AFFIRMATION

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: Chairman Burns

SUBJECT: SECY-16-0080: FINAL RULE: MEDICAL USE OF BYPRODUCT MATERIAL – MEDICAL EVENT DEFINITIONS, TRAINING AND EXPERIENCE, AND CLARIFYING AMENDMENTS (RIN 3150-AI63; NRC-2008-0175)

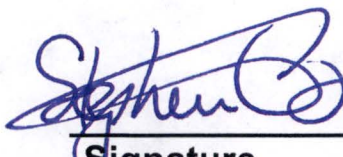
Approved XX **Disapproved** ____ **Abstain** ____ **Not Participating** ____

COMMENTS: **Below** XX **Attached** XX **None** ____

I commend the staff for their efforts in developing this final rule, including the extensive analysis and public outreach to stakeholders over a number of years. The final rule includes several significant updates to requirements related to the medical use of byproduct material that I expect will provide improvements in this important area. While I commend the staff, I must note that I am concerned by the length of time that it has taken to disposition PRM-35-20, which was submitted in September 2006 and which the staff estimates may have inadvertently affected as many as 10,000 board-certified individuals. I urge the staff to continue to seek the proper balance between gaining efficiencies through consolidating various related issues into a single (but complex and lengthy) rulemaking and completing rulemakings on a single issue or a small set of issues more expeditiously.

I approve the final rule for publication in the *Federal Register*, subject to the attached edits, and certify, under the Regulatory Flexibility Act, 5 U.S.C. 605(b), that this rule will not, if promulgated, have significant economic impact on a substantial number of small entities.

Entered in STARS
Yes ____
No ____



Signature

23 **September 2016**

Date

SGB edits [7950-01-P]

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: Final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations related to the medical use of byproduct material. The final rule will amend the U.S. Nuclear Regulatory Commission (NRC) regulations related to the medical use of byproduct material. This rule amends the reporting and notification requirements for a medical event (ME) for permanent implant brachytherapy. This rule also amends the training and experience (T&E) requirements to (1) remove from multiple sections 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 ~~in multiple sections~~; and (2) 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). Additionally, this rule (1) amends the requirements for measuring molybdenum contamination; (2) adds a new requirement for the reporting of failed technetium and rubidium generators; and (3) allows licensees to name associate radiation safety officers (ARSOs) on a medical license.

DATES: This final rule is effective on **[INSERT DATE 180 DAYS AFTER THE DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

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

- **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: 301-415-3463; e-mail: Carol.Gallagher@nrc.gov. For technical questions, contact the individual listed in the FOR FURTHER INFORMATION CONTACT section of this document.
- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly-available documents online in the ADAMS Public Documents collection at http://www.nrc.gov/reading-rm/adams.html. To begin the search, select "ADAMS Public Documents" and then select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov. For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the "Availability of Documents" section.
- **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.

FOR FURTHER INFORMATION CONTACT: Torre Taylor, Office of Nuclear Material Safety

and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone: 301-415-7900, e-mail: Torre.Taylor@nrc.gov

SUPPLEMENTARY INFORMATION:

EXECUTIVE SUMMARY:

A. Need for the Regulatory Action and Legal Authority

The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations related to the medical use of byproduct material. These regulations were last amended in their entirety in 2002. Over the last 14 years, stakeholders and members of the medical community have identified certain issues in implementing these regulations. As a result, the NRC is updating its regulations to address technological advances and changes in medical procedures. The amended rule would also enhance patient safety. The NRC is revising 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, and the Energy Reorganization Act of 1974, as amended.

B. Major Provisions

- The final rule establishes separate requirements for identifying and reporting MEs involving permanent implant brachytherapy. These new regulations require reporting of an event in which there is actual or potential harm to a patient resulting from an ME. Additionally, licensees are required to develop, implement, and maintain procedures for determining if an ME has occurred, including, for permanent implant brachytherapy, procedures for verifying certain aspects of the treatment within 60 days from the date the treatment was performed. Note that

the terms "ME," "ME definition," "ME criteria," and "ME reporting criteria" are used interchangeably in the Executive Summary and the Discussion sections of this document.

- Training and experience (T&E) requirements are 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. 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, therefore, additional attestation by a preceptor is unnecessary. Individuals who are not board certified will still need to obtain a written attestation; however, the language of the attestation is modified. Additionally, residency program directors will be allowed to provide these written attestations. Note that the terms "written attestation," "attestation," "preceptor statement," and "preceptor attestation" are used interchangeably in the Executive Summary and the Discussion sections of this document.

- The rule addresses 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 will 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 II, Petition for Rulemaking, PRM-35-20, of this document.

- The requirements for measuring the molybdenum-99 (Mo-99) concentration for elutions of Mo-99/Technetium-99m (Tc-99m) generators are changed and requirements are added for reporting and notification of a generator eluate exceeding permissible Mo-99, strontium-82 (Sr-82), or strontium-85 (Sr-85) concentrations. The occurrence of generator

eluate exceeding permissible concentrations is also referred to as "breakthrough." The current requirement to measure the Mo-99 concentration after the first eluate is changed to require that the Mo-99 concentration be measured in each eluate. This requirement is changed in response to several breakthrough incidents reported to the NRC.

- Additionally, licensees will 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 will make it easier for an individual to become a Radiation Safety Officer (RSO) on other medical licenses and will increase the number of individuals who are available to serve as preceptors for individuals seeking to be appointed as RSOs or ARSOs.

C. Costs and Benefits

The NRC has not established a quantitative cutoff for defining an economically significant regulatory action for the purposes of the Congressional Review Act. The NRC assumes "significant" impact if the ratio of annualized costs to estimated annual gross revenues for a licensee exceeds 1 percent. The final rule will have an estimated $7.8 million implementation cost for the medical community. This cost will be spread over the 7,418 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 final rule ~~appears to~~is not ~~be~~ considered an economically significant regulatory action. It will cost the NRC approximately $65,000 to implement this rule.

The benefits of this final rule are associated with reducing unnecessary radiation exposure to patients, removing 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, and affording greater flexibility to licensees. This final rule also

updates, clarifies, and strengthens the existing regulatory requirements, and, thereby, promotes public health and safety.

A regulatory analysis has been developed for this rulemaking and is discussed in Section VIII, Regulatory Analysis, of this document.

TABLE OF CONTENTS

I. 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 10 CFR part 35 ~~of title 10 of the *Code of Federal Regulations* (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 amending its regulations in 10 CFR part 35 to address these issues. This final rule modifies the written directive (WD) requirements in 10 CFR 35.40 and the ME reporting requirements in 10 CFR 35.3045 to establish separate ME reporting criteria for permanent implant brachytherapy. This final rule also modifies 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. The NRC's purpose for requiring licensees to report MEs is to allow the NRC to follow up on incidents and determine if other licensees might

be making the same or similar mistakes, or experiencing the same or similar challenges. When the NRC identifies similarities in the problems reported from multiple facilities, it can provide information that may help prevent additional incidents. The information collected is also valuable in assessing trends or patterns, identifying generic issues, and recognizing any inadequacies or unreliability of specific equipment or procedures.

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 ME criteria amendments 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 amendments in this final rule are based on the NRC staff recommendations contained in SECY-12-0053, "Recommendations on Regulatory Changes for Permanent Implant Brachytherapy Programs," and the comments received on the proposed rule "Medical Use of Byproduct Material - Medical Event Definitions, Training and Experience, and Clarifying Amendments," published in the Federal Register on July 21, 2014 (79 FR 42410).

On August 6, 2008, the NRC 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* (73 FR 45635), for public comment. This proposed rule included revised ME criteria for permanent implant brachytherapy. The majority of commenters were in agreement ~~to~~ on converting 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 NRC staff re-evaluated the proposed rule that was published in 2008 and developed a re-proposed rule.

In SECY-10-0062, "Re-proposed Rule: Medical Use of Byproduct Material – Amendments/Medical Event Definitions," dated May 18, 2010, the NRC staff requested that the

Commission approve for publication the re-proposed rule for public comment. Prior to the Commission voting on the re-proposed rule, on July 8, 2010, a Commission briefing was held on the re-proposed rule. 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 re-proposed 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 re-proposed rule.

In the Staff Requirements Memorandum (SRM) for SECY-10-0062, dated August 10, 2010, the Commission disapproved the NRC staff's recommendation to publish the re-proposed rule. ~~and~~ The Commission 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 authorized users (AUs). The SRM also directed the NRC staff to hold a series of stakeholder workshops to discuss issues associated with the ME definition. ~~The NRC has addressed the issues in the re-proposed rule (RIN 3150-AI26) in this final rule;~~ ~~f~~For more information, including public comments submitted on the proposed rule published on August 6, 2008, ~~(~~see Docket ID NRC-2008-0071 on www.regulations.gov~~)~~. ~~The SRM also directed the NRC 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, and in

Houston, Texas, in August 2011. 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 NRC 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. The recommendations in SECY-12-0053 along with public comments received on the proposed rule published on July 21, 2014 (79 FR 42410), provided the regulatory basis for the ME reporting criteria in this final rule.

In addition to revising the ME definitions for permanent implant brachytherapy, the NRC is amending 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 and notification when a generator eluate exceeds permissible Mo-99, Sr-82, or Sr-85 concentrations; 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 make several clarifying amendments.

Finally, this final rule addresses issues that were raised in PRM-35-20 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 petition is discussed in detail in Section II, Petition for Rulemaking, PRM-35-20, of this document. This final rule completes action on PRM-35-20.

~~This final rule completes action on PRM-35-20.~~

II. Petition for Rulemaking, PRM-35-20

The NRC has incorporated into this 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 (Ritenour Petition). A notice of receipt and request for public comments on this petition was published in the *Federal Register* on November 1, 2006 (71 FR 64168).

The petitioner requested that 10 CFR 35.57, "Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist," be revised to: 1) recognize medical physicists certified by either the American Board of Radiology or the American Board of Medical Physics on or before October 24, 2005, as "grandfathered" for the modalities that they practiced as of October 24, 2005, independent of whether or not a medical physicist was named on an NRC or an Agreement State license as of October 24, 2005; and 2) recognize all diplomates certified by the named boards in former subpart J of 10 CFR part 35, which was removed from 10 CFR part 35 in a rulemaking dated March 30, 2005 (70 FR 16336), as RSOs who have relevant timely work experience (even if they have not been formally named as an RSO). The petitioner requested that experienced board-certified RSOs and medical physicists not named on a license who had practiced certain modalities prior to October 24, 2005, be exempted from the specific T&E requirements in 10 CFR 35.50 and 35.51, respectively. In effect, they would be "grandfathered" for these training requirements for the modalities that they practiced as of October 24, 2005. The petitioner was concerned that as a result of the amendments to the T&E regulations in 2005, an individual could become authorized on a license only if he or she had been certified by a specialty board whose certification process was recognized under this regulation 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 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. This group of board-certified individuals 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). 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 (73 FR 27773; May 14, 2008).

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 amendments to the T&E ~~grandfathering provisions of the~~ regulations in 2005, 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, t~~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 and thus allow them to continue to practice using the same modalities. This final rule, in response to the petition, amends § 35.57 to recognize all individuals who 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.

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, the petitioner stated that these individuals will be required to provide preceptor attestations. In this rulemaking, the NRC has eliminated the requirement for preceptor attestations for 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 will fall under the provisions of § 35.59 and will need to provide evidence of continued education and experience. Therefore, the NRC believes that preceptor attestations are not warranted for these "grandfathered" individuals as long as the provisions of § 35.59 are met, and the individual only requests authorizations for the modalities the individual practiced as of October 24, 2005.

III. Discussion

A. What Action is the NRC Taking?

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 NRC published a proposed rule on July 21, 2014 (79 FR 42410), for a 120-day public comment period to address these issues. The NRC developed this final rule based on the comments received on the proposed rule. The comments are discussed in Section V, Public Comment Analysis, of this document.

The final rule clarifies the current regulations and provides greater flexibility to licensees without compromising patient, worker, or public health and safety. The amendments in this final rule include:

a. adding separate ME definitions for permanent implant brachytherapy;
b. amending preceptor attestation requirements;
c. grandfathering certain board-certified individuals, as discussed in Section II, 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 when a generator eluate exceeds permissible concentrations of Mo-99, Sr-82, Sr-85;
f. allowing ARSOs to be named on a medical use license; and additional issues and clarifications.

The major revisions are:

a. Adding separate ME definitions for permanent implant brachytherapy.

This final rule establishes separate ME definitions and reporting requirements for permanent implant brachytherapy. As explained in Section I, Background, of this document, these amendments are based on the recommendations developed in close cooperation with the ACMUI, with substantial input from various stakeholders, and from public comments

received on the proposed rule. During its meeting in March 2004, the ACMUI discussed the inadequacy of the definition of MEs as applied to permanent implant brachytherapy. The ACMUI explained that for these implants, the plus or minus 20 percent variance from the WD criteria in the existing rule was only appropriate if both the WD and the variance could be expressed in units of activity, rather than in units of dose. The ACMUI explained that there is no suitable clinically used dose metric available for judging the occurrence of MEs for permanent implant brachytherapy. In June 2005, the ACMUI recommended that new language be developed to define MEs for permanent implant brachytherapy.

Based on the recommendations from the ACMUI, the NRC staff submitted a paper to the Commission, SECY-05-0234, "Adequacy of Medical Event Definitions in 10 CFR 35.3045, and Communicating Associated Risks to the Public," dated December 27, 2005. In this paper, the NRC staff recommended that the Commission approve, for permanent implant brachytherapy, the NRC staff's plan to revise the ME definitions in § 35.3045 and the associated requirements for WDs in § 35.40 to be activity-based, instead of dose-based. In the SRM for SECY-05-0234, dated February 15, 2006, the Commission directed the NRC staff to proceed directly with the development of a proposed rule to modify both the WD requirements in § 35.40(b)(6) and the ME reporting requirements in § 35.3045 for permanent implant brachytherapy medical use, to convert from dose-based to activity-based ME criteria.

As discussed in Section I, Background, of this document, a proposed rule was published in the *Federal Register* on August 6, 2008 (73 FR 45635). A substantial number of MEs were reported in 2008 that would not have met the criteria for reporting under the activity-based ME reporting criteria as noticed in the proposed rule. Therefore, the NRC staff drafted a different rule that contained absorbed dose-based ME reporting criteria for the treatment site. The NRC staff submitted recommendations for ME reporting criteria to the Commission in SECY-10-0062, "Reproposed Rule: Medical Use of Byproduct Material – Amendments/Medical Event

Definitions," dated May 18, 2010. In the SRM for SECY-10-0062, dated August 10, 2010, the Commission disapproved the NRC staff's recommendations and directed the NRC 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.

During the ACMUI meeting held on October 20, 2010, the ACMUI unanimously approved the Permanent Implant Brachytherapy Subcommittee report as an interim report, "Advisory Committee on Medical Uses of Isotopes Permanent Implant Brachytherapy Interim Report," dated October 20, 2010. The ACMUI meeting held 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 submitted its final report on permanent implant brachytherapy, dated October 18, 2011, to the NRC following the ACMUI October 18, 2011, public teleconference meeting. The final report reflected the principal positions and recommendations provided by participants during the NRC public workshops. In particular, the report included the recommendation to change from dose-based ME criteria for the treatment site to source-strength based criteria. The final report included a quantitative metric, the "octant approach," for determining that a distribution of implanted sources was irregular enough (i.e., demonstrating "bunching") to consider the procedure as an ME. The final report also included a dose-related ME criterion for the treatment site.

However, in a letter to the Chairman of the ACMUI dated November 30, 2011, 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. Subsequently, the ACMUI issued a revised final report, "Advisory Committee on Medical Use of Isotopes (ACMUI) Permanent

Implant Brachytherapy Revised Final Report," dated February 7, 2012. The ACMUI simplified the ME criteria for the treatment site, removing the "octant approach" and direct reference to absorbed dose to the treatment site. The revised final report was, with minor modifications, approved by the ACMUI during its public teleconference meeting held on February 7, 2012, meeting. The ASTRO, in a letter to the Chairman of the ACMUI, characterized this report as an improvement on the earlier report.

The NRC staff used the recommendations in the ACMUI revised final report dated February 7, 2012, 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 (discussed earlier in this section), to develop the recommendations submitted to the Commission on April 6, 2012, in SECY-12-0053, "Recommendations on Regulatory Changes for Permanent Implant Brachytherapy Programs." In a Commission meeting held April 24, 2012, participating representatives from ACMUI, ASTRO, and the American Brachytherapy Society (ABS) endorsed the recommendations in SECY-12-0053 for modification of the requirements in § 35.40 and § 35.3045 ~~that were contained in SECY-12-0053~~. The NRC notes that ASTRO and ABS representatives suggested eliminating the recommended criterion for ME reporting that would have required 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 the ACMUI and the NRC staff determined that there should be some form of ME reporting criterion for overdosing of normal tissue structures located within the treatment site. In the SRM for SECY-12-0053, ~~"Recommendations on Regulatory Changes for Permanent Implant Brachytherapy Programs,"~~ dated August 13, 2012, the Commission approved the NRC staff recommendations. The recommendations are applicable to all permanent implant brachytherapy procedures using radioactive sources for all treatment sites.

The proposed rule published on July 21, 2014 (79 FR ~~4214042~~42410) also included ME criteria in § 35.3045(a)(2)(iii) and (iv) as follows: 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 ~~by~~ 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 exceeds ~~by~~ 150 percent of the dose the tissue would have received based on the approved pre-implantation dose distribution. The size of the normal tissue, 5 cubic centimeters, was based on an ACMUI recommendation in its October 20, 2010, 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 the ACMUI cited literature to support 5 cubic centimeters as being a relevant quantity for toxicity. In the proposed rule, the NRC specifically invited comments on the selection of the specified volume of the normal tissues located both outside and within the treatment site in defining MEs.

The NRC received numerous comments expressing concern about the proposed ME criteria related to the absorbed dose to normal tissues located outside and within the treatment site. The commenters expressed concerns that they would have technical difficulties assessing dose to normal tissues located outside and within the treatment site. They stated that their treatment planning systems are not equipped to make such assessments. They believed the regulators may not be able to inspect such requirements. They stated that these requirements may cause confusion and result in licensees not performing permanent implant brachytherapy treatments. The comments are discussed in Section V, Public Comment Analysis, of this document.

Based on public comments and recommendations from the ACMUI, the ME criteria in

this final rule for permanent implant brachytherapy in § 35.3045(a)(2) do not include absorbed doses to normal tissues located outside of or within the treatment site. Instead, the ME criteria in the final rule for permanent implant brachytherapy are:

1) An ME has occurred if the total source strength administered differs by 20 percent or more from the total source strength documented in the post-implantation portion of the WD;

2) An ME has occurred if the total source strength administered outside of the treatment site exceeds 20 percent of the total source strength documented in the post-implantation portion of the WD; or

3) An ME has occurred if an administration involves: a) using the wrong radionuclide, b) delivery to the wrong individual or human research subject, c) sealed source(s) implanted directly into a location discontiguous from the treatment site as documented in the post-implantation portion of the WD (as discussed in this document, discontiguous means a location that is not physically adjacent to the treatment site), or d) a leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue.

In supporting these recommendations, the NRC believes that source strength is the measurable metric for defining MEs involving permanent implant brachytherapy. The 20 percent variance threshold is consistent with the recommendation of the ACMUI for all medical uses of byproduct material as described in SECY-05-0234, discussed earlier in this section.

Another ME criterion included in the proposed rule published on July 21, 2014, (79 FR ~~42140~~42410) was related to source(s) implanted directly into the wrong site or body part (i.e., not in the treatment site identified in the WD). This criterion stated that "even a single sealed source directly delivered to the wrong treatment site would constitute an ME that must be reported." The NRC received several comments on this issue. The commenters believed a single source delivered outside the treatment site was an inappropriate criterion for ME reporting. They proposed that in order to capture instances where a source is implanted in a

distinctly wrong location (for example, left breast versus the right breast), the criterion should say, "Even a single sealed source directly delivered to a noncontiguous wrong treatment site would constitute an ME that must be reported."

In response to these comments and a recommendation from the ACMUI in its final report on the draft final rule ("Advisory Committee on the Medical Uses of Isotopes Comments on the Draft Final Rule, 10 CFR Parts 30, 32, and 35, Final Report," dated January 6, 2016), the NRC has changed § 35.3045(a)(2)(v)(C) [redesignated as § 35.3045(a)(2)(iii)(C)] to read "Sealed source(s) implanted directly into a location discontiguous from the treatment site as documented in the post-implantation portion of the written directive."

This "wrong treatment site" ME criterion will capture cases in which total source strength administered outside of the treatment site did not exceed 20 percent of the total source strength documented in the post-implantation portion of the WD, but one or more sources were directly implanted into a location far from the treatment site. An example is a case in which 100 sources were implanted; and 81 were determined to be within the treatment site, 18. Eighteen sources were outside and contiguous to the treatment site, and. However, one source was erroneously implanted directly into a site discontiguous from the treatment site. This case would not be an ME under the "exceeds 20 percent of the total source strength"based on the total source strength criterion ; however, it isbut would be defined as an ME under the "wrong treatment site" criterion because of the one erroneously implanted source met the "wrong treatment site" criterion.

The proposed criterion specified in § 35.3045(a)(2)(v)(E), "a 20 percent or more error in calculating the total source strength documented in the pre-implantation portion of the written directive," in the proposed rule published on July 21, 2014, was not included in the final rule. The decision to not include this criterion is based on the comments received on the proposed rule and is discussed in Section V, Public Comment Analysis, of this document.

The new ME criteria for permanent implant brachytherapy in § 35.3045 require amendments to § 35.40 and § 35.41. The previous WD requirements were primarily associated with temporary implant brachytherapy medical use. This final rule establishes separate WD requirements in § 35.40 that are appropriate for permanent implant brachytherapy. This rule requires that the WD for permanent implant brachytherapy consist of two portions. The first portion of the WD must be prepared before the implantation, and the second portion of the WD must be completed after the procedure but before the patient leaves the post-treatment recovery area. For permanent implant brachytherapy, this rule requires that the WD portion prepared before the implantation include documentation of the treatment site, the radionuclide, and the total source strength. This final rule requires that the post-implantation portion of the WD contain documentation of the treatment site, the number of sources implanted, the total source strength implanted, and the date.

Based on ACMUI input discussed earlier in this section and information gained at public workshops, the NRC understands that the final WD documentation related to these § 35.40 permanent implants must allow for unanticipated medical situations encountered during the procedure. For instance, an AU might need to adjust the number of sources implanted because the volume of the treatment site may have decreased since the treatment plan was developed. Therefore, in defining an ME involving the treatment site for permanent implants, the NRC based the criterion for an ME on the percentage of implanted sources that are outside the treatment site as documented in the post-implantation portion of the WD rather than by defining an ME based on a comparison of the implanted total source strength to the total source strength documented in the pre-implantation portion of the WD. This definition differs from the ME definition for all other brachytherapy procedures where dose comparisons are made with reference to what was prescribed in the WD that was prepared before the procedure.

This final rule also makes conforming changes to § 35.41, "Procedures for

administrations requiring a written directive," to include permanent implant brachytherapy. Although § 35.41(a)(2) requires licensees to determine if the administration is in accordance with the WD, there is no specific requirement that a licensee determine that an administered dose or dosage met an ME criterion as defined in § 35.3045. Section 35.41 is amended to require that a licensee ~~include~~ develop procedures for determining if an ME has occurred. For all permanent implant brachytherapy, § 35.41 is also amended to require that a licensee develop additional procedures to include an evaluation of the placement of sources as documented in the post-implantation portion of the WD. The procedures must include a provision that these assessments must be made within 60 days from the date the treatment was performed. Although there is no requirement in § 35.41 to use imaging to determine the occurrence of an ME, imaging is the best (and in some circumstances may be the only) method to determine source strength outside of the treatment site and is routinely practiced in most clinical facilities.

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 the certification and the alternate pathway, an individual seeking authorization for medical byproduct material must obtain a 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 Commission briefing held on April 29, 2008, 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. In other words, 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 asserted that an additional attestation for the board-certified individuals was not needed.

The ACMUI also recommended that the attestation requirements associated with the alternate pathways be amended to delete the requirement to attest to an individual's radiation safety-related competency. 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 it is provided by a residency program director representing a consensus of an authoritative group, irrespective of whether the program director personally met the requirements for AU 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, Commission briefing, in an SRM dated May 15, 2008, the Commission directed the NRC 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 Commission also directed the NRC staff to consider additional methods, such as having the attestation provided by consensus of an authoritative group.

Following both consideration of the ACMUI's position, which was consistent with its long-held position on this issue, and interactions with the Agreement States, the NRC 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." The NRC staff recommended that the Commission approve development of the following amendments 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, the Commission approved these recommendations and directed the NRC staff to develop the proposed rule language for the

attestation requirements for the alternate pathway in concert with the ACMUI and the Agreement States.

Participants at public workshops held in the summer of 2011 broadly supported the proposed changes to remove the attestation requirement for board-certified individuals. The workshop panelists (which included members of the ACMUI and the Agreement States) recommended that the NRC 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 attest to someone's competency; rather, they should attest that the individuals received the T&E that is 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. In the final rule, the attestation language is revised accordingly.

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

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

The petition ~~is~~ and its resolution are discussed in Section II, 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. However, a generator can be eluted several times to obtain Tc-99m for formulating radiopharmaceuticals for patient use.

If Mo-99 breakthrough exceeds the permissible concentration listed in § 35.204(a), it may cause unnecessary radiation exposures to patients. The administration of higher levels of Mo-99 could potentially affect health and safety and 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-99 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 is amending § 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 at the time of generator elution.

e. Requiring reporting and notification of generator eluates exceeding permissible concentrations of molybdenum-99, strontium-82, or strontium-85

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 Mo-99/Tc-99m 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, issues with Sr-82/Rb-82 generators were discovered when several individuals were identified with unexpectedly high levels of Sr-82 and Sr-85. These individuals had undergone Rb-82 chloride cardiac scanning procedures several months prior 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 generator when the eluate exceeded permissible concentrations was voluntary, the NRC had difficulty determining the extent of potential problems. 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 levels of Sr-82 and Sr-85 ~~levels~~. Breakthrough of Mo-99, or Sr-82 and Sr-85 contaminants can lead to unnecessary radiation exposure to patients.

This final rule also adds a new reporting requirement for a generator eluate exceeding permissible concentrations of Mo-99 or Sr-82 and Sr-85. This new reporting requirement in § 35.3204(a) requires a licensee to report to the NRC and the manufacturer or distributor of medical generators within 7 calendar days any measurement that exceeds the limits in § 35.204(a), at the time of generator elution.

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. Further, 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, ACMUI members expressed a concern that this restriction has contributed to a shortage of available RSOs to serve as preceptors. The ACMUI stated that the restriction has created 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 this restriction has created 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 final rule amends 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 will 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 will have oversight duties for the radiation safety operations of their assigned sections, while reporting to the named RSO. The regulation will continue to allow a licensee to name only one RSO on a license. The RSO will 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 will remain responsible for the overall licensed program. Under the final rule, the ARSO will be named on the license for the types of use of byproduct material for which this individual is qualified and has been assigned duties and tasks by the RSO.

The NRC believes that allowing an ARSO to be named on a license will increase the number of individuals who will be available to serve as preceptors for individuals seeking to be appointed as RSOs or ARSOs. Also, an ARSO named on a license 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 ~~any~~ medical use license they are identified on, the NRC believes that it is overly restrictive to not allow them to serve as an RSO on any medical use license. Therefore, a modification is made that will allow an AU, AMP, or ANP listed on any medical use license or permit to serve as an RSO or ARSO. This change will 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.

Participants at the public workshops held in the summer of 2011 broadly supported the proposed change to allow an ARSO to be named on a license. 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 final rule amends multiple sections of 10 CFR part 35 to accommodate the new ARSO position.

g. Additional issues and clarifications

Additional amendments are discussed in Section VI, Section-by-Section Analysis, of this document.

B. *When ~~Would~~ Will These Actions Become Effective?*

The final rule will become effective 180 days from its publication in the *Federal Register*. In the proposed rule published on July 21, 2014, the NRC ~~had~~ requested comments on whether a 180-day effective date for the final rule is sufficient to communicate the changes to all practitioners, and for practitioners to revise procedures, train on them, and implement the changes. The NRC received three comments on this question. These comments are discussed

in Section V, Public Comment Analysis, of this document. Based on the comments received, the NRC has determined that a 180-day effective date is sufficient to implement the final rule.

IV. Opportunities for Public Participation

The NRC staff submitted a proposed rule to the Commission for approval on August 8, 2013, SECY-13-0084, "Proposed Rule: Medical Use of Byproduct Material - Medical Event Definitions, Training and Experience, and Clarifying Amendments." The Commission approved the NRC staff's recommendation to publish the proposed rule, with certain changes directed by the Commission, in the SRM to SECY-13-0084, dated, January 6, 2014. The proposed rule (79 FR 42410) was published on July 21, 2014, for a 120-day comment period that ended on November 18, 2014. However, the proposed rule inadvertently omitted the one-time implementation costs from the information collection burden estimate. Therefore, a correction to the proposed rule (79 FR 56524) was published in the *Federal Register* on September 22, 2014, correcting the information collection burden estimate and allowing the public 30 days to comment on the information collection burden.

During the comment period, the NRC staff held a public meeting on October 8, 2014, to better inform stakeholders of the proposed amendments, and the various methods by which to provide comments on the proposed rule. Also, a public meeting was held on February 10, 2015, to better understand the comments made by Spectrum Pharmaceuticals. Spectrum Pharmaceuticals expressed concern about the proposed additional case work requirements in § 35.396 for the radionuclides used primarily for their alpha emissions. It also requested the NRC to require ~~only~~ 80 hours rather than the required 700 hours of specialized training for any physician so that an oncologist or a hematologist may administer parenteral radioactive drugs.

Early public input on the proposed rule was solicited through various mechanisms. The proposed amendments and preliminary draft rule text were 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 the definition of an ME, including the requirements for reporting and notifications of MEs for permanent implant brachytherapy, and on other medical issues that were being considered in the proposed rulemaking. These workshops were initiated as a result of the Commission's direction to the NRC staff in the SRM to SECY-10-0062, to work closely with the ACMUI and the medical community to develop ME 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 representatives from the ACMUI, Agreement States, and professional societies, and a patients' rights advocate.

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 11 comment letters on this preliminary draft rule text. These comment letters 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.

V. Public Comment Analysis

A. Overview of Public Comments

The NRC received 69 comment letters that contained over 100 individual comments. The comment letters are posted on www.regulations.gov under Docket ID NRC-2008-0175.

The commenters included several professional societies including the American Brachytherapy Society, American College of Radiology, Health Physics Society, American Academy of Health Physics, American Society for Radiation Oncology, American Association of Physicists in Medicine, Council on Radionuclides and Radiopharmaceuticals, the Organization of the Agreement States, and the Conference of Radiation Control Program Directors. Other commenters included individual States, practicing physicians, medical physicists, RSOs, nuclear pharmacists, individual members of the public, and a member of Congress. The NRC also received several comment letters after the public comment period closed. The NRC was able to consider and respond to several of these comments. However, two comment letters on the T&E requirements for alpha and beta emitters were submitted so late in the rulemaking process that it was not practical for the NRC to consider these comments in this rulemaking.

