NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30, 32, and 35

[NRC-2008-0175]

RIN 3150-AI63

Medical Use of Byproduct Material - Medical Event Definitions, Training and Experience, and Clarifying Amendments

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations related to the medical use of byproduct material. In this action the NRC addresses three ongoing rulemaking projects and several other related topics. First, this rule proposes amendments to the reporting and notification requirements for a medical event for permanent implant brachytherapy. Second, the rule proposes changes to the training and experience (T&E) requirements for authorized users, medical physicists, Radiation Safety Officers, and nuclear pharmacists; to the requirements for measuring molybdenum (Mo) contamination and reporting of failed technetium and rubidium generators; and to allow Associate Radiation Safety Officers to be named on a medical license. Third, the rule proposes changes to address a request filed in a petition for rulemaking (PRM), PRM-35-20, to exempt certain board-certified individuals from certain T&E requirements (i.e., “grandfather” these individuals) so they may be identified on a license or permit for materials and uses that they performed on or before October 24, 2005, the expiration date of the prior T&E requirements.

DATES: Submit comments by **[INSERT DATE 120 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]**. Submit comments specific to the information collections aspects of this proposed rule by **[INSERT DATE 30 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]**. Comments received after these dates will be considered if it is practical to do so, but the NRC is able to assure consideration only for comments received on or before these dates.

ADDRESSES: You may submit comments by any one of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- **Federal rulemaking Web site:** Go to http://www.regulations.gov and search for Docket ID NRC-2008-0175. Address questions about NRC dockets to Carol Gallagher, telephone: 301-287-3422, e-mail: Carol.Gallager@nrc.gov. For technical questions, contact the individual listed in the FOR FURTHER INFORMATION CONTACT section of this document.
- **E-mail comments to:** Rulemaking.Comments@nrc.gov. If you do not receive an automatic e-mail reply confirming receipt, then contact us directly at 301-415-1677.
- **Fax comments to:** Secretary, U.S. Nuclear Regulatory Commission at 301-415-1101.
- **Mail comments to:** Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.
- **Hand deliver comments to:** 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. (Eastern Time) Federal workdays; telephone: 301-415-1677.

For additional direction on accessing information and submitting comments, see "Obtaining Information and Submitting Comments" in the SUPPLEMENTARY INFORMATION section of this document.

FOR FURTHER INFORMATION CONTACT: Neelam Bhalla, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone: 301-415-0978, e-mail: Neelam.Bhalla@nrc.gov.

SUPPLEMENTARY INFORMATION:

EXECUTIVE SUMMARY:

A. Need for the Regulatory Action and Legal Authority

The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations related to the medical use of byproduct material. These regulations were last amended in their entirety in 2002. Over the last 12 years, stakeholders and members of the medical community have identified certain issues in implementing these regulations. As a result, the NRC is proposing changes to update its regulations to address technological advances and changes in medical procedures. The proposed rule would also enhance patient safety. The NRC is proposing to revise parts 30, 32, and 35 of Title 10 of the *Code of Federal Regulations* (10 CFR) under the legal authority granted to the NRC by the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553.

B. Major Provisions

- The proposed rule would establish separate requirements for identifying and reporting medical events (ME) involving permanent implant brachytherapy programs. These new regulations would require reporting of an event in which there is actual or potential harm to a patient resulting from an ME. Additionally, licensees would be required to develop, implement, and maintain procedures for determining if an ME has occurred, including, for permanent

implant brachytherapy, procedures for making certain assessments within 60 days from the date the treatment was performed;

- Training and experience requirements would be amended in multiple sections to remove the requirement to obtain a written attestation for an individual who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. This requirement is being removed because the NRC has determined that certification by a specialty board, coupled with meeting the recentness of training requirements, is sufficient to demonstrate that an individual seeking authorization on a license has met the training and experience (T&E) requirements and has the requisite current knowledge and that additional attestation by a preceptor is therefore unnecessary. Individuals who are not board certified would still need to obtain a written attestation; however, the language of the attestation would be modified. Additionally, residency program directors would be able to provide these written attestations;

- The requirements for measuring the Mo-99 concentration for elutions of Mo-99m/Tc generators would be changed and reporting requirements added for failed Mo-99/Tc-99m and strontium-82 (Sr-82)/Rb-82 generators. The current requirement to measure the Mo-99 concentration after the first eluate would be changed to require that the Mo-99 concentration be measured in each eluate because of several incidents reported to the NRC of breakthrough; and

- Licensees would be allowed to appoint a qualified individual with expertise in certain uses of byproduct material to be named on a license to serve as an Associate Radiation Safety Officer (ARSO). This would make it easier for an individual to become a Radiation Safety Officer (RSO) on other medical licenses and would increase the number of individuals who would be available to serve as preceptors for individuals seeking to be appointed as RSOs or ARSOs.

Additionally, the proposed rule would address the issues raised in a petition for rulemaking (PRM-35-20) that was submitted to the NRC in 2006. The petition requested that experienced board-certified RSOs and medical physicists not named on a license who had practiced certain modalities prior to October 24, 2005, be exempt from the specific T&E requirements in 10 CFR 35.50 and 35.51, respectively. In effect, they would be "grandfathered" for these training requirements for the modalities that they practiced as of October 24, 2005. This petition is discussed in detail in Section III, Petition for Rulemaking, PRM-35-20, of this document.

C. Costs and Benefits

The NRC has not established a quantitative cutoff for defining an economically significant regulatory action. The NRC assumes "significant" impact if the ratio of annualized costs to estimated annual gross revenues for a licensee exceeds 1 percent. The proposed rule would have an estimated $8.3 million implementation cost for the medical community. This cost would be spread over the 7,845 impacted licensees for an average implementation cost of approximately $1,100 per licensee. The NRC assumes that all affected licensees have annual revenues greater than $110,000. Therefore, the estimated cost impacts do not exceed the 1 percent criterion for "significant" impacts, and the proposed rule appears not to be an economically significant regulatory action. It would cost the NRC approximately $400,000 to implement this rule.

The benefits of this proposed rule are associated with potentially reducing unnecessary radiation exposure to patients, potentially reducing requirements for T&E, and potentially affording more latitude to licensees. The proposed rule would also update, clarify, and strengthen the existing regulatory requirements, and thereby promote public health and safety.

A draft regulatory analysis has been developed for this proposed rulemaking and is available for public comment (see Section XVI, Regulatory Analysis, of this document).

TABLE OF CONTENTS

I. Obtaining Information and Submitting Comments.

II. Background.

III. Petition for Rulemaking, PRM-35-20.

IV. Discussion.

A. What Action is the NRC Proposing to Take?

B. When Would These Actions Become Effective?

C. Are There Any Cumulative Effects of Regulation Associated With This Rule?

D. Is the NRC Requesting Comments on Other Specific Issues?

E. What Should I Consider as I Prepare My Comments to the NRC?

V. Discussion of Proposed Amendments by Section.

VI. Criminal Penalties.

VII. Coordination with NRC Agreement States.

VIII. Agreement State Compatibility.

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

X. Plain Writing.

XI. Consistency with Medical Policy Statement.

XII. Voluntary Consensus Standards.

XIII. Environmental Impact: Categorical Exclusion.

XIV. Finding of No Significant Environmental Impact: Availability.

XV. Paperwork Reduction Act Statement.

XVI. Regulatory Analysis.

XVII. Regulatory Flexibility Certification.

XVIII.Backfitting and Issue Finality.

I. Obtaining Information and Submitting Comments.

A. Obtaining Information

Please refer to Docket ID NRC-2008-0175 when contacting the NRC about the availability of information for this proposed rule. You may access publicly-available information related to this proposed rule by any of the following methods:

- **Federal Rulemaking Web Site:** Go to http://www.regulations.gov and search for Docket ID NRC-2008-0175.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may access publicly-available documents online in the ADAMS Public Documents collection at http://www.nrc.gov/reading-rm/adams.html**.** To begin the search, select "ADAMS Public Documents" and then select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov. The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that a document is referenced.

- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC-2008-0175 in the subject line of your comment submission, to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at http://www.regulations.gov as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

II. Background

The NRC published a final rule in the *Federal Register* on April 24, 2002 (67 FR 20250), that revised the medical use regulations in part 35 of Title 10 of the *Code of Federal Regulations* (10 CFR) in their entirety. The training and experience (T&E) requirements in 10 CFR part 35 were further revised through an additional rulemaking, "Medical Use of Byproduct Material – Recognition of Specialty Boards," published in the *Federal Register* on March 30, 2005 (70 FR 16336).

In implementing the current regulations in 10 CFR part 35, the NRC staff, stakeholders, and the Advisory Committee on the Medical Uses of Isotopes (ACMUI) have identified numerous issues that need to be addressed through the rulemaking process.

As a result, the NRC is proposing to amend its regulations in 10 CFR part 35 to address these issues. The proposed rule would modify the written directive (WD) requirements in 10 CFR 35.40 and the medical event (ME) reporting in 10 CFR 35.3045 to establish separate ME reporting criteria for permanent implant brachytherapy. The proposed rule would accordingly also modify the requirements for procedures for administrations requiring a WD in 10 CFR 35.41 to require licensees to develop written procedures for determining if an ME has occurred as a result of any administrations requiring a WD, including permanent implant brachytherapy.

Currently, the ME criteria for brachytherapy implants in 10 CFR 35.3045, "Report and Notification of a Medical Event," are based on the dose administered to the patient. The proposed amendment would establish separate ME criteria for permanent implant brachytherapy in terms of the total source strength administered (activity-based) rather than the dose delivered (dose-based). The ME criteria would also include absorbed doses to normal tissues located outside of the treatment site as well as within the treatment site. The proposed amendments are based on the staff recommendations contained in SECY-12-0053, "Recommendations on Regulatory Changes for Permanent Implant Brachytherapy Programs" (ADAMS Accession No. ML12072A306).

The NRC previously published a proposed rule, "Medical Use of Byproduct Material – Amendments/Medical Event Definitions," to revise ME definitions for permanent implant brachytherapy in the *Federal Register* on August 6, 2008 (73 FR 45635), for public comment. The majority of commenters were in agreement to convert the ME criteria from dose-based to activity-based. However, during late summer and early fall of 2008, a substantial

number of MEs involving permanent implant brachytherapy were reported to the NRC. Based on the circumstances involving the MEs reported in 2008, the staff re-evaluated the previously published proposed rule and developed a reproposed rule.

In SECY-10-0062, "Reproposed Rule: Medical Use of Byproduct Material – Amendments/Medical Event Definitions," dated May 18, 2010 (ADAMS Accession No. ML100890121), the staff requested the Commission to approve for publication the revised proposed rule for public comment. Prior to Commission voting on the reproposed rule, a Commission briefing was held on the reproposed rule on July 8, 2010 (ADAMS Package Accession No. ML101930532). The presenters included a member of the ACMUI, a representative from the Organization of Agreement States (OAS), a physician from the American Brachytherapy Society, the National Director of the Radiation Oncology Program of the Department of Veterans Affairs, a representative from the American Association of Physicists in Medicine (AAPM), and a representative from Us-TOO (a support group for prostate cancer patients). The presenters urged the Commission not to publish the reproposed rule as developed. They believed that MEs should be based on events of potential clinical significance and recommended that the NRC seek stakeholder input in revising this rule.

In Staff Requirements Memorandum (SRM) SECY-10-0062, dated August 10, 2010 (ADAMS Accession No. ML102220233), the Commission disapproved the staff's recommendation to publish the reproposed rule and directed the staff to work closely with the ACMUI and the broader medical and stakeholder community to develop ME definitions that would protect the interests of patients and allow physicians the flexibility to take actions that they deem medically necessary, while continuing to enable the agency to detect failures in process, procedure, and training, as well as any misapplication of byproduct materials by AUs. The NRC is addressing the issues in the reproposed rule (RIN 3150-AI26) in this proposed rulemaking; for more information, including public comments submitted on the earlier rule, see

Docket ID NRC-2008-0071 on www.regulations.gov. The SRM also directed the staff to hold a series of stakeholder workshops to discuss issues associated with the ME definition.

Following Commission direction, the NRC conducted two workshops in the summer of 2011. These facilitated workshops were held in New York, New York, in June 2011 (ADAMS Accession No. ML111930470), and in Houston, Texas, in August 2011 (ADAMS Accession No. ML112900094). The NRC staff also requested the ACMUI to prepare a report on ME definitions for permanent implant brachytherapy. In February 2012, the ACMUI submitted its final revised report to the NRC (ADAMS Accession No ML12038A279). The staff used the recommendations in the ACMUI revised final report, along with the substantial input from stakeholders, to develop the recommendations in SECY-12-0053, which provided the regulatory basis for the ME definitions in this proposed rule.

In addition to revising the ME definitions for permanent implant brachytherapy, the NRC is proposing to amend its regulations in 10 CFR part 35 to revise the preceptor attestation requirements, require increased frequency of testing for measuring Mo-99 concentration in a Mo-99/Tc-99m generator, require reporting of failed tests of a Mo-99/Tc-99m generator and failed strontium-82 (Sr-82) and strontium-85 (Sr-85) tests of a Rb-82 generator, allow ARSOs to be named on a medical use license, extend the 5-year inspection frequency for a gamma stereotactic radiosurgery unit to 7 years, and to make several clarifying amendments.

Finally, the proposed rule would address issues that were raised in PRM-35-20 (ADAMS Accession No. ML062620129) filed by E. Russell Ritenour, Ph.D., on behalf of the AAPM on September 13, 2006. The petition requested that the training requirements for experienced RSOs and medical physicists in 10 CFR 35.57 be amended to recognize board certified physicists and RSOs as “grandfathered” for the modalities that they practiced as of October 24, 2005. The following section discusses the petition in detail.

III. Petition for Rulemaking, PRM-35-20.

The NRC has incorporated into this proposed rulemaking the resolution of PRM-35-20 filed by E. Russell Ritenour, Ph.D. (the petitioner), dated September 10, 2006, on behalf of the AAPM. A notice of receipt and request for comments on this petition was published in the *Federal Register* on November 1, 2006 (71 FR 64168).

The petitioner requested that 10 CFR 35.57, ''Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist,'' be revised to: 1) recognize medical physicists certified by either the American Board of Radiology or the American Board of Medical Physics on or before October 24, 2005, as ''grandfathered" for the modalities that they practiced as of October 24, 2005, independent of whether or not a medical physicist was named on an NRC or an Agreement State license as of October 24, 2005; and 2) recognize all diplomates certified by the named boards in former subpart J of 10 CFR part 35, which was removed from 10 CFR part 35 in a rulemaking dated March 30, 2005 (70 FR 16336), as RSOs who have relevant timely work experience (even if they have not been formally named as an RSO). The petitioner requested that experienced board-certified RSOs and medical physicists not named on a license who had practiced certain modalities prior to October 24, 2005, be exempted from the specific T&E requirements in 10 CFR 35.50, and 35.51, respectively. In effect, they would be "grandfathered" for these training requirements for the modalities that they practiced as of October 24, 2005. The petitioner was concerned that as a result of the amendments to the T&E regulations in 2005, an individual could become authorized on a license only if he or she had been certified by a specialty board whose certification process was recognized under the new regulations by the NRC or an Agreement State or was already identified on an existing NRC or Agreement State license. If the individual had been certified prior to the effective date for

recognition of the certifying board but had not been listed on a license, he or she would not be "grandfathered," and would have to obtain training through the so-called "alternate pathway," which establishes the specific training requirements for the non-certified individuals. The petitioner did not believe that it was the intent of the Commission to deny recognition to individuals currently practicing or to minimize the importance of certification by a certifying board. The NRC received 168 comments from professional organizations and individuals on the petition. The majority of the commenters supported the petition.

The NRC reviewed the petitioner's request and comments received on the petition and concluded that revisions made to the regulations in 2005 may have inadvertently affected a group of board certified professionals insofar as they may now have to use the alternate pathway option to demonstrate that they meet the T&E requirements in 10 CFR part 35 rather than the certification pathway for recognition on an NRC license as an RSO or an authorized medical physicist (AMP) (73 FR 27773; May 14, 2008). Therefore, the NRC concluded that the issues raised in the petition would be considered in the rulemaking process if a regulatory basis could be developed to support a rulemaking.

In October 2008, the NRC staff sent letters to all of the certifying boards whose certification processes are currently recognized by the NRC and to certifying boards previously named in the former 10 CFR part 35, subpart J, whose certification processes currently are not recognized by the NRC. To determine the scope of the medical community that might be negatively impacted by the T&E grandfathering provisions of the regulations, the NRC asked each organization to provide the number and percentage of its currently active diplomates who are not grandfathered under 10 CFR 35.57 by virtue of not being named on a license or permit. The organizations were asked to include individuals who are now or may in the future be seeking to be named as an RSO, AMP, AU, or authorized nuclear pharmacist (ANP) on an NRC or an Agreement State medical use license. Based on the responses, the NRC estimates that

as many as 10,000 board certified individuals may have been affected by the 2005 T&E rulemaking.

Accordingly, the NRC believes that these individuals should be eligible for grandfathering for the modalities that they practiced as of October 24, 2005, and that their previously-acceptable qualifications for authorized status should continue to be adequate and acceptable from a health and safety standpoint such as to allow them to continue to practice using the same modalities. This proposed rule, in response to the petition, would amend § 35.57 to recognize all individuals that were previously certified by boards recognized under the previous 10 CFR part 35, subpart J, as RSOs, teletherapy or medical physicists, AMPs, AUs, nuclear pharmacists, and ANPs for the modalities that they practiced as of October 24, 2005.

The petitioner, in his support for "grandfathering" the RSOs who have relevant work experience and were not formally named on an NRC or an Agreement State license or permit as an RSO, stated that these individuals will be required to provide preceptor attestations. In this proposed rulemaking, the NRC would eliminate the requirement for preceptor attestations for all individuals certified by NRC recognized boards. The NRC believes that attestations are not necessary in this particular situation because the provisions of § 35.59, "Recentness of training," require that the T&E 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 T&E was completed. The "grandfathered" individuals would fall under the provisions of § 35.59 and would need to provide evidence of continued education and experience. Therefore, the NRC believes that preceptor attestations are not warranted for these "grandfathered" individuals so long as the provisions of § 35.59 are met and the individual requests authorizations only for the modalities the individual practiced as of October 24, 2005.

IV. Discussion.

A. What Action is the NRC Proposing to Take?

In implementing the current regulations in 10 CFR part 35, the NRC staff, stakeholders, and the ACMUI identified numerous issues that need to be addressed through the rulemaking process. The proposed revisions would clarify the current regulations, and provide greater flexibility to licensees without compromising patient, worker, and public health and safety. The proposed amendments include:

a. Adding separate ME definitions for permanent implant brachytherapy.

b. Amending preceptor attestation requirements.

c. "Grandfathering" certain board-certified individuals (PRM-35-20) discussed in Section III, Petition for Rulemaking, PRM-35-20, of this document.

d. Requiring increased frequency of testing to measure Mo-99 breakthrough.

e. Requiring reporting and notification of failed Mo-99/Tc-99m and Sr-82/Rb-82 generators.

f. Allowing ARSOs to be named on a medical use license.

g. Additional issues and clarifications.

Early public input on this proposed rule was solicited through various mechanisms. For certain amendments the NRC posted preliminary draft rule text (ADAMS Accession No. ML111390420) for a 75-day comment period on www.regulations.gov. The availability of the draft rule language was noticed in the *Federal Register* on May 20, 2011 (76 FR 29171). The NRC received 10 comment letters, which are also posted on www.regulations.gov under Docket ID NRC-2008-0175. The NRC staff reviewed the comments and considered them in developing the proposed rule text.

The proposed amendments and preliminary draft rule text were also discussed at the two transcribed facilitated public workshops that were conducted in New York City, New York,

on June 20-21, 2011, and in Houston, Texas, on August 11-12, 2011. The purpose of the workshops was to solicit key stakeholder input on topics associated with definition of an ME, including the requirements for reporting and notifications of MEs for permanent implant brachytherapy, and on other medical issues that are being considered in the proposed rulemaking. These workshops were initiated as a result of the Commission's direction to staff in SRM-SECY-10-0062 to work closely with the ACMUI and the medical community to develop event definitions that would protect the interests of patients. The Commission also directed that these definitions should allow physicians the flexibility to take actions that they deem medically necessary, while preserving the NRC's ability to detect misapplications of radioactive material and failures in processes, procedures, and training. The panelists for the workshops included representation from the ACMUI, Agreement States, professional societies, and a patients' rights advocate.

The major proposed revisions are:

a. Adding separate ME definitions for permanent implant brachytherapy.

