RULEMAKING ISSUE
NOTATION VOTE

August 8, 2013 SECY-13-0084

FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

SUBJECT: PROPOSED RULE: MEDICAL USE OF BYPRODUCT MATERIAL – MEDICAL EVENT DEFINITIONS, TRAINING AND EXPERIENCE, AND CLARIFYING AMENDMENTS (RIN 3150-AI63)

PURPOSE:

To request Commission approval to publish a proposed rule in the *Federal Register* that would amend Parts 30, 32, and 35 of Title 10 of the *Code of Federal Regulations* (10 CFR) to enhance the U.S. Nuclear Regulatory Commission (NRC) regulations for medical use of byproduct material.

SUMMARY:

The proposed rule 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 (ME) for permanent implant brachytherapy. Second, the rule proposes changes: (1) to the training and experience (T&E) requirements for authorized users (AUs), medical physicists, Radiation Safety Officers (RSOs), and nuclear pharmacists; (2) to the requirements for measuring molybdenum contamination and reporting of failed technetium and rubidium generators, and (3) to allow Associate Radiation Safety Officers (ARSOs) to be named on a

SECY NOTE: THIS SECY PAPER, WITH THE EXCEPTION OF ENCLOSURE 7, WILL BE RELEASED TO THE PUBLIC IN 10 WORKING DAYS.

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Enclosure 7 transmitted herewith contains Official Use Only - Sensitive Internal Information. When separated from Enclosure 7 this transmittal document is decontrolled.

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 that 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 former Subpart J of Part 35 which contained the prior T&E requirements.

BACKGROUND:

Part 35 was revised in its entirety in 2002 (67 FR 20250), and the T&E requirements were further revised in 2005 (70 FR 16336). In implementing the current regulations, 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. These issues would be addressed in this proposed rule.

The proposed rule would modify the written directive (WD) requirements in 10 CFR 35.40 and the ME reporting in 10 CFR 35.3045 to establish separate ME criteria for permanent implant brachytherapy. The proposed amendments would define ME criteria in terms of the total source strength administered (activity-based) rather than the dose delivered (dose-based) for permanent implant brachytherapy. The ME criteria would also include absorbed dose to normal tissues located both inside and outside of the treatment site. The proposed amendments are based on the staff recommendations contained in SECY-12-0053 entitled "Recommendations on Regulatory Changes for Permanent Implant Brachytherapy Programs," (Agencywide Documents Access and Management System (ADAMS) Accession No. ML12072A306). In the SRM to SECY-12-0053, dated August 13, 2012, the Commission approved the staff recommendations for revising ME definitions for permanent implant brachytherapy and directed the staff to include the ME definition rulemaking in an ongoing medical rulemaking (the expanded rulemaking). That rulemaking had been separately initiated to address other issues that had been identified by the NRC staff, stakeholders, and the ACMUI. This proposed rule consolidates the expanded rulemaking and the ME definition rulemaking as per Commission direction.

The proposed rule would also address issues that were raised in PRM-35-20 (ADAMS Accession No. ML062620129) filed by E. Russell Ritenour, Ph.D., on behalf of the American Association of Physicists in Medicine (AAPM) in September 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.

DISCUSSION:

All the proposed revisions to the regulations are fully discussed in the enclosed draft *Federal Register* notice (FRN) (Enclosure 1). Major issues addressed in the proposed rule include:

ME definitions for permanent implant brachytherapy.

The proposed rule would establish separate ME definitions and reporting requirements for permanent implant brachytherapy from other brachytherapy procedures. The criteria for determining whether an ME had occurred with regard to permanent implant brachytherapy

would be primarily source-strength-based for the treatment site and dose-based for the absorbed dose to normal tissues. Separate WD requirements in § 35.40 for permanent implant brachytherapy would also be established. Although the majority of permanent implants are performed to treat prostate cancer, the proposed rule is intended to apply to all forms of permanent implants.

The staff notes that one of the new criteria for determining whether an ME has occurred, related to the assessment of dose to normal tissue, would establish a specific volume of 5 contiguous cubic centimeters as the size of normal tissue, based on a recommendation by the ACMUI. Because this is a new standard, the staff is seeking specific comments on the proposed selection of the specified volume of 5 cubic centimeters for an absorbed dose to normal tissues located both outside and within the treatment site in defining an ME.

Additionally, the proposed rule adds a requirement for licensees to have procedures to determine if an ME has occurred and to make certain assessments related to the permanent implant brachytherapy implantation within 60 days after the procedure is completed.

Preceptor attestation requirements.

The proposed rule would eliminate written attestations for individuals who are certified by a board that is recognized by the NRC or an Agreement State, modify the text of the written attestation that would still be required for individuals who are not board certified, and allow a residency program director to provide a written attestation. These proposed changes are based on ACMUI recommendations approved by the Commission in SRM-SECY-08-0179 "Recommendations on Amending Preceptor Attestation Requirements in 10 CFR Part 35, Medical Use of Byproduct Material," (ADAMS Accession No. ML083170176).

The proposed changes to the written attestation requirements were broadly supported during the public workshops conducted in the summer of 2011 where the panelists included members of the ACMUI, Agreement States, and others.

Petition for Rulemaking PRM-35-20

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 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 reviewed the petitioner's request and comments received on the petition (73 FR 27773, May 14, 2008) and concluded that the revisions made to the regulations in 2005 may have inadvertently affected a group of medical professionals. The proposed rule would resolve the issues raised in this petition and amend the regulations to recognize all individuals 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 modalities they practiced on or prior to October 24, 2005.

Increased frequency of testing to measure molybdenum-99 breakthrough.

Current regulations in § 35.204(a) prohibit a licensee from administering a radiopharmaceutical to humans that exceeds 0.15 microcuries of molybdenum-99 (Mo-99) per millicurie of technetium-99m (Tc-99m). Although a generator can be eluted several times to obtain Tc-99m for formulating a radiopharmaceutical for patient use, current regulations require licensees to measure the Mo-99 concentration only the first time a generator is eluted.

From October 2006 through 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 proposed rule would amend the requirement to measure the Mo-99 concentration of the first eluate to return to a pre-2002 performance standard in the regulations which had required licensees to measure the Mo-99 concentration for each elution of the Mo-99/Tc-99m generator.

The proposed change to measure Mo-99 for each elution was broadly supported during the public workshops conducted in the summer of 2011.

Reporting of failed technetium and rubidium generators.

The staff also proposes to add two new reporting requirements related to the issue of breakthrough of Mo-99, Sr-82, and Sr-85 in generators. One reporting requirement would require licensees to report to the NRC and the manufacturers or distributors of medical generators any measurement that exceeds the limits specified in § 35.204(a). The second requirement in § 30.50 would require manufacturers/distributors to report to the NRC when they receive such a notification from a licensee. The staff believes that requiring reporting of each incidence of a failed generator by both the licensee and the manufacturer or distributor would provide the NRC the opportunity to receive all the necessary information to evaluate these instances and take prompt action as needed to prevent unnecessary exposure to patients.

The staff notes that some commenters at the public workshops conducted in the summer of 2011 objected to these new reporting requirements. The commenters stated that the manufacturers are required to report failed generators to the Food and Drug Administration (FDA). The FDA may not investigate each reported incident and may take a considerable amount of time in investigating the cause of reported failures. The staff believes that requiring

reporting of each incident of a failed generator would provide the NRC the opportunity to evaluate and take prompt action as needed.

Naming Associate Radiation Safety Officers on a medical use license.

The proposed rule would amend the regulations to allow a licensee to appoint a qualified individual with expertise in certain uses of byproduct material to serve as an Associate Radiation Safety Officer (ARSO). This change is based on an ACMUI concern that the restriction in 10 CFR Part 35 that does not allow the naming of more than one permanent RSO on a license has been contributing to a shortage of available RSOs to serve as preceptors. The ACMUI further stated that due to this restriction, individuals who are qualified and are performing the same duties as an RSO cannot be recognized or listed as RSOs on a medical use license.

The proposed change to allow ARSOs to be named on a medical license was broadly supported during the public workshops conducted in the summer of 2011.

Coordination with the Advisory Committee on the Medical Uses of Isotopes

Generally, the NRC staff consults with the ACMUI when it identifies any significant issue with implementation of its medical regulations. As such, all of the proposed amendments have been discussed at the ACMUI meetings spanning over the past 9 years. In addition, the entire ACMUI meeting held on April 20-21, 2011, was devoted to the issues addressed in this proposed rule.

Following FSME procedures, the NRC staff provided the draft proposed rule to the ACMUI for its review and comments for a 90-day review. The draft (ADAMS at ML13014A487) was made publicly available to facilitate ACMUI review prior to discussion at two publicly held teleconferences on March 5, and March 12, 2013 (conference transcripts are available in ADAMS at ML13087A474 and ML13087A477, respectively). The ACMUI provided a final report to the NRC on April 9, 2013 (ADAMS at ML13071A690, Enclosure 4).

In its report, the ACMUI was supportive of the majority of the proposed amendments, expressed concerns on some issues, and provided recommendations. The staff considered all of ACMUI's recommendations and revised the discussion of the proposed rule in the *Federal Register* notice to incorporate many of ACMUI's comments. However, the staff did not accept all of the ACMUI recommendations. Enclosure 5 provides the staff's response to the ACMUI recommendations which the staff did not accept.

Outcome of this Proposed Rule: Advancing the NRC's Strategic Goals and Objectives

The staff recommends approval of this proposed rule because it best addresses long-standing issues that warrant resolution. The proposed rulemaking is consistent with the agency's goals of ensuring adequate protection of public health and safety and the environment, secure use and management of radioactive material, and effectiveness and openness in the regulatory process. Establishing separate ME criteria for permanent implant brachytherapy would enable licensees to be able to more efficiently identify any MEs and take appropriate corrective actions, resulting in an increase in patient health and safety. Many of the proposed changes increase

safety of patients, e.g., requiring reporting when generators fail, increasing training for staff using therapeutic delivery devices, and assuring that brachytherapy doses are assessed within 60 days of the date that the implant was performed.

In the area of organizational excellence, the proposed rule supports the openness objective. The rulemaking is being conducted in an open and collaborative process. The staff conducted public workshops in the summer of 2011 on MEs and other complex issues to better inform the public of this proposed rule. Also, the proposed rule and associated draft guidance will be available for public comment for 90 days.

Cumulative Effects of Regulation

In developing this proposed rule, the NRC has had considerable public interaction. Two public workshops were conducted in the summer of 2011. The first day was dedicated to discussing the ME definition for permanent brachytherapy, and the second day included discussion of other complex issues. Also, the entire ACMUI public meeting held on April 20-21, 2011, was devoted to the issues addressed in this proposed rule.

Additionally, in the FRN for the proposed rule, the staff has included a request for specific comments on the cost estimates provided in the Regulatory Analysis, and any potential unintended consequences of the proposed rule. The staff is also publishing draft guidance for public comments along with the proposed rule.

AGREEMENT STATE ISSUES:

The Agreement States were involved throughout the rulemaking process. Agreement State representatives, nominated through the Organization of Agreement States (OAS), served on the Working Group that developed the proposed amendments and on the steering committee for the rulemaking.

Through an All Agreement State letter (FSME-11-044, dated May 20, 2011), the Agreement States were notified of the availability of preliminary rule text for comments posted at the Federal rulemaking Web site at www.regulations.gov and noticed in the *Federal Register* (76 FR 29171, May 20, 2011).

Through a Radiation Control Program Directors letter (RCPD-13-001, dated January 31, 2013) a copy of the draft proposed rule FRN was provided to the Agreement States so that they could have an early opportunity for review and provide comments.

The OAS and the following Agreement States provided comments on the draft FRN: Alabama, Arkansas, Illinois, New Jersey, Virginia, Washington, and Wisconsin. Comments related to implementation were referred to the guidance working group for consideration. Several comments resulted in revisions to the discussion of the proposed rule and the rule text in the draft FRN.

Some of the major topics of concern raised by the Agreement States related to the proposed ME definition for permanent implant brachytherapy; the proposed compatibility category for T&E

requirements; the proposed compatibility category for ME reporting; the proposed new ARSO designation on a license; allowing an AU the flexibility to use sealed sources and devices for

medical uses not specifically listed in the sealed source and device registry; the proposed changes to the categories of parenteral administration (radiopharmaceuticals not administered by mouth) of byproduct material for which work experience would be required; a need for clarification on the use of transmission sources when they are used for patient diagnosis; and the proposed implementation time of 120 days for the final rule. Major comments on these issues are discussed in Enclosure 6 of this document.

NRC staff has analyzed the proposed rule in accordance with the procedures established within Part III of the Handbook to Management Directive 5.9, "Categorization Process for NRC Program Elements." The staff has determined that the proposed rule is classified as Compatibility Category "B," "C," "D," or "H&S," as appropriate. The Standing Committee on Compatibility reviewed the proposed rule and agreed with the Compatibility Categories that are in the draft proposed rule and that these amendments to the NRC regulations are a matter of compatibility between the NRC and the Agreement States.

The staff notes that currently the compatibility category for ME reporting is designated as compatibility category C. However, the ACMUI recommended that it should be designated as compatibility category B. The staff is seeking specific comments on the compatibility category for ME reporting.

COMMITMENTS:

The staff will make the draft guidance for the proposed 10 CFR Part 35 rulemaking (ADAMS Accession No. ML13172A189) available for public comment concurrent with the publication of the proposed rule.

RECOMMENDATIONS:

That the Commission:

1. Approve for publication, in the *Federal Register*, the proposed amendments to 10 CFR Parts 30, 32, and 35 (Enclosure 1).

2. To satisfy requirements of the Regulatory Flexibility Act of 1980, as amended (5 U.S.C. § 605(b)), certify that this rule, if promulgated, will not have a significant economic impact on a substantial number of small entities.

Note:

a. That the proposed amendments will be published in the *Federal Register*, allowing 90 days for public comment.

b. That the Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification and the reasons for it, as required by the Regulatory Flexibility Act, 5 U.S.C. 605(b).

c. That a draft Regulatory Analysis has been prepared for this rulemaking (Enclosure 2).

d. That a draft Environmental Assessment has been prepared for this rulemaking (Enclosure 3).

e. That appropriate Congressional committees will be informed of this action.

f. That a press release will be issued by the Office of Public Affairs when the proposed rulemaking is filed with the Office of the Federal Register.

g. The resources needed to complete the rulemaking are discussed in Enclosure 7.

Office of Management and Budget (OMB) Paperwork Reduction Act review is required and a clearance package will be forwarded to OMB no later than the date the proposed rule is submitted to the Office of the Federal Register for publication.

COORDINATION:

The Office of the General Counsel has no legal objection to the proposed rulemaking. The Office of the Chief Financial Officer has reviewed this SECY Paper for resource implications and has no objections.

/RA by Michael F. Weber for/

R. W. Borchardt
Executive Director
for Operations

Enclosures:
1. Draft *Federal Register* notice
2. Draft Regulatory Analysis
3. Draft Environmental Assessment
4. ACMUI Report on Part 35 Draft Proposed Rule
5. Staff Response to ACMUI Report on Part 35 Draft Proposed Rule
6. Summary of Major Agreement State Comments and Staff Responses
7. Resources for Part 35 Rulemaking

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 (ME) for permanent implant brachytherapy. Second, the rule proposes changes: (1) to the training and experience (T&E) requirements for authorized users (AUs), medical physicists, Radiation Safety Officers (RSOs), and nuclear pharmacists; (2) to the requirements for measuring molybdenum (Mo) contamination and reporting of failed technetium (Tc) and rubidium (Rb) generators, and (3) to allow Associate Radiation Safety Officers (ARSOs) 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 that 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 former subpart J of part 35 which contained the prior T&E requirements.

DATES: Submit comments by **[INSERT DATE: 90 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 301-492-3668, 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 "Accessing Information and Submitting Comments" in the Table of Contents 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: 301-415-6843, e-mail: Neelam.Bhalla@nrc.gov.

EXECUTIVE SUMMARY:

A. Need for the Regulatory Action and Legal Authority

The 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. 553.

B. Major Provisions

- The proposed rule would establish separate requirements for identifying and reporting MEs 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 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. Additionally, two new reporting requirements related to Mo-99 and Sr-82 breakthrough and strontium-85 (Sr-85) contamination would be added to assist the NRC in evaluating these events; 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 ARSO. This would make it easier for an individual to become an 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 $8.2 million implementation cost for the medical community. This cost would be spread over the 7,473 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 $415,000 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 licenses. 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

This proposed rule is organized as follows:

I. Accessing Information and Submitting Comments

A. Accessing 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 information related to this proposed rule, which the NRC possesses and is publicly available, 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 NRC Library 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 10 CFR in their entirety. The 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 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. ML100890086), 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 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 proposed rule (Regulation Identifier Number 3150-AI26) in this 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. 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 Sr-82 and 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 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 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. ML041620583), 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, which revised the earlier interim report on prostate brachytherapy regulation, was provided to the NRC following the ACMUI October 18, 2011, teleconference public meeting (ADAMS Accession No. ML11292A139). 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 by ASTRO as an improvement.

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. 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 these implants must allow for final WD documentation based on the medical situation encountered during the surgical procedure. Therefore, in defining an ME involving the treatment site, the criterion is based on the percentage of implanted sources documented in the post-implantation portion of the WD that is outside of the treatment site, and not 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.

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 superfluous.

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 Advisory Committee on the Medical Uses of Isotopes (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 Tc-99m. 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. Although a generator can be eluted several times to obtain Tc-99m for formulating radiopharmaceuticals for patient use, current regulations require licensees to measure the Mo-99 concentration only the first time a generator is eluted.

The Mo-99 breakthrough measurements which exceed 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 two new reporting requirements related to breakthrough of Mo-99, and Sr-82 and Sr-85 contamination. One reporting requirement in § 35.3204(a) would require a licensee to report to the NRC and the manufacturer or distributor of medical generators any measurement that exceeds the limits specified in § 35.204(a) within 24 hours. The second requirement in § 30.50 would require a manufacturer or distributor to report to the NRC within 24 hours of receipt of such a notification from a licensee.

Several commenters at the June and August 2011 public workshops stated that the NRC should not require this reporting because the manufacturers are required to report failed generators to the Food and Drug Administration (FDA). The FDA may not investigate each reported incident and may take a considerable amount of time in investigating the cause of reported failures. The NRC believes that requiring each incident of a failed generator to be

reported would provide the NRC the opportunity to evaluate and take prompt action as needed. This new reporting requirement is being proposed to allow the NRC to assess potential situations in a timely manner so that appropriate action may be taken to avoid unwarranted radiation exposure to patients.

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). 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 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. ML13073A035.

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

1) 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 this issue, please use one of the methods described in Section I, Accessing Information and Submitting Comments, of this document.

2) 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. In responding to this issue, please use one of the methods described in Section I, Accessing 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: Section C. and D. of IV of this document requests comment on the cumulative effects of regulation, Agreement Compatibility designations for the proposed rule, and the volume for determining an absorbed dose to normal tissue for MEs; Section X requests comment on the use of plain writing; Section XIV requests comment on the environmental assessment; Section XV requests comment on the information collection requirements; Section XVI requests comment on the draft regulatory analysis; and Section XVII 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 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 record 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 30.50 Reporting requirements.

Paragraph (b)(5). This new paragraph would be added to require manufacturers or distributors of medical generators to notify the NRC within 24 hours of receipt of a notification required by § 35.3204(a). Section 35.3204(a) requires licensees to notify the manufacturers or distributor of the generator when an eluate from a generator exceeds the permissible concentration listed in § 35.204(a). Further discussion of reporting of failed generators is found 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)(1). 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 to amend paragraph (b), include two new paragraphs, and redesignate current paragraphs (d) through (g).

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.

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 of "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.

This section would be restructured and amended to accommodate specific requirements for a WD for permanent implant brachytherapy. 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.

Section 35.41 Procedures for administrations requiring a written directive.

This section would add 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 requirement now would be applicable only to an RSO or an ARSO using the alternate pathway. 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.

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 effect 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 renumber from current paragraph (a)(3) and has not been 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 this part.

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 this part 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 this part 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 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 § 35.190.

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 in each eluate. 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 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 § 35.290.

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). 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 is under 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 has 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 in research in these units 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 in 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, as postponing the training of new staff until the required annual training, 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 has 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.

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 related to § 35.41 of this part were made;

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 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 an 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 no later than

the next calendar day 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 15 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.

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. ML13025A073), 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, thus, 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

Section	Change	Subject	Compatibility	
			Existing	New
30.50(b)(5)	New	Reporting requirements	-	C
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

Section	Change	Subject	Compatibility	
			Existing	New
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

Section	Change	Subject	Compatibility	
			Existing	New
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

Section	Change	Subject	Compatibility	
			Existing	New
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

Section	Change	Subject	Compatibility	
			Existing	New
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

Section	Change	Subject	Compatibility	
			Existing	New
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

Section	Change	Subject	Compatibility	
			Existing	New
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

Section	Change	Subject	Compatibility	
			Existing	New
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

Section	Change	Subject	Compatibility	
			Existing	New
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

Section	Change	Subject	Compatibility	
			Existing	New
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

Section	Change	Subject	Compatibility	
			Existing	New
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

Section	Change	Subject	Compatibility	
			Existing	New
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

Section	Change	Subject	Compatibility	
			Existing	New
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	C
35.3045(a)(2)	New	Report and notification of a medical event	-	C

Section	Change	Subject	Compatibility	
			Existing	New
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 which 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 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, an 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 an 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 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 Environmental Assessment and this proposed rule to every State Liaison Officer and requested their comments on the Environmental Assessment. The Environmental Assessment is available in ADAMS under Accession No. ML13059A059.

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: 27,728 (4,078 from NRC licensees and 23,650 from Agreement State licensees).

The estimated number of annual respondents: 7,473 (1,083 from NRC licensees and 6,390 from Agreement State licensees).

An estimate of the total number of hours needed annually to complete the requirement or request: 8,274 hours (1,202 hours for NRC licensees and 7,072 hours for Agreement State licensees).

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, Chad J. Whiteman, 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 Chad_J._Whiteman@omb.eop.gov or comment by telephone at (202) 395-4718.

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. ML13073A035 and available for inspection in the NRC's PDR, 11555 Rockville Pike, Rockville, MD 20852.

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. ML13073A035). 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) How 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 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

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 final 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; and 5 U.S.C. 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 continues 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. No. 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.

* * * * *

3. In § 30.50, add a new paragraph (b)(5) to read as follows:

§ 30.50 Reporting requirements.

* * * * *

(b) * * *

(5) For a manufacturer or a distributor of medical generators, the receipt of a notification required by § 35.3204(a).

* * * * *

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

4. The authority citation for part 32 continues 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. No. 109-58, 119 Stat. 806-810 (42 U.S.C. 2014, 2021, 2021b, 2111).

5. 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) Shall provide to the Commission:

(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

6. The authority citation for part 35 continues 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); 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).

7. In § 35.2, modify the definition for *Preceptor*, and add, in alphabetical order, the definitions for *Associate Radiation Safety Officer* and *Ophthalmic physicist* 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.

* * * * *

8. 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.

* * * * *

9. In § 35.13, redesignate paragraphs (d), (e), (f), and (g) as paragraphs (e), (f), (g), and (h), respectively, revise newly redesignated paragraphs (g) and (h), and add new paragraphs (b), (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.

10. 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.

* * * * *

11. 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).

* * * * *

12. 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.

* * * * *

13. 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.

* * * * *

14. 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 which 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.

15. In § 35.51, revise the introductory text of paragraph (a), and 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 which 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

* * * * *

16. In § 35.55, revise the introductory text of paragraph (a) and 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 which 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.

17. 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 **[DATE THAT IS 180 DAYS AFTER THE DATE OF 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.

18. 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.

19. In § 35.190, revise the introductory text of paragraph (a) and 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 which 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.

20. 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.

21. 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 which 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.

22. 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—

* * * * *

23. In § 35.390, revise the introductory text of paragraph (a), and 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. (Specialty boards whose certification processes 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*).

24. 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 which 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.

25. 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 which 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.

26. 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.

27. 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.