For the ME criteria for permanent implant brachytherapy, the commenters generally supported the activity-based criteria instead of the current dose-based criteria for the treatment site. The commenters did not support the criteria related to the dose to normal tissues located outside the treatment site, and normal tissues located within the treatment site. The commenters also expressed concern with the proposed 5 cubic centimeter volume of the normal tissue specification for the absorbed dose criteria for the normal tissues. The commenters stated numerous practical difficulties in making these dose assessments. They stated that the volume of a maximally exposed 5 contiguous cubic centimeters of normal tissue appears reasonable in theory. However, it will be difficult to determine in practice with current technology. They expressed concern that the treatment planning systems typically report dose-volume histograms to structures, but they do not identify contiguous volumes. Based on these concerns, this final rule ME criteria in § 35.3045 does not include dose to normal tissues located outside, or within the treatment site.

There were numerous comments on the compatibility category for the Agreement States for § 35.3045, Report and notification of a medical event. Members of the medical community submitted ten comments in support of Compatibility Category B. The OAS, the Conference of Radiation Control Program Directors (CRCPD), and all 7 of the Agreement States that submitted comments supported Compatibility Category C. This issue is fully discussed in Part I, Public Comments on the Specific Issues on Which the NRC Requested Comments.

The commenters expressed concern about confusion among AUs surrounding the definition of ME and WDs related to Yttrium-90 (Y-90) microspheres. The NRC staff has determined that the use of Y-90 would continue to be licensed under § 35.1000, "Other medical uses of byproduct material or radiation from byproduct material."

The commenters were generally supportive of the proposed regulation that allows for the naming of an ARSO on the license.

The commenters were supportive of the proposed removal of attestation requirements for the board-certified individuals, and other changes to the attestation requirements that are retained for individuals applying through the alternate pathway.

The commenters were not supportive of the proposed additional case work requirements for the radionuclides used primarily for their alpha emissions. They were concerned that the proposed regulation has the unintended consequence of increasing the burden of the work experience requirement for those seeking to administer therapeutic radiopharmaceuticals such as alpha and beta emitters. They indicated that it may prove too burdensome for certain practitioners, particularly those in areas far removed from teaching hospitals and urban centers, to participate in three proctored cases in each of these very specific categories. They stated that the result will be to limit patient access to these safe and effective pharmaceuticals among what is already a disadvantaged population.

With regard to the proposed reporting and notification of failed Mo-99/Tc- 99m and Sr-

82/Rb-82 generators in § 35.3204, the commenters stated that the 30-day deadline to report should be shortened to more effectively address patient safety concerns. In response to this comment, the final rule has been changed to require a 7-calendar-day reporting and notification time for a failed generator.

B. Public Comments and NRC Responses

The NRC carefully considered the public comments in developing the final rule. This section summarizes the comments that the NRC received on the proposed rule and provides responses to these comments. Part I discusses the specific comments received on the issues on which the NRC specifically requested comments and discusses the NRC's responses to these comments. Part II discusses comments received on the specific sections of the part 35 amendments in the proposed rule and the NRC's responses to these comments.

Part I Public Comments on the Specific Issues on Which the NRC Requested Comments

In the proposed rule, the NRC requested comments on the following specific issues:

1. Dose-volume specification for determining absorbed dose to normal tissue for MEs under § 35.3045, Report and notification of an ME

The NRC asked whether, in defining MEs, 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 is appropriate. The NRC also asked whether the application of the proposed ME definition for normal tissue based on the absorbed dose to the maximally exposed 5 contiguous cubic centimeters during permanent implant brachytherapy is appropriate for all potential treatment modalities, or whether it may result in unintended

consequences for tissues or organs adjacent to the treatment site.

The NRC received numerous comments on this issue. The comment summaries and NRC responses to comments on this issue are discussed in Part II, Comments on Specific Sections in the Proposed Rule, under §§ 35.41 and 35.3045.

2. Implementation Period

The NRC asked whether a 180-day effective date for the final rule is sufficient to communicate the changes to all practitioners, and for practitioners to revise procedures, train on them, and implement the changes. Three commenters responded to this question. One commenter stated that 180 days is sufficient to implement the rule. However, two commenters stated that 365 days or more is needed to implement significant changes related to the dose evaluation requirements proposed for the ME criteria portion of the rule. Two commenters also recommended that the amendments related to PRM-35-20 ~~petition~~ should be implemented immediately, or in no more than 30 days. Because the ME criteria related to the dose evaluations to normal tissues are removed in the final rule, the NRC determined that 180 days is sufficient to implement the final rule.

3. Impact on Clinical Practice

The NRC asked if any of the changes in the proposed rule are likely to discourage licensees from using certain therapy options or otherwise adversely impact clinical practice, and if so, how.

The NRC received several comments on this issue. The comment summaries and NRC responses to comments on this issue are discussed in Part II, Comments on Specific Sections in the Proposed Rule, under §§ 35.390 and 35.396.

4. Compatibility Category for the Agreement States for § 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 that 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 if they do not create a conflict, duplication or gap with the essential objectives of the regulation.

Some medical licensees have multiple locations, some of which are NRC-regulated and some of which are Agreement State-regulated. Many of 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.

During the development of the proposed rule, the OAS expressed a strong desire to retain a dose-based ME reporting criterion for the treatment site if NRC regulations are revised to include only activity-based criteria for determining MEs for permanent implant brachytherapy. The OAS had no objection to the introduction of the activity-based criteria, as long as the dose-based criteria could be retained by the Agreement States. With a Compatibility Category C designation, some Agreement States indicated they could require both the dose-based criterion and source-strength based criterion, as long as the Agreement State reports to the NRC using the reporting criteria that meets the essential objectives of the NRC regulatory requirements. As discussed in the proposed rule published on July 21, 2014, for some Agreement States, Compatibility Category B is difficult to achieve because their regulations must 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.

The ACMUI in its report to the NRC (Enclosure 4 to SECY-13-0084) recommended that MEs related to permanent implant brachytherapy be designated as Compatibility Category B. 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 ~~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 only specifically capture clinically significant MEs in permanent implant brachytherapy.

The Commission, in the SRM to SECY-13-0084, directed ~~that~~ the NRC staff to designate § 35.3045 ~~be designated~~ as ~~a~~ Compatibility Category B in the proposed rule published on July 21, 2014 (79 FR 42410). The NRC specifically invited comments on the appropriate compatibility category for ME reporting under § 35.3045.

The NRC received 19 comments on this issue. The medical community submitted ten comments in support of Compatibility Category B. The Organization of the Agreement States (OAS), the Conference of Radiation Control Program Directors (CRCPD), and 7 Agreement States submitted comments in support of Compatibility Category C. The medical community

commenters stated that some medical licensees practice at multiple locations, some of which are NRC-regulated and some of which are Agreement State-regulated. These commenters stated that a Compatibility Category B designation would allow for uniformity of practice and procedures across the country. They stated that moving § 35.3045 from Compatibility Category C to B is appropriate and necessary. The commenters from the medical community also stated that they recognize that the Agreement States oppose a change in ~~compatibility~~ Compatibility ~~level~~Category, citing state legislative requirements, the difficulty in changing state regulations, and the fact that States do not perceive a problem with the current dose-based definition. While the commenters from the medical community appreciate these concerns, they believed these concerns are outweighed by the importance of having a consistent definition throughout the country to prevent confusion and unnecessary reporting of otherwise medically acceptable events. They expressed concern that a Compatibility C designation would allow Agreement States to implement unnecessarily more restrictive definitions that may classify medically acceptable procedures as an ME.

The Agreement States, OAS, and CRCPD strongly recommended that the compatibility designation for ME reporting under § 35.3045 be designated as Compatibility C. They argued that under Compatibility Category C the Agreement States would continue to have the flexibility to add additional reporting terms (for example, shorter timelines for reporting, or a requirement to report diagnostic MEs). Several Agreement States questioned how a single medical incident at a single facility can have "direct and significant effects in multiple jurisdictions." They further added that the Compatibility Category C designation has been adequate for the reporting requirements for radiography, irradiator, and well logging licensees who routinely work in multiple jurisdictions. One Agreement State stated that the proposed activity-based ME reporting criteria should be added to the existing dose-based criteria, rather than replace it. The Agreement State stated that it would require licensees to apply both criteria, and only those

MEs that meet the NRC's proposed activity-based criteria would be reported to the NRC.

Based on these comments, and review of the NRC's Management Directive 5.9 "Adequacy and Compatibility of Agreement State Programs," NRC staff determined that ME reporting under § 35.3045 should be designated as Compatibility Category C. Under Compatibility Category C, the Agreement States must adopt the essential objective of the requirement to avoid conflicts, duplications, or gaps. The essential objective of § 35.3045 is to maintain a consistent national program for reporting MEs. A consistent national program for reporting MEs allows the NRC to identify trends or patterns, identify generic issues or concerns, recognize inadequacies or unreliability of specific equipment or procedures, and determine why an event occurred and whether any actions are necessary to improve the effectiveness of NRC and Agreement State regulatory programs.

The NRC has determined that allowing Agreement States to use the dose-based criteria in addition to the activity-based criteria for permanent implant brachytherapy MEs in § 35.3045(a)(2) would result in over reporting of non-significant events. Over reporting MEs would create inconsistencies in the national reporting program and disrupt the NRC and Agreement States' ability to use the national program for reporting MEs for the purposes described above. As a result, the use of dose-base criteria instead of activity-based criteria would create a conflict with the NRC's essential objective of this regulatory provision, which could impair the effective and orderly regulation of agreement material on a nationwide basis.

The NRC staff concluded that the continued use of a dose-based criteria could: 1) preclude a practice in the national interest to have consistent reporting and notification standard; 2) impair effective communication; and 3) preclude an effective review or evaluation by the Commission and Agreement State programs for agreement material with respect to protection of public health and safety. Under Compatibility Category C for reporting permanent implant brachytherapy ME's, the regulatory provision uses activity-based criteria to ensure the

consistent reporting of significant events as MEs across the country. Agreement States' use of dose-based criteria for ~~implementing~~ these reporting requirements would not be compatible with this provision because it conflicts with the essential objective of this provision to maintain a consistent national program for reporting MEs.

The NRC staff considered Compatibility Category B for the ME criteria for permanent implant brachytherapy in § 35.3045(a)(2), but concluded that this designation is not justified, because ME reporting, while important to the effective and orderly regulation of agreement material on a nationwide basis, does not have significant direct transboundary implications. As a Compatibility Category C regulatory provision, the Agreement States have the flexibility to include, for example, a shorter reporting time, but the use of dose-based ME reporting criteria for permanent implant brachytherapy would create conflicts and inconsistencies with respect to the national reporting program. Therefore, the NRC will not accept, under Compatibility Category C, Agreement State use of dose-based criteria for permanent implant brachytherapy ME reporting.

The comment summaries and NRC responses on this issue are discussed in Part II of this section, under § 35.3045.

Part II Comments Received on the Specific Sections in the Proposed Rule

Section 30.34(g) Terms and conditions of licenses

Comment: One commenter noted that Tc-99m decays much faster than Mo-99, therefore, every Tc-99m generator eluate will eventually exceed the regulatory limit. Because of this, the commenter stated that the language in the proposed rule text would require every eluate to be reported. The commenter proposed revising the rule text in § 30.34(g) to clarify that the licensee would only report measurements of a Tc-99m generator elution that

exceeded the regulatory limits at the time of generator elution.

Response: The rule text was modified in response to this comment. The NRC agrees with the commenter that the proposed rule text was not clear in § 35.204(e) and has amended it to clarify that the reporting requirements only apply at the time of generator elution.

Section 35.2 Definitions

Issue 1: Definition of an *Associate Radiation Safety Officer*

Comment: One commenter agreed with and supported the new definition of an Associate Radiation Safety Officer.

Response: The comment supports language in the rule; therefore, no response is required.

Comment: One commenter stated that some Agreement States are already using the term Assistant Radiation Safety Officer and suggested the NRC allow the use of a term other than "Associate," such as "Assistant." The commenter stated that this change would alleviate the workload required to modify certain Agreement States' medical licenses. Another commenter requested that the terms Assistant and Associate be used interchangeably.

Response: No change was made to the rule text based on this comment. To avoid confusion and to establish a clear regulatory requirement, the term Associate Radiation Safety Officer (ARSO) is retained. Although the term Assistant RSO is used in some Agreement States, each Agreement State may require individuals to meet different T&E standards to be named as an Assistant RSO on a license. Therefore, any individual whom an Agreement State has designated as an Assistant RSO is not recognized by the NRC and may not be recognized by other Agreement States. The new definition will establish clear and concise requirements that an individual would need to meet in order to be recognized as an Associate RSO by the NRC and ~~all the~~ Agreement States.

Issue 2: Definition of *an ophthalmic physicist*

Comment: One commenter asserted that there was not a sufficient need to create an

ophthalmic physicist designation and that by doing so the NRC will set a precedent for other source-specific designations, rendering the AMP obsolete.

Response: No change was made to the rule text based on this comment. The designation of an o*phthalmic physicist* is retained. Authorized Users who work in remote areas may not have ready access to an AMP to perform the necessary calculations and other activities outlined in the new § 35.433 to support the ophthalmic treatments. This rule change will make the procedure involving the use of Sr-90 sources for ophthalmic treatments available to more patients located in remote areas. The NRC does not believe the addition of the ophthalmic physicist will render the AMP obsolete because the primary role of the AMP is to support the medical uses under § 35.600 and certain uses under § 35.1000. The proposed revision would not prohibit an AMP from assisting the ophthalmic AU.

Issue 3: Definition of a *Preceptor*

Comment: One commenter agreed with and supported the new definition of a *Preceptor*.

Response: The comment supports language in the rule; therefore, no response is required.

Section 35.24 Authority and responsibilities for the radiation protection program

Comment: One commenter asserted that ARSOs should not be named on a medical license but licensees should be allowed to name ARSOs in their radiation programs. The commenter disagreed with the NRC's argument that licensees are having a difficult time in naming an RSO due to an RSO not being able to sign a preceptor form. Further, the commenter stated that "~~The~~ [t]he NRC and Agreement States are authorized to approve a proposed licensee's RSO based upon their T&E without the preceptor attestation."

Response: No change was made to the rule text based on this comment. The NRC

maintained the provision to name ARSOs on medical licenses to avoid confusion between individuals named on a license as opposed to individuals working in a radiation program and to establish regulatory requirements for training and experience. This will allow the individual who is named as an ARSO to be recognized by Agreement States and the NRC as an RSO or ARSO for the same medical uses on another license without resubmitting his or her T&E documents.

The ACMUI identified two issues with respect to securing an RSO's signature on a preceptor statement: there were not enough preceptors and some preceptors were not willing to sign preceptor statements. Naming the ARSOs on a license and permitting them to sign preceptor forms will increase the number of individuals who may sign the preceptor forms. Changes to the attestation language will remove impediments for individuals who were not willing to sign the previous preceptor statements. These changes will enhance opportunities for RSO candidates.

The NRC disagrees with the comment that RSOs are approved based upon their T&E without a preceptor statement. Under current regulations, an individual seeking to be named as an RSO on a medical license must submit a preceptor statement. The new provision in this rulemaking will only remove the preceptor attestation requirements for individuals who are certified by a board recognized by the NRC or Agreement States. Individuals seeking to be named as a RSO or ARSO under the alternate pathway will need to submit a preceptor statement.

Comment: One commenter recommended revising the rule text in § 35.24(b) to read, "These duties and tasks are restricted to the types of use for which the Associate Radiation Safety Officer is listed on the license as an AU, AMP or ANP, or has training in the radiation safety, regulatory issues and emergency procedures." The commenter believed that this revision "would align it with 30.50(d)."

Response: The NRC assumes the commenter intended to reference proposed § 35.50(d) not § 30.50(d). The ARSO must be listed on a license before being assigned duties and tasks as an ARSO. The individual may be assigned tasks outside of the agreed upon list of ARSO duties and tasks in order to obtain additional T&E.

The commenter's proposed text would imply that the ARSO is listed on a license as an AU, AMP, or ANP. This is not always the case. Further, as written in the proposed rule and in the rule text suggested by the commenter, the regulations could have permitted the RSO to assign duties and tasks to the individual as the ARSO for which he or she was not fully qualified (i.e., assigned duties and tasks for a type of use for which he or she was not listed on the license). Therefore, for clarification, the NRC has revised the rule text in § 35.24(b) to read, "These duties and tasks are restricted to the types of use for which the Associate Radiation Safety Officer is listed on the license."

Comment: Two commenters expressed concern that there is no clear guidance or a policy on the number of licenses on which an individual could be named as an RSO or an ARSO. One commenter requested that the NRC develop this policy or guidance. The other commenter recommended that the NRC, Agreement States, ACMUI, and the medical community work together to develop guidance or a policy that can be consistently applied across all regulatory jurisdictions to establish the minimum amount of time an RSO or an ARSO listed on multiple licenses would be required to spend at each licensed facility.

Response: No change was made to the rule text based on these comments. Current NRC regulations do not limit the number of licenses on which an RSO can be listed concurrently. Some Agreement States limit the number of licenses on which an individual may be named as the RSO. The NRC regulations do not impose any such limit. Rather, the NRC evaluates, on a case-by-case basis, whether the proposed RSO would have sufficient involvement in the program, and if necessary limits the number of licenses on which that RSO is

named.

Section 35.40 Written directives

Comment: One commenter questioned the phrase in § 35.40 (b)(6)(i): "... if appropriate, the expected absorbed doses to normal tissues located within the treatment site," and stated that the term "appropriate" is very subjective. The commenter also asked who decides if normal tissues are located within the treatment site and if this is a clinical decision. The commenter was concerned that an inspector might determine appropriateness differently than the licensee's AU or AMP, resulting in a potential violation based on a difference in interpretation. The commenter believes that the WD should not include expected doses to normal tissues located within the treatment site because there may be clinical reasons for an AU to accept a higher dose to a normal structure in close proximity to involved tissues.

Response: The rule text was modified based on this and other comments. The NRC agrees that, for permanent implant brachytherapy, the determination of the appropriate dose to normal tissue (if any) located within the treatment site is a matter of medical judgment. The NRC has removed the reference to dose to normal tissue located within the treatment site. The rule text in § 35.40(b)(6)(i) was modified to remove the requirement to include in the pre-implantation WD the language "if appropriate, the expected doses to normal tissues located within the treatment site."

Comment: One commenter stated that the wording of § 35.40(b)(6) refers to "permanent implant brachytherapy," but the remainder of the rule reads as if it was written for brachytherapy seeds. The commenter noted that Y-90 microspheres are sealed brachytherapy sources that are permanently implanted. The commenter asked if the new rule may be used in place of the existing guidance for Y-90 microsphere use under § 35.1000.

Response: No change was made to the rule text based on this comment. The term

"permanent implant brachytherapy" is used to refer to manual brachytherapy procedures performed in accordance with § 35.400. The NRC considers Y-90 microspheres to be manual brachytherapy sources; however, they have unique properties that prevent them from being regulated under all the provisions of § 35.400. Therefore, they are regulated under § 35.1000. Consequently, the new rule does not apply to the use of Y-90 microspheres.

Comment: One commenter supported specification of a "before implantation" and an "after implantation" assessment as an excellent improvement from the current regulations. However, the commenter stated that defining the "treatment site" is a concern for prostate procedures. The commenter noted that an AU may need to change the definition of the treatment site and intended doses to critical structures based on intraoperative imaging results. This could result in the evaluation for an ME for absorbed dose to normal tissue to be based on a condition that changed during the implant procedure.

Response: The rule text was modified in response to this comment. The rule text in § 35.40(b)(6)(ii) was changed to allow the AU to change the description of the treatment site in the post-implantation WD. The NRC agrees that an AU needs flexibility to change the definition of the treatment site based on the condition of the patient and imaging results obtained during the implant procedure. Further, based on other comments, the NRC removed the requirements to include, in the WD, the absorbed dose to normal tissue in § 35.40(b)(6)(i).

Comment: One commenter stated that the after implantation WD requirement in § 35.40(b)(6)(ii) is consistent with clinically relevant circumstances. However, the commenter believes that it would be appropriate to list the number of seeds purposely implanted outside "the prostate plus margin specified in the prescription," because this information will be needed when determining an ME.

Response: No change was made to the rule text based on this comment. The AU defines the treatment site in the WD in the way he or she believes to be medically appropriate,

including any margin. The AU may define the treatment site to include all tissues into which sources have been purposely implanted.

Comment: Two commenters supported the requirement in § 35.40(b)(6) for a two-part WD for permanent implant brachytherapy, with one part before implantation and a second part after implantation. One commenter stated that "documentation of the number of sources and total source strength is easily determined within 24 hours after implant completion."

Response: The comment supports language in the rule; therefore, no~~No~~ response is required~~;~~. ~~however~~However, the NRC notes that the ~~post~~ post-treatment WD has to be completed before the patient leaves the ~~post~~ post-treatment recovery area.

Comment: Two commenters supported the proposal to allow modification of the WD based on the medical situation encountered by the physician during the permanent implant brachytherapy procedure. One of the commenters noted that when modifications to the WD are medically necessary, these modifications should not constitute an ME.

Response: The comment supports language in the rule; therefore, no response is required.

Section 35.41 Procedures for administrations requiring a written directive

Comment: One commenter stated that the method and timing of the comparison in § 35.41(b)(6)(i) is unclear. The commenter noted that there is no requirement to include in the post-implantation WD the number of sources implanted outside the treatment site. The commenter believes that comparing the total source strength implanted outside of the treatment site with the total source strength implanted inside the treatment site is unreasonable because some sources may intentionally be implanted outside the treatment site as defined in the pre-implantation WD. The commenter suggested rewriting this section to clearly specify that the concern is errors in source placement, not sources outside the treatment site.

Response: No change was made to the rule text based on this comment. Section 35.41(b)(6)(i) requires a licensee to determine, within 60 days from the date the permanent brachytherapy implant was performed, 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. The AU defines the treatment site (as defined in § 35.2) in the WD in any way he or she believes to be medically appropriate. The AU may define the treatment site to include all tissues into which sources will be purposely implanted. Therefore, the total source strength implanted in unintended locations would be compared with the total source strength documented in the post-implantation portion of the WD.

Comment: One commenter stated that it appears reasonable in theory to determine absorbed dose to the maximally exposed 5 contiguous cubic centimeters of normal tissue. However, the commenter believes that it will be difficult to make this determination using current technology. The commenter stated that "planning systems typically report dose-volume histograms to structures, but they do not identify contiguous volumes."

Response: The rule text was modified based on this comment. The rule text in § 35.41(b)(6) was modified to remove § 35.41(b)(6)(ii) and (iii). The NRC acknowledges that while some treatment planning systems can identify contiguous volumes, others cannot. In response to this concern and concerns raised by other commenters, the NRC removed subparagraphs (ii) and (iii), which would have required the licensee to determine the absorbed dose to normal tissues located both outside and within the treatment site.

Comment: One commenter recommended modifying § 35.41(a) by adding:

"(3) After administration, a ME as defined in § 35.3045 has not occurred..."

Response: No change was made to the rule text based on this comment. The NRC determined that the recommended rule change is not necessary because § 35.41(b)(5) requires that at a minimum, the procedures required by § 35.41(a) include "[d]etermining if a medical

event, as defined in § 35.3045, has occurred."

Comment: Several commenters noted that the proposed regulation would apply to all permanent brachytherapy implants, including lung mesh procedures. They stated that licensees do not routinely perform dose assessments because the mesh is visually sewn to the lung in the prescribed location and the sources are not vulnerable to migration. The commenters recommended excluding lung mesh treatments from the requirements of § 35.41(b)(6).

Response: The rule text was modified based on this and other comments. The NRC recognizes the difficulty in determining the absorbed dose to normal tissues for treatments that use mesh material with permanent brachytherapy sources incorporated into the mesh. In response to this concern and those raised by other commenters, the NRC removed subparagraphs (ii) and (iii) in § 35.41(b)(6), which would have required the licensee to determine the absorbed dose to normal tissues located both outside and within the treatment site. The NRC retained § 35.41(b)(6)(i) to determine the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation WD for all permanent brachytherapy, including mesh procedures. The NRC retained this requirement because it is important to ensure that the use of the radionuclide is in accordance with the WD.

Comment: Several commenters stated that they support the requirement for performing a ~~post~~ post-implant dosimetric evaluation of each permanent brachytherapy implant within 60 days. However, there may be other obstacles to meeting this 60-day requirement, beyond patient unavailability, that should be added to the rule text. For example, one commenter noted that a machine may be broken and the facility may not have a backup, or the facility may have lost electricity because of a storm. The commenters suggested modifying the language in § 35.41(b)(6) to also allow written justification related to other factors "outside the control" of the licensee.

Response: No change was made to the rule text based on these comments. A 60-calendar-day time frame ensures that the licensee has ample time to make arrangements for the required determination in § 35.41(b)(6). If the licensee's imaging device malfunctioned or the facility lost electricity, it should be possible to refer the patient to another facility for the imaging study within the 60-day time frame. Further, in response to other comments, NRC re-evaluated the requirements for post-implant dosimetric evaluation to the normal tissue and has removed this requirement.

Comment: One commenter believes that the assessment of permanent brachytherapy implants described in § 35.41(b)(6) should be part of the medical evaluation of the treatment and not part of the procedures to provide high confidence that the administration is in accordance with the WD. The commenter also noted the difficulty in meeting this requirement, if it is retained, for permanent implants of certain large tumors. In these cases, a surgical procedure to remove part of the tumor may be performed shortly after the implant and this may result in intentional removal of many of the seeds. Post-implant removal of sources will change the dose to normal tissues. The commenter stated that the proposed regulation appears to require re-imaging to localize the remaining sources to perform the required assessment; however, it is unlikely that this additional assessment was intended.

Response: The rule text was modified in response to other comments. The NRC modified the rule text in § 35.41(b)(6) to remove the requirement to determine the absorbed dose to normal tissues located outside the treatment site and within the treatment site. The NRC retained the requirement to determine the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation WD. It is likely that most licensees will perform the determination of total source strength administered outside of the treatment site by performing an imaging study such as a computed tomography scan. If it is necessary to remove part of the tumor shortly after the implant, this

imaging study may be performed before the tumor removal.

Section 35.50 Training for Radiation Safety Officer and Associate Radiation Safety Officer

Comment: One commenter agreed with the changes in the T&E requirements for AUs, medical physicists, RSOs, and nuclear pharmacists. The commenter also supported the establishment of the ARSO because they believe it provides a pathway for more individuals to be RSOs and increases the number of preceptors available for future RSOs and ARSOs.

Response: The comment supports language in the rule; therefore, no response is required.

Comment: One commenter supported the inclusion of an ANP in the pathway to be identified as an ARSO on a medical license.

Response: The comment supports language in the rule; therefore, no response is required.

Comment: Several commenters supported the removal of the preceptor statement requirement for individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State and are applying to be named as an RSO, ARSO, ANP, AMP, or AU.

Response: The comment supports language in the rule; therefore, no response is required.

Comment: One commenter supported ARSOs being named on licenses and being able to serve as preceptors.

Response: The comment supports language in the rule; therefore, no response is required.

Comment: One commenter stated that the ARSO position created in the proposed rule does not create a new pathway for an individual to become an RSO. The commenter proposed

that the NRC create a new pathway for an individual to qualify as an RSO by relaxing the T&E requirements for an ARSO. This new pathway would require an individual to meet only the education requirements in § 35.50 to be named as an ARSO and then participate in a year-long training program. The commenter's expectation was that, at the end of the year-long training program, the ARSO would have gained proficiency in each of the areas listed in the regulations and could work independently and be qualified to be an RSO. The commenter also proposed that management would have the ARSO agree in writing to be responsible for implementing the radiation protection program.

Response: No change was made to the rule text based on this comment. The ARSO position created in the proposed rule does create a new pathway for an individual to become an RSO. An ARSO can become an RSO for the same types of use of byproduct material for which he or she was assigned duties and tasks as an ARSO on a medical license. This new pathway requires the same T&E for ARSOs as the current regulations for individuals seeking to be an RSO.

The commenter proposed adding a pathway for an individual to qualify as an RSO via the ARSO position. This proposed pathway is problematic because it would create a training program for an individual to become an ARSO without the individual meeting all the required T&E for an ARSO or an RSO. ~~This rulemaking had no intent~~The NRC does not intend for this rule to create a training program for an individual to become an ARSO who is not fully qualified to be an RSO. The NRC did not include a provision to require management to have the ARSO agree in writing to be responsible for implementing the radiation safety program because the RSO is responsible for the radiation safety program. The RSO may delegate tasks and duties to the ARSO but the final rule at § 35.24(b) states that the RSO "shall not delegate the authority or responsibilities for implementing the radiation protection program."

Comment: Two commenters recommended relaxing the qualifications for the ARSO to

allow on-the-job training while serving in an assistant or associate position.

Response: No change was made to the rule text based on these comments. The commenters' proposal would have resulted in recognition of an individual as an ARSO when the individual had not satisfactorily completed all the training and experience qualifications to perform his or her duties and tasks and could be recognized as an RSO at a later date. An ARSO may receive additional on-the-job training to expand his or her training and skills to apply for ARSO status for additional types of use.

Comment: One commenter asserted that the changes to the regulations would permit AUs to be RSOs. Doing so, according to the commenter, would weaken the position held by the RSO because a physician AU acting as the RSO is doing so as an additional duty. The commenter asserted that these RSOs were neither familiar with the regulations nor the recordkeeping requirements of a radiation safety program. The commenter further stated that if they made a mistake as an AU, it was often overlooked or corrected by simply re-writing a prescription for a particular treatment.

Response: No change was made to the rule text based on this comment. Current regulations recognize an AU as being qualified to be an RSO consistent with the AU's authorization and required radiation safety experience. This provision was unchanged in this rulemaking. The NRC expects that all AUs/RSOs take their responsibilities and obligations seriously and notes that AUs/RSOs should not overlook or "correct" errors by "simply re-writing a prescription for a particular treatment."

Comment: Several commenters opposed having an ARSO provide a preceptor attestation for an individual seeking to be named as an RSO. The commenters stated that an ARSO is only responsible for certain duties or limited sections of the program while the RSO is responsible for the entire radiation safety program. One commenter further recommended that an ARSO should only be permitted to provide a preceptor statement for an individual seeking to

be named as an ARSO.

Response: No change was made to the rule text based on these comments. For each medical use for which an ARSO is authorized, the T&E requirements are the same as that of an RSO. Further, the requirements for the preceptor are the same, regardless of whether they are an RSO or an ARSO. Therefore, an ARSO can be a preceptor for a potential RSO or an ARSO, but only for those uses for which the ARSO is authorized.

Comment: Two commenters recommended that AUs, ANPs, or AMPs be allowed to serve as RSOs on individual licenses for private practices (i.e. non-hospital sites).

Response: No change was made to the rule text based on these comments. The current regulations already allow AUs, AMPs, and ANPs to serve as RSOs on private practice licenses and other non-hospital medical facilities.

Comment: One commenter requested that the rule text in § 35.50(c)(1), (2), and (3) be consistent with respect to the description of the radiation safety experience and types of use to avoid confusion. The commenter pointed out that the text in paragraphs (c)(1) and (2) included "similar types of use" whereas paragraph (c)(3) implies the exact same types of use.

