S.C.), as amended, to submit an annual report to Congress of unscheduled incidents or events which the Commission considers significant from the standpoint of public health and safety, e.g., abnormal occurrences. (The "Reports Elimination Act," Pub. L. 104-66, changed the Abnormal Occurrence (AO) report to a yearly publication.)

The NRC identifies an abnormal occurrence using the revised abnormal occurrence criteria that were published in the Federal Register (62 FR 18820; April 17, 1997). Section II of that policy statement defines unintended radiation exposure as "any occupational exposure, exposure to the general public, or exposure as a result of a medical misadministration (as defined in § 35.2) involving the wrong individual that exceeds the reporting values established in the regulations." This section also states that "All other reported medical misadministrations will be considered for reporting as an Abnormal Occurrence under the criteria for medical

licensees. In addition, unintended radiation exposures include any exposure to a nursing child, fetus, or embryo as a result of an exposure (other than an occupational exposure to an undeclared pregnant woman) to a nursing mother or pregnant woman above specified values." Appendix A, Section I.A.2., "Abnormal Occurrence Criteria," of the policy statement, states that NRC will provide information on "any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual total effective dose equivalent of 50 mSv (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more."

At the present time, the NRC has no regulatory requirements that require licensees to report those types of events. Therefore, the Commission considered two alternatives: revise the current Abnormal Occurrence Criteria to delete the requirement to report this type of event to Congress; or develop a reporting requirement for licensees that would provide the information needed by the Commission to comply with Section 208.

After extensive discussion and consideration of the public comments, we have decided to pursue the second option. We are not convinced that it is inappropriate for the NRC to report this type of event to Congress and that the reporting requirement in § 35.3047 will be overly burdensome or unwarranted. We are also not inclined to further revise the AO criteria because they have recently been revised and limited comments were received on the proposed criteria.

The thresholds for reporting an unintended dose to an embryo/fetus or a nursing child have been raised in the final rule to the reporting levels in Appendix A, Section I.A.2, of the AO policy statement. Licensees are now required to report any unintended dose to an

embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent and any dose to a nursing child that is either greater than 50 mSv (5 rem) effective dose equivalent or results in unintended permanent functional damage to an organ or a physiological system, as determined by a physician. We believe that § 35.3047, as revised in the final rule, provides a balanced resolution of this issue. The regulatory burden on licensees will be substantially less than it would have been under the proposed § 35.3047 because of the higher reporting thresholds in the final rule; and the NRC will receive the information it needs to report to Congress. In addition, because of the more serious consequences associated with these higher thresholds, we believe that the NRC should receive reports of these unintended doses to an embryo/fetus or nursing child.

Issue 2: What is the impact of the proposed reporting requirement on licensee procedures, activities, or medical practices?

Comment. According to the comments, the biggest impact of the proposed reporting requirement on licensees is associated with the need to determine the pregnancy status of individuals. Commenters had many concerns about NRC's expectations of pregnancy testing, such as delays in emergency scans pending the completion of pregnancy tests; the sensitivity of pregnancy tests; false negative tests in early pregnancy; the age range for pregnancy testing; privacy of minors; patients refusing to pay for pregnancy tests; and the method for calculating conception dates.

Commenters were also concerned about the licensees' responsibilities when they find out later that there was an unintended exposure to a pregnant individual. This can happen if,

for example, the patient may not be aware of, or opts to conceal, the fact that she is pregnant. Licensees should not be held responsible for what patients do against medical advice and reporting such incidents will not prevent a recurrence. Unintended exposures may also occur in cases where the AU is not required to examine the patient, consult with the referring physician, or see the patient's chart, e.g., non-iodine diagnostic studies.

Commenters said that the overwhelming majority of nuclear medicine procedures are safe to perform on pregnant women. In fact, they are often the tests of choice for pregnant women because other radiologic procedures frequently involve higher radiation doses. For the few cases in which administration of a pharmaceutical is not recommended (e.g., sodium iodide I-131), pregnancy information is ascertained. They believe that, by default, the proposed requirement will require pregnancy testing on every female of childbearing age. The inaccuracy, costs, etc. of the tests will lead patients to seek alternative, and often less effective, treatments.

Response. The Commission recognizes that the standard of practice for AUs is to assess the pregnancy or nursing status of their patients (reference 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.

We do believe that it is appropriate to require the licensee to inform the NRC when the licensee learns of an unintended dose to an embryo/fetus or a nursing child that exceeds the

thresholds in § 35.3047. The occurrence of such an unintended dose does not necessarily mean that the licensee is in violation of the requirements in Part 35 as long as the licensee reports it and it is not otherwise in violation of NRC regulatory requirements.

However, the NRC acknowledges that, in some cases, the licensee might not be able to prevent the dose to an embryo/fetus or nursing child. For example, there is no way for an AU to prevent administration of an unintended dose to an embryo/fetus if the pregnancy test was negative because it was given very early in the pregnancy.

Issue 3: What should be the reporting threshold for a dose to an embryo/fetus or a nursing child?

Comment. Commenters said that the proposed reporting level of 5 mSv (500 millirem) to an embryo/fetus or a nursing child is not consistent with the Commission's intent of making Part 35 more risk-informed and performance based because it cannot be justified on the basis of risk. This reporting level is also not consistent with the NRC's need to submit an annual report to Congress on unscheduled incidents or events which the Commission considers significant from the standpoint of public health and safety, i.e., abnormal occurrences. One commenter noted that significant biological effects would not be observable at this reporting level in either an embryo/fetus or a nursing child, as demonstrated by the healthy births of children who were exposed to radiopharmaceuticals in utero for the purpose of diagnosing the mothers of these children. The only radiation doses that truly present a significant health and safety issue are those which result in actual non-stochastic effects. Therefore, another commenter suggested that the NRC consider only those medical events which result in actual

non-stochastic effects as abnormal occurrences. In addition, one commenter said that there is no similar requirement by agencies regulating diagnostic x-ray machines. Furthermore, the proposed reporting level is going to result in NRC receiving a number of reports of questionable accuracy and utility.

Commenters suggested a range of reporting levels from 1-25 rem dose equivalent. One commenter suggested that the reporting level should be the same as for medical events: 5 rem total effective dose equivalent or 50 rem to an organ or tissue. Another commenter noted that at his institution, genetic counselors do not consider radiation to be a risk until about 15-20 rem to the embryo/fetus. One commenter suggested that licensees report only radiation-induced injuries and deaths from radiopharmaceuticals and radiologic devices that were due to accidents and that were not reportable to the FDA.

A commenter noted that NCRP Report No. 54, “Medical Radiation Exposure of Pregnant and Potentially Pregnant Women” (1977), states that the risk to the embryo/fetus is negligible below 5 rad and is only significant when compared to other risks of pregnancy above 15 rad. This is consistent with the recommendations in AAPM Radiation Therapy Task Group No. 36 - Fetal Dose from Radiotherapy with Photon Beams, 1995 (AAPM TG-36).

Commenters also noted that the lack of adequate data makes it virtually impossible to accurately calculate radiation doses to an embryo/fetus at various gestational periods from radiopharmaceuticals. They also questioned how the NRC suggests that patients be monitored to ensure that they are complying with instructions about breast feeding if the nursing child could receive a dose in excess of 100 millirem.

Response. Following an evaluation of the comments and further review of published recommendations and literature, the NRC changed the reporting thresholds in § 35.3047 in the final rule. Paragraph (a) requires that a licensee report to the NRC any administration of byproduct material or radiation from byproduct material to a pregnant woman that results in a dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent unless the administration was specifically approved, in advance, by the AU. We emphasize that only unintended exposures must be reported to the NRC. If a licensee knows that an individual is pregnant and makes the decision that it is necessary to proceed with a test involving the administration of byproduct material or radiation from byproduct material, the licensee would not have to report the dose to the pregnant individual as a medical event. Paragraph (b) requires that a licensee report to NRC any administration of byproduct material to a breast-feeding woman that results in a dose to the nursing child that is greater than 50 mSv (5 rem) total effective dose equivalent or a dose that has resulted in unintended permanent functional damage to an organ or a physiological system, as determined by a physician. These reporting levels are consistent with the recommendations in NCRP Commentary No. 9, "Considerations Regarding the Unintended Radiation Exposure of the Embryo, Fetus or Nursing Child" (1994). At a reporting threshold of 50 mSv (5 rem), there are no detectable deterministic effects, and the risk of stochastic effects (e.g., cancer) is less than 1 percent. This report concluded that "setting requirements for action after radiation exposure of the embryo, fetus, or nursing child at some level below an effective dose of 100 mSv (10 rem) to allow for a margin of safety should enable all such incidents with the potential for harm to be dealt with appropriately."

We believe that the reporting threshold on the final rule is not overly burdensome on licensees. Unintended doses to an embryo/fetus or nursing child exceeding 50 mSv (5 rem) are rarely encountered in the practice of nuclear medicine (refer, for example, to Russell, J.R., et. al, Radiation Absorbed Dose to the Embryo/Fetus from Radiopharmaceuticals, Health Physics 73:756-769;1997).

Issue 4: Should § 35.3047 include a requirement for a licensee to notify a pregnant individual or mother about an event that must be reported to the NRC in accordance with this section?

Comment. The physician should be able to determine whom to notify. The method and extent of notifying a pregnant individual or mother are solely a matter of the physician's judgment, within the context of the physician-patient relationship. In some cases, the best individual to notify may be the pediatrician (or future pediatrician), which is not an option in the rule. The pediatrician, not the mother's referring physician, will be caring for the infant. The notification requirements in this section are an intrusion into the practice of medicine.

Response. The NRC retained the requirement for notification of the pregnant individual or mother in the final rule. Although notification of the pregnant individual or mother may represent the "standard of care," that practice may not be uniformly followed. We believe that the pregnant individual or mother should be notified so that she can participate in any decisions on follow-up medical care, if necessary.

Issue 5: Is there a better term than “responsible relative or guardian” that could be applied to those situations where the mother is not notified, e.g., in the referring physician’s medical judgment telling the mother would be harmful; the mother is a minor; or the mother is not competent to make decisions regarding medical care?

Comment. Several comments were received in response to this question, which was published in the proposed rule. Some commenters said that the term “responsible relative or guardian” itself was sufficient, and recommended no alternative wording. The term “guardian” appears to be very clear because the only comment on guardian said that it does not need to be fixed.

The NRC also received several comments on the interpretation of “responsible relative.” Several commenters hoped that “responsible” is not used as a substitute for “legal.” The term “responsible” should allow for notification of someone who cares for the minor but who is neither a blood relative nor a legal guardian. Not telling the mother only because she is a minor is not a responsible rule and is inappropriate. The medical community and the laws of each state determine if a mother is allowed information that may affect her child if she is a minor. The other two situations, it would be harmful to the mother or the mother is not competent, should cover when notification of the responsible relative or guardian is necessary. Another commenter said that for an adult, what is really meant by notifying the “responsible relative” is notifying the relative or individual who has medical power of attorney.

Response. The final rule retains the current phrase “responsible relative or guardian” because the NRC did not receive any suggested term that better captures the intent of this

requirement, which is that *someone* be told in those situations where the mother is not notified. We believe this terminology could include an individual who has medical power of attorney. However, it would be unduly restrictive to limit the individual to be notified, in lieu of the patient, to an individual with medical power of attorney. A physician's decision on whom to notify is based on many factors, including the Code of Medical Ethics of the American Medical Association and state laws that govern the release of a patient's medical information to another individual.

To assist with the interpretation of the current notification requirements in the misadministration rule, the Commission had previously provided the examples used in the question of when it expects that a "responsible relative or guardian," rather than the patient, would be notified about a misadministration. These were provided only as examples, and are not part of the actual regulatory text, e.g., we did not intend by the examples that a mother should not necessarily be notified if she is a minor. We believe that the referring physician should have the discretion to either inform the mother or to determine that, based on medical judgment, telling her would be harmful, in which case the mother's or child's responsible relative should be notified.

Issue 6: Why do licensees need to notify the NRC, by telephone, within 5 days and in writing no later than 15 days after discovery of a dose to an embryo/fetus or nursing child that requires a report under this section?

Comment. Commenters questioned the need to notify NRC by telephone within 5 days and in writing no later than 15 days after discovery of a dose to an embryo/fetus or nursing child

that requires a report under this section. These reporting requirements give the perception that there is much greater harm than there actually is. One commenter said that the licensee should only have to report in writing to the Regional Office within 30 days after discovery of the dose. The other commenter said that notification of the NRC should be changed from 5 days to 15 days after discovery of the event, or at least changed to 5 working days so there is ample time over a holiday period. The additional time is needed for the licensee to assure the validity of the information in the report.

Response. The final rule contains a significantly higher reporting threshold than the proposed rule for reporting an unintended dose to a nursing child or an embryo/fetus as a result of the unintentional administration of byproduct material or radiation from byproduct material. Licensees are now required to report any dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent and any dose to a nursing child that is either greater than 50 mSv (5 rem) effective dose equivalent or results in unintended permanent functional damage to an organ or a physiological system, as determined by a physician. More serious consequences are associated with these higher thresholds. Therefore, the reporting requirement in the proposed rule to notify the NRC within 5 days after discovery of the unintended dose has been revised to require notification of the NRC no later than the next calendar day. Early telephone notification will allow the NRC to promptly take any necessary actions based on the circumstances, e.g., dispatch a medical consultant. Prompt notification of events that trigger these thresholds is important because the circumstances of the medical event may need to be reviewed as soon as possible to determine if any follow-up actions are necessary.

The reporting requirement in the proposed rule to submit a written report to the NRC Regional Office no later than 15 days after discovery of the dose has also been retained in the final rule. We believe that the 15 day reporting period is justified by the more serious consequences associated with the higher reporting thresholds. It is important that the NRC has all of the information in the written report as soon as possible to evaluate the event and to determine if any follow-up actions are available. The rule language recognizes that the licensee may not have all of the *final* information on the event at the time the report is submitted to NRC.

Issue 7: Were there any other changes made in this section between the proposed and final rules?

Response. Yes. The NRC amended the title of this section to state more correctly that this section includes *both* reporting *and* notification requirements following a dose to an embryo/fetus or nursing child that exceeds the thresholds in § 35.3047.

We amended paragraph (b)(2) to read "... permanent functional damage to an organ or a physiological system of the child..." to make it clear that this reporting criterion applies to the nursing child.

We combined paragraphs (d)(1)(vi) and (vii) in the proposed rule into one paragraph [(d)(1)(vi)] in the final rule because they both address actions or improvements that have been taken, or are planned, to prevent recurrence of a medical event.

We reworded paragraphs (d)(1)(v)and (vi) in the final rule to read “the effect, if any, on the embryo/fetus or the nursing child;” and “what actions, if any, have been taken, or are planned, to prevent recurrence.” We added the words “if any” and “are planned” because there might not be any effect or any actions taken at the time the event is reported. We deleted paragraph (d)(1)(vi) in the proposed rule because it was duplicative of paragraph (d)(1)(vii).

We added a new paragraph (d)(1)(vii) to require that the written report include a certification that the licensee notified the pregnant individual or mother (or the mother’s or child’s responsible relative or guardian), and if not, why not. This provides NRC with documentation that the pregnant individual or mother was notified. We made this revision because notifying these individuals is important enough to warrant documentation that the individual(s) was notified. In addition, we believe that it is important that the licensee notify the pregnant individual or mother so that she can be actively involved in any decision about remedial or prospective health care following the event.

We amended paragraph (e) [paragraph (d) of the proposed rule] in the final rule. The words “when appropriate” were deleted from the last sentence in paragraph (d) of the proposed rule because the intent was covered by the phrase “may be made” in the same sentence.

We combined proposed paragraphs (e), (f), and (g) into one paragraph so the format of this section is similar to the section on reporting medical events.

Paragraph (h) of the proposed rule that required the licensee to furnish the mother, or responsible relative or guardian, with a written report was deleted in the final rule. Instead,

paragraph (e) in the final rule requires licensees to inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. Licensees are required to provide such a written description to the individual, if requested. We believe that a written description would be especially useful to an individual who needs to make decisions about any follow-up medical care, and provides the individual a permanent record to refer to for information about the event.

We added paragraph (f) to the final rule to require that licensees annotate a copy of their report to the NRC about the event and provide it to the referring physician, if other than the licensee, within 15 days after discovery of the event. We believe that it is important for the referring physician to have all the available documentation about the event to support any decision about remedial or prospective health care. The 15-day time period to provide the referring physician with a copy of the record was based on paragraph (d) which requires a licensee to submit a report to the NRC within 15 days. We have attempted to have consistency in the requirements in Subparts L and M, where possible, to simplify compliance with the recordkeeping and reporting requirements.

Section 35.3067, Report of a leaking source.

Issue: Where there any changes made in this section between the proposed and final rules?

Response. Yes. The NRC changed the title of this section so that it refers to a single report. This change makes the title of this section consistent with the titles of the other sections in Subpart M.

We made this section more performance based by using “the results of the test” instead of the more detailed requirements of “the measured activity of each test sample expressed in microcuries” and “a description of the method used to measure each test sample.” These changes are consistent with changes made in response to comments on § 35.2067, Records of leaking sources.

IV. Summary of Comments on Agreement State Compatibility and Responses to Comments

Part 1: General Questions

Issue 1: How does NRC determine if a requirement should be given a health and safety (H&S) classification?

Comment. Several commenters expressed a concern regarding the compatibility categories, especially those designated as “D (H&S)”. Commenters stated that the (H&S) classification has nothing to do with compatibility but does apply to adequacy of a State’s radiation control program. They further stated that, if the NRC finds it necessary to use this classification, then it should define the “significant safety issues” that led to the (H&S) designation. Other commenters stated that H&S designations for Agreement State

requirements is a “back door” to compatibility requirements and may be unevenly and/or inappropriately enforced. Commenters recommended that if a requirement must be adopted by an Agreement State in order for that State’s program to be found “adequate,” the requirement should be assigned a “compatibility” designation. H&S designations should be assigned only when a requirement has a direct Part 20 connection.

Response. On September 3, 1997, the Commission approved an Adequacy and Compatibility Policy for Agreement State Programs. This policy was developed in an open environment, with early and substantive involvement by Agreement State representatives. Management Directive 5.9, “Adequacy and Compatibility of Agreement State Programs” (Adequacy and Compatibility Policy) provides guidance on applying the Adequacy and Compatibility Policy to Agreement State program elements including regulations.

The assignment of compatibility categories to each requirement in the revised rule was made in accordance with the Adequacy and Compatibility Policy. The compatibility category assignments are needed to assure that byproduct material is used with a minimum level of safety nationwide. Those program elements (including regulations) which are not required for compatibility, as noted in the Adequacy and Compatibility Policy, may be required because of their health and safety (H&S) significance. The NRC has reviewed and revised, where appropriate, the chart detailing the compatibility categories for each requirement in the final rule. Each requirement in the rule, identified for compatibility or adequacy, has an accompanying rationale explaining its health and safety significance or its need based on consistency between NRC and Agreement State programs.

NRC conducts performance based reviews of Agreement State programs in accordance with the Integrated Materials Performance Evaluation Program (IMPEP). Findings of Adequacy and Compatibility for each Agreement State program are made by a management review board (MRB) consisting of senior NRC managers along with a manager from an Agreement State. These findings are made based on a number of factors, including regulations.

Under the Adequacy and Compatibility Policy, and the review of Agreement State programs under IMPEP, the Agreement States are provided flexibility in administering their programs. Regulations and other program elements identified as having adequacy or health and safety significance may be addressed through the promulgation of compatible regulations or the adoption of other legally binding documents. Final findings of Agreement State program adequacy and compatibility are made by the MRB based on their assessment of the entire program, not just its regulations. This process assures a level of consistency in the review of Agreement State programs. Each Agreement State program director is afforded an opportunity to appear before the board to explain his or her State's performance and answer questions from the MRB.

Issue 2: What flexibility should be given to Agreement States?

Comment. A commenter stated that Part 35 should not be a matter of compatibility for the Agreement States beyond requiring that states have a system for authorizing the medical use of byproduct material. Another commenter stated that the Agreement States should be allowed to regulate medical users as appropriate and as needed. They believed that the rule should be a low compatibility issue. Another commenter stated that the proposed Part 35 will

deal a death blow to the Agreement State Program by demanding that every Agreement State adopt the essential portions of NRC's new Part 35 under threat of being incompatible and inadequate. The commenter stated that the Agreement States want flexibility. A commenter also expressed that this may cause Agreement States to give back their programs.

On this same topic, a commenter stated that nearly all of NRC's policy on Agreement State adequacy and compatibility should be rejected. The practices of medicine and pharmacy have no "transboundary implications" and should be changed from compatibility Category "B" to"D" because they are State functions. All compatibility category "C" items should be changed to "D" because they are too restrictive. All "Health and Safety" (H&S) requirements for adequacy should be removed because they are not necessary for "Health and Safety." The commenter further stated that, "Health and Safety" is accomplished by starting with qualified professionals who follow professional standards.

In contrast, commenters stated that a uniform or relatively uniform approach nationwide between Agreement State regulations and NRC regulations can be worked out and can be adopted. In particular, the American Association for Nuclear Cardiology requested that the NRC require the new Part 35 requirements to be at least a level C compatibility for the Agreement States.

Response. The Adequacy and Compatibility Policy for Agreement States Programs is explained in response to Issue 1. The assignment of the specific compatibility categories to the requirements in the revised rule is necessary to assure that byproduct material is used with a

uniform level of radiation safety nationwide. This is different from the State regulation of medicine and pharmacy, which addresses global safety and competency issues.

Issue 3: Was the comment period on the proposed rule and on compatibility assignments extended?

Comment. Agreement State representatives commented that the comment period was too brief to allow a comprehensive review of the rule, the licensing guide, and the compatibility listing. They also asked that we provide a listing of essential objectives for each section and why particular designations were assigned. In addition, Agreement State representatives asked that the comment period for the rationale for compatibility assignments should be extended up to 90-days after publication of the listing. They further stated that the degree of flexibility allowed the Agreement States is an important issue and should not be omitted from the discussion because information was not available in a timely manner.

Response. Supplement III of this document contains more detailed discussion of the comments that we received on the length of the comment period. As a result of public comment, we extended the comment period on the proposed rule from November 12, 1999 to December 16, 1999.

The proposed rule contained a brief explanation of the compatibility assignments that were made for the proposed rule. Subsequent to that publication, we received requests from Agreement State representatives to provide supporting documentation for how the assignments were made and to provide the essential objectives for each section. This information was made

available to the Agreement States in an All Agreement States letter, dated January 4, 1999. We asked that the States provide comments and suggestions on the compatibility designations by February 12, 1999.

The NRC considered all comments received on the compatibility designations and, where appropriate, made changes to either the assignment or to the rationale for the assignment. Section X of this document contains a summary of the compatibility designations. A more detailed compatibility chart which provides the essential objectives for each section and why particular designations were assigned is posted on the NRC Website at http://www.hsrd.ornl.gov/nrc/home/html. Click on [NRC-State Letters] and then select Part 35 Compatibility Chart.

Issue 4: How has NRC incorporated comments from the Agreement States on Agreement State issues?

Comment. A commenter questioned how the Agreement States comments were considered during the rulemaking.

Response. In the early stages of the rulemaking process, the NRC established a working group and a steering committee comprised of State personnel and NRC staff. One member of the NRC working group was also a member of the Conference of Radiation Control Program Director's, Inc., SR-6 Committee. This Committee is responsible for revising Part G, "Medical Use of Radionuclides," of the Suggested State Regulations. As such, there was a considerable amount of information exchanged between the States and the NRC staff during

the development of the proposed and final rule. We also discussed the revision of Part 35 with representatives of the Agreement States at the 1997, 1998, and 1999 annual meetings of the Organization of Agreement States. In addition, we received numerous comment letters from the States, all of which were considered in developing the final rule.

Technical comments and our response to the comments are discussed under the specific section headings. More general comments or comments that pertain exclusively to the compatibility level assigned to the requirement are discussed in this section.

Part 2 - Comments on compatibility designations

The NRC received numerous comments on the compatibility designations assigned to specific sections. The following part provides the comments and our response to the comments. In many cases, but not all, we made changes to the compatibility designation based on the comment.

PART 20 - Standards for Protection Against Radiation

Section 20.1301, Dose limits for individual members of the public.

Comment. A commenter stated that this requirement should not be a compatibility category A. The compatibility category for this requirement should be D.

Response. This section meets the criteria for compatibility category A because it is an NRC program element which is generally applicable and is a dose limit. No change is required.

PART 35 - Medical Use of Byproduct Material

Section 35.6, Provision for research involving human subjects.

Comment. A commenter stated that compelling Agreement States to adopt this requirement does not reflect that there may be other criteria affecting human research subjects.

Response. A further review of this section indicates that Agreement States should adopt this requirement in order to avoid a gap in the consistent nationwide application of this Federal policy. The compatibility category was changed from “D” to “C.” The NRC also added a requirement to the section indicating that nothing in this section relieved licensees from complying with the other requirements in Part 35.

Section 35.24, Authority and responsibilities for the radiation protection program.

Comment. A commenter stated that this requirement should be classified compatibility category D, not D Health and Safety (H&S). The commenter indicated that, while management should be responsible for the areas identified here, there may be other ways to ensure radiation safety. Further, in the opinion of the commenter, the intent of this requirement will be defeated for small facilities where the AU/RSO is management’s designee.

Response. Section 35.24 in the final rule is assigned a compatibility category D, with the exception of paragraphs (b) and (f). These two paragraphs are assigned to compatibility category H&S. The H&S compatibility category provides the Agreement States with the flexibility needed to use other methods such as legally binding requirements to achieve the essential objective of this rule. In addition, § 35.24(b) and (f) meet the two failure test criteria for the assignment of compatibility category H&S. This designation provides a minimum level of safety in the implementation of a radiation protection program.

Section 35.40, Written directives.

Comment. A commenter stated that the requirement for a written directive may not be contained in the State's radiation regulations. Another commenter stated that written directives do not meet the definition for a compatibility category C in Subpart A, because it does not create a gap or a duplication. It was also noted that written directives are a compatibility category "D (H&S)" in Subpart B. Another commenter stated that written directives should not be designated compatibility category H&S and that there are other methods to ensure the right dose is delivered to the right patient (e.g., requiring the physician to be present during a therapy treatment).

Response. In the final rule, paragraphs (a) and (b) of § 35.40, "Written Directives," are assigned a compatibility category H&S. The NRC believes that it may be possible to ensure the right dose is delivered to the right patient if a legally binding requirement is in effect and there is some documentation by the physician in the routine radionuclide use log. In accordance with the Policy on Adequacy and Compatibility for Agreement State Programs, legally binding

requirements may be acceptable in lieu of a specific regulation on written directives if the essential objectives of this rule are achieved. Section 35.40 meets the two failure test criteria for the assignment of compatibility category H&S. This designation provides a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event.

Section 35.61, Calibration of survey instruments.

Comment. A commenter stated that the requirement in § 35.61 to note the date of the calibration on an instrument should not be a compatibility category H&S. The length of time for record retention is not a compatibility category H&S and should be designated a compatibility category C in all areas of the regulations.

Response. The NRC agrees with the commenter that the requirement to note the calibration date on a survey instrument and the record retention requirement should not be a compatibility category H&S. Therefore, these requirements have been revised from H&S to a compatibility category D. All of the other requirements in § 35.61 remain compatibility category H&S.

Section 35.63, Determination of dosages of unsealed byproduct material for medical use.

Comment. A commenter stated that there may be some confusion regarding the compatibility category assigned to the requirement covering radiopharmaceutical dosages

prepared by the medical use licensee under 10 CFR 35.63 versus those prepared by a commercial pharmacy/manufacturer under 10 CFR 32.72.

Response. Both medical licensees and the commercial preparer of radiophamaceuticals must determine and record the activity of each dosage intended for medical use. Therefore, this requirement is a compatibility category H&S.

Section 35.67, Requirements for possession of sealed sources and brachytherapy sources.

Comment. A commenter stated that paragraph (a) should be a compatibility category C. The commenter believed that licensees can develop better procedures and should have the opportunity to submit them for review and approval by the licensing agency.

Response. Section 35.67(a) meets the two failure test criteria for the assignment of compatibility category H&S. This designation assists in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event and worker overexposure.

Comment. A commenter stated that paragraph (f) rather than (e) should be a compatibility category D and paragraph (e) should be a compatibility category “D (H&S)”. Another commenter stated that paragraph (f) which provides a waiver of leak test requirements does not meet the criteria for compatibility category H&S.

Response. Paragraph (e) is a compatibility category H&S because the technical requirements are already addressed in Part 20 and Part 30 and the actual reporting requirement for leaking sources is contained in § 35.3067 which is a compatibility category C. We agree with the commenters. The compatibility category for paragraph (f) was revised from H&S to D.

Section 35.70, Surveys of ambient radiation exposure rate.

Comment. A commenter questioned the need for a compatibility category H & S for paragraph (b).

Response. The NRC agrees with the commenters and have revised this section to indicate that § 35.70(b) is assigned a compatibility category D.

Section 35.75, Release of individuals containing radioactive drugs or implants containing byproduct material.

Comment. A commenter stated that 10 CFR 35.75, which has been assigned a compatibility category C, should be changed to category B due to significant transboundary implications.

Response. The assignment of a compatibility category C to this requirement is appropriate because the term transboundary applies to the use of byproduct material by

licensees which operate in multiple locations. The compatibility category C designation provides a minimum level of safety, while providing some flexibility to Agreement States to be more restrictive.

Section 35.80, Provisions of mobile medical service.

Comment. A commenter did not agree with the original basis for designating this section as D compatibility. They disagreed with the following statement: "since there is no potential for medical use of byproduct material in other regulatory jurisdictions under reciprocity" the section is designated a D compatibility."

Other commenters commented on specific paragraph designations. A commenter stated that paragraph (a)(1) should not be a compatibility category H&S issue. Another commenter stated that paragraph (a)(4) should be a compatibility category H&S issue, but that the designation is inconsistent with the requirements for fixed facilities. (Note: Fixed facilities have to conduct surveys only for procedures requiring a written directive (§ 35.70)).

Response. The Agreement State representatives informed the NRC staff that not all Agreement States authorize mobile services and that there are a number of additional State professional and technical licensing issues which complicate this activity. The medical use of byproduct material (diagnostic or therapeutic) as a mobile service has been designated a compatibility category D for all Agreement States (not required for compatibility) and category H&S for those Agreement States which authorize mobile services. This designation H&S

assists in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event and worker overexposure.

The NRC agrees with the specific comments on paragraphs (a)(1) and (a)(4). The compatibility categories were revised from H&S to D in these sections.

Section 35.92, Decay-in-storage.

Comment. A commenter stated that this section should not be a compatibility category H&S issue. The failure scenario is in error in that it assumes waste would be placed in ordinary trash if storage of isotopes with longer or shorter half-lives were permitted. Permitting decay-in-storage does not mean material that has not decayed would be placed in ordinary trash.

Response. This section is a compatibility category D for those States that choose not to allow the decay-in-storage option. For States allowing this option, the compatibility category is H&S. The two or fewer failure test scenario was reworded to better reflect the importance of the H&S assignment for this requirement.

Sections 35.100, Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required and 35.200, Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.

Comment. A commenter questioned the assignment of a compatibility category H&S to §§ 35.100 and 35.200 because they are very low risk procedures.