28. 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.

29. 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 which 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.

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

§ 35.491 Training for ophthalmic use of strontium-90.

* * * * *

(b) * * *

(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.

31. 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.

32. 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 which 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.

33. 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.

34. 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.

35. 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.

* * * * *

36. 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 which 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;

* * * * *

37. 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).

38. 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.

39. 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.

* * * * *

40. 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.

* * * * *

41. 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 no later than the next calendar day 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 15 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_____day of_____, 2013.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,
Secretary of the Commission.

Draft Regulatory Analysis for Proposed Rule: Amendments to Medical Use of Byproduct Material Regulations (10 CFR Parts 30, 32, and 35)

U.S. Nuclear Regulatory Commission

Office of Federal and State Materials and Environmental Management Programs

Division of Intergovernmental Liaison Rulemaking

XXXX 2013

Table of Contents

Executive Summary

The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend Parts 30, 32, and 35 of Title 10 of the *Code of Federal Regulations* (10 CFR) related to 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 (ME) for permanent implant brachytherapy. Second, the rule proposes changes: (1) to the training and experience (T&E) requirements for authorized users (AUs), medical physicists, Radiation Safety Officers (RSOs), and nuclear pharmacists; (2) to the requirements for measuring molybdenum contamination and reporting of failed technetium and rubidium generators, and (3) to allow Associate Radiation Safety Officers (ARSOs) 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 that 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 former Subpart J of Part 35 which contained the prior T&E requirements. Currently there are 1,083 NRC and 6,390 Agreement State medical licensees that would be affected by this proposed rulemaking. Existing guidance documents (NUREG-1556, Volumes 9 and 13) would be revised to reflect these changes.

This regulatory analysis examines the benefits and costs of the proposed changes to these regulations. The analysis makes the following key findings:

- Cost to Industry. The proposed rule would result in a total one-time cost to the Industry of approximately $8.3 million followed by total annual costs of approximately $775,000. This results in costs of approximately $1,000 per licensee in one-time cost and approximately $100 per licensee in annual cost.

- Costs to the NRC. The proposed rule would result in a one-time cost to the NRC of approximately $400,000 followed by an annual savings of approximately $75,000.

- Cost to the Agreement States. The proposed rule would result in a one-time cost to the Agreement States of approximately $5.1 million followed by an annual savings of approximately $325,000.

- Decision Rationale. The NRC has determined that the proposed rule is cost-justified because the proposed regulatory initiatives would potentially reduce unnecessary radiation exposure to patients. Additionally, the proposed rule would update, clarify, and strengthen the existing regulatory requirements, and thereby promote public health and safety. Cost reductions would be realized by removing attestation requirements for certain board certified individuals, by modifying ME reporting criteria to ensure only significant events need to be reported, and by other proposed modifications to the regulations.

- The NRC evaluated the impact that a small entity would be expected to incur as a result of the rule. The proposed rule would have an average implementation cost of approximately $1,000 per licensee and an annual cost impact of an estimated $100 per

licensee. Thus, even though the proposed rule would affect a substantial number of licensees that are small entities, it would not have a significant economic impact on these entities.

Acronyms

ACMUI	Advisory Committee on the Medical Uses of Isotopes
ADAMS	Agencywide Documents Access and Management System
AMP	Authorized medical physicist
ANP	Authorized nuclear pharmacist
ARSO	Associate Radiation Safety Officer
AU	Authorized user
CFR	*Code of Federal Regulations*
FR	*Federal Register*
FTE	full-time equivalent
ME	medical event
Mo-99	molybdenum-99
NRC	U.S. Nuclear Regulatory Commission
OMB	Office of Management and Budget
PRM	petition for rulemaking
Rb-82	rubidium-82
RSO	Radiation Safety Officer
SRM	Staff Requirements Memorandum
SSDR	Sealed Source and Device Registry
Sr-82	strontium-82
Sr-85	strontium-85
Tc-99m	technetium-99m
T&E	training and experience
WD	written directive

1. Statement of the Problem and Objective of the Rulemaking

The NRC is proposing to amend Parts 30, 32, and 35 of 10 CFR related to the medical use of byproduct material. Medical use regulations in 10 CFR Part 35 were revised in their entirety in April 2002 (67 FR 20250). The T&E requirements in Part 35 were further revised through an additional rulemaking published in the *Federal Register* (70 FR 16336) on March 30, 2005. In implementing the regulations, 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.

In Staff Requirements Memorandum (SRM) dated May 15, 2008, entitled "Meeting with Advisory Committee on the Medical Uses of Isotopes (ACMUI), 1:30 p.m., Tuesday April 29, 2008," (Agencywide Documents Access and Management System (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 an alternate pathway. The staff was also directed to consider additional methods, such as the attestation being provided by consensus of an authoritative group.

Additionally, the Commission directed the staff in SRM-SECY-10-0062, dated August 10, 2010 (ADAMS Accession No. ML102220233), to work closely with the ACMUI and the medical community to develop event definitions for permanent implant brachytherapy that would protect the interests of patients, and 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 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 and those located within the treatment site. Other changes include amending preceptor attestation requirements, allowing ARSOs to be named on a medical use license, changing the requirements for measuring molybdenum contamination and reporting of failed technetium and rubidium generators, extending the 5-year inspection frequency for a gamma stereotactic radiosurgery unit to 7 years, and several clarifying amendments.

The proposed rulemaking would also consider issues that were raised in a petition for rulemaking (PRM-35-20, ADAMS Accession No. ML062620129) filed by E. Russell Ritenour, Ph.D., on behalf of the American Association of Physicists in Medicine 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 proposed rule addresses the petition and Commission direction to clarify the current regulations, provides greater flexibilities to licensees, revises medical event criteria for permanent implant brachytherapy without compromising patient, worker, and public health and safety.

This analysis presents background material, rulemaking objectives, alternatives considered, input assumptions, analysis of the costs and benefits of the proposed rule, and decision rationale. It describes the consequences of the rule language and alternative approaches necessary to accomplish the regulatory objectives.

2. Identification and Preliminary Analysis of Alternative Approaches

The following sections describe the two regulatory options that the NRC is considering to meet the rulemaking objective identified in section 1.1. Section 3 presents a detailed cost and benefit analysis.

2.1 Option 1: No Action

Under Option 1, the no-action alternative, the NRC would not amend the current regulations in 10 CFR Parts 30, 32, and 35.

Option 1 would avoid costs and savings that the proposed rule would impose; however, the benefits from updating, clarifying, and consolidating the current requirements to enhance the current level of protection for public health and safety would not be realized. Also, there would be no changes made to improve regulatory efficiency and the resulting benefits to the medical use of byproduct material. Option 1, which is the no-action alternative, is the baseline for this regulatory analysis.

2.2 Option 2: Amend 10 CFR Parts 30, 32, and 35

The changes listed below are consistent with Option 2 to revise 10 CFR Parts 30, 32, and 35 and would result in incremental increase or decrease in cost or benefit.

Section 30.34(g). This new requirement would be added to require licensees to report to the NRC the results of any test of generator elutions for molybdenum-99 (Mo-99) breakthrough or strontium-82 (Sr-82) and strontium-85 (Sr-85) contamination that exceeds the permissible concentration listed in § 35.204(a). Reporting would be in accordance with the reporting and notifications in § 35.3204. While this proposed reporting requirement as well as testing every elution is new, the requirement for licensees to test the first elution to ensure that it does not exceed the permissible concentration listed in § 35.204(a), and record the results of these tests, is already in current regulations. On several occasions in 2006, 2007, and 2008, medical licensees voluntarily reported to the NRC that generators had failed the Mo-99 breakthrough tests. In 2011, contamination issues were reported with Sr-82 rubidium-82 (Rb-82) generators. Because the reporting was voluntary, the NRC had difficultly determining the extent of the issues and the underlying cause. Breakthrough of Mo-99 and contamination of Sr-85 may lead to unnecessary exposure to radiation for patients. The proposed change would allow the NRC to assess the situation quickly and efficiently when issues occur with generators that may cause unwarranted radiation exposure to patients.

Section 30.50 (b)(5). This new paragraph would be added to require manufacturers or distributors of medical generators to notify the NRC within 24 hours when they receive a notification required by § 35.3204(a). Section 35.3204(a) requires licensees to notify the manufacturer or distributor of the generator when an eluate from a generator exceeds the

permissible concentration listed in § 35.204(a). On several occasions in 2006, 2007 and 2008, eluates from generators exceeded the permissible concentration listed in § 35.204(a). Current regulations do not require manufacturers and/or distributors to notify the NRC of these incidents. This hindered the NRC's efforts to determine the extent of the issues, which in turn caused a delay in the NRC's ability to take action to protect medical patients from receiving unnecessary exposure to radiation. Reporting the incidents to the NRC within 24 hours would allow for interim actions to be taken quickly to protect patients while the causes and corrections of the issues are being determined.

Section 35.12 (b)(1). This paragraph would be amended to remove the requirement to submit additional copies of NRC Form 313 when applying for a license. The proposed change would relieve cost to the licensees by requiring less paperwork to be submitted. This paragraph would also add a requirement to submit information on an individual seeking to be identified on a license as an ARSO or as an ophthalmic physicist.

Section 35.12 (c)(1). This paragraph would be amended to remove the requirement to submit an additional copy of NRC Form 313 or a letter containing information required by NRC Form 313 for license amendments or renewals. This change would relieve cost to the licensees by requiring less paperwork to be submitted.

Section 35.13(d). This new paragraph would require a licensee to apply for and receive a license amendment prior to permitting an individual to work as an ARSO or before the RSO assigns different tasks and duties to an ARSO who is authorized on the license. The NRC determined that allowing ARSOs 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, ARSOs could more easily become RSOs on other licenses for the types of uses for which they qualify.

Section 35.13(i). This new paragraph would allow licensees who are authorized for manual brachytherapy to receive certain sealed sources without seeking a license amendment. Specifically, a licensee would be able 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. This change is proposed to make it easier for the licensee to obtain the appropriate sealed sources necessary for patient treatments in a timely manner.

Section 35.14(a). This paragraph would be amended to remove the requirement to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State when using the notification process.

Section 35.14(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.

Section 35.14(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(b). This paragraph would be modified to allow the licensee's management to appoint one or more qualified individuals to serve as ARSOs. These appointed ARSOs would have to be currently identified on a medical license or permit for the types of use of byproduct material for which the RSO would assign tasks and duties. Each ARSO would have to agree in writing to the tasks and duties assigned by the RSO.

Section 35.41(b)(5). This new paragraph would require licensees to add procedures for any administrations requiring a WD to determine if an ME as defined in § 35.3045 has occurred.

Section 35.41(b)(6). This new paragraph would require licensees to add procedures for permanent implant brachytherapy that include a procedure for determining dose/activity parameters within 60 calendar days from the date the implant was performed. If the licensee cannot make these determinations within the 60 calendar days because of the patient not being available, then the licensee must justify the reason for not making these determinations in writing.

Section 35.50(a). For individuals seeking to be named as an RSO or an ARSO, this paragraph would be amended to remove the requirement to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State.

Section 35.50(c)(3). This new paragraph would allow an individual who is qualified to be an AU, but is not named as an AU on a medical license or permit, to be named simultaneously as the RSO and the AU on the same new medical license. Under current § 35.50(c)(2), an AU identified on a medical license or permit can be named as the RSO for the same byproduct material for which the AU is authorized. This new provision would expand this principle and allow an individual who is qualified to be the AU, but is not named on a medical license or permit, to be named simultaneously as both the AU and the RSO for the same uses on a new medical license. The provision would make it easier for an individual qualified to be an AU to open a physician's office or a clinic and make medical procedures more widely available, especially in rural areas.

Section 35.51(a). This paragraph would be amended to remove the requirement for individuals seeking to be named as an authorized medical physicist (AMP) to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State.

Section 35.55(a). This paragraph would be amended to remove the requirement for individuals seeking to be named as an authorized nuclear pharmacist (ANP) to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State.

Section 35.57(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.

Section 35.57(a)(2). This paragraph would be modified to recognize individuals certified by the named boards in the now removed subpart J of 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 a RSO 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. Training requirements excepted under this paragraph would be limited to 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 training requirements in § 35.59 and, for new materials and uses, the training requirements in § 35.50(d).

Section 35.57(a)(3). This paragraph would be modified to 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 an 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. Training requirements excepted under this paragraph would be limited to 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 training requirements in § 35.59 and, for new materials and uses, the training requirements in § 35.51(c).

Section 35.57(b)(1). This paragraph would be amended to change the date from October 24, 2002, to October 24, 2005, for individuals named on a license as AUs because during the 3-year time frame, applicants could have qualified under the old Subpart J or the new T&E requirements in subparts D through H of 10 CFR Part 35 to qualify as AUs. Additionally, the paragraph would be amended to clarify that individuals 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.

Section 35.57(b)(2). This paragraph would be restructured and expanded to recognize physicians, dentists, or podiatrists who were certified by the named boards in the now-removed subpart J of Part 35 on or before October 24, 2005, 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 these individuals performed on or before October 24, 2005.

Section 35.65(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 that authorized by § 35.65. Sources that consist of multiple single sources greater than authorized by § 35.65 would be treated as one single source and would have to meet all the regulatory requirements for that single source including, if appropriate, listing on a specific medical license, leak testing, and security requirements.

Section 35.190(a). This paragraph would be amended to remove the written attestation requirement for a physician who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State and is seeking to be named as an AU for byproduct material authorized under § 35.100.

Section 35.204(b). This paragraph has been modified to require licensees to measure the Mo-99 concentration after each eluate from a Mo-99/Tc-99m generator. Generator manufacturers recommend testing each elution prior to use in humans. Mo-99 breakthrough measurements which exceed the permissible concentration listed in § 35.204(a) may cause unnecessary radiation exposures to patients.

Section 35.204(e). This new paragraph would require licensees to report any measurement that exceeded the limits specified in § 35.204(a) for Mo-99/Tc-99m and Sr-82 Rb-82 generators. Although current regulations require licensees to measure Mo-99, Sr-82, and Sr-85 concentrations and record the results, there is no provision to report when a result exceeds the regulatory limits. The new reporting requirement would provide information that would allow the NRC to respond to the potential patient safety issue in a timely manner.

Section 35.290(a). This paragraph would be amended to remove the written attestation requirement for a physician who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State and is seeking to be named as an AU for byproduct material authorized under § 35.200.

Section 35.390(a). This paragraph would be amended to remove the written attestation requirement for a physician who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State and is seeking to be named as an AU for byproduct material authorized under § 35.300.

Section 35.392(a). This paragraph would be amended to remove the written attestation requirement for a physician who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State and is 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).

Section 35.394(a). This paragraph would be amended to remove the written attestation requirement for a physician who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State and is seeking to be named as an AU for the oral administration of sodium iodide I-131 in quantities greater than 1.22 gigabecquerels (33 millicuries) requiring a WD.

Section 35.433(a)(2). This paragraph would be amended to add the T&E requirements for an ophthalmic physicist who is not an AMP but who could be involved with ophthalmic treatments using strontium-90 sealed sources. These requirements are similar to the T&E requirements for an AMP, but would include only the requirements related to brachytherapy programs. The ophthalmic physicist would not need an attestation. This change would increase the number of qualified individuals available to support the use of strontium-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 change would

make the procedure involving use of strontium-90 sources for ophthalmic treatments available to more patients located in remote areas.

Section 35.490(a). This paragraph would be amended to remove the written attestation requirement for a physician who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State and is seeking to be named as an AU for byproduct material authorized under § 35.400.

Section 35.610(d)(1). This paragraph would be amended and restructured to add a new training requirement for 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 instructions 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.

Section 35.655(a). This paragraph would be amended to extend the time interval for fully inspecting and servicing a gamma stereotactic radiosurgery unit from 5 years to 7 years.

Section 35.690(a). This paragraph would be amended to remove the written attestation requirement for a physician who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State and is seeking to be named as an AU for byproduct material authorized under § 35.600.

Section 35.2024(c)(1) and (2). 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 35.2041. This section is impacted due to the recordkeeping requirements of the added procedures required in § 35.41(b)(5) and (6).

Section 35.3045(a)(2). In this amended section, separate criteria for reporting an ME for permanent implant brachytherapy procedures are established. The new criteria are expected to capture events that are clinically significant and would reduce the number of reportable MEs related to permanent implant brachytherapy resulting in cost reduction in § 35.3045(c), (d), and (e) related to event notification and follow-up reports.

Section 35.3045(c). The telephone reporting costs to the Agreement States and the NRC would be reduced because the requirements for reporting an ME for permanent implant brachytherapy are changed in § 35.3045(a)(2). The new requirements would not capture events that are not of significance and would reduce the number of reportable MEs related to permanent implant brachytherapy.

Section 35.3045(d). The written reporting costs to the Agreement States and the NRC would be reduced because the requirements for reporting an ME for permanent implant brachytherapy are changed in § 35.3045(a)(2). The new requirements would not capture events that are not

significant and would reduce the number of reportable MEs related to permanent implant brachytherapy.

Section 35.3045(e). The licensee reporting costs to the physician and patients would be reduced because the requirements for reporting an ME for permanent implant brachytherapy are changed in § 35.3045(a)(2). The new requirements would not capture events that are not significant and would reduce the number of reportable MEs related to permanent implant brachytherapy.

The NRC has estimated the benefits and costs of this option, which are described in Sections 3 and 4 of this regulatory analysis, and has pursued Option 2 for the reasons discussed in Section 5.

3. Estimation and Evaluation of Benefits and Costs

This section describes the analysis that the NRC conducted to identify and evaluate the benefits and costs of the two regulatory options. Section 3.1 identifies the attributes that the staff expects the proposed rulemaking to affect. Section 3.2 describes how the benefits and costs have been analyzed. Finally, Section 3.3 presents the detailed results of the projected benefits and costs.

3.1 Identification of Affected Attributes

This section identifies the factors within the public and private sectors that the final rule is expected to affect, using the list of potential attributes in Chapter 5 of NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook," issued January 1997, and in Chapter 4 of NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," Revision 4, issued September 2004. This evaluation considered each attribute listed in Chapter 5 of NUREG/BR-0184. The basis for selecting those attributes is presented below.

Affected attributes include the following:

- Industry Implementation - Under the proposed action, the industry would incur a one-time cost to implement the proposed rule.

- NRC Implementation - Under the proposed action, the NRC would develop the proposed rule package to be published by the Office of the *Federal Register* and prepare the final rule package that responds to comments from stakeholders and sets forth the final rule text for publication by the Office of the *Federal Register*. The NRC would revise guidance and inspection procedures to accommodate the requirements that would be added or modified by the rulemaking process.

- Industry Operations - The proposed changes to 10 CFR Parts 30, 32, and 35 would require licensees to meet the new and amended requirements discussed in Section 2.2.

- NRC Operations - The proposed changes would require the NRC to process and review submitted licensing amendments and reports.

- Other Government - The Agreement States would incur an implementation cost to issue compatible regulatory requirements and guidance. The Agreement States would incur annual operational cost as well.

- Regulatory Efficiency - The action would result in enhanced regulatory efficiency through regulatory and compliance improvements.

- Public Health (routine) - Several proposed amendments would reduce the potential radiation exposure to patients.

Attributes that the rulemaking options would not affect include the following: occupational health (routine), occupational health (accidents), public health (accidents), environmental considerations, general public, safeguards and security considerations, improvements in knowledge, offsite property, onsite property, antitrust considerations, and other considerations.

3.2 Analytical Methodology

This section describes the methodology used to analyze the benefits and costs associated with the proposed rule. The benefits include any desirable changes in the affected attributes. The costs include any undesirable changes in the affected attributes.

As described in Section 3.1, the attributes expected to be affected include the following:

- Industry Implementation
- Industry Operation
- NRC Implementation
- NRC Operations
- Regulatory Efficiency
- Other Government
- Public Health (routine)

The analysis evaluates several attributes on a quantitative basis. Quantitative analysis requires a baseline characterization, including factors such as the number of licensees affected, the nature of activities being conducted, and the types of new activities that licensees would implement as a result of the rule. The analysis proceeds quantitatively for these attributes by making general assumptions. Sections 3.2.1 – 3.3 describe the most significant analytical data and assumptions used in the quantitative analyses of these attributes.

The proposed rule includes changes that affect attributes in a positive but not easily quantifiable manner. For example, the attribute of Regulatory Efficiency would be enhanced by the proposed changes made in requirements for submitting an application for a license such as in § 35.50. In this section, the regulations would be changed to make it easier for a physician to open an office by allowing this individual to be the AU and the RSO on the same license application.

One way public health (routine) would be positively affected is by reducing the potential for unnecessary radiation exposure to patients with the changes to § 35.204. This section would

require licensees to test each eluate from a generator rather than just the first eluate. In the past several years, generators have had breakthrough issues that have resulted in unnecessary radiation exposure to patients.

The NRC's input assumptions used data and information from NRC workgroups, staff experience, and the NRC's databases to estimate the costs associated with implementation, and the costs associated with annual operations of industry and the NRC.

In accordance with guidance from the Office of Management and Budget (OMB) and NUREG/BR-0058, Revision 4, this regulatory analysis presents the results of the analysis using both 3 percent and 7 percent real discount rates. The real discounted rates or present-worth calculation simply determines how much society would need to invest today to ensure that the designated dollar amount is available in a given year in the future. By using present-worth, costs and benefits, regardless of when averted in time, are valued equally. Based on OMB guidance (OMB Circular No. A-4, September 17, 2003), present-worth calculations are presented using both 3 percent and 7 percent real discount rates. The 3 percent rate approximates the real rate of return on long-term government debt which serves as a proxy for the real rate of return on savings. This rate is appropriate when the primary effect of the regulation is on private consumption. Alternatively, the 7 percent rate approximates the marginal pretax real rate of return on an average investment in the private sector, and is the appropriate discount rate whenever the main effect of a regulation is to displace or alter the use of capital in the private sector. The NRC seeks public comments on the accuracy of these regulatory analysis assumptions and on the validity of the proposed rule's value and impact estimation methods.

3.2.1 Data and Assumptions

The analysis assumes that one-time implementation cost for Industry, the Agreement States and NRC-proposed changes to §§ 35.13(d) and 35.65(b)(1) would be incurred in calendar year 2015. The analysis assumes that NRC one-time implementation costs associated with rule development and guidance documents are incurred in years 2012-2015. The analysis assumes that ongoing costs related to revised and consolidated requirements in 10 CFR Parts 30, 32, and 35 would begin in 2015 and would be modeled on an annual cost basis. The analysis calculated cost and savings over a 10-year time horizon with each year's costs or savings discounted back at a 7 percent and 3 percent discount rate in accordance with NUREG/ BR-0058, Revision 4. Costs and savings are expressed in 2013 dollars.

Data/Affected Entities

The analysis assumes that the following entities would be affected by this rule:

- NRC
- NRC licensees
- Agreement States
- Agreement State licensees
- Manufacturers and/or distribution licensees
- Authorized users

- Associate Radiation Safety Officers
- Radiation Safety Officers
- Authorized medical physicists
- Authorized nuclear pharmacists
- Medical patients

Number and Type of Licensees

Licensees regulated by the NRC (those licensed by the NRC to use radioactive materials including NRC Master Material Licensees) and the Agreement States (states who have assumed regulatory authority over the use of certain radioactive materials in their states) are equally impacted by the proposed rule. Table 1 provides data from NRC's License Tracking System on the number of NRC licensees, by category, as of November 2012. The number of Agreement State licensees is estimated at 5.9 times the number of NRC licensees, based on historical data obtained from NRC databases. This regulatory analysis is based on the assumption that all the Agreement States will adopt all of the proposed regulatory changes.

