

Preliminary Draft for ACMUI Review
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. In this action the NRC addresses three ongoing rulemaking projects and several other related topics. First, this rule amends the reporting and notification requirements for a medical event for permanent implant brachytherapy. Second, the rule amends the training and experience (T&E) requirements for authorized users, medical physicists, radiation safety officers, and nuclear pharmacists; amends the requirements for measuring molybdenum (Mo) contamination and the reporting of failed technetium and rubidium generators; and allows associate radiation safety officers to be named on a medical license. Third, the rule amends the T&E requirements to address a request filed in a petition for rulemaking (PRM), PRM-35-20, to exempt certain board-certified individuals from certain T&E requirements (i.e., “grandfather” these individuals) so they may be identified on a license or permit for materials and uses that they performed on or before October 24, 2005, the expiration date of the prior T&E requirements.

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

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: Neelam Bhalla, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone: (301) 415-0978, e-mail: Neelam.Bhalla@nrc.gov.

SUPPLEMENTARY INFORMATION:

EXECUTIVE SUMMARY:

A. Need for the Regulatory Action and Legal Authority

The U.S. Nuclear Regulatory Commission (NRC) is 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 medical events (MEs) involving permanent implant brachytherapy programs. 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,

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- implement, and maintain procedures for determining if an ME has occurred, including, for permanent implant brachytherapy, procedures for making certain assessments within 60 days from the date the treatment was performed;
- Training and experience requirements 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. This requirement is being removed because the NRC has determined that certification by a specialty board, coupled with meeting the recentness of training requirements, is sufficient to demonstrate that an individual seeking authorization on a license has met the training and experience (T&E) requirements and has the requisite current knowledge and that additional attestation by a preceptor is therefore unnecessary. Individuals who are not board certified 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;
 - The requirements for measuring the Mo-99 concentration for elutions of Mo-99/Tc-99m generators are changed and reporting requirements are added for failed Mo-99/Tc-99m and strontium-82 (Sr-82)/Rb-82 generators. The current requirement to measure the Mo-99 concentration after the first eluate is changed to require that the Mo-99 concentration be measured in each eluate because several breakthrough incidents reported to the NRC; and
 - 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 Associate

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Radiation Safety Officer (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.

Additionally, 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.

C. Costs and Benefits

The NRC has not established a quantitative cutoff for defining an economically significant regulatory action. The NRC assumes “significant” impact if the ratio of annualized costs to estimated annual gross revenues for a licensee exceeds 1 percent. The 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 not to be 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, reducing requirements for T&E, and affording more latitude to licensees.

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The 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 XVII, Regulatory Analysis, of this document.

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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 part 35 of Title 10 of the *Code of Federal Regulations* (10 CFR) in their entirety. The training and experience (T&E) requirements in 10 CFR part 35 were further revised through an additional rulemaking, “Medical Use of Byproduct Material – Recognition of Specialty Boards,” published in the *Federal Register* on March 30 2005 (70 FR 16336).

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

As a result, the NRC is amending its regulations in 10 CFR part 35 to address these issues. The rule modifies the written directive (WD) requirements in 10 CFR 35.40 and the medical event (ME) reporting requirements in 10 CFR 35.3045 to establish separate ME reporting criteria for permanent implant brachytherapy. The rule accordingly 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

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administrations requiring a WD, including permanent implant brachytherapy.

Currently, the ME criteria for brachytherapy implants in 10 CFR 35.3045, “Report and Notification of a Medical Event,” are based on the dose administered to the patient. The amendment establishes 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 amendments are based on the 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,” (79 FR 42410) published in the Federal Register on July 21, 2014.

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

In SECY-10-0062, “Re-proposed Rule: Medical Use of Byproduct Material – Amendments/Medical Event Definitions,” dated May 18, 2010, the staff requested that Commission approve for publication the revised proposed rule for public comment. Prior to Commission voting on the re-proposed rule, a Commission briefing was held on the re-proposed rule on July 8, 2010. The presenters included a member of the ACMUI, a representative from the Organization of Agreement States (OAS), a physician from the American Brachytherapy

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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 rule.

In Staff Requirements Memorandum (SRM) SECY-10-0062, dated August 10, 2010, the Commission disapproved the staff's recommendation to publish the re-proposed rule and directed the staff to work closely with the ACMUI and the broader medical and stakeholder community to develop ME definitions that would protect the interests of patients and allow physicians the flexibility to take actions that they deem medically necessary, while continuing to enable the agency to detect failures in process, procedure, and training, as well as any misapplication of byproduct materials by AUs. The NRC is addressing the issues in the re-proposed rule (RIN 3150-A126) in this rulemaking; for more information, including public comments submitted on the earlier rule, see Docket ID NRC-2008-0071 on www.regulations.gov. The SRM also directed the staff to hold a series of stakeholder workshops to discuss issues associated with the ME definition.

Following Commission direction, the NRC conducted two workshops in the summer of 2011. These facilitated workshops were held in New York, New York, in June 2011, 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 staff used the recommendations in the ACMUI revised final report, along with the substantial input from stakeholders, to develop the recommendations in SECY-12-0053, which along with public comments received on the

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proposed rule published July 21, 2014 (79 FR 42410), provided the regulatory basis for the ME definitions 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 of failed tests of a Mo-99/Tc-99m generator and failed strontium-82 (Sr-82) and strontium-85 (Sr-85) tests of a Rb-82 generator, allow ARSOs to be named on a medical use license, extend the 5-year inspection frequency for a gamma stereotactic radiosurgery unit to 7 years, and to make several clarifying amendments.

Finally, the 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.

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. A notice of receipt and request for comments on this petition was published in the *Federal Register* on November 1, 2006 (71 FR 64168).

The petitioner requested that 10 CFR 35.57, “Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear

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

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

In October 2008, the NRC staff sent letters to all of the certifying boards whose certification processes are currently recognized by the NRC and to certifying boards previously named in the former 10 CFR part 35, subpart J, whose certification processes currently are not recognized by the NRC. To determine the scope of the medical community that might be negatively impacted by the T&E grandfathering provisions of the regulations, the NRC asked each organization to provide the number and percentage of its currently active diplomates who are not grandfathered under 10 CFR 35.57 by virtue of not being named on a license or permit. The organizations were asked to include individuals who are now or may in the future be seeking to be named as an RSO, AMP, AU, or authorized nuclear pharmacist (ANP) on an NRC or an Agreement State medical use license. Based on the responses, the NRC estimates that as many as 10,000 board certified individuals may have been affected by the 2005 T&E rulemaking.

Accordingly, the NRC believes that these individuals should be eligible for grandfathering for the modalities that they practiced as of October 24, 2005, and that their previously-acceptable qualifications for authorized status should continue to be adequate and acceptable from a health and safety standpoint such as to allow them to continue to practice

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using the same modalities. This 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.

The petitioner, in his support for “grandfathering” the RSOs who have relevant work experience and were not formally named on an NRC or an Agreement State license or permit as an RSO, stated that these individuals will be required to provide preceptor attestations. In this rulemaking, the NRC has eliminated the requirement for preceptor attestations for all individuals certified by NRC recognized boards. The NRC believes that attestations are not necessary in this particular situation because the provisions of § 35.59, “Recentness of training,” require that the T&E must have been obtained within the 7 years preceding the date of application, or the individual must have had related continuing education and experience since the required T&E was completed. The “grandfathered” individuals 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 so long as the provisions of § 35.59 are met and the individual requests authorizations only for the modalities the individual practiced as of October 24, 2005.

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, for a 120-day public comment period a proposed rule on July 21, 2014, (79 FR 42410) to address these issues. The NRC developed the final rule based on the

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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 (PRM-35-20) 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 of failed Mo-99/Tc-99m and Sr-82/Rb-82 generators.
- f. Allowing ARSOs to be named on a medical use license.
- g. Additional issues and clarifications.

The major revisions are:

a. Adding separate ME definitions for permanent implant brachytherapy.

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

During its meeting in March 2004, the ACMUI recognized the existing inadequacy of defining MEs with regard to permanent implant brachytherapy. The ACMUI explained that for these implants, the plus or minus 20 percent variance from the prescription criterion in the existing rule was only appropriate if both the prescription and the variance could be expressed in units of

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activity, rather than in units of dose, as there is no suitable clinically used dose metric available for judging the occurrence of MEs. In June 2005, the ACMUI recommended that new language should be developed to define MEs related to permanent implant brachytherapy.

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

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

The ACMUI Permanent Implant Brachytherapy Subcommittee (PIBS) issued a report, with recommendations, which was unanimously approved by the ACMUI at its October 20, 2010, meeting. The PIBS report included the caveat that it was to be considered an interim report and that it might be revised in response to additional stakeholder input. The ACMUI meeting in April 2011 was devoted to issues associated with the ME definition. The

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meeting was webcast, providing an opportunity for further public involvement on this issue.

The ACMUI final report, which revised the earlier PIBS interim report was provided to the NRC following the ACMUI October 18, 2011, teleconference public meeting. The final report reflected the principal positions and recommendations provided by participants during the NRC public workshops; in particular, the report included the recommendation to change from dose-based ME criteria for the treatment site to source-strength based criteria. The final report included a quantitative metric, the “octant approach,” for determining that a distribution of implanted sources was irregular enough (i.e., demonstrating “bunching”) to consider the procedure as an ME. The final report also included a dose-related ME criterion for the treatment site.

However, in a letter to the Chairman of the ACMUI dated November 30, 2011, the American Society for Radiation Oncology (ASTRO) expressed criticism of the ACMUI final report. The ASTRO considered the ME definition recommended by the ACMUI to be complex, difficult to regulate, and likely to cause confusion in practice. Consequently, the PIBS issued a revised final report that simplified the ME criteria for the treatment site, and removed the “octant approach” and direct reference to absorbed dose to the treatment site. The revised final report was, with minor modification, approved by the ACMUI during its February 7, 2012, teleconference public meeting. The ASTRO, in a letter to the Chairman of the ACMUI, characterized this report as an improvement to the earlier report.

The staff used the recommendations in the ACMUI revised final report, along with the substantial input from stakeholders gathered in the two facilitated public workshops and the three ACMUI public meetings in 2011 and early 2012, to develop the recommendations conveyed to the Commission on April 6, 2012, in SECY-12-0053. In a Commission meeting held April 24, 2012, participating representatives from ACMUI, ASTRO, and the American

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Brachytherapy Society (ABS) endorsed the recommendations for modification of the requirements in 10 CFR 35.40 and 35.3045 that are contained in SECY-12-0053. The NRC notes that ASTRO and ABS representatives suggested eliminating the 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 staff determined there should be some form of ME reporting criterion for overdosing of normal tissue structures located within the treatment site. The ACMUI recommendations, as approved by the Commission in SRM to SECY-12-0053, “Recommendations on Regulatory Changes for Permanent Implant Brachytherapy Programs,” are applicable to all permanent implant brachytherapy procedures using radioactive sources for all treatment sites.

The ME criteria in the final rule do not include absorbed doses to normal tissues located outside of the treatment site or located within the treatment site. The criteria related to the absorbed doses to normal tissues were included in the proposed rule that was published on July 21, 2014 (79 FR 42140). Based on the comments received on this issue, the NRC did not include these criteria in defining a medical event for permanent brachytherapy in the final rule. Comments related to the ME criteria involving absorbed dose to normal tissues is in Section V, Public Comment Analysis, of this document. The final rule ME criteria 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 written directive;
- 2) For the treatment site documented in the post-implantation portion of the WD, an ME

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has occurred if 20 percent or more of the implanted sources documented in the post-implantation portion of the WD are located outside of the intended implant location.

3) An ME has occurred if a treatment involves: a) using the wrong radionuclide; b) delivery to the wrong patient or human research subject; c) sealed source(s) implanted directly into a location where the radiation from the source(s) will not contribute dose to the treatment site as defined in the written directive; or d) using leaking sources.

In supporting these recommendations, the NRC believes that source strength is the measurable metric for defining MEs involving permanent brachytherapy implants. 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.

In the proposed rule published on July 21, 2014, the ME criteria had also included: for normal-tissue structures, an ME has occurred if: a) for structures located outside of the treatment site (for example the bladder or rectum for prostate implant treatments), the dose to the maximally exposed 5 contiguous cubic centimeters of tissue exceeds 150 percent of the absorbed dose prescribed to the treatment site in the pre-implantation portion of the WD; or b) for intra-target normal structures, the maximum absorbed dose to any 5 contiguous cubic centimeters of tissue exceeds 150 percent of the dose the tissue would have received based on the approved pre-implant dose distribution. The size of the normal tissue, 5 cubic centimeters, was based on an ACMUI recommendation. 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 cited literature to support that 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.

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The NRC received several comments expressing concern about the proposed medical event criterion related to the absorbed dose to normal tissues located outside of the treatment site or located within the treatment site. The commenters expressed technical difficulties in assessing dose to normal tissues located outside and within the treatment site. They stated that their treatment planning systems were not equipped to make such assessments. They believed the regulators may not be able to inspect such a requirement. They stated that this requirement may cause confusion and result in licensees not performing permanent implant brachytherapy treatments. Based on the comments received on these proposed criteria, these criteria have been eliminated in the final rule. The comments are discussed in section V, Public Comment Analysis, of this document.

Although there is no requirement to determine dose to normal tissue, imaging is the best (and maybe the only) method to determine source strength outside of the treatment site and is routinely practiced in most clinical facilities.

In the proposed rule published on July 21, 2014, the criterion related to source(s) implanted directly into the wrong site or body part (i.e., not in the treatment site identified in the WD) 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 classifying a single source delivered outside the treatment site was an inappropriate criterion. 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, in the final rule, the NRC has changed § 35.3045(a)(2)(v)(C) to read “[s]ealed source(s) implanted directly into a location where the

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radiation from the source(s) will not contribute dose to the treatment site as defined in the written directive.”

This wrong treatment site medical event 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 written directive, 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. Eighteen sources were outside and directly adjacent to the treatment site, in locations where they contributed dose to the treatment site. However, one source was erroneously implanted directly into a site many inches away from the treatment site, in a location that will not contribute dose to the treatment site. This would not be a medical event based on the total source strength criterion, however it is defined as a medical event because one source met the wrong treatment site criterion. It is appropriate for the case to be captured as a medical event because a source directly implanted into a location that contributes no dose to the treatment site is not useful to the treatment; it contributes dose only to unintended locations. This criterion is not more restrictive than the current regulation, which requires reporting of a dose of 0.5 sievert (50 rem) to an organ or tissue, because the localized dose associated with even one misplaced source would far exceed the current 0.5 sievert (50 rem) dose threshold.