Response: The rule text was modified based on this comment. NRC agrees with the commenter that there should be consistency between the rule text in § 35.50 (c)(1) and (2). The rule text in paragraphs (c)(1) and (2) was changed to read "has experience with the radiation safety aspects of similar types of use of byproduct material for which the licensee seeks the approval of the individual as the Radiation Safety Officer or Associate Radiation Safety Officer." However, a similar change was not made to the rule text in § 35.50(c)(3). The provisions in § 35.50(c)(3) only address a new license application where the applicant is requesting that a qualified individual, who has not previously been named on a license, be named as both an AU and the RSO on the new license. The new license will authorize only those types of uses for which the proposed AU/RSO has T&E.

Comment: One commenter sought clarification on whether § 35.50(c)(3) applied to a new license with just one potential AU. The commenter believes that license reviewers would use paragraph (c)(3), as written in the proposed rule, to add the first AU/RSO and then process a separate licensing action to add other AUs.

Response: The rule text was modified based on this comment. NRC's intent in the proposed rule was for the provision in § 35.50(c)(3) to apply to a single physician applicant who was not yet authorized to be an AU and has requested to be both the AU and RSO. Based on the comment, NRC has broadened the provision in § 35.50(c)(3) to include an applicant for a new medical use license with multiple AUs who requests an individual, qualified but not yet recognized to be an AU, to be both an AU and the RSO on the new license.

Comment: One commenter asserted that the provisions in § 35.50(c)(2) were all that were needed in a rural setting to appoint an individual as both an AU and an RSO simultaneously, and § 35.50(c)(3) was not needed, unless § 35.50(c)(3) individuals are not subject to the requirements in § 35.50(d).

Response: The rule text was modified based on this comment. The rule text was revised to add a reference to § 35.50(d) in § 35.50(c)(3) based on both this and another comment. The provisions in § 35.50(c)(3) are distinctly different from the provisions of § 35.50(c)(2) and both can be used in rural areas. Section 35.50(c)(3) addresses only a new license where the physician whom the applicant is requesting to be named as an RSO has not yet been listed on a license as an AU. Section 35.50(c)(2) applies to a new application or amendment to an existing license where the applicant or licensee is requesting to identify an individual already identified as an AU, AMP, or ANP on a license or permit as the RSO. The individuals who meet the requirements in § 35.50(c)(2) or (c)(3) must also meet the requirements in paragraph (d) of this section.

Comment: One commenter stated that the provisions in § 35.50 in the proposed rule

could be interpreted two ways. Due to the word "and" between § 35.50(c)(3) and § 35.50(d), the provision in § 35.50(d) could be interpreted to apply to § 35.50(c)(3). Alternatively, the provision in § 35.50(d) could be interpreted to not apply to § 35.50(c)(3). The commenter stated that a revision is necessary to clarify whether or not paragraph (d) applies to (c)(3). The commenter also stated that if paragraph (d) does not apply to § 35.50(c)(3), this pathway would permit a large institution applying for a new license to have an RSO that did not demonstrate compliance with § 35.50(d).

Response: The rule text was revised based on this comment. The rule text was revised to add a reference to § 35.50(d) in § 35.50(c)(3). NRC agrees that § 35.50(d) applies to § 35.50(c)(3). Although the NRC intended to provide a pathway for a single practice physician, if a medical institution wants to apply for a Part 35 medical use license by adding a physician (who is qualified but not yet authorized as an AU) to be both an AU and the RSO, then the institution could also use the provisions of § 35.50(c)(3) to obtain a medical use license. Note that once a hospital has obtained a medical use license, the provisions of § 35.50(c)(3) no longer apply because they only apply to new licenses.

Comment: One commenter stated that the rule text in § 35.50(c)(3) appeared to be "backward" and suggested that the paragraph should read "Is an individual who is seeking simultaneous approval both as the Radiation Safety Officer and the AU on the same new Commission or Agreement State license and who has experience with the radiation safety aspects of the types of use of byproduct material for which the individual has Radiation Safety Officer responsibilities."

Response: No change was made to the rule text based on this comment. Starting the paragraph with "Is an individual who..." would result in redundant language because § 35.50 reads "Except as provided in 35.57, the licensee shall require an individual ...to be an individual who - ...(c)(3)." Additionally, because the individual has not yet been identified as an AU or

RSO, the individual does not yet have the responsibilities of a RSO.

Comment: One commenter stated that the ARSOs should be fully trained to manage the radiation safety program issues for all modalities authorized on the license. This would simplify the license in that specialty areas of use would not have to be listed and amendments would not be needed for changes to ARSO specialty areas. The ARSO would be ready to replace the RSO with only the delegation of authority letter from management needed to qualify the ARSO as RSO.

Response: No change was made to the rule text based on this comment. Limiting the ARSO designation ~~for~~ to only those individuals that have T&E in all the medical types and uses on the license would not permit individuals with T&E for some of the medical types of use on the license to be recognized as ARSOs. The NRC disagrees with the commenter's assertion that the individuals should be trained for all modalities so that they could be ready to replace the RSO. A trained individual is not necessarily qualified to be the RSO; the individual would also need to meet the experience requirements. Additionally, the NRC disagrees with the commenter's assertion that only ~~the~~ a delegation of ~~an~~ authority letter is needed for the ARSO to become an RSO. Only a regulator can name an individual as the RSO on a license.

Comment: One commenter agreed with the proposed addition of ARSOs but requested a requirement that the ARSO's performance and level of activity be reviewed on an annual basis by the licensee's RSO or Radiation Safety Committee. The commenter believed this would ensure that only the active ARSOs with recent experience are listed on the license.

Response: No change was made to the rule text based on this comment. The requirement in § 35.14(b) for a licensee to notify NRC no later than 30 days after an ARSO permanently discontinues performance of duties as an ARSO is adequate without adding a prescriptive requirement to annually review the performance of the ARSO.

Comment: One commenter believed the T&E of the ARSO should be designated as

Compatibility Category "C." This would give the state program the flexibility to more effectively monitor the roll out of this new provision without adversely affecting either the individuals seeking ARSO listing/approval or the licensees.

Response: No change was made to the ~~compatibility~~ Compatibility ~~level~~ Category for the ARSO training and experience requirements. The NRC has determined that § 35.50 is a Compatibility Category B because T&E requirements have "significant direct transboundary implications." Assistant RSOs might not meet the requirements to be an ARSO. Therefore, they may not be automatically listed as an ARSO on a license. Individuals named as assistant RSOs on a state license may continue to work as an assistant RSO on that license, but will be required to meet the requirements in §§ 35.50 and 35.51 if they would like to be named as an ARSO.

Comment: Two commenters supported the establishment of an ARSO, but the commenters believed the NRC overemphasized the need to provide more preceptors. The commenters stated that the more important reason for establishing an ARSO is to recognize more qualified individuals and increase the pool of RSOs. One of the commenters further stated that many states have had ARSOs or similar individuals or multiple RSOs on a license for many years and this has not caused problems.

Response: No change was made to the rule text based on these comments. The NRC recognizes that the increase in the number of individuals meeting the qualifications in § 35.50 and being recognized as ARSOs both increases the number of individuals recognized as meeting the qualifications for being RSOs and the number of available preceptors. NRC continues to require that only one RSO be listed on each medical use license because that is the individual responsible for the day-to-day oversight of the entire radiation safety program.

~~*Comment:* One commenter noted that Agreement States have had ARSOs (or a similarly named entity) or multiple RSOs listed on the same license for many years with no~~

Commented [SGB1]: This appears to be the same comment noted in the last sentence of the comment summary above.

~~adverse effects or consequences.~~

~~*Response:* The comment supports language in the rule; therefore, no response is required.~~

Section 35.55 Training for an authorized nuclear pharmacist

Comment: One commenter asserted that specialized residencies in pharmacy practice are available and more are emerging, including nuclear pharmacy practice residency programs. The commenter provided a web site for the American Society of Health-System Pharmacists residency directory, which contains an online directory of pharmacy residency programs, in support of this assertion. The commenter recommended amending § 35.55(b)(2) to read:

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 nuclear pharmacist.

The attestation must be obtained from either:

(i) A preceptor authorized nuclear pharmacist who meets the requirements in § 35.57, or 35.55, 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 nuclear pharmacist who meets the requirements in § 35.57 or 35.55 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 Commission on Credentialing of the American Society of Health-System Pharmacists and must include training and experience specified in § 35.55(b)(1).

The recommended amendment would add provisions that would allow the residency program director to provide an attestation to the T&E requirements for an ANP similar to those

provisions added for an AU, AMP, and RSO.

Response: No change was made to the rule text based on this comment. The NRC reviewed the American Society of Health-System Pharmacists residency directory at the provided Web site. The residency directory included residency programs in the United States and two foreign countries. The Web site lists only one nuclear pharmacy residency program in the United States. Other residency programs included in Part 35 have been accredited by either the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Council on Postdoctoral Training of the American Osteopathic Association. The Commission on Credentialing of the American Society of Health-System Pharmacists has not been evaluated by the NRC to determine if this accreditation group is equivalent to the accreditation groups listed above, and to do so would be beyond the scope of this rulemaking. Therefore, the nuclear pharmacy residency program has not been included in this rulemaking. The commenter may submit its recommendation to the NRC as a petition for rulemaking under 10 CFR 2.802.

Comment: One commenter recommended that the NRC recognize structured nuclear pharmacy training programs, sometimes referred to as certificate programs, by amending 35.55(b)(2) to provide:

> (iii) A program director of a structured nuclear pharmacy training program who affirms in in [sic] writing that the attestation represents the consensus of the training program faculty where at least one faculty member is an authorized nuclear pharmacist who meets the requirements in § 35.57 or 35.55 or equivalent Agreement State requirements and concurs with the attestation provided by the program director. The nuclear pharmacy training program must be part of a College or School of Pharmacy that is accredited by the Accreditation Council for Pharmacy Education.

This recommended amendment would permit program directors of these programs to sign the

preceptor statement when certain conditions, similar to the medical residency criteria, are met. The commenter also stated that the nuclear pharmacy training program must be part of a College or School of Pharmacy and accredited by the Accreditation Council of Pharmacy Education.

Response: No change was made to the rule text based on this comment. The regulations permit a pharmacist to be recognized as an ANP as long as the § 35.55 T&E requirements are met. Therefore, if the pharmacist receives his or her training from a nuclear pharmacy training program in a college or school of pharmacy that meets this criterion, the pharmacist can be recognized as an ANP. The NRC has not had an opportunity to evaluate the Accreditation Council of Pharmacy Education's nuclear pharmacy educational programs, and to do so would be beyond the scope of this rulemaking. The commenter may submit its recommendation to the NRC as a petition for rulemaking under 10 CFR 2.802.

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

Comment: Several commenters supported the revision of § 35.57 to recognize individuals certified by the boards named in the previous Subpart J of 10 CFR part 35 for the modalities that they practiced as of October 24, 2005.

Response: The comment supports language in the rule; therefore, no response is required.

Comment: One commenter requested clarification on the type and extent of documentation an individual will need to produce to demonstrate that he or she was practicing certain modalities prior to 2005 in order to meet the requirements in § 35.57.

Response: No change was made to the rule text based on this comment. The NRC

provides T&E guidance in NUREG-1556, Vol. 9 "Consolidated Guidance about ~~materials~~ Materials ~~licenses~~Licenses: ~~Program~~ Program-Specific Guidance about Medical Use Licenses." This NUREG provides information for meeting the requirements in § 35.57. Because each situation is unique, the applicant's submitted documentation will need to be evaluated on a case-by-case basis.

Comment: One commenter stated that the proposed additional dosage category at § 35.390(b)(1)(ii)(G)(*4*) for the medical use of alpha-emitting radionuclides such as Radium-223 dichloride would result in an unintended consequence. Specifically, an AU currently authorized to use Radium-223 dichloride would be required to have additional work experience to be authorized for parenteral use of radiopharmaceuticals used primarily for their alpha-emitting characteristics under § 35.390(b)(1)(ii)(G)(*4*). The commenter requested that, if the NRC retained the additional proposed dosage category, that the NRC amend the date in § 35.57(b)(1) and (2) from October 24, 2005, to December 31, 2014, or a later date, to grandfather such individuals.

Response: The rule text was modified based on a recommendation from the ACMUI. The effective date of the grandfathering provisions in the rule text in § 35.57(b)(1) is changed from October 24, 2005, to the effective date of the rule. The commenter is correct that, as proposed, the rule text would not permit an AU currently administering Radium-223 dichloride to be authorized to use it after the effective date of the rule, and that was not the intent of the NRC. The final rule grandfathers all AUs authorized for medical uses, including Radium-223 dichloride, on the effective date of the rule to continue to be able to administer it after the rule becomes effective without needing to reapply for authorization under the new requirements in §§ 35.390 or 35.396. However, no change was made to the rule text in § 35.57(b)(2) because this section pertains only to those individuals certified by boards recognized in Subpart J.

Note that § 35.390(b)(1)(ii)(G)(*4*) was deleted and provisions within that section have

been incorporated within § 35.390(b)(1)(ii)(G)(*3*) based on other comments. Therefore, the category "parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its alpha radiation characteristics, for which a written directive is required" is now included in § 35.390(b)(1)(ii)(G)(*3*). After reviewing the ACMUI final recommendations on the revised part 35 rule, the NRC has determined that an additional three cases of administering dosages of radioactive drugs for alpha-emitting radiopharmaceuticals for parenteral administration is not necessary.

Comment: Two commenters support the concept of grandfathering the RSO, medical physicist, teletherapy physicist, AMP, AU, nuclear pharmacist, and ANP. However, the commenters stated that the date of certification does not have an impact on an individual's qualifications to perform the duties of an RSO and they do not agree with limiting the grandfathering provisions to "those materials and uses that these individuals performed on or before October 24, 2005." The commenters believe the continuing education requirements for periodic certification renewal assures that the individual remains qualified. Thus, all board certified individuals, regardless of the date of their initial certification, are equally qualified to be named as an RSO or ARSO and that the initial certification date is immaterial to one's present technical expertise.

Response: No change was made to the rule text based on these comments. The board certification pathway includes not only the requirement to be certified but also that the individual has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval. That is why the grandfathering provisions for the RSO include the phrase "those materials and uses that these individuals performed on or before October 24, 2005." The NRC retained the date of October 24, 2005, because that was the expiration date of the prior T&E requirements (Subpart J).

Comment: Several commenters supported the grandfathering of board-certified

individuals but requested the rule text be changed from "for the modalities that they practiced on or before October 24, 2005," to the ACMUI-recommended language "for the uses [or procedures] covered by their board certification on October 24, 2005." These commenters stated that the ACMUI language would eliminate any potential uncertainty concerning what the term "practiced" means.

Response: No change was made to the rule text based on these comments. In the Ritenour Petition, the petitioner requested that the NRC grandfather individuals certified by boards listed in Subpart J for the modalities that they practiced as of October 24, 2005. Further, the board certification pathway includes not only the requirement to be certified but also that the individual has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval. Therefore, it is necessary to identify the modalities that the individual performed and not "the uses [or procedures] covered by their board certification."

Comment: Two commenters supported the revisions to § 35.57 with respect to the Ritenour Petition. However, the commenters stated that the preceptor statements should not be required for those individuals requesting to be grandfathered under the provisions of § 35.57.

Response: No change was made to the rule text based on these comments. The revised rule text in §§ 35.50, 35.51, 35.55, 35.190, 35.290, 35.390, 35.392, 35.394, 35.490, 35.590, and 35.690 also applies to board-certified individuals under § 35.57 and does not require preceptor statements for individuals who are qualified to be authorized under the board certification T&E requirements.

Comment: Two commenters requested that individuals meeting the board certification requirements in § 35.57(a)(2), (a)(3), and (b)(2) must be immediately grandfathered because the NRC failed to respond to the Ritenour Petition in a timely manner. Further, the commenters stated that these individuals should not have to fulfill the burdensome "alternate pathway" or

preceptor attestation if they wish to become authorized on a license, but have not been so named by an NRC or Agreement State license.

Response: No change was made to the rule text based on these comments. NRC recognizes that individuals may not have been listed on a license but were practicing certain modalities on or before October 24, 2005. Individuals meeting the board certification requirements in § 35.57 have to provide evidence that they practiced the modalities for which they are seeking authorized status and may also have to provide evidence of continuing education and experience if it has been more than 7 years since their certification. Individuals being grandfathered under the provisions of § 35.57(a)(2), (a)(3), and (b)(2) do not need preceptor attestations and do not need to meet the training requirements of the alternate pathway.

Comment: Two commenters requested that the NRC consider removing dates from the board certification requirements for the currently recognized boards, as well as the boards affected by the Ritenour Petition. They based the request on their assertion that there has not been any evidence of an ME or regulatory violation before 2005 or since that has demonstrated, or even suggested, that the year of board certification has any association with better or worse regulatory compliance or radiation safety.

Response: No change was made to the rule text based on these comments. NRC is retaining the board certification dates for all boards recognized under the requirements in 10 CFR part 35. This is because the boards change their certification processes; no longer certify individuals for life; and, in some cases, only guarantee the certification status for a few years requiring verification of the current certification status of its diplomates. Further, the NRC does not require reporting of the board certification status of an individual associated with an ME or a violation of NRC requirements.

Section 35.65 Authorization for calibration, transmission, and reference sources

Comment: One commenter noted that the explanation for the proposed changes for § 35.65 in the *Federal Register* notice stated that there were two new paragraphs whereas the text contained three new paragraphs.

Response: The NRC agrees with the commenter's observation. Section VI, Section-by-Section Analysis, of this document indicates that. ~~T~~ three new paragraphs were added to § 35.65.

Comment: One commenter stated that the transmission sources should be removed entirely from §§ 35.65 and 35.500 and should be placed in § 35.200. Additionally, the commenter stated that the use of spot markers/anatomical markers should be added to § 35.200 because they are used on patients and are not used for instrument calibration purposes. The commenter explained that transmission sources, unlike sources currently in § 35.500, are not used to render a diagnosis and are not consistent with that category of use. The commenter agreed with the NRC that materials authorized by § 35.65 should be prohibited for human use but went further to say that sources authorized by § 35.65 should be limited to only non-human use including calibration and reference sources for instrument/equipment calibration and testing. The commenter further recommended that the text proposed in § 35.500 should be edited and moved to § 35.200.

Response: No change was made to the rule text based on this comment. The final rule clarifies that some sealed sources authorized under § 35.65 may be used under both §§ 35.65 and 35.500. Furthermore, sources that meet the § 35.65 criteria are not required to be listed on a license when they are used under the provisions of § 35.500. The NRC considers the use of a transmission source to be diagnostic medical use when a patient is exposed to its radiation. Additionally, § 35.200, which authorizes the medical use of unsealed byproduct material, is not the appropriate section for sealed sources.

Comment: Several commenters stated that referring to § 35.500 in the proposed rule text in § 35.65 was confusing. They recommended that the phrase "except in accordance with the requirements in § 35.500" be removed from § 35.65 (b)(1). They stated that the sources in § 35.65 do not need to be listed on a license but the current regulation in § 35.500 requires that sources and users be listed on a license. Furthermore, the commenters stated that sources in § 35.65 are to be used for reference, transmission, and calibration, but sources in § 35.500 are to be used for diagnosis.

Response: No change was made to the rule text based on these comments. The rule text was not changed because removal of the phrase "except in accordance with the requirements in § 35.500" would change paragraph (b)(1) to read that the byproduct material authorized under § 35.65 would not be permitted for medical use. For example, removing this text would prohibit the use of a transmission source when a patient is exposed to its radiation, which is a diagnostic medical use.

Comment: One commenter noted that it listed transmission sources and transmission source devices on medical use licenses. It was "unaware of any circumstances in which a licensee bundled sources currently authorized by 35.65 (individual source activity limit) in aggregation that are not listed or approved in the SS&D registry." The commenter stated "that the proposed rule should be modified to clearly distinguish authorization for medical use and instrument calibration."

Response: No change was made to the rule text based on this comment. The commenter noted correctly that licensees cannot use sealed sources in a manner inconsistent with the sealed source and device registry (SSDR). The SSDR does not prohibit the "bundling" of sealed sources to create a ~~larger~~ greater source activity, but § 35.65 limits the activity of each sealed source authorized under this section. Some licensees have interpreted § 35.65 incorrectly to mean that these sealed sources could be bundled to create an aggregated source

with a ~~larger~~ greater activity than is allowed. The rule change makes it clear that the maximum activity authorized by § 35.65 applies to all sealed sources whether used singularly or in a bundled configuration.

The NRC reviewed the rule language and believes it is clear that when sealed sources are used as part of a diagnostic medical procedure, these uses are authorized under § 35.500. Possession of the sources may be authorized under § 35.65, but medical use of the sources is only authorized under § 35.500. For example, a transmission source may be possessed under § 35.65, but can only be used as part of a medical diagnostic procedure under § 35.500.

The following comments were common to the Training and Experience Requirements in Sections 35.51, 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.490 and 35.690

Comment: Several commenters agreed with the NRC's proposal to remove the preceptor attestation requirements for individuals seeking authorized status via the board certification pathway.

Response: The comment supports language in the rule; therefore, no response is required.

~~No response is required.~~

Comment: Several commenters agreed with the proposed change to the attestation language from "achieved a level of competency to function independently" to "verify that the individual can independently fulfill the radiation safety-related duties" for those individuals applying through the alternate pathway. They further stated that the term "competency" has certain implications and liabilities in the medical domain which should not factor into an attestation statement, which is meant to assure regulators that the individual received an adequate amount of radiation safety-specific T&E.

Response: The comment supports language in the rule; therefore, no response is required.

~~No response is required.~~

Comment: One commenter noted that based on the revision to the T&E requirements, an individual who is board certified will no longer need a preceptor attestation to become an AU or AMP. Further, the commenter noted that the argument for this change is that some preceptors have been reluctant to attest due to concerns related to personal liability based on possible future actions of the proposed AU or AMP. The commenter stated that if someone truly has these reservations, there may be a good reason they are not willing to sign off on the attestation.

Response: No change was made to the rule text based on this comment. The NRC believes that certification by a specialty board coupled with the recentness of training requirements in 35.59 and, as appropriate, the requirements in 35.50(d), 35.51(c), 35.390(b)(1)(ii)(G), or 35.690(c) is sufficient to demonstrate that the individual seeking authorization on a license has met the T&E requirements in the board certification pathway. NRC concluded that these three elements show the individual has the requisite knowledge and that an additional attestation is not necessary. For the non-board certified applicants, the attestation requirement is retained but the attestation language is revised in response to concerns that preceptors are reluctant to sign preceptor attestations due to personal liability concerns.

Comment: Two commenters endorsed retaining the attestation requirement for those individuals pursuing initial board certification (but not yet certified) and alternate pathways. The commenters stated that retaining the preceptor attestation helps ensure accountability and credibility by clearly identifying an AU who can attest that the individual has satisfactorily completed the required NRC training.

Response: The comment supports language in the rule; therefore, no response is required.

Comment: One commenter pointed out that the correct terminology for the American Osteopathic Association residency approval organization is the "Council on Postdoctoral Training."

Response: The rule text was modified based on this comment. The rule text is changed to replace the "Committee on Post-Graduate Training" with the phrase "Council on Postdoctoral Training."

Comment: One commenter supported permitting residency program directors to provide attestations based on the consensus of the residency faculty.

Response: The comment supports language in the rule; therefore, no response is required.

Comment: One commenter recommended that the NRC recognize the Nuclear Medicine Advanced Associate (NMAA) position as an AU for § 35.100 and § 35.200 medical uses. The commenter described the NMAA as a physician extender in Nuclear Medicine who has been trained at the master's level, tested, and board certified in advanced nuclear medicine practice. The commenter stated that "[t]he nuclear medicine advanced associate prescribes and administers pharmacologic and non-pharmacologic interventions under the direction of the supervising physician and, as indicated by patient profile and diagnostic procedure as allowable by state and federal statutes, which includes, but is not limited to:

1. Perform pre-procedure requirements and interventions as may be required.

2. Perform intra-procedure requirements as may be required.

3. Perform post-procedure requirements as may be required."

The commenter clarified that, as with other physician extenders, i.e., physician assistants and nurse practitioners, NMAA's are allowed to prescribe substances that are

allowed under the scope of their practice, such as radiopharmaceuticals. The commenter believes that this opens the pathway for physician extenders in nuclear medicine to become authorized users, just as physician assistants and nurse practitioners are allowed to prescribe medications on behalf of their supervising physicians. The commenter believes that the training and practical experience of NMAAs creates ideal candidates for AUs and that the NMAA has met the qualifications required under § 35.200 to become AUs. The commenter concluded that the NRC should also recognize their board certification (Nuclear Medicine Technology Certification Board (NMTCB)) under §§ 35.190 and 35.290. The commenter recommended that NMAAs be added to the candidates for authorized user for radioactive byproduct materials use for uptake, dilution, excretion, imaging and localization and that their board certification be added to NRC recognized boards. The commenter proposed specific rule text to accomplish this.

Response: No change was made to the rule text based on this comment. The comment is outside the scope of this rulemaking. Currently, an AU under § 35.190, "Training for uptake, dilution, and excretion studies," or § 35.290, "Training for imaging and localization studies," must be "a physician." An AU is defined at § 35.2 as "a physician, dentist, or podiatrist who..." and a physician is defined as "a medical doctor or doctor of osteopathy licensed...to prescribe drugs in the practice of medicine." AU recognition under §§ 35.190 and 35.290 is currently limited to physicians because these T&E requirements and board recognition criteria are premised on the high level of education and training obtained by medical doctors and doctors of osteopathy who are licensed to practice medicine. These T&E requirements are not premised on the level of education and training obtained by physician extenders or assistants. These T&E requirements ensure that AUs use byproduct material for medical purposes in a way that is radiologically safe for workers, patients, and the public. The change that the commenter requests would require the NRC to consider whether it is acceptable, from a radiological health and safety standpoint,

to permit physician extenders or assistants such as NMAAs to be eligible to become AUs. Such a change is outside the scope of this rulemaking. Moreover, before making any such change, the NRC would need to carefully consider the radiological health and safety issues attendant to such a change and consult with the ACMUI. Although the commenter's recommendation is outside the scope of this rulemaking, the commenter may submit a petition for rulemaking on this issue pursuant to 10 CFR§ 2.802.

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

Comment: Several commenters agreed with the proposed changes to measure every elution. One commenter noted that the new elution requirements are already included in standards of practice and manufacturer recommendations.

Response: The comment supports language in the rule; therefore, no response is required.

Comment: One commenter noted that Tc-99m decays much faster than Mo-99; therefore, every Tc-99m generator eluate will eventually exceed the regulatory limit. Because of this, the commenter stated that the language in the proposed rule text would require every eluate to be reported. The commenter proposed revising the rule text in § 35.204(e) to clarify that the licensee would only report measurements of a Tc-99m generator elution that exceeded the regulatory limits at the time of generator elution.

Response: The rule text was modified based on this comment. The NRC agrees with the commenter that the proposed rule text was not clear in § 35.204(e) and has amended it to clarify that the reporting requirements only apply at the time of generator elution.

Comment: One commenter stated that on two occasions in the last 10 years its generator elution measurements exceeded the regulatory limit, but on subsequent elutions, the

measurements were below the limit. The Tc-99m from these subsequent elutions was used for patients. The commenter recommended that the reporting requirement of § 35.204 be revised to require a licensee to report to the NRC and the manufacturer or the distributor of medical generators within 30 days when "consecutive measurements on the same generator" exceed the limits specified in § 35.204(a).

Response: No change was made to the rule text based on this comment. The commenter suggested changing the regulation to require consecutive measurements on the same generator to exceed the regulatory limits before reporting the failure. The ratio of Mo-99 to Tc-99m measured in any eluate intended for patient use must never exceed the regulatory limits. Because safety of patients is paramount, reporting any failure to the NRC and manufacturer/distributer allows for determinations to be made and actions to be taken to prevent similar occurrences. If any eluate measurement exceeds the regulatory limit, the generator should be removed from service until the cause is determined.

Comment: One commenter suggested revising § 35.204(b) to remove the phrase "after receipt" in the proposed requirements to measure the eluate from the generator in order to demonstrate compliance with the regulations because measuring the eluate after receipt of the generator is already implied.

Response: ~~No change was made to the rule text based on this comment. The purpose of the requirement for the eluate to be measured from the generator after it is received is to ensure that the eluate is measured by the user of the generator and not predetermined by the manufacturer or distributor. Although the commenter asserted that it is implied that the measurement of Mo-99 concentration is made after a generator is received, for clarity the phrase "after receipt" is retained~~The rule text was modified based, in part, on this comment. The rule text was changed to delete "after receipt" in §35.204(b). The previously proposed language could be subject to misinterpretation by the regulated community and, as suggested

by the commenter, measuring the eluate after receipt of the generator is already implied. Deletion of "after receipt" more clearly describes the intent of this change to the regulation that each and every eluate intended for medical use of each generator must be tested for breakthrough.

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

Comment: One commenter questioned the statement about § 35.300 in the "Discussion of Proposed Amendments by Section" in the *Federal Register* notice for the proposed rule. The statement was that an AU may be authorized for one or more of the specific categories described in 10 CFR 35.390(b)(1)(ii)(G), but not for all unsealed byproduct material. The commenter specifically wanted to know what other unsealed therapeutic byproduct material is referenced and why a trained and experienced AU could not be authorized for all unsealed therapeutic byproduct material.

Response: No change was made to the rule text based on this comment. ~~The NRC is ensuring that a~~Any new unsealed byproduct material requiring a WD ~~which~~ that is not ~~included~~ specifically addressed in § 35. 390(b)(1)(ii)(G) ~~will~~ would be regulated under the provisions of § 35.1000. This allows the NRC to evaluate each new radionuclide for possible unsealed byproduct material use and determine whether it falls within the scope of § 35. 390(b)(1)(ii)(G) or instead should be regulated under the provisions of § 35.1000.

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

Comment: One commenter suggested the elimination of the attestation requirement for physicians meeting the "alternate pathway" T&E criteria in § 35.390(b) as was done for the

"board certification pathway" under § 35.390(a).

Response: No change was made to the rule text based on this comment. The NRC is retaining the attestation statement requirement for individuals authorized under the "alternate pathway" provisions. This is because it is important to know that the individual not only successfully completed the T&E requirements but is also able to independently fulfill the radiation safety-related duties of an AU.

Comment: One commenter believed the use of the word "radiopharmaceutical" in the introduction section of § 35.390(b)(1)(ii)(G) and the phrase "any radionuclide" in the parenteral administration regulations (i.e., § 35.390(b)(1)(ii)(G)(*3*) or (b)(1)(ii)(G)(*4*)) ~~were~~ was confusing and would permit the use of a radionuclide that is not a component of a radiopharmaceutical. The commenter used the example of yttrium-90 (Y-90) microspheres containing the radionuclide Y-90. The commenter recommended revising the wording in § 35.390(b)(1)(ii)(G)(*3*) and (b)(1)(ii)(G)(*4*) to say, "Parenteral administration of any radioactive drug...."

Response: The rule text was modified based on this and other comments. The rule text was changed to include the phrase "radioactive drug that contains a" in § 35.390(b)(1)(ii)(G)(*3*). The NRC agrees that the proposed language could be clearer. Additionally, based on a recommendation from the ACMUI, the NRC deleted § 35.390(b)(1)(ii)(G)(*4*) and included radioactive drugs primarily used for their alpha characteristics in § 35.390(b)(1)(ii)(G)(*3*).

