[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30, 32 and 35

RIN: 3150-AI63

[NRC-2008-0175]

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

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The U. S. Nuclear Regulatory Commission (NRC or the Commission) is proposing to amend its medical use regulations related to medical event (ME) definitions for permanent implant brachytherapy; training and experience (T&E) requirements for authorized users (AU), medical physicists, Radiation Safety Officers (RSO), and nuclear pharmacists; consideration of Ritenour Petition (PRM-35-20) to "grandfather" certain experienced individuals for T&E requirements; measuring molybdenum contamination for each elution and reporting of failed breakthrough tests; allowing Associate Radiation Safety Officers (ARSO) to be named on a medical license; and several minor clarifications.

DATES: Submit comments by **[INSERT DATE 90 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]**. Submit comments specific to the information collections aspects of this proposed rule by **[INSERT DATE 30 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]**. Comments received after these dates will be considered if it is practical to do so, but the NRC is able to assure consideration only for comments received on or before these dates.

ADDRESSES: You may access information and comment submissions related to this proposed rule, which the NRC possesses and are publicly available, by searching on http://www.regulations.gov under Docket ID NRC-2008-0175. You may submit comments by any one of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- **Federal rulemaking Web site:** Go to http://www.regulations.gov and search for Docket ID NRC-2008-0175. Address questions about NRC dockets to Carol Gallagher, telephone 301-492-3668, e-mail Carol.Gallager@nrc.gov.
- **E-mail comments to***:* Rulemaking.Comments@nrc.gov. If you do not receive an automatic e-mail reply confirming receipt, then contact us directly at 301-415-1677.
- **Fax comments to***:* Secretary, U.S. Nuclear Regulatory Commission at 301-415-1101.
- **Mail comments to:** Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.
- **Hand deliver comments to:** 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. (Eastern Time) Federal workdays; telephone: 301-415-1677.

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

FOR FURTHER INFORMATION CONTACT: Neelam Bhalla, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone: 301-415-6843, e-mail: neelam.bhalla@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Accessing Information and Submitting Comments

A. Accessing Information

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

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

- **NRC's Agencywide Documents Access and Management System (ADAMS):**

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

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

B. Submitting Comments

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

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

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

II. Background

The NRC published a final rule in the *Federal Register* on April 24, 2002 (67 FR 20250), that revised the medical use regulations in 10 CFR part 35 in their entirety. The T&E requirements in 10 CFR part 35 were further revised through an additional rulemaking published in the *Federal Register* on March 30, 2005 (70 FR 16336).

In implementing the current regulations in 10 CFR part 35, the NRC staff, stakeholders, and the Advisory Committee on the Medical Uses of Isotopes (ACMUI) have identified numerous issues that need to be addressed through the rulemaking process. As a result, the NRC is proposing to amend its regulations in part 35 to address these issues. The proposed amendments include: revising the preceptor attestation requirements, allowing ARSOs to be named on a medical use license, requiring increased frequency of testing for measuring molybdenum-99 (Mo-99) concentration in a Mo-99/technetium-99m (Tc-99m) generator, requiring 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 rubidium-82 (Rb-82) generator, extending the 5-year inspection frequency for a gamma stereotactic radiosurgery unit to 7 years, and several clarifying amendments.

In addition, the proposed rule would address issues that were raised in a petition for rulemaking (PRM) (PRM-35-20, ADAMS Accession No. ML062620129) filed by E. Russell Ritenour, Ph.D., on behalf of the American Association of Physicists in Medicine (AAPM) 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. This issue is discussed in greater detail in Section III, Petition for Rulemaking PRM-35-20, of this document.

Finally, the proposed rule would modify the written directive (WD) requirements in 10 CFR 35.40 and the ME reporting in 10 CFR 35.3045 to establish separate ME reporting criteria for permanent implant brachytherapy.