The proposed rule would establish separate ME definitions and reporting requirements for permanent implant brachytherapy programs. As explained in Section II, Background, of this document, the proposed amendments are based on the recommendations developed in close cooperation with the ACMUI, as well as with substantial input from various stakeholders. During its meeting in March 2004, the ACMUI recognized the existing inadequacy of defining MEs with regard to permanent implant brachytherapy. The ACMUI explained that for these implants, the plus or minus 20 percent variance from the prescription criterion in the existing rule was only appropriate if both the prescription and the variance could be expressed in units of activity, rather than in units of dose, as there is no suitable clinically used dose metric available for judging the occurrence of MEs. In June 2005, the ACMUI recommended that new language should be developed to define MEs related to permanent implant brachytherapy.

In SECY-05-0234, “Adequacy of Medical Event Definitions in 10 CFR 35.3045, and Communicating Associated Risks to the Public,” dated December 27, 2005 (ADAMS Accession No. ML053180408), based on recommendations received from the ACMUI, the staff recommended that for permanent implant brachytherapy the Commission approve the staff’s plan to revise the ME definitions and the associated requirements for WDs to be activity-based, instead of dose-based. In SRM-SECY-05-0234, dated February 15, 2006 (ADAMS Accession No. ML060460594), the Commission directed the staff to proceed directly with the development of a proposed rule to modify both the WD requirements in 10 CFR 35.40(b)(6) and the ME reporting requirements in 10 CFR 35.3045 for permanent implant brachytherapy medical use, to convert from dose-based to activity-based ME criteria.

As discussed in Section II, Background, of this document, a proposed rule was published in the *Federal Register* on August 6, 2008 (73 FR 45635). Due to the substantial number of MEs reported in 2008, the staff submitted a reproposed rule to the Commission for consideration in May of 2010. However, the Commission disapproved the staff’s recommendations and directed the staff to work closely with the ACMUI and the broader medical and stakeholder community to develop ME definitions and to hold a series of stakeholder workshops to discuss issues associated with the MEs.

The ACMUI Permanent Implant Brachytherapy Subcommittee (PIBS) issued a report, with recommendations, which was unanimously approved by the ACMUI at its October 20, 2010, meeting (ADAMS Accession No. ML103540385). The PIBS report included the caveat that it was to be considered an interim report and that it might be revised in response to additional stakeholder input. The ACMUI meeting in April 2011 was devoted to issues associated with the ME definition. The meeting was webcast, providing an opportunity for further public involvement on this issue.

The ACMUI final report (ADAMS Accession No. ML11292A139), which revised the earlier interim report on prostate brachytherapy regulation, was provided to the NRC following the ACMUI October 18, 2011, teleconference public meeting. The final report reflected the principal positions and recommendations provided by participants during the NRC public workshops; in particular, the report included the recommendation to change from dose-based ME criteria for the treatment site to source-strength based criteria. The final report included a quantitative metric, the "octant approach," for determining that a distribution of implanted sources was irregular enough (i.e., demonstrating "bunching") to consider the procedure as an ME. The final report also included a dose-related ME criterion for the treatment site.

However, in a letter to the Chairman of the ACMUI dated November 30, 2011 (ADAMS Accession No. ML11341A051), the American Society for Radiation Oncology (ASTRO) expressed criticism of the ACMUI final report. The ASTRO considered the ME definition recommended by the ACMUI to be complex, difficult to regulate, and likely to cause confusion in practice. Consequently, a revised final report (ADAMS Accession No. ML12038A279) that simplified the ME criteria for the treatment site, and removed the "octant approach" and direct reference to absorbed dose, was issued by the PIBS. The revised final report was, with minor modification, approved by the ACMUI during its February 7, 2012, teleconference public meeting and was subsequently, in a letter to the Chairman of the ACMUI (ADAMS Accession No. ML12044A358), characterized as an improvement by ASTRO.

The staff used the recommendations in the ACMUI revised final report, along with the substantial input from stakeholders gathered in the two facilitated public workshops and the three ACMUI public meetings in 2011 and early 2012, to develop the recommendations conveyed to the Commission on April 6, 2012, in SECY-12-0053. In a Commission meeting held April 24, 2012 (ADAMS Accession No. ML12116A294), participating representatives from

ACMUI, ASTRO, and American Brachytherapy Society (ABS) endorsed the recommendations for modification of the requirements in 10 CFR 35.40 and 35.3045 that are contained in SECY-12-0053. The NRC notes that ASTRO and ABS representatives suggested eliminating the criterion for ME reporting, which requires reporting of excessive dose to normal tissue structures within the treatment site. However, this ACMUI-recommended ME reporting criterion for normal tissue structures located within the treatment site was retained in SECY-12-0053 because ACMUI and the staff determined there needs to be some form of ME reporting criterion for overdosing of normal tissue structures located within the treatment site.

The ACMUI recommendations, as approved by the Commission in SRM-SECY-12-0053, "Recommendations on Regulatory Changes for Permanent Implant Brachytherapy Programs" (ADAMS Accession No. ML122260211), are applicable to all permanent implant brachytherapy procedures using radioactive sources for all treatment sites.

Consistent with the ACMUI recommendations, all of the proposed ME criteria reflect circumstances in which there is actual or potential harm to a patient resulting from an ME. The proposed ME criteria are primarily source-strength based for the treatment site, and dose-based for the absorbed dose to normal tissues. The proposed ME criteria for permanent implant brachytherapy are:

1) For the treatment site (documented in the pre-implantation portion of the WD), an ME has occurred if 20 percent or more of the implanted sources documented in the post-implantation portion of the WD are located outside of the intended implant location.

In supporting this recommendation, the NRC believes that source strength/positioning is the measurable metric/surrogate for dose, as related to harm/potential harm for permanent brachytherapy implant MEs. The 20 percent variance limit (from physician intention) is consistent with the recommendation of the ACMUI for all medical uses of byproduct material as described in SECY-05-0234.

2) For normal-tissue structures, an ME has occurred if: a) for structures located outside of the treatment site (for example the bladder or rectum for prostate implant treatments), the dose to the maximally exposed 5 contiguous cubic centimeters of tissue exceeds 150 percent of the absorbed dose prescribed to the treatment site in the pre-implantation portion of the WD; or b) for intra-target normal structures, the maximum absorbed dose to any 5 contiguous cubic centimeters of tissue exceeds150 percent of the dose the tissue would have received based on the approved pre-implant dose distribution.

The size of the normal tissue, 5 cubic centimeters, is based on ACMUI's recommendation in its report. In its recommendation, the ACMUI stated that the 5 contiguous cubic centimeters dose-volume specification avoids the high variation in dose sometimes seen in point doses and has cited literature to support that as being a relevant quantity for toxicity. In this proposed rule, the NRC is specifically inviting comments on the selection of the specified volume of the normal tissues located both outside and within the treatment site in defining MEs.

The proposed rule specifies that these dose determinations must be made within 60 days from the date the treatment was administered unless accompanied by written justification about patient unavailability after treatment. The NRC believes that 60 days provides adequate time to make implanted source location and dose assessments to determine if an ME has occurred. The AAPM, in its Task Group Report 137, entitled, "AAPM recommendations on dose prescription and reporting methods for permanent interstitial brachytherapy for prostate cancer," recommends that post-implant dosimetry for iodine-125 implants should be performed at 1 month (plus or minus 1 week) after the procedure. For palladium-103 and cesium-131 implants, it recommends that post-implant dosimetry be performed at 16 (plus or minus 4) days and 10 (plus or minus 2) days, respectively. The 60-day time limit is also consistent with the ACMUI recommendation. The NRC recognizes that some patients may not be able to return to the

treatment center for the dose assessment, and the proposed rule addresses that concern by adding “unless accompanied by written justification about patient unavailability.”

Because of this dose-based ME criterion for organs and tissues other than the treatment site, there is an implicit operational requirement for post-implant imaging, as strongly recommended during the public workshops and as practiced in most clinical facilities.

3) An ME has occurred if a treatment involves: a) using the wrong radionuclide; b) delivery to the wrong patient or human research subject; c) source(s) implanted directly into the wrong site or body part, i.e., not in the treatment site identified in the WD; d) using leaking sources; or e) a 20 percent or more error in calculating the total source strength documented in the pre-implantation WD (plus or minus 20 percent is used for the ME threshold for source strength variance because plus or minus 10 percent is considered too close to the actual variance associated with this quantity in clinically acceptable implant procedures).

The proposed criterion related to sources implanted directly into the wrong site or body part (i.e., not in the treatment site identified in the WD) directly reflects an ACMUI recommendation. Note that the proposed criterion would require that even a single sealed source directly delivered to the wrong treatment site would constitute an ME that must be reported. However, this proposed criterion is not more restrictive than the current regulation, which requires reporting of a dose of 0.5 sievert (50 rem) to an organ or tissue, since the localized dose associated with even one misplaced source would far exceed the current 0.5 sievert (50 rem) dose threshold.

The current WD requirements for manual brachytherapy in § 35.40(b)(6) primarily reflect requirements associated with temporary implant brachytherapy medical use. The WD requirements in § 35.40 would be amended to establish separate WD requirements appropriate for permanent implant brachytherapy. The WD for permanent implant brachytherapy would consist of two portions: the first portion of the WD would be prepared before the implantation,

and the second portion of the WD would be completed after the procedure, but before the patient leaves the post-treatment recovery area. For permanent implant brachytherapy, the WD portion prepared before the implantation would require documentation of the treatment site, the radionuclide, the intended absorbed dose to the treatment site, and the corresponding calculated source strength to deliver that dose. If the treatment site has normal tissues located within it, the WD would also allow documentation of the expected absorbed dose to normal tissue as determined by the AU. The post-implantation portion of the WD would require the documentation of the number of sources implanted, the total source strength implanted, the signature of an AU for § 35.400 uses for manual brachytherapy, and the date. It would not require the documentation of dose to the treatment site.

Based on ACMUI input and information gained at public workshops, the NRC understands that the final WD documentation related to these § 35.40 permanent implants must reflect the medical situation encountered during the surgical procedure. Therefore, in defining an ME involving the treatment site for permanent implants, the NRC based the criterion for an ME on the percentage of implanted sources that are outside the treatment site as documented in the post-implantation portion of the WD rather than defining an ME based on a comparison of the implanted total source strength to the calculated total source strength documented in the pre-implantation portion of the WD. This proposed definition differs from the ME definition for all other brachytherapy procedures where the dose comparisons are made with what was prescribed in the WD prepared/revised before the procedure.

Conforming changes would be made to § 35.41, “Procedures for administrations requiring a written directive,” to include permanent implant brachytherapy. Although the current § 35.41(a)(2) requires licensees to determine if the administration is in accordance with the written directive, there is no specific requirement that a licensee determine that an administered dose or dosage has met an ME criterion defined in § 35.3045. The ME reporting criteria are

defined in § 35.3045, but the current regulations do not require that a licensee have procedures to make that determination. Section 35.41 would be amended to require that a licensee include procedures for determining if an ME has occurred. For all permanent implant brachytherapy, this section would also be amended to require that a licensee develop additional procedures to include an evaluation of the placement of sources as documented in the completion portion of the WD, dose assessments to maximally exposed 5 contiguous cubic centimeters of normal tissue located both inside and outside of the treatment site, and to include that these assessments be made within 60 days from the date the treatment was performed.

Currently § 35.3045, Report and notification of a medical event, is designated as Compatibility Category C for the Agreement States. Input provided at the public meetings conducted in New York City, New York, on June 20-21, 2011, and in Houston, Texas, on August 11-12, 2011, and from the ACMUI prompted the NRC to revisit compatibility category. The Commission, after considering the issue, is proposing that the compatibility for reporting MEs for the Agreement States be designated as a Compatibility Category B.

Additional information on Agreement State compatibility designations can be found in Section VIII, Agreement State Compatibility, of this document.

b. Amending preceptor attestation requirements.

The current regulations in 10 CFR part 35 provide three pathways for individuals to satisfy T&E requirements to be approved as an RSO, AMP, ANP, or AU. These pathways are: 1) approval of an individual who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State (certification pathway); 2) approval based on an evaluation of an individual's T&E (alternate pathway); or 3) identification of an individual's approval on an existing NRC or Agreement State license.

Under both the certification and the alternate pathway, an individual seeking authorization for medical byproduct material must obtain written attestation signed by a

preceptor with the same authorization. The attestation must state that the individual has satisfactorily completed the necessary T&E requirements and has achieved a level of competency sufficient to function independently in the position for which authorization is sought.

During a briefing held on April 29, 2008 (ADAMS Accession No. ML12116A294), with the Commission, the ACMUI recommended that the attestation requirements be revised. The ACMUI expressed concern that the existing requirements have had unintended consequences that, if not corrected, would impact the availability of authorized individuals; i.e., there would likely be a shortage of authorized individuals to provide medical care as a result of the reluctance of preceptors to sign attestations. The ACMUI recommended that attestations be eliminated for the board certification pathway. In the ACMUI's view, by meeting the board requirements, a curriculum and a body of knowledge can be defined, and progress toward meeting defined requirements can be measured. Further, the ACMUI asserted that a board certification indicates that the T&E requirements have been met, and the Maintenance of Certification provides ongoing evidence of current knowledge. Therefore, the ACMUI argued that an additional attestation for the board certified individuals was not needed.

The ACMUI also recommended that the attestation requirements associated with the alternate pathways be modified to delete the requirement for an attestation of an individual's radiation safety-related competency being sufficient to function independently as an authorized person for the medical uses being requested. The reason for the recommendation was that the ACMUI believed that signing an attestation of competence results in a perceived risk of personal liability on the part of the individual signing the attestation and that preceptors are reluctant to accept this risk.

In addition, the ACMUI recommended that the attestation submitted under the alternate pathway be considered acceptable if provided by a residency program director representing a consensus of an authoritative group, irrespective of whether the program director personally met

the requirements for authorized user status. The ACMUI advised that training of residents is a collective process and entails the collective judgment of an entire residency program faculty, whereas preceptor attestation is an individual process, and an individual preceptor typically would provide only a small portion of the T&E.

Following the April 29, 2008, meeting of the ACMUI, in an SRM dated May 15, 2008 (ADAMS Accession No. ML081360319), the Commission directed the staff to work with the ACMUI and the Agreement States to provide recommendations to the Commission with regard to amending the NRC's requirements for preceptor attestation for both board certified individuals and for individuals seeking authorization via the alternate pathway. The staff was also directed to consider additional methods, such as the attestation being provided by consensus of an authoritative group.

Following both consideration of the position of the ACMUI, which the staff determined was clear and consistent with its long-held position on this issue, and interactions with regional NRC staff and the Agreement States, the staff provided its recommendations on this issue to the Commission on November 20, 2008, in SECY-08-0179, "Recommendations on Amending Preceptor Attestation Requirements in 10 CFR part 35, Medical Use of Byproduct Material" (ADAMS Accession No. ML083170176). The staff recommended that the Commission approve development of the following modifications to the 10 CFR part 35 attestation requirements: 1) eliminate the attestation requirement for individuals seeking authorized status via the board certification pathway; 2) retain the attestation requirement for individuals seeking authorized status via the alternate pathways; however, replace the text stating that the attestation demonstrates that the individual "has achieved a level of competency to function independently" with alternative text such as "has demonstrated the ability to function independently" to fulfill the radiation safety-related duties required by the license; and 3) accept attestations from residency program directors, representing consensus of residency program faculties as long as at least

one member of the residency program faculty is an authorized individual in the same category as that requested by the applicant seeking authorized status.

In an SRM dated January 16, 2009, to SECY-08-0179 (ADAMS Accession No. ML090160275), the Commission approved these recommendations and directed the staff to develop the proposed rule language for the attestation requirements for the alternate pathway in concert with the ACMUI and the Agreement States.

The proposed changes to remove the attestation requirement for board certified individuals were broadly supported during the public workshops conducted in the summer of 2011. The panelists (which included members of the ACMUI and the Agreement States) at the workshops recommended that the NRC should remove the requirement for attestation for board certified individuals. They believed that board certification coupled with the recentness of training requirements should be sufficient for the regulator's needs. With regard to the language of attestation (for the alternate pathway), they believed that the preceptors should not be attesting to someone's competency; rather, they should be attesting to the individual's T&E necessary to carry out one's responsibility independently. At the April 2011 ACMUI meeting, the ACMUI advised that the attestation language should be revised to say that the individual has received the requisite T&E to fulfill the radiation safety-related duties required by the license. The proposed rule language reflects this approach.

The proposed rule would amend T&E requirements in multiple sections of 10 CFR part 35 with regard to the attestation requirements in accordance with the staff's recommendations in SECY-08-0179.

c. Extending grandfathering to certain certified individuals (PRM-35-20).

The petition is discussed in Section III, Petition for Rulemaking (PRM-35-20), of this document.

d. Requiring increased frequency of testing to measure Mo-99 breakthrough.

Current regulations in § 35.204(a) prohibit a licensee from administering a radiopharmaceutical to humans that exceeds 0.15 microcuries of Mo-99 per millicurie of Tc99m. Section 35.204(b) requires that a licensee that uses Mo-99/Tc-99m generators for preparing a Tc-99m radiopharmaceutical measure the Mo-99 concentration of the first eluate to demonstrate compliance with the specified concentrations; however a generator can be eluted several times to obtain Tc-99m for formulating radiopharmaceuticals for patient use.

The Mo-99 breakthrough, which exceeds the permissible concentration listed in § 35.204(a), may cause unnecessary radiation exposures to patients. The administration of higher levels of Mo-99 could potentially affect health and safety, as well as have an adverse effect on nuclear medicine image quality and medical diagnosis.

Generator manufacturers have always recommended testing each elution prior to use in humans. Before 2002, § 35.204 required a licensee to measure the Mo-99 concentration of each eluate. However, the NRC revised § 35.204 in April 2002 because the medical and pharmaceutical community considered frequency of Mo breakthrough to be a rare event. Therefore, the Commission decided that measuring only the first elution was necessary to detect manufacturing issues or generators that may have been damaged in transport.

From October 2006 to February 2007, and again in January 2008, medical licensees reported to the NRC that numerous generators had failed the Mo-99 breakthrough tests. Some licensees reported the failed tests in the first elution, while some reported an acceptable first elution but failed subsequent elutions. One generator manufacturer voluntarily reported 116 total elution test failures in 2008. Based upon the numerous reports of failed Mo-99 breakthrough measurements noted in the subsequent elutions, the NRC proposes to amend § 35.204 to return to the pre-2002 performance standard, which required licensees to measure the Mo-99 concentration for each elution of the Mo-99/Tc-99m generator.

e. Requiring reporting and notification of failed Mo-99/Tc-99m and Sr-82/Rb-82 generators.

The regulations do not currently require reporting to the NRC when an elution from a Mo-99/Tc-99m or Sr-82/Rb-82 generator exceeds the regulatory limit in § 35.204(a). As discussed in this section, eluates from generators for making Tc-99m radioactive drugs exceeded the permissible concentration listed in § 35.204(a) on numerous occasions in 2006, 2007, and 2008. Additionally, in 2011, contamination issues with Sr-82/Rb-82 generators were discovered when several individuals were identified with unexpected levels of Sr-82 and Sr-85. These individuals had undergone Rb-82 chloride cardiac scanning procedures several months before and had received these radionuclides in levels greatly in excess of the administration levels permitted in § 35.204 for Sr-82/Rb-82 generators. Further investigations showed that at least 90 individuals at one facility and 25 at another facility received levels of Sr-82 or Sr-85 that exceeded the levels permitted in § 35.204. Of these patients, at least three had levels of Sr-82 and Sr-85 high enough to result in reportable MEs as defined in § 35.3045.

Because the reporting of a failed generator is voluntary, the NRC had difficulty determining the extent of the problem. Reporting of results in excess of the levels in § 35.204 for the Sr-82/Rb-82 generators could have alerted users and regulators to issues associated with these generators and possibly reduced the number of patients exposed to excess Sr-82 and Sr-85 levels. Breakthrough of Mo-99, Sr-82 and Sr-85 contamination can lead to unnecessary radiation exposure to patients.

The NRC proposes to add a new reporting requirement related to breakthrough of Mo-99, and Sr-82 and Sr-85 contamination. This new reporting requirement in § 35.3204(a) would require a licensee to report to the NRC and the manufacturer or distributor of medical generators within 30 days any measurement that exceeds the limits specified in § 35.204(a).

f. Allowing ARSOs to be named on a medical use license.

Currently, § 35.24(b) requires a licensee's management to appoint an RSO who, in writing, agrees to be responsible for implementing the radiation protection program. However, the regulations in 10 CFR part 35 do not allow the naming of more than one permanent RSO on a license.