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, is removed in the final rule. The removal of 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 require amendments to

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§ 35.40 and § 35.41. The current WD requirements for manual brachytherapy in § 35.40(b)(6) primarily reflect requirements associated with temporary implant brachytherapy medical use. This final rule establishes separate WD requirements in § 35.40 that are appropriate for permanent implant brachytherapy. The 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, the rule requires that the WD portion prepared before the implantation include documentation of the treatment site, the radionuclide, and the total source strength. The rule requires that the post-implantation portion of the WD contain the documentation of the treatment site, number of sources implanted, the total source strength implanted, the signature of an AU for § 35.400 uses for manual brachytherapy, and the date.

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

This final rule makes conforming changes to § 35.41, “Procedures for administrations requiring a written directive,” to include permanent implant brachytherapy. Although the current

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§ 35.41(a)(2) requires licensees to determine if the administration is in accordance with the written directive, there is no specific requirement that a licensee determine that an administered dose or dosage has met an ME criterion as defined in § 35.3045. Section 35.41 is amended to require that a licensee include procedures for determining if an ME has occurred. For all permanent implant brachytherapy, this section 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, and to include that these assessments be made within 60 days from the date the treatment was performed.

b. Amending preceptor attestation requirements.

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

Under both the certification and the alternate pathway, an individual seeking authorization for medical byproduct material must obtain written attestation signed by a preceptor with the same authorization. The attestation must state that the individual has satisfactorily completed the necessary T&E requirements and has achieved a level of competency sufficient to function independently in the position for which authorization is sought.

During a 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; i.e., there would likely be a shortage of authorized

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individuals to provide medical care as a result of the reluctance of preceptors to sign attestations. The ACMUI recommended that attestations be eliminated for the board certification pathway. In the ACMUI's view, by meeting the board requirements, a curriculum and a body of knowledge can be defined, and progress toward meeting defined requirements can be measured. Further, the ACMUI asserted that a board certification indicates that the T&E requirements have been met, and the Maintenance of Certification provides ongoing evidence of current knowledge. Therefore, the ACMUI argued that an additional attestation for the board certified individuals was not needed.

The ACMUI also recommended that the attestation requirements associated with the alternate pathways be modified to delete the requirement of 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 provided by a residency program director representing a consensus of an authoritative group, irrespective of whether the program director personally met the requirements for authorized user status. The ACMUI advised that training of residents is a collective process and entails the collective judgment of an entire residency program faculty, whereas preceptor attestation is an individual process, and an individual preceptor typically would provide only a small portion of the T&E.

Following the April 29, 2008, Commission briefing of the ACMUI, in an SRM dated May 15, 2008, the Commission directed the staff to work with the ACMUI and the Agreement States to provide recommendations to the Commission with regard to amending the NRC's requirements for preceptor attestation for both board certified individuals and for individuals

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seeking authorization via the alternate pathway. The staff was also directed to consider additional methods, such as the attestation being provided by consensus of an authoritative group.

Following both consideration of the ACMUI's position, which the staff determined was clear and consistent with its long-held position on this issue, and interactions with the Agreement States, the staff provided its recommendations on this issue to the Commission on November 20, 2008, in SECY-08-0179, "Recommendations on Amending Preceptor Attestation Requirements in 10 CFR part 35, Medical Use of Byproduct Material." The 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 staff to develop the proposed rule language for the attestation requirements for the alternate pathway in concert with the ACMUI and the Agreement States.

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The proposed changes to remove the attestation requirement for board certified individuals were broadly supported during the public workshops conducted in the summer of 2011. The workshop panelists (which included members of the ACMUI and the Agreement States) recommended that the NRC should remove the requirement for attestation for board certified individuals. They believed that board certification coupled with the recentness of training requirements should be sufficient for the regulator's needs. With regard to the language of attestation (for the alternate pathway), they believed that the preceptors should not be attesting to someone's competency; rather, they should be attesting to the individual's T&E necessary to carry out one's responsibility independently. At the April 2011 ACMUI meeting, the ACMUI advised that the attestation language should be revised to say that the individual has received the requisite T&E to fulfill the radiation safety-related duties required by the license. 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 staff's recommendations in SECY-08-0179.

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

The petition is 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

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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, as well as have an adverse effect on nuclear medicine image quality and medical diagnosis.

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

From October 2006 to February 2007, and again in January 2008, medical licensees reported to the NRC that numerous generators had failed the Mo-99 breakthrough tests. Some licensees reported the failed tests in the first elution, while some reported an acceptable first elution but failed subsequent elutions. One generator manufacturer voluntarily reported 116 total elution test failures in 2008. Based upon the numerous reports of failed Mo-99 breakthrough measurements noted in the subsequent elutions, the NRC 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 failed Mo-99/Tc-99m and Sr-82/Rb-82 generators.

The regulations do not currently require reporting to the NRC when an elution from a Mo-99/Tc-99m or Sr-82/Rb-82 generator exceeds the regulatory limit in § 35.204(a). As discussed in this section, eluates from generators for making Tc-99m radioactive drugs

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exceeded the permissible concentration listed in § 35.204(a) on numerous occasions in 2006, 2007, and 2008. Additionally, in 2011, contamination issues with Sr-82/Rb-82 generators were discovered when several individuals were identified with unexpected levels of Sr-82 and Sr-85. These individuals had undergone Rb-82 chloride cardiac scanning procedures several months before and had received these radionuclides in levels greatly in excess of the administration levels permitted in § 35.204 for Sr-82/Rb-82 generators. Further investigations showed that at least 90 individuals at one facility and 25 at another facility received levels of Sr-82 or Sr-85 that exceeded the levels permitted in § 35.204. Of these patients, at least three had levels of Sr-82 and Sr-85 high enough to result in reportable MEs as defined in § 35.3045.

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

This final rule adds a new reporting requirement related to breakthrough of Mo-99, and Sr-82 and Sr-85 contamination. This new reporting requirement in § 35.3204(a) 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

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license.

During an ACMUI meeting in June 2007, concern was expressed that this restriction has been contributing to a shortage of available RSOs to serve as preceptors. The ACMUI stated that the restriction has been creating a situation in which an individual who is qualified and performing the same duties as an RSO cannot be recognized or listed as an RSO, and that it has been creating a situation in which an individual working as a contractor RSO at several hospitals or other licensed locations is unable to have actual day-to-day oversight at the various facilities.

The 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, by being named on a license, an ARSO could more easily become an RSO on other licenses for the types of uses for which the ARSO is qualified.

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In addition, the current regulations allow AUs, AMPs and ANPs to serve as the RSO only on the license for which they are listed. Because AUs, AMPs and ANPs must meet the same requirements to serve as the RSO regardless of which Commission medical license they are identified on, the NRC believes that it is overly restrictive to not allow them to serve as an RSO on any Commission medical license. Therefore, a modification is made that will allow an AU, AMP, or ANP listed on any 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.

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

The final rule amends multiple sections of 10 CFR part 35 to accommodate the new ARSO position.

g. Additional issues and clarifications.

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

B. When Would 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 180 days are sufficient to implement the final rule.

IV. Opportunities for Public Participation

The NRC staff submitted a proposed rule for Commission 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 Commission 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

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NRC to require only 80 hours of specialized training for all physicians so that an oncologist or a hematologist be able to administer parenteral administration of 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 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 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 10 comment letters, which are also posted on www.regulations.gov under Docket ID NRC-2008-0175. The NRC staff reviewed the comments and considered them in developing the proposed rule text.

V. Public Comment Analysis.

A. Overview of Public Comments

The NRC received 48 comment letters that contained several hundred individual comments. The comment letters are posted on www.regulations.gov under Docket ID NRC-2008-0175. The commenters included several medical 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, the Conference of Radiation Control Program Directors, individual States, practicing physicians, medical physicists, radiation safety officers, nuclear pharmacists, individual members of the public, and a member of the Congress.

For the medical event criteria for permanent brachytherapy implants, the commenters generally supported the activity-based criteria instead of the current dose-based criteria. However, 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.

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There were numerous comments on the compatibility category for the Agreement States for § 35.3045, Report and notification of a medical event. The ten comments in support of Compatibility Category B were submitted by the medical community. The Organization of the Agreement States (OAS), the Conference of Radiation Control Program Directors (CRCPD), and 7 of the 37 Agreement States submitted comments in support of Compatibility Category C. This issue is fully discussed in Part I, Public Comments on the Specific Issues on Which the NRC Requested Comments, in this section.

The commenters expressed concern about confusion among authorized users surrounding the definition of medical event and written directives 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.

The commenters were supportive of the proposed position of the ARSO but numerous commenters asked for further clarifications.

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

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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 days should be shortened to more effectively address patient safety concerns. In response to this comment, the reporting time for a failed generator in the final rule is changed to 7 calendar days.

B. Public Comments and Overall 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 for 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 a medical event.

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 medical event definition for normal tissue based on the absorbed

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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 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 proposed 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 five comments on this issue. One of the commenters stated that

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this impact is always possible but generally believed that there is no current impact. Other commenters stated that the current framework creates an adverse impact, would discourage clinicians, and may result in licensees avoiding offering certain treatments. One commenter expressed concern over the shortage of AUs for alpha- and beta-emitting products and asked the agency to consider reducing the training and experience for these lower risk products.

The comments and NRC responses 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

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retain a dose-based ME reporting criterion for the treatment site if NRC regulations are revised to include 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, which requires § 35.3045 to remain as Compatibility Category C. 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. A Compatibility Category B designation would prevent the Agreement State requirements from including any additional requirements, such as diagnostic reports, shorter reporting times, or lower dose limits for reporting.

The ACMUI in its report to the NRC (early review of the proposed rule, 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 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

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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 § 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 ten comments in support of Compatibility Category B were submitted by the medical community. The Organization of the Agreement States (OAS), the Conference of Radiation Control Program Directors (CRCPD), and 7 of the 37 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 level, 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

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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 medical events.

The Agreement States, OAS, and CRCPD strongly recommended that the compatibility designation for medical event reporting under § 35.3045 be designated as Compatibility C. They argued that under Compatibility 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 medical events). 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 C designation has been adequate for the reporting requirements for radiography, irradiators, and well logging licensees who work routinely in multiple jurisdictions. One Agreement State stated that the proposed activity-based medical event 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 medical events 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 medical event 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 medical events. A consistent national program for reporting medical events allows the NRC to identify trends or patterns, identify

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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-base criteria instead of or in addition to activity-based criteria for permanent implant brachytherapy MEs in § 35.3045(a)(2) would result in an over reporting of non-significant events, which would create inconsistencies in the national reporting program and disrupt the NRC and Agreement States' ability to use the national program for reporting medical events 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. Specifically, 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 medical events 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 medical events.

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 medical event reporting, while important to the effective and orderly regulation of

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agreement material on a nationwide basis, does not appear to 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 medical event reporting criteria for permanent implant brachytherapy would create conflicts and inconsistencies with respect to the national reporting program. Therefore, the NRC will not accept Agreement State use of dose-based criteria for permanent implant brachytherapy medical event reporting.

The comment summaries and NRC responses on this issue are discussed in Part II, Comments Received on the Specific Sections in the Proposed Rule, 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 Tc99m decays much faster than Mo99; therefore, every Tc99m 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 Tc99m 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*

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

Response: No response 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 in the rule text has been made. To avoid confusion and to establish a regulatory requirement, the term Associate Radiation Safety Officer (RSO) is retained. Although the term Assistant RSO is used in some Agreement States, each Agreement State may require individuals to meet different training and experience standards to be named as an Assistant RSO on a license. Therefore, any individual an Agreement State has designated as an Assistant RSO is not recognized by the NRC or 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 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 authorized medical physicist (AMP) obsolete.

Response: The NRC disagrees with the commenter and the designation of an *ophthalmic 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 § 35.491(b) to support the ophthalmic treatments. This rule change will make the

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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 authorized user. Further, in § 35.13, License Amendments, only specific use licensees and not broad scope licensees can name an *ophthalmic physicist* on their licenses as broad scope licensees have ready access to AMPs.

Issue 3: Definition of a *Preceptor*

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

Response: No response 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 able to sign a preceptor form. Further, the commenter stated that "The NRC and Agreement States are authorized to approve a proposed licensee's RSO based upon their training and experience without the preceptor attestation."

Response: 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, the provision to name ARSOs on medical licenses is retained. This will allow the individual who is named as an ARSO to be recognized by Agreement States and the NRC

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as an RSO or ARSO for the same medical uses on another license without resubmitting their training and experience 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 can 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 commenter's statement that RSOs are approved based upon their training and experience 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 say, "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 authorized user, authorized medical physicist or authorized nuclear pharmacist, 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) [sic]."

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

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and tasks as an ARSO. The individual may be assigned tasks outside of the agreed to list of ARSO duties and tasks in order to obtain additional training and experience.

The commenter's proposed text would imply that the ARSO is listed on a license as an authorized user, authorized medical physicist or authorized nuclear pharmacist. 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/she was not fully qualified (i.e., listed on the license for). 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/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: The commenters raise a valid concern. 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 evaluates on a case-by-case basis, whether the proposed RSO would have sufficient involvement in the program. However, the issue of the number of licenses on which an individual may be named as the RSO or ARSO was not included in the proposed rule. As such, the comment is beyond the scope of the current rulemaking.

Section 35.40 Written directives.

Comment: The commenter questioned the following 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 authorized user or authorized medical physicist, resulting in a potential violation based on a difference in interpretation. The commenter believes that the written directive should not include expected doses to normal tissues located within the treatment site because there may be clinical reasons for an authorized user to accept a higher dose to a normal structure in close proximity to involved tissues.

Response: The NRC agrees that the determination of the appropriate dose to normal tissue (if any) located within the treatment site is a matter of medical judgement. 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 written directive 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.

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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 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 authorized user 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 a medical event for absorbed dose to normal tissue to be based on a condition that changed during the implant procedure.

Response: The rule text in § 35.40(b)(6)(ii) was changed to allow the authorized user to change the description of the treatment site in the post-implantation written directive. The NRC agrees that an authorized user 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.

Comment: The commenter stated that the after implantation written directive 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 a medical event.

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Response: No change was made to the rule text. The authorized user defines the treatment site in the written directive in any way he or she believes to be appropriate, including any margin. The authorized user 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 written directive 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: No response is required; however, the NRC notes that the post treatment written directive has to be completed before the patient leaves the post treatment recovery area.