Currently, the ME criteria for brachytherapy implants in 10 CFR 35.3045, “Report and Notification of a Medical Event,” are based on the dose administered to the patient. The proposed amendment would establish separate ME criteria for permanent implant

brachytherapy in terms of the total source strength administered (activity-based) rather than the dose delivered (dose-based). The ME criteria would also include absorbed doses to normal tissues located outside of the treatment site and within the treatment site. The proposed amendments are based on the staff recommendations contained in SECY-12-0053 "Recommendations on Regulatory Changes for Permanent Implant Brachytherapy Programs," (ADAMS Accession No. ML12072A306).

NRC previously published a proposed rule 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, "Reproposed Rule: Medical Use of Byproduct Material – Amendments/Definitions," dated May 18, 2010, (ADAMS Accession No. ML100890086) the staff requested the Commission to publish 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 Society, the National Director of the Radiation Oncology Program, 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, (ADAMS Accession No. ML102220233) 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 SRM also directed the staff to hold a series of stakeholder workshops to discuss issues associated with the ME definitions.

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 NRC. The staff used the recommendations in the ACMUI revised final report, along with the substantial input from stakeholders to develop the recommendations in SECY-12-0053 which provided the regulatory basis for the ME definitions in this proposed rule.

III. Petition for Rulemaking PRM-35-20

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

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

pharmacist, and authorized nuclear pharmacist,'' be revised to recognize: 1) 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) all diplomates certified by the named boards in former 10 CFR Subpart J, which was removed from 10 CFR part 35 in a rulemaking dated March 30, 2005 (70 FR 16336), for RSOs who have relevant timely work experience even if they have not been formally named as an RSO. The petitioner believed that these individuals should be grandfathered as RSOs by virtue of certification providing the appropriate preceptor statement is submitted. The NRC received 168 comments from professional organizations and individuals on the petition. The majority of the commenters supported the petition.

The NRC reviewed the petitioner's request and comments received on the petition and concluded (73 FR 27773, May 14, 2008) 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). 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 presently recognized by the NRC and to certifying boards previously named in the former 10 CFR part 35 Subpart J whose certification processes are not presently recognized by the NRC. The staff 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, and 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 Agreement State medical use license. It is these individuals who might be negatively impacted by the T&E grandfathering provisions of the current medical use rule. 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.

This proposed rule, in response to the petition, would amend § 35.57 to recognize all individuals that were previously certified by boards recognized under the previous 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 staff believes that these individuals should be eligible for grandfathering for the modalities that they practiced as of October 24, 2005 and that their previously-acceptable qualifications for authorized status should continue to be adequate and acceptable from a health and safety standpoint such as to allow them to continue to practice using the same modalities.

The petitioner, in its support for “grandfathering” the RSOs who have relevant work experience and were not formally named on NRC or Agreement State licenses or permits as an RSO, stated that these individuals will be required to provide preceptor attestations. In this proposed rulemaking, the NRC is eliminating the requirement for preceptor attestations for all individuals certified by NRC recognized boards. The NRC believes that attestations are not necessary in this particular situation because the provisions of § 35.59, Recentness of training, require that the T&E must have been obtained within the 7 years preceding the date of application, or the individual must have had related continuing education and experience since the required T&E was completed. The “grandfathered” individuals would fall under the provisions of § 35.59 and would need to provide evidence of continuation of education and experience. Therefore, staff believes that preceptor attestations are not warranted for these

"grandfathered" individuals so long as the provisions of § 35.59 are met and the individual requests authorizations only for the modalities the individual practiced as of October 24, 2005.

IV. Discussion

A. What Action is the NRC 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 proposed revisions would clarify the current regulations, and provide greater flexibility to licensees without compromising patient, worker, and public health and safety. The proposed amendments include:

a. Adding separate ME definitions for permanent implant brachytherapy.

b. Amending preceptor attestation requirements.

c. Extending grandfathering to certain certified individuals (Ritenour petition) discussed in Section III, Petition for Rulemaking (PRM-35-20), of this document.

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

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

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

g. Additional issues and clarifications which are discussed in Section V, Discussion of Proposed Amendments by Section, of this document.