During an ACMUI meeting in June 2007 (ADAMS Accession No. ML072060526), concern was expressed that this restriction has been contributing to a shortage of available RSOs to serve as preceptors. The ACMUI stated that the restriction has been creating a situation in which an individual who is qualified and performing the same duties as an RSO cannot be recognized or listed as an RSO, and that it has been creating a situation in which an individual working as a contractor RSO at several hospitals or other licensed locations is unable to have actual day-to-day oversight at the various facilities.

The proposed rule would amend the regulations in 10 CFR part 35 to allow a licensee to appoint a qualified individual with expertise in certain uses of byproduct material to serve as an ARSO. This individual would be required to complete the same T&E requirements as the named RSO for the individual's assigned sections of the radiation safety program. The ARSOs would have oversight duties for the radiation safety operations of their assigned sections, while reporting to the named RSO. The proposed regulation would continue to allow a licensee to name only one RSO on a license. The RSO would continue to be responsible for the day-to-day oversight of the entire radiation safety program. Similarly, a licensee with multiple operating locations could appoint a qualified ARSO at each location where byproduct material is used; however, the named RSO would remain responsible for the overall licensed program. Under the proposed rule, the ARSO would be named on the license for the types of use of byproduct material for which this individual has been assigned duties and tasks by the RSO.

The NRC believes that allowing an ARSO to be named on a license would increase the number of individuals who would be available to serve as preceptors for individuals seeking to

be appointed as RSOs or ARSOs. Also, by being named on a license, an ARSO could more easily become an RSO on other licenses for the types of uses for which the ARSO is qualified.

In addition, the current regulations allow AUs, AMPs and ANPs to serve as the RSO only on the license for which they are listed. Because AUs, AMPs and ANPs must meet the same requirements to serve as the RSO regardless of which Commission medical license they are identified on, the NRC believes that it is overly restrictive to not allow them to serve as an RSO on any Commission medical license. Therefore, a modification is proposed that would allow an AU, AMP, or ANP listed on any license or permit to serve as an RSO or ARSO. This proposed change would increase the number of individuals available to serve as RSOs and ARSOs on NRC medical licenses. Additionally, these ARSOs and RSOs could serve as preceptors for an individual seeking to be named as the RSO.

The proposed change to allow an ARSO to be named on a license was broadly supported during the public workshops conducted in the summer of 2011. The T&E requirements for an ARSO were discussed, and stakeholders strongly supported the NRC's position that the ARSOs must meet the same qualifications as the RSO for their assigned sections of the radiation safety program.

The proposed rule would amend multiple sections of 10 CFR part 35 to accommodate the new ARSO position.

g. Additional issues and clarifications.

There are additional amendments, which are discussed in Section V, Discussion of Proposed Amendments by Section, of this document.

B. When Would These Actions become Effective?

Generally, the NRC allows an adequate time (30 to 180 days) for a final rule to become effective. The time for the final rule to become effective depends on the scope of the

rulemaking, availability of the conforming guidance, and the complexity of the final rule. With regard to this proposed rule, the NRC proposes that the final rule would become effective 180 days from its publication in the *Federal Register*.

C. Are There Any Cumulative Effects of Regulation Associated With This Rule?

Cumulative effects of regulation (CER) describes the challenges that licensees, certificate holders, States, or other entities may encounter while implementing new regulatory requirements (e.g., rules, generic letters, orders, backfits, inspection findings). The CER is an organizational effectiveness challenge that results from a licensee or impacted entity implementing a significant number of new and complex regulatory actions stemming from multiple regulatory actions, within a limited implementation period and with available resources (which may include limited available expertise to address a specific issue). The CER can potentially distract licensee or entity staff from executing other primary duties that ensure safety or security. The NRC is specifically requesting comment on the cumulative effects of this rulemaking. In developing comments on CER, consider the following questions:

1) In light of any current or projected CER challenges, does the proposed rule's effective date, compliance date, or submittal date(s) provide sufficient time to implement the proposed requirements, including changes to programs, procedures, and the facility?

2) If current or projected CER challenges exist, what should be done to address this situation (e.g., if more time is required to implement the new requirements, what period of time would be sufficient)?

3) Do other (NRC, Agreement States, or other agency) regulatory actions (e.g., orders, generic communications, license amendment requests, and inspection findings of a generic nature) influence the implementation of the proposed requirements?

4) Are there unintended consequences? Does the proposed rule create conditions that would be contrary to the proposed rule's purpose and objectives? If so, what are the consequences and how should they be addressed?

5) Please comment on the NRC's cost and benefit estimates in the regulatory analysis that supports this proposed rule. The draft regulatory analysis is available in ADAMS under Accession No. ML14184A620.

D. Is the NRC Requesting Comments on Other Specific Issues?

1) Volume for determining an absorbed dose to normal tissue for MEs under § 35.3045, Report and notification of a medical event.

Two new criteria for determining if a licensee must report an ME involving permanent implant brachytherapy have a dose-volume specification for an absorbed dose to normal tissue. One proposed criterion is for normal tissue within the treatment site (such as the urethra in prostate implants) and the other proposed criterion is for normal tissue outside the treatment site (such as the bladder or the rectum in prostate implants).

The proposed volume, 5 contiguous cubic centimeters of normal tissue, is based on the recommendations from the ACMUI (ADAMS Accession No. ML12038A279). In its recommendation, the ACMUI stated that the 5 contiguous cubic centimeters dose-volume specification avoids the high variation in dose sometimes seen in point doses and has literature to support it being a relevant quantity for toxicity to an organ at risk.

Because the majority of permanent implants are performed to treat prostate cancer, examples and guidance for the ACMUI recommendations related extensively to that procedure. However, the proposed rule is intended to apply generally to all forms of permanent implants.

The NRC is seeking specific comments, in defining MEs, on the proposed volume of 5 contiguous cubic centimeters dose-volume specification for an absorbed dose to normal tissue located both outside and within the treatment site.

The NRC is also seeking specific comments on whether the application of the proposed medical event definition for normal tissue based on the absorbed dose to the maximally exposed 5 contiguous cubic centimeters during permanent implant brachytherapy is appropriate for all potential treatment modalities, or whether it may result in unintended consequences for tissues or organs adjacent to the treatment site.

2) Implementation Period.

In Section IV.B of this document, the NRC is proposing the effective date of the final rule to be 180 days from the date it is published in the *Federal Register*. The NRC is seeking specific comments on whether a 180 day effective date for the final rule is sufficient to communicate the changes to all practitioners, revise procedures, train on them, and implement the changes.

3) Impact on Clinical Practice.

The NRC is seeking comments on whether any of the proposed changes in this rulemaking are likely to discourage licensees from using certain therapy options or otherwise adversely impact clinical practice, and if so, how.

4) Compatibility Category for the Agreement States on § 35.3045, *Report and notification of a medical event.*

Currently § 35.3045, Report and notification of a medical event, is designated as Compatibility Category C for the Agreement States. This 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 requirements need not be the same as NRC requirements, provided the essential objectives are

met. Under Compatibility Category C, Agreement States may require the reporting of MEs with more restrictive criteria than those required by the NRC.

Some medical licensees have multiple locations, some of which are NRC-regulated and some which are Agreement State-regulated. These licensees would prefer a Compatibility Category B designation for uniformity of practice and procedures among their different locations. A Compatibility Category B designation is for those program elements that apply to activities that have direct and significant effects in multiple jurisdictions.

The OAS has expressed a strong desire to retain a dose-based ME reporting criterion for the treatment site if NRC regulations are revised to include source-strength based criteria for determining MEs for permanent implant brachytherapy. The OAS has no objection to the introduction of the source-strength based criteria, as long as the dose-based criteria can be retained by the Agreement States, which requires § 35.3045 to remain as Compatibility Category C. With a Compatibility Category C designation, the Agreement States could require both the dose-based criterion and source-strength based criterion, as long as the Agreement State reports to the NRC only include the information required by the NRC.

For some Agreement States, Compatibility Category B is difficult to achieve because their regulations have to also meet specific state requirements based on the state agencies in which the radiation control regulators reside. Also, Agreement States may have existing laws requiring the collection of additional information on medical diagnostic and therapy procedures.

If the level of compatibility for § 35.3045 were to be raised to Compatibility Category B, Agreement State requirements would need to be essentially identical to those of the NRC. Compatibility Category B is applied to requirements that have significant direct transboundary health and safety implications. A Compatibility Category B designation would prevent the Agreement State requirements from including any additional requirements, such as diagnostic reports, shorter reporting times, or lower dose limits for reporting.

The ACMUI in its report to the NRC (ADAMS Accession No. ML13071A690), recommended that MEs related to permanent implant brachytherapy be designated as Compatibility Category B. The ACMUI was concerned with proposed designation as Compatibility Category C which would allow the Agreement States to retain the dose-based criteria for definition of an ME for permanent implant brachytherapy. The ACMUI asserted that a Compatibility Category C would continue to result in clinically insignificant occurrences being identified as MEs by Agreement States and thereby perpetuate the confusion associated with the current dose-based criteria. The ACMUI stated that the most important component of the rationale for conversion from dose-based to activity-based criteria is the failure of dose-based criteria to sensitively and to only specifically capture clinically significant MEs in permanent implant brachytherapy.

Because of these divergent positions (the OAS favoring Compatibility Category C and some medical use licensees and the ACMUI favoring Compatibility Category B), the NRC invites comments on the appropriate compatibility category for ME reporting under § 35.3045.

In responding to these issues, please use one of the methods described in Section I, Obtaining Information and Submitting Comments, of this document.

E. What Should I Consider as I Prepare My Comments to the NRC?

Tips for preparing your comments. When submitting your comments, remember to:

i. Identify the rulemaking (RIN 3150- AI63; NRC-2008-0175).

ii. Explain why you agree or disagree with the proposed rule; suggest alternatives and substitute language for your requested changes.

iii. Describe any assumptions and provide any technical information and/or data that you used.

iv. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

v. Provide specific examples to illustrate your concerns, and suggest alternatives.

vi. Explain your views as clearly as possible.

vii. Make sure to submit your comments by the comment period deadline identified.

viii. The NRC is particularly interested in your comments concerning the following issues: Sections IV.C and D. of this document request comment on the cumulative effects of regulation, whether the proposed volume for determining an absorbed dose to normal tissue for MEs is appropriate and applicable for all potential treatment modalities related to permanent implant brachytherapy, the proposed 180-day effective date for the final rule, the proposed rule's impact on clinical practice, and Compatibility Category for the Agreement States on § 35.3045, *Report and notification of a medical event*; Section X of this document requests comment on the use of plain writing; Section XIV requests comment on the draft environmental assessment; Section XV of this document requests comment on the information collection requirements; Section XVI of this document requests comment on the draft regulatory analysis; and Section XVII of this document requests comment on the impact of the proposed rule on small businesses.

V. Discussion of Proposed Amendments by Section

Section 30.34 Terms and conditions of licenses.

Paragraph (g). A new requirement would be added requiring radiopharmacy licensees to report to the NRC the results of testing of generator elutions for Mo-99 breakthrough or Sr-82 and Sr-85 contamination that exceed the permissible concentration listed in § 35.204(a). Reporting would be in accordance with the reporting and notifications in § 35.3204. While the

proposed reporting requirement as well as the requirement to test every elution is new, the testing by licensees of the first elution to ensure that it does not exceed the permissible concentration listed in § 35.204(a) and recording the results of these tests is already required by this paragraph.

This change is being proposed to provide the information to allow the NRC to assess a potential situation quickly and efficiently when issues occur with generators that may cause unwarranted radiation exposure to patients. This issue is discussed further in Section IV, Discussion, of this document.

Section 32.72 Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under 10 CFR part 35.

Paragraph (a)(4). This paragraph would be modified to clarify that the applicant "commits to" rather than "satisfies" the label requirements. Committing to the prescriptive labeling requirements in the regulation in the license application would remove ambiguity related to what must appear on the label.

Paragraph (b)(5)(i). This paragraph would be amended to remove the requirement to obtain a written attestation for individuals seeking to be named as an ANP and who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State to be an ANP. This is a conforming change in support of the removal of the attestation requirement in § 35.55(a) of this chapter for a board certified ANP.

Paragraph (d). The existing requirements in paragraph (d) would be redesignated as (e), and a new paragraph (d) would be added to clarify that the labeling requirements that applicants commit to in paragraph (a) of this section are also applicable to current licensees.

Section 35.2 Definitions.

New definitions for *Associate Radiation Safety Officer* and for *Ophthalmic physicist* would be added to this section and the definition for *Preceptor* would be amended.

The new definition for *Associate Radiation Safety Officer* would identify the requirements an individual would need to meet to be recognized as an ARSO. These requirements include that the individual must meet the specified T&E criteria and that the individual be currently listed as an ARSO on a medical license or permit for the types of use of byproduct material for which the individual had been assigned tasks and duties by the RSO. Additional information on ARSOs is located in Section IV, Discussion, of this document.

The new definition for O*phthalmic physicist* would identify the requirements an individual would need to meet to be recognized as an ophthalmic physicist. These requirements include that the individual must meet the specified T&E criteria in § 35.433(a)(2) and that the individual must be currently listed as an ophthalmic physicist on a specific medical use license issued by the Commission or an Agreement State or a medical use permit issued by a Commission master material licensee. A written attestation would not be required for this individual.

The definition for *Preceptor* would be amended to add ARSO to the list of individuals who provide, direct, or verify T&E required for an individual to become an AU, an AMP, an ANP, or an RSO. This is a conforming change in support of the new definition for *Associate Radiation Safety Officer.*

Section 35.12 Application for license, amendment, or renewal.

This section would be amended to remove the requirement to submit copies of NRC Form 313, Application for Material License, or a letter containing information required by NRC Form 313 when applying for a license, an amendment, or renewal. This section would clarify what information should be submitted and add a requirement to submit information on an individual seeking to be identified as an ARSO or as an ophthalmic physicist.

Paragraph (b)(1). As part of the application for a medical use license, this paragraph would be amended to remove the requirement to submit an additional copy of NRC Form 313. This change would relieve the burden on the applicant by requiring less paperwork to be submitted. It would also require the applicant to submit the T&E qualifications for one or more ARSOs and ophthalmic physicists that are to be identified on the license.

Paragraph (c). For license amendments or renewals, this paragraph would be amended to remove the requirement to submit a copy of NRC Form 313 or a letter containing information required by NRC Form 313. This change would relieve the burden on the licensee by requiring less paperwork to be submitted. Additionally, it would clarify that the letter submitted in lieu of NRC Form 313 must contain all the information required by NRC Form 313.

Paragraph (d). This paragraph would be amended and restructured to clarify what information must be included in an application for a license or amendment for medical use of byproduct material as described in § 35.1000.

Section 35.13 License amendments.

This section would be amended by revising paragraph (b), redesignating paragraphs (d) through (g) as paragraphs (e) through (h), revising redesignated paragraphs (g) and (h), and adding new paragraphs (d) and (i).

Paragraph (b). The paragraph would be amended to allow a licensee to permit an individual to work as an ophthalmic physicist before applying for a license amendment, provided that the individual is already listed on a medical license or permit. The definition of an O*phthalmic physicist* in § 35.2 would allow the ophthalmic physicist to be named only on a specific medical use license and not on a broad scope medical license. This limitation is to ensure that individuals seeking to be named as an ophthalmic physicist have their T&E reviewed by a regulatory authority as the position is new and unfamiliar to the medical

community. Additionally, broad scope licensees already have ready access to AMPs to perform the requirements listed in § 35.433.

Paragraph (d). This new paragraph would be added to require a licensee to apply for and receive a license amendment before permitting an individual to work as an ARSO or before the RSO assigns different tasks and duties to an ARSO currently authorized on the license.

Paragraph (i). This new paragraph would be added to this section to allow a licensee to receive sealed sources from a new manufacturer or a new model number for a sealed source listed in the Sealed Source and Device Registry (SSDR) used for manual brachytherapy for quantities and isotopes already authorized by its license without first seeking a license amendment. This change is proposed to provide manual brachytherapy licensees greater flexibility in obtaining the sealed sources necessary for patient treatments in a timely manner.

Section 35.14 Notifications.

Paragraph (a). The paragraph would be restructured to separate the notification requirements for an individual who is certified by a board that is recognized by the NRC or an Agreement State from the requirements for an individual who is not certified by a board that is recognized by the NRC or an Agreement State but is listed on a license. Additionally, the requirement to provide a written attestation is removed for an individual who is certified by a board that is recognized by the NRC or an Agreement State. Further discussion on removing the written attestation requirement can be found in Section IV, Discussion, of this document. Licensees may not permit an individual who is not certified by a board that is recognized by the NRC or an Agreement State or does not meet the requirements in § 35.13(b) to work under their license without first obtaining an amendment to their license.

Paragraph (a)(1). This paragraph would be restructured to more clearly identify the verification that a board certified individual would need to provide along with a copy of the individual's board certification. This proposed change does not impose any new requirements.

Paragraph (a)(2). This paragraph would retain the notification requirements for individuals who are authorized to work under § 35.13(b) who are not certified by a board that is recognized by the NRC or an Agreement State but are listed on a license. These individuals would be only authorized for the materials and uses for which they were previously authorized. This proposed change does not impose any new requirements.

Paragraph (b)(1). This paragraph would be amended to require a licensee to notify the Commission within 30 days after an ARSO or ophthalmic physicist has a name change or discontinues performance of their duties under the license.

Paragraph (b)(6). This new paragraph would require a licensee to notify the NRC no later than 30 days after receiving a sealed source from a new manufacturer or a new model number listed in the SSDR for manual brachytherapy for quantities and isotopes already authorized by the license.

Section 35.24 Authority and responsibilities of the radiation protection program.

This section would be amended to allow licensees to appoint qualified individuals with expertise in certain uses of byproduct material to be named as ARSOs on a license or permit.

Paragraph (b). This paragraph would be modified to specify that a licensee's management may appoint one or more ARSOs. These appointed ARSOs would have to be named on a medical license or permit for the types of use of byproduct material for which the RSO, with the written agreement of the licensee's management, would assign tasks and duties.

The licensee's management would still be limited to naming one RSO who would remain responsible for implementing the entire radiation protection program. The RSO would be

prohibited from delegating authority and responsibilities for implementing the radiation protection program. Each ARSO would have to agree in writing to the tasks and duties assigned by the RSO.

Paragraph (c). An administrative change would be made to this paragraph to remove the phrase "an authorized user or" as it is redundant with "an individual qualified to be a Radiation Safety Officer under 35.50 and 35.59" in the same sentence.

The proposed position of ARSO is discussed further in Section IV, Discussion, of this document.

Section 35.40 Written Directives.

Paragraph (b) of this section would be restructured and amended to accommodate specific requirements for a WD for permanent implant brachytherapy. Existing paragraph (b)(6) would be redesignated as paragraph (b)(7) and a new paragraph (b)(6) would be added to specify the information that must be included in the pre-implantation (before implantation) and post-implantation (after implantation) portions of the WD for permanent implant brachytherapy.

Paragraph (b)(6). This new paragraph would detail the specific WD requirements for permanent implant brachytherapy. Specifically, it would clarify that the WD is divided into two portions, i.e., the pre-implantation portion and the post-implantation portion. The pre-implantation WD portion would require documentation of the treatment site, the radionuclide, the intended absorbed dose to the treatment site, and the corresponding calculated source strength to deliver that dose. If the treatment site has normal tissues located within it (such as the urethra in prostate implants), the WD would also allow documentation of the expected absorbed dose to normal tissue as determined by the AU. The information required by the pre-implantation portion of the WD must be documented prior to the start of the implantation and cannot be modified once the implantation begins. The proposed rule would

retain the current provision that an AU could revise an existing WD in writing or orally before the implantation begins.

The post-implantation portion of the WD would require the documentation of the number of sources implanted, the total source strength implanted, the signature of an AU for § 35.400 uses for manual brachytherapy, and the date. It would not require the documentation of dose to the treatment site. The information required by the post-implantation portion of the WD must be documented before the patient leaves the post-treatment recovery area. The term "post-treatment recovery area," as used in paragraph (b)(6)(ii), means the area or place where a patient recovers immediately following the brachytherapy procedure before being released to a hospital room or, in the case of an outpatient treatment, released from the licensee's facility.

Paragraph (c) of this section would be restructured for clarity.

Section 35.41 Procedures for administrations requiring a written directive.

This section would be amended by adding two new paragraphs with requirements that the licensee must address when developing, implementing, and maintaining written procedures to provide high confidence that each administration requiring a WD is in accordance with the WD.