Comment: Two commenters supported the proposal to allow modification of the written directive 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 written directive are medically necessary, these modifications should not constitute a medical event.

Response: No response required.

Section 35.41 Procedures for administrations requiring a written directive.

Comment: The 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 written directive 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

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the pre-implantation written directive. 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. Section 35.41(b)(6)(i) requires a licensee to determine, anytime 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 written directive.

The authorized user defines the treatment site (as defined in § 35.2) in the written directive in any way he or she believes to be appropriate. The authorized user 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 written directive.

Comment: The 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 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 may not. In response to this concern and those 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: The commenter recommended modifying § 35.41(a) by adding:

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

Response: No change was made to the rule text. 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 NRC recognizes the difficulty in determining the absorbed dose to normal tissues for lung mesh treatments. 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) because it is important to determine the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation written directive for all permanent brachytherapy, including lung mesh procedures.

Comment: Several commenters stated that they support the requirement for performing a 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

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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. 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. In addition, please note that in response to other comments, NRC re-evaluated the requirements for post-implant dosimetric evaluation to the normal tissue and removed this requirement.

Comment: The 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 written directive. 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: In response to concerns raised by other commenters, 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 written directive. 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 surgery.

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

The following comments were in support of the proposed amendments:

Comment: One commenter agreed with the changes in the training and experience 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: No response required.

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

Response: No response 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 for applying to be named as an RSO, ARSO, ANP, AMP, or AU.

Response: No response required.

Comment: One commenter supported ARSOs being named on licenses and serving as

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preceptors.

Response: No response required.

The following comments required a response from the NRC.

Comment: The commenter stated that the ARSO position created in the proposed rule does not create a new pathway for an individual to become an RSO. However, the commenter proposed that the NRC create a new pathway for an individual to qualify to be an RSO by relaxing the training and experience 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. The NRC disagrees with the commenter because 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 they were assigned duties and tasks as an ARSO on a medical license. This new pathway requires the same training and experience 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 training and experience for an ARSO or an RSO because the qualifications are the same. This is outside the scope of this rulemaking because this rulemaking had no intent to create a

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training program for an individual to become an ARSO who is not fully qualified to be an RSO.

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. The commenters' proposal would have resulted in recognition of an individual as an ARSO who had not satisfactorily completed all the training and experience qualifications to perform his/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/her training and skills to apply for ARSO status for additional types of use.

Comment: The commenter asserted that the changes to the regulations would permit AUs to be RSOs and in doing so, 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. 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 seriously.

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

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be named as an ARSO.

Response: No change was made to the rule text. For each medical use for which an ARSO is authorized, the training and experience 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 authorized users (AU), authorized nuclear pharmacists (ANP), or authorized medical physicists (AMP) 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. The current regulations already allow AUs, AMPs, and ANPs to serve as RSOs on private practice licenses and other non-hospital medical facilities.

Comment: The commenter requested that the rule text in § 35.50(c)(1), (c)(2), and (c)(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 (c)(1) and (c)(2) included “similar types of use” whereas (c)(3) implies the exact same types of use.

Response: NRC agrees with the commenter that there should be consistency between the rule text in § 35.50 (c)(1) and (c)(2). The rule text in paragraphs (c)(1) and (c)(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

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and the RSO on the new license. The new license will authorize only those types of uses for which the proposed AU/RSO has training and experience.

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

Response: The rule text in § 35.50(c)(3) was revised in response to this comment. NRC's original 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 this provision 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 revised to add a reference to § 35.50(d) in § 35.50(c)(3) based on both this and the next 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 that 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

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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: A commenter stated that the provisions in § 35.50 in the proposed rule could be interpreted two ways. First, 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). Second, 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 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: The 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 authorized user on the same new Commission or Agreement State license and who has experience with the radiation

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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. Starting the paragraph with "Is an individual who..." would result in redundant language since § 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 Radiation Safety Officer.

Comment: One commenter believed 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. Limiting the ARSO designation for only those individuals that have training and experience in all the medical types and uses on the license would not permit individuals with training and experience 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; they would also need to meet the experience requirements. Additionally, the NRC disagrees with the commenter's assertion that only the 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

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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. 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 Agreement State believed the training and experience 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 ASRO listing/approval or the licensees.

Response: No change was made to the compatibility level for the ARSO training and experience requirements. The NRC has determined that § 35.50 is a compatibility category B because training and experience requirements have "significant direct transboundary implications." Licensees, license applicants, and individuals seeking authorized status need to know that the training and experience qualifications are essentially identical for RSOs and ARSOs.

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. The NRC recognizes that the increase in the number of individuals meeting the qualifications in § 35.50 and being recognized

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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 similarly named entity) or multiple RSOs listed on the same license for many years with no adverse effects or consequences.

Response: No response required.

Section 35.55 Training for an authorized nuclear pharmacist.

Comment: A commenter asserted that specialized residencies in pharmacy practice were 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

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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 training and experience requirements for an ANP similar to those provisions added for an AU, AMP, and a RSO.

Response: No change was made to the rule text. 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 Committee on Post-Graduate 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 as a petition for rulemaking under 10 CFR 2.802.

Comment: The 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

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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. The regulations permit a pharmacist to be recognized as an authorized nuclear pharmacist as long as the § 35.55 training and experience 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 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.

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Response: No response 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. The NRC provides training and experience guidance in NUREG-1556, Vol. 9 “Consolidated Guidance about materials licenses: Program Specific Guidance about Medical Use.” 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: A 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 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 authorized user 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 NRC will grandfather all authorized users authorized for medical uses, including Radium-223 dichloride, on the [effective date of the

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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.

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 a Radiation Safety Officer or an Associate Radiation Safety Officer and that the initial certification date is immaterial to one's present technical expertise.

Response: No change was made to the rule text. 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 training and experience requirements (Subpart J).

Comment: Three commenters supported the grandfathering of board certified individuals but requested the rule text be changed from "for the modalities that they practiced on

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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. 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. 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 training and experience 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

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named by an NRC or Agreement State license.

Response: No change was made to the rule text. 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 a medical event 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 to the rule text was made. 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 a medical event or a violation of NRC requirements.

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

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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. There are three new paragraphs 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 to the rule text was made. The NRC amended the regulations to clarify that some sealed sources authorized under § 35.65 can 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

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text in § 35.65 was confusing. They recommended that “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 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 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: An Agreement State 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/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 to the rule text was made. The commenter noted correctly that licensees cannot use sealed sources in a manner inconsistent with the SS&D registry. The SS&D registration sheet does not prohibit the “bundling” of sealed sources to create a larger 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 activity than is allowed. The rule change makes it clear that the maximum activity authorized by § 35.65 applies to all

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sealed sources whether used singularly or in a bundled configuration.

The NRC reviewed the rule language and believes it is very 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: No response required.

Comment: A few 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 training and experience.

Response: No response required.

Comment: One commenter noted that based on the revision to the training and experience requirements, an individual who is board certified will no longer need a preceptor

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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. 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 training and experience 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 the reluctance 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 authorized user who can attest that the individual has satisfactorily completed the required NRC training.

Response: No response 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 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: No response required.

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: No response 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 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.

Comment: The 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 requested that the reporting requirement of § 35.204 be revised to

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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. 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/distributor 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. 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 molybdenum-99 concentration is made after a generator is received, for clarity the phrase “after receipt” is retained.

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

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Comment: A 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. The NRC is ensuring that any new unsealed byproduct material requiring a written directive not included in § 35.390(b)(1)(ii)(G) will be regulated under the provisions of § 35.1000. This approach will allow the NRC to evaluate each new proposed radionuclide and determine the appropriate training and experience needed. This is why an AU cannot be authorized for all possible unsealed byproduct material uses under § 35.300.

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

Comment: The commenter suggested the elimination of the attestation requirement for physicians meeting the “alternate pathway” training and experience 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. 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 training and experience requirements but is also able to independently fulfill the radiation safety-related duties of an authorized user.

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Comment: The 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)) 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 changed to include the phrase “radioactive drug that contains a” in § 35.390(b)(1)(ii)(G)(3) and (4). The NRC agrees that the proposed language could be clearer.

Comment: The 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. The NRC believes it is unlikely that there will be a radioactive drug requiring a written directive 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: The 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 did not believe these physicians need additional training to use materials for which they are already

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authorized.

Response: 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. No change was made to the rule text in § 35.390(b)(1)(ii)(G)(4). The NRC agrees that physicians already using Ra-223 dichloride at the time the rule becomes effective should be permitted to continue use of the radioactive drug. An AU currently authorized for parenteral administration of unsealed byproduct material requiring a written directive, and using Ra-223 dichloride would be grandfathered for all materials in the new § 35.390(b)(1)(ii)(G)(4) or § 35.396 because Ra-223 dichloride is used primarily for its alpha emission.

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 authorized user 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 in § 35.390(c) was revised to address any additional authorizations for which an individual is seeking AU status. Section 35.390 (b)(ii)(G) has four 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 training and experience 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 training and experience.

In response to this comment, the NRC revised § 35.396(a) to delete “[this] individual must meet the supervised work experience requirements in (d)(2) of this section for each new parenteral

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administration listed in § 35.390(b)(1)(ii)(G) for which the individual is requesting authorized user status.” The NRC made this change because this requirement is addressed in § 35.390(c).

Comment: The 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 Advisory Committee on the Medical Use of Radioisotopes (ACMUI) recommendation not to separate the parenteral administration of beta/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 need for emission specific T&E requirements.

Response: No change was made to the rule text. The NRC determined that there are fundamental differences between the clinical use and the radiation safety of the radioactive drugs used primarily for their beta emission or alpha emission. The radiation detection equipment used to monitor and detect photons and beta particles can be very different from that used to monitor and detect alpha particles, and calibration procedures for measuring activities of beta emitters and alpha emitters are more complicated than for photon emitters. Further, the relationship between activity and radiation dose delivered to the patient for alpha emitters is not the same as that for low-energy photons and beta emitters.

The NRC recognizes that the medical community has used low-energy photon and beta-emitting radionuclides for many years and that there are more radiopharmaceuticals

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

Comment: One commenter believed NRC's separation of categories 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

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defined category 3 and be consistent with the placement of radium-223 dichloride.

Response: No change was made to the rule text. 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 written directive. The commenter's proposal would result in implementation difficulties without a commensurate increase in safety.

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: No change was made to the rule text. The NRC is retaining the separate dosage category used primarily for alpha emitters because there are fundamental differences between the clinical use and the radiation safety of the radioactive drugs used primarily for their alpha emission versus beta emission. The NRC has established the new category of radioactive drugs primarily used for their alpha emission. NRC anticipates that all radiopharmaceuticals that will be used for their alpha emission will be regulated under this new category in § 35.390(b)(1)(ii)(G).

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 Ra-223 dichloride and a potential new actinium alpha emitter. The commenter suggested that NRC should create a new training and experience requirement specific to

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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 training and experience requirement review, due to its administration profile and safety characteristics.

Response: No change was made to the rule text. 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. The NRC licenses a new radioactive drug 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 radioactive drug is placed under § 35.1000, specific training and experience requirements are included in the guidance for that particular radioactive drug.

Comment: Several commenters stated several reasons why it would be difficult for authorized users 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.

Response: No change was made to the rule text. The NRC recognizes that there is currently only one radioactive drug that is used primarily for its alpha emissions but that others

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are being developed. The supervised work experience requirements for each category of radioactive drugs requiring written directives in § 35.390(b)(1)(ii)(G) was set very low (a minimum of 3 cases) to account for the small number of potential patients. Although NRC does not restrict where physicians go to receive required training, they generally go to teaching hospitals and urban medical centers for training because these facilities tend to offer new or more advanced treatment procedures.

Comment: A few 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 suggest 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.

Response: No change was made to the rule text. The NRC recognizes that the medical community has used low-energy photon and beta-emitting radionuclides for many years and that there are more radioactive drugs containing beta emitters than the alpha emitters. The NRC determined that there are fundamental radiation safety differences associated with alpha-emitting radioactive drugs. They include patient radiation safety (e.g., administrative controls to prevent an ME), steps to ensure the proper dosage is delivered (e.g., quality control procedures on instruments used to determine the activity of dosages, calculating, measuring, and safely preparing dosages), and basic radiation safety (e.g., ordering, receiving, performing radiation surveys, containing spills safely and proper decontamination procedures). Therefore, the NRC has determined that an AU must have experience with a minimum of three cases involving alpha-emitting radioactive drugs, in addition to a minimum of three cases the AU must have with the low-energy photon-and beta-emitting radionuclides, if the AU is to be authorized for both

categories.

Comment: A few 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: No change was made to the rule text. The proposed requirements will ensure that AUs have the proper radiation safety training in the use of radioactive drugs used primarily for their alpha emitters. The supervised work experience requirements for each category of radioactive drugs requiring written directives in § 35.390(b)(1)(ii)(G) was set very low (a minimum of three cases) and should not pose a significant burden.

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

Comment: One commenter strongly 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 Authorized User status to administer parenteral radioactive drugs. The commenter stated that this is an appropriate level of training and experience for administration of a specific radioactive drug used primarily for its beta emissions by hematologist and oncologist.

Response: During the preparation of the proposed rule for publication, an administrative error resulted in the addition of the word “or” between the rule text in §35.396(c) and §35.396(d). 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 in §35.396(c) and §35.396(d). The inadvertent

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typographic error of adding the word “or,” resulted in the commenter to believe that the NRC is requiring only 80 hours of training for parenteral administrations. The NRC notes that authorization to use parenteral radioactive drugs requiring a written directive, the physician must meet the training and experience requirements in either § 35.390 intended for nuclear medicine physicians, or under § 35.490 or § 35.690 with the additional 80 hours of training and clinical experience specified in § 35.396 intended for radiation oncologists.

Comment: One commenter stated that NRC’s regulations create a shortage of authorized users able to administer certain therapeutic radiopharmaceuticals. Specifically under current regulations, a radioactive drug requiring a written directive that is administered parenterally and used primarily for its beta radiation characteristics, can only be administered by an Authorized User (AU) who has met the training and experience requirements set forth in 10 CFR 35.396. These requirements involve either board certification or 700 hours of training and experience specifically in radionuclide handling. The commenter believes that hematologists and oncologists who typically prescribe therapeutic radiopharmaceuticals outside of the hospital setting often do not have the training and experience required to meet the AU requirements and do not work at facilities that have such AUs. They have extensive training and experience, and are frequently board certified, but in different specialized fields.