Early public input on this proposed rule was solicited through various mechanisms. For certain non-complex amendments the NRC posted preliminary draft rule text (ADAMS Accession No. ML111390420) on the website, regulations.gov, for comment for 75 days. The availability of the draft rule language was noticed in the *Federal Register* on May 21, 2011 (76 FR 29171). The NRC received 10 comment letters which are also posted on the

regulations.gov website under Docket I.D. NRC-2008-0175. The NRC staff reviewed the comments and considered them in developing the proposed rule text.

The proposed amendments and preliminary draft rule text were also discussed at the two transcribed facilitated public workshops that were conducted in New York City, New York, on June 20-21, 2011, (ADAMS Accession No. ML111930470) and in Houston, Texas, on August 11-12, 2011, (ADAMS Accession No. ML112900094). The purpose of the workshops was to solicit key stakeholder input on topics associated with definition of an ME including the requirements for reporting and notifications of MEs for permanent implant brachytherapy, and on other medical issues that are being considered in the proposed rulemaking. These workshops were initiated as a result of the Commission's direction to staff in SRM-SECY-10-0062 to work closely with the ACMUI and the medical community to develop event definitions that would protect the interests of patients. The Commission also directed that these definitions should allow physicians the flexibility to take actions that they deem medically necessary, while preserving the NRC's ability to detect misapplications of radioactive material and failures in process, procedure and training. The panelists for the workshops included representation from the ACMUI, Agreement States, professional societies, and a patients' rights advocate.

The major proposed revisions are:

a. Adding separate ME definitions for permanent implant brachytherapy.

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

During its meeting in March 2004, the ACMUI recognized the existing inadequacy of defining MEs with regard to permanent implant brachytherapy. The ACMUI expressed that for these implants, the ± 20 percent variance from the prescription criterion in the existing rule was

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

In SECY-05-0234, "Adequacy of Definitions in 10 CFR 35.3045, and Communicating Associated Risks to the Public," dated December 27, 2005, (ADAMS Accession No. ML041620583) based on recommendations received from the ACMUI, the staff recommended that for permanent implant brachytherapy, the Commission approve the staff's plan to revise the ME definitions and the associated requirements for WDs to be activity-based, instead of dose-based. In SRM-SECY-05-0234, dated February 15, 2006, (ADAMS Accession No. ML060460594) the Commission directed the staff to proceed directly with the development of a proposed rule to modify both the WD requirements in 10 CFR 35.40(b)(6) and the ME reporting requirements in 10 CFR 35.3045 for permanent implant brachytherapy medical use, to convert from dose-based to activity-based ME criteria.

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

The ACMUI Permanent Implant Brachytherapy Subcommittee (PIBS) issued a report, with recommendations, which was unanimously approved by the ACMUI at its October 20, 2010 meeting (ADAMS Accession No. ML103540385). The PIBS report included the caveat that it was to be considered as an interim report that might be revised in the future in response to

additional input, such as that expected to be received from stakeholders at the then-upcoming public workshops. The ACMUI meeting, in April 2011, was devoted to issues associated with the ME definition and was webcast, providing an opportunity for public involvement in this issue.

The ACMUI final report, which revised the earlier interim report, on prostate brachytherapy regulation was provided to the NRC following the ACMUI October 18, 2011, teleconference public meeting (ADAMS Accession No. ML11292A139). The final report reflected the principal positions expressed and recommendations provided by participants during the NRC public workshops, noted earlier, in particular, 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, by letter to the Chairman of the ACMUI dated November 30, 2011 (ADAMS Accession No. ML11341A051), the American Society for Radiation Oncology (ASTRO) expressed criticism of the ACMUI final report. ASTRO considered the ME definition recommended by the ACMUI to be complex, difficult to regulate, and likely to cause confusion in practice. Consequently, a revised final report (ADAMS Accession No. ML12038A279) that simplified the ME criteria for the treatment site, removed the "octant approach" and direct reference to absorbed dose, was issued by the PIBS. The revised final report was, with minor modification, approved by the ACMUI during its February 7, 2012 teleconference public meeting and was subsequently, in a letter to the Chairman of the ACMUI (ADAMS Accession No. ML12044A358), characterized by ASTRO as an improvement.