Table 1 Number and Type of Licenses

License Title	Program codes [1]	NRC[2]	Master Materials License[3]	Total NRC Licensees	Agreement States[4]	Total Licensees
Medical Institution – Broad	2110	23	44	67	395	462
Medical Institution – Written Directive Required	2120	257	81	338	1994	2332
Medical Institution – Written Directive Not Required	2121	145	13	158	932	1090
Medical Private Practice – Written Directive Required	2200	58	0	58	342	400
Medical Private Practice – Written Directive Not Required	2201	286	0	286	1687	1973
Eye Applicators Strontium-90	2210	14	0	14	83	97
Mobile Medicine Service – Written Directive Not Required	2220	41	0	41	242	283
High Dose-Rate Remote Afterloader	2230	85	0	85	502	587
Mobile Medical Service – Written Directive Required	2231	2	0	2	12	14
Medical Therapy – Other Emerging Technology	2240	26	0	26	153	179
Teletherapy	2300	0	0	0	0	0
Gamma Stereotactic Radiosurgery	2310	8	0	8	47	55
Sub totals		945	138	1083	6389	
TOTAL						7472

[1] NRC Material License Program Codes, November 2012.
[2] Data from NRC License Tracking System (LTS), November 2012.
[3] Master Material Licenses (such as Navy and Veterans Affairs)
[4] Estimated, based on 1 to 5.9 ratio of NRC licensees to Agreement State licensees

The NRC estimates that there are two licensees (program code 2511) who are manufacturers or distributors of medical generators. These Part 30 licensees are only impacted by the proposed changes to §§ 30.34(g) and 30.50(b)(5). These licensees are not included in the NRC estimates for medical licensees affected by this proposed rule.

Assumptions

The analysis makes the following other assumptions:

- The NRC estimates that, on average, all licensees will have added one ARSO on their licenses.

- The NRC estimates that, on average, license amendments will take 0.5 hour of NRC/Agreement State time to review/process. To review the entire NRC Form 313/Application will take 4 hours.

- The NRC estimates that, on average, licensee application/NRC Form 313 submitted in its entirety will take 1 hour of physician time and 3 hours of clerical time to prepare and submit. To complete the proposed required amendments, portions of NRC Form 313 will need to be completed. The NRC estimates that it takes 0.5 hour to complete each section of the form.

- The NRC's labor rates are determined using the methodology in Abstract 5.2, "NRC Labor Rates," of NUREG/CR-4627, "Generic Cost Estimates, Abstracts from Generic Studies for Use in Preparing Regulatory Impact Analyses." This methodology considers only variable costs (including salary and benefits) that are directly related to the implementation, operation, and maintenance of the proposed amendments. Currently, the NRC's hourly labor rate is $126. The estimation of costs for rulemaking is based on professional NRC staff full-time equivalent (FTE). Based on actual data from the NRC's time and labor system, the number of hours in 1 year that directly relates to implementation of assigned duties is 1,375 (1,375 was derived by taking the annual number of hours (2,080) and accounting for leave, training, and completing administrative tasks). Therefore, an NRC professional staff FTE hourly rate is based on 1,375 hours.

- Agreement State labor rates were determined from the National Wage Data available on the Bureau of Labor Statistics Web site (www.bls.gov). Because exact hourly rates would be difficult to obtain for each of the 37 Agreement States and may not be sufficiently recent, nationwide mean hourly rates were used. For all Agreement State labor rates, $60.80/hour is used, which is from the Bureau of Labor Statistics Employer Costs for Employee Compensation data set, under the category "Lawyers." The rate was then increased using a multiplier of 1.5 to account for benefits (pension, insurance premiums, and legally required benefits) that resulted in an hourly rate of $91.20.

- Licensee labor rates were obtained from the National Wage Data available on the Bureau of Labor Statistics Web site (www.bls.gov). Depending on the industry and the occupation (e.g., manufacturing, health and safety, etc.), an appropriate mean hourly labor rate was selected. The rate was then increased using a multiplier of 1.5 to account for benefits (pension, insurance premiums, and legally required benefits). Because exact hourly rates

would be difficult to obtain and may not be sufficiently recent, nationwide mean hourly rates were used. The bases for the labor rates are as follows. For licensee labor rates, three labor rates are used. For clerical recordkeeping labor cost, $29.54/hour is used ($19.69 X 1.5), which is from the Compensation data set "Miscellaneous healthcare practitioner and technical workers. For physician labor cost, $128.51/hour is used ($85.67 X 1.5), which is from the data set "Physician." For nuclear technician labor cost, $72.54/hour is used ($48.36 X 1.5), which is from the data set "Nuclear technician." As described in the Office of Management and Budget (OMB) Circular A-76, "Performance of Commercial Activities," the number of productive hours in one year is 1,776. As this actual value is likely to vary from state to state and no specific data was available, the FTE costs for the Agreement States are based on the number of hours estimated in OMB Circular A-76.

- Licensee turnover rates were obtained from Job Openings and Labor Turnover Survey Data available on the Bureau of Labor Statistics Web site (www.bls.gov). Based on this data, the NRC estimates the licensee turnover rate to be 3.0 percent annually. For the purpose of this analysis, the NRC estimates the total number of licensees to be constant over the 10-year analysis period.

- The analysis assumes that the final rule will be published in early 2015 and would be effective in mid-2015.

- The NRC estimates that 30 percent of the applicants and AMPs, AUs, and RSOs currently listed on NRC and Agreement State medical licenses are board certified. For ANPs, this estimate is 10 percent.

- For the purpose of this analysis, the NRC assumes a 10-year licensing period and a 10 percent renewal annually.

- The NRC estimates that 10 percent of licensees will submit an amendment annually to change tasks/duties of ARSOs on their licenses.

- The analysis calculated cost over a 10-year timeframe with each year's costs or savings discounted back at a 7 percent and 3 percent discount rate, in accordance with NUREG/BR-0058,, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," Revision 4.

- To the extent practical, quantitative information (e.g., costs and savings) and qualitative information (e.g., the nature and magnitude of impacts) on attributes affected by the rule were obtained from, or developed in consultation with, the NRC staff.

3.3 Detailed Results

This section presents a detailed estimate of the impacts by attribute for the proposed rulemaking (Option 2). Some benefits and costs are addressed qualitatively for reasons discussed in Section 3.2. Exhibit 4-1 summarizes these results.

Option 1: No Action

By definition, this option does not result in any benefits or costs. The baseline for Option 2 is the No-Action Alternative. The baseline assumes full compliance with existing NRC requirements. This baseline is consistent with NUREG/BR-0058, which states that, "in evaluating a new requirement...the staff should assume that all existing NRC requirements have been implemented."

Option 2: Amend Regulations to Revise 10 CFR Parts 30, 32, and 35

For details of how the NRC determined the number of licensees and individuals affected by Option 2, see Appendix B.

Industry Implementation

Amendment for ARSO

Section 35.13(d) would require a licensee to apply for and receive a license amendment prior to 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. The NRC estimates that all 7,473 licensees will add an ARSO. Some of the larger medical licensees will have several ARSOs, while other smaller licensees will have none, but on average there will be one ARSO per licensee. The NRC determined that allowing ARSOs 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, ARSOs could more easily become RSOs on other licenses for the types of uses for which they qualify. This will be a 0.5 labor hour cost per licensee for processing an amendment.

Recordkeeping

Section 35.24(b) would require the written documentation of the RSO-delegated duties to an ARSO, management's appointment of an ARSO, and the ARSO acceptance of the duties and delegated tasks. This paragraph would be modified to allow the licensee's management to appoint one or more qualified individuals to serve as ARSOs. The NRC estimates this to be a 1 labor hour cost for all 7,473 impacted licensees.

Adding requirements to current procedures

Section 35.41(b)(5) would require that affected licensees add procedures for any administration requiring a WD to include procedures for determining if an ME, as defined in § 35.3045, has occurred. The NRC estimates that 4,126 licensees would add procedures to include this requirement and the associated cost would be 8 hours physician labor and 1 hour clerical labor.

Section 35.41(b)(6) would require the affected licensee to add procedures for permanent implant brachytherapy that include a procedure for determining dose/activity parameters within 60 calendar days from the date the implant was performed. If the licensee cannot make these determinations within the 60 calendar days because of the patient not being available, then the licensee would have to justify the reason for not making these determinations in writing. The

NRC estimates that 3,373 licensees will add procedures to include this requirement and the associated cost will be 8 physician labor hours and 1 clerical labor hour.

Licensee cost to meet additional requirements.

Section 35.65(b)(2) would be modified to require licensees that possess bundled or aggregated single sealed sources with greater than a specified activity to treat them as one single source. These sources with activities larger than authorized by § 35.65 would have to meet all the regulatory requirements for that of a single source including, if appropriate, listing on a specific medical license, leak testing, and security requirements. This requirement is necessary so the NRC can ensure that adequate controls for security and radiation safety are applied to these larger sources. The cost for licensees would encompass recordkeeping of new leak test and security requirements under regulations, if appropriate. In addition, if bundled source activity is treated as a single source, an amendment to the license would be required. The NRC estimates the recordkeeping to be 2 labor hours and 0.5 labor hour for the required amendment. The NRC estimates this to impact 66 licensees.

Recordkeeping

Section 35.2041 would add a one-time recordkeeping cost for the added procedures now required in § 35.41(b)(5) and (6). The NRC estimates the cost for this recordkeeping requirement to be 0.10 labor hour for each of the 7,473 impacted licensees.

Table 1 Summary of Industry Implementation Cost

Description	# of Licensees	One-time cost	Notes
35.13(d)	7473	$110,376	Amend license to add ARSO
35.24(b)	7473	$220,752	RSO delegates duties to ARSO, ARSO accepts and management appoints ARSO
35.41(b)(5)	4126	$4,363,740	Add requirements to existing procedures
35.41(b)(6)	3373	$3,567,352	Add new procedures
35.65(b)(2)	66	$3,899	Recordkeeping for security and leak test requirements
35.65(b)(2)	66	$4,241	Amend license for select bundled single sources
35.2041	7473	$22,075	Recordkeeping cost for § 35.41(b)(5) and (6)
Total		$8,292,435	

NRC Implementation

Processing amendment for ARSO

Section 35.13(d) would require the NRC to process the licensee amendment prior to 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.

The NRC estimates that on average all 1,083 NRC licensees will add an ARSO. Some of the larger medical licensees will have several ARSOs while other smaller licensees will have none, but on average there will be one ARSO per licensee. This will be a 0.5 labor hour cost to the NRC per licensee for processing an amendment.

Processing amendment for bundled sources

Section 35.65(b)(2) would require licensees that possess bundled or aggregated single sealed sources with greater than a specified activity to treat them as one single source. These sources with activities larger than authorized by § 35.65 would have to meet all the regulatory requirements for that single source including, if appropriate, listing on a specific medical license, leak testing, and security requirements. This requirement is necessary so the NRC can ensure adequate controls for security and radiation safety are applied to these larger sources. If bundled source activity is treated as a single source an amendment to the license is required. The NRC estimates 0.5 labor hours to process the required amendments, and this will impact 10 licensees.

Develop rule package and revise guidance documents

The NRC would develop the proposed and final rule packages and revise guidance and inspection procedures to accommodate the requirements that would be added or modified by the rulemaking process. This effort will require 1.5 of an FTE (2,062.5 hours) for participating in the rulemaking activities over a 2-year period. To revise and update the guidance documents will take 0.5 FTE (687.5 hours). This is an approximately $400,000 one-time cost to the NRC. The analysis assumes that NRC one-time implementation costs associated with rule development and guidance documents are incurred in years 2013-2016.

The NUREG guidance documents listed below would be updated:

- NUREG-1556 Volume 9, Program-Specific Guidance About Medical Use Licenses (Revision 2).

- NUREG-1556 Volume 13, Program-Specific Guidance About Commercial Radiopharmacy Licenses (Revision 1).

- Inspection Procedure 87132.

Table 2 Summary of NRC Implementation Cost

Section	Description	One time cost in year 2013	One time cost in year 2014	One time cost in year 2015	Undiscounted cost	Total 3 Yr 3% NPV	Total 3 Yr 7% NPV
35.13(d)	Process amendment			$68,229	$68,229	$68,229	$68,229
35.65(b)(2)	Process amendment			$630	$630	$630	$630
	Rule development	$86,625	$86,625	$86,625	$259,875	$245,028	$227,331
	Guidance documents	$28,875	$28,875	$28,875	$86,625	$81,676	$75,777
	Total	$115,500	$115,500	$184,359	$415,359	$395,563	$371,967

Other Governments Implementation (Agreement States)

Amendment for ARSO

Section 35.13(d) would require a licensee to apply for and receive a license amendment prior to permitting an individual to work as an ARSO or before the RSO assigns different tasks and duties to an ARSO authorized on the license.

The NRC estimates that on average all 6,390 Agreement State licensees will add an ARSO. Some of the larger medical licensees will have several ARSOs, while other smaller licensees will have none, but on average there will be one ARSO per licensee. This will be a 0.5 hour cost per licensee for processing an amendment.

Processing amendment for bundled sources

Section 35.65(b)(2) would require licensees that possess bundled or aggregated single sealed sources with greater than a specified activity to treat them as one single source. These sources with activities larger than authorized by § 35.65 would have to meet all the regulatory requirements for that single source including, if appropriate, listing on a specific medical license, leak testing, and security requirements. This requirement is necessary so the NRC can ensure adequate controls for security and radiation safety are applied to these larger sources. If bundled source activity is treated as a single source an amendment to the license is required. The NRC estimates 0.5 labor hour to process the required amendments, and this will impact 56 licensees.

Develop rule package and revise guidance documents

The Agreement State staffs would develop the rule packages to accommodate the requirements that would be added or modified by the rulemaking process. Revised guidance and inspection procedures may or may not be required depending on each state's process. Some Agreement States adopt the NRC's guidance and inspection procedures without change. The rulemaking effort will require 0.5 of an FTE (888 hours) on average for each of the 37 Agreement States. To revise and update the guidance documents and inspection procedures will take 0.25 FTE (444 hours). This is an estimated $121,500 one-time cost to each of the 37 Agreement States.

Table 3 Summary of Agreement State Implementation Costs

Section	Description	One-time cost
35.13(d)	Process amendment	$582,768
35.65(b)(2)	Process amendment	$5,107
N/A	Update regulations	$2,996,467
N/A	Guidance documents	$1,498,234
	Total	$5,082,576

Industry Operation

Reporting requirement

Section 30.34(g)would require licensees to report to the NRC/Agreement States the results of any test of generator elutions for Mo-99 breakthrough or Sr-82 and Sr-85 contamination that exceeds the permissible concentration listed in § 35.204(a). Issues have occurred with generators that may cause unwarranted radiation exposure to patients.

It is estimated by the NRC that the rule change would impact two licensees. The NRC estimates each licensee will report nine instances annually with a 0.5 labor hour cost for each report.

Reporting requirement

Section 30.50(b)(5) would require manufacturers or distributors of medical generators in receipt of a notification required by § 35.3204(a) to notify the NRC/Agreement States within 24 hours. Section 35.3204(a) would require licensees to notify the manufacturer or distributor of the generator when an eluate from a generator exceeds the permissible concentration listed in § 35.204(a).

It is estimated by the NRC that this change would impact two licensees. The NRC estimates each licensee will report nine instances annually with a 0.5 hour cost for each report.

Savings for the licensees for no longer requiring a copy of application

Section 35.12 (b)(1) would be amended to remove the requirement to submit additional copies of the NRC Form 313 when applying for a license.

The NRC estimates the licensees averaged 0.25 hour to make and submit additional copies of their application. The NRC estimates that there will be 224 new applications submitted annually.

Cost for licensees to submit information on an ARSO

Section 35.12(b)(1) also would add a requirement to submit information on an individual seeking to be identified as an ARSO.

The NRC estimates that there will be 224 new applications submitted annually requiring applicants to submit information on an ARSO with a 0.5 hour cost per applicant.

Savings on copies of amendments or renewals of applications

Section 35.12(c)(1) would remove the requirement to submit an additional copy of NRC Form 313 or a letter containing information required by NRC Form 313 for license amendments or renewals.

The NRC estimates the licensees will save 0.25 hours to copy and submit an additional copy of NRC Form 313 for renewals. The renewal timeframe is 10 years. The NRC estimates that there will be on average 747 renewals submitted annually.

For copies of amendments which are submitted on NRC Form 313, the NRC estimates there will be one amendment per licensee for a total of 7,473 submitted annually.

Licensing amendments for new ARSOs

Section 35.13(d) would require a licensee to apply for and receive a license amendment prior to permitting an individual to work as an ARSO or before the RSO assigns different tasks and duties to an ARSO authorized on the license. For the purpose of this analysis, the NRC assumes a 3 percent licensee turnover rate. This would represent 224 total licensees. In addition, 10 percent of all ARSOs will have their duties and tasks amended annually. This will be a 0.5 hour cost per licensee.

Allow licensees to receive certain sealed sources without first seeking a license amendment

Section 35.13(i) would be added to this section to allow licensees to receive certain sealed sources without first seeking a license amendment. This change is proposed to make it easier for the licensee to obtain the sealed sources necessary for patient treatments in a timely manner. The NRC assumes that each affected licensee will receive two new sealed sources annually. This proposed amendment would allow licensees to save on submittals of two amendments/NRC Form 313s for a 1.0 labor hour savings annually. The NRC estimates this to affect 3,498 licensees annually.

Cost to licensee to process notification

Section 35.14(b)(1) would require a licensee to notify the NRC/Agreement States within 30 days after the ARSO or ophthalmic physicist is removed from the list of individuals that the licensee is required to report when the ARSO or ophthalmic physicist discontinues performance of duties under the license or has a name change.

The NRC estimates that 224 new ARSOs will be named annually due to turnover and 38 (0.5 percent of total) due to a name change. The NRC estimates this to be a 0.25 labor hour cost. The number of new ophthalmic physicists is too low to establish an estimated labor cost.

Costs for licensee to process notification

Section 35.14(b)(6) would require the licensee to notify the NRC if it receives certain sealed sources without first obtaining a license amendment. Specifically, a licensee would have to notify the NRC no later than 30 days after receiving a sealed source from a new manufacturer or a new model number for a sealed source listed in the SSDR used for manual brachytherapy for quantities and isotopes already authorized by the license. The notification is used in lieu of a license amendment which is being removed under § 35.13(i). This notification is required for the NRC to have an accurate record of sealed sources possessed by a licensee.

The NRC estimates that 3.498 licensees will be impacted twice annually, and each notification will take 0.25 hour to process.

Recordkeeping for new ARSOs

Section 35.24(b) would require written documentation for managing appointments of ARSOs, ARSOs acceptance of the appointment, and the RSO assignment of tasks and duties. This paragraph would be modified to allow the licensee's management to appoint one or more qualified individuals to serve as ARSOs. The NRC estimates this to be a 1 hour cost for the 224 licensees impacted with turnover.

Adding new procedures

Section 35.41(b)(5) would require licensees to add procedures for any administration requiring a WD to include procedures for determining if an ME, as defined in § 35.3045, has occurred.

The NRC estimates that 124 licensees, due to turnover, will add procedures to meet this requirement and the associated cost will be 8 physician labor hours and 1 clerical labor hour.

Adding new procedures

Section 35.41(b)(6) would require a licensee to add procedures for permanent implant brachytherapy that would include a procedure for determining several dose/activity parameters within 60 calendar days from the date the implant was performed. If the licensee cannot make these determinations within the 60 calendar days because of the patient not being available, then the licensee would have to justify the reason for not making these determinations in writing.

The NRC estimates that 101 licensees, due to turnover, will add procedures to include this requirement and the associated cost will be 8 physician labor hours and 1 clerical labor hour.

Savings for removing attestation requirement for some individuals

Section 35.14(a) would remove the requirement to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State when using the notification process. The number of ophthalmic physicists is too low to establish an estimated labor savings.

Section 35.50(a) would remove the requirement for individuals seeking to be named as an RSO or ARSO (including medical physicists identified in section 35.50(c)(1)) to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. The NRC estimates that approximately 224 individuals will seek to become RSOs and ARSOs under Section 35.50 annually. Of these, the NRC estimates that 30 percent, or 67, are individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. The NRC estimates a savings of 0.5 labor hour per licensee for no longer requiring the submittal of an amendment.

Licensee savings for processing only one application

Section 35.50(c)(3) would allow an individual who is qualified to be the AU, but is not named on a medical license or permit, to be named simultaneously as both the AU and RSO for the same uses on a new medical license. This new provision saves the applicant from submitting an amendment to the initial AU application to be named as an RSO. The NRC estimates this to affect three applicants annually at a savings of 0.5 hour per application.

Savings for removing the attestation requirement for some individuals

Section 35.51(a) would remove the requirement for individuals seeking to be named as an AMP to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. The NRC estimates that approximately 37 individuals annually will seek to become AMPs under § 35.51 with a savings of 0.5 labor hour per licensee for no longer requiring the submittal of an amendment.

Section 35.55(a) would remove the requirement for individuals seeking to be named as an ANP to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. The NRC estimates this to impact seven licensees annually with a savings of 0.5 labor hour per licensee for no longer requiring the submittal of an amendment.

Savings for removing training requirements for certain AMPS and ANPs

Section 35.57(a)(1) would remove the requirement for AMPs and ANPs who are 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, to comply with the training requirements of §§ 35.50, 35.51, or 35.55, respectively. The NRC estimates that 41 licensees will be impacted annually, and there will be a savings of 0.5 hour associated with the submittal of an amendment on NRC Form 313.

Savings for removing training requirement for certain RSOs

Section 35.57(a)(2) would recognize individuals certified by the named boards in the now removed Subpart J of 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 a RSO 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. The NRC estimates that 75 licensees will be impacted annually, and there will be a savings of 0.5 hour associated with the submittal of an amendment on NRC Form 313.

Savings for removing training requirements for certain individuals

Section 35.57(a)(3) would be modified to remove the requirement for individuals certified by the named boards in the now removed Subpart J of Part 35 on or before October 24, 2005, 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. The NRC estimates that 41 licensees will be impacted annually, and there will be a savings of 0.5 hour associated with the submittal of an amendment on NRC Form 313.

Savings for removing T&E requirements for certain individuals

Section 35.57(b)(1) would be amended to clarify that individuals 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. The NRC estimates that 2,242 or 30 percent of all licensees, will be impacted on an annual basis. The 0.5 labor hour savings will be associated with each submittal of amendment on NRC Form 313.

Section 35.57(b)(2) would be restructured and expanded to recognize physicians, dentists, or podiatrists who were certified by the named boards in the now removed Subpart J of Part 35 on or before October 24, 2005, who would not need to comply with the T&E 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 these individuals performed on or before October 24, 2005. The NRC estimates that 187, or 2.5 percent of all licensees, will be impacted on an annual basis. The 0.5 labor hour savings will be associated with each submittal of amendment on NRC Form 313.

Cost to possess certain bundled sources

Section 35.65(b)(2) would be modified to require licensees that possess bundled or aggregated single sealed sources with greater than a specified activity to treat them as one single source. These sources with activities larger than authorized by § 35.65 will have to meet all the

regulatory requirements for that single source including, if appropriate, listing on a specific medical license, leak testing, and security requirements. This requirement is necessary so the NRC can ensure that adequate controls for security and radiation safety are applied to these larger sources. The cost for licensees will encompass recordkeeping of new leak tests and security requirements under regulations, if appropriate. In addition, if bundled source activity is treated as a single source, an amendment to the license is required. The NRC estimates this to impact 10 licensees annually, for 2 hours of recordkeeping cost and 0.5 hour for submitting an amendment.

Savings for removing attestation requirement for some individuals

Section 35.190(a) would remove the written attestation requirement for a physician who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State and is seeking to be named as an AU for byproduct material authorized under § 35.100. The NRC estimates that this will impact 59 licensees on an annual basis with a savings of 0.5 labor hour for no longer requiring the submittal of a written attestation with the amendment request.

Recordkeeping cost

Section 35.204(b) would be modified to require licensees to measure the Mo-99 concentration after each eluate from a Mo-99/Tc-99m generator. Generator manufacturers recommended testing each elution prior to use in humans. Mo-99 breakthrough measurements which exceed the permissible concentration listed in § 35.204(a) may cause unnecessary radiation exposure to patients. The NRC assumes that each test will be conducted by a nuclear technician who is under the supervision of an ANP. The NRC estimates this to impact 419 licensees (2,795 affected licensees of which 15 percent will have an ANP) who have the generators. The new requirements will require the affected licensees to keep records of their test measurements. The NRC estimates this to require 25 Medical Technician labor hours annually for each affected licensee.