Response: No change was made to the rule text. As clarification the NRC notes that, to be an AU authorized to use parenteral radioactive drugs requiring a written directive, the physician must meet the training and experience requirements in either § 35.390 intended for nuclear medicine physicians or under § 35.490/§ 35.690 with the additional 80 hours of training and clinical experience specified in § 35.396 intended for radiation oncologists.

Section 35.400 Use of sources for manual brachytherapy.

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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 SSD. The commenters believed that this 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 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. Although the statements of consideration states “manual brachytherapy sources can be used for medical uses not listed in the SSD”, 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 Sealed Source and Device Registry.” 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 Sealed Source and Device Registry (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 save resources for industry and regulatory agencies in not having to independently obtain this information.

Response: No change was made to the rule text. NRC is not certain what the

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commenter meant by “SSDR reviewer should identify and list requirement [sic] and discuss issues on how to license these products for safe use.” 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 authorized medical physicists who are involved in the uses allowed under § 35.600 and § 35.1000, were an improvement.

Response: No response 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 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 changed to include the term ophthalmic physicist in §35.433(a)(2). The NRC agrees that, for clarity, the term ophthalmic physicist needs to be included in this section. By including the words “ophthalmic physicist” it makes it very clear that 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.

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Comment: Several commenters questioned the need for § 35.433(b)(2) and recommended its removal. They thought the actions regarding the written directive 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. The purpose of the ophthalmic physicist is to provide physics support to the ophthalmic authorized user when the licensee does not have access to an authorized medical physicist. To further explain, the reason that the ophthalmic physicist cannot work under the supervision of an authorized medical physicist is because the licensee does not have an authorized medical physicist to provide the activities listed in § 35.433(b).

The purpose for § 35.433(b) is to describe the minimum performance-based activities expected by either the authorized medical physicist or the ophthalmic physicist in assisting the licensee and authorized user with the ophthalmic treatment program. The first activity is in the current rule and the second activity codifies that the authorized medical physicist, or ophthalmic physicist, is to assist the licensee and authorized user in assuring that the requirements in § 35.41 are met. Ophthalmologists using these devices are frequently in small programs with limited access to continuing services of an authorized medical physicist. The proposed rule change was made in part to ensure that the ophthalmology physicist (or authorized medical physicist) performs a minimum number of tasks at the ophthalmology office.

The NRC did not specify the frequency of involvement of the authorized medical physicist or ophthalmic physicist because the licensee should determine the best frequency for its program. The NRC requires authorized medical physicists to perform certain tasks at specified

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frequencies for certain medical use programs. Specifically, authorized medical physicists 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, authorized medical physicists 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 authorized medical physicist as authorized by state laws.”

Response: No change was made to the rule text. 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 training and experience requirements. The purpose of adding the ophthalmic physicist was to identify an individual that could assist the licensee when the licensee does not have access to an authorized medical physicist. The reason that the ophthalmic physicist cannot work under the supervision of an authorized medical physicist is because the licensee does not have an authorized medical physicist to provide the activities listed in § 35.433(b). It should be noted that 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

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adequate program.

Comment: An Agreement State pointed out that its licensure requirements for “Medical Physicist” are currently consistent with NRC’s requirement for an authorized medical physicist in 10 CFR 35. The training and experience 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 proposed 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 training requirements for an ophthalmic physicist under § 35.433(a). All NRC training and experience criteria 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 that the authorized medical physicist or “ophthalmic physicist” would observe treatments, review the treatment methodology, calculate

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treatment time for the prescribed dose, and review records to verify the treatment was in accordance with the written directive. 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 authorized medical physicist, 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) was 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. 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. They thought 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 did not approve of the revision and recommended that any other uses of these sealed sources should be approved by the licensing regulatory agency.

Response: No change was made to the rule text. To clarify, the revisions in § 35.500(a) states "[a] A licensee must use only sealed sources not in medical devices for diagnostic medical uses that are approved in the Sealed Source and Device Registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry." And § 35.500(b) states " 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." 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 Sealed Source and Device registry. 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 Sealed Source and Device registry. As long as the limitations and conditions included in the SDDR 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. 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. The 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

Sealed Source and Device Registry (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: A 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 changed. 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.

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Comment: The 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. 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: A 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 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 certified by the device manufacturer to provide the operational and safety training may provide initial instruction to other authorized operators.

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

Comment: A 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.

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Response: No change is made to the Rule text. 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 source replacement 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: A 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. The NRC reviews on a case by-case basis, each applicant who received board certification more than 7 years ago requesting to be authorized as an authorized user or authorized medical physicist. The licensee must demonstrate that the individual has had related continuing education and experience since the required training was completed. 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 because of the rigorous training and experience requirements already in place.

Comment: The commenter believed 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

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institution so long as it has the appropriate authorized users on staff (common with physician faculty practicing at affiliated outpatient facilities). While residents need some direct work experience with, for example, treatment planning for high dose-rate remote after loaders, there are concepts learned in a linear accelerator treatment planning that apply; and this is especially true of external beam therapy from radioactive sources. Thus, if a preceptor judges it to be appropriate, a portion of the required 500 hours of work experience should be allowed to be acquired at a facility that does not use byproduct material in 35.600.

Response: No change was made to the rule text. The change 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 an institution/facility that is authorized for 35.600 uses. The NRC recognizes that the concept learning 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: The commenter was concerned 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. 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/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 concerns raised, the comments are discussed under these distinct issues:

Issue: the medical event reporting criterion are based on the term “potential harm.”

Comment: Several commenters stated that they do not agree with use of the term “potential harm” in the discussion of medical events in the *Federal Register* notice for the proposed rule. The commenters believe that “potential harm” is a medical decision and this approach is a significant departure from the current definition of a medical event. 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.”

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Response: The NRC has confidence that the rule will not discourage licensees from identifying precursor events or making process improvements. The NRC determined that the rule continues to reflect the NRC's position that a medical event 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. The medical event 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 medical event 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 a medical event was exceeded for the urethra, given that the volume is less than 5 cc, that instance require reporting. The commenter also expressed concern that treatment planning systems could not distinguish between a 5 cc volume and a summation of five 1 cc volumes receiving 150 percent of the prescribed dose.

Response: 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

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commenters, the NRC removed the absorbed dose-based medical event 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 medical events 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 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 medical events 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 medical event reporting criterion in § 35.3045(a)(2)(iv).

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

Response: 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

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determine if a medical event occurred under this criterion. In response to this concern and those raised by other commenters, the NRC removed the absorbed dose-based medical event reporting criterion in § 35.3045(a)(2)(iv).

Comment: One commenter expressed concerns about the medical event 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 a medical event would never be found for normal urethral tissue for a prostate implant because there is not 5 cc of contiguous urethral tissue within the treatment site.

Response: 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 a medical event 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 a medical event 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

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normal tissue within the treatment site.

Response: 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 removed the use of absorbed dose based criteria for reporting medical events in § 35.3045(a)(2)(iv).

Comment: One commenter expressed concern about the medical event 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 medical event 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 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 medical event 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

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be to catheterize the patient, which would cause significant pain to the patient, and therefore is not performed.”

Response: 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 medical event 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 medical event definition for “intra-target normal structures” in § 35.3045 (a)(2)(iv).

Response: 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 medical event definition. In response to this concern and those raised by other commenters, the NRC removed the absorbed dose-based medical event 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 medical event reporting criterion in § 35.3045(a)(2)(iii) related to the absorbed dose to normal tissue located outside the

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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 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. In response to this concern and those raised by other commenters, the NRC removed the absorbed dose-based medical event 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 medical event reporting criteria are not consistent with current medical practice and may discourage licensees from performing permanent brachytherapy, thus denying patients access to this technology.

Response: 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

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removed the absorbed dose-based medical event reporting criterion in § 35.3045(a)(2)(iii) and (iv).

Comment: Two commenters expressed concerns about the use of absorbed dose to a contiguous 5 cubic centimeters as a criterion for reporting medical events. The commenters noted that the absorbed dose to a contiguous 5 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 contiguous 5 cubic centimeters regulatory standard.

Response: 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 Advisory Committee on the Medical Uses of Isotopes. However, based on these and other comments, the NRC concluded that absorbed dose to a contiguous 5 cubic centimeters is not a suitable criterion for reporting medical events. Therefore, the NRC removed subparagraphs (iii) and (iv), which would have required licensees to use absorbed dose criteria to report medical events 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

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commenter stated that “planning systems typically report dose volume histograms to structures, but they do not identify contiguous volumes.”

Response: 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 may not. In response to this concern and those raised by other commenters, the NRC removed the absorbed dose-based medical event 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 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

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the prescribed dose by 50 percent. The NRC also acknowledges that authorized users describe “treatment site” in different ways. The NRC expects the authorized user to describe the treatment site (as defined in § 35.2) in the written directive 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 medical event reporting criterion in § 35.3045(a)(2)(iii).

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

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 in to the medical event definition for radiopharmaceuticals, and has been an auditable measure by inspectors since the definition of "misadministration" that was created decades ago.

Response: While the NRC agrees that source strength is a major factor impacting absorbed dose for permanent brachytherapy, the NRC believes that the absorbed dose is determined by a combination of source strength and spatial positioning. Regardless, 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 medical events for permanent implant brachytherapy and removed the absorbed dose-based medical event 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

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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 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 medical events 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 effect of making the commenter's proposed change would be a requirement to report as a medical event 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 it is best to remove and not replace the dose-based medical event 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 as a medical event sealed source(s) directly delivered to the wrong treatment site. 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 a medical event. Several

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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 ninety to one hundred 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 medical events 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 medical event. One commenter suggested that the NRC establish a reasonable de minimus 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 medical events.

Response: The NRC agrees that typical permanent implant procedures result in some sources being implanted outside the treatment site as described in the written directive. In accordance with § 35.3045 (a)(2)(ii), a medical event 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, appears to be in conflict with the provisions of § 35.3045 (a)(2)(ii). To ensure that the provisions of § 35.3045(a)(2)(v)(C) can be distinguished from those in § 35.3045 (a)(2)(ii), the NRC has changed § 35.3045(a)(2)(v)(C) to read: “Sealed source(s) implanted directly into a location where the radiation from the source(s) will not contribute dose to the treatment site, as defined in the written directive.”

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

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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 medical events 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 expected clinical occurrence. The commenters asked the NRC to restore the provision for migrated seeds.

Response: 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 a medical event.

Comment: One commenter expressed concern about the provisions of the proposed rule that a permanent implant brachytherapy procedure in which the sources were placed correctly then migrated, would be considered a medical event. 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 medical events could occur due to circumstances beyond their control, and the damage that can result from the publicity surrounding a medical event.

Response: 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

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considered a medical event.

Comment: 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 a medical event) 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 a medical event 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 a medical event for permanent implant brachytherapy implants.

Response: 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 a medical event.

Issue: ME definition should allow exception for causes outside of the physician’s control

Comment: One commenter suggested that the medical event 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 medical events resulting from patient intervention does not address procedure-related causes that are outside 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

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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 medical events, contrary to our understanding of the NRC’s intent.”

Response: No change was made to the rule text. 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. The NRC believes that the commenter’s concerns are primarily related to the proposed absorbed dose-based reporting criteria in § 35.3045(a)(2)(iii) and (iv), which have been removed. Factors outside of the physician’s control, such as edema and imaging uncertainties, should have limited impact under the source strength-based medical event 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 medical event 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” pursuant to the pre-implantation or post-implantation portion of the written directive. 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 in § 35.3045(a)(2)(v) was revised to delete the medical event criterion described in § 35.3045(a)(2)(v)(E), “[a] 20 percent or more error in calculating the total

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source strength documented in the pre-implantation portion of the written directive.” The NRC agrees with the commenter that this criterion is not needed since it appears to be captured by 35.3045(a)(2)(i) and (a)(2)(ii). However, the NRC determined that § 35.3045(a)(2)(v)(E), was not a true 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 staff in defining a rule to capture medical events from permanent implant brachytherapy procedures. One of the principles recommended a limited dose-based medical event 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” medical event dose pathway would “focus only on preplanning or intraoperative planning, not post-implant evaluation.” Since the revised medical event criteria are based on post-implant evaluations, the NRC agrees that the criterion § 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 in § 35.3045(a)(2)(v) was revised to delete the medical event criterion in § 35.3045(a)(2)(v)(E) of the proposed rule: “[a] 20 percent or more error in

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calculating the total source strength documented in the pre-implantation portion of the written directive.” 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 a medical event.

The NRC considered the commenter’s statement that these types of medical events 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 a medical event 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 medical event reporting for permanent implant brachytherapy must be based on the source strength in the post-administration written directive 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 written directive.

Response: No changes were made in response to these comments. The source strength comparisons for the medical event reporting criteria in § 35.3045(a)(2)(i) and (ii) are with the source strength specified in the post-implantation written directive. Although § 35.3045(a)(2)(iii) of the proposed rule included an absorbed dose comparison with information in the pre-implantation written directive, the NRC removed this criterion in response to different

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comments. Also, § 35.3045(a)(2)(v)(E) of the proposed rule included a calculated total source strength with the pre-implantation written directive, 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 written directive.

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) medical event criteria for permanent implants rather than dose delivered (dose based) criteria for permanent brachytherapy implants.

Response: No response required.

Comment: One commenter expressed several concerns related to the proposed dose-based portion of the criteria for permanent implant brachytherapy medical event reporting. The commenter recommended that any medical event reporting for permanent implant brachytherapy be based solely on a source strength-based definition for the written directive 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 written directive 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 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 cc introduced by the NRC is totally arbitrary and not based on any clinical data; and 5) that the ACMUI in 2008 recommended a source strength ME definition for

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permanent implants and explicitly stated it should not include an absorbed dose criteria.

Response: 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 medical events 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 is not based upon clinical data. In response to these concerns and those raised by other commenters, the NRC removed the absorbed dose-based medical event reporting criterion in § 35.3045(a)(2)(iii) and (iv).

Comment: Two commenters stated that in 2008, the ACMUI recommended a source strength medical event 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 medical event 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

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deviating from these recommendations. One of the commenters stated that the NRC needs to base the medical event 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 adjustment of §35.3045(a)(2).