The staff used the recommendations in the ACMUI revised final report, along with the substantial input from stakeholders gathered in the two facilitated public workshops and the

three ACMUI public meetings in 2011 and early 2012 to develop the recommendations conveyed to the Commission on April 6, 2012 in SECY-12-0053. In a Commission meeting held April 24, 2012, (ADAMS Accession No. ML121116A294) participating representatives from the ACMUI, from ASTRO, and from the American Brachytherapy Society (ABS) endorsed the recommendations for modification of the requirements in 10 CFR 35.40 and 35.3045 that are contained in SECY-12-0053.

The endorsement from the ACMUI representative was unconditional. However, the endorsements from the ASTRO and ABS representatives came with the suggestion that one of the criteria for ME reporting, dealing with excessive dose to normal tissue structures within the treatment site, be eliminated. The NRC decided to retain this ACMUI-recommended ME reporting criterion for normal tissue structures located within the treatment site because there needs to be some form of ME reporting criterion for overdosing of normal tissue structures located within the treatment site.

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

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

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

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

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

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

The proposed rule specifies that these dose determinations must be made within 60 days from the date the treatment was administered unless accompanied by written justification about patient unavailability. NRC believes that 60 days provides adequate time to make implanted source location and dose assessments to determine if a ME has occurred. The AAPM, in its Task Group Report 137, entitled, “AAPM recommendations on dose prescription and reporting methods for permanent interstitial brachytherapy for prostate cancer,” recommends that post-implant dosimetry for iodine-125 implants should be performed at 1

month (plus or minus 1 week) after the procedure. For palladium-103 and cesium-131 implants, it recommends that post-implant dosimetry be performed at 16 (plus or minus 4) days and 10 (plus or minus 2) days, respectively. The 60 day time limit is also consistent with the ACMUI recommendation. The NRC recognizes that some patients may not be able to come back for the dose assessment, and the proposed rule addresses that concern by adding "unless accompanied by written justification about patient unavailability."

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

3) A ME has occurred if a treatment involves: a) Using the wrong radionuclide; b) Delivery to the wrong patient or human research subject; c) Source(s) implanted directly into the wrong site or body part, i.e., into other (distant from the treatment site) locations; d) Using leaking sources, or e), A 20 percent or more error in calculating the total source strength documented in the pre-implantation WD (+/- 20% is used for the ME threshold for source strength variance because +/- 10% is considered too close to the actual variance associated with this quantity in clinically acceptable implant procedures).

Note that the criterion related to sources implanted directly into the wrong site or body part, i.e., into other (distant from the treatment site) locations results in the occurrence of a ME. This criterion directly reflects an ACMUI recommendation. Although the current regulation has a 0.5 sievert (50 rem) organ/tissue dose threshold for ME declaration, the localized dose associated with even one misplaced source far exceeds the 0.5 Sievert (50 rem) dose threshold. Therefore, the recommended regulation is not more restrictive than the current regulation.

The current WD requirements for manual brachytherapy in § 35.40(b)(6) primarily reflect requirements associated with temporary implant brachytherapy medical use. The WD

requirements in § 35.40 would be amended to establish separate WD requirements appropriate for permanent implant brachytherapy. The WD for permanent implant brachytherapy would consist of two portions: the first portion of the WD would be prepared before the implantation, and the second portion of the WD would be completed after the procedure, but before the patient leaves the post procedure recovery area. For permanent implant brachytherapy, the WD portion prepared before the implantation would require documentation of the treatment site, the radionuclide, the intended absorbed dose to the treatment site and the corresponding calculated source strength to deliver that dose. If the treatment site has normal tissues located within it, the WD would also require documentation of the expected absorbed dose to any 5 contiguous cubic centimeter of normal tissue as determined by the AU. The post-implantation portion of the WD would require the documentation of the number of sources implanted, the total source strength implanted, the signature of an AU for § 35.400 uses for manual brachytherapy, and the date. It would not require the documentation of dose to the treatment site.