Paragraph (b)(5). This new paragraph would require that the licensee's procedures for any administration requiring a WD must include procedures for determining if an ME, as defined in § 35.3045 of this part, has occurred.

Paragraph (b)(6). This new paragraph would require the licensee to develop specific procedures for permanent implant brachytherapy programs. At a minimum, the procedures would include determining post-implant source position verification and normal tissue dose assessment within 60 calendar days from the date the implant was performed. If the licensee cannot make these determinations within the 60 calendar days because the patient is not

available, then the licensee would have to provide written justification that these determinations could not be made due to patient unavailability.

The determinations that would be required include: 1) the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the WD; 2) the absorbed dose to the maximally exposed 5 contiguous cubic centimeters of normal tissue located outside of the treatment site; and 3) the absorbed dose to the maximally exposed 5 contiguous cubic centimeters of normal tissue located within the treatment site.

The NRC is proposing this change because the current regulations do not have a defined time within which the licensee must determine if the implantation of radioactive sealed sources was done as prescribed in the WD. The occurrence of a substantial number of MEs in 2008 underscored the need to add this requirement to the regulations, as post-implant source position verifications and normal tissue dose assessments for some of these MEs were not determined for more than a year after the patient was treated. The NRC believes that these determinations must be made in a timely manner to ensure that patients and their physicians have information upon which to base decisions regarding remedial and prospective health care.

A 60-calendar-day time frame is proposed to ensure that the licensee has ample time to make arrangements for the required determinations. These determinations would be used to partially assess if an ME, as defined in § 35.3045, has occurred.

Section 35.50 Training for Radiation Safety Officer.

Multiple changes to this section are proposed. They include amending the title of the section to add “and Associate Radiation Safety Officer” as the T&E requirements for this new position would also be made applicable to the ARSO. Other changes proposed are:
1) removing the requirement to obtain a written attestation for individuals qualified under

paragraph (a) of this section; 2) adding a provision that would allow individuals identified as an AU, AMP, or ANP on a medical license to be an RSO or an ARSO not only on that current license but also on a different medical license; 3) adding a provision to allow an individual to be named simultaneously both as the RSO and AU on a new license application; and 4) certain administrative clarifications.

Paragraph (a). The requirement for individuals seeking to be named as an RSO or ARSO to obtain a written attestation would be removed for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. Individuals seeking to be named as RSOs or ARSOs via the certification pathway would still need to meet the training requirements in the new paragraph (d) of this section. Further discussion on removing the written attestation requirement can be found in Section IV, Discussion, of this document.

Paragraph (b)(1)(ii). This paragraph is amended to allow an ARSO, in addition to the RSO, to provide supervised work experience for individuals under the alternate pathway. The ARSO would be limited to providing supervised work experience in those areas for which the ARSO is authorized on a medical license or permit.

Paragraph (b)(2). Reserved paragraph (b)(2) would be revised to contain the requirements for an RSO or ARSO under the alternate pathway to obtain a written attestation signed by either an RSO or ARSO. The language that is required in the written attestation would be amended to state that the individual "is able to independently fulfill the radiation safety-related duties as an RSO or ARSO," rather than that the individual "has achieved a level of radiation safety knowledge to function independently" as an RSO or ARSO.

Paragraph (c)(1). This paragraph would be modified to allow medical physicists who have been certified by a specialty board whose process has been recognized by the Commission or an Agreement State under § 35.51(a) to be named as ARSOs.

Additionally, the requirement for a written attestation for these medical physicists is removed. A medical physicist seeking to be named as an RSO or an ARSO would still need to meet the training requirements in paragraph (d) of this section.

Paragraph (c)(2). This paragraph would be modified to allow AUs, AMPs, and ANPs identified on a Commission or an Agreement State medical license or permit to be an RSO or ARSO on any Commission or an Agreement State license or Commission master material permit provided that the AU, AMP, or ANP has experience with the radiation safety aspects of similar types of use of byproduct material. The current regulations limit AUs, AMPs and ANPs to serve as an RSO only on the license on which they are listed.

The AUs, AMPs and ANPs must meet the same requirements to serve as the RSO regardless of which Commission medical license they are identified on; therefore, not allowing them to serve as an RSO on any Commission medical license is overly restrictive. This change would increase the number of individuals available to serve as RSOs and ARSOs on NRC medical licenses.

Paragraph (c)(3). This new paragraph would allow an individual who is not named as an AU on a medical license or permit, but is qualified to be an AU, to be named simultaneously as the RSO and the AU on the same new medical license. Current regulations, under § 35.50(c)(2), do not permit an individual who is not an AU on a license, but qualified to be an AU, to be an RSO. The individual must have the experience with the radiation safety aspects of the byproduct material for which the authorization is sought. An individual may meet the qualifications of an AU via the board certification or alternate pathway. An individual who is using the alternate pathway to be named simultaneously as the RSO and the AU on the same new medical license must obtain a written attestation.

The provision would provide flexibility for an individual to serve as both an AU and as the RSO on a new medical license and would make medical procedures more widely available, especially in rural areas.

Paragraph (d). This paragraph would be amended to include ARSOs as individuals who can provide supervised training to an individual seeking recognition as an RSO or ARSO.

Section 35.51 Training for an authorized medical physicist.

Paragraph (a). The requirement for individuals seeking to be named as an AMP to obtain a written attestation would be removed for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. Further discussion on removing the written attestation requirement can be found in Section IV, Discussion, of this document.

Paragraph (a)(2)(i). This paragraph would be amended to clarify that an AMP who provides supervision for meeting the requirements of this section, be certified in medical physics by a specialty board whose certification process has been recognized under this section by the Commission or an Agreement State.

Current regulations allow a medical physicist with any board certification in diagnostic or therapeutic medical physics to serve as a supervising medical physicist in therapeutic procedures. The NRC believes that the supervision for therapeutic procedures must be provided by a medical physicist who is certified in medical physics by a specialty board recognized under § 35.51 by the Commission or an Agreement State.

Paragraph (b)(2). The wording in this paragraph would be revised to conform to the removal of the attestation requirement in paragraph (a) of this section. It would also be amended to incorporate the new language that the written attestation would verify that the

individual is able to independently fulfill the radiation safety-related duties, rather than has achieved a level of competency to function independently, as an AMP.

Section 35.55 Training for an authorized nuclear pharmacist.

Paragraph (a). The requirement for individuals seeking to be named as an ANP to obtain a written attestation would be removed for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State.

Paragraph (b)(2). The wording in this paragraph would be revised to conform to the removal of the attestation requirement in paragraph (a) of this section. It would also be amended to incorporate the new language that the written attestation would verify that the individual is able to independently fulfill the radiation safety-related duties, rather than has achieved a level of competency to function independently, as an ANP.

Section 35.57 Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist.

Multiple changes to this section are proposed. Most of the proposed changes are to the T&E requirements in response to the requested amendments in the Ritenour petition. This includes recognizing the board certifications of individuals certified by boards recognized under subpart J, which was removed from 10 CFR part 35 in a rulemaking dated March 30, 2005 (70 FR 16336), and making administrative clarifications. Additional information on the Ritenour petition, as it relates to this rulemaking, is located in Section IV, Discussion, of this document.

Paragraph (a)(1). This paragraph would be modified to add AMPs and ANPs identified on a Commission or an Agreement State license or a permit issued by a Commission or an

Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope on or before October 24, 2005, as individuals that would not need to comply with the training requirements of §§ 35.50, 35.51, or 35.55, respectively. In addition, the date is changed for individuals named on a license as RSOs, teletherapy or medical physicists, AMPs, nuclear pharmacists, or ANPs from October 24, 2002, to October 24, 2005, because during the 3-year time frame applicants could have qualified under the now removed subpart J or the new T&E requirements under §§ 35.50, 35.51, or 35.55.

However, under the proposed rule, RSOs and AMPs identified by this paragraph would have to meet the training requirements in §§ 35.50(d) or 35.51(c) as appropriate, for any materials or uses for which they were not authorized prior to the effective date of the rule. This is not a new training requirement. Current regulations require individuals qualifying under §§ 35.50 and 35.51 as RSOs and AMPs to meet the training requirements in § 35.50(e) and § 35.51(c). Individuals excepted by this paragraph would still need to meet the recentness-of-training requirements in § 35.59.

Paragraph (a)(2). This paragraph would recognize individuals certified by the named boards in the now-removed subpart J of 10 CFR part 35 on or before October 24, 2005, who would not need to comply with the training requirements of § 35.50 to be identified as an RSO or as an ARSO on a Commission or an Agreement State license or Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005. Individuals excepted by this paragraph would still need to meet the recentness-of-training requirements in § 35.59 and, for new materials and uses, the training requirements in § 35.50(d).

Paragraph (a)(3). This paragraph would recognize individuals certified by the named boards in the now-removed subpart J of 10 CFR part 35 on or before October 24, 2005, who would not need to comply with the training requirements of § 35.51 to be identified as a AMP on

a Commission or an Agreement State license or Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005. Removal of subpart J from 10 CFR part 35 was effective on October 24, 2005. These individuals would be exempted from these training requirements only for those materials and uses these individuals performed on or before October, 24, 2005. Individuals excepted by this paragraph would still need to meet the recentness-of-training requirements in § 35.59 and, for new materials and uses, the training requirements in § 35.51(c).

Paragraph (a)(4). This paragraph would be renumbered from current paragraph (a)(3) and not be revised.

Paragraph (b)(1). This paragraph would be amended to change the date an individual named on a license as an AU from October 24, 2002, to October 24, 2005, because during that 3-year time frame, an applicant could have qualified as an AU either under the former subpart J or the revised T&E requirements in subparts D through H of 10 CFR part 35.

Additionally, the paragraph would be amended to clarify that an individual authorized before, rather than just on, October 24, 2005, would not be required to comply with the T&E requirements in subparts D through H of 10 CFR part 35 for those materials and uses that they performed on or before that date.

Paragraph (b)(2). This paragraph would be restructured and expanded to recognize a physician, dentist, or podiatrist who was certified by the named boards in the now-removed subpart J of 10 CFR part 35 on or before October 24, 2005, and who would not need to comply with the training requirements of subparts D through H of 10 CFR part 35 to be identified as an AU on a Commission or an Agreement State license or Commission master material license permit for those materials and uses that the individual performed on or before October 24, 2005. Removal of subpart J from 10 CFR part 35 was effective on October 24, 2005. An individual

excepted from the T&E requirements by this paragraph would still need to meet the recentness-of-training requirements in § 35.59.

Section 35.65 Authorization for calibration, transmission, and reference sources.

This section would be restructured and amended to include two new paragraphs.

Paragraph (b)(1). This new paragraph would require that medical use of any byproduct material authorized by this section can only be used in accordance with the requirements in § 35.500. This is a clarification that all of the specified byproduct material for medical use must be under the supervision of an AU.

Paragraph (b)(2). This new paragraph would prohibit the bundling or aggregating of single-sealed sources to create a sealed source with an activity larger than authorized by § 35.65. Sources that consist of multiple single sources (bundling) that exceed the limits authorized by § 35.65 would no longer be regulated under § 35.65, would be treated as one single source, and would have to meet all of the regulatory requirements for that single source including, if appropriate, listing on a specific medical license, leak testing, and security requirements.

Paragraph (c). This new paragraph would clarify that a licensee using calibration, transmission, and reference sources in accordance with the requirements in paragraphs (a) or (b) of this section need not list these sources on a specific medical use license.

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

Paragraph (a). For a physician seeking to be named as an AU of unsealed byproduct material for uses authorized under § 35.100, the requirement to obtain a written attestation would be removed for an individual who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. Further discussion on

removing the written attestation requirement can be found in Section IV, Discussion, of this document.

Paragraph (c)(2). This paragraph would be restructured and expanded to allow certain residency program directors to provide written attestations for a physician seeking to be named as an AU of unsealed byproduct material for uses authorized under § 35.100. The residency program director must represent a residency training program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association. The residency training program must include T&E specified in § 35.190.

The residency program director who provides written attestations does not have to be an AU who met the requirements in §§ 35.57, 35.190, 35.290, or 35.390, or equivalent Agreement State requirements. However, the director must affirm in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an AU who meets the requirements in §§ 35.57, 35.190, 35.290, or 35.390, or equivalent Agreement State requirements, and that the AU concurs with the attestation.

Additionally, the paragraph would be amended to incorporate the new language that the written attestation would verify that the physician is able to independently fulfill the radiation safety-related duties, rather than has achieved a level of competency to function independently, as an AU.

Section 35.204 Permissible molybdenum-99, strontium-82, and strontium-85 concentrations.

Paragraph (b). The current requirement to measure the Mo-99 concentration after the first eluate would be changed to require that the Mo-99 concentration be measured after each

elution. A generator can be eluted several times to obtain Tc-99m for formulating radiopharmaceuticals for human use. Current regulations require licensees to measure the Mo-99 concentration only the first time a generator is eluted.

Paragraph (e). This new paragraph would add a requirement that licensees report any measurement that exceeds the limits specified in § 35.204(a) for Mo-99/Tc-99m and Sr-82/Rb-82 generators.

Further discussion on this issue can be found in Section IV, Discussion, of this document.

Section 35.290 Training for imaging and localization studies.

Paragraph (a). For physicians seeking to be named as an AU of unsealed byproduct material for uses authorized under § 35.200, the requirement to obtain a written attestation would be removed for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. Further discussion on removing the written attestation requirement can be found in Section IV, Discussion, of this document.

Paragraph (c)(1)(ii). This paragraph would be amended to allow an ANP who meets the requirements in §§ 35.55 or 35.57 to provide the supervised work experience specified in paragraph (c)(1)(ii)(G) of this section for individuals seeking to be named as an AU of unsealed byproduct material for uses authorized under § 35.200. Paragraph (c)(1)(ii)(G) of this section requires supervised work experience in eluting generator systems. Many medical facilities no longer elute generators and receive unit doses from centralized pharmacies; therefore, training on eluting generators is not available at these facilities. ANPs have the T&E to provide the supervised work experience for AUs on the elution of generators.

Paragraph (c)(2). This paragraph would be restructured and expanded to allow certain residency program directors to provide written attestations for individuals seeking to be named as an AU of unsealed byproduct material for uses authorized under §§ 35.100 and 35.200. The residency program director must represent a residency training program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association. The residency training program must include T&E specified in § 35.290.

The residency program directors who provide written attestations do not have to be AUs who meet the requirements in §§ 35.57, 35.290, or 35.390 and 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements. However, they must affirm in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an AU who meets the requirements in §§ 35.57, 35.290, or 35.390 and 35.290(c)(1)(ii)(G) or equivalent Agreement State requirements, and that the AU concurs with the attestation.

Additionally, the paragraph would be amended to incorporate the new language that the written attestation would verify that the individual is able to independently fulfill the radiation safety-related duties, rather than has achieved a level of competency to function independently, as an AU.

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

The introductory paragraph would be amended to clarify that a licensee may only use unsealed byproduct material identified in § 35.390(b)(1)(ii)(G) under this section. Currently, § 35.300 states that "A licensee may use any unsealed byproduct material…." This change is proposed to clarify that a licensee's authorization of the radiopharmaceuticals requiring a WD is only for those types of radiopharmaceuticals for which the AU has documented T&E. An AU

may be authorized for one or more of the specific categories described in § 35.390(b)(1)(ii)(G), but not for all unsealed byproduct material.

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

Paragraph (a). For physicians seeking to be named as an AU of unsealed byproduct material for uses authorized under § 35.300, the requirement to obtain a written attestation would be removed for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. Further discussion on removing the written attestation requirement can be found in Section IV, Discussion, of this document.

Paragraph (b)(1)(ii)(G). This paragraph would be amended to expand and clarify the categories of parenteral administrations of radionuclides in which work experience is required for an individual seeking to be an AU for uses under § 35.300. Most radionuclides used for parenteral administrations have more than one type of radiation emission. Under the proposed change, the type of radiation emissions of parenteral administrations would be based on the primary use of the radionuclide radiation characteristics. The proposed changes to this paragraph would also further expand the parenteral administration categories to include radionuclides that are primarily used for their alpha radiation characteristics.

The current regulations include a broad category for parenteral administrations of “any other” radionuclide. This broad category would be removed, as any new parenteral administration of radionuclides not listed in this paragraph would be regulated under § 35.1000. This approach would allow the NRC to review each new proposed radionuclide for parenteral administration and determine the appropriate T&E for its use.

Current regulations require physicians requesting AU status for administering dosages of radioactive drugs to humans (including parenteral administration) to have work experience with a minimum of three cases in each category for which they are requesting AU status. This requirement would be retained in the proposed rule with regard to all categories in this paragraph.

Paragraph (b)(2). This paragraph would be restructured and expanded to allow certain residency program directors to provide written attestations for physicians seeking to be named as an AU of unsealed byproduct material for uses authorized under § 35.300. The residency program director must represent a residency training program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association. The residency training program must include T&E specified in § 35.300.

The residency program directors who provide written attestations do not have to be AUs who meet the requirements in §§ 35.57, 35.390, or equivalent Agreement State requirements, or have experience in administering dosages in the same dosage category or categories as the individual requesting AU status. However, they must affirm in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an AU who meets the requirements in §§ 35.57, 35.390, or equivalent Agreement State requirements, has experience in administering dosages in the same dosage category or categories as the physicians requesting AU status, and that the AU concurs with the attestation.

Additionally, the paragraph would be amended to incorporate the new language that the written attestation would verify that the physician is able to independently fulfill the radiation safety-related duties, rather than has achieved a level of competency to function independently, as an AU.

Paragraph (c). This new paragraph is added to clarify that if an individual is a user of any of the parenteral administrations specified in § 35.390(b)(1)(ii)(G) or equivalent Agreement State requirements that individual would be only authorized for that use and not for all of the parenteral administrations. If an individual is seeking authorization for any new type of parenteral administrations then the supervised work experience requirements in paragraph (b)(1)(ii)(G) would have to be met.

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).

Paragraph (a). For physicians seeking to be named as an AU for the oral administration of sodium iodide I-131 requiring a WD in quantities less than or equal to 1.22 gigabecquerels (33 millicuries), the requirement to obtain a written attestation would be removed for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. Further discussion on removing the written attestation requirement can be found in Section IV, Discussion, of this document.

Paragraph (c)(3). This paragraph would be restructured and expanded to allow certain residency program directors to provide written attestations for physicians seeking to be named as an AU of unsealed byproduct material for the oral administration of sodium iodide I-131 requiring a WD in quantities less than or equal to 1.22 gigabecquerels (33 millicuries) authorized under § 35.300. The residency program director must represent a residency training program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association. The residency training program must include T&E specified in § 35.392.

The residency program directors who provide written attestations do not have to be AUs who meet the requirements in §§ 35.57, 35.390, 35.392, 35.394, or equivalent Agreement State requirements, or have experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(*1*) or 35.390(b)(1)(ii)(G)(*2*). However, they must affirm in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an AU who meets the requirements in §§ 35.57, 35.390, 35.392, 35.394, or equivalent Agreement State requirements, and has experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(*1*) or 35.390(b)(1)(ii)(G)(*2*) and that the AU concurs with the attestation.

Additionally, the paragraph would be amended to incorporate the new language that the written attestation would verify that the physician is able to independently fulfill the radiation safety-related duties, rather than has achieved a level of competency to function independently, as an AU.

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).

Paragraph (a). For physicians seeking to be named as an AU for the oral administration of sodium iodide I-131 requiring a WD in quantities greater than 1.22 gigabecquerels (33 millicuries), the requirement to obtain a written attestation would be removed for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. Further discussion on removing the written attestation requirement can be found in Section IV, Discussion, of this document.

Paragraph (c)(3). This paragraph would be restructured and expanded to allow certain residency program directors to provide written attestations for physicians seeking to be named as an AU of unsealed byproduct material for the oral administration of sodium iodide I-131

requiring a WD in quantities greater than 1.22 gigabecquerels (33 millicuries) authorized under § 35.300. The residency program director must represent a residency training program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association. The residency training program must include T&E specified in § 35.394.

The residency program directors who provide written attestations do not have to be AUs who meet the requirements in §§ 35.57, 35.390, 35.394, or equivalent Agreement State requirements, or have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(*2*). However, they must affirm in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an AU who meets the requirements in §§ 35.57, 35.390, 35.394, or equivalent Agreement State requirements, and has experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(*2*) and that the AU concurs with the attestation.

Additionally, the paragraph would be amended to incorporate the new language that the written attestation would verify that the physician is able to independently fulfill the radiation safety-related duties, rather than has achieved a level of competency to function independently, as an AU.

Section 35.396 Training for the parenteral administration of unsealed byproduct material requiring a written directive.