Response: 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 medical event reporting criteria recommendations. However, in 2012, the ACMUI recommended the proposed "hybrid" criteria for reporting medical events 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 medical event 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: some alternate suggestions 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 written directive is fulfilled. The commenter stated that medical events should be rare mistakes because the procedures are required to be performed by physicians that have the required training and experience. The commenter also stated that the NRC should not try to regulate the "medicine side" and that the NRC's determination of

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“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. The NRC agrees, and it is NRC policy, that it should not (and does not) regulate the practice of medicine. Although peer review is good practice, for the NRC to require a peer review is beyond the scope of NRC’s policy. Further, the licensee makes the determination of the actual or potential harm to patients that might result from a medical event. The NRC’s position is that a medical event 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. However, in response to other comments, the NRC removed the absorbed dose-based medical event 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. This is one of the few comments NRC received that supported dose-based medical event 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 medical event reporting criteria for permanent implant brachytherapy. Therefore, the NRC revised the permanent implant brachytherapy medical event reporting criteria in § 35.3045(a)(2) to be based only on total source strength, not dose.

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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 (authorized user (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. This is one of the few comments NRC received that supported the dose-based medical event reporting criteria. The NRC received other comments that identified technical limitations associated with the use of a dose-based medical event 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 medical events. Therefore, the dose to the organs at risk does not need to be determined for medical event 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 medical event 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.

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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 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 medical event 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 new rule does not apply to the use of Y-90 microspheres.

Issue: drift of implanted sources and defining the treatment site in the context of source drift

Comment: The 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 a medical event 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 written directive. 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 a medical event, 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 authorized users to define a treatment site “with huge margins for seed drift.”

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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. The commenter believes that the NRC should “simply require Peer Review as part of high confidence.”

Response: No change was made to the rule text in response to this comment. The NRC has not established a cutoff distance for “drift” or source migration. The authorized user defines the treatment site in the written directive in any way he or she believes to be appropriate, including any margins. The NRC agrees that migration of sources that were implanted into the correct site should not be considered a medical event. In response to other comments, the rule text at § 35.3045(a)(2) was changed to restore the exclusion to medical event 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) 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 where radiation from the source(s) will not contribute dose to the treatment site, as defined in the written directive.” The NRC agrees that the dose distribution within the treatment site is not a suitable medical event criterion because it can vary over time and is not fully under the control of the authorized user. In response to other comments, the NRC revised the permanent implant brachytherapy medical event criteria at § 35.3045(a)(2) to be based only on total source strength, not dose. As a result, no medical event 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.

Although peer review is good practice, for the NRC to require a peer review is beyond the scope of the NRC's medical use policy. The NRC agrees, and it is NRC policy, that it should not (and does not) regulate the practice of medicine.

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 a medical event. 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 of 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. The NRC understands that authorized users may intentionally implant sources into surrounding normal tissues. The authorized user defines the treatment site in the written directive in any way he or she believes to be medically appropriate, including any margin and/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

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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 in response to 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 authorized user defines the treatment site in any 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 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 authorized user defines the treatment site with “tight borders” the licensee may need to report a medical event. However, if another authorized user defines the treatment site more “loosely,” a medical event may not have to be reported.

Response: No change was made to the rule text. The authorized user defines the treatment site in the written directive in any way he or she believes to be appropriate, including any margin. The authorized user 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

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treatment site is a matter of medical judgement.

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. The authorized user defines the treatment site in the written directive in any way he or she believes to be appropriate, including any margin and/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 medical event reporting requirements are complex and may create confusion for regulators and the regulated community when applied to permanent prostate implant procedures.

Response: The NRC acknowledges the commenter’s concern regarding the complexity of the medical event 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 medical event 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 medical event 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 medical event 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 brachytherapy implants. The requirements for procedures requiring a written directive, and the requirements for medical event reporting appear in two different subparts of Part 35—Subpart B – General Administrative requirements, and Subpart M – Reports. To separate the permanent brachytherapy implant 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

The following comments were in support of Compatibility Designation B for medical event reporting under § 35.3045:

Comment: One commenter stated that the written directive requirements under § 35.40(b)(6) and the procedures for permanent implant brachytherapy required under § 35.41(b)(6) should be deemed compatibility B (rather than compatibility C) such that the rules are uniform from one state to another to minimize confusion. The commenter stated that

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because over 90 percent of medical licensees are under Agreement State authority, anything less than compatibility B makes these changes “an over-regulation of the minority.”

Response: The compatibility designation for the written directive requirements under § 35.40(b)(6) and the procedures for permanent implant brachytherapy required under § 35.41(b)(6) is 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 medical event reporting under § 35.3045, which is designated as Compatibility C and which the final rule continues to designate as Compatibility C.

Comment: One commenter stated that they support the Compatibility Category B designation for medical event reporting, in agreement with the opinion of the ACMUI and for the reasons stated in the proposed rule by the NRC. 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 a medical event. The commenter believes that there is merit in consistent rules for subjects that have significant implications, such as the criteria for a medical event, and standardization should remove uncertainty and confusion.

Response: The NRC agrees with the commenter that activity-based criteria are appropriate for medical events for permanent implant brachytherapy procedures, including the prostate implant procedures. As discussed earlier in this Section, NRC has determined that Compatibility C is the appropriate designation for § 35.3045. The NRC determined that Compatibility 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

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maintain a consistent national program for reporting medical events. Agreement State use of dose-based criteria for permanent implant brachytherapy would be inconsistent with this essential objective, because the NRC has determined that dose-based criteria would result in the over 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 the comment response above and in Section V, Public Comment Analysis, of this document. The essential objective of § 35.3045 is to maintain a consistent national reporting program, as further explained in Section V, Public Comment Analysis.

Comment: One commenter, in support of the Compatibility Category B, stated that they recognize that the Agreement States oppose a change in compatibility level, citing state legislative requirements, the difficulty in changing state regulations, and the fact that Agreement

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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 medical events. The commenter expressed concern that a Compatibility C designation would allow Agreement States to implement unnecessarily more restrictive definitions that classify medically acceptable procedures as medical events.

Response: The NRC understands the importance of having consistent medical event reporting criteria throughout the country to prevent confusion and unnecessary reporting of otherwise medically acceptable procedures as medical events. 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 medical event reporting criteria. The Agreement States have the flexibility to include, for example, a shorter reporting time in their medical event reporting criteria, but the use of dose-based medical event 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 medical events.

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 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

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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 the comment responses above, 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, and therefore has identified dose-based criteria as an example of alternative ME criteria that would capture insignificant events as MEs and thus create a conflict and inconsistency in the national reporting program.

Comment: One commenter stated that if the NRC were to revert to a lower-than-proposed compatibility category, they would then 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.

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Response: As recommended by the commenter, the NRC has discussed the program element contained in § 35.3045 and the essential objective of this program element in Section V, Public Comment Analysis, of this document. The program element contained in § 35.3045 is medical event reporting, not activity-based ME metrics. The essential objective of this program element is to maintain a consistent national medical event 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 a consistent national reporting program because it would result in insignificant events being reported as medical events. As explained in Section V, Public Comment Analysis, of this document, 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 medical events, and thus would disrupt these efforts. Therefore, Agreement States cannot adopt dose-based ME reporting criteria for permanent implant brachytherapy.

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

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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. And this uniformity is necessary because a program element has significant direct transboundary implications. As discussed in Section V, Public Comment Analysis, of this document, the NRC has determined that medical event 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

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objective of § 35.3045 is to maintain a consistent national medical event reporting program. Agreement States should ensure that their medical event reporting criteria do not conflict with or create inconsistency within this program. With respect to permanent implant brachytherapy medical event reporting, this means that Agreement States should not adopt dose-based reporting criteria.

The following comments were in support of Compatibility Designation C for medical event reporting under §35.3045:

Comment: One of the Agreement States stated that all medical events 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 a medical event report to its licensing authority. The commenter also stated that all medical events are reported in the Nuclear Materials Event Database, so NRC is notified of all events that meet the NRC's medical event criteria.

Response: The NRC acknowledges that, from the perspective of a single medical facility, medical events appear to be local events only. The NRC has determined that medical event reporting does not rise to the level of having significant direct transboundary implications and therefore Compatibility Category B is inappropriate. However, to assure that Agreement State program meet the essential objective of § 35.3045 to maintain a consistent national medical event reporting program, the Agreement States, for permanent implant brachytherapy treatments, must adopt the activity-based criteria, and not use the dose-based criteria. For the reasons explained in response to comments above and in Section V, Public Comment Analysis, of this document, the use of dose-based criteria would create conflicts and inconsistencies in

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the national medical event reporting program and thus is not acceptable permanent implant brachytherapy ME reporting criteria.

Comment: Several commenters opposing the proposed category B designation for medical event 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 “C” designation has been adequate for the reporting requirements for radiography, irradiator, and well logging licensees who work routinely 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, medical events appear to be local events only. The NRC agrees that medical event 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. Thus the ME reporting criteria do not have to be essentially identical. However, the essential objective of § 35.3045 is to maintain a consistent national medical event reporting program, and to adopt this essential objective Agreement States should adopt ME reporting criteria that do not create conflicts or inconsistencies in medical event reporting. The medical event 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.

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Comment: Several commenters, in support of the Compatibility Category C designation for medical event 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 above 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 medical event 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

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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 certain definitions may be assigned a particular Compatibility Category, 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 medical event reporting appears to be the multiple prostate implant medical events that occurred at the Department of Veterans Affairs facilities.

Response: When drafting the medical event 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 medical event reporting requirements for permanent implant procedures for all treatment sites is sufficient to ensure that significant events involving prostate implants will be reported as medical events. As explained in response to comments above and in Section V, Public Comment

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Analysis, 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 medical event 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 medical events 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 medical event 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 medical events 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 above in response to other comments and in Section V, Public Comment Analysis, the NRC has determined that Agreement State use of dose-based criteria for permanent implant brachytherapy medical event reporting would result in inconsistencies and conflicts with the essential objective of § 35.3045, which is to maintain a consistent national medical event reporting program. Therefore, the use of dose-base criteria instead of or in addition to activity-based criteria would not be compatible with § 35.3045.

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: No response required.

Comment: One commenter noted that Tc99m decays much faster than Mo99; therefore, every Tc99m 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 Tc99m generator elution that exceeded the regulatory limits at the time of generator elution.

Response: The rule text was modified. 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. 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

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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 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 cited that any 30-day notification to the Agreement States only has to be submitted to the NRC using the National Materials Events Database (NMED) and is not required to be submitted to 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 medical event 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,

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the commenter stated that the current IMPEP requirement to report such events to the National Materials Events Database 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. 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 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. 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 Discussion of Amendments by Section.

The following paragraphs describe the specific amendments for this final rule.

Section 30.34 Terms and conditions of licenses.

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

This change 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 10 CFR part 35.

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

Paragraph (b)(5)(i). This paragraph 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

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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 license or permit for the types of use of byproduct material for which the individual had been assigned tasks and duties by the RSO. Additional information on ARSOs is located in Section IV, Discussion, of this document.

The new definition for *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 that the individual must be currently listed as an ophthalmic physicist on a specific medical use license issued by the Commission or an Agreement State or a medical use permit issued by a Commission master material licensee. A written attestation will not be required for this individual.

The definition for *Preceptor* is amended to add ARSO to the list of individuals who provide, direct, or verify T&E required for an individual to become an AU, an AMP, an ANP, or

an RSO. This is a conforming change in support of the new definition for *Associate Radiation Safety Officer*.

Section 35.12 Application for license, amendment, or renewal.

This section is amended to remove the requirement to submit copies of NRC Form 313, Application for Material License, or a letter containing information required by NRC Form 313 when applying for a license, an amendment, or renewal. This section 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 remove the requirement to submit an additional copy of 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 remove the requirement to submit a copy of 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). The 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 on a medical license or permit. The definition of an *ophthalmic physicist* in § 35.2 will allow the ophthalmic physicist to be named only on a specific medical use license and not on a broad scope medical license. This limitation is to ensure that individuals seeking to be named as an ophthalmic physicist have their T&E reviewed by a regulatory authority as the position is new and unfamiliar to the medical community. Additionally, broad scope licensees already have ready access to AMPs to perform the requirements listed in § 35.433.

Paragraph (d). This new paragraph 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 Sealed Source and Device Registry (SSDR) used for manual brachytherapy for quantities and isotopes already authorized by its license without first seeking a license amendment. This change will provide manual brachytherapy licensees greater flexibility in obtaining the sealed sources necessary for patient treatments in a timely manner.

Section 35.14 Notifications.

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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. These individuals will be only authorized for the materials and uses for which they were previously authorized. This change does not impose any new requirements.

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 their duties under the license.

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 SDDR for manual brachytherapy for quantities and isotopes already authorized by

the license.

Section 35.24 Authority and responsibilities of the radiation protection program.

This section 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 will have to be named on a medical license or permit for the types of use of byproduct material for which the RSO, with the written agreement of the licensee's management, would assign tasks and duties.

The licensee's management 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 authorized user or" as it is redundant with "an individual qualified to be a Radiation Safety Officer under 35.50 and 35.59" in the same sentence.

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

Section 35.40 Written Directives.

Paragraph (b) of this section 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 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 and cannot be modified once the implantation begins. The final rule retains the current provision that an AU could revise an existing WD in writing or orally before the implantation begins.

The post-implantation portion of the WD will require the documentation of the treatment site, number of sources implanted, the total source strength implanted, the signature of an AU for § 35.400 uses for manual brachytherapy, 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. The term “post-treatment recovery area,” as used in paragraph (b)(6)(ii), means the area or place where a patient recovers immediately following the brachytherapy procedure before being released to a hospital room or, in the case of an outpatient treatment, released from the licensee’s facility.

Paragraph (c) of this section 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 must 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 verification 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.

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

A 60-calendar-day time frame 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.

Multiple changes are made to this section. They include amending the title of the section to add “and Associate Radiation Safety Officer” as 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) 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

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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 contain the requirements for an RSO or ARSO under the alternate pathway to obtain a written attestation signed by either an RSO or ARSO. The language that is required in the written attestation 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 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

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licenses.

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

The provision will provide flexibility for an individual to serve as both an AU and as the RSO on a new medical 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, be certified in medical physics by a

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specialty board whose certification process has been recognized under this section by the Commission or an Agreement State.

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

Paragraph (b)(2). The wording in this paragraph 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 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). The wording in this paragraph 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 the Ritenour petition. This includes recognizing the board certifications of individuals certified by boards recognized under subpart J, which was removed from 10 CFR part 35 in a rulemaking dated March 30, 2005 (70 FR 16336), and making administrative clarifications. Additional information on the Ritenour petition, as it relates to this rulemaking, is located in Section II, Petition for Rulemaking, PRM-20, of this document.