Through the ACMUI and the information gained at the workshops, NRC understands that these implants must allow final WD documentation based on the medical situation encountered during the surgical procedure. Therefore, in defining a ME involving the treatment site, the criterion is based on the percentage of implanted sources documented in the post-implantation portion of the WD that are outside of the treatment site, and not based on a comparison of the implanted total source strength to the calculated total source strength documented in the pre-implantation portion of the WD. This proposed definition differs from the ME definition for all other brachytherapy where the dose comparisons are made with what was prescribed in the WD prepared/revised before the procedure.

Conforming changes would be made to § 35.41 “Procedures for administrations requiring a written directive” to include permanent implant brachytherapy. Currently, in this

section, there is no requirement that a licensee determine that an administered dose or dosage has met a ME criterion defined in § 35.3045. The ME reporting criteria are defined in § 35.3045, but the current regulations do not require that a licensee have procedures to make that determination. This section would be amended to require that a licensee include procedures for determining if a ME has occurred. For permanent implant brachytherapy, this section would also be amended to require that a licensee develop additional procedures to include an evaluation of the placement of sources as documented in the completion portion of the WD, dose assessments to normal tissues located near and within the treatment site, and procedures that these assessments be made within 60 days from the date the treatment was performed.

b. Amending preceptor attestation requirements.

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

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

During a briefing held on April 29, 2008, with the Commission, the ACMUI recommended that the attestation requirements be revised. The ACMUI expressed concern that the existing requirements have had unintended consequences that if not corrected would impact the

availability of authorized individuals; i.e., there was likely to be a shortage of authorized individuals to provide medical care as a result of the reluctance of authorized individuals to sign preceptor 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. A board certification indicates that the T&E requirements have been met, and the Maintenance of Certification provides ongoing evidence of current knowledge. Therefore, the ACMUI argued that an additional attestation for the board certified individuals was superfluous.

The ACMUI also recommended that the attestation requirements associated with the alternate pathways be modified to delete the requirement for an attestation of an individual's radiation safety-related-competency being sufficient to function independently as an authorized person for the medical uses being requested. The reason for the recommendation was 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 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 status. The ACMUI advised that training of residents is a collective process and entails the collective judgment of an entire residency program faculty. Whereas preceptor attestation is an individual process, and an individual preceptor typically would provide only a small portion of the T&E.

Following the April 29, 2008, meeting, in a Staff Requirements Memorandum (SRM) dated May 15, 2008, entitled "Meeting with Advisory Committee on the Medical Uses of

Isotopes (ACMUI), 1:30 p.m., Tuesday April 29, 2008," (ADAMS Accession No. ML081360319) the Commission directed the staff to work with the ACMUI and the Agreement States to provide recommendations to the Commission with regard to amending the NRC's requirements for preceptor attestation for both board certified individuals and for individuals seeking authorization via the alternate pathway. The staff was also directed to consider additional methods, such as the attestation being provided by consensus of an authoritative group.

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

In an SRM dated January 16, 2009, to SECY-08-0179, (ADAMS Accession No. ML090160275), the Commission approved these recommendations and directed the staff to

develop the proposed rule language for the attestation requirements for the alternate pathway in concert with the ACMUI and the Agreement States.

The proposed changes to remove the attestations requirement for board certified individuals were broadly supported during the public workshops conducted in the summer of 2011. The panelists (which included members of the ACMUI and the Agreement States) at the workshops recommended that the NRC should remove the requirement for attestation for board certified individuals. They believed that board certification coupled with the recentness of training requirement 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 in order to fulfill the radiation safety-related duties required by the licensee. The proposed rule language reflects this approach.

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

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

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

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

Currently, § 35.24(b) requires a licensee's management to appoint an RSO, who agrees in writing to be responsible for implementing the radiation protection program. However, the

regulations in 10 CFR part 35 do not allow the naming of more than one permanent RSO on a license.