Response. Both requirements meet the two or fewer failure test scenario detailed in Management Directive 5.9 for the assignment of compatibility category H&S. These provisions assist in establishing a minimum level of safety in the medical use of agreement materials by reducing the likelihood of a medical event.

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

Comment. A commenter believed that Agreement States should have the option of adopting higher standards for training even if it means the state would become "incompatible."

Response. A compatibility category B was assigned to this requirement, as well as all of the other training and experience requirements in Part 35. This ensures that the training and experience requirements for the medical use of byproduct material are consistent between NRC and the Agreement States.

Section 35.432, Calibration measurements of brachytherapy sealed sources.

Comment. A commenter stated that this requirement should not be a compatibility category C.

Response. This requirement was assigned a compatibility category H&S which provides a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event.

Section 35.604, Surveys of patients and human research subjects treated with a remote afterloader unit.

Comment. A commenter stated that the requirement for after implant surveys is not appropriate for a compatibility category C, since it is a Part 20 requirement.

Response. The NRC agrees with this comment and has changed the requirement to a compatibility category H&S.

Sections 35.610, Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

Comment. A commenter stated that § 35.610 should be compatibility category C, as there can be other ways of meeting the essential objectives.

Response. Section 35.610 meets the two or fewer failure test criteria for the assignment of compatibility category H&S. This designation assists in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event and worker overexposure.

Section 35.615, Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

Comment. A commenter stated that § 35.615 should be compatibility category C, as there can be other ways of meeting the essential objectives.

Response. Section 35.615 meets the two or fewer failure test criteria for the assignment of compatibility category H&S. This designation assists in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event and worker overexposure.

General comments on training.

Comment. A commenter stated that when the Part 35 rulemaking becomes effective, Agreement States that have more strict training and experience requirements for non-board certified physicians will not be able to accept individuals who have met the less restrictive requirements needed to become AUs on NRC licenses as authorized.

Response. When the final Part 35 becomes effective, the Agreement States will have up to 3 years to adopt compatible regulations. The training and experience criteria for physicians is a compatibility category B which means that the requirement has significant direct transboundary implications. Agreement States' requirements should be essentially identical to those of the NRC so that there are consistent training and experience requirements for the

medical use of byproduct material. Non-board certified physicians will continue to be afforded the opportunity to present alternate credentials on a case-by-case basis.

V. Summary of Changes Made Between the Current Part 35 and the Revised Part 35

Subpart A, General Information, contains general information regarding medical use of byproduct material.

Section 35.1, Purpose and scope, was amended to specify that Part 35 provides for the radiation safety of workers, the general public, patients, and human research subjects. The NRC included the phrase “patients, and human research subjects" to make it clear that the provisions of this rule apply to the radiation safety of those individuals. This addition is consistent with the revision of the Medical Use Policy Statement that was published in the Federal Register on August 3, 2000 (65 FR 47654). We also added a reference to Part 171, “Annual Fees for Reactor Operating Licenses, and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed By NRC.” This change makes it clear that the provisions in Part 171 apply to medical licensees.

Section 35.2, Definitions, was amended. The NRC either deleted, revised, or added specific definitions based on the use of the terms within Part 35. Each category of action is discussed separately.

DELETED DEFINITIONS:

The NRC deleted the following terms because they do not appear in the final rule: as low as is reasonably achievable (ALARA), dental use, diagnostic clinical procedures manual, ministerial change, misadministration, podiatric use, recordable event, and teletherapy physicist.

REVISED DEFINITIONS:

The NRC revised the definitions of *address of use* and *area of use* to clarify that they also include the building where byproduct material is prepared for use. This recognizes that licensees not only receive, use, and store byproduct material, but, in the case of medical licensees, they may also prepare the material for use.

The NRC revised the definition for *authorized nuclear pharmacist* (ANP) to eliminate the specific board certifications by name and to refer to the specific section(s) in Part 35 containing the requirements the individual must meet to be considered an ANP. We deleted the reference to the specific board certifications because the regulatory text in Part 35 no longer incorporates a listing of specialty boards whose diplomates automatically fulfill the training and experience requirements. In place of listing the boards, the final rule provides for NRC recognition of the boards. We revised the definition of ANP to include individuals identified as ANPs on a specific license issued by the Commission or Agreement State that authorizes medical use or the practice of nuclear pharmacy; a permit issued by a Commission master material licensee that authorizes medical use or the practice of nuclear pharmacy; a permit issued by a Commission

or Agreement State broad scope medical use 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. In addition, an ANP can be an individual identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy which has been given authorization to identify authorized nuclear pharmacists or an individual designated as an authorized nuclear pharmacist in accordance with § 32.72(b)(4).

The NRC revised the definition for an *authorized user* (AU) to eliminate the specific board certifications by name and to refer to the specific section(s) in Part 35 containing the requirements the individual must meet to be considered or an AU. We deleted the reference to the specific board certifications because the regulatory text in Part 35 no longer incorporates a listing of specialty boards whose diplomates automatically fulfill the training and experience requirements. In place of listing the boards, the final rule provides for NRC recognition of the boards. We revised the definition of AU to include individuals identified as AUs on a Commission or Agreement State license that authorizes the medical use of byproduct material; a permit issued by a Commission master material licensee that is authorized to permit the medical use of byproduct material; a permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of byproduct material; or a permit issued by a Commission master material license broad scope permittee that is authorized to permit the medical use of byproduct material.

The NRC revised the definition for a *brachytherapy source* to acknowledge current practices within the radiation oncology field. In addition, we deleted the word “sealed” from the

definition to include sources that do not meet the definition of “sealed source,” i.e., radioactive plated, embedded, and activated sources.

The NRC revised the definition of *management* to recognize an individual having the authority to manage, direct, or administer the licensee’s activities who may not have the title of Chief Executive Officer.

The NRC amended the definition of *medical use* to replace the word “therefrom” with the phrase “from byproduct material” because the regulations in Part 35 apply only to the medical use of byproduct material.

The NRC replaced the definition of *mobile nuclear medicine service* with a definition for *mobile medical service* because it is a broader term that encompasses all modalities that could be performed by a mobile medical service.

The NRC revised the definition of *output* to refer to the exposure rate or dose rate coming from a brachytherapy source, remote afterloader, or gamma stereotactic radiosurgery unit. The current rule only addresses the output from a teletherapy unit.

The NRC revised the definitions of *prescribed dosage* and *prescribed dose*. As modified, the definition of prescribed dosage allows the AU to prescribe a range of activity, without reference to the diagnostic clinical procedures manual. The term unsealed byproduct material in this definition replaces the term radiopharmaceutical. We added a reference to remote afterloaders to the definition of prescribed dose.

The NRC revised the definition of *Radiation Safety Officer* (RSO) to include a reference to the specific requirements an individual must meet in order to be authorized as an RSO. This change makes the definition of RSO consistent with the definitions of ANP, AU, and authorized medical physicist (AMP). We also amended the definition to state that an RSO could also be an individual identified on a specific medical use license issued by the Commission or Agreement State license or a permit issued by a Commission master material licensee.

The NRC revised the definition of *written directive* to delete the provisions for the date the directive was signed, the signature of the AU before administration of any byproduct material or radiation from byproduct material to a specific patient or human research subject, and the specific information that must be included in written directives. These provisions were considered to be substantive requirements and were moved to § 35.40, Written directives.

NEW DEFINITIONS

The NRC added the following definitions either because they are used in the final Part 35 or the stakeholders asked that definitions of the terms be added to help clarify regulatory text. Definitions were added for the following terms: authorized medical physicist, brachytherapy, client's address, high dose-rate remote afterloader, low dose-rate remote afterloader, manual brachytherapy, medical event, medium dose-rate remote afterloader, patient intervention, preceptor, pulsed dose-rate remote afterloader, Sealed Source and Device Registry, stereotactic radiosurgery, structured educational program, teletherapy, temporary job site, therapeutic dosage, therapeutic dose, treatment site, type of use, and unit dosage.

The NRC amended § 35.5, Maintenance of records, to insert “and” in the current phrase “drawings and specifications.”

The NRC amended the title of § 35.6 to read Provisions for the protection of human research subjects. We also restructured this section to make it easier to read. We 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 for medical use under §§ 35.100, 35.200, and 35.300 and Cs-137 for calibration of survey instruments, it cannot conduct medical research using the Cs-137 source. However, the same licensee can conduct research using materials authorized under §§ 35.100, 35.200, or 35.300.

We added paragraph (d) to codify the Commission’s intent that § 35.6 does not relieve licensees from complying with other provisions in Part 35 and that all relevant radiation safety provisions of Part 35 are applicable to research involving human subjects. This position is further discussed in the regulatory history of § 35.6. For further information on this issue, see the Federal Register of December 2, 1994 (59 FR 61767).

The NRC made no changes in § 35.7, FDA, other Federal, and State requirements.

The NRC amended § 35.8, Information collection requirements; OMB approval, to reflect the renumbering of some sections within the rule and the additional recordkeeping and reporting sections which are in separate subparts in the new rule.

Section 35.10, Implementation, is a new section that discusses the provisions for implementing the final rule. A detailed discussion of the implementation provisions can be found in Section IX of the SUPPLEMENTARY INFORMATION section. This section replaces the current § 35.999, Resolution of conflicting requirements during transition period.

The NRC revised § 35.11, License required. Paragraph (a) was revised to state more clearly that a person may manufacture, produce, acquire, receive, possess, prepare, use, or transfer byproduct material for medical use only in accordance with a specific license issued by the Commission or an Agreement State or as allowed in paragraphs (b)(1) and (b)(2) of this section. We added “prepare” to recognize that medical use licensees may also prepare the byproduct material for use and need a license to do so. We amended paragraphs (b)(1) and (b)(2) to reflect that the requirements for supervision in the current § 35.25 were replaced by the requirements in the final § 35.27.

The NRC revised § 35.12, Application for license, amendment, or renewal.

We revised paragraph (a) to state that any application for a license, amendment, or renewal must be signed by the applicant’s or licensee’s management. The current rule indicates that any person may apply if the application is for medical use not sited in a medical institution and that only management may apply for a license if the application is for use in a medical institution. We believe it is important that management apply for a license, regardless of where the byproduct material is used, because NRC holds the licensee responsible for any actions of its employees.

We revised paragraph (b) to address license applications for uses authorized under §§ 35.600 and 35.1000. Therefore, the current paragraph (c) was no longer needed and was deleted. We no longer require licensees to have separate licenses for teletherapy or gamma stereotactic radiosurgery units. In addition, paragraph (b) lists the items that must be submitted to NRC in support of a license application. The new paragraph (c) provides a list of the items that must be submitted to NRC in support of a license amendment. The lists in paragraphs (b) and (c) codify existing licensing practices. Finally, we amended paragraphs (b) and (c) to delete the reference to the regulatory guides. Guidance for completing an application is in NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses." NUREG-1556, Vol 9, is available for inspection at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC.

We deleted the statement in the current paragraph (d) that referenced where to find copies of regulatory guides, application forms, or where to submit an application or an amendment request. This information is not needed in the regulation. The new paragraph (d) addresses applications for medical use of byproduct material as described in § 35.000, i.e. applications that are not specifically included in Subparts D through H of the final rule and are referred to as "emerging technologies." The current rule does not address emerging technologies. Therefore, it does not provide for efficient licensing of emerging technologies. Paragraph (d)(1) provides a list of the additional information needed by NRC to approve a license or license amendment for a use not specifically addressed in Subparts D through H of the new rule. This additional submittal will provide NRC with information on the radiation safety aspects of the specific medical use of the material. Applicants for uses under § 35.1000 must also submit the information required by paragraph (b) and (c) of this section.

The NRC revised § 35.13, License amendments. We revised paragraph (a) 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. Paragraph (a) was also changed to reference "type of use" rather than "clinical procedure." In addition, paragraph (a) was expanded to include AUs, AMPs, and 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 by a commercial nuclear pharmacy that has been given authorization to identify authorized nuclear pharmacists. The term "type of use" is defined in Part 35 and is more appropriate for use in this requirement. We added the reference to an AMP to paragraph (b). A medical use licensee is no longer required to amend its license before allowing anyone to work as an AMP if that individual meets the training and experience requirements in § 35.51(a), and the training and experience requirements were met within the 7 years preceding the date of the application in accordance with § 35.59. In addition, paragraphs (a) and (b) were reworded to indicate clearly the subject of each paragraph.

In paragraph (c), we deleted the requirement for a licensee to apply for a license amendment if the teletherapy physicist changes, provided the individual meets the requirements in §§ 35.51(a) and 35.59. This change is consistent with licensing requirements for AUs and ANPs. Additionally, in the revised § 35.24(c), the Commission recognizes that unusual conditions may arise when the RSO leaves a licensee with little to no advance warning. In this event, the licensee may want to consider using an AU or other individual qualified to be an RSO to fill the position, pending appointment of a new RSO. Under these conditions, the licensee must move expeditiously to permanently fill the position of RSO and should contact the appropriate NRC regional office and explain the situation.

We revised paragraph (d) to require the licensee to apply for and receive a license amendment before it receives byproduct material in excess of the amount or in a different form or it receives a different radionuclide than is authorized on the license. This change clarifies that the requirement is tied to a licensee's authorization to possess, not order, byproduct material and to clarify when an amendment is needed. For example, if a license authorizes possession of any byproduct material identified in §§ 35.100, 35.200, and 35.300, in any chemical and/or physical form, a licensee would be required to obtain a license amendment if it wanted to possess sealed sources for manual brachytherapy (§ 35.400). This same licensee would not need to amend its license if it wanted to use sodium iodide I-131 for thyroid carcinoma because that use is authorized by § 35.300. Further, an amendment would not be required if the licensee wanted to use Tc-99m labeled methylene diphosphonate (MDP) rather than Tc-99m labeled sestamibi because the use is authorized by § 35.200.

To reduce regulatory burden, we deleted the requirement in paragraph (e) for a licensee to apply for a license amendment if there is a change in the areas where byproduct material is used under either § 35.100 or § 35.200. In addition, the requirement in the current paragraph (e) for a licensee to apply for an amendment before it changes the address(es) of use identified in the application or on the license was moved to the final paragraph (f).

We added a new paragraph (g) 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 the revision reduces radiation safety. This applies to procedures required by §§ 35.610, 35.642, 35.643, and 35.645, as applicable.

The NRC revised § 35.14, Notifications. Paragraph (a) was revised to include a requirement for the licensee to notify NRC no later than 30 days after the date the licensee permits an individual to work as an AMP under § 35.13(b), which is comparable to the notification requirements for AUs or ANPs. This change was needed because we would like to be notified when an AMP who has been approved by the licensee begins work. (Reference change made to § 35.13(b)). We revised paragraph (b) to require that the licensee notify NRC when an AMP permanently discontinues performance of duties under the license and to require that a licensee notify NRC when the licensee changes its name. This provision applies only if there is no change in ownership, as described in § 30.34 of this chapter. If there is a change in ownership, the licensee must take appropriate action to have its license amended before the transfer occurs. We also added a requirement to paragraph (b) for a licensee to notify NRC of any changes in areas where byproduct material is used in accordance with either § 35.100 or § 35.200. These revisions to the requirements for notifications were warranted because of the associated revisions to the requirements for license amendments in § 35.13.

The NRC amended § 35.15, Exemptions regarding Type A specific licenses of broad scope, to add the term “authorized medical physicist” to paragraph (e). This change is needed because, under the revised requirements in § 35.13, broad scope licensees have the authority to appoint AUs, ANPs, or AMPs without applying for a license amendment if the individuals meet the approved criteria in Subparts B and D through H.

We added a new paragraph (f) to exempt broad scope licensees from § 35.14(b)(4), which requires licensees to notify NRC if there have been any changes in the areas where byproduct material is used in accordance with either § 35.100 or § 35.200. This provision for

exemptions is consistent with the current exemption these licensees have from applying for a license amendment before they add to or change the areas of use identified in the application or on the license.

We added a new paragraph (g) to also exempt these broad scope licensees from § 35.49(a). This change codifies an exemption currently provided to these licensees through a standard license condition. NRC's medical use licensees with a Type A specific license of broad scope currently receive a standard license condition that exempts the licensee from only receiving sealed sources or devices manufactured from licensees with medical distribution licenses issued in accordance with § 32.74. This change replaces the license condition.

The NRC revised § 35.18, License issuance. Paragraph (a) lists the conditions that must be met in order for the Commission to issue a license. We added requirements for a mobile medical service license as paragraph (b). The NRC will issue a license for mobile medical service if the applicant meets the requirements specified in paragraph (a) of the section and if the individual or human research subject to whom the applicant administers byproduct material, or radiation from byproduct material, may be released following treatment in accordance with § 35.75. The later provision is necessary because mobile medical service licensees do not have the capability of controlling individuals who cannot be released under § 35.75.

The NRC amended § 35.19, Specific exemptions, to delete the statement that the Commission will review requests for exemptions from training and experience requirements with

the assistance of its Advisory Committee on the Medical Uses of Isotopes (ACMUI). This statement is a matter of Commission policy rather than a regulatory requirement.

Subpart B, General Administrative Requirements, contains the general administrative requirements regarding medical use of byproduct material.

The NRC deleted the current § 35.20, ALARA program. ALARA is discussed in § 20.1101, Radiation protection programs, and medical licensees must comply with the requirements of that section. That section requires, in part, that a licensee develop, document, and implement a radiation protection program and use, to the extent practicable, procedures and engineering controls to achieve occupational doses and doses to members of the public ALARA. Therefore, we do not believe that the current § 35.20 is needed in light of the requirements in § 20.1101. A medical use licensee should have flexibility in developing, maintaining, and implementing a radiation protection program that meets the requirements of Part 20.

The NRC deleted the current § 35.21, Radiation Safety Officer. The requirements in paragraph (a) were moved to § 35.24. The list of the RSO's duties in paragraph (b) was deleted because it is overly prescriptive and in some cases overlaps with the requirements in § 20.1101. We believe that the licensee should have flexibility in developing, maintaining, and implementing its radiation protection program, including establishing the RSO's duties.

The NRC deleted the current § 35.22, Radiation Safety Committee. The issue of whether the NRC should require a Radiation Safety Committee (RSC) was identified as a

cross-cutting issue. Therefore, this issue was discussed at public meetings throughout the rulemaking process. Comments received on this topic are discussed in Section III of the SUPPLEMENTARY INFORMATION section. The basic requirement for certain medical licensees to have an RSC to oversee all uses of byproduct material permitted by the license was moved to § 35.24. However, the requirement was modified so that 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 units under Subpart H, are required to establish an RSC. Several other requirements that are currently in § 35.22 were also moved to § 35.24 and are discussed under that section. However, most of the requirements that are currently in § 35.22 have been deleted to provide licensees with more flexibility in how they use the Committee to oversee the radiation safety aspects of the medical use of byproduct material.

The NRC deleted the current § 35.23, Statements of authority and responsibilities. The requirements in this section, with some modifications, were moved to § 35.24.

The NRC added a new § 35.24, Authority and responsibilities for the radiation protection program. A number of the current, prescriptive requirements associated with the radiation protection program have been deleted to provide licensees more flexibility in achieving the objective of radiation safety.

Paragraph (a) requires licensee management to approve, in writing, licensing actions; individuals before allowing them to work as an AU, ANP, or AMP; and radiation protection program changes that do not require a license amendment and are permitted under § 35.26. We believe that licensee management should be responsible for these approvals as part of

their overall responsibility for the radiation protection program. This is a change from the current § 35.22, which gives the RSC the responsibility for two of these approvals: approval of individuals before allowing them to work as an RSO, AU, ANP, or AMP; and approval of radiation protection program changes that do not require a license amendment.

The requirement in paragraph (b) to appoint an RSO is currently in § 35.21. Paragraph (b) also includes a new requirement that the RSO agree, in writing, to be responsible for implementing the radiation protection program. The requirements in paragraphs (e) and (g), associated with the authorities, duties, and responsibilities of the RSO, are similar to the requirements in the current § 35.23.

Paragraph (c) includes a new provision that allows a licensee to have a temporary RSO for up to 60 days a year if the individual is qualified to be an RSO under §§ 35.50 and 35.59 and if the licensee meets the requirements for RSOs in paragraphs (b), (e), (g), and (h) of this section. We added this new provision so that licensees can appoint someone to fulfill the duties and responsibilities of the RSO in a timely manner, following the sudden departure of the permanent RSO named on the license. Licensees are required by § 35.14(b) to notify the Commission in writing no later than 30 days after an RSO permanently discontinues performance of duties under the license.

Paragraph (d) 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.

Paragraph (f) contains a requirement for certain medical licensees to have an RSC to oversee all the uses of byproduct material permitted by the license. We modified the current requirement in § 35.22 so that 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 units under Subpart H, are required to establish an RSC. For example, licensees that are permitted on their license to use therapeutic quantities of unsealed byproduct material (§ 35.300) and manual brachytherapy (§ 35.400), or manual brachytherapy (§ 35.400) and low dose-rate remote afterloaders (§ 35.600), or teletherapy (§ 34.600) and gamma stereotactic radiosurgery (§ 35.600) would be required to have an RSC. However, we believe that many other medical licensees will also continue to use an RSC to oversee the use of byproduct material. Licensees should note that the requirement for an RSC is no longer limited to medical institutions, which means that it now also applies to free-standing clinics.

The new requirement for an RSC is much less prescriptive than the requirements in the current § 35.22. For example, paragraph (f) does not include the list of administrative requirements and committee tasks that are specified in the current rule. However, based on public comment, we have specified that the membership of the committee should include an AU of each type of use permitted by the license, the RSO, a representative of the nursing service, a representative of management who is neither an AU nor an RSO, and other members the licensee considers appropriate.

Paragraph (h) requires that the licensee retain a record of management's approval of actions in paragraph (a); written acceptance of RSO duties as specified in paragraph (b); and

the duties, responsibilities, and authority of the RSO specified in paragraph (e) in accordance with § 35.2024, Records of authority and responsibilities for radiation protection programs.

The NRC deleted the current § 35.25, Supervision. The requirements in this section, with some modifications, were moved to § 35.27. The requirements in paragraphs (a)(3) and (b)(3) for periodic reviews of the work of supervised individuals were deleted because we believe that these requirements are too prescriptive. Licensees should have flexibility in how they evaluate supervised individuals because they are held responsible for their acts and omissions.

Section 35.26, Radiation protection program changes, is a new section. The requirements in this section are similar to the requirements in the current § 35.31, which was deleted. This section allows licensees to revise their radiation protection programs without Commission approval if the revision does not require an amendment in accordance with § 35.13; if the revision is in compliance with the regulations and license; if the change has been reviewed and approved by the RSO, and reviewed and approved in writing by licensee management; and if the affected individuals have been instructed on the revised program before the changes are implemented. This requirement provides licensees with flexibility to manage their radiation protection programs and clearly defines the situations that will not require Commission approval of an amendment to their license. The NRC believes that many licensees were reluctant to make changes to their current program because the term "ministerial changes," as defined in the current § 35.2 and as used in the current § 35.31, was subject to misinterpretation. This change is intended to provide clear guidance to licensees on

when they can revise their radiation protection programs without obtaining Commission approval.

We believe that it is important to instruct individuals in program changes, including those permitted under § 35.26, before they are implemented. This instruction may be provided in writing or orally and may be conducted on an informal or formal basis. It is not necessary to document that this instruction has been provided to affected parties, because these changes should not reduce radiation safety. At the time of inspection, NRC inspectors may question whether this instruction was provided.

Section 35.27, Supervision, is a new section. The requirements in this section are similar to the requirements in the current § 35.25, which was deleted. The NRC deleted the requirement to instruct individuals in the principles of radiation safety from paragraphs (a)(1) and (b)(1). This type of instruction is adequately addressed by § 19.12, Instructions to workers, of this chapter. We also amended paragraphs (a)(1) and (b)(1) to require that, in addition to the requirements in § 19.12, the licensee shall instruct supervised individuals in the written radiation protection procedures, written directive procedures, regulations of this chapter, and license conditions. We revised paragraph (a)(2) to clarify that the instructions, procedures, regulations, and license conditions that supervised individuals are required to follow are limited in this part to those involving the medical use of byproduct material. We deleted paragraphs (a)(3) and (b)(3) of the current § 35.25 because the licensee should have flexibility in evaluating employee performance. We amended paragraph (b)(2) to require supervised individuals to follow the instructions of the supervising AU or ANP regarding the preparation of byproduct material for medical use, written radiation protection procedures, regulations of this chapter,

and license conditions. The statement in paragraph (c) that licensees are responsible for the acts and omissions of supervised individuals is similar to the statement in the current § 35.25(c).

The NRC deleted the current § 35.29, Administrative requirements that apply to the provision of mobile service. The conditions for the Commission to issue a mobile medical service license were moved to § 35.18. The requirements in paragraphs (b) and (d) were moved to § 35.80. We deleted paragraph (c) because this requirement, which addressed the client's responsibilities, was viewed as being overly prescriptive. Mobile medical service licensees are required to comply with all the provisions of the license that authorize the use, possession, and transfer of material.

The NRC deleted the current § 35.31, Radiation safety program changes. The requirements, with some modifications, were moved to § 35.26 so that all the requirements pertaining to management of the licensee's radiation protection program appear in one area of Subpart B.

The NRC deleted the current § 35.32, Quality management program. The issue of whether the Commission should continue to require that a licensee develop, implement, and maintain a quality management program was identified as a cross-cutting issue and was discussed at public meetings throughout the rulemaking. Comments received on this topic are discussed in Section III of the SUPPLEMENTARY INFORMATION section. Based on these comments, the Commission deleted the requirements for a quality management program. However, the Commission believes there are three elements of the current quality management

program that should continue to be addressed in the rule for certain procedures: confirming patient identity, requiring written directives, and verifying dose. The requirements for these three elements are in §§ 35.40 and 35.41. However, we believe that licensees will continue to implement other elements of the current quality management program as part of the "standard of care" in medicine. In this regard, the Commission acknowledges that other factors, such as accreditation, have resulted in medical institutions adopting programs similar to those specified in the current rule.

The NRC deleted the current § 35.33, Notifications, reports, and records of misadministrations. The recordkeeping and reporting requirements were moved to Subparts L and M, respectively.

Section 35.40, Written directives, is a new section. This section contains requirements for the preparation of written directives that are similar to the requirements in the current §§ 35.2 and 35.32. Written directives are no longer required for administrations of sodium iodide I-125 because sodium iodide I-131 is primarily used now. Based on public comments and discussions with the ACMUI, changes were made in the information that must be included in written directives. For gamma stereotactic radiosurgery, the requirements for target coordinates, collimator size, plug pattern, and total dose have been deleted, and requirements for total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site have been added. For teletherapy, the requirement for overall treatment period has been deleted and a requirement for number of fractions has been added. For high dose-rate remote afterloading brachytherapy, requirements have been added for the dose per fraction and the number of fractions. For all other brachytherapy, before

implantation, the requirements for number of sources and source strengths have been deleted and requirements for treatment site and dose have been added; and after implantation, but before completion of the procedure, a requirement for the number of sources has been added. Licensees should refer to § 35.41 for the requirements for procedures for administrations requiring written directives.

Section 35.41, Procedures for administrations requiring a written directive, is a new section. Paragraph (a) of this section requires licensees to develop, implement, and maintain written procedures to provide high confidence that, before each administration, the patient's or human research subject's identity is verified and that each administration is in accordance with the written directive. The specific details to be included in the written directives are in § 35.40. Paragraph (b) of this section specifies the items that must, at a minimum, be addressed in the procedures. The items identified in § 35.41 are viewed by the Commission as key elements of a program that will provide high confidence that byproduct material will be administered as directed by the AU. However, the regulations are not prescriptive about how these objectives are met, allowing licensees the flexibility to develop procedures to meet their needs. This section includes no requirement for submittal or approval of the procedures, as was previously required by the quality management rule. The recordkeeping requirements for this section are in § 35.2041, Records for procedures for administrations requiring a written directive.

The NRC retained § 35.49, Suppliers for sealed sources or devices for medical use with one modification. We added a new paragraph (b) to this section to permit noncommercial transfer of sealed sources or devices for medical use between Part 35 licensees that have a license to possess the source or device. Currently, licensees must obtain an amendment

exempting them from the requirements in this section following initial distribution of the sealed source or device.

Section 35.50, Training for Radiation Safety Officer, is a new section. The training and experience requirements for an RSO were moved, with some modifications, from the current § 35.900, Radiation Safety Officer. Two changes made in the new section should be noted. First, the listing of specialty boards by name was deleted because the regulatory text in Part 35 will no longer incorporate a listing of specialty boards whose diplomates automatically fulfill the training and experience requirements for RSOs. In place of listing the boards, the final rule provides for NRC recognition of the boards. Second, an individual must obtain written certification from a preceptor indicating that the individual has satisfactorily completed the requirements in this section and has achieved a level of competency sufficient to function independently as an RSO. Section III of the SUPPLEMENTARY INFORMATION section contains a detailed discussion of the Commission's changes to the training and experience requirements in Part 35.

The NRC deleted the current § 35.50, Possession, use, calibration and check of dose calibrators. The requirements in this section, with some modifications, were moved to § 35.60.

Section 35.51, Training for an authorized medical physicist, is a new section. The training and experience requirements for an AMP were moved, with some modifications, from the current § 35.961, Training for teletherapy physicist. Three changes made in the new section should be noted. First, the title of this section was revised because the training and experience requirements in this section now apply to AMPs, rather than just teletherapy

physicists, because requirements for gamma stereotactic radiosurgery units and remote afterloader units have been codified in the revised Part 35. Second, the listing of specialty boards by name was deleted because the regulatory text in Part 35 will no longer incorporate a listing of specialty boards whose diplomates automatically fulfill the training and experience requirements for AMPs. In place of listing the boards, the final rule provides for NRC recognition of the boards. Third, an individual must obtain written certification from a preceptor indicating that the individual has satisfactorily completed the requirements in this section and has achieved a level of competency sufficient to function independently as an AMP. Section III of the SUPPLEMENTARY INFORMATION section contains a detailed discussion of the Commission's changes to the training and experience requirements in Part 35.

The NRC deleted the current § 35.51, Calibration and check of survey instruments. The requirements in this section, with some modifications, were moved to § 35.61.

The NRC deleted the current § 35.52, Possession, use, calibration, and check of instruments to measure dosages of alpha- or beta-emitting radionuclides. The requirements in this section, with some modifications, were moved to § 35.60.

The NRC deleted the current § 35.53, Measurements of dosages of unsealed byproduct material for medical use. The requirements in this section, with some modifications, were moved to § 35.63.

Section 35.55, Training for an authorized nuclear pharmacist, is a new section. The training and experience requirements for an ANP were moved, with some modifications, from

the current § 35.980, Training for an authorized nuclear pharmacist. One change made in the new section should be noted. The listing of specialty boards by name was deleted because the regulatory text in Part 35 will no longer incorporate a listing of specialty boards whose diplomates automatically fulfill the training and experience requirements for ANPs. In place of listing the boards, the final rule provides for NRC recognition of the boards. Section III of the SUPPLEMENTARY INFORMATION section contains a detailed discussion of the new training and experience requirements in Part 35.

Section 35.57, Training for an experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist, is a new section that replaces the current requirements in §§ 35.901, 35.970, and 35.981, which were deleted. All individuals who are identified as RSOs, teletherapy or medical physicists, AUs, and nuclear pharmacists on an NRC or Agreement State license or an equivalent permit issued before the effective date of the final rule will have “deemed” status after the rule becomes effective. These individuals do not need to comply with the new training and experience requirements unless they want to be named on a license for other types of uses.