Paragraph (a)(1). This paragraph is modified to add AMPs and ANPs identified on a Commission or an Agreement State license or a permit issued by a Commission or an Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope on or before October 24, 2005, as individuals that will not need to comply with the training requirements of §§ 35.50, 35.51, or 35.55, respectively. In addition, the date is changed for individuals named on a license as RSOs, teletherapy or medical physicists, AMPs, nuclear pharmacists, or ANPs from October 24, 2002, to October 24, 2005, because during the 3-year time frame applicants could have qualified under the now removed subpart J or the new T&E requirements under §§ 35.50, 35.51, or 35.55.

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

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§ 35.59.

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, who will not need to comply with the training requirements of § 35.50 to be identified as an RSO or as an ARSO on a Commission or an Agreement State license or Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005. Individuals excepted by this paragraph will still need to meet the recentness-of-training requirements in § 35.59 and, for new materials and uses, the training requirements in § 35.50(d).

Paragraph (a)(3). This paragraph 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, who will 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 will be exempted from these training requirements only for those materials and uses these individuals performed on or before October, 24, 2005. Individuals excepted by this paragraph will still need to meet the recentness-of-training requirements in § 35.59 and, for new materials and uses, the training requirements in § 35.51(c).

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

Paragraph (b)(1). This paragraph is amended to change the date an individual named on a license as an AU from October 24, 2002, to October 24, 2005, because during that 3-year time frame, an applicant could have qualified as an AU either under the former subpart J or the

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revised T&E requirements in subparts D through H of 10 CFR part 35.

Additionally, the paragraph is amended to clarify that an individual authorized before, rather than just on, October 24, 2005, 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 that date.

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, and who will not need to comply with the training requirements of subparts D through H of 10 CFR part 35 to be identified as an AU on a Commission or an Agreement State license or Commission master material license permit for those materials and uses that the individual performed on or before October 24, 2005. Removal of subpart J from 10 CFR part 35 was effective on October 24, 2005. An individual excepted from the T&E requirements by this paragraph will still need to meet the recentness-of-training requirements in § 35.59.

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 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 than authorized by § 35.65. Sources that consist of multiple single sources (bundling) that exceed the limits

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authorized by § 35.65 will no longer be regulated under § 35.65, will be treated as one single source, and will have to meet all of the regulatory requirements for that single source including, if appropriate, listing on a specific medical license, leak testing, and security requirements.

Paragraph (c). This new paragraph 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 met the requirements in §§ 35.57, 35.190, 35.290, or 35.390, or equivalent Agreement State requirements. However, the director must affirm in writing that the attestation represents

the consensus of the residency program faculty where at least one faculty member is an AU who meets the requirements in §§ 35.57, 35.190, 35.290, or 35.390, or equivalent Agreement State requirements, and that the AU concurs with the attestation.

Additionally, the paragraph 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 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

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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 receive unit doses from centralized pharmacies; therefore, training on eluting generators is not available at these facilities. ANPs have the T&E to provide the supervised work experience for AUs on the elution of generators.

Paragraph (c)(2). This paragraph 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.

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

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

Paragraph (a). For physicians seeking to be named as an AU of unsealed byproduct material for uses authorized under § 35.300, the requirement to obtain a written attestation 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). This paragraph is amended to expand and clarify the categories of parenteral administrations of radionuclides in which work experience is required for an individual seeking to be an AU for uses under § 35.300. Most radionuclides used for parenteral administrations have more than one type of radiation emission. In the final rule, the type of

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radiation emissions of parenteral administrations are based on the primary use of the radionuclide radiation characteristics. The changes to this paragraph also further expand the parenteral administration categories to include radionuclides that are primarily used for their alpha radiation characteristics.

The current regulations include a broad category for parenteral administrations of “any other” radionuclide. This broad category is removed, as any new parenteral administration of radionuclides not listed in this paragraph will be 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

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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 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.

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

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

Paragraph (a). For physicians seeking to be named as an AU for the oral administration of sodium iodide I-131 requiring a WD in quantities less than or equal to 1.22 gigabecquerels (33 millicuries), the requirement to obtain a written attestation 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

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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, and has experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(1) or 35.390(b)(1)(ii)(G)(2) and that the AU concurs with the attestation.

Additionally, the paragraph 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).

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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, and has experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(2) and that the AU concurs with the attestation.

Additionally, the paragraph 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.

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

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

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

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

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

Paragraph (d)(3). This paragraph is restructured and expanded to allow certain

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

Additionally, the paragraph 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 sources that are listed in the SSDR for manual brachytherapy to be used for other medical uses that are not explicitly listed in the SSDR.

Paragraph (a). This paragraph is amended to allow sources that are listed in the SSDR

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for manual brachytherapy medical uses to be used for other manual brachytherapy medical uses that are not explicitly listed in the SDR provided that these sources are used in accordance with the radiation safety conditions and limitations described in the SDR. These radiation safety conditions and limitations described in the SDR may apply to storage, handling, sterilization, conditions of use, and leak testing of radiation sources.

The NRC recognizes that the medical uses specified in the SDR may not be all inclusive. The revision will permit physicians to use manual brachytherapy sources to treat sites or diseases not listed in the SDR. For example, the SDR 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 latitude should be afforded to physicians to use their discretion in the practice of medicine.

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

The section title is modified by deleting “Decay of” at the beginning of the title. The new title reflects the expanded information and requirements in the 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, will have to meet the T&E requirements detailed in the new paragraph (a)(2) of this section to perform the specified activities but will not require an attestation. These requirements are similar to the T&E requirements for an AMP, but include only the requirements related to brachytherapy programs.

This amendment is to increase the number of qualified individuals available to support the use of Sr-90 sources for ophthalmic treatments. Often, AUs who work in remote areas do

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not have ready access to an AMP to perform the necessary calculations to support the ophthalmic treatments. This change will make the procedure involving use of Sr-90 sources for ophthalmic treatments available to more patients located in remote areas.

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

The second task is related to the requirements in § 35.41 and is included in this final rule to ensure the safe use of Sr-90 for ophthalmic treatments. Both the AMP and the individuals identified under paragraph (a)(2) of this section will be required to assist the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the dose administration is in accordance with the WD. Under this paragraph, the licensee will have to modify its procedures required under § 35.41 to specify the frequencies that the AMP and/or the individuals identified under paragraph (a)(2) of this section 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 new paragraph is unchanged from the recordkeeping requirements in the current regulation under § 35.433(b).

Section 35.490 Training for use of manual brachytherapy sources.

Paragraph (a). For a physician seeking to be named as an AU of a manual brachytherapy source for the uses authorized under § 35.400, the requirement to obtain a written attestation is removed for an individual who is certified by a specialty board whose

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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 will be 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

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residency program faculty where at least one faculty member is an AU who meets the requirements in §§ 35.57, 35.490, or equivalent Agreement State requirements, and that the AU concurs with the attestation.

Additionally, the paragraph 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 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 35.500 Use of sealed sources 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. The section title is modified to add “and medical devices” as the use of medical devices is added to this section.

Paragraph (a). This paragraph is amended to clarify that sealed sources not in medical devices for diagnostic medical uses approved in the SSDR can be used for other diagnostic medical uses that are not explicitly listed in an SSDR provided that they are used in accordance with radiation safety conditions and limitations described in the SSDR. These radiation safety

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conditions and limitations described in the SSDR may include storage, handling, sterilization, conditions of use, and leak testing of radiation sources.

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

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

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

The section 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

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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 continue to require that a licensee only use photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units approved in the SSDR or for research in accordance with an active IDE application accepted by the FDA provided the requirements of § 35.49(a) are met. However, this paragraph 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

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radiosurgery units. This amendment will require 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 an individual who operates these units be provided safety instructions initially, and at least annually; however, there is no requirement for this individual to receive instructions when the unit is upgraded. In addition, the amendment requires an individual who operates these new or upgraded units to receive training prior to first use for patient treatment.

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 the potential for training of new staff to be delayed until the required annual training, which could lead to having undertrained individuals operating the unit.

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

Section 35.655 5-year inspection for teletherapy and gamma stereotactic radiosurgery units.

The section title is modified to delete “5-year inspection” and insert “Full-inspection servicing” to more accurately reflect the requirements in the section of inspection and servicing

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of teletherapy unit 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). Due to the cost to replace the decaying sources in a gamma stereotactic radiosurgery unit, 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 assure 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, the 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 to help prevent potentially serious radiation exposure of teletherapy operators and patients in the event that the source exposure mechanism failed. The radioactive source contained in a teletherapy unit produces radiation fields on the order of hundreds of rads per minute in areas accessible to patients and operators. In the event of a source exposure mechanism failure, the exposed source could result in overexposure of a

patient or operating personnel in a short period of time.

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

Paragraph (a). For a physician seeking to be named as an AU for sealed sources for uses authorized under § 35.600, the requirement to obtain a written attestation 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 § 35.600 rather than at a medical institution. The current term “medical institution” in this paragraph is defined in § 35.2 as an organization in which more than one medical discipline is practiced. This definition unnecessarily limits where the work experience must be obtained. Moreover, the fact that an organization practices more than one medical discipline does not ensure that one of the medical disciplines will be related to uses authorized under § 35.600. The 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

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Osteopathic Association. The residency training program must include T&E specified in § 35.690.

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

Additionally, the paragraph 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 5-year inspection for teletherapy and gamma stereotactic radiosurgery units.

The 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) of this section 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 that require a WD. 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, “A licensee shall report as a medical event, any administration requiring a written directive, except for an event that results from patient intervention...,” is corrected to keep the current requirement that medical event reporting is required for all events that meet the ME criteria, and not limited to procedures that require a written directive.

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

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new paragraph (a)(1)(ii)(A) of this section for reporting as an ME an administration involving the wrong radionuclide for a brachytherapy procedure.

Paragraph (a)(2). This new paragraph 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 include:

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

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

3) An administration that includes the wrong radionuclide; the wrong individual or human research subject; sealed source, or sources implanted directly into a location where the radiation from the source(s) will not contribute dose to the treatment site, as defined in the written directive; 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 a medical event.

Several situations that will meet this criterion are self-evident, i.e., wrong patient, wrong treatment site, or leaking sealed source. A criterion related to an error of 20 percent or more in calculating the total source strength, proposed in the proposed rule published on July 21, 2014, has been deleted in the final rule. This deletion is 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 is added to require reporting and notification of an elution from a Mo-99/Tc-99m or Sr-82/Rb-82 generator that exceeds the regulatory requirements in §§ 30.34 and 35.204(a). Further discussion on reporting failed generators can be found in Section III, Discussion, of this document.

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

Paragraph (b). This new section will require 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 will have to be submitted by an appropriate method listed in § 30.6(a). The report will include the

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action taken by the licensee, patient dose assessments, the methodology used in making the patient dose assessment if the eluate was administered to patients or human research subjects, probable cause and assessment of failure in the licensee's equipment, procedures or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination, and the information in the telephone report as required by paragraph (a) of this section.

Administrative Changes to Authority Citations.

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

VII. Criminal Penalties

For the purpose of Section 223 of the Atomic Energy Act of 1954, as amended (AEA), the Commission is amending 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.

VIII. Coordination with NRC Agreement States

The Agreement States have been involved throughout the development of this 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.

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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 NRC staff responses to the comments are 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). Finally, in preparing both the proposed rule, and the final rule, the rulemaking working group considered the comments provided by the Agreement States. (place holder for the preliminary draft final rule review)

IX. 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

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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, above, and, thus, 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 Atomic Energy Act of 1954, as amended, or provisions of Title 10 of the *Code of Federal Regulations*. These program elements should not be adopted by the Agreement States. 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. The compatibility categories are designated in the following table:

Discussion on changing the Compatibility Category for § 35.3045, Report and notification of a

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medical event, can be found in V, Public Comment Analysis, of this document.

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

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35.12(d)(3)	New	Application for license, amendment, or renewal	-	D
35.12(d)(4)	Amend	Application for license, amendment, or renewal	D	D
35.13(b)	Amend	License amendments	D	D
35.13(d)	New	License amendments	-	D
35.13(i)	New	License amendments	-	D
35.14(a)	Amend	Notifications	D	D
35.14(b)(1)	Amend	Notifications	D	D
35.14(b)(2)	Amend	Notifications	D	D
35.14(b)(6)	New	Notifications	-	D
35.24(b)	Amend	Authority and responsibilities for the radiation protection program	H&S	H&S
35.24(c)	Amend	Authority and responsibilities for the radiation protection program	D	D
35.40(b)(6)	Amend	Written directives	H&S	H&S
35.41(b)(5)	New	Procedures for administrations requiring a written directive	-	H&S
35.41(b)(6)	New	Procedures for administrations requiring a written directive	-	H&S
35.50	Amend	Training for Radiation Safety Officer and Associate Radiation Safety Officer	B	B
35.50(a)	Amend	Training for Radiation Safety Officer and Associate Radiation Safety Officer	B	B
35.50(a)(2)(ii)(B)	Amend	Training for Radiation Safety Officer and Associate Radiation Safety Officer	B	B
35.50(b)(1)(ii)	Amend	Training for Radiation Safety Officer and Associate Radiation Safety Officer	B	B
35.50(b)(2)	New	Training for Radiation Safety Officer and Associate Radiation Safety Officer	-	B
35.50(c)(1)	Amend	Training for Radiation Safety Officer and Associate Radiation Safety Officer	B	B
35.50(c)(2)	Amend	Training for Radiation Safety Officer and Associate Radiation Safety Officer	B	B
35.50(c)(3)	New	Training for Radiation Safety Officer and Associate Radiation Safety Officer	-	B
35.50(d)	Amend	Training for Radiation Safety Officer and Associate Radiation Safety Officer	B	B

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35.51(a)	Amend	Training for an authorized medical physicist	B	B
35.51(a)(2)(i)	Amend	Training for an authorized medical physicist	B	B
35.51(b)(2)	Amend	Training for an authorized medical physicist	B	B
35.55(a)	Amend	Training for an authorized nuclear pharmacist	B	B
35.55(b)(2)	Amend	Training for an authorized nuclear pharmacist	B	B
35.57(a)(1)	Amend	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist	B	B
35.57(a)(2)	New	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist	-	B
35.57(a)(3)	New	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist	-	B
35.57(b)(1)	Amend	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist	B	B
35.57(b)(2)	Amend	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist	B	B
35.57(b)(2)(i)	New	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist	-	B
35.57(b)(2)(ii)	New	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist	-	B