Reporting requirement

Section 35.204(e) would require licensees to report any measurement that exceeded the limits specified in § 35.204(a) for Mo-99/Tc-99m and Sr-82/Rb-82 generators. Generator manufacturers recommended testing each elution prior to use in humans. Mo-99 breakthrough measurements which exceed the permissible concentration listed in § 35.204(a) may cause unnecessary radiation exposure to patients. The NRC estimates the affected licensees to report seven occurrences on average annually. The reporting requirement includes an initial phone notification within 1 calendar day from occurrence, followed up with a written report due in 15 days. The NRC estimates this to be a 2.25 physician labor hour cost (0.25 hour for the phone call and 2 hours for the written report).

Savings for removing the attestation requirement for some individuals

Section 35.290(a) would remove the requirement for physicians seeking to be named as an AU of unsealed byproduct material for uses authorized under § 35.200 to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been

recognized by the NRC or an Agreement State. The NRC estimates that this will impact 59 licensees on an annual basis with a savings of 0.5 physician labor hour per licensee for no longer requiring the submittal of a written attestation with the amendment request.

Savings for removing the attestation requirement for some individuals

Section 35.390(a) would remove the requirement for physicians seeking to be named as an AU of unsealed byproduct material which requires a written directive for uses authorized under § 35.300 to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. The NRC estimates that this will impact 29 licensees on an annual basis with a savings of 0.5 physician labor hour per licensee for no longer requiring the submittal of a written attestation with the amendment request.

Savings for removing the attestation requirement for some individuals

Section 35.392(a) would remove the requirement for physicians seeking to be named as an AU for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries) to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. The NRC estimates that this will impact 29 licensees on an annual basis with a savings of 0.5 physician labor hour per licensee for no longer requiring the submittal of a written attestation with the amendment request.

Savings for removing attestation requirement for some individuals

Section 35.394(a) would remove the requirement for physicians seeking to be named as an AU for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries) to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. The NRC estimates that this will impact 29 licensees on an annual basis with a savings of 0.5 physician labor hour per licensee for no longer requiring the submittal of a written attestation with the amendment request.

Flexibility for AMP turnover

Section 35.433 would be amended and expanded to allow certain individuals who are not AMPs to calculate the activity of strontium-90 sources that is used to determine the treatment times for ophthalmic treatments. These individuals who are not AMPs would have to meet the T&E requirements detailed in the new paragraph (a)(2) of this section to perform the specified activities. These requirements are similar to the T&E requirements for an AMP, but include only the requirements related to brachytherapy programs. The NRC determined that this will increase the number of qualified individuals available to support the use of ophthalmic treatments. This will expand the pool of qualified individuals and provide the licensees greater flexibility with no associated cost.

Savings for removing attestation requirement for some individuals

Section 35.490(a) would remove the requirement for physicians seeking to be named as an AU of a manual brachytherapy source for the uses authorized under § 35.400 to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. The NRC estimates that this will impact 31 licensees on an annual basis with a savings of 0.5 physician labor hour per licensee for no longer requiring the submittal of a written attestation with the amendment request.

Cost for training

Section 35.610(d)(1) would be restructured to add a new training requirement for 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. The NRC assumes this will impact 172 licensees on an annual basis who will add a new unit or modify an existing unit. The NRC assumes this training to take 1 physician labor hour.

Change to inspections and servicing intervals

Section 35.655(a) would be amended to change the requirement for intervals for full inspection and servicing for gamma stereotactic radiosurgery units from 5 years to 7 years. The cost to replace the sources in a gamma stereotactic radiosurgery unit can be exorbitant. Licensees have routinely requested, and the NRC has granted, extensions for the full inspection service for these units beyond 5 years. The NRC does not anticipate any savings or cost to the licensees for this change.

Savings for removing attestation requirement for some individuals

Section 35.690(a) would remove the requirement for physicians seeking to be named as an AU for sealed sources for uses authorized under § 35.600 to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. The NRC estimates this to impact 10 licensees annually with a savings of 0.5 physician labor hour per licensee for no longer requiring the submittal of a written attestation with the amendment request.

Recordkeeping

Section 35.2024(c)(1) and (2) would require licensees 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). The NRC estimates that due to turnover, 224 ARSOs will be removed from licenses annually with a cost of 1 clerical labor hour.

Savings on phone notifications of MEs

Section 35.3045(c) would reduce telephone reporting costs to the NRC because the requirements for reporting an ME for permanent implant brachytherapy are changed in § 35.3045(a)(2). The new requirements will not capture events that are not of significance and will reduce the number of reportable MEs related to permanent implant brachytherapy. The NRC estimates 7 licensees will be impacted annually with a saving of 0.5 medical technician labor hour on each notification.

Savings on written follow-up reports on MEs

Section 35.3045(d) would reduce written reporting costs to the NRC because the requirements for reporting an ME for permanent implant brachytherapy are changed in § 35.3045(a)(2). The new requirements will not capture events that are not of significance and will reduce the number of reportable MEs related to permanent implant brachytherapy. The NRC estimates 7 licensees will be impacted annually with a savings of 2 physician labor hours and 6 clerical labor hours on each report.

Savings for the licensee on reporting MEs

Section 35.3045(e) would reduce licensee reporting costs to the physician, because the requirements for reporting an ME for permanent implant brachytherapy are changed in § 35.3045(a)(2). The new requirements will not capture events that are not of significance and will reduce the number of reportable MEs related to permanent implant brachytherapy. The NRC estimates 7 licensees will be impacted annually with a total savings of 5 physician labor hours for each licensee.

Increased flexibility for AUs for use of sealed sources and devices for manual brachytherapy

Sections 35.400, 35.500, and 35.600 would be amended to allow AUs to use sealed sources and devices listed in SSDRs for manual brachytherapy for other 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. This increased flexibility is not quantifiable.

Table 4 Summary of Industry Annual Costs

Citation	Description	No. of Licensees Affected	Annual Costs
30.34(g)	Reporting requirement	2	$266
30.50(b)(5)	Reporting requirement	2	$266
35.12(b)(1)	Savings for no longer requiring copy of application	224	-$1,654
35.12(b)(1)	Cost for licensees to submit information on ARSO	224	$3,308
35.12 (c)(1)	Savings on copy of renewals	747	-$5,517
35.12 (c)(1)	Savings on copy of amendments	7473	-$55,188
35.13(d)	Licensing amendments for new ARSOs	224	$3,308
35.13(d)	Licensing amendments for new tasks/duties for existing ARSO	747	$11,033
35.13(i)	Savings exemption for need for amendment for sealed source	3498	-$51,665
35.14(b)(1)	Cost for notification for when ARSO or ophthalmic physicist leaves or changes name	262	$1,935
35.14(b)(6)	Notification costs for reporting	3498	$25,833
35.24(b)	Recordkeeping for new ARSOs	224	$6,617
35.41(b)(5)	Adding new procedures	124	$131,145
35.41(b)(6)	Adding new procedures	101	$106,820
35.50(a)	Savings for some RSO for attestation	67	-$4,305
35.50(c)(3)	Savings for processing only one application	3	-$193
35.51(a)	Savings for removing attestations for some individuals	37	-$2,377
35.55(a)	Savings for removing attestations for some individuals	7	-$450
35.57(a)(1)	Savings for individuals who want to be ANPs and AMPs	41	-$2,634
35.57(a)(2)	Savings for individuals certain RSOs	75	-$4,819
35.57(a)(3)	Savings for individuals who want to be identified as AMPs	41	-$2,634
35.57(b)(1)	Savings for AU on T&E from 10/24/02 to 10/24/05	2242	-$144,060
35.57(b)(2)	Savings for individuals who want to be AUs	187	-$12,016
35.65(b)(2)	Recordkeeping requirements for leak tests and security	10	$591
35.65(b)(2)	Cost requiring a licensee to submit an amendment	10	$148
35.190(a)	Savings for removing attestations for some individuals	59	-$3,791
35.204(b)	Cost to check generators for each elution	419	$760,066
35.204(e)	Reporting requirement (cost in § 35.3204)	7	$2,024
35.290(a)	Savings for removing attestations for some individuals	59	-$3,791
35.390(a)	Savings for removing attestations for some individuals	29	-$1,863
35.392(a)	Savings for removing attestations for some individuals	29	-$1,863
35.394(a)	Savings for removing attestations for some individuals	29	-$1,863
35.433(a)(2)	No additional cost	0	$0
35.490(a)	Savings for removing attestations for some individuals	31	-$1,992
35.610(d)(1)	Cost for training for operations and safety	172	$22,104
35.690(a)	Savings for removing attestations for some individuals	10	-$643
35.2024(c)	Recordkeeping cost (Removing ARSO)	224	$2,203

35.2024(c)(1)	Recordkeeping cost (ARSO appointment)	224	$2,203
35.2024(c)(2)	Recordkeeping cost (ARSO signed agreement)	224	$2,203
35.3045(c)	Phone notifications reduced	7	-$254
35.3045(d)	Written reports reduced	7	-$3,040
35.3045(e)	Physician notifications reduced	7	-$1,799
Total			$773,661

NRC Operation

Processing reports

Section 30.34(g) would require the NRC to process licensee reports of any test that exceeds the permissible concentration listed in § 35.204(a). The NRC estimates it will receive one report annually, and 1 labor hour would be needed to process it.

Processing reports

Section 30.50(b)(5) would require the NRC to process reports from manufacturers or distributors of medical generators in receipt of a notification required by § 35.3204(a). The NRC estimates it will receive one report annually, and 1 labor hour would be needed to process it.

Processing licensee application due to turnover of ARSOs

Section 35.12(b)(1) would require an applicant to include T&E qualifications for each ARSO as part of its license application. The NRC estimates it will receive 29 new applications annually, and that it will take 0.25 hour to process each application.

Amendment processing due to turnover of ARSOs

Section 35.13(d) would require a licensee to apply for and receive a license amendment prior to 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. The NRC estimates it will receive 29 amendments annually and each amendment will take 0.5 hour to process.

Savings for processing amendments for sealed sources

Section 35.13(i) would allow licensees who are authorized for brachytherapy sources to receive certain sealed sources without first seeking a license amendment. This change is proposed to make it easier for the licensee to obtain the sealed sources necessary for patient treatments in a timely manner. The NRC will no longer need to review and process the license amendments, and estimates it will receive 1,014 fewer amendments annually with each amendment saving 0.5 hour to process.

Processing of notifications of ARSOs

Section 35.14(b)(1) would require a licensee to notify the Commission within 30 days of removal of the ARSO or ophthalmic physicist from the list of individuals that the licensee is required to

report when the ARSO discontinues performance of duties under the license or has a name change.

The NRC estimates that 38 notifications will be made annually due to turnover or name changes, and it will take 0.25 hour to process each notification. The number of ophthalmic physicist is too low to establish an estimated labor cost.

Processing of notifications of sealed sources

Section 35.14(b)(6) would require licensees to notify the NRC if it receives certain sealed sources without first obtaining a license amendment. Specifically, a licensee would have to notify the NRC no later than 30 days after receiving a sealed source from a new manufacturer or a new model number for a sealed source listed in the SSDR used for manual brachytherapy for quantities and isotopes already authorized by the license. The notification is used in lieu of a license amendment, which is being removed under § 35.13(i). The NRC estimates this to impact 507 licensees each year, and each licensee will submit two notifications on average per year with an associated processing cost of 5 minutes. This cost is offset by the savings from not requiring an amendment in § 35.13(i).

Savings for processing attestations

Section 35.14(a) would remove the requirement to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State when using the notification process. The number of ophthalmic physicists is too low to establish an estimated labor savings.

Section 35.50(a) would remove the requirement for individuals seeking to be named as an RSO or ARSO to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. The NRC estimates that approximately 32 individuals will seek to become RSOs under § 35.50 annually. Of these, the NRC estimates that 30 percent, or 10, are individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. The NRC estimates that approximately 0.5 hour of the cost associated with processing the amendment will be saved for each applicant.

Savings for processing and reviewing applications

Section 35.50(c)(3) would allow an individual who is qualified to be the AU, but is not named on a medical license or permit, to be named simultaneously as both the AU and RSO for the same uses on a new medical license. This new provision saves the NRC from processing the license amendment for adding an RSO. The NRC estimates this to affect one applicant annually at a savings of 0.5 hour for processing the amendment.

Savings for processing attestations

Section 35.51(a) would remove the requirement to obtain a written attestation, for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State, for individuals seeking to be named as an AMP.

The NRC estimates that approximately five individuals will seek to become AMPs under § 35.51 annually. NRC estimates that approximately 0.5 hour cost associated with reviewing the amendment will be saved for each applicant.

Section 35.55(a) would remove the requirement to obtain a written attestation, for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State, for individuals seeking to be named as an ANP. The NRC estimates this to impact one licensee annually with 0.5 hour of the cost associated with processing a written attestation with the amendment request.
Savings for processing amendments

Section 35.57(a)(1) would remove the requirement for an RSO, an AMP and an ANP identified on a NRC license or a permit issued by the NRC broad scope licensee or master material license permit or by a master material license permittee of broad scope on or before October 24, 2005, to comply with the training requirements of §§ 35.50, 35.51, or 35.55, respectively. The NRC estimates that six licensees will be impacted with a savings of 0.5 hour associated with the processing of each amendment.

Section 35.57(a)(2) would recognize individuals certified by the named boards in the now removed Subpart J of 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 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. The NRC estimates that 11 licensees will be impacted with a savings of 0.5 hour associated with the processing of each amendment.

Section 35.57(a)(3) would be modified to remove the requirement for individuals certified by the named boards in the now removed Subpart J of Part 35 on or before October 24, 2005, 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. The NRC estimates that six licensees will be impacted with a savings of 0.5 hour associated with the processing of each amendment.

Section 35.57(b)(1) would be amended to clarify that individuals 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. The NRC estimates that 325 licensees will be impacted on an annual basis with a savings of 0.5 hour associated with the processing of each amendment.

Section 35.57(b)(2) would be restructured and expanded to recognize physicians, dentists, or podiatrists who were certified by the named boards in the now removed subpart J of part 35 on or before October 24, 2005, 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 an NRC license or an NRC master material license permit for those materials and uses that these individuals performed on or before October 24, 2005. The NRC estimates that 27 licensees will be impacted on an annual basis with a savings of 0.5 hour associated with the processing of each amendment.

Processing amendments for bundled sources

Section 35.65(b)(2) would be modified to require licensees that possess bundled or aggregated single sealed sources with greater than a specified activity to treat them as one single source. These sources with activities larger than authorized by § 35.65 will have to meet all the regulatory requirements for that single source including, if appropriate, listing on a specific medical license, leak testing, and security requirements. This requirement is necessary so the NRC can ensure that adequate controls for security and radiation safety are applied to these larger sources. The NRC estimates this to impact one licensee annually with the amendment requiring 0.5 hour to process.

Savings for processing attestations

Section 35.190(a) would remove the requirement to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC and for physicians seeking to be named as an AU of unsealed byproduct material for uses authorized under § 35.100. The NRC estimates that this will impact eight NRC licensees on an annual basis with a savings of 0.5 labor hour for no longer requiring the submittal of a written attestation with the amendment request.

Cost to process new reporting requirement

Section 35.204(e) would require licensees to report any measurement that exceeded the limits specified in § 35.204(a) for Mo-99/Tc-99m and Sr-82/Rb-82 generators. Generator manufacturers recommended testing each elution prior to use in humans. Mo-99 breakthrough measurements which exceed the permissible concentration listed in § 35.204(a) may cause unnecessary radiation exposure to patients. The NRC estimates that this will impact one licensee to report one occurrence on average annually. The reporting requirement includes an initial phone notification to NRC within 1 calendar day from occurrence and followed up with a written report due in 15 days. The NRC estimates this to be a 2.25 labor hour cost (0.25 hour to process the phone call and 2 hours to review the written report).

Savings for processing attestations

Section 35.290(a) would remove the requirement for physicians seeking to be named as an AU of unsealed byproduct material for uses authorized under § 35.200 to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC. The NRC estimates that this will impact 8 licensees on an annual basis with a savings of 0.5 labor hour for no longer requiring the submittal of an amendment.

Savings for removing attestation requirement for some individuals

Section 35.390(a) would remove the requirement for physicians seeking to be named as an AU of unsealed byproduct material which requires a written directive for uses authorized under § 35.300 to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. The NRC estimates that this will impact 4 licensees on an annual basis with a savings of 0.5 labor hour per licensee for no longer requiring the submittal of an amendment.

Savings for processing attestations

Section 35.392(a) would remove the requirement to obtain a written attestation, for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC, for physicians seeking to be named as an AU for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries). The NRC estimates that this will impact four licensees on an annual basis with a savings of 0.5 labor hour for no longer requiring the submittal of a written attestation with the amendment request.

Savings for processing attestation

Section 35.394(a) would remove the requirement to obtain a written attestation, for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC, for physicians seeking to be named as an AU for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries). The NRC estimates that this will impact four licensees on an annual basis with a savings of 0.5 labor hour for no longer requiring the submittal of an amendment.

Savings for processing attestation

Section 35.490(a) would remove the requirement to obtain a written attestation, for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC, for physicians seeking to be named as an AU of a manual brachytherapy source for the uses authorized under § 35.400. The NRC estimates that this will impact five licensees on an annual basis with a savings of 0.5 labor hour for no longer requiring the submittal of an amendment.

Savings for processing attestations

Section 35.690(a) would remove the requirement to obtain a written attestation, for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC, for physicians seeking to be named as an AU for sealed sources for uses authorized under § 35.600. The NRC estimates this to impact two licensees annually with a savings of 0.5 labor hour for no longer requiring the submittal of a written attestation with the amendment request.

Savings on phone notifications

Section 35.3045(c) would reduce telephone reporting cost to the NRC because the requirements for reporting an ME for permanent implant brachytherapy are changed in § 35.3045(a)(2). The new requirements will not capture events that are not of significance and will reduce the number of reportable MEs related to permanent implant brachytherapy. The NRC estimates this to impact one licensee annually with a savings of 2.5 NRC labor hours to process the ME notification.

Savings on written follow-up report to the NRC

Section 35.3045(d) would reduce written reporting costs to the NRC because the requirements for reporting an ME for permanent implant brachytherapy would be changed in § 35.3045(a)(2). The new requirements will not capture events that are not of significance and will reduce the number of reportable MEs related to permanent implant brachytherapy. The NRC estimates this to impact one licensee annually with a savings of 3 NRC labor hours to process the written report.

Other Governments' Operation (Agreement States)

The Agreement States are required to adopt the NRC regulations within 3 years after they go into effect. Although each state has its own regulations with unique sections and numbering systems, for the purpose of this regulatory analysis, the NRC section and numbering system is used.

Processing reports

Section 30.34(g) would require the Agreement States to process licensee reports of any test that exceeds the permissible concentration listed in § 35.204(a). The NRC estimates the Agreement States will receive one report annually and 1 labor hour would be needed to process it.

Section 30.50(b)(5) would require the Agreement States to process reports from manufacturers or distributors of medical generators in receipt of a notification required by § 35.3204(a). The NRC estimates the Agreement States will receive one report annually and 1 labor hour would be needed to process it.

Licensee application request processing

Section 35.12(b)(1) would require a licensee to apply for and receive a license amendment prior to 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. The NRC estimates the Agreement States will receive 195 amendment requests annually and that each will take 0.25 hours to process.

Licensee amendment processing

Section 35.13(d) would require a licensee to apply for and receive a license amendment prior to 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. The NRC estimates the Agreement States will receive 195 amendments annually and each amendment will take 0.5 hour to process.

Savings for processing amendments for sealed sources

Section 35.13(i) would allow licensees to receive certain sealed sources without first seeking a license amendment. This change is proposed to make it easier for the licensee to obtain the

sealed sources necessary for patient treatments in a timely manner. The Agreement States will no longer need to review and process the license amendments. The NRC estimates that the Agreement States will receive 5,982 fewer amendments annually, with each amendment saving 0.5 hour to process.

Processing of notifications

Section 35.14(b)(1) would require a licensee to notify the Agreement States within 30 days of when the ARSO or the ophthalmic physicist is removed from the list of individuals that the licensee is required to report or when the ARSO or the ophthalmic physicist discontinues performance of duties under the license or has a name change.

The NRC estimates that 224 ARSOs will be named annually due to turnover or changing their names, and it will take 0.25 labor hour for the Agreement States to process each notification. The number of ophthalmic physicist is too low to establish an estimated labor cost.

Section 35.14(b)(6) would require licensees to notify the Agreement States if they receive certain sealed sources without first obtaining a license amendment. Specifically, a licensee would have to notify the Agreement State no later than 30 days after receiving a sealed source from a new manufacturer or a new model number for a sealed source listed in the SSDR used for manual brachytherapy for quantities and isotopes already authorized by the license. The notification is used in lieu of a license amendment which would be removed under § 35.13(i). This notification is required for the Agreement States to have an accurate record of sealed sources possessed by a licensee.

The NRC estimates this to impact 2,991 licensees each year; each licensee will submit two notifications on average per year. The NRC estimates that the associated Agreement State cost to process each notification is 0.08 labor hours. This cost would be offset by the savings outlined § 35.13(i).

Savings for processing attestations

Section 35.14(a) would remove the requirement to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State when using the notification process. The number of ophthalmic physicists is too low to establish an estimated labor savings.

Section 35.50(a) would remove the requirement for individuals seeking to be named as an RSO or ARSO to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by an Agreement State. The NRC estimates that approximately 192 individuals will seek to become RSOs under § 35.50 annually. Of these, the NRC estimates that 30 percent, or 57, are individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. The NRC estimates that approximately 0.5 labor hour of the cost associated with processing each amendment will be saved by the Agreement States for each applicant.

Savings for processing and reviewing applications

Section 35.50(c)(3) would allow an individual who is qualified to be the AU, but is not named on a medical license or permit, to be named simultaneously as both the AU and RSO for the same uses on a new medical license. This new provision saves the Agreement States from processing the license amendment. The NRC estimates this to affect two applicants annually at a savings of 0.5 labor hour per application.

Savings for processing the attestations

Section 35.51(a) would remove the requirement to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State, for individuals seeking to be named as an AMP. The NRC estimates that approximately 32 individuals will seek to become AMPs annually and that 0.5 hour associated with reviewing the amendment will be saved for each applicant.

Savings for processing attestations

Section 35.55(a) would remove the requirement to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State, for individuals seeking to be named as an ANP. The NRC estimates this to impact six licensees annually, and 0.5 hour of the labor cost associated with processing a written attestation with the amendment request amendment would be saved.

Section 35.57(a)(1) would remove the requirement for an RSO, an AMP, and an ANP identified on an Agreement State license or a permit issued by 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, to comply with the training requirements of §§ 35.50, 35.51, or 35.55, respectively. The NRC estimates that 35 licensees will be impacted with a savings of 0.5 hour associated with the processing of a written attestation with the amendment request.

Savings for processing amendments

Section 35.57(a)(2) would recognize individuals certified by the named boards in the now removed Subpart J of 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 a RSO 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. The NRC estimates that 64 licensees will be impacted with a savings of 0.5 hour associated with the processing of each amendment.

Section 35.57(a)(3) would be modified to remove the requirement for individuals certified by the named boards in the now removed Subpart J of Part 35 on or before October 24, 2005, 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. The NRC estimates that 35 licensees will be impacted with a savings of 0.5 hour associated with the processing of each amendment.

Section 35.57(b)(1) would be amended to clarify that individuals 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. The NRC estimates that 1,917 licensees will be impacted on an annual basis with a savings of 0.5 hour associated with the processing of each amendment.

Section 35.57(b)(2) would be restructured and expanded to recognize physicians, dentists, or podiatrists who were certified by the named boards in the now removed Subpart J of Part 35 on or before October 24, 2005, 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 an NRC license or an NRC master material license permit for those materials and uses that these individuals performed on or before October 24, 2005. The NRC estimates that 160 licensees will be impacted on an annual basis with a savings of 0.5 hour associated with the processing of each amendment.