Comment: One commenter stated that both the current and proposed categories in § 35.390(b)(1)(ii)(G)(*3*) and (*4*) are confusing. The commenter asked what the purpose is for specifying the 150 keV limit in category (*3*). The commenter stated that if there is a new use for a photon emission greater than 150 keV then there is no provision for it under the regulations.

Response: No change was made to the rule text based on this comment. The NRC believes it is unlikely that there will be a radioactive drug requiring a WD that will be used *primarily* for its photon energy greater than 150 keV. However, as stated in §

35.390(b)(1)(ii)(G), any radioactive drugs not included in paragraph (G) would be regulated under the provisions of § 35.1000.

Comment: One commenter stated that § 35.390(b)(1)(ii)(G)(*4*) would require an AU currently authorized under § 35.390(b)(1)(ii)(G)(*3*) to administer radium-223 dichloride to obtain additional work experience, unless revisions are made to § 35.57. The commenter stated that these physicians do not need additional training to use materials for which they are already authorized.

Response: The rule text was modified based on a recommendation from the ACMUI. The NRC revised § 35.57(b)(1) to grandfather physicians for those medical uses for which they were authorized prior to the effective date of the rule. Also, the NRC deleted § 35.390(b)(1)(ii)(G)(*4*) and included radioactive drugs primarily used for their alpha characteristics in § 35.390(b)(1)(ii)(G)(*3*). These changes ensure that physicians already using Ra-223 dichloride at the time the rule becomes effective are permitted to continue use of the radioactive drug.

Comment: Several commenters questioned the purpose of the proposed paragraph (c) in § 35.390 that applied only to parenteral administrations. They questioned how a physician could be an AU under the provisions of § 35.390 without completing the I-131 cases listed in 35.390(b)(1)(ii)(G). The commenters questioned whether paragraph (c) should be moved to § 35.396.

Response: The rule text was modified based on these and other comments. Section 35.390(c) was removed in the final rule because § 35.390(b)(1)(ii)(G)(*3*) and (*4*) was merged into one category of parenteral administrations of radioactive drugs in the final rule in response to a recommendation from the ACMUI. Section 35.390(c) was no longer needed with this revision in the final rule. Section 35.390(b)(ii)(G) now has three separate categories of radioactive drugs, and a proposed AU is evaluated and authorized for each category separately.

The NRC recognizes that individuals that are board certified or have completed the other T&E criteria under § 35.390 may not have completed their supervised work experience administering all the categories of radioactive drugs in § 35.390(b)(1)(ii)(G). These individuals will be authorized for only those categories for which they have completed their T&E.

Comment: Several commenters opposed the proposed new dosage category for alpha emitters under 10 CFR 35.390(b)(1)(ii)(G)(*4*) because it would require physicians authorized for the parenteral administration of radioactive drugs containing radionuclides used primarily for their electron emitters or for its photon energy of less than 150 keV to have additional work experience involving dosage administrations in a minimum of three cases to attain AU status. The commenter pointed out that under the proposed regulations, those seeking to administer both types would need work experience in a minimum of six cases of administration, three with alpha emitters and three with beta emitters. The commenter referenced the ACMUI recommendation not to separate the parenteral administration of beta and gamma-emitting radiopharmaceuticals from the alpha-emitting radiopharmaceuticals. The commenter also stated that according to the ACMUI, the NRC staff has not provided a compelling radiation safety justification for emission-specific T&E requirements.

Response: The rule text was modified based on a recommendation from the ACMUI. Section 35.390(b)(1)(ii)(G)(*4*) was deleted and provisions within that section have been incorporated into § 35.390(b)(1)(ii)(G)(*3*). The category "parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its alpha radiation characteristics, for which a written directive is required" is now included in § 35.390(b)(1)(ii)(G)(*3*). The NRC has determined that an AU who is authorized under § 35.390(b)(1)(ii)(G)(*3*) would not need three additional cases to administer alpha-emitting radioactive drugs.

Comment: One commenter believed NRC's separation of categories in §§

35.390(b)(ii)(G)(*3*) and 35.390(b)(ii)(G)(*4*) based on the primary emission used for medical use was not the best approach. The commenter cited Lutetium-177 as an example of a radionuclide with a significant gamma emitting branch with energy exceeding 150 keV. The commenter proposed the distinction be based on the prevalence of gamma emissions greater than 150 keV. The commenter's proposal was to modify 35.390(b)(ii)(G)(*3*) to read, "Parenteral administration for which a written directive is required of any radionuclide which emits a photon with energy greater than 150 keV in less than or equal to 10% of all decays, or of any less than 1.0 GBq (27 mCi) of any other radionuclide;" and modify 35.390(b)(ii)(G)(*4*) to read, "Parenteral administration for which a written directive is required of 1.0 GBq (27 mCi) or more of any radionuclide which emits a photon with energy greater than 150 keV in more than 10 percent of all decays." The commenter concluded that most, if not all alpha emitters, would be in the newly defined category 3 and be consistent with the placement of radium-223 dichloride.

Response: No change was made to the rule text based on this comment. The commenter provided an alternative approach for categorizing various radioactive drugs for parenteral administration, but the NRC believes that the categorization is better delineated based upon the most clinically effective emissions of the radioactive drug requiring a WD. The commenter's proposal would result in implementation difficulties without a commensurate increase in safety. Further, the NRC deleted § 35.390(b)(1)(ii)(G)(*4*) and included radioactive drugs primarily used for their alpha characteristics in § 35.390(b)(1)(ii)(G)(*3*).

Comment: One commenter recommended eliminating the separate dosage category used primarily for alpha emitters. The commenter suggested that if a new radioactive drug became available that was more hazardous than radium-223 dichloride and warranted additional radiation safety regulatory requirements, then NRC could license it under the provisions of 10 CFR 35.1000.

Response: The rule text was modified based on a recommendation from the ACMUI.

The NRC deleted § 35.390(b)(1)(ii)(G)(*4*) and included radioactive drugs primarily used for their alpha characteristics in § 35.390(b)(1)(ii)(G)(*3*). The NRC anticipates that all radioactive drugs that will be used for their alpha-emitting characteristics can be regulated under § 35.390(b)(1)(ii)(G)(*3*). However, the NRC may regulate radionuclides under § 35.1000 as appropriate.

Comment: One commenter noted that NRC regulations are designed to provide flexibility for emerging technologies and could be adjusted to recognize that alpha and beta emitters are a new class of therapeutic radiopharmaceutical products. The commenter referenced Radium-223 dichloride and a potential new actinium alpha emitter. The commenter suggested that the NRC should create a new T&E requirement specific to therapeutic radiopharmaceuticals based upon their unique characteristics, typical setting for administration, and safety record (such as was done for sodium iodide I-131 at §§ 35.392 and 35.394). The NRC could give license applicants an option to petition NRC for review under § 35.1000 for a drug that technically fits within the four categories listed in § 35.390(b)(1)(ii)(G), but is deserving of an individualized T&E requirement review, due to its administration profile and safety characteristics.

Response: No change was made to the rule text based on this comment. The NRC's regulations under § 35.1000 allow the NRC to determine when a particular medical use of byproduct material or radiation from byproduct material should be regulated under § 35.1000. In accordance with §35.12(d), the NRC will license a new radionuclide under § 35.1000 if it has unique properties that prohibit it from meeting existing requirements or if additional requirements are needed for safety. When a radionuclide is licensed under § 35.1000, specific T&E requirements are included in the licensing guidance for that particular radioactive drug.

Comment: Several commenters stated it would be difficult for AUs to get the additional supervised work experience associated with three cases using radioactive drugs containing

radionuclides used primarily for their alpha emissions. One commenter pointed out that there is only one FDA-approved alpha-emitting radioactive drug and that it is used in a limited population. Several other commenters stated that patients who do not live near teaching hospitals and urban centers may have limited access to radioactive drugs in the two parenteral categories. Certain practitioners, particularly those in areas far removed from teaching hospitals and urban centers, may find it too burdensome to participate in three proctored cases in each of these very specific categories.

Several commenters stated that the proposed changes in § 35.390(b)(1)(ii)(G) would discourage clinicians from seeking authorization to administer these radioactive drugs and would make an already burdensome regulatory scheme more onerous. The commenters suggested that the NRC revise the proposed work experience requirement in categories in § 35.390 (b)(1)(ii)(G)(*3*) or § 35.390 (b)(1)(ii)(G)(*4*) to have three proctored cases in either category be satisfactory to meet the requirements for both categories.

Several commenters acknowledged that the clarifications of the categories of parenteral administrations were useful and logical. However, they agreed with another commenter that there was an unintended consequence of increasing the work experience burden for those seeking administration of radiopharmaceuticals with alpha and beta emitters.

Response: The rule text was modified based on a recommendation from the ACMUI. The NRC deleted § 35.390(b)(1)(ii)(G)(*4*) and included radioactive drugs primarily used for their alpha characteristics in § 35.390(b)(1)(ii)(G)(*3*).

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

Comment: One commenter supported changes in the proposed rulemaking to permit physicians who have completed the 80 hours of classroom and laboratory training specified in

§ 35.396(d)(1) and who have the relevant work experience described in § 35.396(d)(2) to be eligible for AU status to administer parenteral radioactive drugs. The commenter stated that this is an appropriate level of T&E for administration by hematologists and oncologists of a specific radioactive drug, Zevalin®, used primarily for its beta emissions.

Response: No change was made to the rule text based on this comment. The NRC did not intend to propose any change to this T&E requirement in the proposed rule, and, therefore has not developed the regulatory basis to make any change to this requirement in this final rule. During the preparation of the proposed rule, an administrative error resulted in the addition of the word "or" between the rule text in § 35.396(c) and (d). The NRC did not intend to put an "or" between paragraphs (c) and (d) and is correcting the error by removing the word "or" in the final rule text between paragraphs (c) and (d). This administrative error could have been interpreted to require that a physician complete only 80 hours of T&E for parenteral administration of unsealed byproduct material requiring a WD.

The NRC notes that to obtain authorization to use parenteral radioactive drugs requiring a WD, the physician must either (1) meet the T&E requirement or be certified by a medical specialty board recognized under § 35.390 and meet the clinical case work criteria in § 35.390, or (2) meet the T&E requirement or be certified by a medical specialty board recognized under § 35.490 or § 35.690 and satisfy the additional 80 hours of T&E requirement specified in § 35.396(d).

Comment: Two commenters stated that NRC's regulations create a shortage of AUs able to administer certain therapeutic radioactive drugs. Specifically, under current regulations, a radioactive drug requiring a WD that is administered parenterally and used primarily for its beta radiation characteristics can only be administered by an AU who has met the T&E requirement set forth in § 35.396. This requirement involves either board certification or 700 hours of T&E specifically in radionuclide handling. One of the commenters stated that

hematologists and oncologists who typically prescribe therapeutic radiopharmaceuticals outside of the hospital setting often do not have the T&E required to meet the AU requirements and do not work at facilities that have such AUs. They have extensive T&E, and are frequently board certified, but in different specialized fields.

Response: No change was made to the rule text based on these comments. The NRC believes that the commenters are referring to the requirement in § 35.390, because the 700 hour criterion is in § 35.390 and not in § 35.396.

Without compromising radiological health and safety, the NRC strives to ensure that its regulations do not restrict patient access to diagnostic and treatment options. The intent of NRC's T&E requirements is to ensure that AUs are adequately trained so that their handling and administration of radioactive drugs is radiologically safe for patients, workers, and the public. The current T&E requirements are protective of radiological health and safety. As explained in greater detail in a response to another comment on parenteral administrations, throughout 2015 and early 2016 the ACMUI assessed the concerns raised in this comment. Additionally, the ACMUI established a standing subcommittee that will periodically assess the T&E requirements across all modalities and make recommendations for changes as warranted. The NRC will also continue to consider whether changes to these T&E requirements are warranted.

With respect to the comment that hematologists and oncologists "typically prescribe therapeutic radiopharmaceuticals...," NRC regulations require that such radiopharmaceuticals be administered in accordance with a WD. A WD is an AU's—not a hematologist's or oncologist's—written order for the administration of byproduct material or radiation from byproduct material to a specific patient, as specified in § 35.40.

Comment: Several commenters provided comments after the public comment period on whether the NRC should amend the T&E requirement for the parenteral administration of radioactive drugs as part of this final rule.

One commenter stated that amending § 35.396 to reduce the T&E requirement to 80 hours in this final rule would be a logical outgrowth of the proposed rule and thus would satisfy the Administrative Procedure Act of 1946 (APA) requirement to provide notice and an opportunity for comment. The commenter stated that the NRC provided adequate notice of an amendment to this T&E requirement and that the NRC received substantial public input on these T&E requirements. Alternatively, according to the commenter, the NRC could invoke the "good cause" exemption from the APA notice and comment requirements because the 700 hour T&E requirement for these parenteral radioactive drugs has caused a decrease in the number of AUs for these drugs and a corresponding decrease in patient access to these drugs. The commenter also proposed that the NRC could, instead of amending T&E requirements at § 35.396(d), include in this final rule a new section that would require 80 hours of T&E specifically for the parenteral administration of patient-ready doses of alpha- and beta-emitting radioactive drugs. One other commenter also supported reducing this T&E requirement to 80 hours as part of this final rule and provided a proposed training program.

Several other commenters also expressed support for reducing this T&E requirement in this final rule. Their primary bases were that the 700 hour T&E requirement has caused a lack of AUs available to administer these radioactive drugs; administration of these drugs presents no greater radiation health and safety risk than oral administration of I-131; and 80 hours of T&E is sufficiently protective of radiological health and safety.

Several commenters opposed changing this T&E requirement in the final rule. One commenter stated that the NRC and ACMUI would need to analyze key issues before proposing any changes to this T&E requirement, including whether a reduction in the requirement is advisable from a radiation health and safety perspective. These commenters stated that an AU would need to receive adequate training on a broad array of radiation health and safety topics and that an 80-hour course would not sufficiently cover these topics. These commenters also

described the range of activities, considerations, and procedures necessary to ensure the safe handling and administration of these radioactive drugs.

Response: No change was made to the rule text based on these comments. As stated in response to another comment on § 35.396, the proposed rule text that could have been interpreted to require only 80 hours of T&E for a physician to obtain AU status to administer parenteral radioactive drugs was the result of an administrative error. The NRC did not mention or discuss any changes to these T&E requirements in any other part of the proposed rule *Federal Register* notice. The NRC did not intend to propose any changes to this T&E requirement, and therefore the NRC has not developed a regulatory basis to make any such change in this final rule. The NRC agrees with the comment that, before proposing any changes to this T&E requirement, the NRC and ACMUI should analyze whether a change in the requirement is warranted and advisable from a radiation health and safety perspective.

In response to commenter's concerns about this T&E requirement, the NRC and ACMUI began considering whether a change in this requirement is warranted. Spectrum Pharmaceuticals, Inc. requested a meeting with NRC staff to explain its comments concerning this T&E requirement. The NRC staff agreed and held a public meeting on February 12, 2015, at which Spectrum Pharmaceuticals, Inc. and Florida Cancer Specialists & Research Institute presented their comments and concerns that this T&E requirement causes a shortage of AUs, and, therefore a barrier to patient access. In response to these comments and concerns, throughout 2015 and early 2016 the ACMUI assessed whether this T&E requirement places a hardship on the patient community. In a public teleconference held on June 16, 2015, the Florida Cancer Specialists & Research Institute presented to the ACMUI its concerns that this T&E requirement caused a lack of AUs and thus a barrier to patient access to these radioactive drugs. After this teleconference, the ACMUI formed a subcommittee to assess whether the 700 hour T&E requirement for parenteral administration of this class of radiopharmaceuticals places

a hardship on the patient community by creating a shortage of AUs. In its subcommittee report dated September 21, 2015, which the ACMUI unanimously approved at its Fall 2015 meeting, the ACMUI concluded that it was unable to substantiate this claim. The ACMUI found that the infrequent and steadily decreasing use of specific beta-emitting radioactive drugs—specifically radioactive drugs that are used to treat lymphoma, such as Spectrum Pharmaceuticals, Inc.'s drug Zevalin®—is due to many factors. The ACMUI concluded that it could not determine whether there is a shortage of AUs and, if so, whether the NRC's T&E requirement caused the shortage. The subcommittee was then charged with continuing to assess this issue and to establish a recommendation for the total number of hours of T&E for AUs of this class of radioactive drugs that appropriately balances safety with reasonable patient access to these radioactive drugs.

In its subcommittee report dated March 10, 2016, which the ACMUI unanimously approved at its meeting on this same date, the ACMUI reiterated its conclusion that it could not substantiate the claim that the T&E requirement caused a shortage of AUs and thus a hardship on the patient community. For this reason, and because the ACMUI identified several issues raised by the reduction in T&E requirements that some commenters recommended, the ACMUI recommended against reducing the T&E. However, the ACMUI recognized the need for a thorough review of T&E requirements across all modalities because of the introduction of new radioactive drugs since the requirements were established 15 years ago and because the educational paradigm has shifted from prescriptive curricula to competency-based education. The ACMUI established a standing subcommittee to assess T&E requirements for all modalities and provide recommendations to the NRC staff. As stated in response to other comments, the NRC will continue to consider concerns regarding T&E requirements to ensure that these requirements are sufficient to ensure radiological health and safety for patients, workers, and the public without unnecessarily creating barriers to patient access to diagnostic and treatment

options.

Section 35.400 Use of sources for manual brachytherapy

Comment: Several commenters did not agree with the proposal in § 35.400 that manual brachytherapy sources may be used for medical purposes not listed in the SSDR. The commenters believed that this change would permit sources to be used by medical personnel who have not received any radiation safety training. As an example, they cited the case where brachytherapy sources are used in temporary diagnostic localization procedures under the provisions of § 35.1000. In this case, the guidance requires licensees to submit their training program for nonmedical staff that are not covered under their current medical license. The commenters believed that by requiring these uses under the provisions of § 35.1000, the regulatory agencies can ensure that radiation safety for all workers is verified before use.

Response: No change was made to the rule text based on these comments. Although the statement of considerations for the proposed rule stated "manual brachytherapy sources can be used for medical uses not listed in the SSDR", the rule text is more limiting and states "...manual brachytherapy sources may be used for manual brachytherapy uses that are not explicitly listed in the SSDR." The commenters' example of using a manual brachytherapy source for a temporary diagnostic localization procedure is not permitted under the provisions of § 35.400 because it is a diagnostic use and not a manual brachytherapy use. However, such use may be authorized under the provisions of § 35.1000.

Comment: One commenter agreed with the NRC that the limitations and consideration of use listed in the SSDR be followed. The commenter believed that the "SSDR reviewer should identify and list requirement [sic] and discuss issues on how to license these products for safe use." The commenter stated that, by doing this, the SSDR reviewer helps ensure uniformity in the licensing requirements, and saves resources for industry and regulatory

agencies in not having to independently obtain this information.

Response: No change was made to the rule text based on this ~~rule text~~comment. The NRC is not certain what the commenter meant by "SSDR reviewer should identify and list requirement [sic] and discuss issues on how to license these products for safe use." The NRC revised § 35.400 because existing SSDR sheets do not, nor are they expected to, describe all manual brachytherapy medical procedures for which the manual brachytherapy seeds can be used. During the evaluation, the reviewer focuses on radiation safety conditions and limitations of use.

Section 35.433 Strontium-90 sources for ophthalmic treatments

Comment: One commenter stated that the proposed regulations concerning ophthalmic physicists in § 35.433, which separate physicists who assist in ophthalmic procedures from AMPs who are involved in the uses allowed under § 35.600 and § 35.1000, were an improvement.

Response: The comment supports language in the rule; therefore, no response is required.~~No response is required.~~

Comment: One commenter recommended a revision of § 35.433(a)(2) to specifically include the term "ophthalmic physicist." The commenter pointed out that although the NRC defined the "ophthalmic physicist" to be "an individual who meets the requirements of § 35.433(a)(2)...," the NRC did not use the term "ophthalmic physicist" in § 35.433. The commenter recommends changing the text in § 35.433(a)(2) to read: An individual named as an ophthalmic physicist who: (i) Holds a masters ... "

Response: The rule text was modified based on this comment. The rule text was changed to include the term ophthalmic physicist in §35.433(a)(2). The NRC agrees that, for clarity, the term ophthalmic physicist must be included in this section. By including the term

"ophthalmic physicist," it is clear that the requirements in § 35.433(a)(2) apply to an individual who is named as an ophthalmic physicist and meets the definition of an "ophthalmic physicist" in § 35.2.

Comment: Several commenters questioned the need for § 35.433(b)(2) and recommended its removal. They thought that the actions regarding the WD were already required by the licensee in § 35.41 and that no other modality requires a procedure regarding the frequency of involvement by the medical physicist. The commenters also asked why the other individual [identified in § 35.433(b)(2)] could not work under the supervision of the AMP or request an exemption from the requirement.

Response: No change was made to the rule text based on these comments. Although the regulations do not prohibit a licensee that has an AMP from also having an ophthalmic physicist, the primary purpose of the ophthalmic physicist is to provide physics support to the ophthalmic AU when the licensee does not have access to an AMP. The ophthalmic physicist is an individual recognized by the NRC, Agreement States, medical licensees of broad scope, master material licensees or master material medical permittees of broad scope by T&E, to perform certain functions listed under § 35.433. This individual is authorized to work independently and is not required to work under the supervision of an AMP.

The purpose of § 35.433(b) is to describe the minimum performance-based tasks expected of either the AMP or the ophthalmic physicist in assisting the licensee and AU with the ophthalmic treatment program. The requirement that only an AMP shall calculate the activity of each Sr-90 source is an existing requirement in the regulations under § 35.433(a) and is not a new requirement. The requirement in § 35.433(b)(2) codifies that the AMP, or ophthalmic physicist, is to assist the licensee and AU in assuring that the requirements in § 35.41 are met. Ophthalmologists using these devices are frequently in small programs with limited access to services of an AMP. The proposed rule change was made in part to ensure that the ophthalmic

physicist (or AMP) performs a minimum number of tasks at the ophthalmology office.

The NRC did not specify the frequency of involvement of the AMP or ophthalmic physicist because the licensee should determine the best frequency for its program. The NRC requires AMPs to perform certain tasks at specified frequencies for certain medical use programs. Specifically, AMPs are required to participate initially, and at least annually, in drills of emergency procedures under § 35.610. They also must be physically present during initiation of patient treatment, continuation of the treatment, or the entire treatment, depending on the unit being used under § 35.615. In addition, AMPs must perform the full calibration measurements and decay corrections before first medical use, before medical use under certain conditions, and at intervals not to exceed one year under §§ 35.632, 35.633, and 35.635.

Comment: An Agreement State pointed out that in its State statutes, an individual who practices medical physics is required to be licensed by the State. Because 10 CFR 35.422 is designated as "Health and Safety" (H&S), the Agreement State must promulgate its rule to require medical physicists to comply with its statute. The commenter recommended that the rule text be changed to "allow the individual to work under the supervision of an AMP as authorized by state laws."

Response: No change was made to the rule text based on this comment. The NRC believes that the commenter is referring to § 35.433, not § 35.422 (as there is no § 35.422 in the regulation). The revision of the rule does not prohibit a State from requiring the "ophthalmic physicist" to be licensed by the State as long as the licensure requirements include components essentially identical to NRC T&E requirements. The purpose of adding the ophthalmic physicist was to identify an individual who could assist the licensee when the licensee does not have access to an AMP. In this situation, the ophthalmic physicist cannot work under the supervision of an AMP because the licensee does not have an AMP to perform the activities listed in § 35.433(b). Further, the ophthalmic physicist is authorized independently and is not required to

work under the supervision of an AMP. The designation "H&S" in the summary refers to program elements that are not required for compatibility, but are identified as having a particular health and safety significance. The State should adopt the essential objectives of such program elements in order to maintain an adequate program.

Comment: An Agreement State pointed out that its licensure requirements for "Medical Physicist" are currently consistent with NRC's requirement for an AMP in 10 CFR part 35. The T&E of the "ophthalmic physicist" does not meet its licensure requirements and it is unclear whether the individual would meet the accreditation standards set by the American College of Radiology (ACR) or the American College of Radiation Oncology (ACRO) in radiation oncology, which the State requires for manual brachytherapy. All state licensees that are authorized for possession and use of a Sr-90 eye applicator have the services of an AMP for other brachytherapy and external beam therapy uses. The commenter also questioned whether it would relieve a shortage of physicists in rural areas, because the proposed rule does not require an AMP or ophthalmic physicist to be physically present at the licensee's authorized location of use, with the possible exception of the initial source calibration that is performed on site or to be on site to perform the decay correction and treatment times. The commenter concluded that the addition of this proposed category of physicist did not appear to be applicable in its state and therefore should not be required for state adoption. The commenter proposed that the NRC assign Compatibility Category "B" to those states that will and category "D" to those that will not use the designation of ophthalmic physicist.

Response: No change was made to the rule text or to the compatibility category designation for the T&E requirements for an ophthalmic physicist under § 35.433(a) based on this comment. All NRC ~~training and~~ T&E requirements in 10 CFR part 35 are designated as Compatibility Category B, which means they have direct and significant transboundary effects. The licensee is required to have procedures that specify the frequency at which the AMP or

ophthalmic physicist would observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the treatment was in accordance with the WD. The individual must be physically present at the licensee's authorized location of use on a set frequency to complete these tasks. The NRC believes that having an individual who is not an AMP, but is qualified to perform the tasks specified and to perform some of them on site, will provide assistance to rural licensees.

Section 35.490 Training for use of manual brachytherapy source

Comment: One commenter stated that the requirements for supervised work experience under § 35.490(b)(1)(ii) were written vaguely, and that it can and has been interpreted as 500 hours of work related to radiation therapy, not specifically to brachytherapy. The commenter believed that this interpretation is reasonable, but that it would be helpful to have some specific brachytherapy related guidance on, e.g., the number of cases the proposed AU or AMP should observe and/or perform under supervision, or the length of time they should perform these procedures under supervision.

Response: No change was made to the rule text based on this comment. It appears that the commenter's statement is limited to the rule text in § 35.490(b)(1)(ii). However, § 35.490(b)(1)(ii) should be taken in the context of all of the training requirements in § 35.490(b)(1), which states, "Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes [(i) and (ii)]." Further, the tasks that are to be performed under § 35.490(b)(1)(ii) include § 35.490(b)(1)(ii)(C): preparing, implanting, and removing brachytherapy sources. The NRC is not requiring a minimum number of cases because the requirement for a total of 500 hours of supervised work experience, including the tasks required under § 35.490(b)(1)(ii)(C), is sufficient to ensure the safe use of manual brachytherapy sources.

Section 35.500 Use of sealed sources and medical devices for diagnosis

Comment: Several commenters noted that NRC's revision to § 35.500(a) and (b) states that "[a] licensee must only use sealed sources or diagnostic devices that are approved in the Sealed Source and Device Registry ..." and also states "may be used for... ." The commenter stated that these revisions contradicted each other, because the revision states that the licensee "must" for some uses but then uses "may" for other uses. The commenters thought it put a burden on the SSD reviewing agency to ensure that proper conditions are included in the SSD allowing for other uses. They disagreed with the revision and recommended that any other uses of these sealed sources should be approved by the licensing regulatory agency.

Response: The rule text was modified ~~No change was made to the rule text~~ based on these comments. The rule text in § 35.500(a) was changed in order to make it clear that it is the sealed sources, as opposed to the diagnostic medical uses, that must be approved in the Sealed Source and Device Registry (SSDR). The rule text in § 35.500(b) was not changed because the NRC believes the language in this section is clear. ~~To clarify, t~~The revision in § 35.500(a) now states, "~~[a]~~ A licensee must use only sealed sources that are not in medical devices for diagnostic medical uses ~~that~~ if the sealed sources 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, but~~,~~ must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry." The revision in § ~~Section~~ 35.500(b) continues to state~~s~~, "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 ~~(SSDR)~~ but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry." To clarify, the first part of the requirement in each paragraph is to restrict the licensee to only use sealed sources and devices for diagnostic purposes if they are approved for diagnostic purposes in the SSDR. The purpose of the second part of the requirement in each paragraph is to allow the licensee the flexibility to use diagnostic sealed sources and devices for medical uses other than those that are explicitly included in the SSDR. As long as the limitations and conditions included in the SSDR address those generally needed for diagnostic uses, there is no additional burden on the SSD reviewer to revise the SSD for a new diagnostic use not explicitly stated. If the licensee intends to use a diagnostic sealed source or device for a non-diagnostic use, then the licensing regulatory agency will need to determine how to license such use.

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

Comment: Several commenters stated the revision splits the section into two paragraphs where (a) is used for sources and (b) is used for units. They recommend either changing the name of the section or adding a new section for the units.

Response: No change was made to the rule text based on these comments. The current title of the section already includes the sealed sources and the devices in which the sources are used. The requirements in paragraphs (a) and (b) parallel this structure.

Comment: Several commenters recommended that § 35.600(b) be revised to read: "~~[b]~~ A licensee must use photon emitting remote afterloader units, teletherapy units, or gamma stereotactic units:

i. That are approved in the Sealed Source and Device Registry; or

ii. In research ...."

Response: No change was made to the rule text based on these comments. The purpose of the revisions to § 35.600(b) is~~proposed rule was written~~ to clarify that the photon emitting remote afterloader units, teletherapy units, or gamma stereotactic units must be used in accordance with the limitations and considerations of use listed in the SSDR and to allow the licensee to use the units for medical uses not explicitly listed in the SSDR. The commenters' proposed change would not address these issues.

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

Comment: One commenter questioned why the revisions to § 35.610(d)(1) require training on a new unit to be provided only by the vendor or individuals certified by the vendor. The commenter does not believe there is clear evidence that vendor training is superior to a course the licensee might develop and that the quality of vendor training is quite variable. The commenter was also concerned that if a staff member missed the vendor's training, the licensee would be required to make special arrangements, probably at considerable cost, to have that person trained as required. The commenter stated that in most cases the licensee will choose to have all staff trained by the vendor when a new device is installed. The commenter believed that licensees should be allowed to provide training to their personnel in the manner they deem the best as is the case today and would be the case at existing installations under the proposed rule.

Response: The rule text was modified based on this comment. The rule text was changed to clarify that the individuals certified by the device manufacturer to provide vendor training must be specifically certified to provide this training. The medical device manufacturer is the most knowledgeable entity when it comes to its new devices or upgrades to devices that affect their safety and operation. The NRC's intent is that before the device can be used on the

first patient, each staff member involved in the operation of the device for that first patient's treatment must receive training on the operational and safety features and procedures from the vendor or individuals certified by the vendor to provide the training. For subsequent patient treatments, the requirements in § 35.610(d)(2) apply.

Comment: One commenter agreed that, with respect to the revisions to § 35.610(d)(1), after modifications to the unit, staff authorized to use the unit needs to be trained on the upgrade and how the upgrade affects the operation of the unit. The commenter wanted clarification on whether "...upgrade that affects the operation and safety of the unit" is meant to cover changes to the actual device itself or changes to the device and any changes to the treatment planning system (software/hardware).

Response: No change was made to the rule text based on this comment. The rule covers both software and hardware changes that affect the operation and safety of the remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.

Comment: One commenter wanted clarification on whether the requirement "or by an individual certified by the device manufacturer..." included a person at the organization (one of the authorized operators) who received the device upgrade training from the manufacturer and would then be able to train all other authorized operators at the organization.