Proposed amendments to this section include conforming changes to support the new categories for parenteral administration in § 35.390(b)(1)(ii)(G), changes to allow residency program directors to provide written attestations, and the change to the attestation language. Additionally, the section would be renumbered to accommodate the proposed changes.

Paragraph (a). This paragraph would be amended to revise the categories for parenteral administration of radionuclides listed in § 35.390(b)(1)(ii)(G). The AUs authorized to use any of the categories for parenteral administration of radionuclides in § 35.390(b)(1)(ii)(G) would also have to meet the supervised work experience requirements in paragraph (d)(2) of this section for each new parenteral administration listed in § 35.390(b)(1)(ii)(G) for which the individual is requesting AU status.

Paragraph (d)(1). This paragraph would be amended to conform with the new categories for parenteral administration in § 35.390(b)(1)(ii)(G).

Paragraph (d)(2). This paragraph would be amended to conform with the new categories for parenteral administration in § 35.390(b)(1)(ii)(G) and to clarify that a supervising AU must have experience in administering dosages in the same category or categories as the individual requesting AU status.

Paragraph (d)(2)(vi). This paragraph would be amended to conform with the new categories for parenteral administration in § 35.390(b)(1)(ii)(G).

Paragraph (d)(3). This paragraph would be restructured and expanded to allow certain residency program directors to provide written attestations for physicians seeking to be named as an AU of unsealed byproduct material for the parenteral administration requiring a WD. The residency program director must represent a residency training program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association. The residency training program must include T&E specified in § 35.396.

The residency program directors who provide written attestations do not have to be AUs who meet the requirements in §§ 35.57, 35.390, 35.396, or equivalent Agreement State requirements, or have experience in administering dosages in the same category or categories

as the individual requesting AU status. However, they must affirm in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an AU who meets the requirements in §§ 35.57, 35.390, 35.396, or equivalent Agreement State requirements, and concurs with the attestation. An AU who meets the requirements in §§ 35.390, 35.396, or equivalent Agreement State requirements, must have experience in administering dosages in the same category or categories as the individual requesting AU user status.

Additionally, the paragraph would be amended to incorporate the new language that the written attestation would verify that the physician is able to independently fulfill the radiation safety-related duties, rather than has achieved a level of competency to function independently, as an AU.

Section 35.400 Use of sources for manual brachytherapy.

This section would be expanded to allow sources that are listed in the SSDR for manual brachytherapy to be used for other medical uses that are not explicitly listed in the SSDR.

Paragraph (a). This paragraph would be amended to allow sources that are listed in the SSDR for manual brachytherapy medical uses to be used for other manual brachytherapy medical uses that are not explicitly listed in the SSDR provided that these sources are used in accordance with the radiation safety conditions and limitations described in the SSDR. These radiation safety conditions and limitations described in the SSDR may apply to storage, handling, sterilization, conditions of use, and leak testing of radiation sources.

The NRC recognizes that the medical uses specified in the SSDR may not be all inclusive. The proposed revision would permit physicians to use manual brachytherapy sources to treat sites or diseases not listed in the SSDR. For example, the SSDR may specify that the sources are for interstitial uses, but the proposed change would allow the physician to use the

sources for a topical use. The NRC has determined this latitude should be afforded to physicians to use at their discretion in the practice of medicine.

Section 35.433 Decay of strontium-90 sources for ophthalmic treatments.

The section title would be modified to delete "Decay of" at the beginning of the title. The new title would reflect the expanded information and requirements in the section.

Paragraph (a). This paragraph would be amended and expanded to allow certain individuals who are not AMPs to calculate the activity of strontium-90 (Sr-90) sources that is used to determine the treatment times for ophthalmic treatments. These individuals, defined in § 35.2 as ophthalmic physicists, would have to meet the T&E requirements detailed in the new paragraph (a)(2) of this section to perform the specified activities but would not require an attestation. These requirements are similar to the T&E requirements for an AMP, but include only the requirements related to brachytherapy programs.

This amendment is proposed to increase the number of qualified individuals available to support the use of Sr-90 sources for ophthalmic treatments. Often, AUs who work in remote areas do not have ready access to an AMP to perform the necessary calculation to support the ophthalmic treatment. This proposed change would make the procedure involving use of Sr-90 sources for ophthalmic treatments available to more patients located in remote areas.

Paragraph (b). This new paragraph would establish the tasks that individuals qualified in paragraph (a) of this section would be required to perform in supporting ophthalmic treatments with Sr-90. The first task is based upon the requirements in § 35.432 for calculating the activity of each Sr-90 source used for ophthalmic treatments. This is not a new requirement, as it is required in the current regulation under § 35.433(a).

The second task is related to the requirements in § 35.41 and is included in this proposed rule to ensure the safe use of Sr-90 for ophthalmic treatments. Both the AMP and the

individuals identified under paragraph (a)(2) of this section would be required to assist the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the dose administration is in accordance with the WD. Under this paragraph, the licensee would have to modify its procedures required under § 35.41 to specify the frequencies that the AMP and/or the individuals identified under paragraph (a)(2) of this section would observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the treatment was administered in accordance with the WD.

Paragraph (c). This new paragraph would be unchanged from the recordkeeping requirements in the current regulation under § 35.433(b).

Section 35.490 Training for use of manual brachytherapy sources.

Paragraph (a). For a physician seeking to be named as an AU of a manual brachytherapy source for the uses authorized under § 35.400, the requirement to obtain a written attestation would be removed for an individual who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. Further discussion on removing the written attestation requirement can be found in Section IV, Discussion, of this document.

Paragraph (b)(1)(ii). This paragraph would be amended to require that the work experience required by this section must be received at a medical facility authorized to use byproduct materials under § 35.400 rather than at a medical institution. The current term "medical institution" in this paragraph is defined in § 35.2 as an organization in which more than one medical discipline is practiced. This definition unnecessarily limits where the work experience must be obtained. Moreover, the fact that an organization practices more than one medical discipline does not ensure that one of the medical disciplines will be related to uses

authorized under § 35.400. The proposed change would allow the work experience to be received at a stand-alone single discipline clinic and also ensure that the work experience is related to the uses authorized under § 35.400.

Paragraph (b)(3). This paragraph would be restructured and expanded to allow certain residency program directors to provide written attestations for physicians seeking to be named as an AU of a manual brachytherapy source for the uses authorized under § 35.400. The residency program directors must represent a residency training program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association. The residency training program must include T&E specified in § 35.400.

The residency program directors who provide written attestations do not have to be AUs who meet the requirements in §§ 35.57, 35.490 or equivalent Agreement State requirements. However, they must affirm in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an AU who meets the requirements in §§ 35.57, 35.490, or equivalent Agreement State requirements, and that the AU concurs with the attestation.

Additionally, the paragraph would be amended to incorporate the new language that the written attestation would verify that the physician is able to independently fulfill the radiation safety-related duties, rather than has achieved a level of competency to function independently, as an AU.

Section 35.491 Training for ophthalmic use of strontium-90.

Paragraph (b)(3). This paragraph would be amended to incorporate the new language that the written attestation would verify that the physician is able to independently fulfill the

radiation safety-related duties, rather than has achieved a level of competency to function independently, as an AU.

Section 35.500 Use of sealed sources for diagnosis.

The section would be restructured and expanded to include the use of medical devices to allow sealed sources and medical devices that are listed in the SSDR for diagnostic medical uses to be used for diagnostic medical uses that are not explicitly listed in the SSDR, and to allow sealed sources and medical devices to be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA. The section title would be modified to add "and medical devices" as the use of medical devices is added to this section.

Paragraph (a). This paragraph would be amended to clarify that sealed sources not in medical devices for diagnostic medical uses approved in the SSDR can be used for other diagnostic medical uses that are not explicitly listed in an SSDR provided that they are used in accordance with radiation safety conditions and limitations described in the SSDR. These radiation safety conditions and limitations described in the SSDR may include storage, handling, sterilization, conditions of use, and leak testing of radiation sources.

Paragraph (b). This paragraph would be added to allow diagnostic devices containing sealed sources to be used for diagnostic medical uses if both are approved in the SSDR for diagnostic medical uses that are not explicitly listed in an SSDR, provided that they are used in accordance with radiation safety conditions and limitations described in the SSDR. These radiation safety conditions and limitations described in the SSDR may include storage, handling, sterilization, conditions of use, and leak testing of radiation sources.

Paragraph (c). This new paragraph would allow sealed sources and devices for diagnostic medical uses to be used in research in accordance with an active IDE application accepted by the FDA, provided the requirements of § 35.49(a) are met.

Section 35.590 Training for use of sealed sources and medical devices for diagnosis.

This section would be restructured and expanded to clarify that both diagnostic sealed sources and devices authorized in § 35.500 are included in the T&E requirements of this section.

Paragraph (b). This new paragraph would recognize the individuals who are authorized for imaging uses listed in § 35.200, or equivalent Agreement State requirements, for use of diagnostic sealed sources or devices authorized under § 35.500.

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

The section would be amended to separate the uses of photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units from the uses of the sealed sources contained within these units. The amended section would allow only sealed sources approved in the SSDR in devices to deliver therapeutic medical treatments as provided for in the SSDR; however, the units containing these sources could be used for therapeutic medical treatments that are not explicitly provided for in the SSDR, provided that they are used in accordance with radiation safety conditions and limitations described in the SSDR. The purpose of this amendment is to allow physicians flexibility to exercise their medical judgment and to use these devices for new therapeutic treatments that may not have been anticipated when the devices were registered.

Paragraph (a). This paragraph would require that a licensee use only sealed sources approved in the SSDR for therapeutic medical uses in photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units as provided for in the SSDR or for research in accordance with an active IDE application accepted by the FDA, provided the requirements of § 35.49(a) are met.

Paragraph (b). This paragraph would continue to require that a licensee only use photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units approved in the SSDR or for research in accordance with an active IDE application accepted by the FDA provided the requirements of § 35.49(a) are met. However, this paragraph would be amended to provide that these units may be used for medical uses that are not explicitly provided for in the SSDR, provided that these units are used in accordance with the radiation safety conditions and limitations described in the SSDR.

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

Paragraph (d)(1). This paragraph would be amended and restructured to add a new training requirement for the use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. This proposed amendment would require all individuals who would operate these units to receive vendor operational and safety training prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit. This training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the training.

Currently, § 35.610(d) requires that an individual who operates these units be provided safety instructions initially, and at least annually; however, there is no requirement for this individual to receive instructions when the unit is upgraded. In addition, the proposed

amendment would require an individual who operates these new or upgraded units to receive training prior to first use for patient treatment.

Paragraph (d)(2). This paragraph would be restructured and amended to clarify that the training required by this paragraph on the operation and safety of the unit applies to any new staff who will operate the unit or units at the facility. This requirement would be added to enhance the safety of patients by eliminating the potential for training of new staff to be delayed until the required annual training, which could lead to having undertrained individuals operating the unit.

Paragraph (g). This paragraph would be amended to conform with the restructuring of paragraph (d)(2) of this section.

Section 35.655 Five-year inspection for teletherapy and gamma stereotactic radiosurgery units.

The section title would be modified to delete "Five-year inspection" and insert "Full-inspection servicing" to more accurately reflect the requirements in the section of inspection and servicing of teletherapy unit and gamma stereotactic radiosurgery units.

Paragraph (a). This paragraph would be amended to extend the full inspection and servicing interval between each full inspection servicing for gamma stereotactic radiosurgery units from 5 years to 7 years to assure proper functioning of the source exposure mechanism. The interval between each full inspection and servicing of teletherapy units would remain the same (not to exceed 5 years). For gamma stereotactic radiosurgery units, the full inspection and servicing to assure proper functioning of the source exposure mechanism is performed when the sources are taken out of the unit and before the new sources are placed in the unit (source replacement). Since the cost to replace the decaying sources in a gamma stereotactic radiosurgery unit can be exorbitant, licensees have requested that the intervals between each

full inspection servicing for these units be extended beyond 5 years. The NRC finds that the 6-month routine preventive maintenance that is performed on these units is adequate to assure the proper functioning of the source exposure mechanisms and that therefore this extension may be granted. Additionally, the paragraph would require that the full inspection and servicing of these units be performed during each source replacement regardless of the last time that the units were inspected and serviced.

The full inspection and servicing interval of a teletherapy unit has not been extended from the current interval of 5 years to help prevent potentially serious radiation exposure of teletherapy operators and patients in the event that the source exposure mechanism failed. The radioactive source contained in a teletherapy unit produces radiation fields on the order of hundreds of rads per minute in areas accessible to patients and operators. In the event of a source exposure mechanism failure, the exposed source could result in overexposure of a patient or operating personnel in a short period of time.

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

Paragraph (a). For a physician seeking to be named as an AU for sealed sources for uses authorized under § 35.600, the requirement to obtain a written attestation would be removed for an individual who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. Further discussion on removing the written attestation requirement can be found in Section IV, Discussion, of this document.

Paragraph (b)(1)(ii). This paragraph would be amended to require that the work experience required by this section must be received at a medical facility authorized to use byproduct materials under § 35.600 rather than at a medical institution. The current term "medical institution" in this paragraph is defined in § 35.2 as an organization in which more than

one medical discipline is practiced. This definition unnecessarily limits where the work experience must be obtained. Moreover, the fact that an organization practices more than one medical discipline does not ensure that one of the medical disciplines will be related to uses authorized under § 35.600. The proposed change would allow the work experience to be received at a stand-alone single discipline clinic for the uses authorized under § 35.600.

Paragraph (b)(3). This paragraph would be restructured and expanded to allow certain residency program directors to provide written attestations for physicians seeking to be named as an AU for sealed sources for uses authorized under § 35.600. The residency program directors must represent a residency training program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association. The residency training program must include T&E specified in § 35.690.

The residency program directors who provide written attestations do not have to be AUs who meet the requirements in §§ 35.57, 35.690, or equivalent Agreement State requirements, for the type(s) of therapeutic medical unit(s) for which the individual is requesting AU status. However, they must affirm in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an AU who meets the requirements in §§ 35.57, 35.690, or equivalent Agreement State requirements, for the type(s) of therapeutic medical unit(s) for which the individual is requesting AU status and that the AU concurs with the attestation.

Additionally, the paragraph would be amended to incorporate the new language that the written attestation would verify that the physician is able to independently fulfill the radiation safety-related duties, rather than has achieved a level of competency to function independently, as an AU.

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

Paragraph (c). This new paragraph would require the licensee to keep records of each ARSO assigned under § 35.24(b) for 5 years after the ARSO is removed from the license. These records would have to include the written document appointing the ARSO signed by the licensee's management and each agreement signed by the ARSO listing the duties and tasks assigned by the RSO under § 35.24(b).

Section 35.2310 Records of safety instruction.

This section would be amended to conform to the changes proposed in § 35.610 by adding a requirement to maintain the operational and safety instructions required by § 35.610.

Section 35.2655 Records of 5-year inspection for teletherapy and gamma stereotactic radiosurgery units.

The section title would be modified to delete "5-year inspection" and insert "full-inspection servicing" to reflect the proposed changes to § 35.655 requiring full inspection and servicing of teletherapy units and gamma stereotactic radiosurgery units.

Section 35.3045 Report and notification of a medical event.

Paragraph (a) of this section would be restructured and amended to specify separate specific criteria for reporting an ME involving permanent implant brachytherapy. These new criteria would be different from the criteria for reporting an ME for other administrations that require a WD.

Paragraph (a)(1). This new paragraph would have criteria for reporting an ME for administrations that require a WD other than permanent implant brachytherapy. Criteria for

reporting an ME involving permanent implant brachytherapy would be in a new paragraph (a)(2) in this section. The criteria used to determine if an ME has occurred for administrations that require a WD other than permanent implant brachytherapy would be unchanged except 1) the current paragraph (a)(3) related to the dose to the skin or an organ or tissue other than the treatment site would be restructured for clarity as the new paragraph (a)(1)(iii); and 2) a criterion would be added in the new paragraph (a)(1)(ii)(A) of this section for reporting as an ME an administration involving the wrong radionuclide for a brachytherapy procedure.

Paragraph (a)(2). This new paragraph would be added to establish separate criteria for reporting MEs involving permanent implant brachytherapy. These new criteria are designed to ensure reporting of situations where harm or potential harm to the patient may occur. The new criteria for reporting an ME involving permanent implant brachytherapy include:

1) The total source strength administered differing by 20 percent or more from the total source strength documented in the post-implantation portion of the WD. An example of a situation that would meet this criterion would be if the sealed sources, which were implanted, had a different source strength than what was intended. This situation could occur from ordering, or a vendor shipping, sealed sources with the wrong activity;

2) The total source strength administered outside of the treatment site exceeding 20 percent of the total source strength documented in the post-implantation portion of the WD. An example of a situation that would meet this criterion would be if sealed sources are unintentionally implanted outside of the treatment site. This situation would be identified by the licensee when determinations are made that are related to 10 CFR 35.41;

3) An absorbed dose to the maximally exposed 5 contiguous cubic centimeters of normal tissue located outside of the treatment site that exceeds by 50 percent or more of the absorbed dose prescribed to the treatment site by an AU in the pre-implantation portion of the WD. The ACMUI recommended that for this criterion the absorbed dose to normal tissue

should be measured in a volume large enough such that small fluctuations, such as a single source out of place, would not result in an ME. The ACMUI's recommendation for selecting 5 contiguous cubic centimeters volume related to organ at risk toxicity is based on an article entitled, "Proposed guidelines for image-based intracavitary brachytherapy for cervical carcinoma: Report from Image-Guided Brachytherapy Working Group," by S. Nag, H. Cardenes, S. Chang, I. Das, B. Erickson, G. Ibbott, J. Lowenstein, J. Roll, B. Thomadsen, M. Varia, in the International Journal of Radiation Oncology and Bio Physics 60:1160-1172, 2004.

An example of a situation that would meet this criterion would be if sealed sources are not implanted in the treatment site in a spatially distributed manner, i.e., they are bunched or grouped rather than spatially distributed. This could result in a higher dose than was expected or desired to normal tissues that are located close to the treatment site.

4) An absorbed dose to the maximally exposed 5 contiguous cubic centimeters of normal tissue located within the treatment site that exceeds by 50 percent or more of the absorbed dose to that tissue based on the pre-implantation dose distribution approved by an AU. The ACMUI recommended with regard to this criterion that the absorbed dose to normal tissue should be measured in a volume large enough such that small fluctuations, such as a single source out of place, would not result in an ME. The 5 contiguous cubic centimeters proposed is the largest volume related to organ at risk toxicity in the literature referenced in criterion 3.

An example of a situation that would meet this criterion would be if sealed sources are not implanted in the treatment site as intended. The unintended higher dose could be from the sealed sources being bunched or grouped close to the normal tissue rather than spatially distributed or from sealed sources being unintentionally implanted into the normal tissue. This

could result in a higher dose than was expected or desired to normal tissues that are located within the treatment site.

5) An administration that includes the wrong radionuclide; the wrong individual or human research subject; sealed sources directly delivered to the wrong treatment site; a leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue; or a 20 percent or more error in calculating the total source strength documented in the pre-implantation portion of the WD. Only the proposed criteria for a leaking sealed source retains the dose threshold in current regulations because the NRC determined the leaking sealed source delivering a dose below this threshold does not need to be reported as a medical event.

Several situations that would meet this criterion are self-evident, i.e., wrong patient, wrong treatment site, or leaking sealed source. An error of 20 percent or more in calculating the total source strength could lead to implanting the wrong number of sealed sources, which could result in an under- or over-dosing of the treatment area and possibly a higher dose to normal tissue than was expected.

Section 35.3204 Report and notification for an eluate exceeding permissible molybdenum-99, strontium-82, and strontium-85 concentrations.

This new section would be added to require reporting and notification of an elution from a Mo-99/Tc-99m or Sr-82/Rb-82 generator that exceeds the regulatory requirements in §§ 30.34 and 35.204(a). Further discussion on reporting failed generators can be found in Section IV, Discussion, of this document.

Paragraph (a). This new section would require a licensee to notify both the NRC Operations Center and the manufacturer/distributor of the generator by telephone within 30 calendar days after discovery that an eluate exceeds the permissible concentration listed in

§ 35.204(a). This notification would include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects; whether the manufacturer/distributor was notified; and the action taken.

Paragraph (b). This new section would require a licensee to submit a written report to the appropriate NRC Regional Office listed in § 30.6 within 45 days after discovery of an eluate exceeding the permissible concentration. The report would have to be submitted by an appropriate method listed in § 30.6(a). The report would include the action taken by the licensee, patient dose assessments, the methodology used in making the patient dose assessment if the eluate was administered to patients or human research subjects, probable cause and assessment of failure in the licensee's equipment, procedures or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination, and the information in the telephone report as required by paragraph (a) of this section.