The NRC deleted the current § 35.57, Authorization for calibration and reference sources. The requirements in this section, with some modifications, were moved to § 35.65.

Section 35.59, Recentness of training, is a new section that replaces the current requirements in § 35.972. Although this is not a new requirement, questions have recently been raised regarding whether all elements of the requirements must have been obtained in the last 7 years. The NRC expects that (1) either the individual has been board certified or has

completed the training specified in the alternative pathway within the 7 years preceding the date of the application; or that (2) the individual has had related continuing education and experience since completing the required training and experience requirements. Continuing education and experience requirements are reviewed on a case-by-case basis, with input from the ACMUI, as necessary. We amended the text in the current § 35.972 to reference Subparts B, D, E, F, G, and H because the revised training and experience requirements appear in the subparts with their associated modality.

The NRC deleted the current § 35.59, Requirements for possession of sealed sources and brachytherapy sources. The requirements in this section, with some modifications, were moved to § 35.67.

Subpart C, General Technical Requirements, contains general technical requirements regarding medical use of byproduct material.

Section 35.60, Possession, use, and calibration of instruments used to measure the activity of unsealed byproduct material, is a new section that replaces the current §§ 35.50 and 35.52. This section addresses calibration of all instruments used to measure the activity of all unsealed byproduct materials, rather than only dose calibrators used to measure the activity of dosages of photon-emitting radionuclides (§ 35.50) or instruments used to measure dosages of alpha- or beta-emitting radionuclides (§ 35.52). The change recognizes that there are various types of instruments that can be used to measure the activity of unsealed byproduct materials. This change also gives licensees flexibility in developing a calibration program which meets their program needs.

The NRC deleted prescriptive calibration requirements in the current §§ 35.50 and 35.52. Paragraph (b) in the final rule requires that licensees calibrate the 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 regulation more flexible, more adaptable to new technology, and more performance-based.

Licensees should note that they are required by § 35.63 to determine the activity of each dosage before medical use. If they use only unit dosages of radioactive drugs that meet the definition in § 35.2, then § 35.63 allows the licensee to determine the dosage by direct measurement of radioactivity; or by a decay correction based on the activity or activity concentration determined by either a manufacturer or preparer licensed under § 32.72 or equivalent Agreement State requirements or an NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee (RDRC)-approved protocol or an Investigational New Drug (IND) protocol accepted by the Food and Drug Administration (FDA). If a licensee chooses to determine the dosage using this method, a licensee would not be required to possess instrumentation to measure the activity of the dosage, i.e., the licensee would not be required to comply with § 35.60. However, if a licensee chooses to reassay a unit dosage for the purpose of adjusting the activity, it would no longer be considered a unit dosage once it was altered, and the licensee must comply with § 35.60. This requirement is appropriate because confirmation of a dosage, or adjustment of dosages, must be based on properly-calibrated equipment.

The recordkeeping requirements for this section are in § 35.2060, Records of calibrations of instruments used to measure the activity of unsealed byproduct material.

The requirements in the current § 35.60, with minor modifications, were moved to the final § 35.69.

Section 35.61, Calibration of survey instruments, is a new section that replaces the current § 35.51. The requirements in the current § 35.51 to note the apparent exposure rate from a dedicated check source, as determined at the time of calibration; to attach a correction chart or graph to the instrument; and to check each survey instrument for proper operation with a dedicated check source each day of use were deleted. These changes give the licensee greater flexibility in calibrating instruments.

Paragraph (a) in the new § 35.61 now requires the licensee to calibrate survey instruments used to show compliance with this part and with Part 20 before first use, annually, and following a repair that affects the calibration. Paragraph (b) requires that survey instruments be removed from use if the indicated exposure rate differs from the calculated exposure rate by more than 20 percent. Previously, there was no threshold for removing instruments from use. The requirements in this section are generally consistent with ANSI N323-1978 (R 1993), “Radiation Protection Instrumentation Test and Calibration.”

The recordkeeping requirements for this section are in § 35.2061, Records of radiation survey instrument calibrations.

The requirements in the current § 35.61, with minor modifications, were moved to the final § 35.69.

Section 35.63, Determination of dosages of unsealed byproduct material for medical use, is a new section that replaces the current § 35.53. This section requires licensees to determine and record the activity of each dosage before medical use. For unit dosages as defined in § 35.2, paragraph (b) allows the licensee to determine the dosage by direct measurement of radioactivity; or by a decay correction based on the activity or activity concentration determined by either a manufacturer or preparer licensed under § 32.72 or equivalent Agreement State requirements or an NRC or Agreement State licensee for use in research in accordance with a RDRC-approved protocol or an IND protocol accepted by the 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, the NRC does not believe the Part 35 licensee should be required to reassay the dosage. Licensees should note that if a unit dosage is 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.

For other than unit doses, paragraph (c) allows the licensee to determine the dosage by direct measurement of radioactivity; by combination of direct measurement of radioactivity and mathematical calculations; or by combination of volumetric measurements and mathematical calculations based on the measurement made by a manufacturer or preparer licensed under § 32.72 or an equivalent Agreement State requirement. The current rule limits the licensee to using direct measurement for determining the activity of a photon-emitting radionuclide, but

allows alpha- or beta-emitting radionuclides to be measured either by direct measurement or by combination of measurements and calculations. This change allows licensees flexibility in determining dosages and does not distinguish between the type of the radiation (e.g., alpha, beta, or photon) and the way the determination is made.

Paragraph (d) permits a licensee to use a dosage if the dosage does not differ from the prescribed dosage by more than 20 percent or if the dosage falls within the prescribed dosage range. We believe that the rule should allow for some deviation from the prescribed dosage if the licensee chooses to prescribe a dosage rather than a dosage range. Without this allowed deviation, the administered dosage would need to match the prescribed dosage. We have not allowed a deviation outside of the prescribed range because we believe that allowing the AU to establish a dosage range provides the AU with the needed flexibility. The final paragraph (d) codifies requirements that are currently imposed on licensees by license conditions and provides guidance regarding allowed deviations for a dosage range. This does not prevent an AU from revising the prescribed dosage at any time prior to the administration.

The recordkeeping requirements for this section would appear in § 35.2063, Records of dosages of unsealed byproduct material for medical use.

Section 35.65, Authorization for calibration, transmission, and reference sources, is a new section that replaces the current § 35.57. Paragraph (a) was revised to allow the receipt, possession, and use of sealed sources for the purposes of this section if they do not exceed 1.11 GBq (30 mCi) each and they are manufactured and distributed by a person licensed under § 32.74 or equivalent Agreement State regulations. Paragraph (b) was revised to allow the

receipt, possession, and use of sealed sources for the purposes of this section if they do not exceed 1.11 GBq (30 mCi) each and they are 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. In paragraphs (b) and (c) of the final rule, the references in the current § 35.57 to §§ 35.100 and 35.200 were deleted because specific radionuclides were not listed in these sections. Paragraph (c) was revised to allow possession of calibration and reference sources with half-lives not longer than 120 days. The current section only allows possession of sources with half-lives not longer than 100 days. This change was made so that the section would be consistent with the financial assurance regulations in Part 30. Paragraph (d) was revised to allow possession of any byproduct material with a half-life longer than 120 days in individual amounts that do not exceed the smaller of the following two values: 7.4 Megabecquerels (MBq) (200 μCi) or 1000 times the quantities in Appendix B of Part 30. This change was made to limit the possession activity below the level where financial assurance is required. In paragraph (e), the possession limit for Tc-99m was deleted. The Commission believes that it is not necessary to limit the possession of Tc-99m for calibration and reference sources because there are no possession limits for Tc-99m associated with the use of Tc-99m under § 35.100 or § 35.200.

Section 35.67, Requirements for possession of sealed sources and brachytherapy sources, is a new section that replaces the current § 35.59. Paragraph (a) continues to require that the licensee follow the radiation safety and handling instructions supplied by the manufacturer, but the requirement to maintain the instructions for the duration of source use has been deleted. Paragraph (b) requires that a source be tested for leakage before its first

use, unless the licensee has a certificate from the supplier indicating that the source was tested within 6 months, and the source is tested for leakage at intervals not to exceed 6 months or at other intervals approved in the Sealed Source and Device Registry (SSDR).[1] The SSDR certificates, in most cases, will include a requirement for leak-testing. Approved intervals for testing are based on information regarding source design construction that is provided by the manufacturer.

Paragraph (c) retains the detection level for leakage at 185 Becquerels (Bq) (0.005 microcuries (μCi). The NRC deleted the prescriptive requirements on how to satisfy the leak test requirements in the current § 35.59(c) to reflect the more risk-informed, performance-based nature of this final rule. Paragraph (d) requires that leak test records be maintained in accordance with § 35.2067, Records of leak tests and inventory of sealed sources and brachytherapy sources. We revised paragraph (e) to give the licensee two additional alternatives for action after a leaking source has been identified. The final rule gives the licensee the added flexibility of repairing or disposing of the source in accordance with Parts 20 and 30 if the leakage test reveals the presence of 185 Bq (0.005 μCi) or more of removable contamination. The current rule only allows the licensee to withdraw the sealed source from use and store it in accordance with the requirements in Parts 20 and 30. The licensee is still required to report to the NRC if a leakage test reveals the presence of 185 Bq (0.005 μCi) or more of removable contamination. Reporting requirements for this section are in § 35.3067, Report of a leaking source.

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[1] A national registry that contains all the registration certificates generated by both NRC and the Agreement States. Registration certificates summarize the radiation safety information submitted by the applicant, and describe the licensing and use conditions approved for the product.

We amended paragraph (g) to change the frequency for source inventories from quarterly to semi-annually to reduce the regulatory burden on licensees and to exempt gamma stereotactic radiosurgery sources from the requirement for physical inventories. However, the final rule does not preclude the licensee from conducting an inventory on a more frequent basis. The recordkeeping requirements for this section were moved to § 35.2067, Records of leak tests and inventory of sealed sources and brachytherapy sources.

We deleted paragraphs (h) and (i) in the current § 35.59 because radiation surveys are addressed under Part 20.

Section 35.69, Labeling of vials and syringes, is a new section that replaces the current §§ 35.60 and 35.61. It requires that syringes and vials containing unsealed byproduct material be labeled to identify the radioactive drug. It also requires that syringe shields and vial shields be labeled unless the label on the syringe or vial is visible when shielded. These requirements are needed because the Commission does not believe that the labeling requirements in Part 20 are sufficient to ensure that syringes, vials, syringe shields, or vial shields are properly labeled to identify the radioactive drug. In addition, the Commission believes that labeling helps to reduce administration errors.

The NRC does not address shielding of vials and syringes in this section. Licensees are required to show compliance with the public and occupational dose limits specified in Part 20 of this chapter. We believe that the licensee should have flexibility in complying with these limits.

The NRC revised § 35.70, Surveys of ambient radiation exposure rate, was revised. The term “contamination” was deleted from the title because this section no longer addresses contamination surveys. The final rule requires that licensees survey, at the end of each day of use, all areas where unsealed byproduct material requiring written directives were prepared for use or administered, except area(s) where patients or human research subjects are confined when they cannot be released under § 35.75. Maintaining the requirement for surveys in areas where unsealed byproduct material requiring a written directive is used is consistent with the Commission's direction for a more risk-informed rule.

Licensees are required to show compliance with the public and occupational dose limits specified in Part 20 of this chapter and specifically to develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities (§ 20.1101). In situations where radioactive material is used at levels that would not require a survey under this section, the licensee should be aware that a survey may be required by § 20.1501. The Commission believes that licensees will continue to perform radiation surveys as dictated by “good health physics” practices.

The recordkeeping requirements for this section are in § 35.2070, Records of surveys for ambient radiation exposure rate. All other requirements in the current § 35.70 were deleted.

The NRC revised § 35.75, Release of individuals containing unsealed byproduct material or implants containing byproduct material. We amended the title of the section and paragraph (a) to delete the term "permanent." This clarifies that this section applies to all individuals released from licensee control. Paragraph (b) was revised to specify that licensees

may provide instructions to either the released individual or to the individual's parent or guardian and to replace the term "dose" with the term "total effective dose equivalent." The first change acknowledges that, in some cases, it is not appropriate to provide the individual being released with instructions (e.g., the individual is a minor or incapable of understanding the instructions). The later change was made to clarify what is meant by "dose" in this section.

We modified paragraph (b)(2) to state “potential consequences, if any," of failure to follow the guidance. The Commission recognizes that, at low doses, there may be no consequences to continued breast-feeding. A patient may be unnecessarily alarmed if he/she is provided with information on consequences. Therefore, if consequences are not anticipated, the licensee would not be required to provide information to the individual.

We amended the footnote to reference NUREG-1556, Volume 9, “Consolidated Guidance About Materials Licenses, Program-Specific Guidance About Medical Licenses,” that superseded Regulatory Guide 8.39.

We revised paragraphs (c) and (d) to indicate that the recordkeeping requirements for this section are in § 35.2075, Records of the release of individuals containing radioactive drugs or implants containing byproduct material.

The NRC revised § 35.80, Provision of mobile medical service. We changed the title to make it clear that the provisions in this part apply to all mobile medical services and not just to mobile nuclear medicine services. We deleted the current paragraphs (a), (b), and (c) because the use of unsealed byproduct material is limited by the requirements in §§ 35.100 and 35.200,

and control and security of material are addressed in Part 20. The remainder of the current requirements were incorporated into paragraphs (a) or (c) of the final rule.

Paragraph (a) requires the mobile medical service provider to obtain a letter from its client that permits the use of byproduct material at the client's address. This letter should clearly delineate the authority and responsibility of the licensee and the client. This paragraph also requires that the mobile medical service provider checks the instruments used to measure the activity of unsealed byproduct materials for constancy before medical use at each address of use or on each day of use, whichever is more frequent. For example, if a mobile medical service licensee provides service to more than one client in a day, the instruments would need to be checked at each client’s address. The Commission recognizes that the standard of practice is to check other types of equipment, such as gamma cameras, for proper operation at each place of use. Therefore, the Commission has not included any requirements to check this type of equipment in the final rule.

Paragraph (a) also requires that the licensee check survey instruments for proper operation with a dedicated check source, before use, at each client's address. We believe this is appropriate because extensive movement in a transport vehicle may cause the instruments to become damaged or uncalibrated. Finally, paragraph (a) requires the licensee to survey all areas of use to ensure compliance with the dose limits in Part 20 before leaving each client’s address. This is necessary to ensure that all radioactive material is removed from a client's facility.

Paragraph (b) addresses the delivery of byproduct material. It does not allow byproduct material to be delivered from the manufacturer or the distributor to the client's address, unless the client has a license allowing possession of the byproduct material. This requirement is similar to the requirement in the current § 35.29 (which was deleted by this rulemaking).

The recordkeeping requirements for this section are in § 35.2080, Records of mobile medical services.

The NRC deleted the current § 35.90, Storage of volatiles and gases. Licensees are required to comply with the public and occupational dose limits in Part 20 and to maintain exposures ALARA. We believe that licensees should have flexibility in complying with Part 20, and, therefore, a prescriptive requirement in Part 35 is not needed.

We revised § 35.92, Decay-in-storage, to allow decay-in-storage for byproduct material with a physical half-life of less than 120 days. Under the current rule, decay-in-storage was only authorized for material with a half-life of less than 65 days. This change provides licensees with greater flexibility in handling radioactive waste and codifies current licensing practice. Licensees that would like to decay material with a physical half life greater than 120 days would have to apply for and receive an amendment that would permit the decay-in-storage.

Paragraph (a) was revised to indicate clearly that the provisions in this section pertain only to disposal of material without regard to its radioactivity. The requirement in the current paragraph (a)(1) to hold byproduct material for 10 half-lives was deleted. This requirement was

not needed in light of the requirement in paragraph (a) of the final rule that precludes disposal of radioactive material until radiation levels adjacent to the material do not exceed background levels. Paragraph (a)(2) requires the licensee to remove or obliterate all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee.

The requirement in the current paragraph (a)(4) to separate and monitor each generator column was deleted. This change recognized that the current level of prescriptiveness is not needed because of the requirements in paragraph (a)(1).

The recordkeeping requirements for this section are in § 35.2092, Records of decay-in-storage.

The NRC retitled Subpart D Unsealed Byproduct Material - Written Directive Not Required. This subpart combines the requirements in the current Subpart D, Uptake, dilution, and excretion and Subpart E, Imaging and localization. This change was made to consolidate specific requirements for the use of unsealed byproduct material where a written directive is not required into one subpart. These changes are consistent with the Commission's intent to make Part 35 modality specific where appropriate. We believe that administrations of unsealed byproduct material not requiring a written directive are in a lower risk category than those administrations requiring a written directive. Therefore, we are using the requirement for a written directive as the threshold to distinguish between the two levels of risk associated with administrations of unsealed byproduct material.

The NRC revised § 35.100, Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required. The title and introductory paragraph were changed to state clearly that the provisions in this subpart do not apply to the medical use of byproduct material that would require a written directive.

Paragraph (a) was amended to change the format for citing Title 10 of the Code of Federal Regulations (CFR). The reference to Title 10 is now stated as “of this chapter” instead of using the format “10 CFR.”

We amended paragraph (b) to reflect changes to the section numbers in the final rule (i.e., requirements in §§ 35.25 and 35.920 were moved, with some modification, to §§ 35.27 and 35.290, respectively). We also added a reference to § 35.390 because physicians meeting these training and experience criteria can now elute generators and prepare radioactive drugs. This paragraph permits medical use licensees to prepare radioactive drugs from any unsealed byproduct material (e.g., radiochemicals), provided the drug is prepared by an ANP or AU.

We added paragraph (c) to allow specific licensees to obtain unsealed byproduct material prepared by an NRC or Agreement State licensee for use in research in accordance with a RDRC-approved protocol or an IND protocol accepted by the FDA. This change was made because the current rule did not allow a licensee to use material from a supplier, who was not a § 32.72 licensee, unless the supplier had obtained a license exemption from the NRC. The final rule allows a medical use licensee to receive radioactive drugs that are for use in an RDRC-approved protocol or an IND protocol and are prepared and distributed by NRC or Agreement State licensees who are not § 32.72 licensees.

We added paragraph (d) to allow any individual to prepare a radioactive drug from any unsealed byproduct material (e.g., radiochemicals) for use in research in accordance with either an RDRC-approved protocol or an IND protocol accepted by FDA. This change was made because an AU meeting the qualifications in § 35.910 of the current rule could not prepare radioactive drugs under an RDRC-approved protocol or an IND protocol. Therefore, if a licensee was only authorized to use byproduct material under § 35.100, it could not prepare byproduct material for use under an RDRC-approved protocol or an IND protocol unless the material had been prepared by an ANP or AU who was qualified to prepare radioactive drugs. The final rule resolves the issue by allowing any individual to prepare a radioactive drug in accordance with either an RDRC-approved protocol or an IND protocol.

The NRC deleted the current § 35.120, Possession of survey instruments, because these specific requirements are not needed in Part 35. Section 20.1501 of this chapter requires that the licensee make, or cause to be made, surveys to demonstrate compliance with Part 20, and requires 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 the licensee to have adequate instrumentation. Guidance on the types of instruments medical licensees could consider using is in NUREG-1556, Vol. 9, “Program-Specific Guidance about Medical Use Licenses.”

Section 35.190, Training for uptake, dilution, and excretion studies, is a new section. The training and experience requirements for an AU for unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required were moved, with some modifications, from the current § 35.910, Training for uptake, dilution, and excretion

studies. Three changes made in the new section should be noted. First, the listing of specialty boards by name was deleted because the regulatory text in Part 35 will no longer incorporate a listing of specialty boards whose diplomates automatically fulfill the training and experience requirements for AUs. In place of listing the boards, the final rule provides for NRC recognition of the boards. Second, the new requirements require a total of 60 hours of training and experience that must include classroom, laboratory, and supervised work experience. Third, an individual must obtain written certification from a preceptor indicating that the individual has satisfactorily completed the requirements in this section and has achieved a level of competency sufficient to function independently as an AU. Section III of the SUPPLEMENTARY INFORMATION section a detailed discussion of the Commission's changes to the training and experience requirements in Part 35.

The NRC revised § 35.200, Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required. The title and introductory paragraph were changed to state clearly that the provisions in this subpart do not apply to the medical use of byproduct material that would require a written directive.

We amended paragraph (a) to change the format for citing Title 10 of the Code of Federal Regulations (CFR). The reference to Title 10 is now stated as "of this chapter" instead of using the format "10 CFR."

We amended paragraph (b) to reflect changes to the section numbers in the final rule (i.e., requirements in §§ 35.25 and 35.920 were moved, with some modification, to §§ 35.27 and 35.290, respectively). We also added a reference to § 35.390 because physicians meeting

these training and experience criteria can now elute generators and prepare radioactive drugs. This paragraph permits medical use licensees to prepare radioactive drugs from any unsealed byproduct material (e.g., radiochemicals), provided the drug is prepared by an ANP or AU.

We added paragraph (c) to allow specific licensees to obtain unsealed byproduct material prepared by an NRC or Agreement State licensee for use in research in accordance with an RDRC-approved protocol or an IND protocol accepted by the FDA. This change was made because the current rule did not allow a licensee to use material from a supplier, who was not a § 32.72 licensee, unless the supplier had obtained a license exemption from the NRC. The final rule allows a medical use licensee to receive radioactive drugs that are for use in an RDRC-approved protocol or an IND research protocol and are prepared and distributed by NRC or Agreement State licensees who are not § 32.72 licensees.

We added paragraph (d) to allow any individual to prepare a radioactive drug from any unsealed byproduct material (e.g., radiochemicals) for use in research in accordance with either an RDRC-approved protocol or an IND protocol accepted by FDA. This change was made because an AU meeting the qualifications in § 35.920 of the current rule could not prepare radioactive drugs under an RDRC-approved protocol or an IND protocol. Therefore, if a licensee was only authorized to use byproduct material under § 35.200, it could not prepare byproduct material for use under an RDRC-approved protocol or an IND protocol unless the material had been prepared by an ANP or AU who was qualified to prepare radioactive drugs. The final rule resolves the issue by allowing any individual to prepare a radioactive drug in accordance with either an RDRC-approved protocol or an IND protocol.

The NRC revised § 35.204, Permissible molybdenum-99 concentration. Paragraph (a) was revised to express the permissible concentration level as 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m). This level is identical to that used in the U.S. Pharmacopea (USP) 24 U.S. Pharmacopial Convention, Inc., 2000, pages 1598-1599. Paragraph (b) was revised to require that a licensee measure the molybdenum-99 concentration of the first eluate from a generator. We believe that the licensee should measure the molybdenum-99 concentration in the first elution of a generator after the generator is received at the licensee's facility. Although the frequency of molybdenum breakthrough is exceedingly rare, an initial check may detect generators that have been damaged in transport. The term "extract" was deleted because the term is no longer needed. NRC is not aware of any licensees that prepare technetium-99m by the solvent extraction method.

The recordkeeping requirements for this section were moved to § 35.2204, Records of molybdenum-99 concentration.

The NRC deleted the current § 35.205, Control of aerosols and gases. Part 35 licensees must comply with the occupational and public dose limits of Part 20. Additional prescriptive requirements for limiting airborne concentrations of radioactive material are not needed in Part 35.

The NRC deleted the current § 35.220, Possession of survey instruments because these specific requirements are not needed in Part 35. Section 20.1501 of this chapter requires that the licensee make, or cause to be made, surveys to demonstrate compliance with Part 20,

and requires 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 equipment. Guidance on the types of instruments medical licensees could consider using is in NUREG-1556, Vol. 9.

Section 35.290, Training for imaging and localization studies, is a new section. The training and experience requirements for an AU for unsealed byproduct material for imaging and localization studies for which a written directive is not required were moved, with some modifications, from the current § 35.920, Training for imaging and localization studies. Three changes made in the new section should be noted. First, the listing of specialty boards by name was deleted because the regulatory text in Part 35 will no longer incorporate a listing of specialty boards whose diplomates automatically fulfill the training and experience requirements for AUs. In place of listing the boards, the final rule provides for NRC recognition of the boards. Second, the new requirements require a total of 700 hours of training and experience that must include classroom, laboratory, and supervised work experience. Third, an individual must obtain written certification from a preceptor indicating that the individual has satisfactorily completed the requirements in this section and has achieved a level of competency sufficient to function independently as an AU. Section III of the SUPPLEMENTARY INFORMATION section contains a detailed discussion of the Commission's changes to the training and experience requirements in Part 35.

Subpart E was retitled, Unsealed byproduct material - written directive required. The subpart contains the requirements for any medical use of unsealed byproduct material for which

a written directive is required. This subpart would replace the requirements in the current Subpart F, Radiopharmaceuticals for therapy.

The NRC revised § 35.300, Use of unsealed byproduct material for which a written directive is required. The title and introductory paragraph were changed to clearly state that the provisions in this subpart apply to the medical use of unsealed byproduct material that would require a written directive. The first paragraph in this section was revised to state clearly that medical uses under this section require a written direction. Also, the phrase “therapeutic administration”, used in the current rule, was deleted because some medical uses in this modality will require a written directive, but they are not “therapeutic administrations” (e.g., diagnostic whole body imaging with sodium iodide I-131).

We amended paragraph (a) to change the format for citing Title 10 of the Code of Federal Regulations (CFR). The reference to Title 10 is now stated as “of this chapter” instead of using the format “10 CFR.”

We amended paragraph (b) to reflect changes to the section numbers in the final rule (i.e., requirements in §§ 35.25 and 35.920 were moved, with some modification, to §§ 35.27 and 35.290, respectively). We also added a reference to § 35.390 because physicians meeting these training and experience criteria can now elute generators and prepare radioactive drugs. This paragraph permits medical use licensees to prepare radioactive drugs from any unsealed byproduct material (e.g., radiochemicals), provided the drug is prepared by an ANP or AU.

We added paragraph (c) to allow specific licensees to obtain unsealed byproduct material prepared by other NRC or Agreement State licensees for use in medical research in accordance with an IND protocol accepted by the FDA. This change was made because the current rule did not allow a licensee to use material from a supplier, who was not a § 32.72 licensee, unless the supplier had obtained a license exemption from the NRC. The final rule allows a medical use licensee to receive radioactive drugs, for use in IND research protocols, that are prepared and distributed by NRC or Agreement State licensees who are not § 32.72 licensees. This paragraph is similar to the regulatory text added to §§ 35.100 and 35.200. However, we have not included a reference to RDRC-approved protocols because RDRCs are authorized to approve radioactive drugs for certain types of research uses intended to obtain basic information regarding the metabolism of a radioactive drug, or regarding human physiology, pathophysiology, or biochemistry, but they are not intended for immediate diagnostic, therapeutic, or similar purposes. Additionally, the maximum radiation dose from a single administration of a radioactive drug in an RDRC-approved protocol must be less than 3 rem to the whole body, active blood forming organs, lens of the eye, and gonads, and less than 5 rem to other organs. We expect that doses from materials requiring a written directive would exceed these limits. Thus, research with such materials could not be conducted under the aegis of RDRC approval.

We added paragraph (d) to allow any individual to prepare a radioactive drug from any unsealed byproduct material (e.g., radiochemicals) for use in research in accordance with an IND protocol accepted by FDA. This change was made because an AU meeting the qualifications in §§ 35.930, 35.932, or 35.934 of the current rule could not prepare radioactive drugs under an IND protocol. Therefore, if a licensee was only authorized to use byproduct

material under § 35.300, it could not prepare byproduct material for use under an IND protocol unless the material had been prepared by an ANP or AU who was qualified to prepare radioactive drugs. The final rule resolves the issue by allowing any individual to prepare a radioactive drug in accordance with an IND protocol.

The NRC revised § 35.310, Safety instruction to state explicitly that the instruction requirements of this section are in addition to, and not in lieu of, the training requirements in § 19.12. We believe it is important that personnel caring for patients or human research subjects that have received a dosage requiring a written directive, and cannot be released in accordance with § 35.75, receive instruction in limiting radiation exposure to the public or occupational workers and the actions to be taken in the case of a death or medical emergency.

Paragraph (a) in the final rule requires that safety instruction be provided initially and at least annually. The current rule does not specify when instructions must be given. Typically, the frequency of training has been handled during the licensing process. We do not expect that the same level of training be provided to all individuals caring for the patient. The level of training should be commensurate with the potential radiation exposure the caregiver may receive, based on the level of contact the individual is expected to have with the patient or human research subject. For example, the instruction provided to the registered nurse will not necessarily be the same as the instruction provided to a nursing assistant. We have deleted the reference to “procedures” in paragraph (a) because we have chosen to focus this section on instruction rather than on procedures. The licensee should have flexibility in program management and recognize that licensees may develop alternative ways of addressing the issues in paragraphs (a)(1) through (a)(5). Paragraph (a)(2) was also revised to require that

instruction on visitor control include instruction on routine visitation authorized under the provisions in § 20.1301(a)(1), as well as visitation that is authorized under the final provisions of § 20.1301(c). Paragraph (a)(5) was revised to state that personnel should notify the RSO, or his or her designee, and the AU if the patient or the human research subject has a medical emergency or dies. This change was made to allow the RSO to designate an individual to act in his or her behalf, in such cases, to address radiation protection issues and to ensure that the AU is notified. The recordkeeping requirements for this section are in § 35.2310, Records of safety instruction.

We revised § 35.315, Safety precautions. Paragraph (a) was revised to clarify that the requirements in this section only apply if a patient or research subject cannot be released under § 35.75. Paragraph (a)(1) was revised to give the licensee flexibility in quartering patients. Option 1 is identical to the current rule, i.e., it allows the licensee to quarter the patient or human research subject in a private room with a private sanitary facility. Option 2 allows the licensee to quarter the individual in a room, with a private sanitary facility, with another individual who also has received therapy with a radioactive drug containing byproduct material and who also cannot be released under § 35.75. We included option 2 in the final rule because we believe that the dose that patients would receive from each other would be inconsequential in light of the dose that they receive from the medical treatment that they have undergone.

We revised paragraph (a)(2) to require that the patient's room, rather than the door, be visibly posted to give the licensee some flexibility in determining where to place the posting so it is visible. These requirements are in addition to the posting requirements in Part 20. We believe that the posting requirements in Part 20 are not adequate to ensure that individuals

entering the room would be aware of the presence of radioactive materials in the room. The current requirements in paragraphs (a)(3), (4), (6), (7), and (8) were deleted because they are radiation protection requirements that are covered under Part 20. We revised paragraph (b) to state that the licensee shall notify the RSO, or his or her designee, and the AU as soon as possible if the patient or human research subject has a medical emergency or dies. This change allows the RSO to designate an individual to act in his or her behalf, in such cases, to address radiation protection issues and to ensure that the AU is notified.

The NRC deleted the current § 35.320, Possession of survey instruments because these specific requirements are not needed in Part 35. Section 20.1501 of this chapter requires that the licensee make, or cause to be made, surveys to demonstrate compliance with Part 20, and requires 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 a licensee to have adequate equipment. Guidance on the types of instruments medical licensees could consider using is in NUREG-1556, Vol. 9.