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35.57(b)(2)(iii)	New	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist	-	B
35.57(b)(2)(iv)	New	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist	-	B
35.65(b)	New	Authorization for calibration, transmission, and reference sources	-	D
35.65(b)(1)	New	Authorization for calibration, transmission, and reference sources	-	D
35.65(b)(2)	New	Authorization for calibration, transmission, and reference sources	-	D
35.65(c)	New	Authorization for calibration, transmission, and reference sources	-	D
35.190(a)	Amend	Training for uptake, dilution, and excretion studies	B	B
35.190(c)(2)	Amend	Training for uptake, dilution, and excretion studies	B	B
35.190(c)(2)(i)	New	Training for uptake, dilution, and excretion studies	-	B
35.190(c)(2)(ii)	New	Training for uptake, dilution, and excretion studies	-	B
35.204(b)	Amend	Permissible molybdenum-99, strontium-82, and strontium-85 concentrations	H&S	H&S
35.204(e)	New	Permissible molybdenum-99, strontium-82, and strontium-85 concentrations	-	H&S
35.290(a)	Amend	Training for imaging and localization studies	B	B
35.290(c)(1)(ii)	Amend	Training for imaging and localization studies	B	B
35.290(c)(2)	Amend	Training for imaging and localization studies	B	B
35.290(c)(2)(i)	New	Training for imaging and localization studies	-	B
35.290(c)(2)(ii)	New	Training for imaging and localization studies	-	B
35.300	Amend	Use of unsealed byproduct material for which a written directive is required	B	B
35.390(a)	Amend	Training for use of unsealed byproduct material for which a written directive is required	B	B

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35.390(b)(1)(ii)(G)(3)	Amend	Training for use of unsealed byproduct material for which a written directive is required	B	B
35.390(b)(1)(ii)(G)(4)	New	Training for use of unsealed byproduct material for which a written directive is required	-	B
35.390(b)(1)(ii)(G)(5)	New	Training for use of unsealed byproduct material for which a written directive is required	-	B
35.390(b)(2)	Amend	Training for use of unsealed byproduct material for which a written directive is required	B	B
35.390(b)(2)(i)	New	Training for use of unsealed byproduct material for which a written directive is required	-	B
35.390(b)(2)(ii)	New	Training for use of unsealed byproduct material for which a written directive is required	-	B
35.390(c)	New	Training for use of unsealed byproduct material for which a written directive is required	-	B
35.392(a)	Amend	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)	B	B
35.392(c)(3)	Amend	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)	B	B
35.392(c)(3)(i)	New	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)	-	B
35.392(c)(3)(ii)	New	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)	-	B
35.394(a)	Amend	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	B	B
35.394(c)(3)	Amend	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	B	B

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35.394(c)(3)(i)	New	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	-	B
35.394(c)(3)(ii)	New	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	-	B
35.396(a)	Amend	Training for the parenteral administration of unsealed byproduct material requiring a written directive	B	B
35.396(b)	Amend	Training for the parenteral administration of unsealed byproduct material requiring a written directive	-	B
35.396(c)	Amend	Training for the parenteral administration of unsealed byproduct material requiring a written directive	B	B
35.396(d)(1)	Amend	Training for the parenteral administration of unsealed byproduct material requiring a written directive	B	B
35.396(d)(2)	Amend	Training for the parenteral administration of unsealed byproduct material requiring a written directive	B	B
35.396(d)(2)(iv)	Amend	Training for the parenteral administration of unsealed byproduct material requiring a written directive	B	B
35.396(d)(3)	Amend	Training for the parenteral administration of unsealed byproduct material requiring a written directive	B	B
35.396(d)(3)(i)	New	Training for the parenteral administration of unsealed byproduct material requiring a written directive	-	B
35.396(d)(3)(ii)	New	Training for the parenteral administration of unsealed byproduct material requiring a written directive	-	B
35.400(a)	Amend	Use of sources for manual brachytherapy	C	C
35.400(b)	Amend	Use of sources for manual brachytherapy	C	C
35.433(a)	Amend	Strontium-90 sources for ophthalmic treatments	H&S	B
35.433(b)	New	Strontium-90 sources for ophthalmic treatments	-	H&S
35.433(b)(1)	New	Strontium-90 sources for ophthalmic treatments	-	H&S
35.433(b)(2)	New	Strontium-90 sources for ophthalmic treatments	-	H&S

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35.433(c)	Redesignated	Strontium-90 sources for ophthalmic treatments (Previously 35.433(b))	-	H&S
35.490(a)	Amend	Training for use of manual brachytherapy sources	B	B
35.490(b)(1)(ii)	Amend	Training for use of manual brachytherapy sources	B	B
35.490(b)(3)	Amend	Training for use of manual brachytherapy sources	B	B
35.490(b)(3)(i)	New	Training for use of manual brachytherapy sources	-	B
35.490(b)(3)(ii)	New	Training for use of manual brachytherapy sources	-	B
35.491(b)(3)	Amend	Training for ophthalmic use of strontium-90	B	B
35.500(a)	Amend	Use of sealed sources and medical devices for diagnosis (Previously 35.500)	[C]	C
35.500(b)	New	Use of sealed sources and medical devices for diagnosis	-	C
35.500(c)	New	Use of sealed sources and medical devices for diagnosis	-	C
35.590 (a)	Amend	Training for use of sealed sources for diagnosis	B	B
35.590 (b)	New	Training for use of sealed sources for diagnosis	-	B
35.590 (c)	Redesignated	Training for use of sealed sources for diagnosis (Previously 35.590(b))	B	B
35.590 (d)	Redesignated	Training for use of sealed sources for diagnosis (Previously 35.590(c))	B	B
35.600(a)	Amend	Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit	C	C
35.600(b)	Amend	Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit	C	C
35.610(d)(1)	New	Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	-	H&S
35.610(d)(2)	Amend	Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	H&S	H&S
35.610(g)	Amend	Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	H&S	H&S

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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

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

The NRC staff consults with the ACMUI whenever it identifies an issue with

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implementation of 10 CFR part 35 regulations. Accordingly, issues leading to these amendments have been discussed at ACMUI meetings over the past 10 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 staff to engage the ACMUI in developing the ME definition criterion for permanent implant brachytherapy. Further, the proposals to revise T&E requirements to eliminate preceptor attestation for board-certified individuals, change the language of the attestation, and allow a residency director to provide preceptor attestations were initiated by the ACMUI in its briefing to the Commission held on April 29, 2008 (discussed in detail in Item b, 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 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 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, and provided a final report 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 staff did not accept were discussed in a

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document entitled, “NRC Staff Responses to the ACMUI Comments on the draft Part 35 Proposed Rule,” Enclosure 5, to SECY-13-0084.

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

In October 2015, the NRC provided the preliminary draft final rule to the ACMUI for a 90-day review. (Place holder for a discussion of the draft final rule to the ACMUI and its report.....)

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. 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.

XIII. 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 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 several minor clarifications.

The NRC is not aware of any voluntary consensus standards that address the subject matter of this rule.

XIV. 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).

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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 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 and is discussed in Section XV, 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) increase frequency of measuring Mo-99 tests required in § 35.204, and 2) increase the full inspection time interval for a gamma stereotactic radiosurgery unit from 5 years to 7 years in § 35.655.

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

Place holder for the final Environmental Assessment.

XVI. Paperwork Reduction Act Statement.

This rule contains new or amended information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These requirements were approved

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by the Office of Management and Budget, control number 3150-xxxx. The burden to the public for these information collections is estimated to average _____ hours per response. (Place holder for the OIS clearance)

Send comments on any aspect of these information collections, including suggestions for reducing the burden, to the Records and FOIA/Privacy Services Branch (T-5 F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail to Infocollects.Resource@NRC.gov and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202 (3150-xxxx), Office of Management and Budget, Washington, DC 20503.

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.

XVII. Regulatory Analysis

Placeholder for the final Regulatory Analysis.

XVIII. 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

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indicated in the regulatory analysis available under the “Availability of Documents” section, 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 on this issue.

XIX. 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, backfits, inspection findings). The CER is an organizational effectiveness challenge that results from a licensee or impacted entity implementing a significant number of new and complex regulatory actions stemming from multiple regulatory actions, within a limited implementation period and with available resources (which may include limited available expertise to address a specific issue). The CER can potentially distract licensee or entity staff from executing other primary duties that ensure safety or security. The NRC specifically requested comments on the cumulative effects of this rulemaking in the proposed rule published on July 21, 2014 and asked the public the following questions:

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

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

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would be sufficient)?

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

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

5) Comment on the NRC's cost and benefit estimates in the regulatory analysis that supports this proposed rule.

The NRC received three comments on the CERs. Two Agreement States stated that with steady accretion of regulations, there are always unintended consequences, in that, the additional costs do impact decision 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 the comments received, § 35.40(b)(6)(i) in the final rule does not require for 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.

XX. Backfitting and Issue Finality.

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

XXI. Availability of Guidance.

Published concurrently with this final rule in this issue of the *Federal Register*, the NRC is issuing final 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 rulemaking.

XXII. 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.

DOCUMENT	ADAMS ACCESSION NO.
Staff requirements memorandum for proposed rule (SECY-13-0084)	ML14007A044
SECY-13-0084, “Proposed Rule: Medical Use of Byproduct Material - Medical Event Definitions, Training and Experience, and Clarifying Amendments.”	ML13179A068
Draft Environmental Assessment for the proposed rule	ML14184A621
Draft Regulatory Analysis for the proposed rule.	ML14184A620
Part 35 Proposed Rule Public Meeting, February 10, 2015, (summary)	ML15054A215

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Part 35 Proposed Rule Public Meeting, October 8, 2014 (transcript)	ML15026A317
Draft Implementing Guidance	ML13172A189
preliminary draft proposed rule text	ML111390420
SECY-12-0053, "Recommendations on Regulatory Changes for Permanent Implant Brachytherapy Programs"	ML12072A306
SECY-10-0062, "Reproposed Rule: Medical Use of Byproduct Material – Amendments/Medical Event Definitions," dated May 18, 2010	ML100890121
Commission briefing on "Reproposed Rule: Medical Use of Byproduct Material – Amendments/Medical Event Definitions," July 8, 2010	ML101930532
Staff Requirements Memorandum (SRM) SECY-10-0062, dated August 10, 2010	ML102220233
Public Meeting Summary for Part 35 Medical Workshop, June 20-21, 2011	ML111930470
Transcript of Public Workshop for Discussion of Topics Related to NRC's Medical Regulations, August 11, 2011. Pages 1 240.	ML112900103
Transcript of Public Workshop for Discussion of Topics Related to NRC's Medical Regulations, August 12, 2011. Pages 1 192.	ML112900185
The ACMUI final revised report on permanent implant brachytherapy	ML12038A279
PRM-35-20, petition for rulemaking, filed by E. Russell Ritenour	ML062620129
SECY-05-0234, "Adequacy of Medical Event Definitions in 10 CFR 35.3045, and Communicating Associated Risks to the Public," dated December 27, 2005	ML053180408
SRM-SECY-05-0234, dated February 15, 2006	ML060460594
The ACMUI Permanent Implant Brachytherapy Subcommittee Interim Report, October 20, 2010	ML103540385
The ACMUI Permanent Implant Brachytherapy final report, October 18, 2011	ML11292A139
The American Society for Radiation Oncology (ASTRO) letter to the Chairman of the ACMUI, dated November 30, 2011	ML11341A051

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The ACMUI Permanent Implant Brachytherapy Subcommittee Revised Final Report, February 7, 2012	ML12038A279
ASTRO letter to the Chairman of the ACMUI, dated February 13, 2012	ML12044A358
Commission meeting April 24, 2012, before Commission vote on SECY-12-0053, "Recommendations on Regulatory Changes for Permanent Implant Brachytherapy Programs"	ML12116A294
SRM-SECY-12-0053, "Recommendations on Regulatory Changes for Permanent Implant Brachytherapy Programs"	ML122260211
Commission briefing on April 29, 2008, with the ACMUI	ML12116A294
SRM dated May 15, 2008, Commission briefing April 29, 2008 with the ACMUI	ML081360319
SECY-08-0179, "Recommendations on Amending Preceptor Attestation Requirements in 10 CFR part 35, Medical Use of Byproduct Material"	ML083170176
SRM dated January 16, 2009, to SECY-08-0179	ML090160275
ACMUI meeting June 2007	ML072060526
ACMUI review report to the NRC (early review of the Part 35 proposed rule)	ML13071A690
All Agreement State Letter (FSME-11-044, dated May 20, 2011)	ML111400231
All Agreement State Letter (FSME-14-078, dated August 15, 2014)	ML14226A319
preliminary draft proposed rule FRN to ACMUI	ML13014A487
The ACMUI March 5, 2013 teleconference on the draft proposed rule (conference transcript)	ML13087A474
The ACMUI March 12, 2013 teleconferences on the draft proposed rule (conference transcript)	ML13087A477
The ACMUI report on the draft proposed rule, April 9, 2013	ML13071A690
"NRC Staff Responses to the ACMUI Comments on the draft Part 35 Proposed Rule"	ML13179A073
The ACMUI report on the draft final rule	place holder
Final Environmental Assessment	place holder
Final Regulatory Analysis	place holder
Final Implementing Guidance	place holder

List of Subjects

10 CFR Part 30

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

10 CFR Part 32

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

10 CFR Part 35

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

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is 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 is revised to read as follows:

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

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

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

§ 30.34 Terms and conditions of licenses.

* * * * *

(g) * * * * *The licensee shall report the results of any test that exceeds the permissible concentration listed in § 35.204(a) **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 is revised to read as follows:

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

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

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

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

(a) * * *

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

* * * * *

(b) * * *

(5) * * *

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

* * * * *

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

* * * * *

PART 35 -- MEDICAL USE OF BYPRODUCT MATERIAL

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

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

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

§ 35.2 Definitions.

* * * * *

Associate Radiation Safety Officer means an individual who —

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

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

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

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

* * * * *

Ophthalmic physicist means an individual who meets the requirements in § 35.433(a)(2) and is identified as an ophthalmic physicist on a specific medical use license issued by the

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Commission or an Agreement State or a medical use permit issued by a Commission master material licensee.

* * * * *

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

* * * * *

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

§ 35.12 Application for license, amendment, or renewal.

* * * * *

(b) * * *

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

* * * * *

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

(1) Submitting an original of either—

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

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

(2) Submitting procedures required by §§ 35.610, 35.642, 35.643, and 35.645, as

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applicable.

(d) In addition to the requirements in paragraphs (b) and (c) of this section, an application for a license or amendment for medical use of byproduct material as described in § 35.1000 must also include:

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

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

(3) Any additional specific information on--

(i) Radiation safety precautions and instructions;

(ii) Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

(iii) Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety; and

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

* * * * *

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

§ 35.13 License amendments.