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

The proposed rule would amend the regulations in 10 CFR part 35 to allow licensees to appoint qualified individuals with expertise in certain uses of byproduct material to serve as ARSOs. These individuals would be required to complete the same T&E requirements as the named RSO for their assigned sections of the radiation safety program. The ARSOs would be responsible for overseeing the radiation safety operations of their assigned sections, while reporting to the named RSO. The regulations would continue to allow a licensee to name only one RSO on a license, who would continue to be the individual responsible for the day-to-day oversight of the entire radiation safety program. Similarly, licensees with multiple operating locations could appoint a qualified ARSO at each location of byproduct material use; however the named RSO would remain responsible for the overall licensed program. Under the proposed rule, the ARSOs would be named on the license for the types of use of byproduct material for which these individuals have been assigned duties and tasks by the RSO.

The NRC believes that allowing ARSOs to be named on a license would increase the number of individuals who would be available to serve as preceptors for individuals seeking to be appointed as RSOs or ARSOs. Also, by being named on a license, ARSOs could more easily become RSOs on other licenses for the types of uses for which they qualify.

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

The proposed change to allow ARSOs 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 ARSO must meet the same qualifications as the RSO for their assigned sections of the radiation safety program.

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

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

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

is eluted.

Mo-99 break-through measurements which exceed the permissible concentration listed in § 35.204(a) may cause unnecessary radiation exposures to patients. The administration of higher levels of molybdenum-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. Prior to 2002, § 35.204 required the licensees to measure the Mo-99 concentration of each eluate. However, the NRC had revised § 35.204 in April 2002, because the medical and pharmaceutical community considered frequency of molybdenum 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.

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

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

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

exceeded the permissible concentration listed in § 35.204(a) on numerous occasions in 2006, 2007, and 2008. Additionally, in 2011, contamination issues with Sr-82/Rb-82 generators were discovered when several individuals were identified with unexpected levels of Sr-82 and Sr-85. These individuals had received 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 and Sr-82 and Sr-85 contamination can lead to unnecessary radiation exposure to patients.

The NRC proposes to add two new reporting requirements related to breakthrough of Mo-99 and Sr-82 and Sr-85 contamination. One reporting requirement in § 35.3204(a) would require licensees to report to the NRC and the manufacturers or distributers of medical generators any measurement that exceeds the limits specified in § 35.204(a) within 24 hours. The second requirement in § 30.50 would require manufacturers/distributors to report to the NRC when they receive such a notification from a licensee.

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

reported failures. The NRC believes that requiring each incident of a failed generator to be reported would provide the NRC the opportunity to evaluate and take prompt action as needed. Additionally, some incidents of failed generators may not be reported to the FDA because certain manufacturers are not in the United States, and the generators are distributed by venders who are not required to report to the FDA. This new reporting requirement is being proposed to allow the NRC to assess potential situations in a timely manner so that appropriate action may be taken to avoid unwarranted radiation exposure to patients.

B. When Do These Actions become Effective?

Generally, NRC allows an adequate time (30 to 180 days) for a final rule to become effective. The time for the final rule to become effective depends on the scope of the rulemaking, availability of the conforming guidance, and the complexity of the final rule. With regard to this proposed rule, the NRC proposes that the final rule would become effective 120 days from its publication in the *Federal Register*.

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

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

rulemaking. In developing comments on CER, consider the following questions:

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

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

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

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

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

D. What are the Issues the NRC is seeking Specific Comments On?

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

Currently § 35.3045, Report and notification of a medical event, is designated as Compatibility Category C for the Agreement States. This designation means the essential objectives of the requirement should be adopted by the State to avoid conflicts, duplications, or gaps. The manner in which the essential objectives are addressed in the Agreement State requirements need not be the same as NRC, provided the essential objectives are met. Under

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

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

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

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

If the level of compatibility for § 35.3045 were to be raised to Category B, Agreement State requirements would need to be essentially identical to those of the NRC. Category B compatibility is applied to requirements that have significant direct trans-boundary health and safety implications. This designation would require that the Agreement State requirements could not include any additional requirements, such as diagnostic reports, shorter reporting times, or lower dose limits for reporting.