Section 35.390, Training for use of unsealed byproduct material for which a written directive is required, is a new section. The training and experience requirements for an AU for unsealed byproduct material for which a written directive is required were moved, with some modifications, from the current § 35.930, Training for therapeutic use of unsealed byproduct material. Three changes made in the new section should be noted. First, the listing of specialty boards by name was deleted because the regulatory text in Part 35 will no longer incorporate a listing of specialty boards whose diplomates automatically fulfill the training and experience requirements for AUs. In place of listing the boards, the final rule provides for NRC recognition

of the boards. Second, the new requirements require a total of 700 hours of training and experience that must include classroom, laboratory, and supervised work experience. Third, an individual must obtain written certification from a preceptor indicating that the individual has satisfactorily completed the requirements in this section and has achieved a level of competency sufficient to function independently as an AU. Section III of the SUPPLEMENTARY INFORMATION section contains a detailed discussion of the Commission's changes to the training and experience requirements in Part 35.

Section 35.392, Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries), is a new section. The training and experience requirements for an AU for iodine-131 treatment of hyperthyroidism were moved, with some modifications, from the current 35.932, Training for treatment of hyperthyroidism. Three changes made in the new section should be noted. First, the section is no longer limited to use of iodine-131 for treatment of hyperthyroidism. Second, the final rule provides for NRC recognition of the boards. Third, an individual must obtain written certification from a preceptor indicating that the individual has satisfactorily completed the requirements in this section and has achieved a level of competency sufficient to function independently as an AU. Section III of the SUPPLEMENTARY INFORMATION section contains a detailed discussion of the Commission's changes to the training and experience requirements in Part 35.

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), is a new section. The training and experience requirements for an AU for iodine-131 for treatment of thyroid

carcinoma were moved, with some modifications, from the current 35.934, Training for treatment of thyroid carcinoma. Three changes made in the new section should be noted. First, the section is no longer limited to use of iodine-131 for treatment of thyroid carcinoma. Second, the final rule provides for NRC recognition of the boards. Third, an individual must obtain written certification from a preceptor indicating that the individual has satisfactorily completed the requirements in this section and has achieved a level of competency sufficient to function independently as an AU. Section III of the SUPPLEMENTARY INFORMATION section contains a detailed discussion of the Commission's changes to the training and experience requirements in Part 35.

Subpart F was retitled Manual Brachytherapy. This subpart contains the requirements for medical use of sealed sources for manual brachytherapy and replaces the requirements in the current Subpart G, Sources for Brachytherapy.

The NRC retitled § 35.400, Use of sources for manual brachytherapy, and deleted the specific sources and uses listed in the current paragraphs (a) through (g). This conforms with the more risk-informed, performance-based nature of this final rule. The licensee has the flexibility to use brachytherapy sources for therapeutic medical uses as approved in the SSDR. In addition, we added a new paragraph (b) to allow the use of brachytherapy sources in medical research as long as the research is conducted in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA. With this revision, we allow previously registered sources to be used for uses other than those described in the original sealed source registration process if the research is conducted under an active IDE application accepted by the FDA.

The NRC retitled and revised § 35.404, Surveys after source implant and removal. The current paragraph (a) was redesignated paragraph (b) and was amended to delete the requirement that a licensee may not release a patient or a human research subject treated by temporary implant until all sources have been removed. The release of patients or human research subjects is addressed in § 35.75. The reference to radiation when referring to the survey was also removed because this was repetitive of the requirement to perform the survey with a radiation detection survey instrument. The new paragraph (a) contains the requirements, with minor modifications, that were previously required by § 35.406(c). The survey required by paragraph (a) is performed to locate and account for all sources that have not been implanted. However, this survey does not necessarily have to be a radiation survey. Depending on the area being surveyed and the ability to distinguish from the radiation background around the patient implanted with brachytherapy sources, the survey may be a visual or a radiation survey. Therefore, this section includes all of the survey requirements for this subpart. The recordkeeping requirements for this section are in § 35.2404, Records of surveys after source implant and removal.

The NRC retitled and revised § 35.406, Brachytherapy sources accountability. Paragraph (a) requires that the licensee maintain accountability for all brachytherapy sources in storage or use. We deleted the majority of the prescriptive requirements and associated recordkeeping requirements in the final section to give the licensee flexibility in program management. The requirements in the current paragraph (c) were moved to § 35.404. We believe that the requirements that were retained in this section are essential to the radiation safety program. The recordkeeping requirements for this section are in § 35.2406, Records of brachytherapy source accountability.

The NRC revised § 35.410, Safety instruction to state explicitly that the instruction requirements in this section are in addition to, and not in lieu of, the training requirements of § 19.12. We believe that it is important that personnel caring for patients or human research subjects that have received brachytherapy (and cannot be released under § 35.75), receive instruction in limiting radiation exposure to the public and workers and the actions to be taken in the case of a medical emergency or death.

Paragraph (a) in the final rule requires that safety instruction be provided initially and at least annually. The current rule does not specify when instructions must be given. Typically, the frequency of training has been handled during the licensing process. We do not expect that the same level of training be provided to all individuals caring for the patient. The level of training should be commensurate with the type of care that the personnel may render to the patient or human research subject. We have deleted the reference to “procedures” in paragraph (a) because we have chosen to focus this section on instruction rather than on procedures. We believe the licensee should have flexibility in program management and recognize that licensees may develop alternative ways of addressing the issues in paragraphs (a)(1) through (a)(5). We revised paragraph (a)(4) to require that instruction on visitor control include instruction on routine visitation authorized under the provisions in § 20.1301(a)(1), as well as visitation that is authorized under the final provisions of § 20.1301(c). We revised paragraph (a)(5) to state that personnel should notify the RSO, or his or her designee, and an AU, if the patient or human research subject has a medical emergency or dies. This change provides the RSO flexibility in designating who should be notified to address radiation protection issues and ensures that an AU is notified. The recordkeeping requirements for this section are in § 35.2310, Records of safety instruction.

The NRC revised § 35.415, Safety precautions. Paragraph (a) was amended to clarify that the requirements in this section only apply if a patient or human research subject is receiving brachytherapy and cannot be released in accordance with § 35.75. Paragraph (a)(1) was amended to clarify that a patient or human research subject who is receiving brachytherapy can only share a room with another brachytherapy patient.

We revised paragraph (a)(2) to require that the patient's room, rather than the door, be visibly posted to give the licensee flexibility in determining where to place the posting so it is visible. These posting requirements are in addition to the posting requirements in Part 20. We believe that the posting requirements in Part 20 are not adequate to ensure that individuals entering the room would be aware of the presence of radioactive materials in the room. The requirement to put a note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room was moved from the current paragraph (a)(2) to the new paragraph (a)(3). We deleted the current requirements in paragraphs (a)(3) and (4) because they are radiation protection requirements that are covered under Part 20. We added a new requirement (paragraph b) that requires the licensee to have emergency response equipment available near each treatment room. This addition codifies requirements that are currently imposed on licensees by license conditions. The current paragraph (b) was redesignated as paragraph (c) and was revised to state that the licensee shall notify the RSO, or his or her designee, and an AU as soon as possible if the patient or human research subject has a medical emergency or dies. This change was made: (1) to recognize that in a medical emergency, the licensee's primary responsibility is the care of the patient; (2) to provide the RSO flexibility in whom should be notified to address radiation protection issues; and (3) to ensure that the AU is notified.

The NRC deleted the current § 35.420, Possession of survey instruments because these specific requirements are not needed in Part 35. Section 20.1501 of this chapter requires that the licensee make, or cause to be made, surveys to demonstrate compliance with Part 20 and requires 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 the licensee to have adequate equipment. Guidance on the types of instruments medical licensees could consider using is in NUREG-1556, Vol. 9.

Section 35.432, Calibration measurements of brachytherapy sources, is a new section that requires a licensee authorized to use brachytherapy sources for medical use to perform calibration measurements on brachytherapy sources before the first medical use of the source(s) after the effective date of this rule. The requirements in this section are based on recommendations found in AAPM TG-40 and TG-56, and are consistent with the calibration requirements for sealed sources and devices for therapy. The final rule allows the licensee to rely on the output measurement provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine, as long as the calibration was conducted in accordance with a published protocol accepted by a nationally recognized body and appropriately calibrated equipment was used. As discussed in the Regulatory Impact Statement, the NRC recognizes that licensees may need to procure additional equipment to meet this requirement. We believe that the additional expenditure is warranted in order for the licensee administering brachytherapy doses to ensure that the correct dose is delivered to patients. The recordkeeping requirements for this section are in § 35.2432, Records of calibration measurements of brachytherapy sources.

Section 35.433, Decay of strontium-90 sources for ophthalmic treatment, is a new section. This section requires that only an AMP may calculate the activity of a strontium-90 source that is used to determine the treatment times for ophthalmic treatments. It also requires that the decay must be based on the activity determined under § 35.432. This section was added because the NRC is aware of numerous misadministrations involving strontium-90 for ophthalmic use that were caused by individuals improperly decaying the sources. Given the risks associated with the use of strontium-90 and the numerous misadministrations in this area, more prescriptive requirements are warranted to ensure that the activities of strontium-90 sources are correctly determined. The recordkeeping requirements for this section are in § 35.2433, Records of decay of strontium-90 sources for ophthalmic treatments.

Section 35.457, Therapy-related computer systems, is a new section that requires acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. The requirements in this section are based on recommendations found in AAPM TG-56. The components of the acceptance testing are provided in this section. However, the licensee retains the flexibility in developing the acceptance testing program. The NRC believes that these new requirements are warranted in order for the licensee administering brachytherapy doses to ensure that the correct dose is delivered to patients.

Section 35.490, Training for use of manual brachytherapy sources, is a new section. The training and experience requirements for an AU of manual brachytherapy sources were moved, with some modifications, from the current § 35.940, Training for use of brachytherapy sources. Two changes made in the new section should be noted. First, the listing of specialty boards by

name was deleted because the regulatory text in Part 35 will no longer incorporate a listing of specialty boards whose diplomates automatically fulfill the training and experience requirements for AUs. In place of listing the boards, the final rule provides for NRC recognition of the boards. Second, an individual must obtain written certification from a preceptor indicating that the individual has satisfactorily completed the requirements in this section and has achieved a level of competency sufficient to function independently as an AU. Section III of the SUPPLEMENTARY INFORMATION section contains a detailed discussion of the Commission's changes to the training and experience requirements in Part 35.

Section 35.491, Training for ophthalmic use of strontium-90, is a new section. The training and experience requirements for an AU of strontium-90 sources for ophthalmic treatment were moved, with some modifications, from the current § 35.941, Training for ophthalmic use of strontium-90. Two provisions in the new section should be noted. First, an individual must obtain written certification from a preceptor indicating that the individual has satisfactorily completed the requirements in this section and has achieved a level of competency sufficient to function independently as an AU. Second, the NRC added a provision that a physician who meets the requirements in § 35.490 would automatically meet the requirements to become an AU under § 35.491. Section III of the SUPPLEMENTARY INFORMATION section contains a detailed discussion of the Commission's changes to the training and experience requirements in Part 35.

Subpart G was retitled Sealed Sources for Diagnosis. This subpart contains the requirements for diagnostic medical use of sealed sources and replaces the requirements in the current Subpart H, Sealed Sources for Diagnosis.

In § 35.500, Use of sealed sources for diagnosis, the NRC deleted the specific sources and uses listed in paragraphs (a) and (b). This conforms with the more risk-informed, performance-based nature of this final rule. The licensee has the flexibility to use sealed sources for diagnostic medical uses as approved in the SSDR.

The NRC deleted the current § 35.520, Availability of survey instrument because these specific requirements are not needed in Part 35. Section 20.1501 of this chapter requires that the licensee make, or cause to be made, surveys to demonstrate compliance with Part 20 and requires 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 the licensee to have adequate equipment. Guidance on the types of instruments medical licensees could consider using is in NUREG-1556, Vol. 9.

Section 35.590, Training for use of sealed sources for diagnosis, is a new section. The training and experience requirements for an AU of a diagnostic sealed source in a device were moved, with some modifications, from the current § 35.950, Training for use of sealed sources for diagnosis. One change made in the new section should be noted. The listing of specialty boards by name was deleted because the regulatory text in Part 35 will no longer incorporate a listing of specialty boards whose diplomates automatically fulfill the training and experience requirements for AUs. In place of listing the boards, the final rule provides for NRC recognition of the boards. Section III of the SUPPLEMENTARY INFORMATION section contains a detailed discussion of the Commission's changes to the training and experience requirements in Part 35.

The NRC retitled Subpart H, Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units, and amended its provisions to address all medical uses of photon emitting sealed sources in devices for therapy. Devices such as teletherapy, remote afterloaders, and gamma stereotactic radiosurgery units are addressed in this subpart. This subpart does not contain requirements for manual brachytherapy, which are in Subpart F, nor does it include requirements for beta emitting devices, such as beta emitting intravascular brachytherapy devices. This subpart replaces the requirements in the current Subpart I, Teletherapy.

The NRC retitled § 35.600, Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit, and deleted any references to specific radionuclides and devices in the codified text. The licensee has the flexibility to use sealed sources in photon emitting devices for therapeutic medical uses as approved in the SSDR. In addition, we added paragraph (b) to allow the use of therapy sealed sources in medical research as long as the research is conducted in accordance with an active IDE application accepted by the FDA. This change allows previously registered sources to be used for uses other than those described in the original sealed source registration process, if the research is conducted under an active IDE application accepted by the FDA.

Section 35.604, Surveys of patients and human research subjects treated with a remote afterloader unit, is a new section. This section requires that a licensee make a radiation survey of a patient or human research subject to confirm that the sources have been removed from the individual and returned to a shielded position before releasing the individual from licensee control. For fractionated low dose-rate or pulsed dose-rate treatments where the patient is not

releasable under § 35.75, surveys need only be performed after the last time the source is returned to the shielded position. For example, a survey of the patient is not required every time that the source is retracted into the shielded safe when nursing personnel enter the patient treatment room to provide care to patients undergoing fractionated treatments using a low or pulsed dose-rate remote afterloader unit. This new requirement was previously imposed on remote afterloader licensees by license condition. The recordkeeping requirements for this section are in § 35.2404, Records of radiation surveys of patients and human research subjects.

The NRC retitled § 35.605, Installation, maintenance, adjustment, and repair, and amended the codified text to clarify that only a person specifically licensed by the Commission or an Agreement State can install, maintain, adjust, or repair a unit that involves work on the source shielding, source driving unit, or other electronic or mechanical mechanism that could expose the source, reduce the shielding around the source, or compromise the radiation safety of the unit or the sources. The types of units referred to in this section were revised to include remote afterloader units and gamma stereotactic radiosurgery units, rather than just teletherapy units.

Paragraph (b) also specifies that, except for low dose-rate remote afterloader units, only a person specifically licensed by the Commission or an Agreement State shall install, replace, relocate, or remove a sealed source or source contained in a device. For low dose-rate remote afterloader units, installation, replacement, relocation, or removal of a sealed source must be done by a person specifically licensed by the Commission or an Agreement State or by an AMP. The exception to allow an AMP to perform these activities for low dose-rate remote afterloader units was included in the final rule because we believe that the radiation hazards associated with installation, replacement, relocation, or removal of a sealed source in these devices are similar

to that of manipulation of manual brachytherapy sources. The recordkeeping requirements for this section are in § 35.2605, Records of installation, maintenance, adjustment, and repair.

The NRC deleted the current § 35.606, License amendments. The requirements in the current paragraphs (a), (b), and (d) are addressed in the final § 35.13(e). Paragraph (c) was deleted because the licensees must comply with the dose limit requirements in Part 20, and no further limitations are warranted. Paragraph (e) was deleted because the requirement to file an amendment before allowing an individual to perform the duties of the AMP is addressed in the final § 35.13(b). Paragraph (e) was deleted because the requirements in Subpart H require that the AMP perform specific duties. Any deviations from these requirements would necessitate an exemption from Part 35.

The NRC retitled § 35.610, Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units, and amended the codified text to include remote afterloader units and gamma stereotactic radiosurgery units.

Paragraph (a) requires that a licensee secure the unit, console, console keys, and treatment room when not in use or unattended; permit only approved individuals into the treatment room during treatment; prevent dual operation of radiation producing devices; and develop, implement, and maintain written emergency response procedures.

Paragraphs (a) (1) and (a)(3) codify requirements that are currently imposed on licensees by license conditions related to use of remote afterloaders. Because of the applicability of the requirements to all therapy units, they were added to the rule with the intent of

having the requirements apply to all such units. We expanded paragraph (a)(2) to recognize that there are certain design conditions that will necessitate an individual, other than the patient, being in the treatment room during the treatment. An example of this condition is use of a low energy gamma source in a therapeutic medical device where the AU may need to be in the room with the patient. This exception does not relieve the licensees from complying with the dose limits for occupationally-exposed individuals or the general public in Part 20. In paragraph (a)(4), we codified requirements that are currently imposed on licensees by license conditions related to emergency procedures.

We revised paragraph (b) to require that a copy of the licensee's procedures be physically located at the unit console. We revised paragraph (c) to require that the location of the procedures and emergency response telephone numbers be posted. Previously, all of these procedures were required to be posted. This was impractical with the addition of remote afterloaders because error conditions and responses are often several pages in length.

Paragraphs (d) and (e), previously paragraph (b), were revised to require that the licensee provide initial and at least annual instruction in specifically identified procedures to all individuals who operate the unit, and initial and at least annual practice drills in emergency procedures to unit operators, AMPs, and AUs. The level of instruction should be commensurate with the individual's assigned duties. For example, an individual need not be instructed in equipment inspection, unless it is expected that during the normal course of the day, the individual will be required to inspect the unit. We believe that due to the complexity of therapeutic treatment units, refresher training and practice drills on emergency response are

warranted. The recordkeeping requirements for this section are in § 35.2310, Records of instruction and training.

Paragraph (g) was added to refer to the recordkeeping requirements in § 35.2610 for the procedures required by paragraphs (a)(4) and (d)(2).

The NRC retitled § 35.615, Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units, and amended the codified text to include remote afterloader units and gamma stereotactic radiosurgery units. The current requirements in paragraphs (a) and (b) remain essentially the same, with minor changes to the language to support requirements for remote afterloader units and gamma stereotactic radiosurgery units. We deleted many of the prescriptive requirements [e.g., beam condition indicator light [current paragraph (c)] and radiation monitor [current paragraph (d)] because they are addressed in Part 20.

We added new requirements in paragraph (d) for intercom systems, and in paragraphs (e), (f), and (g) to codify requirements that are currently imposed by license conditions. Current license conditions were modified when they were incorporated into the final rule. For example, the presence of an AU and an AMP during patient treatments was clarified for each type of unit. As used in this provision, physically present means to be within hearing distance of normal voice. Immediately available means that the individual is available on an on-call basis to respond to an emergency. At a minimum, this person must be available by telephone.

We believe that the inherent risk of these procedures justifies the prescriptiveness of this regulation and that it is important for a properly trained physician to be available at all times to respond to an emergency requiring source removal.

We deleted the current § 35.620, Possession of survey instruments, because these specific requirements are not needed in Part 35. Section 20.1501 of this chapter requires that the licensee make, or cause to be made, surveys to demonstrate compliance with Part 20, and that the licensee 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 equipment. Guidance on the types of instruments medical licensees could consider using is in NUREG-1556, Vol. 9.

The NRC amended § 35.630, Dosimetry equipment, to provide calibration requirements for instruments used in this subpart and Subpart F. Paragraph (a)(1) requires that dosimetry systems be calibrated using a source or system traceable to the National Institute of Standards and Technology (NIST) and in accordance with published protocols accepted by a nationally recognized body; or by a calibration laboratory accredited by AAPM. This change gives licensees two alternatives for direct traceability of dosimetry equipment calibration, i.e., either a source or the measurement instrument (e.g., well chamber) can be calibrated against a national standard. We acknowledge that the industry standards for instrument calibration provide adequate assurance that equipment is properly calibrated. We amended paragraph (a)(2) to delete the reference to intercomparison meetings sanctioned by a calibration laboratory or radiologic physics centers accredited by the AAPM. This provision is no longer necessary because the AAPM does not sanction intercomparison meetings. References to cobalt-60 and

cesium-137 contained within teletherapy units were deleted to make the section applicable to dosimetry equipment for all radionuclides and therapy units. In addition, licensees using only low dose-rate remote afterloader units are not required to possess dosimetry equipment if they rely on the source output or activity determined by the manufacturer, as long as the manufacturer uses appropriately calibrated equipment and performs the calibration in accordance with published protocols accepted by a nationally recognized body. This allowance was made to be consistent with the requirements for manual brachytherapy sources. The recordkeeping requirements for this section are in § 35.2630, Records of dosimetry equipment.

The NRC retitled § 35.632, Full calibration measurements on teletherapy units, and amended the codified text to clarify that the requirements in this section apply to teletherapy units. In paragraph (d), we deleted the reference to the AAPM Task Group Reports and replaced it with a requirement that full calibration measurements be done in accordance with published protocols accepted by nationally recognized bodies. This allows the licensee more flexibility in choosing appropriate protocols. We acknowledge that the industry standards for teletherapy unit calibration provide adequate assurance that equipment is properly calibrated. Paragraph (e) was revised to include mathematical correction of output for sources other than cobalt-60 and cesium-137. In paragraph (f), we replaced the term "teletherapy physicist" with the term "authorized medical physicist." The recordkeeping requirements for this section are in § 35.2632, Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations.

Section 35.633, Full calibration measurements on remote afterloader units, is a new section that contains the requirements for the calibration of remote afterloader units. This

section is similar in content to § 35.632. Requirements in this section were based on recommendations found in AAPM Task Group Report No. 56 - Code of Practice for Brachytherapy Physics (1997) and AAPM Task Group Report No. 59. The recordkeeping requirements for this section are in § 35.2632, Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations.

The NRC deleted the current § 35.634, Periodic spot-checks, and moved the requirements of this section, with minor modifications, to § 35.642.

Section 35.635, Full calibration measurements on gamma stereotactic radiosurgery units, is a new section that contains the requirements for the calibration of gamma stereotactic radiosurgery units. This section is similar in content to § 35.632. Requirements in this section are based on recommendations found in AAPM Report No. 54. The recordkeeping requirements for this section are in § 35.2632, Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations.

The NRC deleted the current § 35.636, Safety checks for teletherapy facilities. The requirements in this section were extended to all therapy units and incorporated into the final §§ 35.642, 35.643, 35.645, and 35.647.

The NRC deleted the current § 35.641, Radiation surveys for teletherapy facilities. Radiation surveys at the surface of the main source safe of therapy units were addressed in the final § 35.652. The remaining requirements in the current § 35.641 were deleted to allow the licensee more flexibility in managing its radiation protection program.

Section 35.642, Periodic spot-checks for teletherapy units, is a new section that contains the requirements that were previously found in § 35.634, Periodic spot-checks. The NRC replaced the phrase "teletherapy physicist" with the term "authorized medical physicist" throughout the section. We deleted the requirement in paragraph (c) to maintain a copy of the physicist's notification of the results of spot-checks to the licensee to reduce the recordkeeping requirements for licensees. We modified paragraph (d) to require that the safety spot-checks be performed once in each calendar month and after each source installation. This change replaces the safety check requirements after each source replacement in the current § 35.636, which is deleted in the final rule. We modified paragraph (d)(3) to replace the term "beam condition indicator" with "source exposure indicator" to clarify that indicators were needed to note whether the source was exposed and note to what degree the source was exposed. We revised paragraph (d)(4) to include a requirement for an intercom system that was previously imposed by license condition. An intercom is needed to assure that the licensee's staff and the patients have the ability to communicate verbally in addition to the ability to communicate visually. We revised paragraph (e) to require that if a malfunction is identified during a safety spot-check the licensee lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system. This change makes § 35.642 consistent with the requirement in the current § 35.636 regarding immediate actions to be taken when a malfunctioning system is identified. The recordkeeping requirements for this section are in § 35.2642, Records of periodic spot-checks for teletherapy units.

Section 35.643, Periodic spot-checks for remote afterloader units, is a new section that replaces the current § 35.643, Modification of teletherapy unit or room before beginning a treatment program. The NRC deleted requirements in the current § 35.643 because they were

considered overly prescriptive. This allows the licensee more flexibility in designing a radiation protection program that is specific to its facility and which assures that the dose limits in Part 20 are not exceeded.

The new § 35.643 contains the requirements for periodic spot-checks of remote afterloader units, and is similar in content to § 35.642. Requirements in this section are based on recommendations in AAPM TG-40 and TG-56. The recordkeeping requirements for this section are in § 35.2643, Records of periodic spot-checks for remote afterloader units.

Section 35.645, Periodic spot-checks for gamma stereotactic radiosurgery units, is a new section that replaces the current § 35.645, Reports of teletherapy surveys, checks, tests, and measurements. The requirements in the current § 35.645 were deleted to reduce the reporting burden on medical use licensees. The NRC believes that there is no need to submit survey results to the appropriate Regional Office because the survey results are maintained by a licensee to show compliance with Part 20 and, therefore, are available for review.

The new § 35.645 contains requirements for periodic spot-checks of gamma stereotactic radiosurgery units, and is similar in content to § 35.642. Requirements in this section are based on recommendations found in AAPM Report No. 54. The recordkeeping requirements for this section are in § 35.2645, Records of periodic spot-checks for gamma stereotactic radiosurgery units.

Section 35.647, Additional technical requirements for mobile remote afterloader units, replaces the current § 35.647, 5-year inspection. Requirements in the current § 35.647 were

moved to § 35.655. This section now contains the requirements for mobile remote afterloader units which were previously listed in an internal NRC document entitled, "Supplement 1 to Policy and Guidance Directive FC 86-4; Revision 1, Mobile Remote Afterloading Brachytherapy Licensing Module." The recordkeeping requirements for this section are in § 35.2647, Records of additional technical requirements for mobile remote afterloader units.

Section 35.652, Radiation surveys, is a new section. This section replaces the current requirements in § 35.641. This section requires that, in addition to the surveys required by § 20.1501, the licensee make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe do not exceed the levels stated in the SSDR. These surveys provide added assurance that a device has been manufactured and that source(s) have been installed properly. The recordkeeping requirements for this section are in § 35.2652, Records of surveys of therapeutic treatment units.

Section 35.655, 5-year inspection for teletherapy and gamma stereotactic radiosurgery units, is a new Section and contains the requirements for inspections that were in the current § 35.647. Section 35.655 requires that teletherapy units and gamma stereotactic radiosurgery units be inspected and serviced during source replacement, or at intervals not to exceed 5 years, to assure proper functioning of the source exposure mechanism. Most gamma stereotactic radiosurgery licensees are required, by license condition, to inspect the units every 7 years. However, professionals in the medical community have indicated that the units are inspected on a more frequent basis. The NRC believes that the risk associated with using gamma stereotactic radiosurgery units justifies a change in the inspection frequency to a frequency consistent with teletherapy units, i.e., 5 years. The recordkeeping requirements for

this section are in § 35.2655, Records of 5-year inspection for teletherapy and gamma stereotactic radiosurgery units.

Section 35.657, Therapy-related computer systems, is a new section that requires licensees to perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. These changes are consistent with recommendations found in AAPM TG-56. The components of the testing are provided in this section. However, the licensee retains flexibility in developing the acceptance testing program. The NRC believes that these new requirements are warranted for the licensee administering therapy doses to ensure that the correct dose is delivered to patients.

Section 35.690, Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units, is a new section. This section contains the training and experience requirements for an AU of teletherapy, remote afterloader, and gamma stereotactic radiosurgery units. The current section, § 35.960, Training for teletherapy, was expanded to include the training for AUs of remote afterloaders and gamma stereotactic radiosurgery units because requirements for gamma stereotactic radiosurgery units and remote afterloader units have been codified in the revised Part 35. Two changes made in the new section should be noted. First, the listing of specialty boards by name was deleted because the regulatory text in Part 35 will no longer incorporate a listing of specialty boards whose diplomates automatically fulfill the training and experience requirements for AUs. In place of listing the boards, the final rule provides for NRC recognition of the boards. Second, an individual must obtain written certification from a preceptor indicating that the individual has satisfactorily completed the

requirements in this section and has achieved a level of competency sufficient to function independently as an AU. Section III of the SUPPLEMENTARY INFORMATION section contains a detailed discussion of the Commission's changes to the training and experience requirements in Part 35.

Subpart J, Training and Experience Requirements, was deleted. The revised training and experience requirements are in Subparts B and D through H. A detailed discussion of the changes to the training and experience requirements is in Section III of the SUPPLEMENTARY INFORMATION section.

The NRC deleted the current § 35.900, Radiation Safety Officer. The requirements in this section, with some modifications, were moved to the new § 35.50, Training for Radiation Safety Officer.

The NRC deleted the current § 35.901, Training for experienced Radiation Safety Officer. The requirements, with some modifications, were moved to the new § 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist.

The NRC deleted the current § 35.910, Training for uptake, dilution, and excretion studies. The requirements in this section, with some modifications, were moved to the new § 35.190, Training for uptake, dilution, and excretion studies.

The NRC deleted the current § 35.920, Training for imaging and localization studies. The requirements in this section, with some modifications, were moved to the new § 35.290, Training for imaging and localization studies.

The NRC deleted the current § 35.930, Training for therapeutic use of unsealed byproduct material. The requirements in this section, with some modifications, were moved to the new § 35.390, Training for use of unsealed byproduct material for which a written directive is required.

The NRC deleted the current § 35.932, Training for treatment of hyperthyroidism. The requirements in this section, with some modifications, were moved to the new § 35.392, Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries)

The NRC deleted the current § 35.934, Training for treatment of thyroid carcinoma. The requirements in this section, with some modifications, were moved to the new § 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)

The NRC deleted the current § 35.940, Training for use of brachytherapy sources. The requirements in this section, with some modifications, were moved to the new § 35.490, Training for use of manual brachytherapy sources.

The NRC deleted the current § 35.941, Training for ophthalmic use of strontium-90. The requirements in this section, with some modifications, were moved to the new § 35.491, Training for ophthalmic use of strontium-90.

The NRC deleted the current § 35.950, Training for use of sealed sources for diagnosis. The requirements in this section, with some modifications, were moved to the new § 35.590, Training for use of sealed sources for diagnosis.

The NRC deleted the current § 35.960, Training for teletherapy. The requirements in this section, with some modifications, were moved to the new § 35.690, Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

The NRC deleted the current § 35.961, Training for teletherapy physicist. The requirements in this section, with some modifications, were moved to the new § 35.51,Training for an authorized medical physicist.

The NRC deleted the current § 35.970, Training for experienced authorized users. The requirements of this section, with minor modifications, were moved to the new § 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist.

The NRC deleted the current § 35.971, Physicians training in a three-month program because three-month nuclear medicine programs are no longer available. The criteria for AUs are now specified in other areas of the rule.

The NRC deleted the current § 35.972, Recentness of training. The requirements of this section, with minor modifications, were moved to the new § 35.59, Recentness of training.

The NRC deleted the current § 35.980, Training for an authorized nuclear pharmacist. The requirements of this section, with minor modifications, were moved to the new § 35.55, Training for an authorized nuclear pharmacist.

The NRC deleted the current § 35.981, Training for experienced nuclear pharmacists. The proposed rule solicited comments on the impact of deleting this section. All of the commenters that responded to this question said that there would be no impact if this section were deleted because the requirements for experienced nuclear pharmacists are covered in § 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist.

The NRC deleted the current § 35.990, Violations, and moved the requirements of this section, with minor modifications, to the new § 35.4001, Violations.