Response: The rule text was modified based on this comment. The rule text in 35.610(d)(1) was revised to clarify that the vendor training can only be provided by either the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training. Therefore, an authorized operator at the licensee's facility that is certified by the device manufacturer to provide the operational and safety training may provide initial instruction to other authorized operators at the facility.

Section 35.655 Full-inspection servicing for teletherapy and gamma stereotactic

radiosurgery units

Comment: One commenter stated that a full inspection is only possible when the sources in a gamma stereotactic radiosurgery unit are replaced. The commenter recommended that the full inspection frequency be revised to occur upon source exchange.

Response: No change was made to the rule text based on this comment. The NRC agrees that the full inspection is only possible when the sources in a gamma stereotactic radiosurgery unit are replaced. Further, the NRC believes that the source replacement interval for a gamma stereotactic radiosurgery unit can be extended to 7 years because of the 6-month routine preventive maintenance performed on these units.

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

Comment: One commenter stated that it was unclear how an individual who is board certified but beyond 7 years of the required training may seek AU or AMP status. The commenter believed that, for safety, there should be some minimum number of cases the individual must observe prior to obtaining AU or AMP status especially in light of the complexity of interstitial procedures such as LDR or HDR prostate.

Response: No change was made to the rule text based on this comment. The NRC reviews, on a case by-case basis, each applicant who received board certification more than 7 years ago and requests to be authorized as an AU or AMP. The licensee must demonstrate that the individual has had related continuing education and experience since the required training was completed. Because of the rigorous T&E requirements already in place, the NRC has not set a minimum number of cases a physician or a medical physicist must observe prior to obtaining AU or AMP status.

Comment: One commenter stated that replacing "institution" in 35.690(b)(1)(ii) with

"facility that is authorized to use byproduct material in 35.600" may cause difficulties without any apparent benefit. Under current regulations, a residency program at an institution that has only linear accelerators can provide some of the work experience pertinent to the requirements at its institution so long as it has the appropriate AUs on staff (which is common with physician faculty practicing at affiliated outpatient facilities). While residents need some direct work experience with, for example, treatment planning for HDR after loaders, there are concepts learned in a linear accelerator treatment planning that apply. This is especially true of external beam therapy from radioactive sources. Therefore, if a preceptor judges it to be appropriate, an individual should be allowed to acquire a portion of the required 500 hours of work experience at a facility that does not use byproduct material in § 35.600.

Response: No change was made to the rule text based on this comment. The amendment the commenter described was made to ensure that the supervised work experience was obtained at a medical facility (including a stand-alone single discipline clinic) where the facility is authorized for uses under 35.600. Section 35.690 also includes a requirement that the individual complete a 3-year accredited residency program in radiation therapy. This residency program is not restricted to a facility that is authorized for § 35.600 uses. The NRC recognizes that the "concepts learned" that the commenter referred to may be obtained from such a facility but that the individual still needs 500 hours of supervised work experience with the § 35.600 devices.

Comment: One commenter expressed concern regarding whether a residency program approved by the Royal College of Physicians and Surgeons of Canada can be used to meet the requirements in 35.690 (b)(2) because of the specific mention of a medical facility authorized to use byproduct material in 35.600. Currently, the NRC's, "Procedures for Recognition of Foreign Trained Physicians and Physicists Applying for Authorized User (AU) and Authorized Medical Physicist (AMP) Status," states that a physician coming out of a residency approved by the

Royal College of Physicians and Surgeons of Canada would need to work under a physician who also practices in the United States. While such physicians likely exist, adding the additional requirement that the facility is authorized to use byproduct material in 35.600 appears to add an additional hurdle to allowing hours from these residencies.

Response: No change was made to the rule text based on this comment. The commenter is correct that a physician completing a residency program approved by the Royal College of Physicians and Surgeons of Canada may have to complete his or her 500 hours of supervised work experience at another facility that is authorized for uses under 35.600.

Section 35.3045 Report and notification of a medical event

The NRC received many comments on various issues related to the permanent brachytherapy event reporting criteria under this section. For better understanding of the concerned raised, the comments are grouped according to the distinct issues commenters raised.

Issue: The medical event reporting criterion are based on the term "potential harm"

Comment: Several commenters stated that they do not agree with the use of the term "potential harm" in the discussion of MEs in the *Federal Register* notice for the proposed rule. The commenters believe that "potential harm" is a medical decision and that this approach is a significant departure from the current definition of an ME. The commenters believe that this approach will eliminate the opportunity for licensees to identify precursor events and make process improvements, and that it could have the unintended consequence of providing additional support for malpractice suits. In articulating their objection to NRC's position, some commenters stated that "[a]s regulators, we are not tasked for determining what the 'potential

harm' is, our mission is to ensure licensees abide by the required regulations."

Response: The NRC believes that the rule will not discourage licensees from identifying precursor events or making process improvements. The rule continues to reflect the NRC's 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. This position ~~was~~ is based on the NRC staff recommendations submitted to the Commission 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. The NRC staff recommendations were approved by the Commission in SRM to SECY-05-0234, dated February 15, 2006. The ME criteria for permanent implant brachytherapy are now consistent with the criteria for other therapeutic modalities by reflecting circumstances in which there may be harm or potential harm to the patient.

Issue: The medical event reporting criterion related to the absorbed dose to normal tissues located within the treatment site

Comment: One commenter had questions and expressed concerns about the ME reporting criterion in § 35.3045 related to "intra-target" normal tissue. The commenter stated that the urethra is the only such structure to consider, and the volume is much less than 5 cubic centimeters. The commenter wanted to know whether, if the dose threshold for reporting an ME was exceeded for the urethra, given that the volume is less than 5 cubic centimeters, if that instance would require reporting. The commenter also expressed concern that treatment planning systems could not distinguish between a 5 cubic centimeters volume and a summation of five 1 cubic centimeters volumes receiving 150 percent of the prescribed dose.

Response: The rule text was modified based on this comment. The rule text in § 35.3045(a)(2) was modified to remove § 35.3045(a)(2)(iv), which would have required the

assessment of the absorbed dose to normal tissue within the treatment site. The NRC understands that the volume of the urethra within the treatment site is typically less than 5 cubic centimeters. In addition, the NRC acknowledges the commenter's concern that treatment planning systems may not distinguish contiguous volumes from non-contiguous, summated volumes. In response to this concern and those raised by other commenters, the NRC removed the absorbed dose-based ME reporting criterion in § 35.3045(a)(2)(iv).

Comment: One commenter expressed concerns about the absorbed dose-based criterion for normal tissue within the treatment site and stated that it is common for 50 percent or more of the treatment site to receive a dose that exceeds the prescribed dose by greater than 50 percent. The commenter was concerned that quality implants may be categorized as MEs using this criterion. The commenter also stated that its vendor's software does not provide a method to evaluate dose to contiguous volumes of tissue within the treatment site.

Response: The rule text was modified based on this comment. The rule text in § 35.3045(a)(2) was modified to remove § 35.3045(a)(2)(iv), which would have required the assessment of the absorbed dose to normal tissue within the treatment site. The NRC agrees that quality implants may be categorized as MEs if 50 percent or more of the treatment site intentionally receives a dose that exceeds the prescribed dose by greater than 50 percent. The NRC understands that some treatment planning software may be unable to distinguish contiguous volumes of tissue. In response to this concern and those raised by other commenters, the NRC removed the absorbed dose-based ME reporting criterion in § 35.3045(a)(2)(iv).

Comment: One commenter expressed concerns about the ME reporting criterion in § 35.3045(a)(2)(iv). The commenter stated that, using this criterion, it would be difficult for licensees to determine if an ME had occurred and nearly impossible for regulators to independently determine if a licensee is appropriately classifying and reporting MEs.

Response: The rule text was modified based on this comment. The rule text in § 35.3045(a)(2) was modified to remove § 35.3045(a)(2)(iv), which would have required the assessment of the absorbed dose to normal tissue within the treatment site. The NRC understands that it may be difficult for licensees and regulators to determine if an ME occurred under this criterion. In response to this concern and those raised by other commenters, the NRC removed the absorbed dose-based ME reporting criterion in § 35.3045(a)(2)(iv).

Comment: One commenter expressed concerns about the ME reporting criterion in § 35.3045 related to the normal tissue located within the treatment site. The commenter stated that the normal tissue within the treatment site for prostate implants is the urethra and it is necessary to place a catheter in the urethra to assess dose to this tissue. The commenter noted that licensees may not routinely catheterize the patient during post-implantation imaging; therefore, they do not have the imaging information necessary to assess urethral dose. The commenter further stated that pre-implantation images performed on catheterized patients show that the urethral volume is typically 1 cubic centimeter or less. The commenter concluded that an ME would never be found for normal urethral tissue for a prostate implant because there is not 5 cubic centimeters of contiguous urethral tissue within the treatment site.

Response: The rule text was modified based on this comment. The rule text in § 35.3045(a)(2) was modified to remove § 35.3045(a)(2)(iv), which would have required the assessment of the absorbed dose to the maximally exposed 5 contiguous cubic centimeters of normal tissue within the treatment site. The NRC understands that licensees may not routinely acquire the imaging information necessary to assess post-implantation urethral dose. The NRC also understands that the urethral volume within the treatment site is typically considerably less than 5 cubic centimeters, and as a result it is unlikely that an ME would occur using the proposed criterion.

Comment: One commenter stated that using absorbed dose-based criteria may limit the

licensee's ability to determine if an ME has occurred when evaluating dose to normal structures located within the treatment site that are even more difficult to contour than the prostate. The commenter suggested removing the use of absorbed dose-based criterion for normal tissue within the treatment site.

Response: The rule text was modified based on this comment. The rule text in § 35.3045(a)(2) was modified to remove § 35.3045(a)(2)(iv), which would have required the assessment of the absorbed dose to normal tissue within the treatment site. The NRC agrees with the commenter's suggestion and in response to this concern and those raised by other commenters, the NRC removed the use of absorbed dose-based criteria for reporting MEs in § 35.3045(a)(2)(iv).

Comment: One commenter expressed concern about the ME reporting criterion in § 35.3045(a)(2)(iv) related to the absorbed dose to normal tissue located within the treatment site. The commenter stated that "precise control of source location inside the treatment site over several half-lives is impossible (and not necessary), so absorbed dose to intra-target structures is impossible to control." The commenter believes this is a medical decision, not a suitable ME criterion. The commenter stated "[m]edicine has to operate in a risk-benefit balance when it comes to normal tissues, so the NRC has no role here."

Response: The rule text was modified based on this comment. The rule text in § 35.3045(a)(2) was modified to remove § 35.3045(a)(2)(iv), which would have required the assessment of the absorbed dose to normal tissue within the treatment site. The NRC acknowledges the commenter's concern that absorbed dose to intra-target structures is impossible to control and is a medical decision. In response to this concern and those raised by other commenters, the NRC removed the dose-based ME reporting criterion in § 35.3045(a)(2)(iv).

Comment: One commenter stated that "[i]dentification of normal tissue in the treatment

volume (urethra) is difficult if not impossible with a CT scan." The commenter also stated that the radiation dose is variable across the treatment site and therefore the "determination" of the dose to the normal tissue within the treatment site is "ambiguous." The commenter further stated that "[t]he only way to clearly define the urethra during the post Dosimetry CT scan would be to catheterize the patient, which would cause significant pain to the patient, and therefore is not performed."

Response: The rule text was modified based on this comment. The rule text in § 35.3045(a)(2) was modified to remove § 35.3045(a)(2)(iv), which would have required the assessment of the absorbed dose to normal tissue within the treatment site. The NRC acknowledges the commenter's concerns related to difficulties associated with imaging the urethra and estimating the dose to it. In response to these concerns and those raised by other commenters, the NRC removed the absorbed dose-based ME reporting criterion in § 35.3045(a)(2)(iv).

Comment: One commenter expressed difficulty in understanding how clinics that use a nomogram-based approach to "pre-planning," where there is no pre-implant dose distribution, would evaluate the ME definition for "intra-target normal structures" in § 35.3045(a)(2)(iv).

Response: The rule text was modified based on this comment. The rule text in § 35.3045(a)(2) was modified to remove § 35.3045(a)(2)(iv), which would have required the assessment of the absorbed dose to normal tissue within the treatment site. The NRC understands the commenter's concern that clinics that use a nomogram-based approach to "pre-planning," where there is no pre-implant dose distribution, may have difficulty in evaluating the dose to normal tissue within the treatment site under the proposed ME definition. In response to this concern and those raised by other commenters, the NRC removed the absorbed dose-based ME reporting criterion in § 35.3045(a)(2)(iv).

Issue: The medical event reporting criterion in § 35.3045 related to the absorbed dose to normal tissues located outside the treatment site

Comment: One commenter expressed concerns about the ME reporting criterion in § 35.3045(a)(2)(iii) related to the absorbed dose to normal tissue located outside the treatment site. The commenter stated that their treatment planning software does not have an automated method for determining the volume of normal tissue that exceeds the prescribed dose by 50 percent. They stated that a manual method for making such a determination would lead to different results depending on who contours the normal tissue volume being assessed. The commenter also noted that the definition of "contiguous normal tissue" is not clear.

Response: The rule text was modified based on this comment. The rule text in § 35.3045(a)(2) was modified to remove § 35.3045(a)(2)(iii), which would have required the assessment of the absorbed dose to normal tissue outside the treatment site. The NRC acknowledges the commenter's concern that some treatment planning software may is not capable of automatically determining the volume of normal tissue that exceeds the prescribed dose by 50 percent. In response to this concern and those raised by other commenters, the NRC removed the absorbed dose-based ME reporting criterion in § 35.3045(a)(2)(iii).

Comment: Two commenters expressed concerns about the requirement to evaluate and determine the absorbed dose to the maximally exposed 5 contiguous cubic centimeters of normal tissue "around" the treatment site. The commenters further stated that these proposed ME reporting criteria are not consistent with current medical practice and may discourage licensees from performing permanent brachytherapy, which would deny patients access to this technology.

Response: The rule text was modified based on these comments. The rule text in § 35.3045(a)(2) was modified to remove § 35.3045(a)(2)(iii) and (iv), which would have required the assessment of the absorbed dose to the maximally exposed 5 contiguous cubic centimeters

of normal tissue outside and within the treatment site. The NRC acknowledges the commenters' concern that the proposed rule text is not consistent with current medical practice and may discourage some licensees from performing permanent brachytherapy. In response to this concern and those raised by other commenters, the NRC removed the absorbed dose-based ME reporting criterion in § 35.3045(a)(2)(iii) and (iv).

Comment: Two commenters expressed concerns about the use of absorbed dose to 5 contiguous cubic centimeters as a criterion for reporting MEs. The commenters noted that the absorbed dose to 5 contiguous cubic centimeters was proposed as a guideline for treating cancer of the cervix in a single journal article published 10 years ago. The commenters also pointed out that these guidelines were proposed "for research purposes," reflected the personal opinions of the authors, and were not endorsed or adopted by any of the radiation oncology professional organizations. The commenters requested that the NRC provide further justification for establishing a 5 contiguous cubic centimeters regulatory standard.

Response: The rule text was modified based on these comments. The rule text in § 35.3045(a)(2) was modified to remove § 35.3045(a)(2)(iii) and (iv), which would have required the assessment of the absorbed dose to the maximally exposed 5 contiguous cubic centimeters of normal tissue outside and within the treatment site. The NRC included these requirements in the proposed rule based on a recommendation from the ACMUI. However, based on these and other comments, the NRC concluded that absorbed dose to 5 contiguous cubic centimeters is not a suitable criterion for reporting MEs. Therefore, the NRC removed subparagraphs (iii) and (iv), which would have required licensees to use absorbed dose criteria to report MEs for permanent brachytherapy.

Comment: One commenter stated that the volume for determining an absorbed dose to normal tissue for compliance with the reporting requirements in § 35.3045 is not clearly defined. The commenter noted that it appears reasonable in theory to determine absorbed dose to the

maximally exposed 5 contiguous centimeters of normal tissue. However, the commenter believes that it will be difficult to make this determination using current technology. The commenter stated that "planning systems typically report dose volume histograms to structures, but they do not identify contiguous volumes."

Response: The rule text was modified based on this comment. The rule text in § 35.3045(a)(2) was modified to remove §§ 35.3045(a)(2)(iii) and (iv), which would have required the assessment of the absorbed dose to normal tissue outside and within the treatment site. The NRC acknowledges that while some treatment planning systems can identify contiguous volumes, others cannot. In response to this concern and those raised by other commenters, the NRC removed the absorbed dose-based ME reporting criterion in § 35.3045(a)(2)(iii) and (iv).

Comment: One commenter stated that the requirement in § 35.3045(a)(2)(iii) (absorbed dose to the maximally exposed 5 contiguous centimeters of normal tissue located outside of the treatment site) will be difficult to implement. The commenter stated that treatment planning systems report dose-volume histograms to structures but do not identify contiguous volumes. The commenter also stated that the term "treatment site" is not well defined. The commenter used the prostate as an example and pointed out that some licensees identify the prostate as the treatment site and develop the treatment plan with a particular margin of normal tissue around it, while others include a PTV (planning treatment volume) around the prostate and plan for that volume. The commenter explained that seeds may be placed in interstitial tissue outside the prostate to ensure adequate dose is delivered to the prostate. The commenter expressed concern that "[i]f the normal tissue involved interstitial tissue, it would not cause a medically significant event to the patient."

Response: The rule text was modified based on this comment. The rule text in § 35.3045(a)(2) was modified to remove § 35.3045(a)(2)(iii), which would have required the assessment of the absorbed dose to normal tissue outside the treatment site. The NRC

acknowledges the commenter's concern that some treatment planning software may be unable to automatically determine the volume of normal tissue that exceeds the prescribed dose by 50 percent. The NRC also acknowledges that AUs describe "treatment site" in different ways. The NRC expects the AU to describe the treatment site (as defined in § 35.2) in the WD in any way he or she believes to be medically appropriate. In response to these concerns and those raised by other commenters, the NRC removed the absorbed dose-based ME reporting criterion in § 35.3045(a)(2)(iii).

Issue: Source-strength based criteria as the metric for permanent brachytherapy versus absorbed dose-based criteria

Comment: Two commenters stated that the use of source-strength based criteria as the metric for permanent brachytherapy is directly proportional to the absorbed dose, and consistent with nuclear medicine administrations of radiopharmaceutical therapy whose purpose is to achieve a prescribed tumor dose. The commenters also pointed out that dose is not factored into the ME definition for radiopharmaceuticals, and has been an auditable measure by inspectors since the definition of "misadministration" that was created decades ago.

Response: The rule text was modified based on this and other comments. While the NRC agrees that source strength is a major factor impacting absorbed dose for permanent brachytherapy, the absorbed dose is determined by a combination of source strength and spatial positioning. Despite this fact, in response to this comment and different concerns raised by other commenters, the NRC determined that a source-strength based criterion is appropriate to define MEs for permanent implant brachytherapy and removed the absorbed dose-based ME reporting criterion in § 35.3045(a)(2)(iii) and (iv).

Issue: Require licensees to establish certain documented criteria for a medically

acceptable implant instead of the absorbed dose to normal tissues

Comment: Two commenters suggested the modification of § 35.3045(a)(2) to remove both criteria for absorbed dose to 5 contiguous centimeters of tissue and require instead that licensees establish documented criteria such as D90 or V100 that provide for a medically acceptable permanent implant.

Response: The rule text was modified based on other comments. The rule text in § 35.3045(a)(2) was modified to remove § 35.3045(a)(2)(iii) and (iv), which would have required the assessment of the absorbed dose to the maximally exposed 5 contiguous cubic centimeters of normal tissue outside and within the treatment site. The NRC agrees with removing the proposed absorbed dose-based criteria for reporting MEs for normal tissue. However, the NRC is not changing the rule text to require licensees to establish documented dose-based criteria such as D90 or V100 that would provide for a medically acceptable implant, as suggested by the commenter. The term "D90" is the dose reported in Gray or as a percentage of the prescribed dose that covers 90 percent of the target volume. The term "V100" is the fractional volume of the target usually reported as a percentage that receives 100 percent of the prescribed dose. The effect of making the commenter's proposed change would be a requirement to report as an ME under § 35.3045(a)(2) any permanent implant that is not deemed medically acceptable. The NRC believes that such a requirement could risk interfering with the practice of medicine. The NRC determined, for reasons explained in response to other comments, that it is best to remove and not replace the dose-based ME reporting criteria.

***Issue:* Sealed source(s) directly delivered to the wrong treatment site**

Comment: Several commenters expressed concern with the proposed rule text in § 35.3045(a)(2)(v)(C), which requires reporting sealed source(s) directly delivered to the wrong treatment site as an ME. Two commenters specifically pointed out that § 35.3045(a)(2)(v)(*C*) is

in direct conflict with § 35.3045(a)(2)(ii), which allows for 20 percent of the implanted source activity to be outside of the intended treatment site. Further, ~~all of~~ the commenters pointed out that, as proposed, this section would require that even a single sealed source directly delivered to the wrong treatment site be reported as an ME. Several commenters pointed out that when performing a normal implant procedure, sources can occasionally be deposited outside the treatment site due to various factors such as uncertainties in intraoperative imaging, patient motion, suction of seeds due to needle withdrawal, or seed migration. For example, one commenter stated that because in a prostate implant 90 to 100 seeds are routinely implanted, "[a] seed could end up in tissue surrounding the prostate, in the bladder, or in the rectum. The overall impact would be numerous MEs of no clinical significance reported." Other commenters stated that source(s) implanted directly into the wrong site or body part, e.g., if the right breast was implanted when the left breast was intended to be implanted, should constitute a reportable ME. One commenter suggested that the NRC establish a reasonable de ~~minimus~~ minimis threshold. Several commenters suggested revising § 35.3045(a)(2)(v)(C) to require that "sealed source(s) directly delivered to a "non-contiguous" wrong treatment site" be reported as MEs.

Response: The rule text was modified based on these comments and a recommendation from the ACMUI. The NRC agrees that typical permanent implant procedures result in some sources being implanted outside the treatment site as described in the WD. In accordance with § 35.3045(a)(2)(ii), an ME has not occurred when less than 20 percent of the sources are implanted outside the treatment site. The NRC also agrees that § 35.3045(a)(2)(v)(*C*), as proposed [now § 35.3045(a)(2)(iii)(*C*)], appears to be in conflict with the provisions of § 35.3045(a)(2)(ii). To ensure that the provisions of § 35.3045(a)(2)(iii)(*C*) can be distinguished from those in § 35.3045(a)(2)(ii), the NRC has changed § 35.3045(a)(2)(iii)(*C)* to read: "Sealed source(s) implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the WD."

Issue: Sources that were implanted in the correct site but migrated outside the treatment site

Comment: Several commenters noted that §35.3045(a)(3) currently includes the phrase, "excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site" but that this provision was not included in the proposed rule. They said that removal of this provision "will cause numerous spurious reported MEs which will be unnecessarily burdensome and time consuming to the NRC and the licensee without increasing patient safety." One commenter stated that migration of seeds from a prostate treatment site is a potential clinical occurrence. The commenters asked the NRC to restore the provision for migrated seeds.

One commenter expressed concern that failure to include an exclusion for migrated sources would require reporting as ME permanent implant brachytherapy procedures in which the sources were placed correctly then migrated. The commenter suggested that "...images taken 15, or 30, or 60 days after an implant cannot unambiguously determine the placement of sources at the time of implant. Only placement meeting Medical Event criteria in 35.3045(a)(2) at time of implant should constitute a Medical Event." The commenter also stated that some licensees do not offer permanent brachytherapy because of a concern that MEs could occur due to circumstances beyond their control, and the damage that can result from the publicity surrounding an ME.

One commenter noted that in the 2002 revisions to Part 35, the term "recordable event" was eliminated and the term "misadministration" was changed to "medical event." The commenter stated that the definition (of an ME) did not change. The definition compares the treatment administered to what the AU intended to administer. The commenter expressed concern that, as proposed, a treatment could be identified as an ME if the seeds moved after

they were implanted correctly. The commenter stated that the proposed rule as written may inhibit a physician from helping a patient if migration of seeds is not taken into account in defining an ME for permanent implant brachytherapy implants.

Response: The rule text was modified based on these comments. The rule text in §35.3045(a)(2) was modified to restore the provision for sources that were implanted in the correct site but migrated outside the treatment site. The NRC agrees that migration of sources that were implanted in the correct site should not be considered an ME.

Comment: One commenter expressed concern about the phrase "outside of the treatment site" at § 35.3045(a)(2)(ii). This is the proposed criterion to define as an ME a permanent implant brachytherapy administration that results in the total source strength administered outside of the treatment site exceeding 20 percent of the source strength documented in the post-administration WD. The commenter noted that, for permanent prostate implants, most of the seeds are purposely implanted in and around the periphery of the gland and many can drift. The commenter stated that 20 percent of the sources may drift, even when linked together, and asked if the NRC has established a cutoff distance for drift. The commenter also expressed concern about the statement that if even one source is apparently "directly implanted...into another (distant from the treatment site) location," it is an ME, and noted that it may be difficult to distinguish a seed that drifted a long distance from one that was directly implanted into a location distant from the treatment site. The commenter believes that these questions will force AUs to define a treatment site "with huge margins for seed drift."

The commenter also asked what rule would apply if all seeds are in the treatment site, but "badly distributed around the periphery." The commenter stated that this could result in a "bad cold spot" in the treatment site dose distribution and noted that many permanent prostate implants "show this tendency naturally 30 days after implant."

The commenter stated that these issues pertain to the practice of medicine and should

not be regulated by the NRC.

Response: No change was made to the rule text based on this comment. The NRC has not established a cutoff distance for "drift" or source migration. The AU defines the treatment site in the WD in any way he or she believes to be medically appropriate, including any margins. The NRC agrees that migration of sources that were implanted into the correct site should not be considered an ME. In response to other comments, the rule text at § 35.3045(a)(2) was changed to restore the exclusion to ME reporting requirements for sources that were implanted in the correct site but migrated outside the treatment site. In response to other comments, the rule text at § 35.3045(a)(2)(v)(C) [now § 35.3045(a)(2)(iii)(C)] was also changed to replace the phrase "[s]ealed source(s) directly delivered into the wrong treatment site" with "[s]ealed source(s) implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the written directive."

The NRC agrees that the dose distribution within the treatment site is not a suitable ME criterion because it can vary over time and is not fully under the control of the AU. In response to other comments, the NRC revised the permanent implant brachytherapy ME criteria at § 35.3045(a)(2) to be based only on total source strength, not dose. As a result, no ME has occurred if at least 80 percent of the sources are in the treatment site, regardless of the distribution of the sources or the existence of a "cold spot" in the dose distribution. The NRC agrees, and it is NRC policy, that the NRC should not (and does not) regulate the practice of medicine.

Issue: Medical Event definition should allow an exception for causes outside of the physician's control

Comment: One commenter suggested that the ME definition should allow exceptions for patient-related and procedure-related causes (other than seed migration) that are outside of the

physician's control. The commenter noted that the exception for MEs resulting from patient intervention does not address procedure-related causes that are outside of the physician's control. The commenter recommended that § 35.3045(a)(2) be revised to read: "For permanent implant brachytherapy, the administration of byproduct material or radiation from byproduct material (not resulting from patient-related or procedure-related causes – such as edema, source migration after placement or imaging uncertainties) that results in..." The commenter stated a concern that, without an exception for patient-related and procedure-related causes, "many medically acceptable procedures will be labeled as MEs, contrary to our understanding of the NRC's intent."

Response: No change was made to the rule text based on this comment. The NRC did not modify the rule to include exceptions for patient-related and procedure-related causes (other than seed migration) that are outside of the physician's control. Factors outside of the physician's control, such as edema and imaging uncertainties, should have limited impact under the source-strength based ME reporting criteria in § 35.3045(a)(2)(ii).

Issue: Error in calculating the total source strength

Comment: One commenter stated that it is not clear why the ME criterion in § 35.3045(a)(2)(v)(E), i.e., "[a] 20 percent or more error in calculating the total source strength documented in the pre-implantation portion of the written directive," was proposed. The commenter believes that this criterion was based on an "ACMUI proposal of using the wrong activity or source strength (+/- 20 percent) as specified in the written directive," and noted that the ACMUI did not specify whether this is "wrong" as compared to the pre-implantation or post-implantation portion of the WD. The commenter stated that the requirement in § 35.3045(a)(2)(v)(E) appears to be a duplication of the intent of § 35.3045(a)(2)(i) and recommended deleting § 35.3045(a)(2)(v)(E).

Response: The rule text was modified based on this comment. The rule text in § 35.3045(a)(2)(v) was revised to delete the ME criterion described in § 35.3045(a)(2)(v)(E), "[a] 20 percent or more error in calculating the total source strength documented in the pre-implantation portion of the written directive." However, the NRC determined that § 35.3045(a)(2)(v)(E) was not a duplication of § 35.3045(a)(2)(i), but agrees that the provision is not needed. As stated by the commenter, this criterion was originally recommended by the ACMUI. In July 2005, the ACMUI submitted to the NRC a set of guiding principles to assist the NRC staff in defining a rule to capture MEs from permanent implant brachytherapy procedures. One of the principles recommended a limited dose-based ME criterion: "[a]n implant is a medical event if the dose calculations used to determine the total source strength documented in the written directive are in error by more than 20 percent in either direction." The ACMUI explained that this "limited" ME dose pathway would "focus only on preplanning or intraoperative planning, not post-implant evaluation." Since the revised ME criteria are based on post-implant evaluations, the NRC agrees that the criterion at § 35.3045(a)(2)(v)(E) is not needed.

Comment: One commenter stated that the criterion in § 35.3045(a)(2)(i) is consistent with clinically relevant circumstances. The commenter expressed concern that this is exactly the same as the requirement in § 35.3045(a)(2)(v)(E). The commenter noted that the rationale is unclear for comparing against the post-implantation source strength in § 35.3045(a)(2)(i) and comparing against the pre-implantation source strength in § 35.3045(a)(2)(v)(E). The commenter also stated that current practice is "to assay a portion of the seeds to ensure the total source strength is as ordered, which would prevent both of these medical events from occurring."

Response: The rule text was modified based on this comment. The rule text in ~~in~~_____ § 35.3045(a)(2)(v) was revised to delete the ME criterion in § 35.3045(a)(2)(v)(E) of the proposed rule: "[a] 20 percent or more error in calculating the total source strength documented

in the pre-implantation portion of the written directive." Although these criteria are not exactly the same, ~~T~~the NRC agrees with the commenter that~~, although these criteria are not exactly the same,~~ the criterion at § 35.3045(a)(2)(v)(E) is not needed because such situations will almost always be captured by the criteria at § 35.3045(a)(2)(i) and (a)(2)(ii). In the rare situation where a calculation error would not be captured by the criteria at (a)(2)(i) or (a)(2)(ii)—for example, because the calculation error was later corrected—then the NRC would not deem it appropriate to report the calculation error itself as an ME.

The NRC considered the commenter's statement that these types of MEs would be prevented by assaying a portion of the seeds to ensure the total source strength is as ordered and concluded that this may not be fully correct. For example, it is possible for an ME to occur if there was an error of 20 percent or more in the total source strength ordered and administered.

Issue: Comparison of source strength specified in the pre-implantation written directive

Comment: Several commenters stated that ME reporting for permanent implant brachytherapy must be based on the source strength in the post-administration WD as described in § 35.40(b)(6)(ii). Some of the commenters stated that the proposed changes to § 35.3045 wrongly specified the pre-implantation WD.