Because of these divergent positions (the OAS favoring Compatibility Category C and some medical use licensees favoring Compatibility Category B), the NRC invites comments on the appropriate compatibility category for ME reporting under § 35.3045. In responding to this issue, please use one of the methods described in Section I, Accessing Information and Submitting Comments, of this document.

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

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

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

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

The NRC is seeking specific comments on the proposed volume of 5 cubic centimeters contiguous dose-volume specification for an absorbed dose to normal tissue located both outside and within the treatment site in defining MEs. In responding to this issue, please use one of the methods described in Section I, Accessing Information and Submitting Comments, of

this document.

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

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

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

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

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

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

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

vi. Explain your views as clearly as possible.

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

viii. The NRC is particularly interested in your comments concerning the following issues; Section IV of this document contains a request for comment on the Agreement Compatibility designations for the proposed rule and a request for comment on the volume for determining an absorbed dose to normal tissue for MEs; Section X contains a request for comments on the use of plain language; Section XIV contains a request for comments on the environmental assessment; Section XV contains a request for comments on the information collection requirements; Section XVI contains a request for comments on the draft regulatory analysis; and Section XVII contains a request for comments on the impact of the proposed rule on small businesses.

V. Discussion of Proposed Amendments by Section

Section 30.34 Terms and conditions of licenses.

Paragraph (g). A new requirement would be added requiring licensees to report to the NRC the results of generator eluations for Mo-99 breakthrough or Sr-82 and Sr-85 contamination that exceeds the permissible concentration listed in § 35.204(a). Reporting would be in accordance with the reporting and notifications in § 35.3204. While the proposed reporting requirement is new, the requirement for licensees to test eluates to ensure that they do not exceed the permissible concentration listed in § 35.204(a) and record the results of these tests are already required by this paragraph

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

Section 30.50 Reporting requirements.

Paragraph (b)(5). This new paragraph would be added to require manufacturers or distributers of medical generators to notify the NRC within 24 hours of receipt of a notification required by § 35.3204(a). Section 35.3204(a) requires licensees to notify the manufacturers or distributor of the generator when an eluate from a generator exceeds the permissible concentration listed in § 35.204(a). Further discussion of reporting of failed generators is found in Section IV, Discussion, of this document.

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

Paragraph (a)(4). This paragraph would be modified to clarify that applicants commit to following the label requirements rather than satisfying the label requirements.

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

Paragraph (d). This new paragraph would be added to clarify that the labeling requirements that applicants commit to in paragraph (a) of this section are also applicable to current licensees.

Section 35.2 Definitions.

A new definition for *Associate Radiation Safety Officer* would be added to this section. This new definition would identify the requirements an individual would need to meet in order to be recognized and listed as an ARSO on a medical license or permit. In order to qualify as an ARSO, an individual would have to be currently identified 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 definition for *Preceptor* would be amended to add ARSO to the list of individuals who provide, direct, or verify T&E required for an individual to become an AU, an AMP, an ANP, or a RSO. This is a conforming change in support of the new definition for *Associate Radiation Safety Officer.*

Section 35.12 Application for license, amendment, or renewal.

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

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

Paragraph (c)(1). For license amendments or renewals, this paragraph would be amended to remove the requirement to submit a copy of the NRC Form 313 or a letter containing information required by the NRC Form 313. This change would relieve the burden on the licensee by requiring less paperwork to be submitted. Additionally, it would clarify that the letter submitted in lieu of the NRC Form 313 must contain all the information required by the NRC Form 313.

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

Section 35.13 License amendments.

This section would be amended to include two new paragraphs and current paragraphs (d) through (g) would be redesignated.