The NRC deleted the current § 35.991, Criminal penalties, and moved the requirements of this section, with minor modifications, to the new § 35.4002, Criminal penalties.

The NRC deleted the current § 35.999, Resolution of conflicting requirements during transition period, and moved the requirements of this section, with modifications, to the new § 35.10, Implementation.

Subpart K, Other Medical Uses of Byproduct Material or Radiation from Byproduct Material, is a new subpart. This subpart includes all new medical uses of byproduct material or radiation from byproduct material, i.e., types of uses that are not regulated under Subparts D through H.

Section 35.1000, Other medical uses of byproduct material or radiation from byproduct material, is a new section. It has been added so that there are codified regulatory requirements and a more clearly defined process to obtain a license, or an amendment to a license, for a new medical use of byproduct material or radiation from byproduct material, i.e., an emerging technology. The specific information that must be provided to the Commission in support of an application for use under § 35.1000 is provided in § 35.12(d). The Commission intends to evaluate each application on a case-by-case basis and to work with the ACMUI, the medical community, and the developers of the new technology, as appropriate, to determine the risks associated with the technology and the appropriate regulatory requirements, including the training and experience requirements, for use of the technology.

Subpart L, Records, is a new subpart. This subpart contains all the specific recordkeeping requirements necessary to implement the requirements in Part 35. The general requirements for record maintenance, such as electronic storage, are provided in § 35.5. The records are grouped in one subpart to facilitate use by the licensees. A licensee may refer to this subpart to determine whether something must be recorded, instead of having to review the entire regulation to find out if there is a particular recordkeeping requirement. Many of the recordkeeping requirements remain unchanged from the current Part 35. However, some new sections have been added as a result of new requirements, especially in Subpart H, that codify

requirements for remote afterloaders and gamma stereotactic radiosurgery units that are currently imposed by license conditions.

Section 35.2024, Records of authority and responsibilities for radiation protection programs, requires the licensee to retain a record of actions taken by the licensee's management in accordance with § 35.24(a) for 5 years. The Commission believes that it is important to document the licensee's management review and approval of licensing actions and changes to the radiation protection program. The record of licensing actions and radiation protection program changes must include a summary of the actions taken and a signature of licensee management. The 5-year retention period is a reduction from the current requirements to maintain records of the approval of licensing actions, individuals, and radiation protection program changes. Similar records in the current §§ 35.23 and 35.31 are required to be maintained for the duration of the license. The 5-year retention period will decrease the recordkeeping burden on licensees and will also allow sufficient time for NRC to review records of licensee actions.

Paragraph (b) of this section requires the licensee to retain a copy of both the authorities, duties, and responsibilities of the RSO in accordance with § 35.24(e) and a signed copy of each RSO's agreement to be responsible for implementing the radiation safety program, in accordance with § 35.24(b), for the duration of the license. These records must include the signatures of both the RSO and licensee management. The current Part 35 requires that the signed copy of the authorities, duties, and responsibilities of the RSO be retained until the Commission terminates the license.

Section 35.2026, Records of radiation protection program changes, requires the licensee to retain a record of each radiation protection program change made in accordance with § 35.26(a) for 5 years. The record must include a copy of the old and new procedures, the effective date of the change, and the signature of the licensee management that reviewed and approved the change. The requirements in the current § 35.31 to include the reasons for the change, and a summary of radiation safety matters that were considered before making the change, have been deleted. The Commission recognizes that the requirement for management's signature is redundant with the requirement in § 35.2024. However, it believes this approach is warranted in light of the importance of these actions. This record is needed to document what radiation changes were made in the program to facilitate the Commission's evaluation of minor radiation safety program changes, and provides licensees with a record of the changes. Currently, licensees must retain a record of each "radiation safety program" change until the license has been renewed or terminated. Therefore, the 5-year retention period in the final rule represents a reduction in the licensee's recordkeeping burden.

Section 35.2040, Records of written directives, requires the licensee to retain a copy of written directives required by § 35.40 for 3 years. The final rule includes only minor changes to the specific items that must currently be recorded in written directives in accordance with § 35.32. These records will help to ensure that administrations are in accordance with the written directives. The 3-year recordkeeping retention period corresponds with the current retention period for written directives in § 35.32(d). These changes are discussed under § 35.40.

Section 35.2041, Records for procedures for administrations requiring a written directive, is a new section. This section requires licensees to retain a copy of the procedures required by § 35.41(a) for the duration of the license.

Section 35.2060, Records of calibrations of instruments used to measure the activity of unsealed byproduct material, requires the licensee to maintain a record of instrument calibrations performed in accordance with § 35.60 for 3 years. These records are required to document that the instruments are calibrated properly. This section replaces the requirements in the current § 35.50 (e) and adds recordkeeping requirements for instruments used to measure the activity of dosages of nonphoton-emitting radionuclides. The prescriptive requirements for the record were deleted because licensees should have flexibility in determining how the results of the calibration are recorded. The final rule requires that the name of the individual who performed the calibration be documented in the record, rather than the initials of the individual who performed the constancy check and the identity of the individual for all other required tests. The NRC believes that this change is needed because recording the name of the individual will better ensure future identification of the individual who performed the calibration. The change is also needed because it gives the licensee the flexibility of using paper records or computer-generated records. This requirement does not prohibit licensees from continuing to have the individual who performed the calibration sign the record. The 3-year recordkeeping retention period is consistent with the current retention period for instrument calibrations.

The final rule requires that the record contain 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.

Section 35.2061, Records of radiation survey instrument calibrations, requires the licensee to maintain a record of radiation survey instrument calibrations required by § 35.61 for 3 years. This record is needed to provide adequate documentation of instrument calibration. This section replaces the requirements in the current § 35.51(d). The NRC deleted the requirement to include the descriptions of the calibration procedure and the source used; the certified exposure rates from the source and the rates indicated by the instrument being calibrated; and the correction factors deduced from the calibration data. This revision is consistent with the revisions made to § 35.61. The 3-year recordkeeping retention period is consistent with the current retention period for instrument calibrations.

The final rule requires 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.

Section 35.2063, Records of dosage of unsealed byproduct material for medical use, requires the licensee to maintain a record of dosage determinations required by § 35.63 for 3 years. This record is needed to show that material has been administered to a patient or human research subject. This section replaces the requirements in the current § 35.53(c). Changes have been made from the current recordkeeping requirements for dosage measurement. The NRC deleted the requirement to include the generic name, trade name, or abbreviation of the radiopharmaceutical; its lot number and expiration date; and the activity of the dosage at the time of measurement. With the exception of the expiration date, the requirements were deleted to make the rule less prescriptive. We deleted the expiration date because it is primarily related to drug stability and sterility. The term “dosage measurement”

was replaced by the term “dosage determination” to be consistent with the changes made in § 35.63. Finally, a change was made to require that the name of the individual who determined the dosage be documented rather than the initial of the individual who made the record. We believe that this change is needed because recording the name of the individual will better ensure future identification of the individual who determined the dosage. The 3-year recordkeeping retention period corresponds with the current retention period for dosage records.

The final rule requires that licensees record the radiopharmaceutical; the patient’s or human research subject’s name, or identification number if one has been assigned; the prescribed dosage, the determined dosage, or a notation that the total activity is less than 1.1 MBq (30 μCi); the date and time of the dosage determination; and the name of the individual who determined the dosage.

Section 35.2067, Records of leak tests and inventory of sealed sources and brachytherapy sources, requires the licensee to retain records of the leak tests and inventory required by § 35.67(b) and (g), respectively, for 3 years. Leak test records are required to show that the leak test was done at the appropriate time interval and that sealed sources are not leaking. Inventory records are necessary to show that the possession of sealed sources did not exceed the amount authorized by the license. This section replaces the requirements in the current § 35.59(d) and (g). The NRC deleted the requirement to record the measured activity of each leak test sample and a description of the method used to measure each test sample. These changes were done to make the rule less prescriptive. We also revised the rule to require that the name of the individual performing the leak test and inventory be recorded rather than the signature of the RSO. We believe this change is needed because recording the name

of the individual will ensure future identification of the individual who performed the leak test or inventory. The record retention period was reduced from 5 years to 3 years to reduce regulatory burden. The Commission does not believe the longer record retention period is warranted.

The final rule requires that leak test records must contain the model number, and serial number if one has been assigned, of each source tested; the identity of each source radionuclide and its estimated activity; the results of the test; the date of the test; and the name of the individual who performed the test. Inventory records must contain the model number of each source, and serial number if one has been assigned; the identity of each source radionuclide and its nominal activity; the location of each source; and the name of the individual who performed the inventory.

Section 35.2070, Records of surveys for ambient radiation exposure rate, requires the licensee to maintain records of radiation surveys for 3 years. These records are needed to document that surveys were performed. This section replaces the requirements in the current § 35.70(h). The NRC revised the current requirements to delete the need to record a plan of each area surveyed; the trigger level established for each area; and the detected dose rate at several points in each area expressed in millirem per hour or the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters. These deletions were done to make the rule less prescriptive and to delete reference to surveys for removable contamination. The final rule requires that the name of the individual performing the survey be recorded rather than the initials of the individual. We believe this change is needed because recording the name of the individual will ensure easier identification of the individual who

performed the survey. The 3-year recordkeeping retention period is consistent with the current retention period for radiation surveys.

The final rule requires that the record include the date of the survey; the results of the survey; the instrument used to make the survey; and the name of the individual who performed the survey.

Section 35.2075, Records of the release of individuals containing unsealed byproduct material or implants containing byproduct material, requires the licensee to maintain records of patient release required by § 35.75 for 3 years. This record is needed to show compliance with the requirements in § 35.75. No changes have been made from the recordkeeping requirements in the current § 35.75 (c) and (d).

Section 35.2080, Records of mobile medical services, requires the licensees to maintain a copy of each letter that permits the use of byproduct material at a client's address of use for 3 years after the last provision of service; and to retain the records of the surveys for 3 years. The records are needed to show compliance with the requirements in § 35.80. The NRC deleted the requirements to record a plan of each area that was surveyed and the measured dose rate at several points in each area of use expressed in millirem per hour. This change was done to make the rule less prescriptive. The final rule requires that the name of the individual performing the survey rather than the initials of the individual be recorded. We believe this change is needed because recording the name of the individual will ensure easier identification of the individual who performed the survey.

Paragraph (a) of the final rule requires that the record include a copy of each letter that permits the use of byproduct material at a client's address. Paragraph (b) requires that the record of each survey include the date of survey, the result of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

Section 35.2092, Records of decay-in-storage, requires the licensee to maintain records of the disposal of licensed materials made in accordance with § 35.92 for 3 years. This record is needed to document that radioactive material is not disposed of as ordinary waste. This section replaces the requirements in the current § 35.92 (b). The NRC deleted the requirement to record the date that the material was placed in storage and the radionuclides because the requirement to store material for 10 half-lives was deleted. We also revised the requirement so that the record includes the name of the individual who performed the survey, rather than the name of the individual who performed the disposal. We believe that it is important to have a record of the individual who actually surveyed the material and determined that it could be disposed without regard to its radioactivity. The 3-year recordkeeping retention period is consistent with the current retention period for waste disposal records.

The final rule requires that the record include the date of the disposal; the survey instrument used; the background radiation level; the radiation level measured at the surface of each waste container; and the name of the individual who performed the survey

Section 35.2204, Records of molybdenum-99 concentrations, requires the licensee to maintain a record of the molybdenum-99 concentration tests required by § 35.204(b) for 3 years. This record is needed to document that the concentration measurement was made and that the

maximum molybdenum-99 concentration level was not exceeded. This section replaces the requirements in the current § 35.204 (c). The NRC deleted the requirements to record the measured activity of the technetium expressed in millicuries and the measured activity of the molybdenum expressed in microcuries. The 3-year recordkeeping retention period is consistent with the current retention period for records of molybdenum-99 concentration.

The final rule requires that the record include, for each measured elution of technetium-99m, the ratio for the measures expressed as kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (microcuries of molybdenum per millicurie of technetium); the time and date of the measure; and the name of the individual who made the measurement.

Section 35.2310, Records of safety instruction, requires the licensee to maintain a record of radiation safety instructions required by §§ 35.310, 35.410, and 35.610 for 3 years. This record is needed to document that the instruction was given. This section replaces the requirements in §§ 35.310, 35.410, and 35.610. The rule has been revised to require that the licensee record the topics covered rather than a description of the instruction. The NRC believes the term “description of the instruction” was too vague and could have been interpreted too broadly. For example, the licensee could question whether the rule required a listing of the topics or a general description, e.g., such as laboratory or classroom training. The change makes it clear that the record should contain the topics, e.g., patient, visitor, waste, or contamination control. The 3-year recordkeeping retention period is consistent with the current retention period for training records.

The final rule requires that the record include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

Section 35.2404, Records of surveys after source implant or removal, requires the licensee to maintain a record of the surveys required by §§ 35.404 and 35.604 for 3 years. The licensee is no longer specifically required to record the dose rate from the patient or the human research subject expressed as millirem per hour and measured at 1 meter from the patient or human research subject. Each record must include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey. These records are used to show that sources have not been misplaced and that all sources have been removed from the patient. The 3-year recordkeeping retention period is consistent with the current retention period for surveys found in Part 20.

Section 35.2406, Records of brachytherapy source accountability, requires the licensee to maintain a record of brachytherapy source accountability required by § 35.406 for 3 years. Changes have been made in the recordkeeping requirements found in the current rule. The licensee is no longer required to record the following items because they were deleted from § 35.406: the names of the individuals permitted to handle the sources; name and room number of the patient or the human research subject receiving the implant; number and activity of the sources in storage after the removal; and the number and activity of sources in storage after the return.

The final rule requires that, for temporary implants, the record must include the number and activity of sources removed from and returned to storage; the time and date they were removed from and returned to storage; the name(s) of the individual(s) who removed them from and returned them to storage; and the location of use. For permanent implants, the record must include the number and activity of sources removed from storage; the number and activity of sources permanently implanted in the patient or human research subject; the number and activity of sources not implanted; the date they were removed from and returned to storage; and the name(s) of the individual(s) who removed them from and returned them to storage. This record is required so that if a brachytherapy source is misplaced or missing the licensee is immediately alerted and can take appropriate action. The 3-year recordkeeping retention period is consistent with the current retention period for inventory records.

Section 35.2432, Records of calibration measurements of brachytherapy sources, requires the licensee to retain a record of the results of brachytherapy source calibrations required by § 35.432 for 3 years after the last use of the source. This is a new recordkeeping section. The record must contain the date of the calibration; the manufacturer's name, model number, and serial number for the source and instruments used to calibrate the source; the source output or activity; the source positioning accuracy within the applicators; and the signature of the AMP. These records are needed to document that the brachytherapy sources have been calibrated.

Section 35.2433, Records of decay of strontium-90 sources for ophthalmic treatments, requires the licensee to maintain a record of the activity of a strontium-90 source, as required by § 35.433, for the life of the source. This is a new recordkeeping section. The records for each

strontium-90 source must include the date and initial activity of the source as determined under § 35.432; and, for each decay calculation, the date and the source activity as determined under § 35.433. These records are needed to document that the treatment times for ophthalmic uses of strontium-90 are based on properly decayed sources.

Section 35.2605, Records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units, requires the licensee to retain a record of the installation, maintenance, adjustment, and repair of these units as required by § 35.605, for 3 years. This is a new recordkeeping section. Previously, licensees were not required to keep records of installation, maintenance, adjustment, and repair. For each installation, maintenance, adjustment, and repair, the record must include the date, description of the service, and name(s) of the individual(s) who performed the work. This record is necessary to document that the units are properly installed, maintained, adjusted, and repaired; to establish trends in unit performance; and to establish a service history that may be used in evaluation of generic equipment problems.

Section 35.2610, Records of safety procedures, is a new section. This section requires licensees to retain a copy of the procedures required by §§ 35.610(a)(4) and (d)(2) until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.

Section 35.2630, Records of dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units, requires the licensee to retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in

accordance with § 35.630 for the duration of the license. Some changes have been made in the recordkeeping requirements from the current rule. For example, a requirement, similar to requirements for other instruments, has been added to record the manufacturer's name of the instruments that were calibrated. These records are needed to show that calibrations of medical units were made with properly calibrated instruments.

Section 35.2632, Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations, requires the licensee to maintain a record of the full calibrations required by §§ 35.632, 35.633, and 35.635 for 3 years. The record retention period was decreased from the duration of the use of the unit's source to 3 years to reduce regulatory burden. The term "teletherapy physicist" was replaced with the term "authorized medical physicist." In addition, the current recordkeeping requirements for this section were reduced to recording the date of the calibration; manufacturer's name, model number, and serial number for the unit, source and instruments used to calibrate the unit; the results and assessment of the calibration; the results of the autoradiograph required for low dose-rate remote afterloader units; and the signature of the AMP who performed the full calibration. These records are needed to document that calibrations were performed in accordance with §§ 35.632, 35.633, and 35.635.

Section 35.2642, Records of periodic spot-checks for teletherapy units, requires the licensee to retain a record of each periodic spot-check for teletherapy units required by § 35.642 for 3 years. Minor changes have been made in the recordkeeping requirements from the current rule. For instance, the licensee is no longer required to record the operability of the beam condition indicator light, but is required to record the operability of the source exposure indicator light. This change reflects corresponding changes made in § 35.642. These records are

needed to document that spot-checks were performed in accordance with § 35.642. The 3-year recordkeeping retention period is consistent with the current retention period for periodic spot-checks.

Paragraph (c) requires that the licensee retain a copy of the procedures required by § 35.642(b) until the licensee no longer possesses the teletherapy unit.

Section 35.2643, Records of periodic spot-checks for remote afterloader units, requires the licensee to retain a record of each spot-check for remote afterloader units required by § 35.643 for 3 years. This is a new recordkeeping section. The record must include the date of the spot-check; the manufacturer's name, model number, and serial number for both the remote afterloader unit and source; an assessment of timer accuracy; notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, clock and decayed source activity in the unit's computer; the name of the individual who performed the periodic spot-check; and the signature of the AMP who reviewed the record of the spot-check. These records are needed to document that spot-checks were performed in accordance with § 35.643

Paragraph (c) requires that the licensee retain a copy of the procedures required by § 35.643 (b) until the licensee no longer possesses the remote afterloader.

Section 35.2645, Records of periodic spot-checks for gamma stereotactic radiosurgery units, requires the licensee to retain a record of each spot-check for gamma stereotactic radiosurgery units required by § 35.645 for 3 years. This is a new recordkeeping section. The

record must include the date of the spot-check; the manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit; an assessment of timer linearity and accuracy; the calculated on-off error; a determination of trunnion centricity; the difference between the anticipated output and the measured output; an assessment of source output against computer calculations; notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, stereotactic frames and localizing devices (trunnions); the name of the individual who performed the periodic spot-check; and the signature of the AMP who reviewed the periodic spot-check. This record is needed to show that spot-checks were performed in accordance with § 35.645.

Paragraph (c) requires that the licensee retain a copy of the procedures required by § 35.645 (b) until the licensee no longer possesses the gamma stereotactic radiosurgery unit.

Section 35.2647, Records of additional technical requirements for mobile remote afterloader units, requires the licensee to retain a record of each check for mobile remote afterloader units required by § 35.647 for 3 years. This is a new recordkeeping section. The record must include the date of the check; the manufacturer's name, model number, and serial number for the remote afterloader unit; notations accounting for all sources before departing from a facility; notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators, source transfer tubes, and transfer tube applicator interfaces, and source positioning accuracy;

and the signature of the individual who performed the check. This record is needed to show that required spot-checks were performed in accordance with § 35.647 and that the unit is operable.

Section 35.2652, Records of surveys of therapeutic treatment units, requires the licensee to maintain a record of radiation surveys made in accordance with § 35.652 for the duration of use of the unit. This recordkeeping requirement has been changed to require that the records of radiation surveys of the treatment unit must be maintained for the duration of use of the unit, rather than for the duration of the license, to reduce regulatory burden. In addition, the licensee is no longer required by this section to maintain a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in millirem per hour, and the calculated maximum quantity of radiation over a period of 1 week for each restricted and unrestricted area. This change reflects corresponding changes made in § 35.652. The record must include the date of the measurements; the manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels; each dose rate measured around the source while the unit is in the off position and the average of all measurements; and the signature of the individual who performed the surveys. This record is needed to document radiation levels in areas surrounding therapeutic devices in accordance with § 35.652.

Section 35.2655, Records of 5-year inspection for teletherapy and gamma stereotactic radiosurgery units, requires the licensee to maintain a record of the 5-year inspection for teletherapy and gamma stereotactic radiosurgery units required by § 35.655 for the duration of the unit. This recordkeeping requirement has been changed to require that the records of inspections of the treatment units must be maintained for the duration of use of the unit, rather

than for the duration of the license, to reduce the regulatory burden. A minor change was made to delete the requirement to maintain a record of the components replaced to also reduce the regulatory burden. The record must contain the inspector's radioactive materials license number; the date of inspection; the manufacturer's name, model number and serial number for both the treatment unit and source; a list of components inspected and serviced; the type of service; and the signature of the inspector. This record is needed to document the type of service that was performed in accordance with § 35.655.

Subpart M, Reports, is a new subpart in Part 35. This subpart contains all the reporting requirements necessary to implement the requirements in Part 35. Grouping of reporting requirements into one subpart was done to facilitate use by licensees. A licensee may refer to this section when determining whether something must be reported, rather than having to review the entire regulation to find out if there is a particular reporting requirement. Two of the reporting requirements appear in the current §§ 35.33 and 35.59. A third reporting requirement was added so that the NRC can comply with the requirement to submit an annual report to Congress of unscheduled incidents or events which the Commission considers significant from the standpoint of public health and safety.

Section 35.3045, Report and notification of a medical event, provides criteria for reporting and notifying individuals about a medical event. The requirements in the final rule are based on the current requirements in § 35.33, Notifications, reports, and records of misadministrations. Changes were made to make the reporting threshold dose-based where possible; to add a dose threshold of 0.5 Sievert (Sv) (50 rem) shallow dose equivalent to the skin; and to address two areas that have caused problems in implementing the current requirements for reporting

misadministrations -- patient intervention and wrong treatment site. In addition, several changes were made to the requirements associated with the report and record of the event.

Patient intervention is not specifically addressed in the current rule. However, a licensee is expected to act reasonably, in accordance with prevailing standards of care, to prevent patient intervention from causing a misadministration. This situation has resulted in numerous debates over whether or not a licensee had done everything it should to prevent patient intervention during treatment. In order to correct the current situation, the NRC defined patient intervention to mean intentional or unintentional actions taken by a patient or human research subject such as dislodging or removing treatment devices or prematurely terminating the administration. We have also added a specific requirement for reporting medical events that occur as a result of patient intervention. Licensees are required to report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician. This reporting requirement should result in minimal regulatory burden on licensees because in most situations where patients or human research subjects intervene, either voluntarily or involuntarily, in their treatment there is no resultant permanent medical damage. Even though there is a high threshold for reporting in the final rule, licensees are expected to continue to act reasonably, as required under the current rule, to prevent medical events caused by patient intervention.

The final rule includes specific criteria for determining when a dose to a wrong treatment site is a reportable medical event: a dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of

the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

The final rule retains the current requirement in § 35.33 that licensees notify the NRC Operations Center, by telephone, no later than the next calendar day after discovery of the medical event. The final rule also retains the current requirement for licensees to submit a written report to the appropriate NRC Regional Office listed in 10 CFR 30.6 within 15 days after discovery of the medical event. This reporting requirement is needed to ensure that NRC is aware of medical events. In addition, the licensee is required to notify the referring physician and the individual affected by the medical event, or the responsible relative or guardian, no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he will inform the individual or that, based on medical judgment, telling the individual would be harmful. The written report to the NRC must include certification that the licensee notified the individual (or the individual's responsible relative or guardian), and, if not, why not. Since licensees are required to report information about the medical event to the NRC and to the referring physician, we believe that it is not necessary to require licensees to retain a record of the medical event.

A change was also made in the current requirement for a written report to be provided to the affected individual within 15 days of discovery of the medical event. In the current rule, licensees can provide the individual with a brief description of both the event and the consequences as they may affect the individual if they include a statement that the individual can also obtain a copy of the report that was submitted to the NRC from the licensee. In the

final rule, the licensee is not required to include this statement because knowledge that a report had to be submitted to the NRC might unduly alarm an individual involved in a medical event with no added benefit. However, licensees are required to inform the individual, or a responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. Licensees are required to provide this written description to the individual, if requested. In addition, licensees are required to annotate a copy of their report to the NRC about the medical event and provide it to the referring physician, if other than the licensee, within 15 days after discovery of the medical event. The NRC believes that this is important so that the individual's referring physician has all the available documentation about the medical event to support any decisions about remedial or prospective health care. The 15-day time period to provide the referring physician with a copy of the record was based on paragraph (d), which requires a licensee to submit a report to the NRC within 15 days. We have attempted to have consistency in the requirements in Subparts L and M, where possible, to simplify compliance with the recordkeeping and reporting requirements. Refer to Section III of the SUPPLEMENTARY INFORMATION section for additional information on the reporting and notification requirements in § 35.3045.

Section 35.3047, Report and notification of a dose to an embryo/fetus or a nursing child, is a new section. Paragraph (a) requires that a licensee report to NRC any administration of byproduct material, or radiation from byproduct material, to a pregnant female that results in a dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent unless the administration was specifically approved, in advance, by the AU. It should be emphasized that only unintended exposures are required to be reported to NRC.

Paragraph (b) requires that a licensee report to NRC any administration of byproduct material to a breast feeding woman that results in a dose to a nursing child that is greater than 50 mSv (5 rem) total effective dose equivalent or a dose that has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

The reporting requirements in this section are similar to the reporting requirements for medical events. Paragraph (c) in the final rule requires that licensees notify the NRC Operations Center, by telephone, no later than the next calendar day after discovery of a dose to an embryo/fetus or a nursing child that requires a report. In paragraph (d), the licensee is required to submit a written report to the appropriate NRC Regional Office listed in 10 CFR 30.6 no later than 15 days after discovery of a dose to an embryo/fetus or a nursing child.

Paragraph (e) requires the licensee to notify the referring physician and the pregnant individual or mother no later than 24 hours after discovery of the event, unless the referring physician personally informs the licensee either that he/she will inform the mother or that, based on medical judgment, telling the mother would be harmful. If verbal notification is made, licensees are required to inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. Licensees are required to provide such a written description, if requested.

Licensees are required in paragraph (f) annotate a copy of their report to the NRC about the event and provide it to the referring physician, if other than the licensee, within 15 days after discovery of the event. The NRC believes that this is important so that the referring physician

has all the available documentation about the event to support any decisions about remedial or prospective health care. The 15-day time period to provide the referring physician with a copy of the record was based on paragraph (d) which requires a licensee to submit a report to the NRC within 15 days. We have attempted to have consistency in the requirements in Subparts L and M, where possible, to simplify compliance with the recordkeeping and reporting requirements. Refer to Section III of the SUPPLEMENTARY INFORMATION section for additional information on the notification requirements in § 35.3047.

Information required by this section is needed so that the NRC can comply with Section 208 of the Energy Reorganization Act of 1974 (Pub. L. 93-438), as amended, to submit an annual report to Congress of unscheduled incidents or events which the Commission considers significant from the standpoint of public health and safety, e.g., abnormal occurrences.

The NRC identifies an abnormal occurrence using the revised abnormal occurrence criteria that were published in the Federal Register on April 17, 1997 (62 FR 18820). Section II of the policy statement defines unintended radiation exposure as “any occupational exposure, exposure to the general public or exposure as a result of a medical misadministration (as defined in § 35.2) involving the wrong individual that exceeds the reporting values established in the regulations.” This section also states that “All other reported medical misadministrations will be considered for reporting as an Abnormal Occurrence under the criteria for medical licensees. In addition, unintended radiation exposures include any exposure to a nursing child, fetus, or embryo as a result of an exposure (other than an occupational exposure to an undeclared pregnant woman) to a nursing mother or pregnant woman above specified values.” Appendix A, Section I. A, of the policy statement, states that NRC will provide information on “any unintended

radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual total effective dose equivalent of 50 mSv (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more."

At the present time, the NRC has no regulatory requirements that require reporting of those types of events. The Commission considered two alternatives that could be pursued: revise the current Abnormal Occurrence Criteria to delete the requirement to inform Congress of this type of event; or develop a reporting requirement that would provide the information needed by the Commission to comply with Section 208. The Commission did not pursue the first option because the Abnormal Occurrence reporting criteria were recently reviewed and revised.

The Commission recognizes that the standard of practice for AUs is to assess the pregnancy or nursing status of their patients (reference American College of Radiology "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, the NRC does not believe that it is appropriate to have a rule that requires a licensee to assess the pregnancy or nursing status of patients prior to a medical treatment involving byproduct material. However, we do believe it is appropriate to require the licensee to inform the NRC when the licensee learns of an unintended dose to an embryo/fetus or a nursing child that exceeds the thresholds in § 35.3047. For example, a licensee must report an unintended dose resulting from an individual not disclosing her pregnancy or nursing status at the time of administration of the byproduct material or radiation from byproduct material. In this situation, the unintended dose could have been prevented if the AU had followed the standard of practice, noted above, to assess the pregnancy status of the patient. The occurrence of such an

incident does not necessarily mean that the licensee is in violation of the requirements in Part 35, as long as the licensee reports it and it is not otherwise in violation of NRC regulatory requirements. For example, a reportable dose to a nursing child under § 35.3047 is not necessarily subject to enforcement action if the licensee has complied with § 35.75.

However, the NRC acknowledges that, in some cases, the licensee might not be able to prevent the dose to an embryo/fetus or nursing child. This type of case is not reportable under § 35.3047. For example, there is no way for an AU to prevent administration of an unintended dose to an embryo/fetus if the pregnancy test was negative because it was given very early in the pregnancy.

Section 35.3067, Report of a leaking source, requires the licensee to file a report with the appropriate NRC Office listed in § 30.6 of this chapter, with a copy to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, within 5 days if a leak test required by § 35.67 reveals the presence of 185 Bq (0.005 microcurie) or more of removable contamination. This reporting requirement is similar to the reporting requirements for leaking sources in the current § 35.59, but the final rule does not require that as much prescriptive information be included in the report. The report must contain the model number and serial number, if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken.

Subpart N, Enforcement, contains statements regarding enforcement. This subpart contains the statements in the current Subpart K, Enforcement.

Section 35.4001, Violations, is a new section that replaces the current § 35.990 which was deleted. Other than changing the number of this section to reflect the new numbering system, no changes were made in the current statements regarding violations.

Section 35.4002, Criminal penalties, is a new section that replaces the current § 35.991 which was deleted. Other than changing the numbers of this section and the sections referenced under paragraph (b) to reflect the new numbering system, no changes were made in the current statements regarding criminal penalties.

VI. Coordination with the Advisory Committee on the Medical Uses of Isotopes.

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) is an advisory body established to advise the NRC staff on matters that involve the administration of radioactive material and radiation from radioactive material. The proposed rule (63 FR 43516, August 13, 1998) for Part 35 summarized the ACMUI positions on the major crosscutting issues that were considered during development of the proposed rule.