Cost for processing amendments

Section 35.65(b)(2) would be modified to require licensees that possess bundled or aggregated single sealed sources with greater than a specified activity to treat them as one single source. These sources with activities larger than authorized by § 35.65 would have to meet all the regulatory requirements for that single source including, if appropriate, listing on a specific medical license, leak testing, and security requirements. This requirement is necessary so the Agreement States can ensure that adequate controls for security and radiation safety are applied to these larger sources. The NRC estimates this to impact nine licensees annually with the amendment requiring 0.5 hour to process.

Savings for processing attestations

Section 35.190(a) would remove the requirement to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State, for physicians seeking to be named as an AU of unsealed byproduct material for uses authorized under § 35.100. The NRC estimates that this will impact 51 Agreement State licensees on an annual basis with a savings of 0.5 labor hour for no longer requiring the submittal of a written attestation with the amendment request.

Cost for processing new reporting requirement

Section 35.204(e) would require licensees to report any measurement that exceeded the limits specified in § 35.204(a) for Mo-99/Tc-99m and Sr-82/Rb-82 generators. Generator manufacturers recommended testing each elution prior to use in humans. Mo-99 breakthrough measurements which exceed the permissible concentration listed in § 35.204(a) may cause unnecessary radiation exposure to patients. The NRC estimates the affected licensees to report six occurrences on average annually. The reporting requirement includes an initial phone notification to the Agreement State within 1 calendar day from occurrence and followed up with a written report due in 15 days. The NRC estimates this to be a 2.25 labor hour cost (0.25 hours to process the phone call and 2 hours to review the written report).

Savings for processing attestations

Section 35.290(a) would remove the requirement to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State, for physicians seeking to be named as an AU of unsealed byproduct material. The NRC estimates that this will impact 51 licensees on an annual basis with a savings of 0.5 labor hour for no longer requiring the submittal of a written attestation with the amendment request.

Savings for removing attestation requirement for some individuals

Section 35.390(a) would remove the requirement to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State, for physicians seeking to be named as an AU of unsealed byproduct material which requires a written directive for uses authorized under § 35.300. The NRC estimates that this will impact 25 licensees on an annual basis with a savings of 0.5 labor hour per licensee for no longer requiring the submittal of a written attestation with the amendment request.

Savings for processing attestations

Section 35.392(a) would remove the requirement to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State, for physicians seeking to be named as an AU for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries). The NRC estimates that this will impact 25 licensees on an annual basis with a savings of 0.5 labor hour for no longer requiring the submittal of a written attestation with the amendment request.

Section 35.394(a) would remove the requirement to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the Agreement State, for physicians seeking to be named as an AU for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries). The NRC estimates that this will impact 25 licensees on an annual basis with a savings of 0.5 labor hour for no longer requiring the submittal of a written attestation with the amendment request.

Section 35.490(a) would remove the requirement to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by an Agreement State, for physicians seeking to be named as an AU of a manual brachytherapy source for the uses authorized under § 35.400. The NRC estimates that this will impact 26 licensees on an annual basis, with a savings of 0.5 labor hour for no longer requiring the submittal of a written attestation with the amendment request.

Section 35.690(a) would remove the requirement to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the Agreement State, for physicians seeking to be named as an AU for sealed sources for uses authorized. The NRC estimates this to impact eight licensees annually with a

savings of 0.5 labor hour for no longer requiring the submittal of a written attestation with the amendment request.

Saving on phone notifications

Section 35.3045(c) would reduce telephone reporting cost to the Agreement State because the requirements for reporting an ME for permanent implant brachytherapy would be changed in § 35.3045(a)(2). The new requirements will not capture events that are not of significance and will reduce the number of reportable MEs related to permanent implant brachytherapy. The NRC estimates this to impact six licensees annually with a savings of 2.5 labor hours to process the ME notification.

Saving on written follow-up report to the Agreement State

Section 35.3045(d) would reduce written reporting costs to the Agreement State because the requirements for reporting an ME for permanent implant brachytherapy would be changed in § 35.3045(a)(2). The new requirements will not capture events that are not of significance and will reduce the number of reportable MEs related to permanent implant brachytherapy. The NRC estimates this to impact six licensees annually with a savings of 3 hours to process the written report.

Regulatory Efficiency

The proposed rule includes changes that would affect regulatory efficiency in a positive, but not easily quantifiable, manner. For example, regulatory efficiency would be enhanced by the proposed changes made in requirements for submitting an application for a license, such as in § 35.50. In this section, the regulations would be changed to make it easier for a physician to open an office by allowing the physician to be the AU and RSO on the same license application. Additionally, the proposed rule would update, clarify, and strengthen the existing regulatory requirements. Cost reductions would be realized by removing attestation requirements for certain board certified individuals, modifying ME reporting criteria to insure that only significant events would be reported, and by other proposed modifications to the regulations.

Public Health (routine)

Several proposed amendments would result in reducing the potential for radiation exposure to patients, but it is difficult to quantify the actual number in rems reduced. An example is the proposed change to § 35.204(b) and (e) which would require licensees to measure the Mo-99 concentration after each eluate from a Mo-99/Tc-99m generator and to report any measurement to the NRC that exceeds the limits specified in § 35.204(a). During October 2006 through February 2007, and again in January 2008, medical licensees reported to the NRC that numerous generators had failed the Mo-99 breakthrough tests. One generator manufacturer voluntarily reported 116 total elution test failures in 2008. The administration of higher levels of Mo-99 provides no benefit and could increase the radiation exposure to the patient, as well as have an adverse effect on nuclear medicine image quality and medical diagnosis.
Another example is the proposed requirement in § 35.41(b)(5) for licenses to have procedures for any administration requiring a WD to include procedures for determining if an ME, as defined in § 35.3045, has occurred. An ME could have occurred because the patient received more or

less radiation dose than was planned, with possible detrimental effect to the patient. The timely review and identification of an ME may result in prompt corrective actions.

4. Presentation of Results

4.1 Benefits and Costs

This section summarizes the benefits and costs estimated for these regulatory options. To the extent that the affected attributes could be analyzed quantitatively, the net effect of each option has been calculated and is presented below. However, some benefits and costs could be evaluated only on a qualitative basis.

The benefits of this proposed rule are associated with the potential reduction in unnecessary radiation exposure to patients. Additionally, the proposed rule would update, clarify, and strengthen the existing regulatory requirements, and thereby promote public health and safety. Cost reductions would be realized by removing attestation requirements for certain board certified individuals, modifying ME reporting criteria to insure that only significant events would be reported, and by other proposed modifications to the regulations.

Exhibit 4-1 summarizes the results of the analysis by attribute. Relative to the no-action alternative (Option 1), Option 2 would result in a net quantitative impact estimation over the 10-year analysis period of approximately $17 million at a 3 percent discount rate and $16 million at a 7 percent discount rate.

Exhibit 4-1
Summary Results by Attribute
at Discount Rates of 3 Percent and 10 Percent for a 10-Year Period

Quantitative Attribute	One-time Implementation Costs	Annual Operating Costs	Total combined Implementation and Annual Cost for 10-year period at 3% discount rate	Total combined Implementation and Annual Cost for 10-year period at 7% discount rate
Industry Costs Option 1	$0	$0	$0	$0
Industry Costs Option 2	$8,292,436	$773,661	$14,891,921	$13,726,307
Agreement States Option 1	$0	$0	$0	$0
Agreement States Option 2	$5,082,576	-$325,105	$2,309,368	$2,799,177
NRC Costs Option 1	$0	$0	$0	$0
NRC Costs Option 2	$415,359	-$76,336	-$235,799	-$120,790
Total Option 1	$0	$0	$0	$0
Total Option 2	$13,790,371	$372,220	$16,965,490	$16,404,694

4.2 Backfitting

The backfit rule (which is found in the regulations at §§ 50.109, 70.76, 72.62, 76.76, and in 10 CFR Part 52) does not apply to this final rule. Parts 30, 32, and 35 of Title 10 of CFR do not contain a backfit requirement. Therefore, a backfit analysis is not required.

5. Decision Rationale

Several proposed amendments would reduce the potential radiation exposure to patients; for example, the proposed change to § 35.204(b) and (e) which would require licensees to measure the Mo-99 concentration after each eluate from a Mo-99/Tc-99m generator and to report any measurement that exceeds the limits specified in § 35.204(a). During October 2006 through February 2007, and again in January 2008, medical licensees reported to the NRC that numerous generators had failed the Mo-99 breakthrough tests. One generator manufacturer voluntarily reported 116 total elution test failures in 2008. The administration of higher levels of Mo-99 provides no benefit and could increase the radiation exposure to the patient as well as have an adverse effect on nuclear medicine image quality and medical diagnosis.

Another example is the proposed requirement in § 35.41(b)(5) for licensees to have procedures for determining if an ME, as defined in § 35.3045, has occurred. An ME could have occurred

because the patient received more or less radiation dose than was planned for, with possible detrimental effect to the patient.

Additional benefits of the proposed rule include allowing ARSOs to be named on a license, which 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, ARSOs could more easily become RSOs on other licenses for the types of uses for which they qualify. Another benefit is the increased flexibility for AUs to use sealed sources and devices for manual brachytherapy for other 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. Providing this flexibility will allow AUs to use medical judgment in determining the medical uses of these sealed sources and devices.

The decision rationale is based on how the benefits and costs have been analyzed. Relative to the no-action alternative, Option 2 would result in a one-time implementation cost to the industry of approximately $8.3 million and a net annual cost to the industry of approximately $775,000. Offsetting the net cost, the NRC determined that Option 2 would result in substantial non-quantifiable benefits related to regulatory efficiency and public health (routine). Although costs would be incurred as a result of the rule, the qualitative benefits associated with the rule would outweigh its cost. The NRC determined that the rule is cost-justified because the proposed regulatory initiatives would promote public health and safety.

6. Implementation

Generally, the NRC allows an adequate time for a final rule to become effective. The time would depend on the scope of the rulemaking, the availability of the conforming guidance, and the complexity of the final rule. The NRC proposes that the final rule become effective 180 days from its publication in the *Federal Register*. For this analysis, the final rule effective date is late 2015.

7. References

- NUREG/BR-0184, “Regulatory Analysis Technical Evaluation Handbook, Final Report,” U.S. Nuclear Regulatory Commission, Washington, DC, January 1997.

- NUREG/BR-0058, “Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission,” Revision 4, U.S. Nuclear Regulatory Commission, Washington, DC, September 2004.

- NUREG/CR-4627, "Generic Cost Estimates, Abstracts from Generic Studies for Use in Preparing Regulatory Impact Analyses."

- OMB Circular No. A-4, September, 17, 2003.

- Department of Labor (U.S.), Bureau of Labor Statistics. Occupational Employment Statistics, Occupational Employment and Wages.

- 2011-2012 Information Digest, NUREG-1350, Volume 24.
- NUREG-1556, Vol. 20, Appendix G: LTS Program Code Descriptions.

Appendix A: Regulatory Flexibility Analysis

1. Steps Taken to Mitigate Economic Impacts on Small Entities

The NRC is required by the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) as amended by the Small Business Regulatory Enforcement Fairness Act, to consider the impact of its rulemakings on small entities and evaluate alternatives that would accomplish regulatory objectives without unduly burdening small entities or erecting barriers to competition. This section describes the assessment of the small entity impacts expected to be incurred by 10 CFR Parts 30, 32, and 35 licensees as a result of the proposed rule. This analysis describes (1) the NRC's definition of “small entities,” including "small businesses," "small governmental jurisdictions," ”small educational institutions,” and "small organizations"; (2) what number constitutes a "substantial number" of these entities; (3) whether "significant impacts" will be incurred by licensees under the rule; and (4) the measures that NRC has adopted in the rule to mitigate impacts on small entities.

1.1 Defining "Small Entities" Affected by the Rule

The NRC established its size standards for small entities on December 9, 1985 (50 FR 50241). On November 6, 1991 (56 FR 56671), the NRC conformed its format for size standards to mirror the definitions of small entities in the Regulatory Flexibility Act of 1980, as amended. In a direct final rule published in the *Federal Register* on August 10, 2007 (72 FR 44951), the NRC adjusted its receipts-based small business size standard to conform to the Small Business Act (SBA) size standard for nonmanufacturing industries. This size standard reflects the most commonly used SBA size standard for nonmanufacturing industries. On July 3, 2012, the NRC increased its receipts-based, small business size standard from $6.5 million to $7 million to conform to the standard set by the SBA.

The NRC uses the size standards contained in 10 CFR 2.810 to determine whether a licensee qualifies as a small entity in its regulatory programs.

The size standards pertinent to Parts 30, 32, and 35 licensees impacted by this proposed rule under 10 CFR 2.810 are:

A small business is a for-profit concern and is a:

> (1) Concern that provides a service or a concern not engaged in manufacturing with average gross receipts of $7 million or less over its last 3 completed fiscal years; or
>
> (2) Manufacturing concern with an average number of 500 or fewer employees based upon employment during each pay period for the preceding 12 calendar months.

A small organization is a not-for-profit organization which is independently owned and operated and has annual gross receipts of $7 million or less.

A small governmental jurisdiction is a government of a city, county, town, township, village, school district, or special district with a population of less than 50,000.

A small educational institution is one that is supported by a qualifying small governmental jurisdiction or is not state or publicly supported and has 500 or fewer employees.

The proposed rule will affect 7,473 NRC/Agreement State licensees. The licenses are issued principally to medical institutions and individual private medical practitioners.

Because NRC licensees with annual gross receipts below $7 million pay reduced fees, the NRC has data on the number of affected licensees who certified that they qualified as small entities for reduced fee purposes. Based on data from the NRC Financial Accounting and Integrated Management Information System in December 2012, 294 affected licensees reported that their annual gross receipts were below $7 million. Using the ratio explained in section 3.2.1 of this document, the NRC estimates that 1,735 NRC/Agreement State licensees are classified as small entities.

In total, therefore, the proportion of impacted licensees that are small entities is estimated to be 23 percent.

1.2 Determining What Number Constitutes a Substantial Number

The NRC has not established a quantitative definition of the number or proportion of licensees that constitutes a substantial number. However, for the purpose of this rulemaking, the NRC assumes that 23 percent of all licensees constitutes a "substantial number" of small entities likely to be impacted by this rule. A substantial number of both of the two categories of licensees considered, medical institutions and individual private medical practitioners, would be impacted by the rule.

1.3 Measuring "Significant Impacts"

To evaluate the impact that a small entity would be expected to incur as a result of the rule, the ratio of annualized costs was calculated as a percentage of estimated gross receipts. The NRC has not established a quantitative cutoff for "significant impact." For the purpose of this rulemaking, the NRC assumes "significant" impact if the ratio of annualized costs to estimated annual gross receipts for a licensee exceeds one percent.

The proposed rule would have an estimated $8.3 million implementation cost impact on the industry. This cost would be spread over the 7,473 impacted licensees or an average implementation cost of approximately $1,100 per licensee. The proposed rule would have an annual cost impact on the industry as well of an estimated $750,000 or an average cost of an estimated $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 one percent criterion for "significant impacts." Thus, even though the proposed rule would affect a substantial number of licensees that are small entities it would not have a significant economic impact on these entities.

1.4 Steps Taken to Mitigate Economic Impacts on Small Entities

The NRC has taken a number of actions in this rule to ensure that the selected alternative is the least costly alternative that adequately protects workers and patients from radiation exposure. As the Regulatory Analysis prepared for this rule demonstrates, many of the proposed amendments eliminate existing costs, and the remaining proposed amendments which would add cost would not place a significant economic impact on small entities.

Appendix B: Assumptions by section determining impacted NRC licensees.

The below table outlines by section the assumptions which determined the number of impacted NRC licensees. To obtain the number of licensees impacted in the Agreement States, use a multiplier of 5.9**,** which is the ratio of NRC licensees to Agreement State licensees from Table 1 - Number and Type of Licenses.

Section	Annual Totals
30.34(g)	(program code 2511) responses from the sole licensee = 9
30.50(b)	(program code 2511) responses from the sole licensee = 9
35.12(b) Add ARSOs	3% of all licensees (1083) = 32
35.12(b) Remove copy	3% of all licensees (1083) = 32
35.12(c)(1) Renewals	10% of all licensees (1083) = 108
35.12(c)(1) Amendments	1 response from all licensees = 1083
35.13(d) (Turnover)	3% of all licensees (1083 X 3%) = 32
35.13(d) (Amendments)	10 % of all licensees (1083 X 10%) = 108
35.13(i)	2 responses from each licensee in 2120, 2200, 2230, 2240 (507 X 2) = 1014
35.14(b)(1)	Turnover – 3% of all licensees (1083 X 3% = 32) + Name changes - 0.5% of all licensees (1083 X 0.5% = 6) = 38 for ARSOs The number of ophthalmic physicists is estimated to be low to calculate.
35.14(b)(6)	2 responses from 2120, 2200, 2230, 2240 (507 X 2) = 1014
35.24(b)	Cost covered in 35.2024(c)
35.41(a)	Cost covered in 35.2041 35.41(b)(5) and 35.41(b)(6) = 33
35.41(b)(5)	Turnover – 3% of 2110, 2120, 2200, 2210, 2230, 2231, 2240, 2310 (598 X 3% = 18
35.41(b)(6)	Turnover – 3% of 2110, 2120, 2200, 2240 (489 X 3% = 15)
35.50(a)	30% of all applicants will be board certified. Turnover - 3% of all licensees (1083) =32 X 30% = 10 (rounded)
35.50(c)(1)	Subset of 35.50(a)
35.50(c)(3)	1 responded from 2201 (286) = 1
35.51(a)	30% of all applicants will be board certified. Turnover – 3% of 2110, 2120, 2200, 2210, 2230, 2231, 2240, 2310 (598) =18 X 30% = 5 (rounded)
35.55(a)	10% of all applicants are board certified. 15% of 2110 and 2120 have ANP (405 X 10% = 41 X 15%) = 6 Turnover – 3% X 6 = 1
35.57(a)(1)	1% of 2210, 2120, 2200, 2210, 2230, 2231, 2240, 2310 (598) = 6
35.57(a)(2)	1% of all licensees (1083) = 11
35.57(a)(3)	1% of 2210, 2120, 2200, 2210, 2230, 2231, 2240, 2310 (598) = 6
35.57(b)(1)	30% of all licensees (1083) = 325
35.57(b)(2)	2.5% of all licensees (1083) = 27

35.65(b((2)	One time cost -1% of 2110, 2120, 2121, 2200, 2201, 2220, 2231 (950) = 10 Annual cost - 0.15% of 2110, 2120, 2121, 2200, 2201, 2220, 2231 (950) = 1.5
35.190(a)	30% of all applicants will be board certified. Turnover – 3% of 2110, 2120, 2121, 2200, 2201, 2220 (948) = 28 X 30% = 8 (rounded)
35.204(b)	Covered under 35.2204 for 2110, 2120 = 405 X 15% = 61 Related to the number of ANP [see 35.55(a)]
35.204(e)	10% of 2110, 2120, 2121,2200, 2201, 2220, 2231 (950) have generators = 95 X 1% estimated to report = 1
35.290(a)	30% of all applicants will be board certified. Turnover – 3% of 2110, 2120, 2121, 2200, 2201, 2220 (948) = 28 X 30% = 8 (rounded)
35.390(a)	30% of all applicants will be board certified. Turnover – 3% of 2110, 2120, 2200, 2231 (465) = 14 X 30% = 4 (rounded)
35.392(a)	30% of all applicants will be board certified. Turnover – 3% of 2110, 2120, 2200, 2231 (465) = 14 X 30% = 4
35.394(a)	30% of all applicants will be board certified. Turnover – 3% of 2110, 2120, 2200, 2231 (465) = 14 X 30% = 4
35.433	No Additional Cost
35.490(a)	30% of all applicants will be board certified. Turnover - 3% of 2110, 2120, 2200, 2210, 2240 (503) = 15 X 30% = 5
35.610(d)	Cost in 35.2310 for 2110, 2120, 2230, 2300, 2310 = 498
35.655(a)	No change in cost
35.690(a)	30% of all applicants will be board certified. Turnover - 3% of 2110, 2230, 2300, 2310 (160) = 5 X 30% = 2 (rounded)
35.2024(c)	Turnover – 3% of all licensees = 32
35.2041	From 35.41(a) = 33
35.2204	From 35.204(b) = 61
35.2310	From 35.610(d) = 498 X 5% = 25
35.3045(a)(2)	Cost in 35.3045(c), (d) and (e)
35.3045(c)	Avg number of ME's each year for permanent implant brachytherapy = 14 X 50% reduction from new criterion = 7 (1 NRC and 6 Agreement States)
35.3045(d)	Avg number of ME's each year for permanent implant brachytherapy = 14 X 50% reduction from new criterion = 7 (1 NRC and 6 Agreement States)
35.3045(e)	Avg number of ME's each year reported to patients = 48 X 35% reduction from new criterion = 18 (3 NRC and 15 Agreement States)
35.3204(a)	10% of 2110, 2120, 2121,2200, 2201, 2220, 2231 (950) have generators = 95 X 1% estimated to report = 1
35.3204(b)	10% of 2110, 2120, 2121,2200, 2201, 2220, 2231 (950) have generators = 95 X 1% estimated to report = 1

ENVIRONMENTAL ASSESSMENT AND FINDING OF
NO SIGNIFICANT IMPACT
FOR THE
PROPOSED RULE
AMENDING 10 CFR PARTS 30, 32 and 35
MEDICAL USE OF BYPRODUCT MATERIAL: MEDICAL EVENT DEFINITIONS, TRAINING AND EXPERIENCE, AND CLARIFYING AMENDMENTS

Office of Federal and State Materials and Environmental Management Programs
U.S. Nuclear Regulatory Commission
XXXXXX 2013

INTRODUCTION AND BACKGROUND

In 2002, the U.S. Nuclear Regulatory Commission (NRC) revised the medical use regulations in Part 35 of Title 10 of the *Code of Federal Regulations* (10 CFR) in their entirety (67 FR 20250). The training and experience requirements in Part 35 were further revised through an additional rulemaking in 2005 (70 FR 16336). In implementing the current regulations in 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.

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 medical event (ME) for permanent implant brachytherapy. Second, the rule proposes changes: (1) to the training and experience (T&E) requirements for authorized users (AUs), medical physicists, Radiation Safety Officers (RSOs), and nuclear pharmacists; (2) to the requirements for measuring molybdenum-99 (Mo-99) contamination and reporting of failed technetium and rubidium generators, and (3) to allow Associate Radiation Safety Officers (ARSOs) 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 that 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 former Subpart J of Part 35 which contained the prior T&E requirements.

Although the majority of the amendments, including the revised ME definitions, being proposed are the types of actions described in categorical exclusions in 10 CFR 51.22(c)(2) and (c)(3)(i-v), there are two actions that need to be considered in the environmental assessment. The proposed actions that do not meet the criterion for categorical exclusions as described in § 51.22 are: 1) Increasing the frequency of measuring Mo-99 concentration required in § 35.204 and 2) Increasing the time interval from 5 years to 7 years for a gamma stereotactic radiosurgery unit full-inspection servicing to assure proper functioning of the source exposure mechanism as required in § 35.655.

THE PROPOSED ACTIONS

1. **Increase the frequency of measuring the Mo-99 concentration required in § 35.204**

The current requirement to measure the Mo-99 concentration of the first eluate would be changed to require that the Mo-99 concentration be measured for each eluate. A Mo-99/technetium-99m (Tc-99m) generator can be eluted several times to obtain Tc-99m for formulating radiopharmaceuticals for human use.

Although generator manufacturers have always recommended testing each elution prior to use in humans, the medical and pharmaceutical community considered frequency of Mo-99 breakthrough to be a rare event. Based on this information, in a 2002 rulemaking, the NRC relaxed the then-existing regulatory requirement to measure all elutes to require only measuring the Mo-99 concentration of the first elution to ensure that the permissible concentrations listed in § 35.204(a) were not exceeded.