Administrative Changes to Authority Citations.

The authority citations for 10 CFR parts 30, 32, and 35 would be revised to make editorial changes that are administrative in nature, including inserting missing parentheses and punctuation. The proposed revisions would not change the statutory authority.

VI. Criminal Penalties

For the purpose of Section 223 of the Atomic Energy Act of 1954, as amended (AEA), the Commission is proposing to amend 10 CFR parts 30, 32, and 35 under one or more of

Sections 161b, 161i, or 161o of the AEA. Willful violations of the rule would be subject to criminal enforcement.

VII. Coordination with NRC Agreement States

The Agreement States have been involved throughout the development of this proposed rule. Agreement State representatives have served on the rulemaking working group that has developed the proposed amendments to 10 CFR part 35 and on the steering committee for the rulemaking.

Through an All Agreement State Letter (FSME-11-044, dated May 20, 2011, ADAMS Accession No. ML111400231), the Agreement States were notified of the availability of preliminary rule text for comments posted on www.regulations.gov and noticed in the *Federal Register* (76 FR 29171; May 20, 2011). The *Federal Register* notice also invited the Agreement States to participate at the two public workshops that were held in New York City, New York, and Houston, Texas, during the summer of 2011. Finally, in preparing the proposed amendments, the rulemaking working group considered the comments provided by the Agreement States.

VIII. Agreement State Compatibility

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" approved by the Commission on June 30, 1997, and published in the *Federal Register* (62 FR 46517; September 3, 1997), this proposed rule would be a matter of compatibility between the NRC and the Agreement States, thereby providing consistency among the Agreement States and NRC requirements. The NRC staff analyzed the proposed

rule in accordance with the procedure established within Part III, “Categorization Process for NRC Program Elements,” of Handbook 5.9 to Management Directive 5.9, “Adequacy and Compatibility of Agreement State Programs” (a copy of which may be viewed at http://www.nrc.gov/reading-rm/doc-collections/management-directives/). The Agreement States have 3 years from the effective date of the final rule in the *Federal Register* to adopt compatible regulations.

The NRC program elements (including regulations) are placed into four compatibility categories (See the Draft Compatibility Table for Proposed Rule in this section). In addition, the NRC program elements can also be identified as having particular health and safety significance or as being reserved solely by the NRC. Compatibility Category A contains those program elements that are basic radiation protection standards and scientific terms and definitions that are necessary to understand radiation protection concepts. An Agreement State should adopt Category A program elements in an essentially identical manner to provide uniformity in the regulation of agreement material on a nationwide basis. Compatibility Category B contains those program elements that apply to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. Compatibility Category C contains those program elements that do not meet the criteria of Category A or B, but provide the essential objectives, which an Agreement State should adopt to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis. An Agreement State should adopt the essential objectives of the Category C program elements. Compatibility Category D contains those program elements that do not meet any of the criteria of Categories A, B, or C, and, therefore, do not need to be adopted by the Agreement States for purposes of compatibility.

The Health and Safety (H&S) category contains program elements that are not required for compatibility but are identified as having a particular health and safety role (i.e., adequacy) in the regulation of agreement material within the State. Although not required for compatibility, the State should adopt program elements in this H&S category based on those of the NRC that embody the essential objectives of NRC program elements because of particular health and safety considerations. Compatibility Category NRC are those program elements that address areas of regulation that cannot be relinquished to the Agreement States under the Atomic Energy Act, as amended, or provisions of 10 CFR. These program elements are not adopted by the Agreement States. The following table lists the parts and sections that would be revised and their corresponding categorization under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs." A bracket around a category means that the section may have been adopted elsewhere, and it is not necessary to adopt it again.

The NRC invites comment on the compatibility category designations in the proposed rule and suggests that commenters refer to Handbook 5.9 of Management Directive 5.9 for more information. The NRC notes that, like the rule text, the compatibility category designations can change between the proposed rule and final rule, based on comments received and Commission decisions regarding the final rule. The NRC encourages anyone interested in commenting on the compatibility category designations in any manner to do so during the comment period. Discussion on changing the Compatibility Category for § 35.3045, Report and notification of a medical event, can be found in Section IV, Discussion, of this document.

Draft Compatibility Table for Proposed Rule

Section	Change	Subject	Compatibility	
			Existing	New
Part 30				
30.34(g)	Amend	Terms and conditions of licenses	B	B
Part 32				
32.72(a)(4)	Amend	Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under 10 CFR part 35	B	B
32.72(b)(5)(i)	Amend	Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under 10 CFR part 35	B	B
32.72(d)	New	Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under 10 CFR part 35	-	B
Part 35				
35.2	New	Definitions – Associate Radiation Safety Officer	-	B
35.2	New	Definitions – Ophthalmic physicist	-	B
35.2	Amend	Definitions – Preceptor	D	D
35.12(b)(1)	Amend	Application for license, amendment, or renewal	D	D
35.12(c)(1)	Amend	Application for license, amendment, or renewal	D	D
35.12(c)(1)(ii)	Amend	Application for license, amendment, or renewal	D	D
35.12(d)	Amend	Application for license, amendment, or renewal	D	D
35.12(d)(1)	New	Application for license, amendment, or renewal	-	D
35.12(d)(2)	New	Application for license, amendment, or renewal	-	D
35.12(d)(3)	New	Application for license, amendment, or renewal	-	D
35.12(d)(4)	Amend	Application for license, amendment, or renewal	D	D
35.13(b)	Amend	License amendments	D	D

35.13(d)	New	License amendments	-	D
35.13(i)	New	License amendments	-	D
35.14(a)	Amend	Notifications	D	D
35.14(b)(1)	Amend	Notifications	D	D
35.14(b)(2)	Amend	Notifications	D	D
35.14(b)(6)	New	Notifications	-	D
35.24(b)	Amend	Authority and responsibilities for the radiation protection program	H&S	H&S
35.24(c)	Amend	Authority and responsibilities for the radiation protection program	D	D
35.40(b)(6)	Amend	Written directives	H&S	H&S
35.41(b)(5)	New	Procedures for administrations requiring a written directive	-	H&S
35.41(b)(6)	New	Procedures for administrations requiring a written directive	-	H&S
35.50	Amend	Training for Radiation Safety Officer and Associate Radiation Safety Officer	B	B
35.50(a)	Amend	Training for Radiation Safety Officer and Associate Radiation Safety Officer	B	B
35.50(a)(2)(ii)(B)	Amend	Training for Radiation Safety Officer and Associate Radiation Safety Officer	B	B
35.50(b)(1)(ii)	Amend	Training for Radiation Safety Officer and Associate Radiation Safety Officer	B	B
35.50(b)(2)	New	Training for Radiation Safety Officer and Associate Radiation Safety Officer	-	B
35.50(c)(1)	Amend	Training for Radiation Safety Officer and Associate Radiation Safety Officer	B	B
35.50(c)(2)	Amend	Training for Radiation Safety Officer and Associate Radiation Safety Officer	B	B
35.50(c)(3)	New	Training for Radiation Safety Officer and Associate Radiation Safety Officer	-	B
35.50(d)	Amend	Training for Radiation Safety Officer and Associate Radiation Safety Officer	B	B
35.51(a)	Amend	Training for an authorized medical physicist	B	B
35.51(a)(2)(i)	Amend	Training for an authorized medical physicist	B	B
35.51(b)(2)	Amend	Training for an authorized medical physicist	B	B
35.55(a)	Amend	Training for an authorized nuclear pharmacist	B	B

35.55(b)(2)	Amend	Training for an authorized nuclear pharmacist	B	B
35.57(a)(1)	Amend	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist	B	B
35.57(a)(2)	New	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist	-	B
35.57(a)(3)	New	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist	-	B
35.57(b)(1)	Amend	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist	B	B
35.57(b)(2)	Amend	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist	B	B
35.57(b)(2)(i)	New	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist	-	B
35.57(b)(2)(ii)	New	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist	-	B
35.57(b)(2)(iii)	New	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist	-	B
35.57(b)(2)(iv)	New	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist	-	B
35.65(b)	New	Authorization for calibration, transmission, and reference sources	-	D

35.65(b)(1)	New	Authorization for calibration, transmission, and reference sources	-	D
35.65(b)(2)	New	Authorization for calibration, transmission, and reference sources	-	D
35.65(c)	New	Authorization for calibration, transmission, and reference sources	-	D
35.190(a)	Amend	Training for uptake, dilution, and excretion studies	B	B
35.190(c)(2)	Amend	Training for uptake, dilution, and excretion studies	B	B
35.190(c)(2)(i)	New	Training for uptake, dilution, and excretion studies	-	B
35.190(c)(2)(ii)	New	Training for uptake, dilution, and excretion studies	-	B
35.204(b)	Amend	Permissible molybdenum-99, strontium-82, and strontium-85 concentrations	H&S	H&S
35.204(e)	New	Permissible molybdenum-99, strontium-82, and strontium-85 concentrations	-	H&S
35.290(a)	Amend	Training for imaging and localization studies	B	B
35.290(c)(1)(ii)	Amend	Training for imaging and localization studies	B	B
35.290(c)(2)	Amend	Training for imaging and localization studies	B	B
35.290(c)(2)(i)	New	Training for imaging and localization studies	-	B
35.290(c)(2)(ii)	New	Training for imaging and localization studies	-	B
35.300	Amend	Use of unsealed byproduct material for which a written directive is required	B	B
35.390(a)	Amend	Training for use of unsealed byproduct material for which a written directive is required	B	B
35.390(b)(1)(ii)(G)(*3*)	Amend	Training for use of unsealed byproduct material for which a written directive is required	B	B
35.390(b)(1)(ii)(G)(*4*)	New	Training for use of unsealed byproduct material for which a written directive is required	-	B
35.390(b)(1)(ii)(G)(*5*)	New	Training for use of unsealed byproduct material for which a written directive is required	-	B
35.390(b)(2)	Amend	Training for use of unsealed byproduct material for which a written directive is required	B	B
35.390(b)(2)(i)	New	Training for use of unsealed byproduct material for which a written directive is required	-	B

35.390(b)(2)(ii)	New	Training for use of unsealed byproduct material for which a written directive is required	-	B
35.390(c)	New	Training for use of unsealed byproduct material for which a written directive is required	-	B
35.392(a)	Amend	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)	B	B
35.392(c)(3)	Amend	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)	B	B
35.392(c)(3)(i)	New	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)	-	B
35.392(c)(3)(ii)	New	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)	-	B
35.394(a)	Amend	Training for the oral administration of sodium iodide I–131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	B	B
35.394(c)(3)	Amend	Training for the oral administration of sodium iodide I–131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	B	B
35.394(c)(3)(i)	New	Training for the oral administration of sodium iodide I–131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	-	B
35.394(c)(3)(ii)	New	Training for the oral administration of sodium iodide I–131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	-	B
35.396(a)	Amend	Training for the parenteral administration of unsealed byproduct material requiring a written directive	B	B
35.396(b)	Amend	Training for the parenteral administration of unsealed byproduct material requiring a written directive	-	B
35.396(c)	Amend	Training for the parenteral administration of unsealed byproduct material requiring a written directive	B	B

35.396(d)(1)	Amend	Training for the parenteral administration of unsealed byproduct material requiring a written directive	B	B
35.396(d)(2)	Amend	Training for the parenteral administration of unsealed byproduct material requiring a written directive	B	B
35.396(d)(2)(iv)	Amend	Training for the parenteral administration of unsealed byproduct material requiring a written directive	B	B
35.396(d)(3)	Amend	Training for the parenteral administration of unsealed byproduct material requiring a written directive	B	B
35.396(d)(3)(i)	New	Training for the parenteral administration of unsealed byproduct material requiring a written directive	-	B
35.396(d)(3)(ii)	New	Training for the parenteral administration of unsealed byproduct material requiring a written directive	-	B
35.400(a)	Amend	Use of sources for manual brachytherapy	C	C
35.400(b)	Amend	Use of sources for manual brachytherapy	C	C
35.433(a)	Amend	Strontium-90 sources for ophthalmic treatments	H&S	B
35.433(b)	New	Strontium-90 sources for ophthalmic treatments	-	H&S
35.433(b)(1)	New	Strontium-90 sources for ophthalmic treatments	-	H&S
35.433(b)(2)	New	Strontium-90 sources for ophthalmic treatments	-	H&S
35.433(c)	Redesignated	Strontium-90 sources for ophthalmic treatments (Previously 35.433(b))	-	H&S
35.490(a)	Amend	Training for use of manual brachytherapy sources	B	B
35.490(b)(1)(ii)	Amend	Training for use of manual brachytherapy sources	B	B
35.490(b)(3)	Amend	Training for use of manual brachytherapy sources	B	B
35.490(b)(3)(i)	New	Training for use of manual brachytherapy sources	-	B
35.490(b)(3)(ii)	New	Training for use of manual brachytherapy sources	-	B
35.491(b)(3)	Amend	Training for ophthalmic use of strontium-90	B	B
35.500(a)	Amend	Use of sealed sources and medical devices for diagnosis (Previously 35.500)	[C]	C

35.500(b)	New	Use of sealed sources and medical devices for diagnosis	-	C
35.500(c)	New	Use of sealed sources and medical devices for diagnosis	-	C
35.590 (a)	Amend	Training for use of sealed sources for diagnosis	B	B
35.590 (b)	New	Training for use of sealed sources for diagnosis	-	B
35.590 (c)	Redesignated	Training for use of sealed sources for diagnosis (Previously 35.590(b))	B	B
35.590 (d)	Redesignated	Training for use of sealed sources for diagnosis (Previously 35.590(c))	B	B
35.600(a)	Amend	Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit	C	C
35.600(b)	Amend	Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit	C	C
35.610(d)(1)	New	Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	-	H&S
35.610(d)(2)	Amend	Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	H&S	H&S
35.610(g)	Amend	Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	H&S	H&S
35.655(a)	Amend	Full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units	H&S	H&S
35.690(a)	Amend	Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	B	B
35.690(b)(1)(ii)	Amend	Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	B	B
35.690(b)(3)	Amend	Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	B	B
35.690(b)(3)(i)	New	Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	-	B
35.690(b)(3)(ii)	New	Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	-	B

35.2024(c)	New	Records of authority and responsibilities for radiation protection programs	-	D
35.2024(c)(1)	New	Records of authority and responsibilities for radiation protection programs	-	D
35.2024(c)(2)	New	Records of authority and responsibilities for radiation protection programs	-	D
35.2310	Amend	Records of safety instruction	D	D
35.2655(a)	Amend	Records of full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units	D	D
35.3045(a)(1)	Amend	Report and notification of a medical event	C	B
35.3045(a)(2)	New	Report and notification of a medical event	-	B
35.3204(a)	New	Report and notification for an eluate exceeding permissible molybdenum-99, strontium-82, and strontium-85 concentrations	-	C
35.3204(b)	New	Report and notification for an eluate exceeding permissible molybdenum-99, strontium-82, and strontium-85 concentrations	-	C

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

The NRC staff consults with the ACMUI whenever it identifies an issue with implementation of 10 CFR part 35 regulations. Accordingly, issues leading to these proposed amendments have been discussed at ACMUI meetings over the past 9 years. The ACMUI meetings are transcribed. Full transcripts of the ACMUI meetings can be found online in the NRC Library at http://www.nrc.gov/reading-rm/doc-collections/acmui/tr. In addition, in SRM-SECY-10-0062, the Commission specifically directed the staff to engage the ACMUI in developing the ME definition criterion for permanent implant brachytherapy. Further, the proposals to revise T&E requirements to eliminate preceptor attestation for board-certified individuals, change the language of the attestation, and allow a residency director to provide preceptor attestations were initiated by the ACMUI in its briefing to the Commission held on April 29, 2008 (discussed in detail in item b in Section IV, Discussion, of this document).

Similarly, the issue of naming more than one RSO was initiated by the ACMUI at the June 2007 ACMUI meeting (discussed in detail in item d in Section IV, Discussion, of this document). Finally, the entire ACMUI meeting held on April 20-21, 2011, was devoted to discussion of the rulemaking issues addressed in this proposed rule, so that the staff would be better able to understand ACMUI's position and views on the issues raised.

In December 2012, the NRC provided the preliminary draft proposed rule to the ACMUI for a 90-day review. The draft (ADAMS Accession No. ML13014A487) was made public to facilitate the ACMUI review in a public forum. The ACMUI discussed the draft proposed rule at two publicly held teleconferences on March 5 and March 12, 2013 (conference transcripts are available in ADAMS at ML13087A474 and ML13087A477, respectively), and provided a final report to the NRC on April 9, 2013 (ADAMS Accession No. ML13071A690).

While the ACMUI was supportive of most of the proposed amendments, it expressed concerns on some issues and provided its recommendations on those issues. Several comments resulted in revisions to the discussion section of this document to provide additional emphasis or clarity. However, the NRC did not accept all of the ACMUI recommendations. The recommendations that the staff did not accept are discussed in a document entitled, "NRC Staff Responses to the ACMUI Comments on the draft Part 35 Proposed Rule" (ADAMS Accession No. ML13179A073).

In addition, in the report, the ACMUI recommended that for permanent implant brachytherapy procedures, licensees be allowed to use total source strength as a substitute for total dose for determining MEs until the 10 CFR part 35 rulemaking is completed. In response, on July 9, 2013, the Commission issued an interim enforcement policy (78 FR 41125) that addresses this issue.

X. Plain Writing.

The Plain Writing Act of 2010 (Pub. L. 111-274) requires Federal agencies to write documents in a clear, concise, and well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, "Plain Language in Government Writing," published June 10, 1998 (63 FR 31883). The NRC requests comment on the proposed rule with respect to the clarity and effectiveness of the language used.

XI. Consistency with Medical Policy Statement.

The proposed amendments to 10 CFR part 35 are consistent with the Commission's Medical Use Policy Statement published August 3, 2000 (65 FR 47654). This proposed rule is consistent with the Commission's statement because it balances the interests of the patient with the flexibility needed by the AU to take the actions that he or she deems medically necessary, while continuing to enable the NRC to detect deficiencies in processes, procedures, and training, as well as any misapplication of byproduct materials.

XII. Voluntary Consensus Standards.

The National Technology Transfer and Advancement Act 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 law or otherwise impractical. In this proposed rule, the NRC would amend its medical use regulations related to ME definitions for permanent implant brachytherapy; T&E

requirements for AUs, medical physicists, RSOs, and nuclear pharmacists; consideration of the Ritenour Petition (PRM-35-20) to “grandfather” certain experienced individuals; measuring Mo contamination for each elution and reporting of failed breakthrough tests; naming ARSOs on a medical license; and several minor clarifications.

The NRC is not aware of any voluntary consensus standards that address the proposed subject matter of this proposed rule. The NRC will consider using a voluntary consensus standard if an appropriate standard is identified. If a voluntary consensus standard is identified for consideration, the submittal should explain why the standard should be used.

XIII. Environmental Impact: Categorical Exclusion.

The NRC has determined that the following actions in the proposed rule are the types of actions described in categorical exclusions in 10 CFR 51.22(c)(2) and (c)(3)(i-v):

1) The amendments to the general administrative requirements and general technical requirements meet the categorical exclusion criteria under § 51.22 (c)(2).

2) The amendments to sealed sources usage provide clarifications to the current regulations and meet the categorical exclusion criteria under § 51.22(c)(2).

3) The amendments to the requirements for reporting MEs and reporting failed generator tests meet the categorical exclusion criteria under § 51.22(c)(3)(iii).

4) The amendments related to the record-keeping requirements meet the categorical exclusion criteria under § 51.22(c)(3)(ii).

5) The amendments related to the T&E requirements meet the categorical exclusion criteria under § 51.22(c)(3)(iv).

There are two proposed amendments that do not meet the categorical exclusions in § 51.22. Therefore, a draft environmental assessment has been prepared for this proposed rule

for the two proposed actions that do not meet the categorical exclusions in § 51.22 and is discussed in Section XIV, Finding of No Significant Environmental Impact: Availability, of this document**.** The proposed amendments that do not meet the categorical exclusions in § 51.22 are: 1) increase frequency of measuring Mo-99 tests required in § 35.204, and 2) increase the full inspection time interval for a gamma stereotactic radiosurgery unit from 5 years to 7 years in § 35.655.