During the development of the final rule, the NRC held public meetings of the ACMUI subcommittees for diagnostic and therapeutic medical uses on February 23-24, 1999, and February 25-26, 1999, respectively. The subcommittees reviewed the comments received by NRC during the public comment period and during the three facilitated public meetings held during that period. They also reviewed a first draft of the final rule that addressed the public comments. The subcommittees' comments are summarized in "Summary of Discussion: Public Meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) Diagnostic

Subcommittee Held in Rockville, Maryland on February 23-24, 1999" (April 22, 1999) and "Summary of Discussion: Public Meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) Therapeutic Subcommittee Held in Rockville, Maryland on February 25-26, 1999" (April 22, 1999). The summary documents are available for inspection at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the summary documents are available as indicated in the For Further Information Contact section of this document.

The full ACMUI held a public meeting on March 24-25, 1999, to discuss specific issues that the Part 35 Working Group wanted the ACMUI to review and comment on before it forwarded a draft final rule for Commission consideration. The issues included training and experience; Radiation Safety Committee; temporary Radiation Safety Officer; information that must be included in a written directive; determination of dosages of unsealed byproduct material; reports of medical events; and report of an unintended dose to an embryo/fetus or nursing child. The ACMUI presented their position on these and other issues at their annual briefing of the Commission on March 25, 1999. The ACMUI meeting was transcribed and the minutes are available for inspection at the NRC Public Document Room. Single copies of the minutes are available as indicated in the For Further Information Contact section of this document. The Commission briefing was also transcribed, and the transcript is available for inspection at the NRC Public Document Room.

On October 20, 1999, the ACMUI met to prepare for a Commission briefing, the next day, on the draft final rule for Part 35. Because the briefings are public opportunities for the Commission to hear from ACMUI, the Committee identified specific issues that they wanted to

bring to the Commission's attention. The ACMUI meeting was transcribed and the minutes are available for inspection at the NRC Public Document Room. Single copies of the minutes are available as indicated in the For Further Information Contact section of this document.

At the October 21, 1999, briefing of the Commission, the ACMUI reaffirmed that stakeholders were involved throughout the rulemaking process, including extensive involvement of the ACMUI and its subcommittees and the regulated community. In addition, the Committee believed that the draft final rule forwarded to the Commission in August 1999 (SECY-99-201) was more risk-informed and more performance-based, while maintaining occupational, public, and patient safety. ACMUI endorsed the provisions in the draft final rule for the Radiation Safety Committee, the dose thresholds for reporting medical events, and the reporting threshold for unintended exposure of an embryo/fetus or nursing child. In addition, the ACMUI endorsed the training and experience requirements for authorized users, authorized medical physicists, authorized nuclear pharmacists, and radiation safety officers, and, in particular, encouraged uniform national standards for training and experience. The ACMUI noted that it does not support any regulation requiring notification of physicians and patients, as this is redundant of existing standards of care. However, if notification requirements for medical events continue to be in Part 35, the ACMUI said that it would prefer the alternative rule language provided by the NRC staff over the existing requirements (refer to SECY-99-201, Attachment 4, for further discussion of the alternative text). (Note: A modification of the alternative rule language was approved by the Commission and is in § 35.3045 of the final rule.) In addition, the Committee encouraged early recognition of the medical specialty boards and use of the guidance document, as well as focusing NRC license reviewers and inspectors on licensee performance

and high risk procedures. The Commission briefing was transcribed and is available for inspection at the NRC Public Document Room.

VII. Coordination with NRC Agreement States.

The NRC staff discussed the revision of Part 35 with representatives of the Agreement States at the 1997, 1998, and 1999 annual meetings of the Organization of Agreement States. In addition, a draft compatibility chart for the proposed revision was developed in accordance with the compatibility categorization criteria detailed in NRC Management Directive 5.9, "Adequacy and Compatibility of Agreement State Programs" (dated February 27, 1998), and was published for comment with the proposed rule (63 FR 43516; August 13, 1998). The compatibility chart was later updated and provided to the Agreement States for comment on January 4, 1999. A summary of the comments received on the Agreement State compatibility designations and NRC's responses to the comments, and the compatibility designations for the final rule are found in Sections IV and X, respectively, of the SUPPLEMENTARY INFORMATION section.

Both the Working Group and Steering Group that developed the revision of Part 35 included Agreement State representatives. The Agreement State representative on the Working Group is also a member of the Conference of Radiation Control Directors' Suggested State Regulation Committee on Medical Regulation, which has been working toward parallel development of suggested state medical regulations. State participation in the process provided an early and continuous opportunity for State input and enhanced the development of corresponding rules in State regulations.

VIII. Consistency with Medical Policy Statement.

The Commission has revised its General Policy on the Regulation of the Medical Uses of Radioisotopes that was issued on February 9, 1979 (44 FR 8424), as part of the Commission's overall program for revising its regulatory framework for medical use. The proposed revision and detailed discussion on the need for the revision was published for comment in the Federal Register (63 FR 43580; August 13, 1998), concurrently with publication of the proposed revision to Part 35 (63 FR 43516; August 13, 1998). The revised MPS was published on August 3, 2000, 65 FR 47654. That document addressed the comments received on the proposed revision to the MPS.

The revision of Part 35 is consistent with the Commission's revision of the Medical Use Policy Statement. The consistency of the final rule with each policy statement is discussed below.

The first statement of the revised policy reads "NRC will continue to regulate the uses of radionuclides in medicine as necessary to provide for the radiation safety of workers and the general public." The final rule is consistent with the statement because one of its purposes is to provide for the radiation safety of workers and individual members of the public, which is central to fulfillment of the Commission's statutory mandate in the Atomic Energy Act of 1954, as amended, to "protect health and minimize danger to life."

The second statement of the revised policy reads "NRC will not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers

and the general public." The final rule is consistent with this statement because its focus is on protecting the public and workers from patients who have been administered byproduct material or radiation from byproduct material for medical use.

The third statement of the revised policy reads "NRC will, when justified by the risk to patients, regulate the radiation safety of patients primarily to assure the use of radionuclides is in accordance with the physician's directions." The final rule is consistent with this statement because it includes provisions, where warranted by the risk, to provide high confidence that the authorized user's directions for the administration of byproduct material are followed.

The fourth statement of the revised policy reads "NRC, in developing a specific regulatory approach, will consider industry and professional standards that define acceptable approaches of achieving radiation safety." The final rule is consistent with this statement because the rulemaking process included NRC examining relevant industry and professional standards to determine if specific areas of concern to NRC were included in the standards, or whether regulatory requirements needed to be included in Part 35.

IX. Implementation.

The revised regulations in 10 CFR Parts 20, 32, and 35 become effective [insert date 6 months after publication in the Federal Register], 6 months after publication of this final rule. Because the consolidated guidance document for medical use licensees has been developed in parallel with the revised regulatory requirements in Part 35, the Commission believes that a longer implementation period is not necessary. The 6-month implementation period allows the

NRC time to train licensing and inspecting staff so that the revised Part 35 will be uniformly implemented; and provides licensees the time to understand the specific features of the revised Part 35, and to develop and implement any changes in their radiation safety programs or procedures that are required to comply with the revised requirements. The NRC is evaluating what type of workshops might need to be offered for the benefit of licensees, Regional Offices, States, and others who are affected by the revision.

Section 35.10 of the rule addresses how a licensee can determine if it must comply with the requirements of the revised Part 35 when it becomes effective or if it must continue to comply with the requirements of its license conditions. If a license condition exempts a licensee from a provision of the current Part 35 on the effective date of the final rule, paragraph (b) of this section states that the license condition will continue to exempt the licensee from the requirements in the corresponding provision in the revised Part 35. Paragraph (c) states that if a requirement in the revised Part 35 differs from the requirements in an existing license requirement that addresses the same issue, the requirement in Part 35 governs. Under most circumstances, medical use licensees will not be required to have their licenses amended in this situation, even if the revised requirement is less restrictive than their current license condition. The exceptions to paragraph (c) are listed in paragraph (d), which requires a licensee to continue to comply with any licensee condition to have procedures for responding to emergency situations (§ 35.610) and spot checks involving teletherapy units (§ 35.642), photon emitting remote afterloader units (§ 35.643), or gamma stereotactic radiosurgery units (§ 35.645).

X. Issues of Compatibility for Agreement States

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" approved by the Commission on June 30, 1997 (62 FR 46517), specific requirements within this rule should be adopted by Agreement States for purposes of compatibility or because of their health and safety significance. Implementing procedures for the Policy Statement establish specific categories which have been applied to categorize the requirements in Parts 20, 32, and 35. A Compatibility Category "A" designation means the requirement is a basic radiation protection standard or deals with related definitions, signs, labels, or terms necessary for a common understanding of radiation protection principles. Compatibility Category "A" designated Agreement State requirements should be essentially identical to those of the NRC. A Compatibility Category "B" designation means the requirement has significant direct transboundary implications. Compatibility Category "B" designated Agreement State requirements should be essentially identical to those of the NRC. A Compatibility Category "C" designation means the essential objectives of the requirement should be adopted by the State to avoid conflicts, duplications, or gaps. The manner in which the essential objectives are addressed in the Agreement State requirement need not be the same as NRC provided the essential objectives are met. A Compatibility Category "D" designation means the requirement does not need to be adopted by an Agreement State for purposes of compatibility. The Compatibility Category Health and Safety (H&S) identifies requirements that are not required for compatibility, but which have particular health and safety significance. Agreement States should adopt the essential objectives of such requirements in order to maintain an adequate program.

Summary of NRC Rules with Compatibility or Health and Safety Designations
Under the Revision of 10 CFR Parts 20, 32 & 35
All Sections not listed here are Compatibility Category D

Category A

Section and paragraph		Section title
20.1003,	Occupational dose Public dose	Definitions
20.1301,	(a) & (c)	Dose limits to individual members of the public

Category B

Section and paragraph		Section title
32.72,	(b)(1) & (b)(2)(ii)	Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under Part 35
32.74,	(a) & (a)(3)	Manufacture and distribution of sources or devices containing byproduct material for medical use
35.2,	Agreement State Authorized medical physicist Authorized nuclear pharmacist Authorized user Radiation safety officer Sealed source	Definitions
35.50		Training for Radiation Safety Officer
35.51		Training for an authorized medical physicist

35.55	Training for an authorized nuclear pharmacist
35.57	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist
35.59	Recentness of training
35.190	Training for uptake, dilution and excretion studies
35.290	Training for imaging and localization studies
35.390	Training for use of unsealed byproduct material for which a written directive is required
35.392	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries)
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)
35.490	Training for use of manual brachytherapy sources
35.491	Training for ophthalmic use of strontium-90
35.590	Training for use of sealed sources for diagnosis
35.690	Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units

Category C

Section and paragraph		Section title
35.2,	Medical use Prescribed dosage Prescribed dose Treatment site	Definitions
35.6		Provisions for the protection of human research subjects
35.11		License required
35.49		Suppliers for sealed sources or devices for medical use
35.75,	(a) & (b)	Release of individuals containing unsealed byproduct material or implants containing byproduct material
35.400		Use of sealed sources for manual brachytherapy
35.500		Use of sealed sources for diagnosis
35.600		Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit
35.3045		Report and notification of a medical event
35.3047		Report and notification of a dose to an embryo/fetus or a nursing child
35.3067		Report of a leaking source

Category H&S

Section and paragraph		Section title
35.24,	(b) & (f)	Authority and responsibilities for the radiation protection program
35.27		Supervision
35.40,	(a) & (b)	Written directives
35.41,	(a)	Procedures for administrations requiring a written directive
35.60,	(a) & (b)	Possession, use and calibration of instruments used to measure the activity of unsealed byproduct material
35.61,	(a)(1), (a)(2), (b), & (c)	Calibration of survey instruments
35.63,	(a) - (d)	Determination of dosages of unsealed byproduct material for medical use
35.67,	(a) - (e) & (g)	Requirements for possession of sealed sources and brachytherapy sources
35.69		Labeling of vials and syringes
35.70,	(a)	Surveys of ambient radiation exposure rate
35.80,	(a)(2), (a)(3), & (b)	Provision of mobile medical service
35.92		Decay-in-storage

35.100		Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required
35.200		Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required
35.204,	(a) & (b)	Permissible molybdenum-99 concentration
35.300		Use of unsealed byproduct material for which a written directive is required
35.310,	(a)	Safety instruction
35.315		Safety precautions
35.404,	(a) & (b)	Surveys after source implant and removal
35.406,	(a) & (b)	Brachytherapy sources accountability
35.410,	(a)	Safety instruction
35.415		Safety precautions
35.432,	(a) - (c)	Calibration measurements of brachytherapy sealed sources
35.433,	(a)	Decay of strontium-90 sources for ophthalmic treatments
35.457		Therapy-related computer systems

35.604,	(a)	Surveys of patients and human research subjects treated with a remote afterloader unit
35.605,	(a) - (c)	Installation, maintenance, adjustment and repair
35.610,	(a) - (e)	Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units
35.615		Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units
35.630,	(a) & (b)	Dosimetry equipment
35.632,	(a) - (f)	Full calibration measurements on teletherapy units
35.633,	(a) - (h)	Full calibration measurements on remote afterloader units
35.635,	(a) - (f)	Full calibration measurements on gamma stereotactic radiosurgery units
35.642,	(a) - (e)	Periodic spot-checks for teletherapy units
35.643,	(a) - (e)	Periodic spot-checks for remote afterloader units
35.645,	(a) - (f)	Periodic spot-checks for gamma stereotactic radiosurgery units
35.647,	(a) - (d)	Additional technical requirements for mobile remote afterloader units

35.652,	(a) & (b)	Radiation surveys
35.655,	(a) & (b)	Five-year inspection for teletherapy and gamma stereotactic radiosurgery units
35.657		Therapy-related computer systems

XI. Assessment of Federal Regulations and Policies on Families.

In accordance with Section 654 of the Treasury and General Government Appropriation Act of 1999, Pub. L. No. 105-277, 112 Stat. 2681, 528-29 (1998), to be codified at 5 USC 601 note, the NRC has assessed this action against the seven factors set forth in the Act. The NRC has determined that this action will not negatively affect family well-being.

XII. Finding of No Significant Environmental Impact: Availability.

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that this rule is a major Federal action but will not significantly affect the quality of the human environment, and, therefore, an environmental impact statement is not required. The amendments relax some requirements, eliminate certain procedural restrictions, focus on those requirements that are essential for patient safety, reduce or eliminate duplications or overlaps between Part 35 and the other parts of 10 CFR, and provide greater flexibility for licensees in how they meet the objectives in the requirements. The Commission believes that the more risk-informed, performance-based amendments will provide greater flexibility in the medical use of byproduct material while continuing to adequately protect public health and safety. With the exception of

the amendment to 10 CFR 20.1301, the rulemaking action will not lead to an increase in radiation exposure to the public or health care workers, or radiation releases to the environment beyond the exposures or releases currently resulting from the medical use of byproduct material or radiation from byproduct material. The amendment to 10 CFR 20.1301 is expected to result in an increase in radiation exposure to the public. However, this alternative is consistent with generally accepted radiation protection principles, such as those expressed by the International Commission on Radiation Protection (ICRP), the National Council on Radiation Protection and Measurements (NCRP), and the International Atomic Energy Agency (IAEA).

The NRC requested public comments on any environmental justice considerations that may be related to this rule. Because there were no comments specific to those considerations, the environmental assessment has not changed in this regard as a result of public comment.

The NRC requested the views of the States on the environmental assessment for this rule. Because there were no comments specific to the environmental assessment, the environmental assessment has not changed as a result of the views of the States.

The environmental assessment is available for inspection as indicated in the ADDRESSES section of this document. Single copies of the environmental assessment are available as indicated in the FOR INFORMATION CONTACT section of this document.

XIII. Paperwork Reduction Act Statement.

This final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.) These requirements were approved by the Office of Management and Budget, approval numbers 3150-0010 and 3150-0120.

Because the rule will reduce existing information collection requirements, the public burden for this information collection is estimated to be decreased by 65 hours per licensee. This reduction includes the time required for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments on any aspect of this information collection, including suggestions for further reducing the burden, to the Records Management Branch (T-6-E6), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail at BJS1@NRC.GOV; and to the Desk Officer, Office of information and Regulatory Affairs, NEOB-10202 (3150-0010 and 3150-0120), Office of Management and Budget, Washington, DC 20503.

Public Protection Notification

If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

XIV. Regulatory Analysis.

The Commission has prepared a regulatory analysis on this final regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission. The analysis is available for inspection as indicated in the ADDRESSES section of this document. Single copies of the analysis are available as indicated in the FOR INFORMATION CONTACT section of this document.

XV. Regulatory Flexibility Analysis

The NRC has prepared a final regulatory flexibility analysis of the impact of this rule on small entities as required by Section 604 of the Regulatory Flexibility Act. The analysis indicates that 40 percent of the medical licensees are small entities. Although the final rule has an economic impact of an estimated $8,000 annually on the smallest of these licensees, the selected alternative is the least costly alternative that provides adequate protection from radiation exposure to the public, patients and workers. The analysis is available for inspection as indicated in the ADDRESSES section of this document. Single copies of the analysis are available as indicated in the FOR INFORMATION CONTACT section of this document.

XVI. Backfit Analysis.

The NRC has determined that the backfit rule does not apply to this final rule; and therefore, a backfit analysis is not required for this final rule because these amendments do not involve any provisions that would impose backfits as defined in 10 CFR Chapter I.

XVII. Small Business Regulatory Enforcement Fairness Act.

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a major rulemaking and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

List of Subjects

10 CFR Part 20

Byproduct material, Criminal penalties, Licensed material, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Special nuclear material, Source material, Waste treatment and disposal.

10 CFR Part 32

Byproduct material, Criminal penalties, Labeling, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 35

Biologics, Byproduct material, Criminal penalties, Drugs, Health facilities, Health professions, Medical devices, Nuclear materials, Occupational safety and health, Radiation protection, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR parts 20, 32 and 35.

PART 20--STANDARDS FOR PROTECTION AGAINST RADIATION

1. The authority citation for Part 20 continues to read as follows:

AUTHORITY: Secs. 53, 63, 65, 81, 103, 104, 161, 182, 186, 68 Stat. 930, 933, 935, 936, 937, 948, 953, 955, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201, 2232, 2236, 2297f), secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

2. Section 20.1002 is revised to read as follows:

§ 20.1002 Scope.

The regulations in this part apply to persons licensed by the Commission to receive, possess, use, transfer, or dispose of byproduct, source, or special nuclear material or to operate a production or utilization facility under Parts 30 through 36, 39, 40, 50, 60, 61, 70, or 72 of this chapter, and in accordance with 10 CFR 76.60 to persons required to obtain a certificate of compliance or an approved compliance plan under part 76 of this chapter. The limits in this part do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, to exposure from individuals administered radioactive material and released, under § 35.75, or to exposure from voluntary participation in medical research programs.

3. In § 20.1003, the definitions for occupational dose and public dose are revised to read as follows:

§ 20.1003 Definitions

* * * * *

Occupational dose means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or to radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or other person. Occupational dose does not include doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released, under § 35.75, from voluntary participation in medical research programs, or as a member of the public.

* * * * *

Public dose means the dose received by a member of the public from exposure to radiation or to radioactive material released by a licensee, or to any other source of radiation under the control of a licensee. Public dose does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released, under § 35.75, or from voluntary participation in medical research programs.

* * * * *

4. In § 20.1301, the introductory text of paragraph (a) and paragraph (a)(1) are revised, paragraphs (c), (d), and (e) are redesignated as paragraphs (d), (e), and (f), and a new paragraph (c) is added to read as follows:

§ 20.1301 Dose limits for individual members of the public.

(a) Each licensee shall conduct operations so that --

(1) The total effective dose equivalent to individual members of the public from the licensed operation does not exceed 0.1 rem (1 mSv) in a year, exclusive of the dose contributions from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released, under § 35.75, from voluntary participation in medical research programs, and from the licensee's disposal of radioactive material into sanitary sewerage in accordance with § 20.2003, and

* * * * *

(c) Notwithstanding paragraph (a)(1) of this section, a licensee may permit visitors to an individual who cannot be released, under § 35.75, to receive a radiation dose greater than 0.1 rem (1 mSv) if--

(1) The radiation dose received does not exceed 0.5 rem (5 mSv); and

(2) The authorized user, as defined in 10 CFR Part 35, has determined before the visit that it is appropriate.

* * * * *

PART 32--SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

5. The authority citation for Part 32 continues to read as follows:

AUTHORITY: Secs. 81, 82, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

§ 32.72 [Amended]

6. In § 32.72, in paragraph (b)(1), the reference to “paragraph (b)(2) and (b)(3)” is revised to read “paragraphs (b)(2) and (b)(4)” and the reference to “10 CFR 35.25" is revised to read “10 CFR 35.27" and in paragraph (b)(2)(ii), the reference to “10 CFR 35.980(b) and 35.972" is revised to read “10 CFR 35.55(b) and 35.59.”

§ 32.74 [Amended]

7. In § 32.74, in the introductory text of paragraph (a), the reference to ”§§ 35.400 and 35.500" is revised to read “§§ 35.400, 35.500, and 35.600" and in paragraph (a)(3), the reference to “§§ 35.57, 35.400, or 35.500" is revised to read “§§ 35.65, 35.400, 35.500, and 35.600."

8. 10 CFR Part 35 is revised to read as follows:

PART 35--MEDICAL USE OF BYPRODUCT MATERIAL

Subpart A-- General Information

35.1 Purpose and scope.

35.2 Definitions.

35.5 Maintenance of records.

35.6 Provisions for the protection of human research subjects.

35.7 FDA, other Federal, and State requirements.

35.8 Information collection requirements: OMB approval.

35.10 Implementation.

35.11 License required.

35.12 Application for license, amendment, or renewal.

35.13 License amendments.

35.14 Notifications.

35.15 Exemptions regarding Type A specific licenses of broad scope.

35.18 License issuance.

35.19 Specific exemptions.

Subpart B-- General Administrative Requirements

35.24 Authority and responsibilities for the radiation protection program.

35.26 Radiation protection program changes.

35.27 Supervision.

35.40 Written directives.

35.41 Procedures for administrations requiring a written directive.

35.49 Suppliers for sealed sources or devices for medical use.

35.50 Training for Radiation Safety Officer.

35.51 Training for an authorized medical physicist.

35.55 Training for an authorized nuclear pharmacist.

35.57 Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist.

35.59 Recentness of training.

Subpart C-- General Technical Requirements

35.60 Possession, use, and calibration of instruments used to measure the activity of unsealed byproduct material.

35.61 Calibration of survey instruments.

35.63 Determination of dosages of unsealed byproduct material for medical use.

35.65 Authorization for calibration, transmission, and reference sources.

35.67 Requirements for possession of sealed sources and brachytherapy sources.

35.69 Labeling of vials and syringes.

35.70 Surveys of ambient radiation exposure rate.

35.75 Release of individuals containing unsealed byproduct material or implants containing byproduct material.

35.80 Provision of mobile medical service.

35.92 Decay-in-storage.

Subpart D-- Unsealed Byproduct Material - Written Directive Not Required

35.100 Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.

35.190 Training for uptake, dilution, and excretion studies.

35.200 Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.

35.204 Permissible molybdenum-99 concentration.

35.290 Training for imaging and localization studies.

Subpart E-- Unsealed Byproduct Material -Written Directive Required

35.300 Use of unsealed byproduct material for which a written directive is required.

35.310 Safety instruction.

35.315 Safety precautions.

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

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

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).

Subpart F-- Manual Brachytherapy

35.400 Use of sources for manual brachytherapy.

35.404 Surveys after source implant and removal.

35.406 Brachytherapy sources accountability.

35.410 Safety instruction.

35.415 Safety precautions.

35.432 Calibration measurements of brachytherapy sources.

35.433 Decay of strontium-90 sources for ophthalmic treatments.

35.457 Therapy-related computer systems.

35.490 Training for use of manual brachytherapy sources.

35.491 Training for ophthalmic use of strontium-90.

Subpart G-- Sealed Sources for Diagnosis

35.500 Use of sealed sources for diagnosis.

35.590 Training for use of sealed sources for diagnosis.

Subpart H-- Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

35.600 Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.

35.604 Surveys of patients and human research subjects treated with a remote afterloader unit.

35.605 Installation, maintenance, adjustment, and repair.

35.610 Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

35.615 Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

35.630 Dosimetry equipment.

35.632 Full calibration measurements on teletherapy units.

35.633 Full calibration measurements on remote afterloader units.

35.635 Full calibration measurements on gamma stereotactic radiosurgery units.

35.642 Periodic spot-checks for teletherapy units.

35.643 Periodic spot-checks for remote afterloader units.

35.645 Periodic spot-checks for gamma stereotactic radiosurgery units.

35.647 Additional technical requirements for mobile remote afterloader units.

35.652 Radiation surveys.

35.655 Five-year inspection for teletherapy and gamma stereotactic radiosurgery units.

35.657 Therapy-related computer systems.

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

Subpart I-- Reserved

Subpart J-- Reserved

Subpart K-- Other Medical Uses of Byproduct Material or Radiation from Byproduct Material

35.1000 Other medical uses of byproduct material or radiation from byproduct material.

Subpart L-- Records

35.2024 Records of authority and responsibilities for radiation protection programs.

35.2026 Records of radiation protection program changes.

35.2040 Records of written directives.

35.2041 Records for procedures for administrations requiring a written directive.

35.2060 Records of calibrations of instruments used to measure the activity of unsealed byproduct materials.

35.2061 Records of radiation survey instrument calibrations.

35.2063 Records of dosages of unsealed byproduct material for medical use.

35.2067 Records of leaks tests and inventory of sealed sources and brachytherapy sources.

35.2070 Records of surveys for ambient radiation exposure rate.

35.2075 Records of the release of individuals containing unsealed byproduct material or implants containing byproduct material.

35.2080 Records of mobile medical services.

35.2092 Records of decay-in-storage.

35.2204 Records of molybdenum-99 concentrations.

35.2310 Records of safety instruction.

35.2404 Records of surveys after source implant and removal.

35.2406 Records of brachytherapy source accountability.

35.2432 Records of calibration measurements of brachytherapy sources.

35.2433 Records of decay of strontium-90 sources for ophthalmic treatments.

35.2605 Records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

35.2610 Records of safety procedures.

35.2630 Records of dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

35.2632 Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations.

35.2642 Records of periodic spot-checks for teletherapy units.

35.2643 Records of periodic spot-checks for remote afterloader units.

35.2645 Records of periodic spot-checks for gamma stereotactic radiosurgery units.

35.2647 Records of additional technical requirements for mobile remote afterloader units.

35.2652 Records of surveys of therapeutic treatment units.

35.2655 Records of 5-year inspection for teletherapy and gamma stereotactic radiosurgery units.

Subpart M-- Reports

35.3045 Report and notification of a medical event.

35.3047 Report and notification of a dose to an embryo/fetus or a nursing child.

35.3067 Report of a leaking source.

Subpart N-- Enforcement

35.4001 Violations.

35.4002 Criminal penalties.

AUTHORITY: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

Subpart A--General Information

§ 35.1 Purpose and scope.

This part contains the requirements and provisions for the medical use of byproduct material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects. The requirements and provisions of this part are in addition to, and not in substitution for, others in this chapter. The requirements and provisions of parts 19, 20, 21, 30, 71, 170, and 171 of this chapter apply to applicants and licensees subject to this part unless specifically exempted.

§ 35.2 Definitions.

Address of use means the building or buildings that are identified on the license and where byproduct material may be received, prepared, used, or stored.

Agreement State means any State with which the Commission or the Atomic Energy Commission has entered into an effective agreement under subsection 274b of the Atomic Energy Act of 1954, as amended.

Area of use means a portion of an address of use that has been set aside for the purpose of receiving, preparing, using, or storing byproduct material.

Authorized medical physicist means an individual who --

(1) Meets the requirements in §§ 35.51(a) and 35.59; or

(2) Is identified as an authorized medical physicist or teletherapy physicist on --

(i) A specific medical use license issued by the Commission or Agreement State;

(ii) A medical use permit issued by a Commission master material licensee;

(iii) A permit issued by a Commission or Agreement State broad scope medical use licensee; or

(iv) A permit issued by a Commission master material license broad scope medical use permittee.

Authorized nuclear pharmacist means a pharmacist who --

(1) Meets the requirements in §§ 35.55(a) and 35.59; or

(2) Is identified as an authorized nuclear pharmacist on --

(i) A specific license issued by the Commission or Agreement State that authorizes medical use or the practice of nuclear pharmacy;

(ii) A permit issued by a Commission master material licensee that authorizes medical use or the practice of nuclear pharmacy;

(iii) A permit issued by a Commission or Agreement State broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or

(iv) 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

(3) Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

(4) Is designated as an authorized nuclear pharmacist in accordance with § 32.72(b)(4).

Authorized user means a physician, dentist, or podiatrist who --

(1) Meets the requirements in §§ 35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), or 35.690(a); or

(2) Is identified as an authorized user on --

(i) A Commission or Agreement State license that authorizes the medical use of byproduct material;

(ii) A permit issued by a Commission master material licensee that is authorized to permit the medical use of byproduct material;

(iii) A permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of byproduct material; or

(iv) A permit issued by a Commission master material license broad scope permittee that is authorized to permit the medical use of byproduct material.

Brachytherapy means a method of radiation therapy in which sources are used to deliver a radiation dose at a distance of up to a few centimeters by surface, intracavitary, intraluminal, or interstitial application.

Brachytherapy source means a radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

Client's address means the area of use or a temporary job site for the purpose of providing mobile medical service in accordance with § 35.80.

Dedicated check source means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years.

Dentist means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice dentistry.

High dose-rate remote afterloader, as used in this part, 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.

Low dose-rate remote afterloader, as used in this part, 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.

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.

Manual brachytherapy, as used in this part, means 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 event means an event that meets the criteria in § 35.3045(a).

Medical institution means an organization in which more than one medical discipline is practiced.

Medical use means 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 authorized user.

Medium dose-rate remote afterloader, as used in this part, means a brachytherapy device that remotely delivers a dose rate of greater than 2 gray (200 rads), but less than 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

Mobile medical service means the transportation of byproduct material to and its medical use at the client's address.

Output means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a brachytherapy source or a teletherapy, remote afterloader, or gamma stereotactic radiosurgery unit for a specified set of exposure conditions.

Patient intervention means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

Pharmacist means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.

Physician means a medical doctor or doctor of osteopathy licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine.

Podiatrist means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice podiatry.

Preceptor means an individual who provides or directs the training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a Radiation Safety Officer.

Prescribed dosage means the specified activity or range of activity of unsealed byproduct material as documented --

(1) In a written directive; or

(2) In accordance with the directions of the authorized user for procedures performed pursuant to §§ 35.100 and 35.200.

Prescribed dose means --

(1) For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

(2) For teletherapy, the total dose and dose per fraction as documented in the written directive;

(3) For manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or

(4) For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

Pulsed dose-rate remote afterloader, as used in this part, means a special type of remote afterloading brachytherapy device that uses a single source capable of delivering dose rates in the “high dose-rate” range, but --

(1) Is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and

(2) Is used to simulate the radiobiology of a low dose-rate treatment by inserting the source for a given fraction of each hour.

Radiation Safety Officer means an individual who --

(1) Meets the requirements in §§ 35.50(a) and 35.59; or

(2) Is identified as a Radiation Safety Officer on --

(i) A specific medical use license issued by the Commission or Agreement State; or

(ii) A medical use permit issued by a Commission master material licensee.