This proposed change to return to the original requirement is in response to several incidents reported to the NRC in 2006, 2007, and 2008 of Mo-99 measurements exceeding the permissible concentration listed in § 35.204(a) in subsequent elutions beyond the initial one. Mo-99 concentrations exceeding the permissible concentration listed in § 35.204(a) may cause unnecessary radiation exposure to patients.

2. **Increase the full-inspection servicing interval for a gamma stereotactic radiosurgery unit from 5 years to 7 years**

Currently, licensees are required to perform a full inspection and service of a teletherapy unit or a gamma stereotactic radiosurgery unit at intervals not to exceed 5 years to assure proper functioning of the source exposure mechanism. Generally, these inspections are done at the time of the source exchange when the decayed source is taken out of the unit and before the new radioactive source is installed. The proposed rule would allow a time interval of 7 years to perform this full service and inspection of a gamma stereotactic radiosurgery unit. Extending the inspection and service interval would provide licensees greater flexibility in arranging the radioactive source replacement.

THE NEED FOR THE PROPOSED ACTIONS

The first proposed action (i.e., more frequent measurement of Mo-99 concentration) would assure that the patients are administered radiopharmaceuticals that meet the regulatory limits defined in § 35.204(a). The second proposed action (i.e., increasing the inspection interval for a gamma stereotactic radiosurgery unit) would provide greater flexibility to licensees in arranging for source replacement and the full inspection and servicing of a gamma stereotactic radiosurgery unit.

ENVIRONMENTAL IMPACTS OF PROPOSED ACTIONS

The proposed amendments to increase the frequency of Mo-99 tests required in § 35.204 and to increase the inspection interval required in § 35.655 for a gamma stereotactic radiosurgery unit from 5 years to 7 years are the types of actions that would have no significant impact on public health and safety, occupational health and safety, and the environment. By following standard radiological precautions (i.e., using tongs to handle radioactive material) the operator would receive minimum radiation exposure performing the Mo-99 tests. Extending the inspection frequency for a gamma stereotactic radiosurgery unit from 5 years to 7 years will not result in any additional radiation exposure to the public, workers, or the environment because the radiation sources in these units are sealed sources, securely located and adequately shielded, and the access to the units is limited to authorized personnel only.

ALTERNATIVES TO THE PROPOSED ACTION

The alternative to this proposed action is to take no action. This would leave in place the current regulations. This alternative was rejected for the Mo-99/Tc-99m generators because NRC must be assured that patients are administered only the permissible amounts of Mo-99 in the radiopharmaceutical that contains Tc-99m. For the gamma stereotactic radiosurgery unit licensees, the no action alternative was rejected because that alternative would deprive licensees of having the necessary flexibility to extend the full inspection to more than 5 years to coincide with radioactive source replacement.

ALTERNATIVE USE OF RESOURCES

There were no irreversible commitments of resources determined in this assessment.

AGENCIES AND PERSONS CONTACTED

No agencies or persons outside the NRC were contacted in connection with the preparation of this draft environmental assessment. The NRC has sent a copy of the draft environmental assessment and the proposed rule to every State Liaison Officer and requested their comments on the environmental assessment.

FINDING OF NO SIGNIFICANT IMPACT

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that the proposed amendments are not a major Federal action significantly affecting the quality of the human environment, and therefore, an environmental impact statement is not required. The proposed amendments would establish more frequent measuring of Mo-99 and increase the inspection interval for a gamma stereotactic radiosurgery unit from 5 years to 7 years. The proposed amendments are procedural in nature and of themselves would have no significant impact on the environment.

The determination of this 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. Comments on any aspect of the environmental assessment may be submitted to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attn: Rulemakings and Adjudications Staff.

Advisory Committee on Medical Uses of Isotopes
Sub-Committee on Proposed Rule

Comments on

NUCLEAR REGULATORY COMMISSION (NRC)

10 CFR Parts 30, 32 and 35

RIN: 3150-AI63 [NRC-2008-0175]

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

Subcommittee Members:
Susan Langhorst, Ph.D., Steven Mattmuller, Bruce Thomadsen, Ph.D., Laura Weil, James Welsh, M.D., Pat Zanzonico, Ph.D. (Chair)

Date: March 28, 2013
revised, April 5, 2013

Note

This document provides comments by a Sub-Committee of the Advisory Committee on Medical Uses of Isotopes (ACMUI) on the public version of 10 CFR Parts 30, 32 and 35, RIN: 3150-AI63 [NRC-2008-0175] - Medical Use of Byproduct Material - Medical Event Definitions, Training and Experience, and Clarifying Amendments. The Sub-Committee identifies many of its comments with respect to the relevant page and/or line numbers in a version of the foregoing document in which it has inserted line numbers.

The ACMUI has unanimously approved this current, final version of this report.

General Comments

1. **Medical event definitions for permanent implant brachytherapy**
   a. Historical review of permanent implant brachytherapy misadministration/medical event.

      In considering the criteria for an medical event (ME) in permanent implant brachytherapy, it would be helpful to review the recent regulatory history of MEs for this form of therapy. In the current 10 CFR 35.2 (Definitions), "prescribed dose" for manual brachytherapy is defined as "…either the total source strength and exposure time or the total dose, as documented in the written directive." This definition implies that total source strength (activity) or exposure time is interchangeable with total dose. The current ME criteria in 10 CFR 35.3045 (a) (1) (i) do not include any dose unit and so do not appear to exclude use of total source strength (activity) or exposure time. The activity-based criterion for permanent implant brachytherapy MEs in proposed rule thus does not actually differ from that in the current.

To explore this further, previous Part 35 rulemakings were reviewed. NRC's final rule for "Quality Management Program and Misadministrations" published July 25, 1991 [58 FR 34104] established the first definition of a misadministration, which for brachytherapy is as follows.

"A brachytherapy radiation dose:

(i) Involving the wrong patient, wrong radioisotope, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site);

(ii) Involving a sealed source that is leaking;

(iii) When, for a temporary implant one or more sealed sources are not removed upon completion of the procedure; or

(iv) When the calculated administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose." [58 FR 34120].

While item (iv) uses the term, "calculated administered dose," the document also provides the following discussion of a brachytherapy misadministration:

"Paragraph (6) applies to brachytherapy procedures other than those specified in paragraph (5) above. This paragraph is essentially the same as paragraph **(**d) in the proposed definition of prescription. This paragraph requires the authorized user (AU) to specify, before implantation, the radioisotope, the source strengths, and the number of sources, but does not require the total dose because detailed calculations are required to determine the total dose after the sources are implanted. However, following implantation but before completion of the procedure, AU must specify, among other parameters, the total source strength and exposure time. If the AU prefers, the total dose may be used instead of the total source strength and exposure time. This change, using total source strength and exposure time, provides an easy way of specifying the total dose and simplifies the determination of a misadministration. Since the total source strength is fixed when the sources are implanted, delivering the prescribed dose is a matter of using the correct (ie prescribed) exposure time. In other words, after implanting the correct sources, the exposure time (and total dose) will be correct if the sources are removed at the correct time." [58 FR 34115].

The foregoing discussion suggests that the current rule allows use of total source strength and exposure time to identify whether there was a misadministration.

In NRC's final rule for "Medical Use of Byproduct Material" published April 24, 2002 [67 FR 20250], the requirements of 35.3045 "…are based on the current requirements in Section35.33, Notifications, reports, and records of misadministrations" [67 FR 20363]. This rulemaking description does not indicate that NRC will no longer allow use of total source strength and exposure time in determination of a ME. Would that not mean that the 1991 statement allowing use of total source strength and exposure time also applies to identifying a brachytherapy ME? The ACMUI and its Rulemaking Sub-Committee unanimously recommend NRC staff allow use of total source strength as a substitute for

total dose for determining MEs for permanent implant brachytherapy until the Part 35 rulemaking is complete.

b. Changing the number-of-seeds component of the ME definition to be compared to the post-implant written directive (WD) is appreciated, since it clarifies that the AU is allowed to change the implant plan based on his/her medical decision during the implant procedure.

c. There is some concern that the proposed ME definition may discourage practitioners from utilizing this therapy. The ACMUI and its Rulemaking Sub-Committee therefore unanimously recommend that NRC solicit information on whether the proposed ME definition for permanent implant brachytherapy will discourage licensees from using this therapy option or will otherwise adversely impact clinical practice, with the recognition that NRC may utilize language it deems most appropriate for soliciting this type of information from its stakeholders.

d. There is also concern with the Organization of Agreements States position (page 29, lines 871-879, and page 77 ("Draft Compatibility Table for Proposed Rule")) that the draft rule re-defining MEs in permanent implant brachytherapy should be designated as Compatibility Category C for the Agreement States, thereby allowing them to retain the dose-based criteria for definition of a ME. The rationale for conversion from dose-based to activity-based criteria has been detailed, with the most important component of this rationale being the failure of dose-based criteria to sensitively and specifically capture clinically significant "misadministrations" in permanent implant brachytherapy. Retaining the current
dose-based criteria (as specified in Section 35.3045), would still result in clinically insignificant occurrences being identified as MEs and thereby perpetuate the confusion associated with the current activity-based criteria. The ACMUI and its Rulemaking Sub-Committee recommend that the draft rule re-defining medical events in permanent implant brachytherapy be designated as Compatibility Category B. This recommendation was approved by the ACMUI with one dissenting vote.

e. Rather than ascribing the rationale for the ME criteria based on the absorbed dose to 5 cubic centimeters of contiguous normal tissue "…to the literature…," the following reference should be cited:

S Nag, H Cardenes, S Chang, I Das, B Erickson, G Ibbott, J Lowenstein, J Roll, B Thomadsen, M Varia. Proposed guidelines for image-based intracavitary brachytherapy for cervical carcinoma: Report from Image-Guided Brachytherapy Working Group Int J Radiat Oncol Biol Phys 60:1160-1172, 2004.

The ACMUI and its Rulemaking Sub-Committee unanimously recommend citation of this reference in the proposed rule.

2. Training and experience requirements for authorized users, medical physicists, Radiation Safety Officers, and nuclear pharmacist.

a. There is enthusiastic support for eliminating the preceptor statement requirement for Board-certified individuals.

b. With regard to the sentence on page 48, lined 1447-1448, why do AUs need to have work experience on the elution of generators? This topic should be covered as part of their didactic (ie classroom and laboratory) training. It is likely that the vast majority of § 35.200 AUs are not responsible for a generator system because they obtain unit dosages or bulk radionuclide from a commercial radiopharmacy. Would it not make more sense, therefore, that licensees approved to use generator systems show specific training on the requirement now listed under § 35.290 (c) (1) (ii)(G) for those individuals (AUs and others) who are responsible for proper operation and test of the generator as part of their license conditions? This could be similar to the way boiler-plate license conditions are used for sealed-source leak test requirements or for decay-in-storage requirements. The ACMUI and its Rulemaking Sub-Committee thus recommend unanimously that (a) licensees approved to use generator systems show specific training on the requirement now listed under 35.290 (c) (1) (ii) (G) for those individuals (Authorized Users and others) who are responsible for proper operation and testing of the generator as part of their license conditions and (b) that Authorized Nuclear Pharmacists who have the adequate training and experience (T&E) are able to provide the supervised work experience for Authorized Users on the elution of generators.

c. With respect to the amended requirements for preceptor attestation for an individual seeking regulatory authorization as an Radiation Safety Officers (RSO), AMP, ANP, or AU, the ACMUI and its Rulemaking Sub-Committee unanimously endorse the attestation language in the proposed rule stating that the individual can "…independently fulfill the radiation safety-related duties…" associated with the authorization being requested. This replaces the language in the current rule requiring the preceptor to attest that the individual "…has achieved a level of competency to function independently…" for the authorization. The proposed language thus eliminates burdening preceptors with making a subjective judgment as to the professional competency of an individual. The latter language requires, more reasonably, the preceptor to simply attest that an individual satisfactorily completed the residency and other requirements of a training program (an objective determination) but does not require the preceptor to make a judgment as to the actual competency of the individual (a subjective determination).

d. The ACMUI has reservations about certain elements of Section 35.390 (Training for use of unsealed byproduct material for which a written directive is required) (pages 49-51) and of Section 35.396 (Training for the parenteral administration of unsealed byproduct material requiring a written directive) pages (53-55). Specifically, lines 1503 to 1508 (Section 35.390) state, "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." And lines 1628-1632 (Section 35.396) state, "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) of this section for each new parenteral administration listed in § 35.390(b) (1) (ii) (G) for which the individual is requesting AU status." The proposed radionuclide-by-radionuclide determination by the NRC of T&E requirements is unnecessary, places an unnecessary regulatory burden on practitioners, and may delay or prevent patient

access to effective radionuclide-based diagnostics and therapeutics. There are only several types of radiations associated with radioactive decay: photons (x- and gamma-rays), beta particles (positrons and negatrons), electrons (internal conversion and Auger), and alpha particles, and there is no *fundamental* difference in the clinical applications and radiation safety among these radiations. The ACMUI believes the training and experience a physician receives to perform parenteral administration of a radiopharmaceutical, including the three cases of work experience, is sufficient in demonstrating that physician's competency to function as an AU for both beta-/gamma-emitting and alpha-emitting radiopharmaceuticals. NRC staff has not provided a compelling radiation-safety need for emission-specific T&E requirements. The ACMUI is concerned that this separation would have the opposite effect: the separation of beta-/gamma-emitting alpha-emitting radiopharmaceuticals expends licensee and regulatory staff resources in the prescriptive bookkeeping needed to track all these separate work experiences that the supervising AU and the physician being trained has had. In addition, the ACMUI is concerned that the proposed separation does not address how AUs currently approved under § 35.390 and § 35.396 will be grandfathered to allow parenteral administration alpha-emitting radiopharmaceuticals and to act as supervising AUs for § 35.390 (b) (1) (ii) (G). Therefore, The ACMUI and its Rulemaking Sub-Committee recommend unanimously (with one abstention) that the work experience for parenteral administrations under § 35.390 (b) (1) (ii) (G) and § 35.396 **not** be separated between parenteral administration of a beta/gamma-emitting radiopharmaceutical versus an alpha-emitting radiopharmaceutical as proposed.

3. Extending grandfathering to certain certified individuals (Ritenour petition)

a. The ACMUI recommended in September 2012 that all individuals who were able to meet the requirements of the previous Subpart J for an authorized user, authorized radiation safety office, authorized medical physicist, or authorized nuclear pharmacist before that subpart was eliminated as of October 24, 2005 should be grandfathered, thus relieving them of meeting the current training and experience requirements. The draft proposed regulations contain the provision, "…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." See related Specific Comments below.

b. Some of the terminology NRC has historically used and now uses in the proposed rule is somewhat confusing. For clarification of meaning, it is suggested that the terms, "type of use", "modality", and "category," be explicitly defined in Section 35.2 (Definitions), so that the regulatory meaning of these three terms is clearly understood.

c. What remains unclear with respect to the Ritenour petition is the impact of the date of recognition of a certifying board by the NRC. The ACMUI and its Rulemaking Sub-Committee unanimously recommend that the date of recognition by the NRC of a certifying board should *not* impact individuals seeking to be named as an authorized user, authorized radiation safety office, authorized medical physicist, or authorized nuclear pharmacist through the certification pathway. Once a board has been recognized by the NRC, the date of recognition is irrelevant. This point should be stated explicitly in the proposed rule.

4. Measuring molybdenum contamination for each elution and reporting of failed breakthrough tests

a. Only two generator systems are specified in the current and proposed rules, molybdenum-89 (Mo-99)/technetium-99m (Tc-99m) and strontium-82 (Sr-82)/ rubidium-89 (Rb-89) generators. Should other generator systems be included or should this section be generalized to all medical generator systems?

The current Food and Drug Administration (FDA) labeling requirements (ie the package insert) for a Mo-99/Tc-99m generator states that each eluate should be tested for Mo-99 content, to verify it does not exceed the stipulated limit of 0.15 Ci of Mo99 per mCi of Tc99m at the time of patient administration. The current FDA labeling is therefore more restrictive than the current NRC rule, while the proposed rule will match that of the FDA in terms of frequency of eluate testing (ie for each elution). Therefore, The ACMUI and its Rulemaking Sub-Committee unanimously recommend the NRC adopt the FDA-approved package insert for parent-breakthrough limits for radioisotope generators.

Pursuant to its recently revised labeling requirements for strontium-89 (Sr-89)/ rubidium-89 (Rb-89) generators, the FDA's regulation is now more restrictive than the NRC's rule in terms of breakthrough limits. The new FDA limits are one-half of those of the NRC and an action level limit has been introduced. The NRC, however, is not revising its rule to comply with the FDA regulation. As discussed at the 4/17/2012 ACMUI meeting on April 18, 2012, the NRC encourages licensees to follow good medical practice but would not cite a licensee if the licensee did not follow the applicable FDA requirements regulation.

For generator breakthrough testing, conformity between the corresponding FDA regulations and NRC rules is highly recommended. This would be especially beneficial as new generators (eg the germanium-68 (Ge-68)/gallium-68 (Ga-68) generator) become FDA-approved products. The NRC would be able to inspect, immediately, for compliance with the applicable FDA breakthrough testing requirements and thus would not have to await revision of its rules for testing newly introduced generators. Of course, if the NRC feels it cannot inspect a licensee for compliance with the applicable FDA regulation at this time, then the proposed rule for breakthrough testing of Mo-99/Tc-99m generators is recommended.

b. The proposed NRC reporting requirement for out-of-tolerance generator elutions was debated at length by the ACMUI. Specifically, "The NRC proposes to add two new reporting requirements related to breakthrough of Mo-99 and Sr-82 and Sr-85 contamination. One reporting requirement in § 35.3204(a) would require licensees to report to the NRC and the manufacturers or distributers of medical generators any measurement that exceeds the limits specified in § 35.204(a) within 24 hours. The second requirement in § 30.50 would require manufacturers/distributors to report to the NRC when they receive such a notification from a licensee" (page 26 (lines 788-793), Section IV. f. (Requiring reporting and notification of failed Mo-99/Tc-99m and Sr-82/ Rb-82 generators)). To lessen the reporting burden on licensees, the ACMUI considered reducing the reporting requirement for licensees to a single requirement, namely, reporting to the vendor. If licensees were required to report out-of-tolerance elution results to the vendor (which is the standard prevailing practice when

out-of-tolerance generator elutions are found), then a requirement for the vendor to report such results to the NRC could be imposed. By a split vote, the ACMUI does *not* support the requirement in the proposed rule that licensees report to the NRC generator elutions with out-of-tolerance parent-breakthrough, as discussed below.

The ACMUI does not find the NRC's rationale - in lines 768-804 on pages 26 and 27 for its proposed dual-reporting requirement (to the vendor and to the NRC) for out-of-tolerance generator elutions compelling. In the exposition of its rationale, the NRC states, for example, that, "The FDA may not investigate each reported incident and may take a considerable amount of time in investigating the cause of reported failures." Given the FDA's long-standing experience and expertise in the regulation of radiopharmaceuticals, however, it is the regulatory agency of choice for dealing with out-of-tolerance generator elutions. Further, the assertion that, "…some incidents of failed generators may not be reported to the FDA because certain manufacturers are not in the United States, and the generators are distributed by vendors who are not required to report to the FDA," is somewhat specious. If a drug product in used in the United States, it requires FDA approval. And, in either the new drug or an abbreviated new drug application, the manufacturing standard operating procedures (SOPs) and manufacturing site will be reviewed, inspected and approved by the FDA before the product is actually marketed. If a licensee's generator is not performing to specifications and thus cannot be used for patient studies, the manufacturer will be notified immediately, either directly or indirectly through a vendor. The foregoing SOPs include protocols for documenting and reporting a product failure when the manufacturer is contacted by a customer/licensee, including how to form and implement a Deviation Investigation Team (DIT) to investigate such a failure. These SOPs also include a procedure for implementing and performing a Corrective and Preventative Action investigation if a DIT is unsuccessful. Finally, a formal mechanism in already in place for sharing of information among federal agencies, with a memorandum of understanding (MOU) dated December 4, 2002 between the FDA and the NRC - "The purpose of this MOU is to coordinate existing NRC and FDA regulatory programs for (1) medical devices, drugs, and biological products utilizing byproduct, source, or special nuclear material..." The MOU also calls for an annual meeting between the two agencies, providing an appropriate mechanism for addressing criteria for the evaluation process and the assessment of the regulatory response to issues of mutual responsibility.

c. With respect to Sr-82/Rb-82 generators, the proposed "reporting" rule does not actually address the underlying cause - the apparent failure of licensees to perform daily breakthrough testing - of the recent reported instances of excess radiostrontium breakthrough. Appropriate breakthrough testing at the two medical facilities involved very likely would have detected the out-of-tolerance breakthrough results and avoided the resulting large-scale disruption of Rb-82 myocardial perfusion studies. Has the NRC prepared an RIS or other document to emphasize the importance of and the proper method for breakthrough testing for this type of generator? Has it communicated with the Agreement States the importance of inspecting sites for not only regulatory compliance but also for demonstrated competency of a licensee's staff in performing breakthrough tests for Sr-82/Rb-82 generators? Has the NRC addressed training requirements for AUs who wish to use generators under Section 35.290? The current

training requirements are specific to Mo-99/Tc99m generators; training requirements have not kept pace with new and different generators.

d. With respect to item c., it is suggested that NRC solicit comments in Supplementary Information Section IV. D. specifically on whether the proposed notification requirements will discourage licensees from using generators, potentially limiting development of generator-based radiopharmaceuticals and having an adverse economic impact on vendors of generator systems.

5. Allowing Associate Radiation Safety Officers to be named on a medical license

a. With the addition of the term, "Associate Radiation Safety Officers (ARSO)," Section 35.15 (Exemptions regarding Type A specific licenses of broad scope) should also be updated. The ACMUI and its Rulemaking Sub-Committee unanimously recommend that the addition of ARSOs and Temporary RSOs also be included in these exemptions in the same manner as AUs, ANPs, and AMPs and allowed to be named on medical licenses. Specific changes are suggested in the Specific Comments below.

b. When an individual who does not have board certification is named as an RSO, ARSO, or any of the other authorized individuals, does any of their additional future training for an additional type of use (ie "modality" or "category") require a preceptor signature? If so, examples of how this should be done (eg for an RSO) should be provided.

6. "Plain language" requirement

a. Section X. Plain Language (lines 2198-2200) states, "The NRC requests comment on the proposed rule with respect to the clarity and effectiveness of the language." Overall, the proposed rule is well-written and well-organized. It could be shortened, and improved, by eliminating redundancies and consolidating related sections, eliminating identical or nearly identical passages appearing multiple times throughout the draft rule. A further improvement would be the inclusion of a detailed "executive summary"-style section summarizing, perhaps in a "bullet" format, the key changes introduced in the draft rule. This would be in place of the current one-paragraph Summary.

7. Additional general comments

a. Elimination of the requirement to submit a second copy of the 313 application is excellent

b. Use of different sealed sources is a helpful change. However, licensees will have the need to easily access device registry documents. Can NRC provide access to copies of these registrations?

c. The gamma-knife change to 7-year full inspections is also helpful.

Specific Comments - Significant

Pg 10	Lines 323-324	The phrase, "…for the modalities that they practiced as of October 24, 2005…," should be changed to, "…for the modalities covered by their board certification as of October 24, 2005…"
Pg 10	Lines 325-326	The phrase, "…for the modalities that they practiced as of October 24, 2005…," should be changed to, "…for the modalities covered by their board certification as of October 24, 2005…"
Pg 10	Line 343	The phrase, "…for the modalities that they practiced as of October 24, 2005…," should be changed to, "…for the modalities covered by their board certification as of October 24, 2005…"
Pp 10-11	Lines 339-343	Amend Section 35.57 to recognize all individuals that were previously certified by boards recognized under the previous Subpart J as RSOs, teletherapy or medical physicists, AMPs, AUs , nuclear pharmacists, and ANPs for the modalities covered by their board certification as of October 24, 2005. The staff believes that these individuals should be eligible for grandfathering for the modalities that their board certification covered 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. 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's board certification covered as of October 24, 2005.
Pg 29	Lines 866-868	This sentence appears to be incomplete or otherwise grammatically incorrect. In any case, its meaning is not clear. It should be revised and clarified.
Pg 32	Lines 960-963	This statement is not entirely accurate, as § 35.204 (b) requires "A licensee that uses molybdenum-99/ technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration of the *first* eluate after receipt of a generator to demonstrate compliance with paragraph (a) of this section." The proposed rule would require such a measurement after *every* elution, as noted earlier.