XIV. 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, not to prepare an environmental impact statement for this proposed rule because the Commission has concluded on the basis of a draft environmental assessment that this proposed rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment. The amendments would relax certain requirements and eliminate other procedural restrictions associated with the medical use of byproduct material. The Commission believes these amendments would provide greater flexibility in the medical use of byproduct material while continuing to adequately protect public health and safety. It is expected that this rule, if adopted, would not cause any significant increase in radiation exposure to the public or radiation release to the environment beyond the exposures or releases currently resulting from the medical use of byproduct material.

The determination of this draft environmental assessment is that there will be no significant impact to the public from this action. However, the general public should note that the NRC welcomes public participation and comments on any aspect of the Environmental Assessment.

The NRC has sent a copy of the Draft Environmental Assessment and this proposed rule to every State Liaison Officer and requested their comments on the Draft Environmental Assessment. The Draft Environmental Assessment is available in ADAMS under Accession No. ML14184A621.

XV. Paperwork Reduction Act Statement.

This proposed rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). The rule would reduce the burden for existing information collection requirements. This rule has been submitted to the Office of Management and Budget for review and approval of the paperwork requirements.

Type of submission, new or revision: Revision.

The title of the information collection: 10 CFR parts 30, 32, and 35, Medical Use of Byproduct Material - Medical Event Definitions, Training and Experience, and Clarifying Amendments, Proposed Rule.

The form number if applicable: NRC Form 313A Series, “Authorized User Training and Experience and Preceptor Attestation.”

How often the collection is required: The information is collected as needed. Reports required under the proposed rule are based on events that exceed limits stipulated by various sections of the proposed rule. The NRC Form 313A Series or equivalent is required when an applicant or

licensee applies to have a new individual identified as an AU, RSO, ARSO, ANP, or an AMP on a medical use license during a new license, a renewal, or an amendment request.

Who will be required or asked to report: Persons licensed under 10 CFR parts 30, 32, and 35 who possess and use certain byproduct material for medical use.

An estimate of the number of annual responses: 28,049 (4,095 NRC licensees / 23,954 Agreement State licensees).

The estimated number of annual respondents: 7,845 (1,085 NRC / 6,401 Agreement State medical use licensees) and (52 NRC and 307 Agreement State radiopharmacy licensees).

An estimate of the total number of hours needed annually to complete the requirement or request: 6,671 hours (963.75 NRC licensees / 5,739.75 Agreement State licensees / -32.5 third-party burden).

Abstract: The NRC is proposing to amend its regulations related to the medical use of byproduct material. In this action the NRC addresses three ongoing rulemaking projects and several other related topics. First, this rule proposes amendments to the reporting and notification requirements for a ME for permanent implant brachytherapy. Second, the rule proposes changes to the T&E requirements for AUs, medical physicists, RSOs, and nuclear pharmacists; changes to the requirements for measuring Mo contaminations and reporting of failed Tc and Rb generators; and changes that would allow ARSOs to be named on a medical license, as well as other clarifying and conforming amendments. Third, the NRC is considering

a request filed in a petition for rulemaking (PRM-35-20) to “grandfather” certain board-certified individuals.

The NRC is seeking public comment on the potential impact of the information collections contained in the proposed rule and on the following issues:

1. *Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?*

2. *Is the estimate of burden accurate?*

3. *Is there a way to enhance the quality, utility, and clarity of the information to be collected?*

4. *How can the burden of the information collection be minimized, including the use of automated collection techniques?*

The public may examine and have copied, for a fee, publicly available documents, including the draft supporting statement, at the NRC’s PDR, One White Flint North, 11555 Rockville Pike, Room O-1 F21, Rockville, MD 20852. The OMB clearance package and rule are available at the NRC’s Web site: http://www.nrc.gov/public-involve/doc-comment/omb/index.html for 60 days after the signature date of this notice.

Send comments on any aspect of these proposed information collections, including suggestions for reducing the burden and on the above issues, by **[INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]** to the FOIA, Privacy, and Information Collections Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail to INFOCOLLECTS.RESOURCE@NRC.GOV and to the Desk Officer, Danielle Y. Jones, Office of Information and Regulatory Affairs, NEOB-10202, (3150-AI63), Office of Management and Budget, Washington, DC 20503. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot

be given to comments received after this date. You may also e-mail comments to Danielle Y. Jones@omb.eop.gov or comment by telephone at (202) 395-1741.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

XVI. Regulatory Analysis

The Commission has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission.

The Commission requests public comment on the draft regulatory analysis. The draft regulatory analysis is available in ADAMS under Accession No. ML14184A620

XVII. Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this rule would not, if promulgated, have a significant economic impact on a substantial number of small entities. An estimate is provided in Appendix A of the draft Regulatory Analysis for this proposed regulation (ADAMS Accession No. ML14184A620). The NRC is seeking public comment on the potential impact of the proposed rule on small entities. The NRC particularly desires comment from licensees who qualify as small businesses, specifically as to how the proposed regulation will affect them and how the regulation may be

tiered or otherwise modified to impose less stringent requirements on small entities while still adequately protecting the public health and safety and common defense and security. Comments on how the regulation could be modified to take into account the differing needs of small entities should specifically discuss–

a) The size of the business and how the proposed regulation would result in a significant economic burden upon it as compared to a larger organization in the same business community;

b) If the proposed regulation could be further modified to take into account the business's differing needs or capabilities;

c) The benefits that would accrue, or the detriments that would be avoided, if the proposed regulation was modified as suggested by the commenter;

d) How the proposed regulation, as modified, would more closely equalize the impact of the NRC's regulations as opposed to providing special advantages to any individuals or groups; and

e) How the proposed regulation, as modified, would still adequately protect the public health and safety and common defense and security.

XVIII. Backfitting and Issue Finality.

The backfitting rule and issue finality provisions of 10 CFR part 52 (which are found in the regulations at §§ 50.109, 70.76, 72.62, 76.76, and in 10 CFR part 52) do not apply to this proposed rule. Title 10 of the CFR parts 30, 32, and 35 do not contain a backfitting requirement. Therefore, a backfitting analysis is not required.

List of Subjects

10 CFR Part 30

Byproduct material, Criminal penalties, Government contracts, Intergovernmental relations, Isotopes, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 32

Byproduct material, Criminal penalties, Labeling, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 35

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 proposing to adopt the following amendments to 10 CFR parts 30, 32, and 35.

PART 30 -- RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

1. The authority citation for part 30 is revised to read as follows:

Authority: Atomic Energy Act secs. 81, 82, 161, 181, 182, 183, 186, 223, 234 (42 U.S.C. 2111, 2112, 2201, 2231, 2232, 2233, 2236, 2273, 2282); Energy Reorganization Act secs. 201, 202, 206 (42 U.S.C. 5841, 5842, 5846); Government Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note); Energy Policy Act of 2005, Pub. L. 109-58, 119 Stat. 549 (2005).

Section 30.7 also issued under Energy Reorganization Act sec. 211, Pub. L. 95-601, sec. 10, as amended by Pub. L. 102-486, sec. 2902 (42 U.S.C. 5851). Section 30.34(b) also issued under Atomic Energy Act sec. 184 (42 U.S.C. 2234). Section 30.61 also issued under Atomic Energy Act sec. 187 (42 U.S.C. 2237).

2. In § 30.34, add a third sentence to paragraph (g) to read as follows:

§ 30.34 Terms and conditions of licenses.

* * * * *

(g) * * *The licensee shall report the results of any test that exceeds the permissible concentration listed in § 35.204(a), in accordance with § 35.3204 of this chapter.

* * * * *

PART 32 -- SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

3. The authority citation for part 32 is revised to read as follows:

Authority: Atomic Energy Act secs. 81, 161, 181, 182, 183, 223, 234 (42 U.S.C. 2111, 2201, 2231, 2232, 2233, 2273, 2282); Energy Reorganization Act sec. 201 (42 U.S.C. 5841);

Government Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note); Energy Policy Act of 2005, sec. 651(e), Pub. L. 109-58, 119 Stat. 806-810 (42 U.S.C. 2014, 2021, 2021b, 2111).

4. In § 32.72, revise paragraphs (a)(4) and (b)(5)(i), redesignate paragraph (d) as paragraph (e), and add a new paragraph (d) to read as follows:

§ 32.72 Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35.

(a) * * *

(4) The applicant commits to the following label requirements:

* * * * *

(b) * * *

(5) * * *

(i) A copy of each individual's certification by a specialty board whose certification process has been recognized by the Commission or an Agreement State as specified in § 35.55(a) of this chapter; or

* * * * *

(d) A licensee shall satisfy the labeling requirements in (a)(4) of this section.

* * * * *

PART 35 -- MEDICAL USE OF BYPRODUCT MATERIAL

5. The authority citation for part 35 is revised to read as follows:

Authority: Atomic Energy Act secs. 81, 161, 181, 182, 183, 223, 234 (42 U.S.C. 2111, 2201, 2231, 2232, 2233, 2273, 2282); Energy Reorganization Act sec. 201, 206 (42 U.S.C. 5841, 5842, 5846); Government Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note); Energy Policy Act of 2005, sec. 651(e), Pub. L. No. 109-58, 119 Stat. 806-810 (42 U.S.C. 2014, 2021, 2021b, 2111).

6. In § 35.2, add, in alphabetical order, the definitions for *Associate Radiation Safety Officer* and *Ophthalmic physicist* and revise the definition for *Preceptor* to read as follows:

§ 35.2 Definitions.

* * * * *

Associate Radiation Safety Officer means an individual who —

(1) Meets the requirements in §§ 35.50 and 35.59; and

(2) Is currently identified as an Associate Radiation Safety Officer for the types of use of byproduct material for which the individual has been assigned duties and tasks by the Radiation Safety Officer on —

(i) A specific medical use license issued by the Commission or an Agreement State; or

(ii) A medical use permit issued by a Commission master material licensee.

* * * * *

Ophthalmic physicist means an individual who meets the requirements in § 35.433(a)(2) and is identified as an ophthalmic physicist on a specific medical use license issued by the Commission or an Agreement State or a medical use permit issued by a Commission master material licensee.

* * * * *

Preceptor means an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, a Radiation Safety Officer, or an Associate Radiation Safety Officer.

* * * * *

7. In § 35.12, revise paragraphs (b)(1), (c), and (d) to read as follows:

§ 35.12 Application for license, amendment, or renewal.

* * * * *

(b) * * *

(1) Filing an original NRC Form 313, "Application for Material License," that includes the facility diagram, equipment, and training and experience qualifications of the Radiation Safety Officer, Associate Radiation Safety Officer(s), authorized user(s), authorized medical physicist(s), ophthalmic physicist(s), and authorized nuclear pharmacist(s); and

* * * * *

(c) A request for a license amendment or renewal must be made by—

(1) Submitting an original of either—

(i) NRC Form 313, "Application for Material License"; or

(ii) A letter containing all information required by NRC Form 313; 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:

(1) Any additional aspects of the medical use of the material that are applicable to radiation safety that are not addressed in, or differ from, subparts A through C, L, and M of this part;

(2) Identification of and commitment to follow the applicable radiation safety program requirements in subparts D through H of this part that are appropriate for the specific § 35.1000 medical use;

(3) Any additional 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; and

(4) Any other information requested by the Commission in its review of the application.

* * * * *

8. In § 35.13, revise paragraph (b), redesignate paragraphs (d) through (g) as paragraphs (e) through (h), revise redesignated paragraphs (g) and (h), and add new paragraphs (d) and (i) to read as follows:

§ 35.13 License amendments.

* * * * *

(b) Before it permits anyone to work as an authorized user, authorized medical physicist, ophthalmic physicist, or authorized nuclear pharmacist 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), and 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, authorized medical physicist, or an ophthalmic physicist—

* * * * *

(d) Before it permits anyone to work as an Associate Radiation Safety Officer, or before the Radiation Safety Officer assigns duties and tasks to an Associate Radiation Safety Officer that differ from those for which this individual is authorized on the license;

* * * * *

(g) Before it changes the address(es) of use identified in the application or on the license;

(h) Before it revises procedures required by §§ 35.610, 35.642, 35.643, and 35.645, as applicable, where such revision reduces radiation safety; and

(i) Before it receives a sealed source from a different manufacturer or of a different model number than authorized by its license unless the sealed source is used for manual brachytherapy, is listed in the Sealed Source and Device Registry, and is in a quantity and for an isotope authorized by the license.

9. In § 35.14, revise paragraphs (a) and (b) to read as follows:

§ 35.14 Notifications.

(a) A licensee shall provide the Commission, no later than 30 days after the date that the licensee permits an individual to work under the provisions of § 35.13(b) as an authorized user, authorized medical physicist, ophthalmic physicist, or authorized nuclear pharmacist —

(1) A copy of the board certification and as appropriate, verification of completion of:

(i) Training for the authorized medical physicist under § 35.51(c);

(ii) Any additional case experience required in § 35.390(b)(1)(ii)(G) for an authorized user under § 35.300; or

(iii) Device specific training in § 35.690(c) for the authorized user under § 35.600; or

(2) A copy of 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, the permit issued by a Commission master material license broad scope permittee, or documentation that only accelerator-produced radioactive materials, discrete sources of radium-226, or both, were used for medical use or in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC for each individual that the licensee permits to work under the provisions of this section. The licensee shall only permit the individual to work with materials and uses previously authorized as an authorized user, an authorized medical physicist, ophthalmic physicist, or an authorized nuclear pharmacist under § 35.13(b).

(b) A licensee shall notify the Commission no later than 30 days after:

(1) An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer, an Associate Radiation Safety Officer, an authorized medical physicist, or ophthalmic physicist permanently discontinues performance of duties under the license or has a name change;

(2) The licensee permits 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 in accordance with § 35.24(c);

(3) The licensee's mailing address changes;

(4) 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;

(5) 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-

(i) § 35.100 or § 35.200 if the change does not include addition or relocation of either an area where PET radionuclides are produced, or

(ii) A PET radioactive drug delivery line from the PET radionuclide/PET radioactive drug production area; or

(6) The licensee obtains a sealed source for use in manual brachytherapy from a different manufacturer or with a different model number than authorized by its license for which it did not require a license amendment as provided in section 35.13(i). The notification must include the manufacturer and model number of the sealed source, the isotope, and the quantity per sealed source.

* * * * *

10. In § 35.24, revise paragraphs (b) and (c) to read as follows:

§ 35.24 Authority and responsibilities for the radiation protection program.

* * * * *

(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. The Radiation Safety Officer may delegate duties and tasks but shall not delegate the authority or responsibilities for implementing the radiation protection program. A licensee's management may appoint, in writing, one or more Associate Radiation Safety Officers to support the Radiation Safety Officer. The Radiation Safety Officer, with written agreement of the licensee's management, must assign the specific duties and tasks to each Associate Radiation Safety Officer. The Associate Radiation Safety Officer must agree, in writing, to the list of the specific duties and tasks. These duties and tasks are restricted to the types of use for which the Associate Radiation Safety Officer has radiation safety training.

(c) For up to 60 days each year, a licensee may permit 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).

* * * * *

11. In § 35.40, revise paragraphs (b) and (c) to read as follows:

§ 35.40 Written directives.

* * * * *

(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;

(6) For permanent implant brachytherapy:

(i) Before implantation: the treatment site, the radionuclide, the intended absorbed dose to the treatment site and the corresponding calculated total source strength required, and if appropriate, the expected absorbed doses to normal tissues located within the treatment site; and

(ii) After implantation but before the patient leaves the post-treatment recovery area: the number of sources implanted, the total source strength implanted, the signature of an authorized user for § 35.400 uses for manual brachytherapy, and the date; or

(7) 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, total source strength and exposure time (or the total dose), the signature of an authorized user for § 35.400 uses for manual brachytherapy, and the date.

(c)(1) 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.

(2) 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.

* * * * *

12. In § 35.41, revise paragraph (b) to read as follows:

§ 35.41 Procedures for administrations requiring a 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;

(4) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by §§ 35.600 or 35.1000;

(5) Determining if a medical event, as defined in § 35.3045, has occurred; and

(6) Determining, for permanent implant brachytherapy, within 60 calendar days from the date the implant was performed unless accompanied by a written justification related to patient unavailability:

(i) The total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive;

(ii) The absorbed dose to the maximally exposed 5 contiguous cubic centimeters of normal tissue located outside of the treatment site; and

(iii) The absorbed dose to the maximally exposed 5 contiguous cubic centimeters of normal tissue located within the treatment site.

* * * * *

13. Revise § 35.50 to read as follows:

§ 35.50 Training for Radiation Safety Officer and Associate Radiation Safety Officer.

Except as provided in § 35.57, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer or an individual assigned the duties and tasks as an Associate Radiation Safety Officer as provided in § 35.24 to be an individual who--

(a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (d) of this section. (The names of board certifications that have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1)(i) Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

(ii) Have 5 or more years of professional experience in health physics (graduate training may be substituted for no more than 2 years of the required experience) including at least 3 years in applied health physics; and

(iii) Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

(2)(i) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(ii) Have 2 years of full-time practical training and/or supervised experience in medical physics—

(A) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an Agreement State; or

(B) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users in §§ 35.57, 35.290, or 35.390; and

(iii) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

(b)(1) Has completed a structured educational program consisting of both:

(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;

(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 an Agreement State

license or permit issued by a Commission master material licensee that authorizes similar type(s) of use(s) of byproduct material. An Associate Radiation Safety Officer may provide supervision for those areas for which the Associate Radiation Safety Officer is authorized on a Commission or an Agreement State license or permit issued by a Commission master material licensee. The full-time radiation safety experience must involve 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;

(G) Disposing of byproduct material; and

(2) This individual must obtain a written attestation, signed by a preceptor Radiation Safety Officer or Associate Radiation Safety Officer who has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual is seeking approval as a Radiation Safety Officer or an Associate Radiation Safety Officer. The written attestation must state that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (d) of this section, and is able to independently fulfill the radiation safety-related duties as a Radiation Safety Officer or as an Associate Radiation Safety Officer for a medical use license; or

(c)(1) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State under

§35.51(a) and has experience in radiation safety for similar types of use of byproduct material for which the licensee is seeking the approval of the individual as Radiation Safety Officer or an Associate Radiation Safety Officer and who meets the requirements in paragraph (d) of this section; or

(2) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on a Commission or an Agreement State license, a permit issued by a Commission master material licensee, a permit issued by a Commission or an Agreement State licensee of broad scope, or a permit issued by a Commission master material license broad scope permittee 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 or Associate Radiation Safety Officer duties and tasks and who meets the requirements in paragraph (d) of this section; or

(3) Has experience with the radiation safety aspects of the types of use of byproduct material for which the individual is seeking simultaneous approval both as the Radiation Safety Officer and the authorized user on the same new Commission or Agreement State license; and

(d) Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a Radiation Safety Officer, an Associate Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

14. In § 35.51, revise the introductory text of paragraph (a), and revise paragraphs (a)(2)(i) and (b)(2) to read as follows:

§ 35.51 Training for an authorized medical physicist.

* * * * *

(a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (c) of this section. (The names of board certifications that have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

* * * * *

(2) * * *

(i) Under the supervision of a medical physicist who is certified in medical physics by a specialty board whose certification process has been recognized under this section by the Commission or an Agreement State; or

* * * * *

(b) * * *

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (c) of this section, and is able to independently fulfill the radiation safety-related duties as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in §§ 35.51, 35.57, 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; and

* * * * *

15. In § 35.55, revise the introductory text of paragraph (a) and revise paragraph (b)(2) to read as follows:

§ 35.55 Training for an authorized nuclear pharmacist.

* * * * *

(a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State. (The names of board certifications that have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

* * * * *

(b) * * *

(2) Has obtained written attestation, signed by a preceptor-authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist.

16. Revise § 35.57 to read as follows:

§ 35.57 Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist.

(a)(1) An individual identified on a Commission or an Agreement State license or a permit issued by a Commission or an Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope as a Radiation Safety

Officer, a teletherapy or medical physicist, an authorized medical physicist, a nuclear pharmacist or an authorized nuclear pharmacist on or before October 24, 2005, need not comply with the training requirements of §§ 35.50, 35.51, or 35.55, respectively. After **[INSERT DATE 180 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]**, Radiation Safety Officers and authorized medical physicists identified in this paragraph must meet the training requirements in § 35.50(d) or § 35.51(c), as appropriate, for any material or uses for which they were not authorized prior to this date.

(2) Any individual certified by the American Board of Health Physics in Comprehensive Health Physics; American Board of Radiology; American Board of Nuclear Medicine; American Board of Science in Nuclear Medicine; Board of Pharmaceutical Specialties in Nuclear Pharmacy; American Board of Medical Physics in radiation oncology physics; Royal College of Physicians and Surgeons of Canada in nuclear medicine; American Osteopathic Board of Radiology; or American Osteopathic Board of Nuclear Medicine on or before October 24, 2005, need not comply with the training requirements of § 35.50 to be identified as a Radiation Safety Officer or as an Associate Radiation Safety Officer on a Commission or an Agreement State license or Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005.