Sealed source means any byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material.

Sealed Source and Device Registry means the national registry that contains all the registration certificates, generated by both NRC and the Agreement States, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

Stereotactic radiosurgery means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a therapeutic dose to a tissue volume.

Structured educational program means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

Teletherapy, as used in this part, means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.

Temporary job site means a location where mobile medical services are conducted other than those location(s) of use authorized on the license.

Therapeutic dosage means a dosage of unsealed byproduct material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

Therapeutic dose means a radiation dose delivered from a source containing byproduct material to a patient or human research subject for palliative or curative treatment.

Treatment site means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

Type of use means use of byproduct material under §§ 35.100, 35.200, 35.300, 35.400, 35.500, 35.600, or 35.1000.

Unit dosage means a dosage 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.

Written directive means an authorized user's written order for the administration of byproduct material or radiation from byproduct material to a specific patient or human research subject, as specified in § 35.40.

§ 35.5 Maintenance of records.

Each record required by this part must be legible throughout the specified retention period. The record may be the original, a reproduced copy, or a microform if the copy or microform is authenticated by authorized personnel and the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

§ 35.6 Provisions for the protection of human research subjects.

(a) A licensee may conduct research involving human research subjects only if it uses the byproduct materials specified on its license for the uses authorized on its license.

(b) If the research is conducted, funded, supported, or regulated by another Federal agency that has implemented the Federal Policy for the Protection of Human Subjects (Federal Policy), the licensee shall, before conducting research --

(1) Obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy; and

(2) Obtain "informed consent," as defined and described in the Federal Policy, from the human research subject.

(c) If the research will not be conducted, funded, supported, or regulated by another Federal agency that has implemented the Federal Policy, the license shall, before conducting research, apply for and receive a specific amendment to its NRC medical use license. The amendment request must include a written commitment that the licensee will, before conducting research --

(1) Obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy; and

(2) Obtain "informed consent", as defined and described in the Federal Policy, from the human research subject.

(d) Nothing in this section relieves licensees from complying with the other requirements in this part.

§ 35.7 FDA, other Federal, and State requirements.

Nothing in this part relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs or devices.

§ 35.8 Information collection requirements: OMB approval.

(a) The Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements in this part under control number 3150-0010.

(b) The approved information collection requirements contained in this part appear in §§ 35.6, 35.12, 35.13, 35.14, 35.19, 35.24, 35.26, 35.27, 35.40, 35.41, 35.50, 35.51, 35.55, 35.60, 35.61, 35.63, 35.67, 35.69, 35.70, 35.75, 35.80, 35.92, 35.190, 35.204, 35.290, 35.310, 35.315, 35.390, 35.392, 35.394, 35.404, 35.406, 35.410, 35.415, 35.432, 35.433, 35.490, 35.491, 35.590, 35.604, 35.605, 35.610, 35.615, 35.630, 35.632, 35.633, 35.635, 35.642, 35.643, 35.645, 35.647, 35.652, 35.655, 35.690, 35.1000, 35.2024, 35.2026, 35.2040, 35.2041, 35.2060, 35.2061, 35.2063, 35.2067, 35.2070, 35.2075, 35.2080, 35.2092, 35.2204, 35.2310, 35.2404, 35.2406, 35.2432, 35.2433, 35.2605, 35.2610, 35.2630, 35.2632, 35.2642, 35.2643, 35.2645, 35.2647, 35.2652, 35.2655, 35.3045, 35.3047, and 35.3067.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In § 35.12, NRC Form 313, including NRC Forms 313A and 313B, which licensees may use to provide supplemental information, is approved under control number 3150-0120.

(2) [Reserved]

§ 35.10 Implementation.

(a) A licensee shall implement the provisions in this part on or before [insert date 6 months from publication of the Final Rule].

(b) If a license condition exempted a licensee from a provision of Part 35 on [insert date 6 months from publication of the Final Rule], then the license condition continues to exempt the licensee from the requirements in the corresponding provision of §§ 35.1-35.4002.

(c) When a requirement in this part differs from the requirement in an existing license condition, the requirement in this part shall govern.

(d) A licensee shall continue to comply with any license condition that requires it to implement procedures required by §§ 35.610, 35.642, 35.643, and 35.645 until there is a license amendment or renewal that modifies the license condition.

§ 35.11 License required.

(a) A person may manufacture, produce, acquire, receive, possess, prepare, use, or transfer byproduct material for medical use only in accordance with a specific license issued by the Commission or an Agreement State, or as allowed in paragraphs (b)(1) or (b)(2) of this section.

(b) A specific license is not needed for an individual who--

(1) Receives, possesses, uses, or transfers byproduct material in accordance with the regulations in this chapter under the supervision of an authorized user as provided in § 35.27, unless prohibited by license condition; or

(2) Prepares unsealed byproduct material for medical use in accordance with the regulations in this chapter under the supervision of an authorized nuclear pharmacist or authorized user as provided in § 35.27, unless prohibited by license condition.

§ 35.12 Application for license, amendment, or renewal.

(a) An application must be signed by the applicant's or licensee's management.

(b) An application for a license for medical use of byproduct material as described in §§ 35.100, 35.200, 35.300, 35.400, 35.500, 35.600, and 35.1000 must be made by --

(1) Filing an original and one copy of NRC Form 313, "Application for Material License," that includes the facility diagram, equipment, and training and experience qualifications of the Radiation Safety Officer, authorized user(s), authorized medical physicist(s), and authorized nuclear pharmacist(s); and

(2) Submitting procedures required by §§ 35.610, 35.642, 35.643, and 35.645, as applicable.

(c) A request for a license amendment or renewal must be made by --

(1) Submitting an original and one copy of either --

(i) NRC Form 313, "Application for Material License"; or

(ii) A letter requesting the amendment or renewal; and

(2) Submitting procedures required by §§ 35.610, 35.642, 35.643, and 35.645, as applicable.

(d) In addition to the requirements in paragraphs (b) and (c) of this section, an application for a license or amendment for medical use of byproduct material as described in

§ 35.1000 must also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in Subparts A through C of this part.

(1) The applicant shall also provide specific information on --

(i) Radiation safety precautions and instructions;

(ii) Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

(iii) Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.

(2) The applicant or licensee shall also provide any other information requested by the Commission in its review of the application.

(e) An applicant that satisfies the requirements specified in § 33.13 of this chapter may apply for a Type A specific license of broad scope.

§ 35.13 License amendments.

A licensee shall apply for and must receive a license amendment --

(a) Before it receives, prepares, or uses byproduct material for a type of use that is permitted under this part, but that is not authorized on the licensee's current license issued under this part;

(b) Before it permits anyone to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license, except --

(1) For an authorized user, an individual who meets the requirements in §§ 35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), or 35.690(a);

(2) For an authorized nuclear pharmacist, an individual who meets the requirements in §§ 35.55(a) and 35.59;

(3) For an authorized medical physicist, an individual who meets the requirements in §§ 35.51(a)and 35.59;

(4) An individual who is identified as an authorized user, an authorized nuclear pharmacist, or authorized medical physicist --

(i) On a Commission or Agreement State license or other equivalent permit or license recognized by NRC that authorizes the use of byproduct material in medical use or in the practice of nuclear pharmacy;

(ii) On a permit issued by a Commission or Agreement State specific license of broad scope that is authorized to permit the use of byproduct material in medical use or in the practice of nuclear pharmacy;

(iii) 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

(iv) By a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists.

(c) Before it changes Radiation Safety Officers, except as provided in § 35.24(c);

(d) Before it receives byproduct material in excess of the amount or in a different form, or receives a different radionuclide than is authorized on the license;

(e) Before it adds to or changes the areas of use identified in the application or on the license, except for areas of use where byproduct material is used only in accordance with either § 35.100 or § 35.200;

(f) Before it changes the address(es) of use identified in the application or on the license; and

(g) Before it revises procedures required by §§ 35.610, 35.642, 35.643, and 35.645, as applicable, where such revision reduces radiation safety.

§ 35.14 Notifications.

(a) A licensee shall provide the Commission a copy of the board certification, the Commission or Agreement State license, the permit issued by a Commission master material licensee, the permit issued by a Commission or Agreement State licensee of broad scope, or the permit issued by a Commission master material license broad scope permittee for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist, under § 35.13 (b)(1) through (b)(4).

(b) A licensee shall notify the Commission by letter no later than 30 days after:

(1) An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer, or an authorized medical physicist permanently discontinues performance of duties under the license or has a name change;

(2) The licensee's mailing address changes;

(3) The licensee’s name changes, but the name change does not constitute a transfer of control of the license as described in § 30.34(b) of this chapter; or

(4) The licensee has added to or changed the areas of use identified in the application or on the license where byproduct material is used in accordance with either § 35.100 or § 35.200.

(c) The licensee shall mail the documents required in this section to the appropriate address identified in § 30.6 of this chapter.

§ 35.15 Exemptions regarding Type A specific licenses of broad scope.

A licensee possessing a Type A specific license of broad scope for medical use, issued under Part 33, is exempt from --

(a) The provisions of § 35.12(d) regarding the need to file an amendment to the license for medical use of byproduct material, as described in § 35.1000;

(b) The provisions of § 35.13(b);

(c) The provisions of § 35.13(e) regarding additions to or changes in the areas of use at the addresses identified in the application or on the license;

(d) The provisions of § 35.14(a);

(e) The provisions of § 35.14(b)(1) for an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist;

(f) The provisions of § 35.14(b)(4) regarding 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 either § 35.100 or § 35.200.

(g) The provisions of § 35.49(a).

§ 35.18 License issuance.

(a) The Commission shall issue a license for the medical use of byproduct material if --

(1) The applicant has filed NRC Form 313 "Application for Material License" in accordance with the instructions in § 35.12;

(2) The applicant has paid any applicable fee as provided in Part 170 of this chapter;

(3) The Commission finds the applicant equipped and committed to observe the safety standards established by the Commission in this Chapter for the protection of the public health and safety; and

(4) The applicant meets the requirements of Part 30 of this chapter.

(b) The Commission shall issue a license for mobile medical service if the applicant:

(1) Meets the requirements in paragraph (a) of this section; and

(2) Assures that individuals or human research subjects to whom unsealed byproduct material or radiation from implants containing byproduct material will be administered may be released following treatment in accordance with § 35.75.

§ 35.19 Specific exemptions.

The Commission may, upon application of any interested person or upon its own initiative, grant exemptions from the regulations in this part that it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

Subpart B--General Administrative Requirements

§ 35.24 Authority and responsibilities for the radiation protection program.

(a) In addition to the radiation protection program requirements of § 20.1101 of this chapter, a licensee's management shall approve in writing --

(1) Requests for a license application, renewal, or amendment before submittal to the Commission;

(2) Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist; and

(3) Radiation protection program changes that do not require a license amendment and are permitted under § 35.26;

(b) A licensee's management shall appoint a Radiation Safety Officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.

(c) For up to 60 days each year, a licensee may permit an authorized user or an individual qualified to be a Radiation Safety Officer, under §§ 35.50 and 35.59, to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in paragraph (g) of this section, if the licensee takes the actions required in paragraphs (b), (e), (g), and (h) of this section and notifies the Commission in accordance with § 35.14(b).

(d) A licensee may simultaneously appoint more than one temporary Radiation Safety Officer in accordance with paragraph (c) of this section, if needed to ensure that the licensee has a temporary Radiation Safety Officer that satisfies the requirements to be a Radiation Safety Officer for each of the different types of uses of byproduct material permitted by the license.

(e) A licensee shall establish the authority, duties, and responsibilities of the Radiation Safety Officer in writing.

(f) 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 units under Subpart H shall establish a Radiation Safety Committee to oversee all uses of byproduct material permitted by

the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. The Committee may include other members the licensee considers appropriate.

(g) A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative, to --

(1) Identify radiation safety problems;

(2) Initiate, recommend, or provide corrective actions;

(3) Stop unsafe operations; and,

(4) Verify implementation of corrective actions.

(h) A licensee shall retain a record of actions taken under paragraphs (a), (b), and (e) of this section in accordance with § 35.2024.

§ 35.26 Radiation protection program changes.

(a) A licensee may revise its radiation protection program without Commission approval if --

(1) The revision does not require a license amendment under § 35.13;

(2) The revision is in compliance with the regulations and the license ;

(3) The revision has been reviewed and approved by the Radiation Safety Officer and licensee management; and

(4) The affected individuals are instructed on the revised program before the changes are implemented.

(b) A licensee shall retain a record of each change in accordance with § 35.2026.

§ 35.27 Supervision.

(a) A licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user, as allowed by § 35.11(b)(1), shall --

(1) In addition to the requirements in § 19.12, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of this chapter, and license conditions with respect to the use of byproduct material; and

(2) Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of byproduct material, written radiation protection procedures established by the licensee, written directive procedures, regulations of this chapter, and license conditions with respect to the medical use of byproduct material.

(b) A licensee that permits the preparation of byproduct material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by § 35.11(b)(2), shall --

(1) In addition to the requirements in § 19.12, instruct the supervised individual in the preparation of byproduct material for medical use, as appropriate to that individual's involvement with byproduct material; and

(2) Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of byproduct material for medical use, written radiation protection procedures established by the licensee, the regulations of this chapter, and license conditions.

(c) A licensee that permits supervised activities under paragraphs (a) and (b) of this section is responsible for the acts and omissions of the supervised individual.

§ 35.40 Written directives.

(a) A written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 Megabequerels (MBq) (30 microcuries (µCi)), any therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material.

(1) If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within 48 hours of the oral directive.

(b) The written directive must contain the patient or human research subject's name and the following information--

(1) For any administration of quantities greater than 1.11 MBq (30 µCi) of sodium iodide I-131: the dosage;

(2) For an administration of a therapeutic dosage of unsealed byproduct material other than sodium iodide I-131: the radioactive drug, dosage, and route of administration;

(3) For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;

(4) For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site;

(5) For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or

(6) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:

(i) Before implantation: treatment site, the radionuclide, and dose; and

(ii) After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).

(c) A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed byproduct material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

(1) If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.

(d) The licensee shall retain a copy of the written directive in accordance with § 35.2040.

§ 35.41 Procedures for administrations requiring a written directive.

(a) For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:

(1) The patient’s or human research subject’s identity is verified before each administration; and

(2) Each administration is in accordance with the written directive.

(b) At a minimum, the procedures required by paragraph (a) of this section must address the following items that are applicable to the licensee's use of byproduct material--

(1) Verifying the identity of the patient or human research subject;

(2) Verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;

(3) Checking both manual and computer-generated dose calculations; and

(4) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by § 35.600.

(c) A licensee shall retain a copy of the procedures required under paragraph (a) in accordance with § 35.2041.

§ 35.49 Suppliers for sealed sources or devices for medical use.

For medical use, a licensee may only use --

(a) Sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued under 10 CFR Part 30 and 10 CFR 32.74 of this chapter or equivalent requirements of an Agreement State;

(b) Sealed sources or devices noncommercially transferred from a Part 35 licensee; or

(c) Teletherapy sources manufactured and distributed in accordance with a license issued under 10 CFR Part 30 or the equivalent requirements of an Agreement State.

§ 35.50 Training for Radiation Safety Officer.

Except as provided in § 35.57, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in § 35.24 to be an individual who --

(a) Is certified by a specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b)(1) Has completed a structured educational program consisting of both:

(i) 200 hours of didactic training in the following areas--

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Radiation biology; and

(E) Radiation dosimetry; and

(ii) One year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on a Commission or Agreement State license that authorizes similar type(s) of use(s) of byproduct material involving the following--

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

(C) Securing and controlling byproduct material;

(D) Using administrative controls to avoid mistakes in the administration of byproduct material;

(E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

(F) Using emergency procedures to control byproduct material; and

(G) Disposing of byproduct material; and

(2) Has obtained written certification, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; or

(c) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has Radiation Safety Officer responsibilities.

§ 35.51 Training for an authorized medical physicist.

The licensee shall require the authorized medical physicist to be an individual who --

(a) Is certified by a specialty board whose certification process includes all of the training and experience requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b)(1) Holds a master's or doctor's degree in physics, biophysics, radiological physics, medical physics, or health physics and has completed 1 year of full-time training in therapeutic radiological physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist at a medical institution that includes the tasks listed in §§ 35.67, 35.433, 35.632, 35.633, 35.635, 35.642, 35.643, 35.645, and 35.652, as applicable; and

(2) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and has achieved a level of competency

sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written certification must be signed by a preceptor authorized medical physicist who meets the requirements in § 35.51 or equivalent Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.

§ 35.55 Training for an authorized nuclear pharmacist.

The licensee shall require the authorized nuclear pharmacist to be a pharmacist who --

(a) Is certified as a nuclear pharmacist by a specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b)(1) Has completed 700 hours in a structured educational program consisting of both:

(i) Didactic training in the following areas --

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Supervised practical experience in a nuclear pharmacy involving --

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

(C) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

(D) Using administrative controls to avoid medical events in the administration of byproduct material; and

(E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

(2) Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

§ 35.57 Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist.

(a) An individual identified as a Radiation Safety Officer, a teletherapy or medical physicist, or a nuclear pharmacist on a Commission or Agreement State license or master material license permit or by a master material license permittee of broad scope before [insert date 6 months from publication of the Final Rule] need not comply with the training requirements of §§ 35.50, 35.51, or 35.55, respectively.

(b) Physicians, dentists, or podiatrists identified as authorized users for the medical use of byproduct material 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 [insert date 6 months from publication of the Final Rule] who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of Subparts D-H.

§ 35.59 Recentness of training.

The training and experience specified in Subparts B, D, E, F, G, and H must have been obtained within the 7 years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

Subpart C--General Technical Requirements

§ 35.60 Possession, use, and calibration of instruments used to measure the activity of unsealed byproduct material.

(a) For direct measurements performed in accordance with § 35.63, a licensee shall possess and use instrumentation to measure the activity of unsealed byproduct material before it is administered to each patient or human research subject.

(b) A licensee shall calibrate the instrumentation required in paragraph (a) of this section in accordance with nationally recognized standards or the manufacturer's instructions.

(c) A licensee shall retain a record of each instrument calibration required by this section in accordance with § 35.2060.

§ 35.61 Calibration of survey instruments.

(a) A licensee shall calibrate the survey instruments used to show compliance with this part and 10 CFR Part 20 before first use, annually, and following a repair that affects the calibration. A licensee shall --

(1) Calibrate all scales with readings up to 10 mSv (1000 mrem) per hour with a radiation source;

(2) Calibrate two separated readings on each scale or decade that will be used to show compliance; and

(3) Conspicuously note on the instrument the date of calibration.

(b) A licensee may not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than 20 percent.

(c) A licensee shall retain a record of each survey instrument calibration in accordance with § 35.2061.

§ 35.63 Determination of dosages of unsealed byproduct material for medical use.

(a) A licensee shall determine and record the activity of each dosage before medical use.

(b) For a unit dosage, this determination must be made by--

(1) Direct measurement of radioactivity; or

(2) A decay correction, based on the activity or activity concentration determined by --

(i) A manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or

(ii) An NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA.

(c) For other than unit dosages, this determination must be made by--

(1) Direct measurement of radioactivity;

(2) Combination of measurement of radioactivity and mathematical calculations; or

(3) Combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements.

(d) Unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent.

(e) A licensee shall retain a record of the dosage determination required by this section in accordance with § 35.2063.

§ 35.65 Authorization for calibration, transmission, and reference sources.

Any person authorized by § 35.11 for medical use of byproduct material may receive, possess, and use any of the following byproduct material for check, calibration, transmission, and reference use.

(a) 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.

(b) 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.

(c) Any byproduct material with a half-life not longer than 120 days in individual amounts not to exceed 0.56 GBq (15 mCi).

(d) Any byproduct material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 7.4 MBq (200 μCi) or 1000 times the quantities in Appendix B of Part 30 of this chapter.

(e) Technetium-99m in amounts as needed.

§ 35.67 Requirements for possession of sealed sources and brachytherapy sources.

(a) A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer.

(b) A licensee in possession of a sealed source shall --

(1) Test the source for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within 6 months before transfer to the licensee; and

(2) Test the source for leakage at intervals not to exceed 6 months or at other intervals approved by the Commission or an Agreement State in the Sealed Source and Device Registry.

(c) To satisfy the leak test requirements of this section, the licensee shall measure the sample so that the leak test can detect the presence of 185 Bq (0.005 μCi) of radioactive material in the sample.

(d) A licensee shall retain leak test records in accordance with § 35.2067(a).

(e) If the leak test reveals the presence of 185 Bq (0.005 μCi) or more of removable contamination, the licensee shall --

(1) Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements in parts 20 and 30 of this chapter; and

(2) File a report within 5 days of the leak test in accordance with § 35.3067.

(f) A licensee need not perform a leak test on the following sources:

(1) Sources containing only byproduct material with a half-life of less than 30 days;

(2) Sources containing only byproduct material as a gas;

(3) 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;

(4) Seeds of iridium-192 encased in nylon ribbon; and

(5) Sources stored and not being used. However, the licensee shall test each such source for leakage before any use or transfer unless it has been leak tested within 6 months before the date of use or transfer.

(g) A licensee in possession of sealed sources or brachytherapy sources, except for gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such sources in its possession. The licensee shall retain each inventory record in accordance with § 35.2067(b).

§ 35.69 Labeling of vials and syringes.

Each syringe and vial that contains unsealed byproduct material must be labeled to identify the radioactive drug. Each syringe shield and vial shield must also be labeled unless the label on the syringe or vial is visible when shielded.

§ 35.70 Surveys of ambient radiation exposure rate.

(a) In addition to the surveys required by Part 20 of this chapter, a licensee shall survey with a radiation detection survey instrument at the end of each day of use. A licensee shall survey all areas where unsealed byproduct material requiring a written directive was prepared for use or administered.

(b) A licensee does not need to perform the surveys required by paragraph (a) of this section in an area(s) where patients or human research subjects are confined when they cannot be released under § 35.75.

(c) A licensee shall retain a record of each survey in accordance with § 35.2070.

§ 35.75 Release of individuals containing unsealed byproduct material or implants containing byproduct material.

(a) A licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material 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).[2]

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[2] NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Licenses," describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem).

(b) A licensee shall provide the released individual, or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem). If the total effective dose equivalent to a nursing infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption of breast-feeding, the instructions must also include --

(1) Guidance on the interruption or discontinuation of breast-feeding; and

(2) Information on the potential consequences, if any, of failure to follow the guidance.

(c) A licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with § 35.2075(a).

(d) The licensee shall maintain a record of instructions provided to a breast-feeding female in accordance with § 35.2075(b).

§ 35.80 Provision of mobile medical service.

(a) A licensee providing mobile medical service shall --

(1) Obtain a letter signed by the management of each client for which services are rendered that permits the use of byproduct material at the client's address and clearly delineates the authority and responsibility of the licensee and the client;

(2) Check instruments used to measure the activity of unsealed byproduct material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function required by this paragraph must include a constancy check;

(3) Check survey instruments for proper operation with a dedicated check source before use at each client's address; and

(4) Before leaving a client's address, survey all areas of use to ensure compliance with the requirements in Part 20 of this chapter.

(b) A mobile medical service may not have byproduct material delivered from the manufacturer or the distributor to the client unless the client has a license allowing possession of the byproduct material. Byproduct material delivered to the client must be received and handled in conformance with the client's license.

(c) A licensee providing mobile medical services shall retain the letter required in paragraph (a)(1) and the record of each survey required in paragraph (a)(4) of this section in accordance with § 35.2080(a) and (b), respectively.

§ 35.92 Decay-in-storage.

(a) A licensee may hold byproduct material with a physical half-life of less than 120 days for decay-in-storage before disposal without regard to its radioactivity if it --

(1) Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and

(2) Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee.

(b) A licensee shall retain a record of each disposal permitted under paragraph (a) of this section in accordance with § 35.2092.

Subpart D--Unsealed Byproduct Material - Written Directive Not Required

§ 35.100 Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.

Except for quantities that require a written directive under § 35.40(b), a licensee may use any unsealed byproduct material prepared for medical use for uptake, dilution, or excretion studies that is --

(a) Obtained from a manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or

(b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in §§ 35.290 or 35.390, or an individual under the supervision of either as specified in § 35.27; or

(c) Obtained from and prepared by an NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(d) Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

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

Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.100 to be a physician who --

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (c) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b) Is an authorized user under §§ 35.290 or 35.390 or equivalent Agreement State requirements; or

(c)(1) Has completed 60 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies; the training and experience must include --

(i) Classroom and laboratory training in the following areas --

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in § 35.190, § 35.290, or § 35.390 or equivalent Agreement State requirements, involving --

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(F) Administering dosages of radioactive drugs to patients or human research subjects; and

(2) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in §§ 35.190, 35.290, or 35.390 or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.100.

§ 35.200 Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.

Except for quantities that require a written directive under § 35.40(b), a licensee may use any unsealed byproduct material prepared for medical use for imaging and localization studies that is --

(a) Obtained from a manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or

(b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in §§ 35.290 or 35.390, or an individual under the supervision of either as specified in § 35.27;

(c) Obtained from and prepared by an NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(d) Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

§ 35.204 Permissible molybdenum-99 concentration.

(a) A licensee may not administer to humans a radiopharmaceutical that contains more than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m).

(b) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration of the first eluate after receipt of a generator to demonstrate compliance with paragraph (a) of this section.

(c) If a licensee is required to measure the molybdenum-99 concentration, the licensee shall retain a record of each measurement in accordance with § 35.2204.

§ 35.290 Training for imaging and localization studies.

Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.200 to be a physician who --

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (c) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b) Is an authorized user under § 35.390 or equivalent Agreement State requirements; or

(c)(1) Has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies; the training and experience must include, at a minimum, --

(i) Classroom and laboratory training in the following areas --

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use;

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user, who meets the requirements in §§ 35.290 or 35.390 or equivalent Agreement State requirements, involving --

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

(F) Administering dosages of radioactive drugs to patients or human research subjects; and

(G) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(2) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in §§ 35.290 or 35.390 or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under §§ 35.100 and 35.200.

Subpart E--Unsealed Byproduct Material - Written Directive Required

§ 35.300 Use of unsealed byproduct material for which a written directive is required.

A licensee may use any unsealed byproduct material prepared for medical use and for which a written directive is required that is --

(a) Obtained from a manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or

(b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in §§ 35.290 or 35.390, or an individual under the supervision of either as specified in § 35.27; or

(c) Obtained from and prepared by an NRC or Agreement State licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA; or

(d) Prepared by the licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA.

§ 35.310 Safety instruction.

In addition to the requirements of § 19.12 of this chapter,

(a) A licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who cannot be released under § 35.75. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include --

(1) Patient or human research subject control;

(2) Visitor control, including --

(i) Routine visitation to hospitalized individuals in accordance with § 20.1301(a)(1) of this chapter; and

(ii) Visitation authorized in accordance with § 20.1301(c) of this chapter;

(3) Contamination control;

(4) Waste control; and

(5) Notification of the Radiation Safety Officer, or his or her designee, and the authorized user if the patient or the human research subject has a medical emergency or dies.

(b) A licensee shall retain a record of individuals receiving instruction in accordance with § 35.2310.

§ 35.315 Safety precautions.

(a) For each patient or human research subject who cannot be released under § 35.75, a licensee shall --

(1) Quarter the patient or the human research subject either in --

(i) A private room with a private sanitary facility; or

(ii) A room, with a private sanitary facility, with another individual who also has received therapy with unsealed byproduct material and who also cannot be released under § 35.75;

(2) Visibly post the patient's or the human research subject's room with a "Radioactive Materials" sign.

(3) Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room; and

(4) Either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle the material and items as radioactive waste.

(b) A licensee shall notify the Radiation Safety Officer, or his or her designee, and the authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

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

Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.300 to be a physician who --

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b)(1) Has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive; the training and experience must include --

(i) Classroom and laboratory training in the following areas --

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in § 35.390(a), § 35.390(b), or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b), must have experience in administering dosages in the same dosage category or categories (i.e., § 35.390(b)(1)(ii)(G)(1), (2), (3), or (4)) as the individual requesting authorized user status. The work experience must involve --

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Calibrating instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures;

(F) Eluting generator systems, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(G) Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user 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];

(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; and

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[3]Experience with at least 3 cases in Category (G)(2) also satisfies the requirement in Category (G)(1).

(2) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.300. The written certification must be signed by a preceptor authorized user who meets the requirements in § 35.390(a), § 35.390(b), or equivalent Agreement State requirements. The preceptor authorized user, who meets the requirements in § 35.390(b), must have experience in administering dosages in the same dosage category or categories (i.e., § 35.390(b)(1)(ii)(G)(1), (2), (3), or (4)) as the individual requesting authorized user status.

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

Except as provided in § 35.57, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries), to be a physician who--

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (c) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b) Is an authorized user under § 35.390(a), § 35.390(b), for uses listed in § 35.390(b)(1)(ii)(G)(1) or (2), § 35.394, or equivalent Agreement State requirements; or

(c)(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive; the training must include --

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of byproduct material for medical use; and

(v) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in § 35.390(a), § 35.390(b), § 35.392, § 35.394, or equivalent Agreement State requirements. A supervising authorized user who meets the requirements in § 35.390(b), must have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(1) or (2). The work experience must involve --

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a medical event involving the use of byproduct material;

(v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131; and

(3) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section and has achieved a level of

competency sufficient to function independently as an authorized user for medical uses authorized under § 35.300. The written certification must be signed by a preceptor authorized user who meets the requirements in § 35.390(a), § 35.390(b), or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirement in § 35.390(b), must have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(1) or (2).

§ 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).

Except as provided in § 35.57, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries), to be a physician who--

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (c) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b) Is an authorized user under § 35.390(a), § 35.390(b), for uses listed in § 35.390(b)(1)(ii)(G)(2), or equivalent Agreement State requirements; or

(c)(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive; the training must include --

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of byproduct material for medical use; and

(v) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in § 35.390(a), § 35.390(b), § 35.394, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b), must have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(2). The work experience must involve --

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a medical event involving the use of byproduct material;

(v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131; and

(3) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under § 35.300. The written certification must be signed by a preceptor authorized user who meets the requirements in § 35.390(a), § 35.390(b), or equivalent Agreement State

requirements. A preceptor authorized user, who meets the requirements in § 35.390(b), must have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(2).

Subpart F-- Manual Brachytherapy

§ 35.400 Use of sources for manual brachytherapy.

A licensee shall use only brachytherapy sources for therapeutic medical uses:

(a) As approved in the Sealed Source and Device Registry; or

(b) In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of § 35.49(a) are met.

§ 35.404 Surveys after source implant and removal.

(a) Immediately after implanting sources in a patient or a human research subject, the licensee shall make a survey to locate and account for all sources that have not been implanted.

(b) Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed.

(c) A licensee shall retain a record of the surveys required by paragraphs (a) and (b) of this section in accordance with § 35.2404.

§ 35.406 Brachytherapy sources accountability.

(a) A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use.

(b) As soon as possible after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.

(c) A licensee shall maintain a record of the brachytherapy source accountability in accordance with § 35.2406.

§ 35.410 Safety instruction.