Pg 38	Lines 1155-1156	The phrase, "The maximum absorbed dose to any 5 contiguous cubic centimeters…," should be changed to, "The minimum absorbed dose to the maximally exposed 5 contiguous cubic centimeters…" Similar revisions are also suggested in the "Specific Comments - Minor" below.
Pg 39	Lines 1181-1182	It is suggested to revise this passage as follows. 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 ASRSO not only on their current license, but also on a different medical license.
Pg 61	Lines 1852-1852	This sentence states the training must be provided by the device manufacturer or individuals certified by the device manufacturer. How will this requirement impact licensees? Will there be enough trainers for the number of unit operators? Will computer-based training be acceptable?
Pg 90	Line 2653	After this line, insert the following and renumber the items following this addition. 11. In § 35.15, redesignate paragraphs (c), (d), (e), (f), and (g) as paragraphs (d), (e), (f), (h), and (i), respectively, revise newly redesignated paragraphs (d) and (f), and add new paragraphs (c) and (g) to read as follows: § 35.15 Exemptions regarding Type A specific licenses of broad scope. * * * * * (c) The provisions of § 35.13(d); (d) The provisions of § 35.13(f) regarding additions to or changes in the areas of use at the addresses identified in the application or on the license; * * * * * (f) The provisions of § 35.14(b) (1) for an authorized user, an authorized nuclear pharmacist, an Associate Radiation Safety Officer, or an authorized medical physicist; (g) The provisions of § 35.14(b) (2) for a temporary Radiation Safety Officer;

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Pp 99-100	Lines 2944-2950	It is not clear what is meant at the end of this sentence by the phrase, "…any new material." Is this yet another use term that needs to be defined for its regulatory meaning as discussed in Item 3.b. in the General Comments above? It is uncertain, for example, what additional training an experienced, board-certified RSO would need and if a non-board-certified RSO would need a preceptor statement to document this T&E.

Specific Comments - Minor

Pg 1	Line 37	Here and throughout the document, hyphens should be inserted in "compound" adjectives such as "medical use."
Pg 1	Line 37	The phrase, "…molybdenum contamination for each elution…," should be changed to, "…molybdenum-99 contamination for each generator elution…"
Pg 6	Line 225	The phrase, "…on the dose administered to the patient," should be changed to, "…on the radiation absorbed dose delivered to various tissues/structures of the patients body."
Pg 7	Lines 230-231	With the foregoing revision, this sentence should be revised as follows, "The ME criteria would include absorbed doses to normal tissues located outside of the treatment site as well as within the treatment site."
Pg 7	Line 237	The phrase, "…to convert…," should be changed to, "…with the conversion…"
Pg 8	Line 261	The phrase, "…the agency…," should be changed to the word, "regulators."
Pg 8	Line 262	The comma between the words, "training" and "as," should be deleted.
Pg 8	Line 267	The comma between the terms, "New York" and "in," should be deleted.
Pg 8	Line 268	The comma between the terms, "Texas" and "in," should be deleted.
Pg 8	Line 271	A comma should be inserted between the words, "stakeholders" and "to."
Pg 11	Line 353	The comma between the words, "regulations" and "and," should be deleted.

Pg 11	Line 372	Is the term, “noticed,” appropriate in the context in which it is being used?
Pg 11	Line 387	The phrase, “…these definitions…,” should be changed to, “…the definition of an ME…”
Pg 12	Line 399	The comma between the terms, “ACMUI” and “as,” should be deleted.
Pg 12	Line 401	The phrase, “…for distinguishing truly significant events from those related to deviations from the WD but otherwise clinically inconsequential.”
Pg 13	Lines 406-407	The phrase, “…, as there is no suitable clinically used dose metric available for judging the occurrence of MEs,” should be changed to, “…, as dose is generally not a reliable metric for identifying clinically significant MEs,” should be appended to the end of this sentence
Pg 13	Line 413	The comma between the terms, “brachytherapy” and “the,” should be deleted.
Pg 13	Line 421	The comma and the word, “and,” should be transposed.
Pg 14	Line 433	The phrase, “…public involvement in…,” should be changed to, “…for further public comment on…”
Pg 14	Line 433	The term, “regulation,” should be changed to, “MEs.”
Pg 14	Line 438	The phrase, “…, noted earlier…,” should be deleted.
Pg 14	Line 439	A hyphen should be inserted between the terms, “source strength” and “based.”
Pg 14	Lines 439-442	This sentence should be revised as follows, “The final report also included a quantitative consideration of the target site source distribution, the “octant approach,” for if the distribution of implanted sources was irregular enough (i.e., “bunched”) relative to the prescribed distribution to qualify as an ME.”
Pg 14	Lines 442-443	The “dose-related ME criterion for the treatment site” should be specified.
Pg 14	Line 445	The word, “by,” should be changed to the phrase, “…in a…”
Pg 14	Line 447	The phrase, “…expressed criticism…,” should be changed to, “…criticized…”

Pg 14	Line 450	The comma between the words, “site” and “removed,” should be changed to the word, “and.”
Pg 14	Line 451	The comma between the words, “dose” and “was,” should be deleted.
Pg 15	Line 457	A comma should be inserted between the terms, “2012” and “to.”
Pg 15	Line 474	The comma between the words, “sources” and “for,” should be changed to the word, “and.”
Pg 15	Line 477	The comma between the words, “site” and “and,” should be deleted. A hyphen should be inserted between the words, “dose” and “based.”
Pg 15	Line 482	The term, “written directive,” should be changed to the abbreviation, “WD.”
Pg 16	Line 488	The comma between the terms, “ACMUI” and “for,” should be deleted.
Pg 16	Line 499	The phrase, “…the high variation in dose sometimes seen in doses…,” should be changed to, “…the pronounced spatial variation in dose sometimes seen with ‘point’ sources (i.e., seeds)…”
Pg 16	Line 501	The phrase, “…the size of the normal tissues,…,” should be changed to, “…the specified volume of the normal tissue affected,…”
Pg 17	Line 514	A hyphen should be inserted in the term, “60-day.”
Pg 17	Line 515	The phrase, “…come back…,” should be changed to, “…return to the treatment center…”
Pg 17	Line 524	The comma between the words, “sources” or “or,” should be deleted. The comma between the closing parenthesis and the word, “A,” should be deleted.
Pg 17	Line 529	A comma should be inserted between the words, “locations” and “results.”

Pg 17	Line 531	Hyphens should be inserted in the terms, “0.5-sievert” and “50-rem.”
Pg 18	Line 541	The comma at the end of this line should be deleted.
Pg 18	Line 543	A hyphen should be inserted in the term, “post-procedure.”
Pg 18	Line 560	The phrase, “brachytherapy where…,” should be changed to, “brachytherapy procedures, where…”
Pg 19	Line 591	The comma between the terms, “2008” and “with,” should be deleted.
Pg 19	Line 593	Commas should be inserted before and after the phrase, “…if not corrected…”
Pg 20	Line 597	The term, “authorized individuals,” should be changed to, “preceptors.”
Pg 20	Lines 614-617	This sentence should be revised as follows, “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.
Pg 20	Line 618	The comma between the terms, “2008” and “with,” should be deleted.
Pg 22	Line 652	Here and elsewhere in the draft rule, a hyphen should be inserted between the words, “board” and “certified.”
Pg 22	Line 680	The between the terms, “who” and “RSO,” should be deleted.
Pg 22	Line 691	The phrase, “…or other service-provider sites…,” should be inserted between the words, “hospitals” and “are.”
Pg 24	Line 734	The phrase, “…at the time of administration,” should be inserted at the end of the sentence ending with, “99m.”
Pg 24	Line 737	The word, “several,” should be changed to, “multiple.”
Pg 25	Line 746	A period should be inserted at the end of this line.
Pg 25	Lines 753-760	Are there any relevant references which may be cited to support the statements in this paragraph?

Pg 25	Line 756	The phrase, "…failed subsequent elutions," should be changed to, "…excessive Mo-99 concentrations in subsequent elutions."
Pg 25	Line 769	The term, "radioactive drugs," should be changed to, "radiopharmaceuticals."
Pg 25	Line 776	The word, "received," should be changed to, "undergone."
Pg 25	Line 777	The word, "radionuclides," should be changed to, "radionuclidic contaminants."
Pg 27	Line 804	The word, "vendors," is misspelled.
Pg 28	Line 857	The comma between the words, "event" and "is," should be deleted.
Pg 30	Line 908	The phrase, "…the high variation in dose sometimes seen in point doses…," should be changed to, "…the pronounced spatial variation in dose sometimes seen with 'point' sources (i.e., seeds)…"
Pg 31	Line 940	The semi-colon between the words, "issues" and "Section," should be changed to a colon.
Pg 32	Line 963	A period should be inserted at the end of this line.
Pg 33	Lines 989-990	Here and subsequently in the draft rule, the phrase, "by the NRC or Agreement State…," should be changed to, "…by the NRC or an Agreement State."
Pg 36	Line 1091	A comma should be inserted between the terms, "RSO" and "who."
Pg 37	Line 1118	Should the word, "allow," be changed to, "require"?
Pg 38	Lines 1147-1148	The phrase, "…include determining post implant source position verification and normal tissue dose assessment…," should be changed to, "…include performing post-implant source-position verification and normal-tissue dose assessment…"
Pg 38	Line 1154	The word, "minimum," should be inserted between the words, "The" and "absorbed."
Pg 38	Line 1166	A hyphen should be inserted in the term, "60-calendar day."

Pg 39	Line 1182	The comma between the terms, “ANP” and “on,” should be deleted.
Pg 40	Line 1182	The comma between the words, “on” and “therefore,” should be changed to a semi-colon.
Pg 40	Lines 1226-1228	This sentence (in particular, the phrase, “…same new medical license”) is confusing. It should be re-worded and clarified.
Pg 46	Line 1394	The word, “or,” between the words, “Education” and “the,” should be changed to a comma.
Pg 47	Line 1418	The word, “several,” should be changed to, “multiple.”
Pg 48	Line 1453	The word, “or,” between the words, “Education” and “the,” should be changed to a comma.
Pg 51	Line 1557	The word, “or,” between the words, “Education” and “the,” should be changed to a comma.
Pg 53	Line 1598	The word, “or,” between the words, “Education” and “the,” should be changed to a comma.
Pg 54	Line 1645	The word, “or,” between the words, “Education” and “the,” should be changed to a comma.
Pg 56	Lines 1707-1708	The phrase, “…to provide high confidence that…,” should be changed to, “…to ensure that…”
Pg 57	Line 1736	Here and elsewhere, a hyphen should be inserted between the words, “single” and “discipline.”
Pg 58	Line 1744	The word, “or,” between the words, “Education” and “the,” should be changed to a comma.
Pg 60	Line 1816	Here and elsewhere, a hyphen should be inserted between the words, “photon” and “emitting.”
Pg 60	Line 1820	The comma between the terms, “SSDR” and “however,” should be changed to a semi-colon.
Pg 63	Line 1909	The word, “or,” between the words, “Education” and “the,” should be changed to a comma.
Pg 64	Line 1924	The semi-colon between the words, “management” and “and,” should be deleted.
Pg 64	Line 1961	The word, “have, “between the words, “provide” and “criteria,” should be deleted.

Pg 65	Line 1971	The comma between the terms, “ME” and “an,” should be deleted.
Pg 65	Line 1981	The word, “radiation, should be deleted.
Pg 65	Line 1986	The comma at the end of this line should be changed to a period.
Pg 66	Line 1995	Here and elsewhere when used at an adjective, the term, “organ at risk,” should be changed to, “organ-at-risk.”
Pg 66	Line 2016	A hyphen should be inserted between the terms, “20” and “percent.”
Pg 67	Line 2037	The phrase, “…failed generators…,” should be changed to, “…out-of-tolerance generator elutions…”
Pg 67	Line 2044	The comma at the end of this line should be changed to a semi-colon.
Pg 67	Line 2045	The comma between the words, “notified” and “and,” should be changed to a semi-colon.
Pg 70	Line 2127	The phrase, “…, and, thus,…,” should be changed to, “…and thus…”
Pg 78	Line 2213	The word, “failures,” should be changed to, “deficiencies.”
Pg 79	Line 2242	The comma between the words, “regulations and “meet,” should be deleted.
Pg 82	Line 2336	The hyphen at the end of this line should be changed to a colon.
Pg 87	Line 2526	The hyphen at the end of this line should be changed to a colon.
Pg 91	Line 2695	The hyphen at the end of this line should be changed to a colon.
Pg 93	Line 2750	The hyphen at the end of this line should be changed to a colon.
Pp 93-94	Lines 2761-2765	This item is confusing (grammatically incomplete?) as written. It should be revised and clarified.

Pg 94	Line 2769	The word, “mean,” should be inserted between the words, “The” and “mean.”
Pg 94	Line 2771	The phrase, “The maximum absorbed dose to any 5 contiguous cubic centimeters…,” should be changed to, “The mean absorbed dose to the maximally exposed 5 contiguous cubic centimeters…”
Pg 94	Line 2784	The hyphen at the end of this line should be changed to a colon.
Pg 94	Line 2798	A comma should be inserted between the words, “examination” and “administered.”
Pg 95	Line 2805	The hyphen at the end of this line should be changed to a colon.
Pg 95	Line 2816	The hyphen at the end of this line should be changed to a colon.
Pg 96	Line 2832	The hyphen at the end of this line should be changed to a colon.
Pg 105	Line 3108	The word, “or,” between the words, “Education” and “the,” should be changed to a comma.
Pg 106	Line 3152	The hyphen at the end of this line should be changed to a colon.
Pg 106	Line 3169	The word, “or,” between the words, “Education” and “the,” should be changed to a comma.
Pg 107	Line 3183	The hyphen at the end of this line should be changed to a colon.
Pg 108	Line 3212	The hyphen at the end of this line should be changed to a colon.
Pg 108	Line 3219	The comma between the words, “characteristics” and “or.”
Pg 109	Line 3224	The word, “or,” between the words, “Education” and “the,” should be changed to a comma.
Pg 110	Line 3290	The word, “or,” between the words, “Education” and “the,” should be changed to a comma.
Pg 112	Line 3348	The hyphen at the end of this line should be changed to a colon.

Pg 112	Line 3361	The hyphen at the end of this line should be changed to a colon.
Pg 113	Line 3375	The hyphen at the end of this line should be changed to a colon.
Pg 113	Line 3380	The comma between the words, “dosages” and “and,” should be deleted.
Pg 113	Line 3385	The comma between the words, “safely” and “and,” should be deleted.
Pg 113	Line 3387	The comma between the words, “subjects” and “that,” should be deleted.
Pg 114	Line 3413	The word, “or,” between the words, “Education” and “the,” should be changed to a comma.
Pg 114	Line 3425	Here and subsequently, the term, “Sealed Source and Device Registry,” should be replaced by the previously introduced abbreviation, “SSDR.”
Pg 114	Line 3449	A hyphen should be inserted between the words, “full” and “time.”
Pg 114	Line 3465	The phrase, “…to provide high confidence that…,” should be changed to, “…to ensure that…”
Pg 116	Line 3491	The comma between the words, “experience” and “under,” should be deleted.
Pg 116	Line 3493	The comma between the terms, “§ 35.400” and “involving,” should be deleted. The hyphen at the end of this line should be changed to a colon.
Pg 116	Line 3507	The word, “or,” between the words, “Education” and “the,” should be changed to a comma.
Pg 118	Line 3561	The hyphen at the end of this line should be changed to a colon.
Pg 118	Line 3572	The hyphen at the end of this line should be changed to a colon.

Pg 120	Line 3625	The hyphen at the end of this line should be changed to a colon.
Pg 121	Line 3673	The hyphen at the end of this line should be changed to a colon.
Pg 122	Line 3692	The word, “or,” between the words, “Education” and “the,” should be changed to a comma.
Pg 123	Line 3747	The hyphen at the end of this line should be changed to a colon.
Pg 123	Line 3758	The comma between the words, “fraction” and “by,” should be deleted.
Pg 124	Line 3762	The hyphen at the end of this line should be changed to a colon.
Pg 124	Line 3782	The hyphen at the end of this line should be changed to a colon.
Pg 125	Line 3790	The phrase, “An absorbed dose…,” should be changed to, “A mean absorbed dose…”
Pg 125	Line 3794	The phrase, “An absorbed dose…,” should be changed to, “A mean absorbed dose…”

The U.S. Nuclear Regulatory Commission Staff Responses to the Advisory Committee on the Medical Uses of Isotopes Comments on the Draft Part 35 Proposed Rule

Introduction

The proposed rule would amend the regulations related to the medical use of byproduct material. First, this rule proposes amendments to the reporting and notification requirements for a medical event (ME) for permanent implant brachytherapy. Second, the rule proposes changes to the training and experience (T&E) requirements for authorized users (AUs), medical physicists, Radiation Safety Officers (RSOs), and nuclear pharmacists; changes to the requirements for measuring molybdenum contaminations and reporting of failed technetium and rubidium generators, and changes that would allow Associate Radiation Safety Officers (ARSOs) to be named on a medical license, as well as other clarifying and conforming amendments. Third, the U.S Nuclear Regulatory Commission (NRC) is considering a request filed in a petition for rulemaking (PRM) (PRM-35-20) to "grandfather" certain board-certified individuals.

Background

On December 21, 2012, the NRC staff provided the preliminary draft proposed rule to the ACMUI for its review and comments for a 90-day review. The Advisory Committee on the Medical Uses of Isotopes (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 ML13071A690).

In accordance with the Office of Federal and State Materials and Environmental Management Programs procedures, the ACMUI comments and recommendations were considered in developing the proposed rulemaking.

The ACMUI provided its comments and recommendations under three separate sections:

1. General Comments
2. Specific Comments---Significant, and
3. Specific Comments---Minor

All of ACMUI's recommendations were incorporated into the proposed rulemaking except for the following items. In addition, although some of the recommendations were not directly incorporated into the proposed rule, they were addressed in another manner, as is explained below:

1. General Comments

Item 1. Medical event definitions for permanent implant brachytherapy.

ACMUI item a.

Issue: The ACMUI provided the background related to the ME definition and described the inadequacy of the current dose-based definition when applied to permanent implant brachytherapy. In summary, the ACMUI recommended that licensees be allowed to use total

source strength as a substitute for total dose for determining MEs for permanent implant brachytherapy until the Part 35 rulemaking is complete.

Staff response - The staff agrees with the ACMUI recommendation to allow licensees the use of total source strength as a substitute for total dose for determining MEs for permanent implant brachytherapy until the Part 35 rulemaking is complete. In this regard, in a Staff Requirements Memo dated, May 21, 2013, the Commission has approved the staff's proposed interim enforcement policy as described in SECY-13-0044, "Interim Enforcement Policy for Permanent Implant Brachytherapy Medical Event Reporting." On July 9, 2013, the NRC issued the interim enforcement policy for permanent implant brachytherapy ME reporting.

ACMUI item c.

Issue: The ACMUI expressed concern that the proposed ME definitions may discourage practitioners from utilizing this therapy. It recommended that NRC solicit information from its stakeholders on whether the proposed ME definitions for permanent implant brachytherapy will discourage licensees from using this therapy option or will otherwise adversely impact clinical practice.

Staff Response - Although the ACMUI's specific recommendation to solicit information on this subject was not incorporated into the *Federal Register* notice (FRN), we believe we addressed the intent of the ACMUI comment in our general solicitation of information related to the economic impact of the proposed rule. Additionally, the staff has prepared a regulatory analysis which will be available for public comment when the proposed rule is published.

ACMUI item d.

Issue: The ACMUI recommended that MEs related to permanent implant brachytherapy be designated as Compatibility Category B for the Agreement States. The ACMUI was concerned with the proposed designation as Compatibility Category C which would allow the Agreement States to retain the dose-based criteria for determining a ME for permanent implant brachytherapy. In summary, 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. Also, 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.

Staff response - The issue of the Compatibility Category for MEs is discussed in detail in the draft FRN. Currently, MEs are designated as Compatibility Category C. The Standing Committee on Compatibility (SCC) reviewed the proposed rule and strongly supported retaining Compatibility Category C designation for § 35.3045, the section that contains the criteria for determining if a ME has occurred. As noted in the discussion in the proposed draft FRN, with a Compatibility Category C designation, Agreement States would have the flexibility to require both the dose-based criteria and source strength-based criteria as long as the Agreement States' reports to NRC related to MEs are based on the requirements in § 35.3045.

The SCC stated that many Agreement States have additional state requirements and laws to gather information on MEs. A Compatibility Category B requirement would prohibit the Agreement States from gathering additional information, such as diagnostic reports, shorter reporting times, or lower dose limits for reporting. After reviewing the issue, the SCC determined that identical reporting requirements were not necessary for the national program on a transboundary basis. The SCC concluded that a change to a Compatibility B would not acknowledge the inherent state function to protect public health and safety of its citizens which forms the basis of the Section 274b amendment to the Atomic Energy Act of 1959.

Although the staff is proposing to retain the proposed Compatibility for MEs at Compatibility Category C, the NRC is seeking specific comments on the Compatibility Category in the draft FRN.

Item 2. Training and experience requirements for authorized users, medical physicists, Radiation Safety Officers, and nuclear pharmacists.

ACMUI item b.

Issue: The ACMUI recommended removing the work experience requirement on eluting generators for AUs who would not be responsible for proper operation and testing of generators. It asserted that the vast majority of AUs are not responsible for a generator system because they obtain unit dosages or bulk radionuclides from a commercial radiopharmacy. The ACMUI suggested that licensees approved to use generator systems could show specific training on the requirement now listed under § 35.290 (c)(1)(ii)(G) for those individuals (AUs and others) who are responsible for proper operation and test of the generator as part of their license conditions.

Staff response - The suggested change to remove the training requirement for AUs to have work experience in eluting generators is outside the scope of the proposed rulemaking. The staff agrees that a large number of licensees obtain unit dosages or bulk radionuclides from a commercial radiopharmacy. However, AUs at remote locations and large licenses still are involved in the elution of generators.

ACMUI item d.

Issue: The ACMUI recommended that the work experience for parenteral administrations under § 35.390 (b)(1)(ii)(G) and § 35.396 **not** be separated between administration of a beta/ gamma-emitting radiopharmaceutical and an alpha-emitting radiopharmaceutical as proposed. The ACMUI asserted that there is no fundamental difference in the clinical applications and radiation safety precautions among these radiations. Therefore, the T&E a physician receives to perform parenteral administration of a radiopharmaceutical, including the three cases of work experience, is sufficient in demonstrating the physician's competency to function as an AU for both the beta-/gamma-emitting and the alpha-emitting radiopharmaceuticals.

Staff response - The staff has determined that there are fundamental differences between the clinical use and the radiation safety of the two groups identified in proposed § 35.390(b)(1)(G)(3) or (4). The radiation detection equipment used to monitor and detect photons, electrons, and beta particles can be very different from that used to monitor and detect

alpha particles, and calibration procedures for measuring activities of beta emitters and alpha emitters are more complicated than for photon emitters. Further, the relationship between activity and radiation dose delivered to the patient for alpha emitters is not the same as that for low-energy photons, beta particles and electron emitters.

The staff recognizes that medical use licensees have radiation safety T&E, medical use experience, and ready access to low-energy photon and beta-emitting radionuclides. However, radioactive drugs primarily used for their alpha radiation characteristics are new to most medical use licensees (the first alpha-emitting radiopharmaceutical was approved by Food and Drug Administration (FDA) in May 2013). The staff determined that there are important radiation safety considerations associated with alpha-emitting radiopharmaceuticals. They include patient radiation safety (e.g., administrative controls to prevent an ME), steps to ensure the proper dosage is delivered (e.g., quality control procedures on instruments used to determine the activity of dosages, calculating, measuring, and safely preparing dosages), and radiation safety (e.g., ordering, receiving, performing radiation surveys, containing spills safely and proper decontamination procedures). Therefore, the staff has determined that an AU should have experience with alpha-emitting radiopharmaceuticals in addition to the experience the AU may have with the low-energy photon-and beta-emitting radionuclides.