(3) Any individual certified by the American Board of Radiology in therapeutic radiological physics, Roentgen ray and gamma ray physics, x-ray and radium physics, or radiological physics, or certified by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2005, need not comply with the training requirements for an authorized medical physicist described in § 35.51, for those materials and uses that these individuals performed on or before October 24, 2005.

(4) A Radiation Safety Officer, a medical physicist, or a nuclear pharmacist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for

medical uses or in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of § 35.50, § 35.51 or § 35.55, respectively, when performing the same uses. A nuclear pharmacist, who prepared only radioactive drugs containing accelerator-produced radioactive materials, or a medical physicist, who used only accelerator-produced radioactive materials, at the locations and time period identified in this paragraph, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates, for purposes of this chapter.

(b)(1) Physicians, dentists, or podiatrists identified as authorized users for the medical use of byproduct material on a license issued by the Commission or an Agreement State, a permit issued by a Commission master material licensee, a permit issued by a Commission or an Agreement State broad scope licensee, or a permit issued by a Commission master material license broad scope permittee before October 24, 2005, who perform only those medical uses for which they were authorized on or before that date need not comply with the training requirements of subparts D through H of this part.

(2) Physicians, dentists, or podiatrists not identified as authorized users for the medical use of byproduct material on a license issued by the Commission or an Agreement State, a permit issued by a Commission master material licensee, a permit issued by a Commission or an Agreement State broad scope licensee, or a permit issued by a Commission master material license of broad scope before October 24, 2005, need not comply with the training requirements of Subparts D through H of this part for those materials and uses that these individuals performed before October 24, 2005, as follows:

(i) For uses authorized under § 35.100 or § 35.200, or oral administration of sodium iodide I-131 requiring a written directive for imaging and localization purposes, a physician who

was certified on or before October 24, 2005, in nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology by the American Board of Radiology; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or American Osteopathic Board of Nuclear Medicine in nuclear medicine;

(ii) For uses authorized under § 35.300, a physician who was certified on or before October 24, 2005, by the American Board of Nuclear Medicine; the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or the American Osteopathic Board of Radiology after 1984;

(iii) For uses authorized under § 35.400 or § 35.600, a physician who was certified on or before October 24, 2005, in radiology, therapeutic radiology or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British “Fellow of the Faculty of Radiology” or “Fellow of the Royal College of Radiology”; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and

(iv) For uses authorized under § 35.500, a physician who was certified on or before October 24, 2005, in radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

(3) Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses performed at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with

the training requirements of subparts D through H of this part when performing the same medical uses. A physician, dentist, or podiatrist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses at the locations and time period identified in this paragraph, qualifies as an authorized user for those materials and uses performed before these dates, for purposes of this chapter.

(c) Individuals who need not comply with training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on NRC licenses for the same uses for which these individuals are authorized.

17. Revise § 35.65 to read as follows:

§ 35.65 Authorization for calibration, transmission, and reference sources.

(a) 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:

(1) 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;

(2) 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 or equivalent Agreement State regulations, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions;

(3) Any byproduct material with a half-life not longer than 120 days in individual amounts not to exceed 0.56 GBq (15 mCi);

(4) Any byproduct material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 7.4 MBq (200 micro Ci) or 1000 times the quantities in appendix B of part 30 of this chapter; or

(5) Technetium-99m in amounts as needed.

(b) Byproduct material authorized by this provision shall not be:

(1) Used for medical use as defined in § 35.2 except in accordance with the requirements in § 35.500; or

(2) Combined to create (i.e., bundled or aggregated) an activity greater than the maximum activity of any single sealed source authorized under this section.

(c) A licensee using calibration, transmission, and reference sources in accordance with the requirements in paragraphs (a) or (b) of this section need not list these sources on a specific medical use license.

18. In § 35.190, revise the introductory text of paragraph (a) and revise paragraph (c)(2) to read as follows:

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

* * * * *

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State. (The names of board certifications that have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

* * * * *

(c) * * *

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (c)(1) of this section and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under § 35.100. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in §§ 35.57, 35.190, 35.290, or 35.390, or equivalent Agreement State requirements; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in §§ 35.57, 35.190, 35.290, or 35.390, or equivalent Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association and must include training and experience specified in § 35.190.

19. In § 35.204, revise paragraph (b) and add a new paragraph (e) to read as follows:

§ 35.204 Permissible molybdenum-99, strontium-82, and strontium-85 concentrations.

* * * * *

(b) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in each eluate after receipt of a generator to demonstrate compliance with paragraph (a) of this section.

* * * * *

(e) The licensee shall report any measurement that exceeds the limits in paragraph (a) of this section, in accordance with § 35.3204.

20. In § 35.290, revise the introductory text of paragraphs (a) and (c)(1)(ii), and paragraph (c)(2) to read as follows:

§ 35.290 Training for imaging and localization studies.

* * * * *

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State. (The names of board certifications that have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

* * * * *

(c)(1) * * *

(ii) Work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.290, or 35.390 and 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements. An authorized nuclear pharmacist who meets the requirements in §§ 35.55 or 35.57 may provide the supervised work experience for paragraph (c)(1)(ii)(G) of this section. Work experience must involve—

* * * * *

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (c)(1) of this section and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under §§ 35.100 and 35.200. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in §§ 35.57, 35.290, or 35.390 and 35.290(c)(1)(ii)(G) or equivalent Agreement State requirements; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in §§ 35.57, 35.290, or 35.390 and 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association and must include training and experience specified in § 35.290.

21. In § 35.300, revise introductory text to read as follows:

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

A licensee may use any unsealed byproduct material identified in §35.390(b)(1)(ii)(G) prepared for medical use and for which a written directive is required that is—

* * * * *

22. In § 35.390, revise the introductory text of paragraph (a), and revise paragraphs (b)(1)(ii)(G) and (b)(2), and add a new paragraph (c) to read as follows:

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

* * * * *

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraphs (b)(1)(ii)(G) of this section. (The names of board certifications that have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page). To be recognized, a specialty board shall require all candidates for certification to:

* * * * *

(b)(1) * * *

(ii) * * *

(G) Administering dosages of radioactive drugs to patients or human research subjects from the four categories in this paragraph. Radioactive drugs in categories not included in this paragraph are regulated under § 35.1000. This work experience must involve 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, for which a written directive is required;

(*2*) Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131[2];

(*3*) Parenteral administration of any radionuclide that is primarily used for its electron emission, beta radiation characteristics, or for its photon energy of less than 150 keV, for which a written directive is required;

(*4*) Parenteral administration of any radionuclide that is primarily used for its alpha radiation characteristics, for which a written directive is required; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under § 35.300 for

which the individual is requesting authorized user status. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in §§ 35.57, 35.390, or equivalent Agreement State requirements and has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in § 35.57, 35.390, or equivalent Agreement State requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association and must include training and experience specified in § 35.390; or

(c) Is an authorized user for any of the parenteral administrations specified in § 35.390(b)(1)(ii)(G) or equivalent Agreement State requirements. This individual must meet the supervised work experience requirements in (b)(1)(ii) of this section for each new parenteral administration listed in § 35.390(b)(1)(ii)(G) for which the individual is requesting authorized user status.

* * * * *

[2] Experience with at least three cases in Category (G)(*2*) also satisfies the requirement in Category (G)(*1*).

23. In § 35.392, revise paragraphs (a) and (c)(3) to read as follows:

§ 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).

* * * * *

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs (c)(1) and (c)(2) of this section and whose certification process has been recognized by the Commission or an Agreement State. (The names of board certifications that have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.); or

* * * * *

(c) * * *

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section, and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under § 35.300. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in §§ 35.57, 35.390, 35.392, 35.394, or equivalent Agreement State requirements and has experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(*1*) or 35.390(b)(1)(ii)(G)(*2*); or (ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in §§ 35.57, 35.390, 35.392, 35.394, or equivalent Agreement State requirements, has experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(*1*) or 35.390(b)(1)(ii)(G)(*2*), and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of

Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association and must include training and experience specified in § 35.392.

24. In § 35.394, revise paragraphs (a) and (c)(3) to read as follows:

§ 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).

* * * * *

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs (c)(1) and (c)(2) of this section, and whose certification has been recognized by the Commission or an Agreement State. (The names of board certifications that have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.); or

* * * * *

(c) * * *

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section, and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under § 35.300. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in §§ 35.57, 35.390, 35.394, or equivalent Agreement State requirements, and has experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(2); or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in §§ 35.57, 35.390, 35.394, or equivalent Agreement State requirements, has experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(*2*), and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association and must include training and experience specified in § 35.394.

25. Revise § 35.396 to read as follows:

§ 35.396 Training for the parenteral administration of unsealed byproduct material requiring a written directive.

Except as provided in § 35.57, the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who—

(a) Is an authorized user under § 35.390 for uses listed in § 35.390(b)(1)(ii)(G)(*3*) or (b)(1)(ii)(G)(*4*), or equivalent Agreement State requirements. This individual must meet the supervised work experience requirements in (d)(2) of this section for each new parenteral administration listed in § 35.390(b)(1)(ii)(G) for which the individual is requesting authorized user status;

(b) Is an authorized user under §§ 35.490, 35.690, or equivalent Agreement State requirements and who meets the requirements in paragraph (d) of this section;

(c) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State under §§ 35.490 or 35.690, and who meets the requirements in paragraph (d) of this section; or

(d)(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations listed in §35.390(b)(1)(ii)(G). 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 §§ 35.57, 35.390, 35.396, or equivalent Agreement State requirements, in the parenteral administrations listed in § 35.390(b)(1)(ii)(G). A supervising authorized user who meets the requirements in §§ 35.390, 35.396, or equivalent Agreement State requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status. The work experience must involve—

(i) Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;

(ii) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of 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 unsealed 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 include at least three cases in each category of the parenteral administrations as specified in § 35.390(b)(1)(ii)(G) for which the individual is requesting authorized user status; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (d)(1) and (d)(2) of this section, and is able to independently fulfill the radiation safety-related duties as an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in §§ 35.57, 35.390, 35.396, or equivalent Agreement State requirements. A preceptor authorized user who meets the requirements in § 35.390, 35.396, or equivalent Agreement State requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in §§ 35.57, 35.390, 35.396, or equivalent Agreement State requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association and must include training and experience specified in § 35.396.

26. Revise § 35.400 to read as follows:

§ 35.400 Use of sources for manual brachytherapy.

A licensee must use only brachytherapy sources:

(a) Approved in the Sealed Source and Device Registry to deliver therapeutic doses for medical use. The manual brachytherapy sources may be used for manual brachytherapy uses that are not explicitly listed in the Sealed Source and Device Registry, but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

(b) In research to deliver therapeutic doses for medical use in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of § 35.49(a) are met.

27. Revise § 35.433 to read as follows:

§ 35.433 Strontium-90 sources for ophthalmic treatments.

(a) Licensees who use strontium-90 for ophthalmic treatments must ensure that certain activities as specified in paragraph (b) of this section are performed by either:

(1) An authorized medical physicist; or

(2) An individual who holds a master's or doctor's degree in physics, medical physics, other physical sciences, engineering, or applied mathematics from an accredited college or university and has successfully completed 2 years of full-time practical training and/or supervised experience in medical physics and has documented training in:

(i) The creating, modifying, and completing of written directives;

(ii) Procedures for administrations requiring a written directive; and

(iii) Performing the calibration measurements of brachytherapy sources as detailed in § 35.432.

(b) The individuals who are identified in paragraph (a) of this section must:

(1) 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; and

(2) Assist the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the administration is in accordance with the written directive. These procedures must include the frequencies that the individual meeting the requirements in paragraph (a) of this section will observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the administrations were in accordance with the written directives.

(c) Licensees must retain a record of the activity of each strontium-90 source in accordance with § 35.2433.

28. In § 35.490, revise the introductory text of paragraphs (a) and (b)(1)(ii), and paragraph (b)(3) to read as follows:

§ 35.490 Training for use of manual brachytherapy sources.

* * * * *

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State. (The names of board certifications that have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.). To have its certification process recognized, a specialty board shall require all candidates for certification to:

* * * * *

(b)(1) * * *

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.490, or equivalent Agreement State requirements, at a medical facility authorized to use byproduct materials under § 35.400, involving—

* * * * *

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (b)(2) of this section and is able to independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy sources for the medical uses authorized under §35.400. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in §§ 35.57, 35.490, or equivalent Agreement State requirements; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in §§ 35.57, 35.490, or equivalent Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association and must include training and experience specified in § 35.490.

29. In § 35.491, revise paragraph (b)(3) to read as follows:

§ 35.491 Training for ophthalmic use of strontium-90.

* * * * *

(b)(1) * * *

(3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.490, 35.491, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (b) of this section and is able to independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.

30. Revise § 35.500 to read as follows:

§ 35.500 Use of sealed sources and medical devices for diagnosis.

(a) A licensee must use only sealed sources not in medical devices for diagnostic medical uses that are approved in the Sealed Source and Device Registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry. The sealed sources must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

(b) A licensee must only use diagnostic devices containing sealed sources for diagnostic medical uses if both the sealed sources and diagnostic devices are approved in the Sealed Source and Device Registry for diagnostic medical uses. The diagnostic medical devices may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

(c) Sealed sources and devices for diagnostic medical uses may be used 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.

31. Revise § 35.590 to read as follows:

Section 35.590 Training for use of sealed sources and medical devices for diagnosis.

Except as provided in § 35.57, the licensee shall require the authorized user of a diagnostic sealed source or 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 paragraphs (c) and (d) of this section and whose certification has been recognized by the Commission or an Agreement State. (The names of board certifications that have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.);

(b) Is an authorized user for imaging uses listed in § 35.200 or equivalent Agreement State requirements; or

(c) Has completed 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; and

(4) Radiation biology; and

(d) Has completed training in the use of the device for the uses requested.

32. Revise § 35.600 to read as follows:

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

(a) A licensee must only use sealed sources:

(1) Approved and as provided for in the Sealed Source and Device Registry in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units to deliver therapeutic doses for medical uses: or

(2) In research involving photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of § 35.49(a) are met.

(b) A licensee must use photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units:

(1) Approved in the Sealed Source and Device Registry to deliver a therapeutic dose for medical use. These devices may be used for therapeutic medical treatments that are not explicitly provided for in the Sealed Source and Device Registry, but must be used in accordance with radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

(2) 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.

33. In § 35.610, revise paragraphs (d) and (g) to read as follows:

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

* * * * *

(d)(1) Prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit, a licensee shall ensure that vendor operational and safety instructions are provided to all individuals who will operate the unit. The vendor operational and safety instructions must be provided by the device manufacturer or by individuals certified by the device manufacturer.

(2) A licensee shall provide operational and safety instructions initially and at least annually to all individuals who operate the unit at the facility, as appropriate to the individual's assigned duties. The instructions shall include instruction in—

(i) The procedures identified in paragraph (a)(4) of this section; and

(ii) The operating procedures for the unit.

* * * * *

(g) A licensee shall retain a copy of the procedures required by paragraphs (a)(4) and (d)(2)(ii) of this section in accordance with § 35.2610.

34. In § 35.655, revise the section heading and paragraph (a) to read as follows:

§ 35.655 Full-inspection servicing 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 each source replacement to assure proper functioning of the source exposure mechanism and other safety components. The interval between each

full-inspection servicing shall not exceed 5 years for each teletherapy unit and shall not exceed 7 years for each gamma stereotactic radiosurgery unit.

* * * * *

35. In § 35.690, revise the introductory text of paragraphs (a) and (b)(1)(ii), and paragraph (b)(3) to read as follows:

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

* * * * *

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (c) of this section. (The names of board certifications that have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

* * * * *

(b)(1) * * *

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.690, or equivalent Agreement State requirements, at a medical facility that is authorized to use byproduct materials in § 35.600, involving—

* * * * *

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (b)(2), and paragraph (c), of this section, is able to independently fulfill the radiation safety-related duties as an authorized user of each type of

therapeutic medical unit for which the individual is requesting authorized user status. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in §§ 35.57, 35.690, or equivalent Agreement State requirements for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in §§ 35.57, 35.690, or equivalent Agreement State requirements, for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association and must include training and experience specified in § 35.690;

* * * * *

36. In § 35.2024, add a new paragraph (c) to read as follows:

§ 35.2024 Records of authority and responsibilities for radiation protection programs.

* * * * *

(c) For each Associate Radiation Safety Officer appointed under § 35.24(b), the licensee shall retain, for 5 years after the Associate Radiation Safety Officer is removed from the license, a copy of:

(1) The written document appointing the Associate Radiation Safety Officer signed by the licensee's management; and

(2) Each agreement signed by the Associate Radiation Safety Officer listing the duties and tasks assigned by the Radiation Safety Officer under § 35.24(b).

37. Revise § 35.2310 to read as follows:

§ 35.2310 Records of safety instruction.

A licensee shall maintain a record of safety instructions required by §§ 35.310, 35.410, and the operational and safety instructions required by § 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.

38. In § 35.2655, revise the section heading and paragraph (a) to read as follows:

§ 35.2655 Records of full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units.

(a) A licensee shall maintain a record of the full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units required by § 35.655 for the duration of use of the unit.

* * * * *

39. In § 35.3045, revise paragraph (a) to read as follows:

§ 35.3045 Report and notification of a medical event.

(a) A licensee shall report as a medical event any administration requiring a written directive, except for an event that results from patient intervention, in which—

(1) The administration of byproduct material or radiation from byproduct material, except permanent implant brachytherapy, results in--

(i) 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

(A) The total dose delivered differs from the prescribed dose by 20 percent or more;

(B) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

(C) The fractionated dose delivered differs from the prescribed dose for a single fraction, by 50 percent or more.

(ii) 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—

(A) An administration of a wrong radioactive drug containing byproduct material or the wrong radionuclide for a brachytherapy procedure;

(B) An administration of a radioactive drug containing byproduct material by the wrong route of administration;

(C) An administration of a dose or dosage to the wrong individual or human research subject;

(D) An administration of a dose or dosage delivered by the wrong mode of treatment; or

(E) A leaking sealed source.

(iii) A dose to the skin or an organ or tissue other than the treatment site that exceeds by:

(A) 0.5 Sv (50 rem) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and

(B) 50 percent or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.

(2) For permanent implant brachytherapy, the administration of byproduct material or radiation from byproduct material that results in—

(i) The total source strength administered differing by 20 percent or more from the total source strength documented in the post-implantation portion of the written directive;

(ii) The total source strength administered outside of the treatment site exceeding 20 percent of the total source strength documented in the post-implantation portion of the written directive;

(iii) An absorbed dose to the maximally exposed 5 contiguous cubic centimeters of normal tissue located outside of the treatment site that exceeds by 50 percent or more the absorbed dose prescribed to the treatment site in the pre-implantation portion of the written directive approved by an authorized user;

(iv) An absorbed dose to the maximally exposed 5 contiguous cubic centimeters of normal tissue located within the treatment site that exceeds by 50 percent or more the absorbed dose to that tissue based on the pre-implantation dose distribution approved by an authorized user; or

(v) An administration that includes any of the following-

(A) The wrong radionuclide;

(B) The wrong individual or human research subject;

(C) Sealed source(s) directly delivered to the wrong treatment site;

(D) A leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue; or

(E) A 20 percent or more error in calculating the total source strength documented in the pre-implantation portion of the written directive.

* * * * *

40. Add a new § 35.3204 to read as follows:

§ 35.3204 Report and notification for an eluate exceeding permissible molybdenum-99, strontium-82, and strontium-85 concentrations.

(a) The licensee shall notify by telephone the NRC Operations Center and the manufacturer/distributor of the generator within 30 calendar days after discovery that an eluate exceeded the permissible concentration listed in § 35.204(a). The telephone report to the NRC must include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects, whether the manufacturer/distributor was notified: and the action taken.

(b) By an appropriate method listed in § 30.6(a) of this chapter, the licensee shall submit a written report to the appropriate NRC Regional Office listed in § 30.6 of this chapter within 45 days after discovery of an eluate exceeding the permissible concentration. The written report must include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; and probable cause and assessment of failure in the licensee's equipment, procedures or training that contributed to the excessive readings if an error occurred in the

licensee's breakthrough determination, and the information in the telephone report as required by paragraph (a) of this section.

Dated at Rockville, Maryland, this 10th day of July, 2014.

For the Nuclear Regulatory Commission.

/RA/

Richard J. Laufer, Acting,
Secretary of the Commission.