In addition to the requirements of § 19.12 of this chapter,

(a) The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who are receiving brachytherapy and cannot be released under § 35.75. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include the --

(1) Size and appearance of the brachytherapy sources;

(2) Safe handling and shielding instructions;

(3) Patient or human research subject control;

(4) Visitor control, including both:

(i) Routine visitation of hospitalized individuals in accordance with § 20.1301(a)(1) of this chapter; and

(ii) Visitation authorized in accordance with § 20.1301(c) of this chapter; and

(5) Notification of the Radiation Safety Officer, or his or her designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.

(b) A licensee shall retain a record of individuals receiving instruction in accordance with § 35.2310.

§ 35.415 Safety precautions.

(a) For each patient or human research subject who is receiving brachytherapy and cannot be released under § 35.75, a licensee shall --

(1) Not quarter the patient or the human research subject in the same room as an individual who is not receiving brachytherapy;

(2) Visibly post the patient's or human research subject's room with a "Radioactive Materials" sign; and

(3) Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room.

(b) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source --

(1) Dislodged from the patient; and

(2) Lodged within the patient following removal of the source applicators.

(c) A licensee shall notify the Radiation Safety Officer, or his or her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

§ 35.432 Calibration measurements of brachytherapy sources.

(a) Before the first medical use of a brachytherapy source on or after [insert date 6 months from publication of the Final Rule], a licensee shall have –

(1) Determined the source output or activity using a dosimetry system that meets the requirements of § 35.630(a);

(2) Determined source positioning accuracy within applicators; and

(3) Used published protocols currently accepted by nationally recognized bodies to meet the requirements of paragraphs (a)(1) and (a)(2) of this section.

(b) A licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with paragraph (a) of this section.

(c) A licensee shall mathematically correct the outputs or activities determined in paragraph (a) of this section for physical decay at intervals consistent with 1 percent physical decay.

(d) A licensee shall retain a record of each calibration in accordance with § 35.2432.

§ 35.433 Decay of strontium-90 sources for ophthalmic treatments.

(a) Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under § 35.432.

(b) A licensee shall retain a record of the activity of each strontium-90 source in accordance with § 35.2433.

§ 35.457 Therapy-related computer systems.

The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(a) The source-specific input parameters required by the dose calculation algorithm;

(b) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(c) The accuracy of isodose plots and graphic displays; and

(d) The accuracy of the software used to determine sealed source positions from radiographic images.

§ 35.490 Training for use of manual brachytherapy sources.

Except as provided in § 35.57, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under § 35.400 to be a physician who --

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b)(1) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes --

(i) 200 hours of classroom and laboratory training in the following areas --

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity; and

(D) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in § 35.490 or equivalent Agreement State requirements at a medical institution, involving --

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Checking survey meters for proper operation;

(C) Preparing, implanting, and removing brachytherapy sources;

(D) Maintaining running inventories of material on hand;

(E) Using administrative controls to prevent a medical event involving the use of byproduct material;

(F) Using emergency procedures to control byproduct material; and

(2) Has obtained 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in § 35.490 or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and

(3) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in § 35.490 or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (b)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under § 35.400.

§ 35.491 Training for ophthalmic use of strontium-90.

Except as provided in § 35.57, the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who --

(a) Is an authorized user under § 35.490 or equivalent Agreement State requirements; or

(b)(1) Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy; the training must include --

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity; and

(iv) Radiation biology; and

(2) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve --

(i) Examination of each individual to be treated;

(ii) Calculation of the dose to be administered;

(iii) Administration of the dose; and

(iv) Follow up and review of each individual's case history; and

(3) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in § 35.490, § 35.491, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (a) and (b) of this section and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

Subpart G--Sealed Sources for Diagnosis

§ 35.500 Use of sealed sources for diagnosis.

A licensee shall use only sealed sources for diagnostic medical uses as approved in the Sealed Source and Device Registry.

§ 35.590 Training for use of sealed sources for diagnosis.

Except as provided in § 35.57, the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under § 35.500 to be a physician, dentist, or podiatrist who --

(a) Is certified by a specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b) Has had 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device; the training must include --

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity;

(4) Radiation biology; and

(5) Training in the use of the device for the uses requested.

Subpart H-- Photon Emitting Remote Afterloader Units, Teletherapy Units, and

Gamma Stereotactic Radiosurgery Units

§ 35.600 Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.

A licensee shall use sealed sources in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses:

(a) As approved in the Sealed Source and Device Registry; or

(b) In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of § 35.49(a) are met.

§ 35.604 Surveys of patients and human research subjects treated with a remote afterloader unit.

(a) Before releasing a patient or a human research subject from licensee control, a licensee shall survey the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe shielded position.

(b) A licensee shall retain a record of these surveys in accordance with § 35.2404.

§ 35.605 Installation, maintenance, adjustment, and repair.

(a) Only a person specifically licensed by the Commission or an Agreement State shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma

stereotactic radiosurgery unit that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

(b) Except for low dose-rate remote afterloader units, only a person specifically licensed by the Commission or an Agreement State shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

(c) For a low dose-rate remote afterloader unit, only a person specifically licensed by the Commission or an Agreement State or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.

(d) A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with § 35.2605.

§ 35.610 Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

(a) A licensee shall --

(1) Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;

(2) Permit only individuals approved by the authorized user, Radiation Safety Officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s);

(3) Prevent dual operation of more than one radiation producing device in a treatment room if applicable; and

(4) Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures must include --

(i) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

(ii) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

(iii) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

(b) A copy of the procedures required by paragraph (a)(4) of this section must be physically located at the unit console.

(c) A licensee shall post instructions at the unit console to inform the operator of --

(1) The location of the procedures required by paragraph (a)(4) of this section; and

(2) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

(d) A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in --

(1) The procedures identified in paragraph (a)(4) of this section; and

(2) The operating procedures for the unit.

(e) A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

(f) A licensee shall retain a record of individuals receiving instruction required by paragraph (d) of this section, in accordance with § 35.2310.

(g) A licensee shall retain a copy of the procedures required by §§ 35.610(a)(4) and (d)(2) in accordance with § 35.2610.

§ 35.615 Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

(a) A licensee shall control access to the treatment room by a door at each entrance.

(b) A licensee shall equip each entrance to the treatment room with an electrical interlock system that will --

(1) Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

(2) Cause the source(s) to be shielded when an entrance door is opened; and

(3) Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.

(c) A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.

(d) Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

(e) For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

(f) In addition to the requirements specified in paragraphs (a) through (e) of this section, a licensee shall --

(1) For medium dose-rate and pulsed dose-rate remote afterloader units, require --

(i) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and

(ii) An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.

(2) For high dose-rate remote afterloader units, require --

(i) An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and

(ii) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.

(3) For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.

(4) Notify the Radiation Safety Officer, or his/her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

(g) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source --

(1) Remaining in the unshielded position; and

(2) Lodged within the patient following completion of the treatment.

§ 35.630 Dosimetry equipment.

(a) Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met.

(1) The system must have been calibrated using a system or source traceable to the National Institute of Science and Technology (NIST) and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous 2 years and after any servicing that may have affected system calibration; or

(2) The system must have been calibrated within the previous 4 years. Eighteen to thirty months after that calibration, the system must have been intercompared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison must indicate that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a

comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.

(b) The licensee shall have a dosimetry system available for use for spot-check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with paragraph (a) of this section. This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in paragraph (a) of this section.

(c) The licensee shall retain a record of each calibration, intercomparison, and comparison in accordance with § 35.2630.

§ 35.632 Full calibration measurements on teletherapy units.

(a) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit --

(1) Before the first medical use of the unit; and

(2) Before medical use under the following conditions:

(i) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) Following replacement of the source or following reinstallation of the teletherapy unit in a new location;

(iii) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(3) At intervals not exceeding 1 year.

(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include determination of --

(1) The output within +/-3 percent for the range of field sizes and for the distance or range of distances used for medical use;

(2) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(3) The uniformity of the radiation field and its dependence on the orientation of the useful beam;

(4) Timer accuracy and linearity over the range of use;

(5) On-off error; and

(6) The accuracy of all distance measuring and localization devices in medical use.

(c) A licensee shall use the dosimetry system described in § 35.630(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph (b)(1) of this section may be made using a dosimetry system that indicates relative dose rates.

(d) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with published protocols accepted by nationally recognized bodies.

(e) A licensee shall mathematically correct the outputs determined in paragraph (b)(1) of this section for physical decay for intervals not exceeding 1 month for cobalt-60, 6 months for cesium-137, or at intervals consistent with 1 percent decay for all other nuclides.

(f) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (e) of this section must be performed by the authorized medical physicist.

(g) A licensee shall retain a record of each calibration in accordance with § 35.2632.

§ 35.633 Full calibration measurements on remote afterloader units.

(a) A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit --

(1) Before the first medical use of the unit;

(2) Before medical use under the following conditions:

(i) Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and

(ii) Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(3) At intervals not exceeding 1 quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and

(4) At intervals not exceeding 1 year for low dose-rate remote afterloader units.

(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include, as applicable, determination of:

(1) The output within +/- 5 percent;

(2) Source positioning accuracy to within +/- 1 millimeter;

(3) Source retraction with backup battery upon power failure;

(4) Length of the source transfer tubes;

(5) Timer accuracy and linearity over the typical range of use;

(6) Length of the applicators; and

(7) Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

(c) A licensee shall use the dosimetry system described in § 35.630(a) to measure the output.

(d) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with published protocols accepted by nationally recognized bodies.

(e) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in paragraph (b) of this section, a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding 1 quarter.

(f) For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with paragraphs (a) through (e) of this section.

(g) A licensee shall mathematically correct the outputs determined in paragraph (b)(1) of this section for physical decay at intervals consistent with 1 percent physical decay.

(h) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (g) of this section must be performed by the authorized medical physicist.

(i) A licensee shall retain a record of each calibration in accordance with § 35.2632.

§ 35.635 Full calibration measurements on gamma stereotactic radiosurgery units.

(a) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit --

(1) Before the first medical use of the unit;

(2) Before medical use under the following conditions --

(i) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and

(iii) Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and

(3) At intervals not exceeding 1 year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include determination of --

(1) The output within +/-3 percent;

(2) Relative helmet factors;

(3) Isocenter coincidence;

(4) Timer accuracy and linearity over the range of use;

(5) On-off error;

(6) Trunnion centricity;

(7) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(8) Helmet microswitches;

(9) Emergency timing circuits; and

(10) Stereotactic frames and localizing devices (trunnions).

(c) A licensee shall use the dosimetry system described in § 35.630(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph (b)(1) of this section may be made using a dosimetry system that indicates relative dose rates.

(d) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with published protocols accepted by nationally recognized bodies.

(e) A licensee shall mathematically correct the outputs determined in paragraph (b)(1) of this section at intervals not exceeding 1 month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.

(f) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (e) of this section must be performed by the authorized medical physicist.

(g) A licensee shall retain a record of each calibration in accordance with § 35.2632.

§ 35.642 Periodic spot-checks for teletherapy units.

(a) A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit once in each calendar month that include determination of --

(1) Timer accuracy, and timer linearity over the range of use;

(2) On-off error;

(3) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(4) The accuracy of all distance measuring and localization devices used for medical use;

(5) The output for one typical set of operating conditions measured with the dosimetry system described in § 35.630(b); and

(6) The difference between the measurement made in paragraph (a)(5) of this section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

(b) A licensee shall perform measurements required by paragraph (a) of this section in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.

(c) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(d) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility once in each calendar month and after each source installation to assure proper operation of --

(1) Electrical interlocks at each teletherapy room entrance;

(2) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);

(3) Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;

(4) Viewing and intercom systems;

(5) Treatment room doors from inside and outside the treatment room; and

(6) Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

(e) If the results of the checks required in paragraph (d) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(f) A licensee shall retain a record of each spot-check required by paragraphs (a) and (d) of this section, and a copy of the procedures required by paragraph (b), in accordance with § 35.2642.

§ 35.643 Periodic spot-checks for remote afterloader units.

(a) A licensee authorized to use a remote afterloader unit for medical use shall perform spot-checks of each remote afterloader facility and on each unit--

(1) Before the first use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit on a given day;

(2) Before each patient treatment with a low dose-rate remote afterloader unit; and

(3) After each source installation.

(b) A licensee shall perform the measurements required by paragraph (a) of this section in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

(c) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(d) To satisfy the requirements of paragraph (a) of this section, spot-checks must, at a minimum, assure proper operation of --

(1) Electrical interlocks at each remote afterloader unit room entrance;

(2) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(3) Viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;

(4) Emergency response equipment;

(5) Radiation monitors used to indicate the source position;

(6) Timer accuracy;

(7) Clock (date and time) in the unit's computer; and

(8) Decayed source(s) activity in the unit's computer.

(e) If the results of the checks required in paragraph (d) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(f) A licensee shall retain a record of each check required by paragraph (d) and a copy of the procedures required by paragraph (b) of this section in accordance with § 35.2643.

§ 35.645 Periodic spot-checks for gamma stereotactic radiosurgery units.

(a) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit --

(1) Monthly;

(2) Before the first use of the unit on a given day; and

(3) After each source installation.

(b) A licensee shall--

(1) Perform the measurements required by paragraph (a) of this section in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

(2) Have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(c) To satisfy the requirements of paragraph (a)(1) of this section, spot-checks must, at a minimum --

(1) Assure proper operation of --

(i) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(ii) Helmet microswitches;

(iii) Emergency timing circuits; and

(iv) Stereotactic frames and localizing devices (trunnions).

(2) Determine --

(i) The output for one typical set of operating conditions measured with the dosimetry system described in § 35.630(b);

(ii) The difference between the measurement made in paragraph (c)(2)(i) of this section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay);

(iii) Source output against computer calculation;

(iv) Timer accuracy and linearity over the range of use;

(v) On-off error; and

(vi) Trunnion centricity.

(d) To satisfy the requirements of paragraphs (a)(2) and (a)(3) of this section, spot-checks must assure proper operation of --

(1) Electrical interlocks at each gamma stereotactic radiosurgery room entrance;

(2) Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;

(3) Viewing and intercom systems;

(4) Timer termination;

(5) Radiation monitors used to indicate room exposures; and

(6) Emergency off buttons.

(e) A licensee shall arrange for the repair of any system identified in paragraph (c) of this section that is not operating properly as soon as possible.

(f) If the results of the checks required in paragraph (d) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(g) A licensee shall retain a record of each check required by paragraphs (c) and (d) and a copy of the procedures required by paragraph (b) of this section in accordance with § 35.2645.

§ 35.647 Additional technical requirements for mobile remote afterloader units.

(a) A licensee providing mobile remote afterloader service shall --

(1) Check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and

(2) Account for all sources before departure from a client's address of use.

(b) In addition to the periodic spot-checks required by § 35.643, a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the operation of --

(1) Electrical interlocks on treatment area access points;

(2) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(3) Viewing and intercom systems;

(4) Applicators, source transfer tubes, and transfer tube-applicator interfaces;

(5) Radiation monitors used to indicate room exposures;

(6) Source positioning (accuracy); and

(7) Radiation monitors used to indicate whether the source has returned to a safe shielded position.

(c) In addition to the requirements for checks in paragraph (b), a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

(d) If the results of the checks required in paragraph (b) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(e) A licensee shall retain a record of each check required by paragraph (b) of this section in accordance with § 35.2647.

§ 35.652 Radiation surveys.

(a) In addition to the survey requirement in § 20.1501 of this chapter, a person licensed under this subpart shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry.

(b) The licensee shall make the survey required by paragraph (a) of this section at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

(c) A licensee shall retain a record of the radiation surveys required by paragraph (a) of this section in accordance with § 35.2652.

§ 35.655 Five-year inspection for teletherapy and gamma stereotactic radiosurgery units.

(a) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at intervals not to exceed 5 years, whichever comes first, to assure proper functioning of the source exposure mechanism.

(b) This inspection and servicing may only be performed by persons specifically licensed to do so by the Commission or an Agreement State.

(c) A licensee shall keep a record of the inspection and servicing in accordance with § 35.2655.

§ 35.657 Therapy-related computer systems.

The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(a) The source-specific input parameters required by the dose calculation algorithm;

(b) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(c) The accuracy of isodose plots and graphic displays;

(d) The accuracy of the software used to determine sealed source positions from radiographic images; and

(e) The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

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

Except as provided in § 35.57, the licensee shall require an authorized user of a sealed source for a use authorized under § 35.600 to be a physician who --

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b)(1) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes --

(i) 200 hours of classroom and laboratory training in the following areas --

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity; and

(D) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in § 35.690 or equivalent Agreement State requirements at a medical institution, involving --

(A) Reviewing full calibration measurements and periodic spot-checks;

(B) Preparing treatment plans and calculating treatment doses and times;

(C) Using administrative controls to prevent a medical event involving the use of byproduct material;

(D) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

(E) Checking and using survey meters; and

(F) Selecting the proper dose and how it is to be administered; and

(2) Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in § 35.690 or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and

(3) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (b)(2) of this section and has achieved a level of

competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written certification must be signed by a preceptor authorized user who meets the requirements in § 35.690 or equivalent Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status.

Subpart I -- [Reserved]

Subpart J -- [Reserved]

Subpart K--Other Medical Uses of Byproduct Material or Radiation from Byproduct Material

§ 35.1000 Other medical uses of byproduct material or radiation from byproduct material.

A licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in subparts D through H of this part if --

(a) The applicant or licensee has submitted the information required by § 35.12(b) through (d); and

(b) The applicant or licensee has received written approval from the Commission in a license or license amendment and uses the material in accordance with the regulations and specific conditions the Commission considers necessary for the medical use of the material.

Subpart L-- Records

§ 35.2024 Records of authority and responsibilities for radiation protection programs.

(a) A licensee shall retain a record of actions taken by the licensee's management in accordance with § 35.24(a) for 5 years. The record must include a summary of the actions taken and a signature of licensee management.

(b) The licensee shall retain a copy of both authority, duties, and responsibilities of the Radiation Safety Officer as required by § 35.24(e), and a signed copy of each Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by § 35.24(b), for the duration of the license. The records must include the signature of the Radiation Safety Officer and licensee management.

§ 35.2026 Records of radiation protection program changes.

A licensee shall retain a record of each radiation protection program change made in accordance with § 35.26(a) for 5 years. The record must include a copy of the old and new procedures; the effective date of the change; and the signature of the licensee management that reviewed and approved the change.

§ 35.2040 Records of written directives.

A licensee shall retain a copy of each written directive as required by § 35.40 for 3 years.

§ 35.2041 Records for procedures for administrations requiring a written directive

A licensee shall retain a copy of the procedures required by § 35.41(a) for the duration of the license.

§ 35.2060 Records of calibrations of instruments used to measure the activity of unsealed byproduct material.

A licensee shall maintain a record of instrument calibrations required by § 35.60 for 3 years. The records must include 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.

§ 35.2061 Records of radiation survey instrument calibrations.

A licensee shall maintain a record of radiation survey instrument calibrations required by § 35.61 for 3 years. The record must include 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.

§ 35.2063 Records of dosages of unsealed byproduct material for medical use.

(a) A licensee shall maintain a record of dosage determinations required by § 35.63 for 3 years.

(b) The record must contain--

(1) The radiopharmaceutical;

(2) The patient's or human research subject's name, or identification number if one has been assigned;

(3) The prescribed dosage, the determined dosage, or a notation that the total activity is less than 1.1 MBq (30 μCi);

(4) The date and time of the dosage determination; and

(5) The name of the individual who determined the dosage.

§ 35.2067 Records of leaks tests and inventory of sealed sources and brachytherapy sources.

(a) A licensee shall retain records of leak tests required by § 35.67(b) for 3 years. The records must include the model number, and serial number if one has been assigned, of each source tested; the identity of each source by radionuclide and its estimated activity; the results of the test; the date of the test; and the name of the individual who performed the test.

(b) A licensee shall retain records of the semi-annual physical inventory of sealed sources and brachytherapy sources required by § 35.67(g) for 3 years. The inventory records must contain the model number of each source, and serial number if one has been assigned, the identity of each source by radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

§ 35.2070 Records of surveys for ambient radiation exposure rate.

A licensee shall retain a record of each survey required by § 35.70 for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

§ 35.2075 Records of the release of individuals containing unsealed byproduct material or implants containing byproduct material.

(a) A licensee shall retain a record of the basis for authorizing the release of an individual in accordance with § 35.75, if the total effective dose equivalent is calculated by --

(1) Using the retained activity rather than the activity administered;

(2) Using an occupancy factor less than 0.25 at 1 meter;

(3) Using the biological or effective half-life; or

(4) Considering the shielding by tissue.

(b) A licensee shall retain a record that the instructions required by § 35.75(b) were provided to a breast-feeding female if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 mSv (0.5 rem).

(c) The records required by paragraphs (a) and (b) of this section must be retained for 3 years after the date of release of the individual.

§ 35.2080 Records of mobile medical services.

(a) A licensee shall retain a copy of each letter that permits the use of byproduct material at a client's address, as required by § 35.80(a)(1). Each letter must clearly delineate the

authority and responsibility of the licensee and the client and must be retained for 3 years after the last provision of service.

(b) A licensee shall retain the record of each survey required by § 35.80(a)(4) for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

§ 35.2092 Records of decay-in-storage.

A licensee shall maintain records of the disposal of licensed materials, as required by § 35.92, for 3 years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.

§ 35.2204 Records of molybdenum-99 concentrations.

A licensee shall maintain a record of the molybdenum-99 concentration tests required by § 35.204(b) for 3 years. The record must include, for each measured elution of technetium-99m, the ratio of the measures expressed as kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (or microcuries of molybdenum per millicurie of technetium), the time and date of the measurement, and the name of the individual who made the measurement.

§ 35.2310 Records of safety instruction.

A licensee shall maintain a record of safety instructions required by §§ 35.310, 35.410, and 35.610 for 3 years. The record must include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

§ 35.2404 Records of surveys after source implant and removal.

A licensee shall maintain a record of the surveys required by §§ 35.404 and 35.604 for 3 years. Each record must include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

§ 35.2406 Records of brachytherapy source accountability.

(a) A licensee shall maintain a record of brachytherapy source accountability required by § 35.406 for 3 years.

(b) For temporary implants, the record must include --

(1) The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use; and

(2) The number and activity of sources returned to storage, the time and date they were returned to storage, and the name of the individual who returned them to storage.

(c) For permanent implants, the record must include --

(1) The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;

(2) The number and activity of sources not implanted, the date they were returned to storage, and the name of the individual who returned them to storage; and

(3) The number and activity of sources permanently implanted in the patient or human research subject.

§ 35.2432 Records of calibration measurements of brachytherapy sources.

(a) A licensee shall maintain a record of the calibrations of brachytherapy sources required by § 35.432 for 3 years after the last use of the source.

(b) The record must include--

(1) The date of the calibration;

(2) The manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source;

(3) The source output or activity;

(4) The source positioning accuracy within the applicators; and

(5) The signature of the authorized medical physicist.

§ 35.2433 Records of decay of strontium-90 sources for ophthalmic treatments.

(a) A licensee shall maintain a record of the activity of a strontium-90 source required by § 35.433 for the life of the source.

(b) The record must include--

(1) The date and initial activity of the source as determined under § 35.432; and

(2) For each decay calculation, the date and the source activity as determined under

§ 35.433.

§ 35.2605 Records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by § 35.605 for 3 years. For each installation, maintenance, adjustment and repair, the record must include the date, description of the service, and name(s) of the individual(s) who performed the work.

§ 35.2610 Records of safety procedures

A licensee shall retain a copy of the procedures required by §§ 35.610(a)(4) and (d)(2) until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.

§ 35.2630 Records of dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

(a) A licensee shall retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with § 35.630 for the duration of the license.

(b) For each calibration, intercomparison, or comparison, the record must include --

(1) The date;

(2) The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by paragraphs (a) and (b) of § 35.630;

(3) The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and

(4) The names of the individuals who performed the calibration, intercomparison, or comparison.

§ 35.2632 Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations.

(a) A licensee shall maintain a record of the teletherapy unit, remote afterloader unit, and gamma stereotactic radiosurgery unit full calibrations required by §§ 35.632, 35.633, and 35.635 for 3 years.

(b) The record must include --

(1) The date of the calibration;

(2) The manufacturer's name, model number, and serial number of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit(s), the source(s), and the instruments used to calibrate the unit(s);

(3) The results and an assessment of the full calibrations;

(4) The results of the autoradiograph required for low dose-rate remote afterloader units; and

(5) The signature of the authorized medical physicist who performed the full calibration.

§ 35.2642 Records of periodic spot-checks for teletherapy units.

(a) A licensee shall retain a record of each periodic spot-check for teletherapy units required by § 35.642 for 3 years.

(b) The record must include --

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number of the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;

(3) An assessment of timer linearity and constancy;

(4) The calculated on-off error;

(5) A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

(6) The determined accuracy of each distance measuring and localization device;

(7) The difference between the anticipated output and the measured output;

(8) Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and

(9) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(c) A licensee shall retain a copy of the procedures required by § 35.642 (b) until the licensee no longer possesses the teletherapy unit.

§ 35.2643 Records of periodic spot-checks for remote afterloader units.

(a) A licensee shall retain a record of each spot-check for remote afterloader units required by § 35.643 for 3 years.

(b) The record must include, as applicable --

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number for the remote afterloader unit and source;

(3) An assessment of timer accuracy;

(4) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and

(5) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(c) A licensee shall retain a copy of the procedures required by § 35.643(b) until the licensee no longer possesses the remote afterloader unit.

§ 35.2645 Records of periodic spot-checks for gamma stereotactic radiosurgery units.

(a) A licensee shall retain a record of each spot-check for gamma stereotactic radiosurgery units required by § 35.645 for 3 years.

(b) The record must include --

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;

(3) An assessment of timer linearity and accuracy;

(4) The calculated on-off error;

(5) A determination of trunnion centricity;

(6) The difference between the anticipated output and the measured output;

(7) An assessment of source output against computer calculations;

(8) Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and

(9) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(c) A licensee shall retain a copy of the procedures required by § 35.645(b) until the licensee no longer possesses the gamma stereotactic radiosurgery unit.

§ 35.2647 Records of additional technical requirements for mobile remote afterloader units.

(a) A licensee shall retain a record of each check for mobile remote afterloader units required by § 35.647 for 3 years.

(b) The record must include --

(1) The date of the check;

(2) The manufacturer's name, model number, and serial number of the remote afterloader unit;

(3) Notations accounting for all sources before the licensee departs from a facility;

(4) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators, source transfer tubes, and transfer tube applicator interfaces, and source positioning accuracy; and

(5) The signature of the individual who performed the check.

§ 35.2652 Records of surveys of therapeutic treatment units.

(a) A licensee shall maintain a record of radiation surveys of treatment units made in accordance with § 35.652 for the duration of use of the unit.

(b) The record must include --

(1) The date of the measurements;

(2) The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;

(3) Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and

(4) The signature of the individual who performed the test.

§ 35.2655 Records of 5-year inspection for teletherapy and gamma stereotactic radiosurgery units.

(a) A licensee shall maintain a record of the 5-year inspections for teletherapy and gamma stereotactic radiosurgery units required by § 35.655 for the duration of use of the unit.

(b) The record must contain --

(1) The inspector's radioactive materials license number;

(2) The date of inspection;

(3) The manufacturer's name and model number and serial number of both the treatment unit and source;

(4) A list of components inspected and serviced, and the type of service; and

(5) The signature of the inspector.

Subpart M--Reports

§ 35.3045 Report and notification of a medical event.

(a) A licensee shall report any event, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material results in --

(1) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and

(i) The total dose delivered differs from the prescribed dose by 20 percent or more;

(ii) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

(iii) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

(2) A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following –

(i) An administration of a wrong radioactive drug containing byproduct material;

(ii) An administration of a radioactive drug containing byproduct material by the wrong route of administration;

(iii) An administration of a dose or dosage to the wrong individual or human research subject;

(iv) An administration of a dose or dosage delivered by the wrong mode of treatment; or

(v) A leaking sealed source.

(3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

(b) A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

(c) The licensee shall notify by telephone the NRC Operations Center[3] no later than the next calendar day after discovery of the medical event.

(d) The licensee shall submit a written report to the appropriate NRC Regional Office listed in § 30.6 of this chapter within 15 days after discovery of the medical event.

(1) The written report must include --

[3]The commercial telephone number of the NRC Operations Center is (301) 951-0550.

(i) The licensee's name;

(ii) The name of the prescribing physician;

(iii) A brief description of the event;

(iv) Why the event occurred;

(v) The effect, if any, on the individual(s) who received the administration;

(vi) What actions, if any, have been taken or are planned to prevent recurrence; and

(vii) Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

(2) The report may not contain the individual's name or any other information that could lead to identification of the individual.

(e) The licensee shall provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the medical event may be made instead to that individual’s responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(f) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.

(g) A licensee shall:

(1) Annotate a copy of the report provided to the NRC with the:

(a) Name of the individual who is the subject of the event; and

(b) Social security number or other identification number, if one has been assigned, of the individual who is the subject of the event; and

(2) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

§ 35.3047 Report and notification of a dose to an embryo/fetus or a nursing child.

(a) A licensee shall report any dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent that is a result of an administration of byproduct material or radiation from byproduct material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

(b) A licensee shall report any dose to a nursing child that is a result of an administration of byproduct material to a breast-feeding individual that --

(1) Is greater than 50 mSv (5 rem) total effective dose equivalent; or

(2) Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

(c) The licensee shall notify by telephone the NRC Operations Center no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in paragraphs (a) or (b) in this section.

(d) The licensee shall submit a written report to the appropriate NRC Regional Office listed in § 30.6 of this chapter within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in paragraphs (a) or (b) in this section.

(1) The written report must include --

(i) The licensee's name;

(ii) The name of the prescribing physician;

(iii) A brief description of the event;

(iv) Why the event occurred;

(v) The effect, if any, on the embryo/fetus or the nursing child;

(vi) What actions, if any, have been taken or are planned to prevent recurrence; and

(vii) Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

(2) The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

(e) The licensee shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under paragraph (a) or (b) of this section, unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet

the requirements of this paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(f) A licensee shall:

(1) Annotate a copy of the report provided to the NRC with the:

(a) Name of the pregnant individual or the nursing child who is the subject of the event; and

(b) Social security number or other identification number, if one has been assigned, of the pregnant individual or the nursing child who is the subject of the event; and

(2) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

§ 35.3067 Report of a leaking source.

A licensee shall file a report within 5 days if a leak test required by § 35.67 reveals the presence of 185 Bq (0.005 μCi) or more of removable contamination. The report must be filed with the appropriate NRC Regional Office listed in § 30.6 of this chapter, with a copy to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The written report must include the model number and serial number if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken.

Subpart N--Enforcement

§ 35.4001 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of --

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued under those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under Section 234 of the Atomic Energy Act:

(1) For violations of --

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued under the sections specified in paragraph (b)(1)(i) of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under Section 186 of the Atomic Energy Act of 1954, as amended.

§ 35.4002 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation

issued under sections 161b, 161i, or 161o of the Act. For purposes of Section 223, all the regulations in 10 CFR part 35 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in 10 CFR part 35 that are not issued under subsections 161b, 161i, or 161o for the purposes of Section 223 are as follows: §§ 35.1, 35.2, 35.7, 35.8, 35.12, 35.15, 35.18, 35.19, 35.65, 35.100, 35.200, 35.300, 35.4001, and 35.4002 .

Dated at Rockville, Maryland, this day of , 2000.

For the Nuclear Regulatory Commission.

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Annette L. Vietti-Cook,
Secretary of the Commission.