Response: No changes were made in response to these comments. The source strength comparisons for the ME reporting criteria in § 35.3045(a)(2)(i) and (ii) are with the source strength specified in the post-implantation WD. Although § 35.3045(a)(2)(iii) of the proposed rule included an absorbed dose comparison with information in the pre-implantation WD, the NRC removed this criterion in response to other comments. Also, § 35.3045(a)(2)(v)(E) of the proposed rule included a calculated total source strength with the pre-implantation WD, but NRC removed this criterion in response to different comments. As a

result, § 35.3045(a)(2) no longer requires any comparisons with the pre-implantation WD.

Issue: Support source strength-only approach for medical event criteria for permanent implants

Comment: One commenter supported the shift to use total source strength administered (activity-based) ME criteria for permanent implants rather than dose delivered (dose-based) criteria for permanent brachytherapy implants.

Response: The comment supports language in the rule; therefore, no response is required.

Comment: One commenter expressed several concerns related to the proposed dose-based portion of the criteria for permanent implant brachytherapy ME reporting. The commenter recommended that any ME reporting for permanent implant brachytherapy be based solely on a source-strength based definition for the WD as recommended originally by the ACMUI and the radiological societies rather than the proposed hybrid definition based on source strength and absorbed dose. The commenter's concerns included: 1) that the WD has no absorbed dose specification; 2) that regulatory inspectors do not possess the expertise to assess permanent seed implants and determine if any 5 contiguous cubic centimeters have exceeded an expected absorbed dose by 50 percent; 3) that different licensees use different absorbed dose metrics to determine a successful implant; 4) that the dose to 5 contiguous cubic centimeters introduced by the NRC is arbitrary and not based on any clinical data; and 5) that the ACMUI in 2008 recommended a source strength ME definition for permanent implants and explicitly stated it should not include an absorbed dose criteria.

Response: The rule text was modified based on this comment. The rule text in § 35.3045(a)(2) was modified to remove § 35.3045(a)(2)(iii) and (iv), which would have required the assessment of the absorbed dose to normal tissue outside and within the treatment site.

The rule text, as proposed in § 35.40(b)(6)(i), contains a requirement to include the intended absorbed dose to the treatment site. However, in response to other comments, the NRC has decided to remove this requirement from the final rule. The commenter is correct that in 2008 the ACMUI recommended source-strength based criteria. However, in 2012, the ACMUI recommended the proposed "hybrid" criteria for reporting MEs for permanent implants, and that recommendation was endorsed by the American Association for Radiation Oncology. The NRC understands the commenter's concerns that regulatory personnel may have difficulty assessing permanent implants under the proposed rule, and that different licensees may use different criteria for determining a successful implant. The NRC agrees that the proposed absorbed dose-based criteria are not based upon clinical data. In response to these concerns and those raised by other commenters, the NRC removed the absorbed dose-based ME reporting criterion in § 35.3045(a)(2)(iii) and (iv).

Comment: Two commenters stated that in 2008, the ACMUI recommended a source strength ME definition for permanent implants. The commenters stated that nevertheless, the NRC staff added an absorbed dose-based criterion to the definition, and the Commission rejected it. The NRC held national stakeholder workshops in 2011 on this issue and the overwhelming consensus at each workshop attended by professional organizations and radiological professionals was to have source-strength ME reporting criteria rather than absorbed dose-based criteria. The commenters also pointed out that the ACMUI presentations at these workshops stated that a source strength definition was preferable. The commenters recommended that the NRC provide a more comprehensive regulatory basis for deviating from these recommendations. One of the commenters stated that the NRC needs to base the ME definition on source strength rather than the proposed hybrid definition based on source strength and absorbed dose, by removing § 35.41(b)(6)(iii) and (iv) and amending § 35.3045(a)(2).

Response: The rule text was modified based on these comments. The rule text in § 35.3045(a)(2) was modified to remove § 35.3045(a)(2)(iii) and (iv), which would have required the assessment of the absorbed dose to normal tissue outside and within the treatment site. A corresponding change was made to the rule text in § 35.41(b)(6) to remove § 35.41(b)(6)(iii) and (iv). The NRC agrees with the commenters' stated timeline of events regarding ME reporting criteria recommendations. However, in 2012, the ACMUI recommended the proposed "hybrid" criteria for reporting MEs for permanent implants, and that recommendation was endorsed by the American Association for Radiation Oncology. This recommendation was one of the key components of the NRC's regulatory basis for the proposed rule. In response to other comments, the NRC removed the absorbed dose-based ME reporting criterion in § 35.3045(a)(2)(iii) and (iv) and the requirements in § 35.41(b)(6)(iii) and (iv) for determination of absorbed dose to normal tissue outside and within the treatment site.

Issue: Alternate recommendations for ME definitions for permanent implants

Comment: One commenter suggested that the NRC require licensees to establish a "peer review" process in conjunction with the requirements that licensees establish procedures that provide "high confidence" that the WD is fulfilled. The commenter stated that MEs should be rare mistakes because the procedures are required to be performed by physicians that have the required T&E. The commenter also stated that the NRC should not try to regulate the "medicine side" and that the NRC's determination of "'actual or potential harm to a patient' and review of normal tissue doses are not needed."

Response: No change was made to the rule text based on this comment. The NRC agrees that the NRC should not regulate the practice of medicine. In accordance with the Commission's Medical Use Policy Statement published August 3, 2000 (65 FR 47654), the NRC does not intrude into medical decisionmaking except as necessary to provide for the safety of

workers and the general public and to ensure that radionuclides are used in accordance with the physician's directions~~Indeed, it is NRC policy that it should not (and does not) regulate the practice of medicine~~. The NRC disagrees that it should require licensees to establish a peer review process for assessing MEs. The licensee makes the determination of the actual or potential harm to patients that might result from an ME. However, the NRC's position is that an ME may be indicative of a potential problem in a medical facility's use of radioactive materials even if it does not result in harm to the patient.

In response to the portion of this comment concerning dose to normal tissue and other comments, the NRC removed the absorbed dose-based ME reporting criteria for normal tissue in § 35.3045(a)(2)(iii) and (iv).

Comment: One commenter suggested that the reporting criteria for permanent implants should be defined as the "dose coverage to the intended target," which is a much more meaningful indicator of the quality of an implant. The commenter suggested the use of "D90" and provided the D90 definition from the AAPM Task Group 137: "the minimum dose to the hottest 90 percent of the target volume."

Response: No change was made to the rule text based on this comment. This is one of the few comments NRC received that supported dose-based ME reporting criteria for the treatment site. The NRC understands that "D90" is one of the absorbed dose-based parameters that is an accepted professional practice for assessing the clinical quality of an implant. However, the NRC also understands that "D90" is not the only dose-based parameter that is accepted and used. The NRC also received numerous other comments that identified technical limitations associated with the use of dose-based ME reporting criteria for permanent implant brachytherapy. Therefore, the NRC revised the permanent implant brachytherapy ME reporting criteria in § 35.3045(a)(2) to be based only on total source strength, not dose.

Comment: One commenter suggested that the reporting criteria for permanent implants

should be based upon the dose to the organs at risk. The commenter provided the examples of the bladder and the rectum as organs at risk when treating the prostate with permanent implants. The commenter stated that this approach would hold the brachytherapist (AU) accountable for protecting the organs at risk but not penalize the AU for intentionally implanting sources in normal tissue for treatment purposes. The commenter also stated that "[a]nother benefit of both of these suggestions is that current brachytherapy software offers a method of evaluating the dose coverage to the target and organs at risk."

Response: No change was made to the rule text based on this comment. This is one of the few comments NRC received that supported the dose-based ME reporting criteria. The NRC received other comments that identified technical limitations associated with the use of a dose-based ME reporting criteria for dose to normal tissue from permanent implant brachytherapy. The NRC eliminated the dose-based criteria in § 35.3045(a)(2)(iii) and (iv) for normal tissue for reporting MEs. Therefore, the dose to the organs at risk does not need to be determined for ME reporting purposes.

Issue: Concerns regarding regulators' training and ability to inspect and assess permanent implants under the proposed criteria

Comment: Several commenters expressed concerns about the ability of regulators to assess licensees' implementation of the proposed ME reporting criteria in § 35.3045(a)(2)(iii) and (iv). One commenter asked if inspectors are capable of evaluating the methods used by the licensee to determine the 5 contiguous cubic centimeter volume of normal tissue and related dosimetry. Another commenter stated that the proposed change will require substantial retraining of regulatory personnel to make determinations based on the new criteria. The commenter stated "[t]his is unduly burdensome and serves no real value since doses may be clinically off by 200 percent and still be viable for treatment." Two other commenters stated that

most regulatory personnel do not have the tools or expertise to assess a permanent implant and determine if any 5 contiguous cubic centimeters have exceeded an expected absorbed dose by 50 percent. The commenters also expressed concern that the NRC has proposed a dose metric that is not an established standard of clinical practice and appears to infringe on the practice of medicine.

Response: The rule text was modified based on these comments. The rule text in § 35.3045(a)(2) was modified to remove § 35.3045(a)(2)(iii) and (iv), which would have required the assessment of the absorbed dose to normal tissues outside and within the treatment site. The NRC understands the commenters' concerns that regulatory personnel may have difficulty assessing permanent implants under the proposed rule and that the NRC proposed a 5 contiguous cubic centimeter volume dose metric that is not an established standard of clinical practice. In response to these concerns and different concerns raised by other commenters, the NRC removed the absorbed dose-based ME reporting criteria in § 35.3045(a)(2)(iii) and (iv).

Issue: Applicability of the proposed criteria to Y-90 microspheres

Comment: Several commenters questioned whether the new permanent implant brachytherapy requirements at § 35.3045 apply to the use of Y-90 microspheres under § 35.1000. One commenter stated that these new requirements cause confusion when read in conjunction with the NRC licensing guidance for Y-90 microspheres, which describes them as "manual brachytherapy sources used for permanent implantation therapy." The commenters suggested that the rule language be clarified to include a definition of the types of sources to which the permanent implant brachytherapy requirements apply so that it is clear whether they apply to Y-90 microspheres.

Response: No change was made to the rule text. The term "permanent implant brachytherapy" is used to refer to manual brachytherapy procedures performed in accordance

with § 35.400. The NRC considers Y-90 microspheres to be manual brachytherapy sources; however, they have unique properties that prevent them from being regulated under all the provisions of § 35.400 and are regulated under § 35.1000. Consequently, the ME reporting requirements for permanent implant brachytherapy do not apply to the use of Y-90 microspheres.

Issue: Defining the treatment site in the written directive

Comment: The commenter expressed concern that under the proposed rule in § 35.3045(a)(2)(ii), a high quality implant with excellent dose statistics, where many seeds are implanted outside the Planning Target Volume (PTV) to ensure adequate dose coverage, would be viewed as an ME. The commenter stated that its prostate implant program allows for the implantation of I-125 seeds into normal tissues surrounding the prostate so that the prescribed dose covers a treatment margin (PTV) in addition to the prostate, in order to treat extra-capsular extension of prostate cancer. The commenter provided recommendations from the American Association of Physicists in Medicine Task Group Report 137 and the American Brachytherapy Society Prostate Low-Dose Rate Task Group Report on treating a margin of tissue outside of the prostate. The commenter also expressed concern with the criterion in § 35.3045(a)(2)(ii) because its vendor's software does not currently have a satisfactory method of determining whether 20 percent of the source strength is outside of the treatment site.

Response: No change was made to the rule text based on this comment. The NRC understands that AUs may intentionally implant sources into surrounding normal tissues. The AU defines the treatment site in the WD in any way he or she believes to be medically appropriate, including any margin or PTV structure. The NRC acknowledges that treatment planning software may not have an automated method to determine whether 20 percent of the source strength is outside of the treatment site. It may be necessary for licensees to perform a

manual determination of the number of sources outside the treatment site in comparison with the number of sources within the treatment site.

Comment: One commenter stated that the requirement at § 35.3045(a)(2)(ii) would have positive impact if the definition of treatment site is clarified to include implantation of seeds in interstitial tissue, and not critical structures. The commenter believes that this criterion is consistent with clinically relevant circumstances when several seeds are accidentally placed in critical organs to the extent that they could cause a medically significant event to the patient.

Response: No change was made to the rule text based on this comment. The NRC determined that revising the definition of the treatment site to include implantation of sources in interstitial tissue, and not critical structures, is not warranted. The AU defines the treatment site in the way he or she believes to be medically appropriate, which in some cases may include intentional implantation of sources in critical structures. The NRC has determined that the criterion in § 35.3045(a)(2)(ii) appropriately captures those instances where medically significant events may occur. The NRC is not aware of cases where medically significant events have occurred ~~and~~ while 20 percent or less of the source strength was implanted outside the treatment site.

Comment: One commenter stated that compliance with the requirements in § 35.3045 is dependent on how the tumor volume is defined by the physician. The commenter explained that if one AU defines the treatment site with "tight borders" the licensee may need to report an ME. However, if another AU defines the treatment site more "loosely," an ME may not have to be reported.

Response: No change was made to the rule text based on this comment. The AU defines the treatment site in the WD in the way he or she believes to be medically appropriate, including any margin. The AU may define the treatment site to include all tissues into which sources have been purposely implanted. The NRC has determined that the definition of the

treatment site is a matter of medical judgment.

Comment: One commenter stated that the identification of the "treatment site" is not well defined. The commenter stated that some facilities identify the treatment site as the prostate gland only and plan a dose margin around the prostate, while other facilities include a planning target volume (PTV) structure around the prostate as the treatment site and target coverage to that structure.

Response: No change was made to the rule text based on this comment. The AU defines the treatment site in the WD in the way he or she believes to be medically appropriate, including any margin or PTV structure.

Issue: The complexity of the medical event reporting requirements as currently proposed may create confusion

Comment: One commenter stated that the proposed ME reporting requirements are complex and may create confusion for regulators and the regulated community when applied to permanent prostate implant procedures.

Response: The rule text was modified based on other comments. The NRC acknowledges the commenter's concern regarding the complexity of the ME reporting requirements. The NRC noted that this comment is general and does not identify specific portions of the proposed rule that are complex and may create confusion. The NRC received several comments raising concerns about specific portions of the proposed rule and changes were made in response to these comments. One of the major changes was to remove the requirements in § 35.3045(a)(2) related to absorbed dose to normal tissue. The NRC believes that these changes have reduced the complexity of the ME reporting requirements.

Issue: NRC should create a new section in 10 CFR part 35 for permanent implant

brachytherapy regulations only

Comment: One commenter recommended that the NRC create a new section in 10 CFR part 35 for permanent brachytherapy implants only. This new section should include the procedural requirements included in § 35.41(b)(6) and ME reporting criteria specific to permanent brachytherapy implants included in § 35.3045 of the proposed rule. The commenter stated that, if the NRC decides to create this new separate section, then the ME requirements for permanent brachytherapy implants should be separated and handled in a rulemaking separate from the remainder of the proposed amendments, to allow the NRC to finalize all other proposed amendments without delay.

Response: No change was made to the placement of regulations related to permanent implant brachytherapy. The requirements for procedures requiring a WD, and the requirements for ME reporting appear in two different subparts of part 35—Subpart B – General Administrative requirements, and Subpart M – Reports. To separate the permanent implant brachytherapy requirements from these subparts and put them in a separate section would disrupt the logical flow of part 35.

Issue: The Compatibility Designation for Medical Event Reporting under § 35.3045

Comment: One commenter stated that the WD requirements under § 35.40(b)(6) and the procedures for permanent implant brachytherapy required under § 35.41(b)(6) should be deemed Compatibility Category B (rather than Compatibility Category C) such that the rules are uniform from one state to another to minimize confusion. The commenter stated that because over 90 percent of medical licensees are under Agreement State authority, anything less than Compatibility Category B makes these changes "an over-regulation of the minority."

Response: The WD requirements under § 35.40(b)(6) and the procedures for permanent implant brachytherapy required under § 35.41(b)(6) are designated as Compatibility

Category Health and Safety (H&S). This designation was not changed in the proposed rule. The 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. The commenter appears to be referring to the compatibility designation of ME reporting under § 35.3045, which is designated as Compatibility Category C and which the final rule continues to designate as Compatibility Category C.

Comment: One commenter stated that if the NRC were to revert to a lower-than-proposed compatibility category (i.e., Compatibility Category C instead of B), then they recommend, as a last resort, that the NRC explicitly state in the preamble of the final rule that activity-based ME metrics are an essential program element, and that dose-based metrics are unacceptable for use. The commenter stated that the absorbed dose-based ME metrics are not "more restrictive" per se, but are unsuitable and confusing when misapplied to the specific procedures in question.

Response: The NRC has discussed the program element contained in § 35.3045 and the essential objective of this program element in Part I, item 4 of this section based on this comment. The program element contained in § 35.3045 is ME reporting, not activity-based ME metrics. The essential objective of this program element is to maintain a consistent national ME reporting program. In the final rule, the ME criteria for permanent brachytherapy is activity-based and not dose-based. Dose-based ME reporting criteria for permanent implant brachytherapy would conflict with the essential objective of maintaining a consistent national reporting program because it would result in insignificant events being reported as MEs. As explained in Part I, item 4 of this section, consistency in the national reporting program allows the NRC to identify trends or patterns, identify generic issues or concerns, recognize inadequacies or unreliability of specific equipment or procedures, and determine why an event occurred and whether any actions are necessary to improve the effectiveness of NRC and

Agreement State regulatory programs. Dose-based ME reporting criteria would result in inconsistent reporting of permanent implant brachytherapy MEs, and thus would disrupt these efforts.

Comment: One commenter stated that they support the Compatibility Category B designation for ME reporting, in agreement with the opinion of the ACMUI and for the reasons provided in the proposed rule. The commenter stated that, considering the details and clinical implications of the prostate implant procedures, it only makes sense to have activity-based criteria for an ME. The commenter believes that there is merit in consistent rules for subjects that have significant implications, such as the criteria for an ME, and standardization should remove uncertainty and confusion.

Response: The NRC agrees with the commenter that activity-based criteria are appropriate for MEs for permanent implant brachytherapy procedures, including the prostate implant procedures. As discussed earlier in this section, NRC has determined that Compatibility Category C is the appropriate designation for § 35.3045. The NRC determined that Compatibility Category B is not the appropriate designation because the ME reporting criteria, while important to the effective and orderly regulation of agreement material on a nationwide basis, do not have significant direct transboundary implications. The essential objective of § 35.3045 is to maintain a consistent national program for reporting MEs. Agreement State use of dose-based criteria for permanent implant brachytherapy ME reporting would be inconsistent with this essential objective because the NRC has determined that dose-based criteria would result in the reporting of insignificant events. Therefore, Agreement States' use of dose-based reporting criteria either instead of or in addition to activity-based reporting criteria for permanent implant brachytherapy would not be compatible with § 35.3045.

Comment: One commenter expressed support of the Compatibility Category B designation for § 35.3045 and noted that, as discussed by the NRC in the proposed rule, some

medical licensees practice at multiple locations, some of which are NRC-regulated and some of which are Agreement State-regulated. The commenter stated that a Compatibility Category B designation would allow for uniformity of practice and procedures across the country. The commenter further suggested that to make the move from Compatibility Category C to B smooth, the NRC should define the "essential objectives" of § 35.3045 such that the Agreement States' adoption of the new definition is not met with unnecessary delays.

Response: The NRC has determined that Compatibility Category C is the appropriate category for § 35.3045, for the reasons explained in response to another comment and in Part I, item 4 of this section. The essential objective of § 35.3045 is to maintain a consistent national reporting program, as further explained in Part I, item 4 of this section.

Comment: One commenter, in support of the Compatibility Category B, stated that they recognize that the Agreement States oppose a change in ~~compatibility~~ Compatibility ~~level~~Category, citing state legislative requirements, the difficulty in changing state regulations, and the fact that Agreement States do not perceive a problem with the current dose-based definition. The commenter believes that these concerns are outweighed by the importance of having a consistent definition throughout the country to prevent confusion and unnecessary reporting of otherwise medically acceptable procedures as MEs. The commenter expressed concern that a Compatibility Category C designation would allow Agreement States to implement unnecessarily more restrictive definitions that classify medically acceptable procedures as MEs.

Response: The NRC understands the importance of having consistent ME reporting criteria throughout the country to prevent confusion and unnecessary reporting of otherwise medically acceptable procedures as ME. This consistency is necessary to meet the essential objective of § 35.3045, which is to maintain a consistent national reporting program. The NRC disagrees that Compatibility Category B is the appropriate category for § 35.3045 and instead

has determined that Compatibility Category C is the appropriate category. Therefore, Agreement States are required to adopt the essential objectives of this provision, but are not required to adopt essentially identical ME reporting criteria. The Agreement States have the flexibility to include, for example, a shorter reporting time in their ME reporting criteria, but the use of dose-based ME reporting criteria for permanent implant brachytherapy would create conflicts and inconsistencies with respect to the national reporting program, because it would capture insignificant events as MEs.

Comment: Two commenters in support of Compatibility Category B stated that because over 90 percent of medical licensees are under Agreement State authority, anything less than Compatibility Category B makes the proposed changes an "over-regulation of the minority." The commenters stated that it would be counterproductive for Agreement States to maintain alternative ME criteria not listed in the revised § 35.3045. The commenters further stated that because certain healthcare systems may be providing services in both NRC and Agreement State jurisdictions, § 35.3045 should be designated as Compatibility Category B. One commenter said that they strongly support the proposed designation of Compatibility Category B for § 35.3045, thereby requiring Agreement States to adopt ME reporting and notification program elements essentially identical to NRC's. The commenter also stated that it would be counterproductive for Agreement States to maintain alternative ME criteria not listed in the revised § 35.3045. The commenter stated that if the dose-based ME reporting criteria were interpreted by the States as more "restrictive," and States were to continue to have some manner of ill-fitting ME methodology, this would confuse the regulated community and continue to weaken confidence in the significance of reported permanent brachytherapy MEs.

Response: As explained in response to other comments, the NRC has determined that Compatibility Category C is the appropriate category for § 35.3045. Under Compatibility Category C, Agreement States will not be able to maintain alternative ME criteria not listed in

the revised § 35.3045, if those criteria would create conflicts or inconsistencies in the national reporting program. The NRC understands the commenter's concern that alternative ME criteria could weaken the public's confidence in the significance of permanent implant brachytherapy MEs. Therefore, the NRC has identified dose-based criteria as an example of alternative ME reporting criteria that would capture insignificant events as MEs and create a conflict and inconsistency in the national reporting program.

Comment: Several commenters stated that their medical practices are affected by the compatibility category assigned to § 35.3045. They said that they are pleased with the Commission's decision to move § 35.3045 from Compatibility Category C to Compatibility Category B. The commenters stated that it is essential that § 35.3045 be defined and implemented in a consistent manner across the country. The commenters stated that, as the NRC noted in the proposed rule, some medical licensees practice at multiple locations, some of which are NRC-regulated and some of which are Agreement State-regulated. The commenters stated that there are many practices that extend beyond one particular jurisdiction, usually when the main center is near a state border. The commenters further stated that they expect this situation to increase significantly in the coming few years as the consolidation of healthcare institutions into larger entities continues to accelerate. Therefore, a Compatibility Category B designation would allow for uniformity of practice and procedures across the country.

Response: The NRC understands the commenters' concern that § 35.3045 be defined and implemented in a consistent manner across the country. As noted by the commenter, and as the NRC noted in the proposed rule, some medical licensees practice at multiple locations, some of which are NRC-regulated and some of which are Agreement State-regulated.

The NRC disagrees that § 35.3045 should be designated as Compatibility Category B to ensure uniformity of practice and procedures across the country. The NRC designates regulatory program elements as Compatibility Category B if they have significant direct

transboundary implications, not simply for the purpose of ensuring uniformity across the country with respect to a program element. The effect of a Compatibility Category B designation is essentially uniformity across the country with respect to a program element, because this designation requires Agreement States to adopt program elements that are "essentially identical" to that of the NRC. This uniformity is necessary because a program element has significant direct transboundary implications. As discussed in Part I, item 4 of this section, the NRC has determined that ME reporting does not rise to the level of having significant direct transboundary implications. Therefore, Compatibility Category B is inappropriate.

The NRC has determined that Compatibility Category C is the appropriate designation for § 35.3045. Under Compatibility Category C designation, the essential objectives of the regulation should be adopted by the State to avoid conflicts, duplications or gaps. The essential objective of § 35.3045 is to maintain a consistent national ME reporting program. Agreement States should ensure that their ME reporting criteria do not conflict with or create inconsistency within this program.

Comment: One of the Agreement States stated that all MEs are local events and are not transboundary events, regardless of their significance. The commenter stated that even multiple events with a common root cause are considered local events and each licensee is required to submit an ME report to its licensing authority. The commenter also stated that all MEs are reported in the Nuclear Materials Event Database, so NRC is notified of all events that meet the NRC's ME criteria.

Response: The NRC acknowledges that, from the perspective of a single medical facility, MEs appear to be local events only. The NRC has determined that ME reporting does not rise to the level of having significant direct transboundary implications and; therefore, Compatibility Category B is inappropriate. However, to ensure that an Agreement State program meets the essential objective of § 35.3045 to maintain a consistent national ME

reporting program, the Agreement States, for permanent implant brachytherapy treatments, should not use the dose-based criteria. For the reasons explained in response to other comments and in Part I, item 4 of this section, the use of dose-based criteria would create conflicts and inconsistencies in the national ME reporting program.

Comment: Several commenters opposing the proposed category B designation for ME reporting questioned how a single medical incident at a single facility can have "direct and significant effects in multiple jurisdictions." They further added that the Compatibility Category C designation has been adequate for the reporting requirements for radiography, irradiator, and well logging licensees who routinely work in multiple jurisdictions.

Response: The NRC agrees that the Compatibility Category C designation has been adequate for the reporting requirements for radiography, irradiator, and well logging licensees who work routinely in multiple jurisdictions. The NRC has determined that Compatibility Category C is also the appropriate designation for § 35.3045.

The NRC acknowledges that, from the perspective of a single medical facility, MEs appear to be local events only. The NRC agrees that ME reporting does not have direct and significant effects in multiple jurisdictions, and therefore agrees that Compatibility Category B is not the appropriate designation for § 35.3045. Therefore, the ME reporting criteria do not have to be essentially identical. However, the essential objective of § 35.3045 is to maintain a consistent national ME reporting program, and to adopt this essential objective Agreement States should adopt ME reporting criteria that do not create conflicts or inconsistencies in ME reporting. The ME reporting program ensures that the NRC and Agreement States are able to identify trends or patterns, identify generic issues or concerns, recognize inadequacies or unreliability of specific equipment or procedures, and determine why an event occurred and whether any actions are necessary to improve the effectiveness of NRC and Agreement State

regulatory programs. Inconsistent or conflicting ME reporting criteria would frustrate these purposes.

Comment: Several commenters, in support of the Compatibility Category C designation for ME reporting under § 35.3045, stated that currently the only reporting regulations with a Compatibility Category B designation are related to the security requirements and are located in other parts of 10 CFR. The commenter also stated that all the reporting requirements found in 10 CFR part 35 are Compatibility Categories C, H&S, or D. Since § 35.3045 is a reporting requirement and does not relate to the security of Category 1 or Category 2 sources, the commenter recommended that the compatibility category for the reporting requirements in § 35.3045 remain as Compatibility Category C.

Response: It is true that currently the only reporting regulations with Compatibility Category B designation are related to the security requirements and are located in other parts of 10 CFR. However, that does not preclude the NRC from categorizing reporting requirements as Compatibility Category B. Compatibility category designations do not hinge on whether a regulatory requirement pertains to security or any other discrete regulatory issue. Rather, the NRC assigns the appropriate category for each regulatory requirement by considering and applying the criteria for Agreement State compatibility to each particular regulatory requirement. For the reasons stated in response to other comments and as discussed in Section V, Public Comment Analysis, the NRC has determined that Compatibility Category C is the appropriate designation for § 35.3045.

Comment: One commenter, in support of the Compatibility Category C designation for ME reporting under § 35.3045, stated that throughout § 35.3045, the term "treatment site" is used, that it is specifically defined in § 35.2, and that this definition has been designated Compatibility Category C. The commenter stated that since the definition of "treatment site" is remaining a Compatibility Category C, it is possible for an Agreement State to adopt the

essential objective of the definition but it may be a slightly different definition. If the definition for treatment site is slightly different in each jurisdiction, even if § 35.3045 is changed to a Compatibility Category B, the requirement may not be "essentially identical" in each jurisdiction.

Response: It is true that the "treatment site" is defined in § 35.2 and that this definition has been designated Compatibility Category C. While the NRC may assign a particular compatibility category to certain definitions, the regulations in which these terms are used are not confined to this same category. Instead, the NRC assigns the appropriate category for each regulatory requirement by considering and applying the criteria for Agreement State compatibility to each particular regulatory requirement.

Comment: One commenter recommended that, if the NRC insists on changing the Compatibility Category to B, then the rule language be changed to only require the Compatibility Category B designation for permanent prostate implant procedures and no other permanent brachytherapy procedures. The commenter further stated that the main impetus for changing the compatibility category for ME reporting appears to be the multiple prostate implant MEs that occurred at the Department of Veterans Affairs facilities.

Response: When drafting the ME reporting requirements for permanent implant brachytherapy procedures at § 35.3045(a)(2), the NRC developed requirements that would apply to permanent implant procedures for all treatment sites, including prostate implants. Although prostate implants are ~~the~~ more common than other implants, the NRC staff in SECY-12-0053 recommended that the revised ME criteria apply to permanent implant procedures for all treatment sites, not only the prostate. The NRC has determined that the prostate implant procedure does not warrant a separate set of regulations and that including them in the ME reporting requirements for permanent implant procedures for all treatment sites is sufficient to ensure that significant events involving prostate implants will be reported as MEs. As explained in response to other comments and in Part I, item 4 of this section, the NRC has determined

that Compatibility Category C is appropriate for all of § 35.3045, including permanent implant brachytherapy procedures, such as prostate implants.

Comment: One Agreement State stated that the proposed activity-based ME reporting criteria should be added to the existing dose-based criteria, rather than replace it. The Agreement State stated that it would require licensees to apply both criteria, and only those MEs that meet the NRC's proposed activity-based criteria would be reported to the NRC. The commenter explained that this approach would provide the states with the needed flexibility to regulate both radioactive materials and machine-produced sources of radiation in a consistent manner. The commenter also stated that the ME reporting regulations should not be categorized as Compatibility Category B because that would restrict the State's ability to regulate the clinical aspects of the practice of medicine and patient management.

Response: The NRC has determined, as recommended by the medical community, that the activity-based criteria are more appropriate for permanent implant brachytherapy procedures than the dose-based criteria, because activity-based criteria specifically captures significant events for reporting as MEs whereas dose-based criteria would capture insignificant events as well. The NRC has determined that Compatibility Category C is the appropriate designation for § 35.3045. However, as explained in response to other comments and in Part I, item 4 of this section, the NRC has determined that Agreement State use of dose-based criteria for permanent implant brachytherapy ME reporting would result in inconsistencies and conflicts with the essential objective of § 35.3045, which is to maintain a consistent national ME reporting program.

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

Comment: Two commenters supported the proposed generator elution breakthrough

reporting requirements.

Response: The comment supports language in the rule; therefore, no response is required.