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* * * * *

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

(1) For an authorized user, an individual who meets the requirements in §§ 35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), and 35.690(a);

(2) For an authorized nuclear pharmacist, an individual who meets the requirements in §§ 35.55(a) and 35.59;

(3) For an authorized medical physicist, an individual who meets the requirements in §§ 35.51(a) and 35.59;

(4) An individual who is identified as an authorized user, an authorized nuclear pharmacist, authorized medical physicist, or an ophthalmic physicist—

* * * * *

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

* * * * *

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

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

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

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

§ 35.14 Notifications.

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

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

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

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

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

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

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

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

(2) The licensee permits an individual qualified to be a Radiation Safety Officer under §§ 35.50 and 35.59 to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer in accordance with § 35.24(c);

(3) The licensee's mailing address changes;

(4) The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in § 30.34(b) of this chapter;

(5) The licensee has added to or changed the areas of use identified in the application or on the license where byproduct material is used in accordance with either-

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

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

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

* * * * *

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

§ 35.24 Authority and responsibilities for the radiation protection program.

* * * * *

(b) A licensee's management shall appoint a Radiation Safety Officer who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. The Radiation Safety Officer may delegate duties and tasks but shall not delegate the authority or responsibilities for implementing the radiation protection program. A licensee's management may appoint, in writing, one or more Associate Radiation Safety Officers to support the Radiation Safety Officer. The Radiation Safety Officer, with written agreement of the licensee's management, must assign the specific duties and tasks to each Associate Radiation Safety Officer. ~~The Associate Radiation Safety Officer must agree, in writing, to the list of the specific duties and tasks.~~ These duties and tasks are restricted to the types of use for which the Associate Radiation Safety Officer ~~has radiation safety training~~ **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).

* * * * *

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

§ 35.40 Written directives.

* * * * *

(b) The written directive must contain the patient or human research subject's name and the following information--

(1) For any administration of quantities greater than 1.11 MBq (30 μ Ci) of sodium iodide I-131: the dosage;

(2) For an administration of a therapeutic dosage of unsealed byproduct material other than sodium iodide I-131: the radioactive drug, dosage, and route of administration;

(3) For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;

(4) For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site;

(5) For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose;

(6) For permanent implant brachytherapy:

(i) Before implantation: the treatment site, the radionuclide, ~~the intended absorbed dose to the treatment site and the corresponding calculated total source strength required, and if appropriate, the expected absorbed doses to normal tissues located within the treatment site;~~ **and 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, the signature of an authorized user for § 35.400 uses for manual brachytherapy, and the date; or

(7) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:

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- (i) Before implantation: treatment site, the radionuclide, and dose; and
- (ii) After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, total source strength and exposure time (or the total dose), the signature of an authorized user for § 35.400 uses for manual brachytherapy involving § 35.400 materials, or the signature of an authorized user for low, medium, and pulsed dose rate remote afterloaders under § 35.600 for procedures involving low, medium, and pulsed dose rate remote afterloader brachytherapy, and the date.

(c)(1) A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed byproduct material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

(2) If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.

* * * * *

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

§ 35.41 Procedures for administrations requiring a written directive.

* * * * *

(b) At a minimum, the procedures required by paragraph (a) of this section must address the following items that are applicable to the licensee's use of byproduct material—

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- (1) Verifying the identity of the patient or human research subject;
- (2) Verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;
- (3) Checking both manual and computer-generated dose calculations;
- (4) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by §§ 35.600 or 35.1000;
- (5) Determining if a medical event, as defined in § 35.3045, has occurred; and
- (6) Determining, for permanent implant brachytherapy, within 60 calendar days from the date the implant was performed unless accompanied by a written justification related to patient unavailability, ~~(i)~~ the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive.

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

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

* * * * *

13. Revise § 35.50 to read as follows:

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

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

- (a) Is certified by a specialty board whose certification process has been recognized by

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

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

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

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

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

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

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

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

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(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) 1 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

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decontamination procedures;

(F) Using emergency procedures to control byproduct material;

(G) Disposing of byproduct material; and

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

(c)(1) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State under §35.51(a) and has experience ~~with the in~~ radiation safety ~~aspects of~~ for similar types of use of byproduct material for which the licensee ~~is seeking~~ the approval of the individual as Radiation Safety Officer or an Associate Radiation Safety Officer and who meets the requirements in paragraph (d) of this section; or

(2) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on a Commission or an Agreement State license, a permit issued by a Commission master material licensee, a permit issued by a Commission or an Agreement State licensee of broad scope, or a permit issued by a Commission master material license broad scope permittee and has experience with the radiation safety aspects of similar types of use of byproduct material for which the ~~licensee seeks the approval of the~~ individual ~~has as the~~ Radiation Safety Officer ~~responsibilities~~ or Associate Radiation Safety Officer ~~duties and tasks~~

and who meets the requirements in paragraph (d) of this section; or

(3) Has experience with the radiation safety aspects of the types of use of byproduct material for which the individual is seeking simultaneous approval both as the Radiation Safety Officer and the authorized user on the same new Commission or Agreement State license **or permit issued by a Commission master material license and meets the requirements in paragraph (d) of this section**; and

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

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

§ 35.51 Training for an authorized medical physicist.

* * * * *

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

* * * * *

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(2) * * *

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

* * * * *

(b) * * *

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

* * * * *

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

§ 35.55 Training for an authorized nuclear pharmacist.

* * * * *

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

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To have its certification process recognized, a specialty board shall require all candidates for certification to:

- * * * * *
- (b) * * *

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

16. Revise § 35.57 to read as follows:

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

(a)(1) An individual identified on a Commission or an Agreement State license or a permit issued by a Commission or an Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope as a Radiation Safety Officer, a teletherapy or medical physicist, an authorized medical physicist, a nuclear pharmacist or an authorized nuclear pharmacist on or before October 24, 2005, need not comply with the training requirements of §§ 35.50, 35.51, or 35.55, respectively. After **[INSERT DATE 180 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]**, Radiation Safety Officers and authorized medical physicists identified in this paragraph must meet the training requirements in § 35.50(d) or § 35.51(c), as appropriate, for any material or uses for which they were not authorized prior to this date.

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(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

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materials, at the locations and time period identified in this paragraph, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates, for purposes of this chapter.

(b)(1) Physicians, dentists, or podiatrists identified as authorized users for the medical use of byproduct material on a license issued by the Commission or an Agreement State, a permit issued by a Commission master material licensee, a permit issued by a Commission or an Agreement State broad scope licensee, or a permit issued by a Commission master material license broad scope permittee before ~~October 24, 2005~~ **[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 before October 24, 2005, need not comply with the training requirements of Subparts D through H of this part for those materials and uses that these individuals performed before October 24, 2005, as follows:

(i) For uses authorized under § 35.100 or § 35.200, or oral administration of sodium iodide I-131 requiring a written directive for imaging and localization purposes, a physician who was certified on or before October 24, 2005, in nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology by the American Board of Radiology; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or American Osteopathic Board of

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Nuclear Medicine in nuclear medicine;

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

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

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

(3) Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses performed at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of subparts D through H of this part when performing the same medical uses. A physician, dentist, or podiatrist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses at the locations

and time period identified in this paragraph, qualifies as an authorized user for those materials and uses performed before these dates, for purposes of this chapter.

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

17. Revise § 35.65 to read as follows:

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

(a) Any person authorized by § 35.11 for medical use of byproduct material may receive, possess, and use any of the following byproduct material for check, calibration, transmission, and reference use:

(1) Sealed sources, not exceeding 1.11 GBq (30 mCi) each, manufactured and distributed by a person licensed under § 32.74 of this chapter or equivalent Agreement State regulations;

(2) Sealed sources, not exceeding 1.11 GBq (30 mCi) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under § 32.74 of this chapter or equivalent Agreement State regulations, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions;

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

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

of part 30 of this chapter; or

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

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

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

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

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

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

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

* * * * *

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

* * * * *

(c) * * *

(2) Has obtained written attestation that the individual has satisfactorily completed the

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requirements in paragraph (c)(1) of this section and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under § 35.100.

The attestation must be obtained from either:

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

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

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

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

* * * * *

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

* * * * *

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(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.

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

§ 35.290 Training for imaging and localization studies.

* * * * *

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

* * * * *

(c)(1) * * *

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

* * * * *

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

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and 35.200. The attestation must be obtained from either:

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

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

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

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

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

* * * * *

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

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

required.

* * * * *

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

* * * * *

(b)(1) * * *

(ii) * * *

(G) Administering dosages of radioactive drugs to patients or human research subjects from the four categories in this paragraph. Radioactive drugs in categories not included in this paragraph are regulated under § 35.1000. This work experience must involve a minimum of three cases in each of the following categories for which the individual is requesting authorized user status—

(1) Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131, for which a written directive is required;

(2) Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131²;

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

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

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(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 § 35.390; or

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

* * * * *

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

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

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

* * * * *

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

* * * * *

(c) * * *

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

(i) A preceptor authorized user who meets the requirements in §§ 35.57, 35.390, 35.392, 35.394, or equivalent Agreement State requirements and has experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(1) or 35.390(b)(1)(ii)(G)(2); or (ii) A residency program director who affirms in writing that the attestation represents the consensus

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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 § 35.392.

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

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

* * * * *

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

* * * * *

(c) * * *

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

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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 § 35.394.

25. Revise § 35.396 to read as follows:

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

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

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

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~~administration listed in § 35.390(b)(1)(ii)(G) for which the individual is requesting authorized user status;~~

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

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

(d)(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations listed in §35.390(b)(1)(ii)(G). The training must include—

- (i) Radiation physics and instrumentation;
- (ii) Radiation protection;
- (iii) Mathematics pertaining to the use and measurement of radioactivity;
- (iv) Chemistry of byproduct material for medical use; and
- (v) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.390, 35.396, or equivalent Agreement State requirements, in the parenteral administrations listed in § 35.390(b)(1)(ii)(G). A supervising authorized user who meets the requirements in §§ 35.390, 35.396, or equivalent Agreement State requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status. The work experience must involve—

- (i) Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;
- (ii) Performing quality control procedures on instruments used to determine the activity

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of dosages, and performing checks for proper operation of survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(v) Using procedures to contain spilled byproduct material safely, and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that include at least three cases in each category of the parenteral administrations as specified in § 35.390(b)(1)(ii)(G) for which the individual is requesting authorized user status; and

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

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

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in §§ 35.57, 35.390, 35.396, or equivalent Agreement State requirements, has experience in administering dosages in the same dosage

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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 § 35.396.

26. Revise § 35.400 to read as follows:

§ 35.400 Use of sources for manual brachytherapy.

A licensee must use only brachytherapy sources:

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

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

27. Revise § 35.433 to read as follows:

§ 35.433 Strontium-90 sources for ophthalmic treatments.

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

(1) An authorized medical physicist; or

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

- (i) The creating, modifying, and completing of written directives;
- (ii) Procedures for administrations requiring a written directive; and
- (iii) Performing the calibration measurements of brachytherapy sources as detailed in

§ 35.432.

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

(1) Calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under § 35.432; and

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

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

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

§ 35.490 Training for use of manual brachytherapy sources.

* * * * *

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

* * * * *

(b)(1) * * *

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

* * * * *

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

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

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in §§ 35.57, 35.490, or equivalent Agreement State requirements, and concurs with the attestation provided by the residency program

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director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association and must include training and experience specified in § 35.490.

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

§ 35.491 Training for ophthalmic use of strontium-90.

* * * * *

(b)(1) * * *

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

30. Revise § 35.500 to read as follows:

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

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

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accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

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

(c) Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of § 35.49(a) are met.

31. Revise § 35.590 to read as follows:

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

Except as provided in § 35.57, the licensee shall require the authorized user of a diagnostic sealed source or a device authorized under § 35.500 to be a physician, dentist, or podiatrist who—

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

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

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State requirements; or

(c) Has completed 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include—

- (1) Radiation physics and instrumentation;
 - (2) Radiation protection;
 - (3) Mathematics pertaining to the use and measurement of radioactivity; and
 - (4) Radiation biology; and
- (d) Has completed training in the use of the device for the uses requested.

32. Revise § 35.600 to read as follows:

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

(a) A licensee must only use sealed sources:

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

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

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

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

(2) In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of § 35.49(a) are met.

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

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

* * * * *

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

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

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

(a) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during each source replacement to assure proper functioning of the source exposure mechanism and other safety components. The interval between each full-inspection servicing shall not exceed 5 years for each teletherapy unit and shall not exceed 7 years for each gamma stereotactic radiosurgery unit.

* * * * *

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

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

* * * * *

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (c) of this section. (The names of board certifications that have been recognized by

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the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

* * * * *

(b)(1) * * *

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

* * * * *

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (b)(2), and paragraph (c), of this section, is able to independently fulfill the radiation safety-related duties as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The attestation must be obtained from either:

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

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

Osteopathic Association and must include training and experience specified in § 35.690;

* * * * *

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

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

* * * * *

(c) For each Associate Radiation Safety Officer appointed under § 35.24(b), the licensee shall retain, for 5 years after the Associate Radiation Safety Officer is removed from the license, a copy of ~~(1)~~ the written document appointing the Associate Radiation Safety Officer signed by the licensee's management. ~~;~~ ~~and~~

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

37. Revise § 35.2310 to read as follows:

§ 35.2310 Records of safety instruction.

A licensee shall maintain a record of safety instructions required by §§ 35.310, 35.410, and the operational and safety instructions required by § 35.610 for 3 years. The record must include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

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

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

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

* * * * *

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

§ 35.3045 Report and notification of a medical event.

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

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

(i) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and

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

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

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

(ii) A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following—

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(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

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

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

(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) directly delivered to the wrong treatment site **implanted directly into a location where the radiation from the source(s) will not contribute dose to the treatment site, as defined in 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.

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

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

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

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(a) The licensee shall notify by telephone the NRC Operations Center and the manufacturer/distributor of the generator within ~~30-7~~ 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, whether the manufacturer/distributor was notified: and the action taken.

(b) By an appropriate method listed in § 30.6(a) of this chapter, the licensee shall submit a written report to the appropriate NRC Regional Office listed in § 30.6 of this chapter within ~~45-~~ **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 probable cause and assessment of failure in the licensee's equipment, procedures or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination, and the information in the telephone report as required by paragraph (a) of this section.

Dated at Rockville, Maryland, this day of 2016.

For the Nuclear Regulatory Commission.

Annette Vietti Cook,
Secretary of the Commission.

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