Issue: The ACMUI asserted that the separation of beta-/gamma-emitting from alpha-emitting radiopharmaceuticals would expend licensee and regulatory staff resources in the prescriptive bookkeeping needed to track all the separate work experiences for the AUs.

Staff response - The staff has determined that this requirement would not be a burden on licensees. The proposed requirements will ensure that AU's have the proper radiation safety training in the use of alpha emitters. Licensees only need to document the physician's T&E using the broad categories listed in § 35.390(b)(1)(G) and need not document each individual radionuclide used in a category.

Issue: The ACMUI asserted that the proposed rule does not address how AUs currently approved under § 35.390 and § 35.396 for parenteral administration alpha-emitting radiopharmaceuticals will be grandfathered to allow them to continue to use them and to act as supervising AUs for § 35.390 (b)(1)(ii)(G).

Staff response - NRC will allow those AUs currently approved for parenteral administration of alpha-emitting radiopharmaceuticals to continue the medical use of those materials when the final rule goes into effect.

Item 3. Extending grandfathering to certain certified individuals (Ritenour petition).

ACMUI items a and c.

Issue: The ACMUI recommended that all individuals who were able to meet the requirements of the previous Subpart J for an AU, RSO, authorized medical physicist (AMP), or authorized nuclear pharmacist (ANP) before that subpart was eliminated on October 24, 2005, should be grandfathered, thus relieving them of meeting the current training and experience requirements. The ACMUI asserted that the date of recognition by the NRC of a certifying board should not impact individuals seeking to be named on a license via the certification pathway because once

a board has been recognized by the NRC, the date of recognition is irrelevant, and this should be stated in the proposed rule.

Staff response - The date of the individual's board certification is relevant. Boards that were recognized by the NRC or Agreement State on or prior to October 24, 2005 (listed in the now removed Subpart J), met different T&E requirements than boards whose processes have been recognized by the NRC or Agreement States after October 24, 2005.

Further, the staff determined that the ACMUI recommendation that all individuals who were able to meet the requirements of the previous Subpart J should be grandfathered would go beyond the intent of the resolution of the Ritenour petition, which requested recognition of individuals who were certified by boards listed under former Subpart J to perform AMP and RSO duties on or prior to October 24, 2005, but were not named on a license. The NRC, in resolving the Ritenour petition, determined that other medical professionals may have also been adversely affected when Subpart J expired. The intent of the resolution was to include all these individuals and grandfather them for the modalities they practiced on or prior to October 24, 2005. Grandfathering individuals who met the Subpart J requirements but were not board certified would also negate the new T&E requirements that became effective on October 25, 2005.

ACMUI item b.

Issue: Some of the terminology NRC has historically used and now uses in the proposed rule is somewhat confusing. For clarification of meaning, it is suggested that the terms "type of use," "modality," and "category" be explicitly defined in Section 35.2 (Definitions), so that the regulatory meaning of these three terms is clearly understood.

Staff response - The term "type of use" is already defined in Part 35.2. The terms "category" and "modality" were reviewed and determined to be defined by common use (i.e., what is found in a dictionary).

Item 4. Measuring molybdenum contamination for each elution and reporting of failed breakthrough tests.

ACMUI item a.

Issue: The ACMUI noted that only two generator systems are specified in the current and proposed rule, molybdenum-99 (Mo-99)/technetium-99m (Tc-99m) and strontium-82 (Sr-82)/rubidium-82 (Rb-82) generators, and questioned whether other generator systems should be included or whether the proposed rule should be generalized to all medical generator systems.

Staff response - Currently there are no other generator systems that are available for general medical use. Any new generator system that becomes available would need to be evaluated by the NRC before developing any requirements and would be authorized under § 35.1000. Additionally, expanding the regulations from the specific requirements for Mo-99/Tc-99m and Sr-82/Rb-82 generators to apply to generators generally is beyond the scope of this rulemaking.

Issue: The ACMUI recommended that the NRC adopt the FDA-approved package insert for breakthrough limits for radioisotope generators. The ACMUI noted that current FDA labeling is more restrictive than the current NRC rule for Mo-99/Tc-99m generators, (i.e., it requires testing of each elution) and that the proposed rule will match the FDA labeling requirements. The ACMUI asserted that the NRC's breakthrough limits for Sr-82 and Sr-85 are less restrictive than the package inserts and are not being revised. Additionally, the ACMUI asserted that the NRC would be able to inspect for compliance against the applicable FDA breakthrough testing requirements for all generators and thus would not have to await revision of its rules for testing requirements for newly introduced generators.

Staff response - The ACMUI recommendation that the NRC adopt the FDA-approved package insert for breakthrough limits for radioisotope generators was not accepted because revising the regulations to require licensees to follow the FDA-accepted package inserts with regard to testing eluates would reverse the NRC's December 2, 1994, rulemaking (59 FR 61781) that removed the requirements to follow the FDA package inserts for preparation of radiopharmaceuticals from NRCs regulations. The 1994 rulemaking was in response to a petition for rulemaking by the American College of Nuclear Physicians, the Society of Nuclear Medicine, and medical and pharmacy stakeholders. The petition asserted that the NRC was interfering with the practice of medicine and pharmacy by requiring licensees to follow the FDA package inserts. NRC granted the petition, and the ACMUI has not provided a sufficient basis to revisit this determination.

Furthermore, the NRC cannot inspect a licensee for compliance with FDA regulations. Licensees would not have to wait for the NRC to revise its regulations to establish licensing requirements for new generators as the NRC has a mechanism under § 35.1000 for authorizing new products in a timely manner.

Finally, the staff has determined the NRC's current breakthrough limits for both Tc-99m and Rb-82 radioisotope generators are safe. Also, the current FDA label breakthrough limits for Sr-82 and Sr-85 generators are at the lower limits of current standard dose calibrator measurement capabilities.

ACMUI item b.

Issue: The proposed rule would require a licensee to report to both the NRC and the manufacturer or distributor when a generator has failed a breakthrough test. The manufacturer or distributor would also be required to notify the NRC when it received a reported failure from a licensee. Commenters at the public workshops in 2011 stated that this reporting should not be required because the manufacturers are required to report failed generators to the FDA.

The ACMUI did not support this requirement for dual reporting and found that the rationale stated in the FRN (i.e., that the FDA may not investigate each reported incident), may take time in investigating reported failures, and that some incidents of failed generators may not be reported to the FDA because certain manufacturers are not in the United States and generators are distributed by vendors who are not required to report to the FDA somewhat specious. The ACMUI asserted that the licensee should only report to the manufacturer/distributor and not to the NRC when a generator fails. The ACMUI explained that FDA has a process for receiving

reports and investigating product failure and that the Memorandum of Understanding (MOU) between FDA and the NRC would allow the NRC to get this information.

Staff response - The staff agrees with the ACMUI that the FDA authority in relationship to foreign manufacturers or distributors of generators was incorrect and has revised the FRN for the proposed rule.

However, the staff determined that licensees should report to both the NRC and the manufacturer or distributor when a generator fails a breakthrough test because the information that would be reported by medical use licensees to the NRC is different than the information that would be reported to the manufacturers or distributors. For example, reports from a medical use licensee to the NRC would have information on patient exposures, probable cause and assessment of failure in the licensee's equipment, and procedures or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination. The licensee would only report information related to the generator failure to the manufacturer or distributor. Also, the corrective actions reported to the NRC by the licensee and the manufacturer or distributor would be different for each. The licensees' corrective actions would focus on procedures while the manufacturers or distributors' corrective actions would focus on manufacturing processes. Breakthrough tests exceeding the regulatory standard could be due to many different issues including from problems with the generator elution procedures, as a result of transportation, or problems with the manufacturer's production of the generator. The two separate reporting requirements would provide the NRC with the necessary information to determine the scope of the issue and the appropriate actions applicable to each entity.

Although both NRC/Agreement States and FDA have regulatory authority over the radioactive drug manufacturers, their regulatory responsibilities are different. The NRC regulates both the end user and the radioactive drug manufacturer whereas FDA regulates only the product and drug manufacturer. The NRC/FDA MOU was initiated to provide a mechanism for sharing information that is of mutual regulatory interest to both agencies. The NRC believes that it is important for medical use licensees and commercial nuclear pharmacies that elute generators; (i.e., the end users) as well as manufacturers or distributors, to report breakthrough failures to NRC as quickly as possible. If the generator breakthrough values exceed the regulatory limits, the problem could be with the procedures of the generator elution site, a result of transportation, or with the manufacturer's production of the generator. The NRC believes that 24-hour notification will assist in quickly differentiating generator elution licensee problems from those of the manufacturer. Requiring end user reporting also provides the NRC with a confirmation of whether patients were administered radiopharmaceuticals with excessive breakthrough. The generator manufacturer/distributor report to the NRC of breakthrough within 24 hours would assist the NRC and the Agreement States in identifying the scope of the problem and the regulatory efforts needed to address it.

ACMUI item c.

Issue: The ACMUI asserted that with respect to the Sr-82/Rb-82 generator breakthrough issue, the proposed rule does not actually address the underlying cause of recent reported instances of excess radiostrontium breakthrough at two medical facilities which appeared to be the apparent failure of licensees to perform daily breakthrough testing.

Staff response - The staff agrees with the ACMUI that appropriate testing may have detected the occurrences of breakthrough at these sites. However, under current regulations, there is no requirement for the licensee to report the breakthrough failure. Had this information been reported in a timely fashion to the regulators, appropriate steps could have been taken to look at the quality of the licensee's generator testing program as well as the manufacturer's production processes. The new reporting requirements in the proposed rule are intended to correct this situation.

Issue: The ACMUI asserted that current training requirements in § 35.290 are only specific to Mo-99/Tc-99m generators; training requirements have not kept pace with new and different generators.

Staff response - The staff determined that the T&E requirements in § 35.290 apply to all generators. For any new and significantly different generators, T&E would be addressed under the provisions of § 35.1000.

ACMUI item d.

Issue: The ACMUI recommended that the NRC solicit comments in the FRN as to whether the proposed notification requirements would discourage licensees from using generators and would also have adverse economic impact on venders of generator systems.

Staff response: Although the ACMUI's specific recommendation to solicit information on this subject was not incorporated into the FRN, we believe we addressed the intent of the ACMUI comment in our general solicitation of information related to the economic impact of the proposed rule. Additionally, the staff has prepared a regulatory analysis which will be available for public comment when the proposed rule is published.

Item 5. Allowing Associate Radiation Safety Officers to be named on a medical license.

ACMUI item a.

The ACMUI recommended that the addition of ARSOs and Temporary RSOs be included in the broad scope exemptions under § 35.15 in the same manner as AUs, ANPs, and AMPs (i.e., allow broad scope medical licensees to review an individual's T&E and authorize the individual to work under the license).

Staff response - Unlike ANPs, AMPs, and AUs, who are not specifically listed on the broad scope medical use license, RSOs are listed on a broad scope medical use license, and the NRC specifically reviews the T&E of each individual before he/she is listed as an RSO on every medical use license including a broad scope medical license. This review is important because the RSO is responsible for implementing the radiation safety program for the licensee. An ARSO will have similar duties working under the RSO, and like the RSO, would be listed specifically on the license. Because of this, the staff has determined that the NRC needs to review the T&E of each individual before he/she is listed as an ARSO. The NRC does not exempt the medical broad scope licensee in § 35.15 from notifying NRC when it appoints a

temporary RSO because the NRC needs to know when an RSO leaves any medical use licensee and the licensee has to name a temporary RSO.

For these reasons, the provisions in § 35.15 for a temporary RSO is unchanged from the current regulations that allow a licensee to permit a qualified individual to serve as the RSO for up to 60 days each year. Additionally, changes to the temporary RSO provision are beyond the scope of this rulemaking.

ACMUI item b.

Issue: The ACMUI asked whether an individual who does not have board certification is named as an authorized individual, that individual would need a preceptor signature for any additional future training and recommended that, if so, the proposed rule include an example of how this would be done.

Staff response - Under the proposed rule, RSOs, ARSOs, or other authorized individuals who are not board certified would need to obtain a written attestation. The associated guidance will clarify that all individuals coming through the alternate pathway will need a preceptor statement for the additional training.

Item 6. "Plain language" requirements.

The ACMUI noted that although overall the proposed rule was well-written and well-organized, it could be shortened, and improved, by eliminating redundancies and consolidating related sections, eliminating identical or nearly identical passages appearing multiple times throughout the draft rule. A further improvement would be the inclusion of a detailed "executive summary" style section summarizing, perhaps in a "bullet" format, the key changes introduced in the draft rule. This would be in place of the current one-paragraph Summary.

Staff response - Although the staff has added an executive summary summarizing the key changes in the draft rule, the staff must follow the format required by the *Federal Register* and NRC administrative requirements in laying out the proposed rule. Therefore, the staff has retained the one-paragraph summary.

Item 7. Additional general comments.

The ACMUI noted that licensees will need to easily access Sealed Source and Device Registry (SSDR) documents and asked whether the NRC could provide access to copies of these registrations.

Staff response – Since the events of September 11, 2001, public access to the SSDR registry has no longer been provided for security reasons. The Agreement States have access to the registry via a password protected portal. Any licensee with a legitimate reason to have access to an SSDR document may request it from its regulatory authority or the manufacturer of the sealed source or device.

2. Specific Comments – Significant (pages 8 through 10 of the ACMUI's report)

The ACMUI recommended that individuals grandfathered under the provisions of the Ritenour petition be recognized for the modalities covered by their board certification and not for the modalities that they practiced as of October 24, 2005.

Staff response - This issue is related to the ACMUI's recommendation in Item 3 a and c above. The staff disagrees with the change for several reasons. First, all of the individuals grandfathered under the provisions of § 35.57 in the current regulation and the proposed rule are only recognized for the modalities that they practiced as of October 24, 2005. Second, if the NRC were to recognize individuals based on the modalities covered by their board certification, then recognition could be for a modality for which the individual may not have had the T&E, (such as an AU authorized for use of a gamma stereotactic unit prior to October 24, 2005, and who now wants to use a high-dose afterloader unit). Finally, the resolution to the Ritenour petition was based on recognizing individuals for the modalities that they practiced as of October 24, 2005, not for the modalities covered by their board certifications, so that this change would go beyond the intent of the Ritenour Petition.

The ACMUI suggested changing the phrase, "The maximum absorbed dose to any 5 contiguous cubic centimeters…," to "The minimum absorbed dose to the maximally exposed 5 contiguous cubic centimeters…"

Staff response - The staff reviewed the referenced language and did not agree with the suggested change because adding the word "minimum" caused confusion about the intended meaning. However, based on the review of the language, the staff revised the draft proposed rule for clarity. It now reads "the absorbed dose to the maximally exposed 5 contiguous cubic centimeters of normal tissue located within the treatment site."

The ACMUI questioned the proposed requirement to have all individuals who would operate remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units 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. The ACMUI asked how this requirement would impact licensees, if there will be enough trainers for the number of unit operators, and if computer-based training will be acceptable.

Staff response –The current regulations already require individuals who operate remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units to receive the training initially and annual refresher training. The proposed change would add a training requirement for when a new unit is installed or for when there is a manufacturer upgrade to an existing unit that affects the operation and safety of the unit to ensure the continued safe use of the device. The staff believes that vendors are already providing this training to ensure their devices will be used safety and there is little additional impact.

The ACMUI suggested restructuring of § 35.15 related to the ACMUI suggestion that changes be made to § 35.13 related to broad scope licensees being allowed to name their own ARSOs and temporary RSOs in Item 5(a) above.

Staff response – Because the staff did not accept the ACMUI recommendation in Item 5(a), the suggested restructuring of § 35.15 is not needed.

3. Specific Comments - Minor

The staff reviewed each suggested change in this section and incorporated as appropriate. Because the suggested changes in this section were minor, the staff has not included a list of items not accepted. The grammatical suggestions that met the requirements set forth by the Plain Writing Act, the Office of the Federal Register, and the Office of Administration (i.e., format, amendatory language, and the requirements set forth in the NRC Editorial Style Guide (NUREG-1379, Revision 2)) were accepted.

Summary of Major Agreement State Comments

and Staff Response

Medical Event Definition for Permanent Implant Brachytherapy

Issue - Four states and the Organization of Agreement States (OAS) commented on the statement in the discussion section of the medical event (ME) criteria that the revised definitions for MEs are designed to identify situations where harm or potential harm to the patient may occur. One state asserted that virtually any medical action results in potential harm to a patient and that basing a rule on such non-specific criteria was not inspectable and was not advisable. The OAS and these states recommended removing this statement from the discussion to ensure that the regulations address identified risks, not potential risks. The OAS noted that having the regulations identify situations for potential harm represents a significant departure from the current definition for MEs and will eliminate the opportunity for the licensees to identify precursor events and make process improvements.

Response - No changes were made in response to these comments. There is a long-standing U.S Nuclear Regulatory Commission (NRC) position that an ME may be indicative of "potential problems in a medical facility's use of radioactive materials" and "does not necessarily result in harm to the patient." That position continues to be reflected in this proposed rule. In redefining the ME criteria for permanent implant brachytherapy, reflecting the Advisory Committee on the Medical Uses of Isotopes recommendations, the proposed ME criteria are now consistent with the criteria for other treatment modalities by reflecting circumstances in which there may be harm or potential harm to a patient being treated. The proposed criteria were reviewed and determined to be specific and not subjective.

Issue - One state disagreed with eliminating the dose-based option for identifying MEs to the treatment site for permanent implant brachytherapy. Since 2010, this state's brachytherapy licensees have developed quantitative dose-based criteria for identifying MEs in prostate brachytherapy, including overdoses and under doses to the prostate and overdoses to normal surrounding tissue. Developing such dose-based criteria has not led to an increase in medical events reported, the state commented. Another state commented that it did not support a dose-based methodology for establishing ME's for permanent implants.

Response - No changes were made in response to these comments. One of the principal objectives of the proposed changes to the written directive (WD) and ME reporting criteria for permanent implant brachytherapy is to eliminate the dose-based criteria for the treatment site, changing it to a source-strength criteria, to move away from a metric (delivered dose compared to prescribed dose) over which the authorized user (AU) has limited control.

Issue – One state supported the use of the "maximally exposed 5 contiguous cubic centimeters" as a reasonable volume of tissue over which to conduct a dose volume evaluation with regard to determining whether an ME occurred related to assessment of dose to normal tissue, whereas one state recommended removing the prescriptive volume requirements and allowing licensees to identify a reasonable volume in the written directive.

Response - For uniformity of ME reporting among licensees, uniform criteria for excess dose to normal tissues should be established. The size of the minimum volume to be considered for

maximum dose determinations is an item/issue about which stakeholder input is specifically being sought by including it as a specific question in the *Federal Register* notice for the proposed rule.

Issue – With regard to the proposed WD requirements for permanent implant brachytherapy in § 35.41, the OAS and one state recommended moving the new requirement that would require a licensee to make certain assessments related to the permanent implant brachytherapy implantation within 60 days after the procedure from § 35.41 into a new section. They felt that so doing would bring more attention to this requirement. One state suggested that the 60-day dose assessment should apply to all brachytherapy, including lung implants.

Response - No changes have been made to the rule text in response to these comments. Section 35.41(b) includes the minimum required items that must be addressed in the licensee's written procedures. Paragraph (b)(6) is a subset of this; it is one of the items that must be in the licensee's procedures. Also, paragraph (b)(6) is similar to paragraphs (b)(2) and (b)(5), in that it addresses post-implant items. For these reasons, the staff determined that the procedural requirement in paragraph (b)(6) should remain as part of section 35.41.

Compatibility Category for Training and Experience Requirements

Issue - Two states and the OAS commented that all training and experience in Part 35 should be designated as an Agreement State compatibility category "C" or lower. They argued that each individual state already licenses medical doctors through their own process and the individual states should be able to identify issues to be addressed by their process.

Response - No change was made based on these comments. The NRC, in 2002 and 2005 Part 35 rulemakings, determined that all training and experience requirements for use of byproduct material have compatibility "B" designation because these requirements have significant direct transboundary implications. Additionally, changing the compatibility for all training and experience requirements in Part 35 is outside the scope of this rulemaking.

Compatibility Category for Medical Event Reporting

Issue - One state strongly supported the compatibility C category for ME requirements in § 35.3045. Another state believed that for consistency in reporting and to ensure a common basis for trend analysis, the reporting requirement in § 35.3045 should be a compatibility category B.

Response - Currently, the ME reporting is designated as compatibility category C. The issue is discussed in the draft FRN and a specific question on this issue is included.

Naming Associate Radiation Safety Officer on a license

Issue – The OAS and four states expressed concern regarding the proposal to allow an Associate Radiation Safety Officer (ARSO) to provide supervised training and to serve as a

preceptor for an individual seeking to be named as an Radiation Safety Officer (RSO). One state was concerned that the RSO designee (i.e., the ARSO) would still be allowed to operate without further license amendments, since there are many consultants who fulfill certain RSO duties.

Response - No changes have been made on the new ARSO designation in response to state comments. An ARSO can provide an attestation for an individual to be a RSO or ARSO for only similar types of use of byproduct material for which the attesting ARSO is authorized on a license. Because § 35.50 requires an ARSO to have the same radiation safety training and experience for the RSO-assigned duties and tasks as the RSO, he or she is qualified to be a preceptor for an individual seeking to serve as an RSO or ARSO for similar types of use of byproduct material. The naming of an ARSO is optional for a licensee. But the individual who is not listed on a license would not be recognized as an ARSO for regulatory purposes. Nothing in the current regulation or the proposed rule prohibits the naming of a consultant as an RSO on a medical license.

Use of Sealed Sources and Devices for Medical Uses Not Listed in the Sealed Source and Device Registry

Issue - The OAS and four states expressed concerns with regard to the proposal to allow an AU the flexibility to use sealed sources and devices for medical uses not specifically listed in the Sealed Source and Device Registry (SSDR). One state recommended that the NRC should approve each new use for a particular device and, if approved, issue a notice or add it to the Medical toolkit informing all the states that a new use has been approved for a certain source/device. One state wanted clarification on the approval process for off-label uses of brachytherapy sources.

Response - The discussion in the proposed rule on this issue has been revised to be more clear and include additional information to clarify that NRC recognizes that the treatment sites that included in the SSDR are not all inclusive and the proposed revision to the regulations would permit physicians to use manual brachytherapy sources to treat sites or diseases not listed in the SSDR. No approval will be required for uses under § 35.400(a) or § 35.600(a) when an AU wants to use the sources and devices for medical uses not listed in the SSDR as long as they are being used for manual brachytherapy uses (§ 35.400(a)), or HDR, teletherapy, or gamma stereotactic uses (§ 35.600(a)).

Categories of Parenteral Administration of Radionuclides in which Work Experience is Required

Issue - The OAS and 4 States commented on the proposed changes to the categories of parenteral administration of byproduct material for which work experience would be required and asked that more discussion be provided in the proposed rule.

Response - The discussion on this issue has been revised in the proposed rule in response to these comments.

Medical Use of Transmission Sources

Issue - The OAS and four states commented on the use of transmission sources when they are used for patient diagnosis. One state asserted that calibration, transmission, and reference sources are not medical use sources.

Response - The NRC has determined that the use of transmission and references sources for diagnostic determinations on patients constitutes a medical use.

Effective Date for Final Rule

Issue - The OAS and two States recommended that the effective date of the final rule be changed to 180 days from its publication in the *Federal Register* instead of the proposed 120 days. This would allow those Agreement States that incorporate these regulations by reference more time to ensure that their licensees are notified and their staffs are properly trained. This would also allow all Agreement States more time to prepare for amending their regulations in order to be compatible with this revision.

Response – The proposed effective date for the final rule was revised to be 180 days from the date of publication.