Comment: One commenter noted that Tc-99m decays much faster than Mo-99; therefore, every Tc-99m generator eluate will eventually exceed the regulatory limit. Because of this, the commenter stated that the language in the proposed rule text would require every eluate to be reported. The commenter proposed revising the rule text in § 35.3204(a) to clarify that the licensee would only report measurements of a Tc-99m generator elution that exceeded the regulatory limits at the time of generator elution.

Response: The rule text was modified based on this comment. The NRC agrees with the commenter that the proposed rule text in § 35.3204(a) and (b) was not clear and has amended it to clarify that the reporting requirements only apply at the time of generator elution.

Comment: One commenter stated that the reporting and notification requirement for failed Mo-99/Tc-99m and Sr-82/Rb-82 generators was increased from Compatibility Category C to Compatibility Category B. The commenter supports adding specific reporting criteria for failed generators, but wanted to retain the Compatibility Category as C.

Response: No change was made to the compatibility category for reporting and notification requirement for failed Mo-99/Tc-99m and Sr-82/Rb-82 generators based on this comment. In the proposed rule, the NRC designated the reporting requirements in § 35.3204(a) and (b) as Compatibility Category C. The final rule retains the same compatibility category for reporting requirements in § 35.3204(a) and (b).

Comment: Two commenters agreed with the proposed revision but asserted that the proposed § 35.3204(a) initial requirement to report to the NRC Operations Center within 30 days should be shortened. One commenter stated that a shorter reporting requirement was needed to more effectively address patient safety concerns. The other commenter stated that in

order to respond in a timely manner to potential issues regarding the manufacturing and/or use of generators, the reporting period should be less than 30 days.

Response: The rule text was modified based on these comments. The rule text in § 35.3204(a) was revised to require notification within 7 calendar days. The NRC agrees that the time period for notification should be shorter than the proposed 30 calendar days. With the short half-lives of the parent radionuclides, the NRC determined that a 7 calendar-day notification requirement is more appropriate. Seven calendar days gives the licensee an opportunity to evaluate its procedures, measurements, and calculations to determine if the generator failed or if there was an error made by the licensee. The licensee is only required to report generator failures, i.e., when the eluate actually exceeded the permissible concentration listed in § 35.204(a). The shorter reporting requirement would also permit the NRC to determine the extent of generator failures and take quicker action to protect patient safety.

Comment: Several Agreement States disagree that the notification of the discovery of an eluate exceeding the limits needed to be made to the NRC Operations Center. They recommended that a report be submitted to the NRC regional offices instead. The commenters stated that any 30-day notification to the Agreement States must only be submitted to the NRC using the National Materials Events Database (NMED), not the Operations Center. One commenter stated that the doses received from most generators that exceed the eluate breakthrough limits would not meet the reporting requirement for a diagnostic ME and therefore does not meet the urgency for reporting to the Operation Center. The commenter used the CardioGen® Sr/Rb generator recall as an example. Further, the commenter stated that the current Integrated Materials Performance Evaluation Program requirement to report such events to the NMED is more than sufficient. One commenter stated that "[s]hould a trend of these events be found, the Agreement States currently report these events to the Regional Agreement State Officer."

Response: No change was made to the rule text based on these comments. The NRC determined that it is appropriate to report generator failures (i.e., when the eluate exceeds the permissible concentration listed in § 35.204(a)) to the NRC Operations Center. Reporting to the NRC Operations Center will permit the NRC to identify whether this is a limited or more widespread failure of generators and share that information in a timely manner.

Comment: Several commenters recommended that the NRC implement the ACMUI recommendation to only require licensees to report generator elution results with parent breakthrough beyond the § 35.204(a) limits to the manufacturer/distributor, and not to both the manufacturer/distributor and the NRC. The commenters stated that only the manufacturer/distributor should be responsible for reporting "the out-of-tolerance parent breakthroughs to the NRC." The commenters also stated that requiring the licensee to report to both the company and the NRC, while the company also reports to NRC, is unnecessarily duplicative.

Response: No change was made to the rule text based on these comments. The NRC requires that a licensee report to the NRC and the generator manufacturer/distributor when it identifies a generator with an eluate exceeding the permissible concentration limits in 35.204(a). The NRC requires this reporting because it is important that the NRC and the manufacturers/distributors be aware of such events in a timely manner. The reporting requirement is not duplicative because the NRC does not require the manufacturer/distributor to report generator failures to the NRC.

VI Section-by-Section Analysis

This section describes the specific amendments by section for this final rule.

Section 30.34 Terms and conditions of licenses

Paragraph (g). This paragraph adds a new requirement for licensees to report to the NRC when generator eluates exceed the permissible Mo-99 or Sr-82 and Sr-85 concentration limits listed in § 35.204(a). Reporting will be in accordance with the reporting and notifications requirements in § 35.3204. While the reporting requirement as well as the requirement to test every Mo-99 elution is new, the testing by licensees of the first elution to ensure that it does not exceed the permissible concentration listed in § 35.204(a) and recording the results of these tests is already required by this paragraph.

This change provides 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 III, Discussion, of this document.

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

Paragraph (a)(4). This paragraph is amended to clarify that the applicant "commits to" rather than "satisfies" the labeling 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 is 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) are re-designated as (e), and a new paragraph (d) is 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* are added to this section and the definition for *Preceptor* is amended.

The new definition for *Associate Radiation Safety Officer* identifies the requirements an individual will 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 use 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 III, Discussion, of this document.

The new definition for *ophthalmic physicist* identifies the requirements an individual will 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 35.59 and that the individual must be currently listed as an ophthalmic physicist on a 1) specific medical use license issued by the Commission or an Agreement State; 2) permit issued by a Commission or Agreement State broad scope medical use licensee; 3) medical use permit issued by a Commission master material licensee; or 4) permit issued by a Commission master material licensee broad scope medical use permittee. A written attestation will not be required for this individual.

The definition for *Preceptor* is amended to add ARSO to the list of individuals whose ~~can have their~~ T&E is provided, directed, or verified by a preceptor. This is a conforming change in support of the new definition for *Associate Radiation Safety Officer.*

Section 35.8 Information collection requirements: OMB approval

Paragraph (b). This paragraph is amended to include § 35.3204 in the list of sections in which the approved information collection requirements are contained.

Section 35.12 Application for license, amendment, or renewal

This section is amended to require only the submission of the original 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 clarifies what information should be submitted and adds 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 is amended to require the submittal of only the original NRC Form 313. This change will relieve the burden on the applicant by requiring less paperwork to be submitted. It will also require the applicant to submit the T&E qualifications for one or more ARSOs and ophthalmic physicists that are to be identified on the license.

Paragraph (c). For license amendments or renewals, this paragraph is amended to require the submittal of only the original NRC Form 313 or a letter containing information required by NRC Form 313. This change will relieve the burden on the licensee by requiring less paperwork to be submitted. Additionally, it clarifies that the letter submitted in lieu of NRC Form 313 must contain all the information required by NRC Form 313.

Paragraph (d). This paragraph is 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 is amended by revising paragraph (b), re-designating paragraphs (d)

through (g) as paragraphs (e) through (h), revising re-designated paragraphs (g) and (h), and adding new paragraphs (d) and (i).

Paragraph (b). This paragraph is 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~~ identified on a medical license or permit ~~as~~ listed in § 35.13(b)(4).

Paragraph (d). This new paragraph is 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 is 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 SSDR used for manual brachytherapy for quantities and isotopes already authorized by its license without first seeking a license amendment. This change will 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 is 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 III, 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 is restructured to more clearly identify the verification that a board-certified individual will need to provide along with a copy of the individual's board certification. This change does not impose any new requirements.

Paragraph (a)(2). This paragraph retains 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. The sentence in the proposed rule under § 35.14(a)(2), "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)" ~~was~~ is deleted in the final rule. The NRC is removing this sentence because it is not necessary and the requirements are already addressed within § 35.13(b).

Paragraph (b)(1). This paragraph is 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 his or her duties under the license.

Paragraph (b)(5). This paragraph is revised from the proposed rule language that was published on July 14, 2014. In the proposed rule, the structure of § 35.14(b)(5) was changed and this resulted in substantive changes to the paragraph. The NRC did not intend to change the requirements in this paragraph.

Paragraph (b)(6). This new paragraph requires 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 35.15 Exemptions regarding Type A specific licenses of broad scope

This section is amended to make corresponding changes based on amendments to § 35.13 and to § 35.14(b)(1).

Paragraph (c). This paragraph is amended to update the reference from § 35.13(e) to § 35.13(f) as a result of amendments to § 35.13.

Paragraph (e). This paragraph is amended to include ophthalmic physicist as a result of amendments to § 35.14(b).

Section 35.24 Authority and responsibilities for the radiation protection program

This section is 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 is modified to specify that a licensee's management may appoint one or more ARSOs. These appointed ARSOs must 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 will still be limited to naming one RSO who will remain responsible for implementing the entire radiation protection program. The RSO will be prohibited from delegating authority and responsibilities for implementing the radiation protection program. The proposed rule published on July 21, 2014 (79 FR 42410), would have required each ARSO to agree in writing to the tasks and duties assigned by the RSO. The NRC staff determined that this requirement is not necessary because the NRC holds the RSO responsible for implementing the radiation protection program. Therefore, the proposed requirement for each ARSO to agree in writing to the tasks and duties assigned by the RSO is not included in this final rule.

Paragraph (c). An administrative change is made to this paragraph to remove the phrase "an AU or" because it is redundant with "an individual qualified to be a Radiation Safety

Officer under §§ 35.50 and 35.59" in the same sentence.

The position of an ARSO is discussed further in Section III, Discussion, of this document.

Section 35.40 Written Directives

Paragraph (b). This paragraph is restructured and amended to accommodate specific requirements for a WD for permanent implant brachytherapy. Existing paragraph (b)(6) is re-designated as paragraph (b)(7) and a new paragraph (b)(6) is 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 provides details of the specific WD requirements for permanent implant brachytherapy. Specifically, it clarifies that the WD is divided into two portions, i.e., the pre-implantation portion and the post-implantation portion. The pre-implantation ~~WD~~ portion of the WD requires documentation of the treatment site, the radionuclide and the total source strength. The information required by the pre-implantation portion of the WD must be documented prior to the start of the implantation.

The post-implantation portion of the WD will require the documentation of the treatment site, number of sources implanted, the total source strength implanted, and the date. The information required by the post-implantation portion of the WD must be documented before the patient leaves the post-treatment recovery area.

Paragraph (c). This paragraph is restructured for clarity.

Section 35.41 Procedures for administrations requiring a written directive

This section is amended by adding two new paragraphs with requirements that the licensee must address when developing, implementing, and maintaining written procedures to

provide high confidence that each administration requiring a WD is in accordance with the WD.

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

Paragraph (b)(6). This new paragraph requires the licensee to develop specific procedures for permanent implant brachytherapy programs. At a minimum, the procedures will include determining post-implant source position 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 this determination could not be made due to patient unavailability.

The determination that will be required includes 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.

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

Section 35.50 Training for Radiation Safety Officer and Associate Radiation Safety Officer

Multiple changes are made to this section. They include amending the title of the section to add "and Associate Radiation Safety Officer" because the T&E requirements for this new position are also applicable to the ARSO. Other changes are: 1) removing the requirement to obtain a written attestation for individuals qualified under paragraph (a) of this section; 2) adding a provision that will 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) making certain administrative clarifications.

Paragraph (a). The requirement for individuals seeking to be named as an RSO or ARSO to obtain a written attestation is 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 will 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 III, 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 will 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) is revised to include the requirements for an RSO or ARSO under the alternate pathway to obtain a written attestation signed by either an RSO or ARSO. The language that is required in the written attestation is 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 is 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 is 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 license permit provided that the AU, AMP, or ANP has experience with the radiation safety aspects of similar types of use of byproduct material. The current regulations limit AUs, AMPs, and ANPs to serve as an RSO only on the license on which they are listed.

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

Paragraph (c)(3). This new paragraph will allow an individual who is not named as an AU on a medical use 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 use license must obtain a written attestation.

The provision will provide flexibility for an individual to serve as both an AU and as the RSO on a new medical use license (a clinic or a medical institution) and will make medical procedures more widely available, especially in rural areas.

Paragraph (d). This paragraph is 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 is 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 III, Discussion, of this document.

Paragraph (a)(2)(i). This paragraph is amended to clarify that an AMP who provides supervision for meeting the requirements of this section must 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 therapy 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 is revised to remove the requirement for a written attestation that is required in § ~~35.~~35.51(a). It is also amended to incorporate the new language that the written attestation will 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 is 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). This paragraph ~~was~~ is revised to conform to the removal of the attestation requirement in paragraph (a) of this section. It is also amended to incorporate the new language that the written attestation will 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 are made to this section. Most of the changes are to the T&E requirements in response to the requested amendments in PRM-35-20. 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 PRM-35-20, as it relates to this rulemaking, is located in Section II, Petition for Rulemaking, PRM-35-20, of this document.

Paragraph (a)(1). This paragraph ~~was~~ is modified to add AMPs and ANPs. This paragraph was also modified to grandfather individuals listed in this paragraph who were identified on a license or permit on or before **[INSERT DATE 180 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]**. These individuals will not need to comply with the respective training requirements of §§ 35.50, 35.51, or 35.55~~, as applicable~~.

However, this paragraph ~~was~~ is also modified such that RSOs and AMPs identified by this paragraph must meet the training requirements in §§ 35.50(d) or 35.51(c), as appropriate, for any materials or uses for which they were not authorized prior to the effective date of this

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).

Paragraph (a)(2). This paragraph is amended 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. These individuals do 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.

Paragraph (a)(3). This paragraph is amended 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. These individuals do 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.~~ These individuals are exempted from these training requirements only for those materials and uses these individuals performed on or before October, 24, 2005.

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

Paragraph (b)(1). This paragraph is amended to change the date before which an individual is named on a license as an AU to be on or before **[INSERT DATE 180 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]**.

Additionally, this paragraph is amended to clarify that an individual authorized on or before this date will 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 the individual performed on or before

[INSERT DATE 180 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*].

Paragraph (b)(2). This paragraph is 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. These individuals do not need to comply with the training requirements of subparts D through H of 10 CFR part 35 to be identified as an AU on a Commission or an Agreement State license or Commission master material license permit for those materials and uses that the individual performed on or before October 24, 2005. ~~Removal of subpart J from 10 CFR part 35 was effective on October 24, 2005.~~

Section 35.65 Authorization for calibration, transmission, and reference sources

This section is restructured and amended to include three new paragraphs.

Paragraph (b)(1). This new paragraph requires that medical use of any byproduct material in sealed sources 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 prohibits the bundling or aggregating of single-sealed sources to create a sealed source with an activity ~~larger~~ greater than authorized by § 35.65.

Paragraph (c). This new paragraph clarifies 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 is

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 III, Discussion, of this document.

Paragraph (c)(2). This paragraph is restructured and expanded to allow certain residency program directors to provide written attestations for a physician seeking to be named as an AU of unsealed byproduct material for uses authorized under § 35.100. The residency program director must represent a residency training program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Council on Postdoctoral 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 meets 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 is amended to incorporate the new language that the written attestation will 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 only after the first eluate is changed to require that the Mo-99 concentration be measured after each

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

Paragraph (e). This new paragraph adds 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 at the time of generator elution.

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

Paragraph (c)(1)(ii). This paragraph is 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 instead receive unit doses from centralized pharmacies; therefore, training on eluting generators is not available at these facilities. Authorized Nuclear Pharmacists have the T&E to provide the supervised work experience for AUs on the elution of generators.

Paragraph (c)(2). This paragraph is restructured and expanded to allow certain

residency program directors to provide written attestations for individuals seeking to be named as an AU of unsealed byproduct material for uses authorized under §§ 35.100 and 35.200. The residency program director must represent a residency training program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Council on Postdoctoral 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 is amended to incorporate the new language that the written attestation will 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 is 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 clarifies 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 all 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 AUs of unsealed byproduct material for uses authorized under § 35.300, the requirement to obtain a written attestation is 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 III, Discussion, of this document.

Paragraph (b)(1)(ii)(G)(3). This paragraph is amended to identify a single category of parenteral administrations of radionuclides in which work experience is required for an individual seeking to be an AU for uses under § 35.300.

The current regulations include a broad category for parenteral administrations of "any other" radionuclide. This broad category is removed, as any new parenteral administration of radionuclides not listed in this paragraph are regulated under § 35.1000. This approach will 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 is retained in the final rule with regard to all categories in this paragraph.

Paragraph (b)(2). This paragraph is 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 Council on Postdoctoral 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 physician requesting AU status, and concurs with the attestation.

Additionally, the paragraph is amended to incorporate the new language that the written attestation will 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 35.392 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 is 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 III, Discussion, of this document.

Paragraph (c)(3). This paragraph is 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 Council on Postdoctoral 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, 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.

Additionally, this paragraph is amended to incorporate the new language that the written attestation will 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 is 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 III, Discussion, of this document.

Paragraph (c)(3). This paragraph is 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 Council on Postdoctoral 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, has experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(*2*), and concurs with the attestation.

Additionally, the paragraph is amended to incorporate the new language that the written attestation will 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

Amendments to this section include conforming changes to support the new single category for parenteral administration in § 35.390(b)(1)(ii)(G)(*3*), changes to allow residency program directors to provide written attestations, and a change in the attestation language. Additionally, the section is restructured and renumbered to accommodate the final changes.

Paragraph (a). This paragraph was restructured to list the physicians who can seek AU status under paragraphs (a)(1), (2), and (3) that were previously listed as paragraphs (a), (b), and (c). Conforming changes are made to support the new single category for parenteral administration in § 35.390(b)(1)(ii)(G)(*3*).

Paragraph (b). This paragraph was restructured as paragraphs (b)(1), (2), and (3). These paragraphs describe the T&E required for physicians specified in § 35.396(a)(2) and (a)(3). The provisions within these paragraphs were the previous paragraph (d) in the proposed rule. Conforming changes are made to support the new single category for parenteral administration in § 35.390(b)(1)(ii)(G)(*3*).

Paragraph (b)(3). This paragraph is further 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 Council on Postdoctoral 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 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 as the individual requesting AU user status.

Additionally, the paragraph is amended to incorporate the new language that the written attestation will 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 is expanded to allow for sources that are listed in the SSDR for manual brachytherapy to be used for other manual brachytherapy uses that are not explicitly listed in the SSDR.

Paragraph (a). This paragraph is amended to allow sources that are listed in the SSDR for manual brachytherapy medical uses to be used for 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, or leak testing of radiation sources.

The NRC recognizes that the medical uses specified in the SSDR may not be all-inclusive. The final rule will 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 final rule change allows the physician to use the sources for a topical use. The NRC has determined this flexibility should be afforded to physicians to use their discretion in the practice of medicine.

Section 35.433 Strontium-90 sources for ophthalmic treatments

This section title is modified by deleting "Decay of" at the beginning of the title. This new title reflects the expanded information and requirements in this section.

Paragraph (a). This paragraph is 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, must meet the T&E requirements detailed in the new paragraph (a)(2) of this section to perform the specified activities. A written attestation will not be required. These requirements are similar to the T&E requirements for an AMP, but include only the requirements related to brachytherapy programs.

Paragraph (b). This new paragraph establishes the tasks that individuals qualified under paragraph (a) of this section are 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 final rule to ensure the safe use of Sr-90 for ophthalmic treatments. Both the AMP and the ophthalmic physicist are 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 must modify its procedures required under § 35.41 to specify the frequencies at which the AMP or the ophthalmic physicist will 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 paragraph is a designation of the recordkeeping requirements in the

current regulation under § 35.433(b). The requirements have not changed.

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 is 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 III, Discussion, of this document.

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

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 concurs with the attestation.

Additionally, the paragraph is amended to incorporate the new language that the written attestation will 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 is amended to incorporate the new language that the written attestation must 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 and medical devices for diagnosis

The section is 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. This section title is modified to add "and medical devices" because the use of medical devices is added to this

section.

Paragraph (a). This paragraph is amended to clarify that sealed sources that are not in medical devices for diagnostic medical uses and that are approved in the SSDR can be used for other diagnostic medical uses that are not explicitly listed in an SSDR provided that ~~they~~ the sealed sources 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, or leak testing of radiation sources.

Paragraph (b). This paragraph is added to allow ~~diagnostic~~ medical devices containing sealed sources to be used for diagnostic medical uses that are not explicitly listed in an SSDR if both the sealed sources and the medical devices are approved in the SSDR for diagnostic medical uses ~~that are not explicitly listed in an SSDR,~~ and provided that ~~they~~ the medical devices 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 allows 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 is 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 (a). This paragraph ~~was~~ is revised to reference the redesignated paragraphs (c) and (d).

Paragraph (b). This new paragraph recognizes the individuals who are authorized for

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

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

Paragraph (b). This paragraph continues to require that a licensee only use photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units approved in the SSDR or for research in accordance with an active IDE application accepted by the FDA provided the requirements of § 35.49(a) are met. However, this paragraph is 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 is amended and restructured to add a new training requirement for the use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. This amendment requires all individuals who 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. This training is also required when software upgrades are made by the vendor or the manufacturer that affect the operation and safety of the unit.

Currently, § 35.610(d) requires that all individuals who operate these units be provided safety instructions initially, and at least annually; however, there is no requirement for these individuals to receive instructions when the unit is upgraded. The amendment requires individuals who operate these new or upgraded units to receive training prior to first use for patient treatment. These individuals include AUs, AMPs, operators, and others that need to know how the units operate.

Paragraph (d)(2). This paragraph is 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 is added to enhance the safety of patients by eliminating potential delay in training of new staff until the required annual training, which could lead to undertrained individuals operating the unit.

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

Section 35.655 Full- inspection servicing for teletherapy and gamma stereotactic radiosurgery units

This section title is modified to delete "5-year inspection" and insert "Full-inspection servicing" to more accurately reflect the requirements in the section for inspection and servicing of teletherapy units and gamma stereotactic radiosurgery units.

Paragraph (a). This paragraph is 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 remains 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). Because 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. In support of this extension, the NRC finds that the 6-month routine preventive maintenance that is performed on these units is adequate to ensure the proper functioning of the source exposure mechanisms and, therefore, this final rule extends the full inspection and servicing interval for gamma stereotactic radiosurgery units from 5 years to 7 years.

Additionally, this paragraph requires that the full inspection and servicing of these units be performed during each source replacement regardless of the last time 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. The current interval of 5 years helps prevent potentially serious radiation exposure of teletherapy operators and patients in the event that the source exposure mechanism fails. 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 is 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 III, Discussion, of this document.

Paragraph (b)(1)(ii). This paragraph is amended to require that the work experience required by this section be received at a medical facility authorized to use byproduct materials under § 35.600 rather than at a medical institution. The current term "medical institution" in this paragraph is defined in § 35.2 as an organization in which more than one medical discipline is practiced. This definition unnecessarily limits where the work experience must be obtained. Moreover, the fact that an organization practices more than one medical discipline does not ensure that one of the medical disciplines is related to uses authorized under § 35.600. The change allows 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 is 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 Council on Postdoctoral 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 concurs with the attestation.

Additionally, this paragraph is amended to incorporate the new language that the written attestation will 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 requires the licensee to keep records of each ARSO assigned under § 35.24(b) for 5 years after the ARSO is removed from the license. This record must include the written document appointing the ARSO signed by the licensee's management.

Section 35.2310 Records of safety instruction

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

Section 35.2655 Records of full inspection servicing for teletherapy and gamma stereotactic radiosurgery units

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

Section 35.3045 Report and notification of a medical event

Paragraph (a). This paragraph is restructured and amended to specify separate specific criteria for reporting an ME involving permanent implant brachytherapy. These new criteria are different from the criteria for reporting an ME for other administrations. The paragraph retains the current introductory sentence, "A licensee shall report any event as a medical event, except for an event that results from patient intervention..." The introductory sentence of § 35.3045(a), published in the proposed rule in July 21, 2014, provided that "A licensee shall report as a medical event, any administration requiring a written directive, except for an event that results from patient intervention...." The phrase "requiring a written directive" is removed from this sentence in the final rule. This revision in the final rule maintains the current requirement that all events that meet the ME criteria be reported, not just those that require a WD.

Paragraph (a)(1). This new paragraph contains criteria for reporting an ME for all administrations other than permanent implant brachytherapy administrations. Criteria for reporting an ME involving permanent implant brachytherapy are in the new paragraph (a)(2) in this section. The criteria used to determine if an ME has occurred for all administrations, except

permanent implant brachytherapy, are 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 is restructured for clarity as the new paragraph (a)(1)(iii); and 2) a criterion is added in the new paragraph (a)(1)(ii)(A) of this section for reporting an administration involving the wrong radionuclide for a brachytherapy procedure as an ME.

Paragraph (a)(2). This new paragraph is 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 are:

1) The total source strength administered differs 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 meets this criterion is a situation in which the sealed sources that were implanted had a different source strength than what was intended. This situation could occur because the licensee ordered, or the vendor shipped, sealed sources with the wrong activity;

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

3) An administration that includes the wrong radionuclide; the wrong individual or human research subject; sealed source, or sources, implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the WD; or a leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue. Only the criteria for a leaking sealed source retains the dose threshold in current regulations because the NRC determined the leaking sealed source delivering a dose below this

threshold does not need to be reported as an ME. Several situations that will meet this criterion are self-evident, i.e., the wrong patient, the wrong treatment site, or a leaking sealed source. Three criteria published in the proposed rule on July 21, 2014, have been deleted in the final rule: (1) the criterion related to absorbed dose to the maximally exposed 5 contiguous cubic centimeters of normal tissue located outside the treatment site; (2) the criterion related to absorbed dose to the maximally exposed 5 contiguous cubic centimeters of normal tissue located within the treatment site; and (3) the criterion related to an error of 20 percent or more in calculating the total source strength. These deletions are based on the comments received on the proposed rule and is discussed in Section V, Public Comment Analysis, of this document.

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

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

Paragraph (a). This new paragraph requires a licensee to notify both the NRC Operations Center and the manufacturer/distributor of the generator by telephone within 7 calendar days after discovery that an eluate exceeds the permissible concentration listed in § 35.204(a). This notification 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; when the manufacturer/distributor was notified; and the action taken.

Paragraph (b). This new paragraph requires a licensee to submit a written report to the appropriate NRC Regional Office listed in § 30.6 within 30 calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The report

must be submitted by an appropriate method listed in § 30.6(a). The report must 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.

VII. Regulatory Flexibility Certification

Under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the NRC certifies that this rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. This final rule affects a number of "small entities" as defined by the Regulatory Flexibility Act or the size standards established by the NRC (10 CFR 2.810). However, as indicated in the regulatory analysis available as indicated in Section XXIII, "Availability of Documents" section of this document, these amendments do not have a significant economic impact on the affected small entities. The NRC requested comment on the proposed rule and accompanying draft regulatory analysis on the impact of the proposed rule on small entities. The NRC received no comment submissions from an identified small entity.

VIII. Regulatory Analysis

The NRC has prepared a final regulatory analysis on this regulation. The regulatory analysis examines the costs and benefits of the alternatives considered by the NRC. The regulatory analysis is available as indicated in Section XXIII, Availability of Documents, of this

document.

IX. Backfitting and Issue Finality

The backfit 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. Parts 30, 32, and 35 of 10 CFR do not contain a backfitting provision. Therefore, a backfitting analysis is not required.

X. Cumulative Effects of Regulation

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, ~~backfit,~~ inspection findings). The CER is an organizational effectiveness challenge that results from a licensee or impacted entity implementing a significant number of new and complex regulatory actions stemming from multiple regulatory actions, within a limited implementation period and with available resources (which may include limited available expertise to address a specific issue). The CER can potentially distract licensee or entity staff from executing other primary duties that ensure safety or security. The NRC specifically requested comments on the cumulative effects of this rulemaking in the proposed rule published on July 21, 2014, and received three comments on the CER. Two Agreement States stated that with steady accretion of regulations, there are always unintended consequences, in that the additional costs impact decisions on functions of the State radiation control program. With regard to the NRC's cost/benefit analysis in the draft Regulatory Analysis, these commenters stated that the NRC's cost/benefit analysis appeared to support the rule. One of the commenters expressed concern that there is the potential for

applying rules in a manner in which they were not intended based on the permanent implant brachytherapy language in § 35.40(b)(6). The commenter was concerned about the specification of dose to the normal tissues, located within the treatment site, in the proposed rule in § 35.40(b)(6)(i). Based on these comments and other public comments, § 35.40(b)(6)(i) in the final rule does not require the AU to specify dose to the normal tissues located within the treatment site. The comments are discussed in Section V, Public Comment Analysis, of this document.

XI. 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).

XII. Environmental Impact: Categorical Exclusion

The NRC has determined that the following actions in this final 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 amendments that do not meet the categorical ~~exclusions~~ exclusion criteria in § 51.22. Therefore, an environmental assessment has been prepared for this rule for the two amendments that do not meet the categorical exclusions in § 51.22. The environmental assessment is discussed in Section XIII, Environmental Assessment and Final Finding of No Significant Environmental Impact, of this document. The amendments that do not meet the categorical exclusions in § 51.22 are: 1) the increase in the frequency of Mo-99 measurement tests required in § 35.204, and 2) the increase in the full inspection time interval for a gamma stereotactic radiosurgery unit from 5 years to 7 years in § 35.655.

XIII. Environmental Assessment and Final Finding of No Significant Environmental Impact

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the NRC's regulations in Subpart A of 10 CFR Part 51, that this rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment and; therefore, an environmental impact statement is not required. The amendments that were the subject of the Environmental Assessment 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 amendments are procedural in nature. It is expected that this rule will 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 NRC requested the views of the States and State Liaison Officers on the environmental assessment for this rule. The NRC did not receive any comments on the environmental assessment from the States or State Liaison Officers.

The determination of the environmental assessment is that this rule would have no significant impact on the quality of the human environment. The environmental assessment is available as indicated in Section XXIII, Availability of Documents, of this document.

XIV. Paperwork Reduction Act Statement

This final rule contains new or amended collections of information subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). The collections of information were approved by the Office of Management and Budget, control number 3150-0010.

The burden to the public for the information collection(s) is estimated to average 2.52 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection.

The information collection is being conducted to provide the NRC the information it needs to effectively evaluate license applications, applications for amendments, licensee operations, and significant safety events for protection of public health and safety. The information will be used by the NRC in evaluating compliance with licensing requirements. The NRC will assess the adequacy of an applicant's or licensee's physical location, equipment, organization, training, experience, procedures and plans for protection of public health and safety. The NRC review and the findings derived there form the basis of NRC licensing and inspection decisions. The NRC uses reports of significant safety events in evaluating the

protective actions required to avoid exposures to patients and the public that could exceed regulatory limits, and therefore impact public health and safety and the environment. Responses to the information collection requirements at §§ 32.72 and 35.12 are mandatory or are required to obtain or retain a benefit. All other information collection requirements in this final rule are mandatory. Section 161b of the AEA authorizes the NRC to impose these information collections.

You may submit comments on any aspect of the information collection(s), including suggestions for reducing the burden, by the following methods:

- **Federal rulemaking Web Site:** Go to http://www.regulations.gov and search for Docket ID NRC-2008-0175.
- **Mail comments to:** FOIA, Privacy, and Information Collections Branch, Office of Information Services, Mail Stop: T-5 F53, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 or to Vlad Dorjets, Desk Officer, Office of Information and Regulatory Affairs (3150-0010), NEOB-10202, Office of Management and Budget, Washington, DC 20503; telephone: 202-395-1741, e-mail: oira_submission@omb.eop.gov.

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.

XV. Congressional Review Act

This final rule is a rule as defined in the Congressional Review Act (5. U.S.C. §§ 801-808). However, the Office of Management and Budget has not found it to be a major rule as

defined in the Congressional Review Act.

XVI. Criminal Penalties

For the purpose of Section 223 of the Atomic Energy Act of 1954, as amended (AEA), the NRC is issuing this final rule that amends 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 will be subject to criminal enforcement.

XVII. Coordination with NRC Agreement States

The NRC has coordinated with the Agreement States throughout the development of this final rule. Agreement State representatives have served on the rulemaking working group that developed the proposed and final 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), 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.

In February 2013, the NRC provided the preliminary draft proposed rule to the Agreement States for a 30-day review. The Agreement States provided comments on the preliminary draft proposed rule. Several comments resulted in revisions to the discussion section of the proposed rule to provide additional emphasis or clarity. A summary of the

Agreement States comments and the NRC staff responses to the comments ~~are~~ is contained in Enclosure 6 to SECY-13-0084.

Through an All Agreement State Letter (FSME-14-078, dated August 15, 2014), the Agreement States were notified of the availability of the proposed rule noticed in the *Federal Register* (79 FR 42410; July 21, 2014). The Agreement States also had an opportunity to comment on the draft final rule. In preparing both the proposed rule and the final rule, the rulemaking working group considered the comments provided by the Agreement States.

XVIII. 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* on September 3, 1997 (62 FR 46517), NRC program elements (including regulations) are placed into Compatibility Categories A, B, C, D, NRC, or adequacy category Health and Safety (H&S). Compatibility Category A are 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 in order to provide uniformity in the regulation of agreement material on a nationwide basis. Compatibility Category B are 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 are those program elements that do not meet the criteria of Category A or B, but the essential objectives of 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 national basis. An Agreement State should adopt the essential objectives of the

Category C program elements. Compatibility Category D are those program elements that do not meet any of the criteria of Category A, B, or C, and, therefore do not need to be adopted by Agreement States for purposes of compatibility. Compatibility Category NRC are those program elements that address areas of regulation that cannot be relinquished to the Agreement States under the AEA or NRC rules. These program elements should not be adopted by the Agreement States. Adequacy Category H&S are program elements that are required because of a particular health and safety role in the regulation of agreement material within the State and should be adopted in a manner that embodies the essential objectives of the NRC program.

The final rule is a matter of compatibility between the NRC and the Agreement States, thereby providing consistency among Agreement State and NRC requirements. Discussion on the Compatibility Category for § 35.3045, Report and notification of a medical event, can be found in Section V, Public Comment Analysis, of this document. The compatibility categories are designated in the following table:

Compatibility Table

Section	Change	Subject	Compatibility	
			Existing	New
Part 30				
30.34(g)	Amend	Terms and conditions of licenses	B	B
Part 32				
32.72(a)(4)	Amend	Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under 10 CFR part 35	B	B
32.72(b)(5)(i)	Amend	Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under 10 CFR part 35	B	B

32.72(d)	New	Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under 10 CFR part 35	-	B
Part 35				
35.2	New	Definitions – Associate Radiation Safety Officer	-	B
35.2	New	Definitions – Ophthalmic physicist	-	B
35.2	Amend	Definitions – Preceptor	D	D
35.12(b)(1)	Amend	Application for license, amendment, or renewal	D	D
35.12(c)(1)	Amend	Application for license, amendment, or renewal	D	D
35.12(c)(1)(ii)	Amend	Application for license, amendment, or renewal	D	D
35.12(d)	Amend	Application for license, amendment, or renewal	D	D
35.12(d)(1)	New	Application for license, amendment, or renewal	-	D
35.12(d)(2)	New	Application for license, amendment, or renewal	-	D
35.12(d)(3)	New	Application for license, amendment, or renewal	-	D
35.12(d)(4)	Amend	Application for license, amendment, or renewal	D	D
35.13(b)	Amend	License amendments	D	D
35.13(d)	New	License amendments	-	D
35.13(i)	New	License amendments	-	D
35.14(a)	Amend	Notifications	D	D
35.14(b)(1)	Amend	Notifications	D	D
35.14(b)(2)	Amend	Notifications	D	D
35.14(b)(6)	New	Notifications	-	D
35.15(c) and (e)	Amend	Exemptions regarding Type A specific licenses of broad scope	D	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

35.40(b)(7)	Amend Redesignated	Written directives	H&S	H&S
35.41(b)(5)	New	Procedures for administrations requiring a written directive	-	H&S
35.41(b)(6)	New	Procedures for administrations requiring a written directive	-	H&S
35.50	Amend	Training for Radiation Safety Officer and Associate Radiation Safety Officer	B	B
35.50(a)	Amend	Training for Radiation Safety Officer and Associate Radiation Safety Officer	B	B
35.50(a)(2)(ii)(B)	Amend	Training for Radiation Safety Officer and Associate Radiation Safety Officer	B	B
35.50(b)(1)(ii)	Amend	Training for Radiation Safety Officer and Associate Radiation Safety Officer	B	B
35.50(b)(2)	New	Training for Radiation Safety Officer and Associate Radiation Safety Officer	-	B
35.50(c)(1)	Amend	Training for Radiation Safety Officer and Associate Radiation Safety Officer	B	B
35.50(c)(2)	Amend	Training for Radiation Safety Officer and Associate Radiation Safety Officer	B	B
35.50(c)(3)	New	Training for Radiation Safety Officer and Associate Radiation Safety Officer	-	B
35.50(d)	Amend	Training for Radiation Safety Officer and Associate Radiation Safety Officer	B	B
35.51(a)	Amend	Training for an authorized medical physicist	B	B
35.51(a)(2)(i)	Amend	Training for an authorized medical physicist	B	B
35.51(b)(2)	Amend	Training for an authorized medical physicist	B	B
35.55(a)	Amend	Training for an authorized nuclear pharmacist	B	B
35.55(b)(2)	Amend	Training for an authorized nuclear pharmacist	B	B
35.57(a)(1)	Amend	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist	B	B
35.57(a)(2)	New	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist	-	B

35.57(a)(3)	New	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist	-	B
35.57(a)(4)	Redesignated	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist	D	D
35.57(b)(1)	Amend	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist	B	B
35.57(b)(2)	Amend	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist	B	B
35.57(b)(2)(i)	New	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist	-	B
35.57(b)(2)(ii)	New	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist	-	B
35.57(b)(2)(iii)	New	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist	-	B
35.57(b)(2)(iv)	New	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist	-	B
35.65(a)(1)-(5)	Redesignated	Authorization for calibration, transmission, and reference sources	D	D
35.65(b)	New	Authorization for calibration, transmission, and reference sources	-	D
35.65(b)(1)	New	Authorization for calibration, transmission, and reference sources	-	D
35.65(b)(2)	New	Authorization for calibration, transmission, and reference sources	-	D

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

35.392(a)	Amend	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)	B	B
35.392(c)(3)	Amend	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)	B	B
35.392(c)(3)(i)	New	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)	-	B
35.392(c)(3)(ii)	New	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)	-	B
35.394(a)	Amend	Training for the oral administration of sodium iodide I–131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	B	B
35.394(c)(3)	Amend	Training for the oral administration of sodium iodide I–131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	B	B
35.394(c)(3)(i)	New	Training for the oral administration of sodium iodide I–131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	-	B
35.394(c)(3)(ii)	New	Training for the oral administration of sodium iodide I–131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	-	B
35.396(a)(1)	Amend Redesignated	Training for the parenteral administration of unsealed byproduct material requiring a written directive	B	B
35.396(a)(2)	Amend Redesignated	Training for the parenteral administration of unsealed byproduct material requiring a written directive	B	B
35.396(a)(3)	Amend Redesignated	Training for the parenteral administration of unsealed byproduct material requiring a written directive	B	B
35.396(b)(1)	Amend Redesignated	Training for the parenteral administration of unsealed byproduct material requiring a written directive	B	B

35.396(b)(2)	Amend Redesignated	Training for the parenteral administration of unsealed byproduct material requiring a written directive	B	B
35.396(b)(2)(vi)	Amend Redesignated	Training for the parenteral administration of unsealed byproduct material requiring a written directive	B	B
35.396(b)(3)	Amend Redesignated	Training for the parenteral administration of unsealed byproduct material requiring a written directive	B	B
35.396(b)(3)(i)	New	Training for the parenteral administration of unsealed byproduct material requiring a written directive	-	B
35.396(b)(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))	D	D
35.490(a)	Amend	Training for use of manual brachytherapy sources	B	B
35.490(b)(1)(ii)	Amend	Training for use of manual brachytherapy sources	B	B
35.490(b)(3)	Amend	Training for use of manual brachytherapy sources	B	B
35.490(b)(3)(i)	New	Training for use of manual brachytherapy sources	-	B
35.490(b)(3)(ii)	New	Training for use of manual brachytherapy sources	-	B
35.491(b)(3)	Amend	Training for ophthalmic use of strontium-90	B	B
35.500(a)	Amend	Use of sealed sources and medical devices for diagnosis (Previously 35.500)	[C]	C

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

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

XIX. 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 amendments have been discussed at ACMUI meetings over the last several 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 the SRM to-SECY-10-0062, the Commission specifically directed the NRC staff to engage the ACMUI in developing the ME definition criterion for permanent implant brachytherapy. Further, the amendments that 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, Section III, 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 III, 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 the proposed rule, so that the NRC 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 proposed rule 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. The ACMUI provided a final report, "Advisory Committee on the Medical Uses of Isotopes Sub-Committee on Proposed Rule," dated April 5, 2013, to the NRC on April 9, 2013.

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 the proposed rule to provide additional emphasis or clarity. However, the NRC did not accept all of the ACMUI recommendations. The recommendations that the NRC staff did not accept were discussed in a document entitled, "NRC Staff Responses to the ACMUI Comments on the Draft Part 35 Proposed Rule," Enclosure 5, to SECY-13-0084.

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

On October 6, 2015, the NRC provided the preliminary draft final rule to the ACMUI for a 90-day review. The ACMUI held a public teleconference on January 6, 2016, and provided a final report, "Advisory Committee on the Medical Uses of Isotopes Sub-Committee on Draft Final Rule, 10 CFR Parts 30, 32, and 35," dated January 6, 2016, to the NRC on January 6, 2016. The NRC prepared a response to the ACMUI recommendations and the response is listed in the list of available documents, in Section XXIII, "Availability of Documents."

XX. Consistency with Medical Policy Statement

The amendments to 10 CFR part 35 are consistent with the Commission's Medical Use Policy Statement published August 3, 2000 (65 FR 47654). This 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.

XXI. 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 final rule, the NRC is amending its medical use regulations related to ME definitions for permanent implant brachytherapy; T&E requirements for AUs, medical physicists, RSOs, and nuclear pharmacists; completing action on PRM-35-20 to "grandfather" certain experienced individuals; measuring Mo-99 contamination for each

elution and reporting of failed breakthrough tests; naming ARSOs on a medical license; and making several minor clarifications. This action does not constitute the establishment of a standard that contains generally applicable requirements.

XXII. Availability of Guidance

Published elsewhere in this issue of the *Federal Register*, the NRC is issuing new guidance, "Guidance for the Final Rule 'Medical Use of Byproduct Material—Medical Events, Definitions, Training and Experience, and Clarifying Amendments," (NRC-2014-0030), for the implementation of the requirements in this final rule.

XXIII. Availability of Documents

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated.

DATE	DOCUMENT	ADAMS ACCESSION NO.
03/01/2004	03/01/2004 Transcript of Advisory Committee on the Medical Uses of Isotopes Meeting in Rockville MD, Pages 1-194	ML040780651
06/28/2005	Transcript of the Advisory Committee on the Medical Uses of Isotopes Medical Event Subcommittee Meeting	ML052360415
12/27/2005	SECY-05-0234, "Adequacy of Medical Event Definitions in 10 CFR 35.3045, and Communicating Associated Risks to the Public"	ML053180408
02/15/2006	SRM-SECY-05-0234, "Adequacy of Medical Event Definitions in 10 CFR 35.3045, and Communicating Associated Risks to the Public"	ML060460594
09/10/2006	PRM-35-20, "AAPM Petition for Rulemaking to Amend 10 CFR 35.57, Training for Experience Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Medical Physicist, Authorized User, Nuclear Pharmacist, and Authorized Nuclear Pharmacist," filed by E. Russell Ritenour	ML062620129

06/12/2007	Transcript of Advisory Committee on the Medical Uses of Isotopes (ACMUI) Meeting, June 12, 2007, Pages 1-325	ML072340094
04/29/2008	M080429 – Commission Meeting with the Advisory Committee on the Medical Uses of Isotopes, Transcript	ML081270628
05/15/2008	SRM-M080429, Meeting with Advisory Committee on the Medical Uses of Isotopes (ACMUI) 1:30 P.M., Tuesday, April 29, 2008	ML081360319
11/20/2008	SECY-08-0179, "Recommendations on Amending Preceptor Attestation Requirements in 10 CFR part 35, Medical Use of Byproduct Material"	ML083170176
01/16/2009	SRM-SECY-08-0179, "Recommendations on Amending Preceptor Attestation Requirements in 10 CFR part 35, Medical Use of Byproduct Material"	ML090160275
05/18/2010	SECY-10-0062, "Reproposed Rule: Medical Use of Byproduct Material – Amendments/Medical Event Definitions"	ML100890121
07/08/2010	M100708B – Commission Briefing on "Proposed Rule on Part 35 Medical Events Definitions – Permanent Implant Brachytherapy," Transcript	ML101930532
08/10/2010	SRM-SECY-10-0062, "Reproposed Rule: Medical Use of Byproduct Material – Amendments/Medical Event Definitions (RIN 3150-AI26)"	ML102220233
10/20/2010	Final Transcript of Advisory Committee on the Medical Uses of Isotopes (ACMUI) Meeting, Open Session, October 20, 2010, Pages 1-168	ML103350657
10/20/2010	Advisory Committee on the Medical Uses of Isotopes (ACMUI) Permanent Implant Brachytherapy Interim Report	ML103540385
04/11/2011	Final Transcript of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) Meeting, April 11, 2011, Pages 1-226	ML11174A070
05/16/2011	Part 35 Preliminary Draft Proposed Rule Language, provided for ACMUI review	ML111390420
05/20/2011	FSME-11-044, "Opportunity to Comment on Preliminary Proposed Rule Language for Medical Use Regulations"	ML111400231
06/20/2011	Public Meeting Summary for Part 35 Medical Workshop, J une 20-21, 2011	ML111930470
08/11/2011	Transcript of Public Workshop for Discussion of Topics Related to NRC's Medical Regulations, August 11, 2011, Pages 1-240	ML112900103
08/12/2011	Transcript of Public Workshop for Discussion of Topics Related to NRC's Medical Regulations, August 12, 2011, Pages 1-192.	ML112900185
10/18/2011	Advisory Committee on the Medical Uses of Isotopes (ACMUI) Permanent Implant Brachytherapy Final Report	ML11292A139
10/18/2011	Final Transcript of Advisory Committee on the Medical Uses of Isotopes (ACMUI) Teleconference Meeting, October 18, 2011, Pages 1-77	ML12062A275

11/30/2011	The American Society for Radiation Oncology (ASTRO) letter to the Chairman of the ACMUI	ML11341A051
02/07/2012	Advisory Committee on the Medical Uses of Isotopes (ACMUI) Permanent Implant Brachytherapy Revised Final Report	ML12038A279
02/07/2012	Final Transcript of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) Teleconference Meeting, February 07, 2012, Pages 1-85	ML12242A101
02/13/2012	ASTRO letter to the Chairman of the ACMUI	ML12044A358
04/05/2012	SECY-12-0053, "Recommendations on Regulatory Changes for Permanent Implant Brachytherapy Programs"	ML12072A306
04/24/2012	Transcript of Commission Meeting April 24, 2012, before Commission vote on SECY-12-0053, "Recommendations on Regulatory Changes for Permanent Implant Brachytherapy Programs"	ML12116A294
08/13/2012	SRM-SECY-12-0053, "Recommendations on Regulatory Changes for Permanent Implant Brachytherapy Programs"	ML122260211
01/14/2013	Part 35 Preliminary Draft Proposed Rule Federal Register Notice, provided for ACMUI review	ML13014A487
03/05/2013	Final Transcript of Advisory Committee on the Medical Uses of Isotopes (ACMUI) Teleconference Meeting, March 05, 2013, Pages 1-111	ML13175A030
03/12/2013	Final Transcript of Advisory Committee on the Medical Uses of Isotopes (ACMUI) Teleconference Meeting, March 12, 2013, Pages 1-115	ML13175A028
03/28/2013	Advisory Committee on the Medical Uses of Isotopes (ACMUI) Comments on the Proposed Rule, 10 CFR Parts 30, 32 and 35, Final Report	ML13071A690
08/08/2013	SECY-13-0084, "Proposed Rule: Medical Use of Byproduct Material - Medical Event Definitions, Training and Experience, and Clarifying Amendments (RIN 3150-AI63)"	ML13179A068
08/08/2013	SECY-13-0085, Enclosure 5, "NRC Staff Responses to the ACMUI Comments on the Draft Part 35 Proposed Rule"	ML13179A073
01/06/2014	SRM-SECY-13-0084, "Proposed Rule: Medical Use of Byproduct Material - Medical Event Definitions, Training and Experience, and Clarifying Amendments (RIN 3150-AI63)"	ML14007A044
07/23/2014	Draft Environmental Assessment: Proposed Rule Amending 10 CFR Parts 30, 32, and 35 – Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments	ML14184A621
07/23/2014	Draft Regulatory Analysis: Proposed Rule: Amendments to Medical Use of Byproduct Material Regulations, 10 CFR Parts 30, 32, and 35	ML14184A620

08/15/2014	FSME-14-078, "Opportunity to Comment on Proposed Amendments to Medical Use of Byproduct Material Regulations, 10 CFR 30, 32, and 35 and Notification of October 8, 2014 Public Meeting"	ML14226A319
10/08/2014	Part 35 Proposed Rule Public Meeting Transcript, Pages 1-171, October 8, 2014	ML15026A317
02/12/2015	Meeting Summary: Public Meeting Between Spectrum Pharmaceuticals, Inc., and the Nuclear Regulatory Commission (NRC) Regarding Modification of the Training and Experiences Requirements for Beta Emitter Products	ML15054A215
06/16/2015	Final Transcript of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) Teleconference Meeting, June 16, 2015, Pages 1-109	ML15285A016
09/21/2015	Advisory Committee on the Medical Uses of Isotopes (ACMUI) Training and Experience for Authorized Users of Alpha and Beta Emitters Draft Subcommittee Report	ML15271A124
10/08/2015	Final Transcript of Advisory Committee on the Medical Uses of Isotopes (ACMUI) Meeting, October 08, 2015, Open Session, pages 1-255	ML15357A551
10/09/2015	Final Transcript of Advisory Committee on the Medical Uses of Isotopes (ACMUI) Meeting, October 09, 2015, Open Session, pages 1-262	ML15357A552
01/06/2016	Advisory Committee on the Medical Uses of Isotopes (ACMUI) Comments on the Draft Final Rule, 10 CFR Parts 30, 32 and 35, Final Report	ML16007A771
03/16/2016	Advisory Committee on the Medical Uses of Isotopes (ACMUI) Training and Experience for Authorized Users of Alpha and Beta Emitters under 10 CFR 35.390, Final Report	ML16089A271
June 2016	Final Environmental Assessment	ML16124B050
June 2016	Final Regulatory Analysis	ML16124B034
June 2016	NRC Staff Response to the Advisory Committee on the Medical Uses of Isotopes' Part 35 Draft Final Rule – Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments; Final Comments."	ML16124B061
June 2016	Summary of Specific Agreement State and Organization of Agreement States Comments on the Draft Final Rule and Staff Response	ML16124B069
December 2016	Final Implementing Guidance	ML16126A441

List of Subjects

10 CFR Part 30

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

10 CFR Part 32

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

10 CFR Part 35

Biologics, Byproduct material, Criminal penalties, Drugs, Health facilities, Health professions, Labeling, Medical devices, Nuclear energy, Nuclear materials, Occupational safety and health, Penalties, Radiation protection, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR parts 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 of 1954, secs. 11, 81, 161, 181, 182, 183, 184, 186, 187, 223, 234, 274 (42 U.S.C. 2014, 2111, 2201, 2231, 2232, 2233, 2234, 2236, 2237, 2273, 2282, 2021); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842,

5846, 5851); 44 U.S.C. 3504 note.

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) of this chapter at the time of generator elution, in accordance with § 35.3204 of this chapter.

* * * * *

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

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

Authority: Atomic Energy Act of 1954, secs. 81, 161, 170H, 181, 182, 183, 223, 234, 274 (42 U.S.C. 2111, 2201, 2210h, 2231, 2232, 2233, 2273, 2282, 2021); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); 44 U.S.C. 3504 note.

4. In § 32.72:

a. In paragraph (a)(4), revise the introductory text;

b. Revise paragraph (b)(5)(i);

c. Redesignate paragraph (d) as paragraph (e); and

d. Add new paragraph (d).

The revisions and additions 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 labeling requirements:

* * * * *

(b) * * *

(5) * * *

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

* * * * *

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

* * * * *

PART 35 -- MEDICAL USE OF BYPRODUCT MATERIAL

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

Authority: Atomic Energy Act of 1954, secs. 81, 161, 181, 182, 183, 223, 234, 274 (42 U.S.C. 2111, 2201, 2231, 2232, 2233, 2273, 2282, 2021); Energy Reorganization Act of 1974, secs. 201, 206 (42 U.S.C. 5841, 5846); 44 U.S.C. 3504 note.

6. In § 35.2, add, in alphabetical order, the definitions for *Associate Radiation Safety*

Officer and *Ophthalmic physicist* and revise the definition for *Preceptor* to read as follows:

§ 35.2 Definitions.

* * * * *

Associate Radiation Safety Officer means an individual who —

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

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

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

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

* * * * *

Ophthalmic physicist means an individual who—

(1) Meets the requirements in § 35.433(a)(2) and § 35.59; and

(2) Is identified as an ophthalmic physicist on a—

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

(ii) Permit issued by a Commission or Agreement State broad scope medical use licensee;

(iii) Medical use permit issued by a Commission master material licensee; or

(iv) Permit issued by a Commission master material licensee broad scope medical use permittee.

* * * * *

Preceptor means an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an

authorized nuclear pharmacist, a Radiation Safety Officer, or an Associate Radiation Safety Officer.

* * * * *

7. In § 35.8, revise paragraph (b) to read as follows:

§35.8 Information collection requirements: OMB approval.* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 35.6, 35.12, 35.13, 35.14, 35.19, 35.24, 35.26, 35.27, 35.40, 35.41, 35.50, 35.51, 35.55, 35.60, 35.61, 35.63, 35.67, 35.69, 35.70, 35.75, 35.80, 35.92, 35.190, 35.204, 35.290, 35.310, 35.315, 35.390, 35.392, 35.394, 35.396, 35.404, 35.406, 35.410, 35.415, 35.432, 35.433, 35.490, 35.491, 35.590, 35.604, 35.605, 35.610, 35.615, 35.630, 35.632, 35.633, 35.635, 35.642, 35.643, 35.645, 35.647, 35.652, 35.655, 35.690, 35.1000, 35.2024, 35.2026, 35.2040, 35.2041, 35.2060, 35.2061, 35.2063, 35.2067, 35.2070, 35.2075, 35.2080, 35.2092, 35.2204, 35.2310, 35.2404, 35.2406, 35.2432, 35.2433, 35.2605, 35.2610, 35.2630, 35.2632, 35.2642, 35.2643, 35.2645, 35.2647, 35.2652, 35.2655, 35.3045, 35.3047, 35.3067, and 35.3204.

* * * * *

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:

a. Revise paragraph (b);

b. Redesignate paragraphs (d) through (g) as paragraphs (e) through (h);

c. Revise redesignated paragraphs (g) and (h); and

d. Add new paragraphs (d) and (i).

The revisions and addition 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 whom the licensee permits to work under the provisions of this section.

(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 § 35.100 or § 35.200 if the change does not include addition or relocation of either an area where PET radionuclides are produced or 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 § 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 § 35.15, revise paragraphs (c) and (e) to read as follows:

§ 35.15 Exemptions regarding Type A specific licenses of broad scope

* * * * *

(c) 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;

* * * * *

(e) The provisions of § 35.14(b)(1) for an authorized user, an authorized nuclear pharmacist, an authorized medical physicist, or an ophthalmic physicist;

* * * * *

12. 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. These duties and tasks are restricted to the types of use for which the Associate Radiation Safety Officer is listed on a license.

(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).

* * * * *

13. In § 35.40,

a. Revise paragraph (b)(5);

b. Redesignate paragraph (b)(6) as paragraph (b)(7);

c. Revise redesignated paragraph (b)(7);

d. Add new paragraph (b)(6);

e. Redesignate the introductory text of paragraph (c) as paragraph (c)(1); and

f. Redesignate paragraph (c)(1) as paragraph (c)(2)

The revisions and addition read as follows: ~~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, and the total source strength; and

(ii) After implantation but before the patient leaves the post-treatment recovery area: the treatment site, the number of sources implanted, the total source strength implanted, 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); 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.

* * * * *

14. In § 35.41, revise paragraphs (b)(3) and (4) and add new paragraphs (b)(5) and (6) to read as follows:

§ 35.41 Procedures for administrations requiring a written directive.

* * * * *

(b) * * *

(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 ~~(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, unless a written justification of patient unavailability is documented.

* * * * *

15. 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 duties and tasks as an Associate Radiation Safety Officer as provided in § 35.24 to be an individual who—

(a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (d) of this section. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit 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 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; and

(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), has experience with the radiation safety aspects of similar types of use of byproduct material for which the licensee seeks the approval of the individual as Radiation Safety Officer or an Associate Radiation Safety Officer, and 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, has experience with the radiation safety aspects of similar types of use of

byproduct material for which the licensee seeks the approval of the individual as the Radiation Safety Officer or Associate Radiation Safety Officer, and 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 medical use license or new medical use permit issued by a Commission master material license. The individual must also meet the requirements in paragraph (d) of this section.

(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.

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

§ 35.51 Training for an authorized medical physicist.

* * * * *

(a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (c) of this section. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit 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.

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

§ 35.55 Training for an authorized nuclear pharmacist.

* * * * *

(a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses

Licensee Toolkit 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.

18. ~~Revise~~ In § 35.57, revise paragraphs (a) and (b)(1), (b)(2) and (b)(3) 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 **[INSERT DATE 180 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]** need not comply with the training requirements of §§ 35.50, 35.51, or 35.55, respectively, except the 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 during the 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 the 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 on or before **[INSERT DATE 180 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]**, 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 on or 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 on or 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 the 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.~~

19. 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 μCI) 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 in sealed sources 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 (i.e., bundled or aggregated) to create 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.

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

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

* * * * *

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit 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 Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraph (c)(1) of this section.

21. 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 at the time of generator elution, in accordance with § 35.3204.

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

§ 35.290 Training for imaging and localization studies.

* * * * *

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit 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 Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraph (c)(1) of this section.

23. In § 35.300, revise the 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—

* * * * *

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

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

* * * * *

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraphs (b)(1)(ii)(G) of this section. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit 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 three categories in this paragraph. Radioactive drugs containing radionuclides 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 radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, 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 Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraph (b)(1) of this section.

* * * * *

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

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

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

* * * * *

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

* * * * *

(c)(1) * * *

(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 Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs (c)(1) and (2) of this section.

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

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

* * * * *

(a) Is certified by a medical specialty board whose certification process includes all of

the requirements in paragraphs (c)(1) and (c)(2) of this section, and whose certification has been recognized by the Commission or an Agreement State. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page.; or

* * * * *

(c)(1) * * *

(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 Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs (c)(1) and (2) of this section.

27. Revise § 35.396 to read as follows:

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

(a) 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—

(1) Is an authorized user under § 35.390 for uses listed in § 35.390(b)(1)(ii)(G)(*3*), or equivalent Agreement State requirements; or

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

(3) 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 (b) of this section.

(b) The physician—

(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations listed in §35.390(b)(1)(ii)(G)(*3*). 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)(*3*). 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 of the parenteral administrations as specified in § 35.390(b)(1)(ii)(G)(*3*); and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (b)(1) and (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 Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs (b)(1) and (2) of this section.

28. 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 for manual brachytherapy 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 U.S. Food and Drug Administration provided the requirements of § 35.49(a) are met.

29. 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:

(i) is identified as an ophthalmic physicist on a specific medical use license issued by the Commission or an Agreement State; permit issued by a Commission or Agreement State broad scope medical use licensee; medical use permit issued by a Commission master material licensee; or permit issued by a Commission master material licensee broad scope medical use permittee; and

(ii) 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

(iii) has successfully completed 1 year of full-time training in medical physics and an additional year of full-time work experience under the supervision of a medical physicist; and

(iv) Has documented training in:

(A) The creation, modification, and completion of written directives;

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

(C) 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

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 Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs (b)(1) and (b)(2) of this section.

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

§ 35.491 Training for ophthalmic use of strontium-90.

* * * * *

(b)(1) * * *

(3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.490, 35.491, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in 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 strontium-90 for ophthalmic use.

32. 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 that are not in medical devices for diagnostic medical uses ~~that~~ if the sealed sources 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~~ but 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~~ medical devices containing sealed sources for diagnostic medical uses if both the sealed sources and ~~diagnostic~~ medical 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 U.S. Food and Drug Administration provided the requirements of § 35.49(a) are met.

33. Revise § 35.590 to read as follows:

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

Except as provided in § 35.57, the licensee shall require the authorized user of a diagnostic sealed source or a device authorized under § 35.500 to be a physician, dentist, or

podiatrist who—

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

(b) Is an authorized user for 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.

34. 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 U.S. Food and Drug Administration 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.

35. 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 training is provided to all individuals who will operate the unit. The vendor operational and safety training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training.

(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.

36. 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.

* * * * *

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

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

* * * * *

(a) Is certified by a medical specialty board whose certification process has been

recognized by the Commission or an Agreement State and who meets the requirements in paragraph (c) of this section. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit 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), (b)(2), and (c) of this section; and 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 Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs (b)(1) and (b)(2) of this section.

* * * * *

38. 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 the written document appointing the Associate Radiation Safety Officer signed by the licensee's management.

39. 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.

40. 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 the use of the unit.

* * * * *

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

§ 35.3045 Report and notification of a medical event.

(a) A licensee shall report any event as a medical event, 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 (excluding sources that were implanted in the correct site but migrated outside the treatment site) 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; or

(iii) An administration that includes any of the following:

(A) The wrong radionuclide;

(B) The wrong individual or human research subject;

(C) Sealed source(s) implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the written directive; or

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

* * * * *

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

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

(a) The licensee shall notify by telephone the NRC Operations Center and the manufacturer/distributor of the generator within 7 calendar days after discovery that an eluate exceeded the permissible concentration listed in § 35.204(a) at the time of generator elution. 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, when 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 30

calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. 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 the probable cause and an 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 _____, 2016.

For the Nuclear Regulatory Commission.

Annette Vietti Cook,
Secretary of the Commission.