Paragraph (d). This new paragraph would be added to require a licensee to apply for

and receive a license amendment prior to permitting an individual to work as an ARSO or before the RSO assigns different tasks and duties to an ARSO currently authorized on the license.

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

Section 35.14 Notifications.

Paragraph (b)(1). This paragraph would be amended to require a licensee to notify the Commission no later than 30 days after an ARSO or an individual identified in § 35.433(a)(2) discontinues performance of duties under the license or has a name change.

Paragraph (b)(2). An administrative change is being made to this paragraph to remove the phrase “an authorized user or” as it is a redundancy of “an individual qualified to be a Radiation Safety Officer under 35.50 and 35.59” in the same sentence.

Paragraph (b)(6). This new paragraph would be added to allow a licensee to notify the NRC if it receives certain sealed sources without first obtaining a license amendment. Specifically, a licensee would have to notify the NRC no later than 30 days after receiving a sealed source listed in the SSDR for manual brachytherapy with quantities and isotopes already authorized by the license but from a different manufacturer or with a different model number.

Section 35.24 Authority and responsibilities of the radiation protection program.

This section is being amended to allow licensees to appoint qualified individuals with

expertise in certain uses of byproduct material to be named as ARSOs on a license or permit.

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

The licensee's management would still be limited to naming one RSO who would remain responsible for implementing the entire radiation protection program. The RSO would be prohibited from delegating authority and responsibilities for implementing the radiation protection program. Each ARSO would have to agree in writing to the tasks and duties assigned by the RSO.

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

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

Section 35.40 Written Directives.

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

Paragraph (b)(6). This new paragraph would detail the specific WD requirements for permanent implant brachytherapy. Specifically, it would clarify that the WD is divided into two portions; i.e., the pre-implantation portion and the post-implantation portion. The pre-implantation WD portion would require documentation of the treatment site, the radionuclide, the

intended absorbed dose to the treatment site, and the corresponding calculated source strength to deliver that dose. If the treatment site has normal tissues located within it, the WD would also allow documentation of the expected absorbed dose to normal tissue as determined by the AU. The information required by the pre-implantation portion of the WD must be documented prior to the start of the implantation and cannot be modified once the implantation begins. The proposed rule would retain the current provision that an AU could revise an existing WD in writing or orally before the implantation begins.

The post-implantation portion of the WD would require the documentation of the number of sources implanted, the total source strength implanted, the signature of an AU for § 35.400 uses for manual brachytherapy, and the date. It would not require the documentation of dose to the treatment site. The information required by the post-implantation portion of the WD must be documented before the patient leaves the post-treatment recovery area. The term "post-treatment recovery area," as used in paragraph (b)(6)(ii) is intended to mean 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 out-patient treatment, released from the licensee's facility.

Section 35.41 Procedures for administrations requiring a written directive.

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

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

Paragraph (b)(6). This new paragraph would require the licensee to develop specific procedures for permanent implant brachytherapy programs. At a minimum, the procedures would include determining post implant source position verification and normal tissue dose assessment within 60 calendar days from the date the implant was performed. If the licensee cannot make these determinations within the 60 calendar days because of the patient not being available, then the licensee would have to provide written justification that these determinations could not be made due to patient unavailability.

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

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

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

Section 35.50 Training for Radiation Safety Officer.

Multiple changes to this section are proposed. They include amending the title of the section to add "and Associate Radiation Safety Officer" as the T&E requirements for this new position would also be made applicable to the ARSO. Other changes proposed are: 1) removing the requirement to obtain a written attestation for individuals qualified under paragraph (a) of this section; 2) adding a provision that would allow individuals identified as an AU, AMP, or ANP, on a medical license to be an RSO or an ASRSO on a different medical license; 3) adding a provision to allow an individual to be named both as the RSO and AU on a new license application; and 4) certain administrative clarifications.

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

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

Paragraph (b)(2). A paragraph would be inserted (paragraph (b)(2) is currently reserved) that would contain the requirements for an RSO or ARSO under the alternate pathway to obtain a written attestation signed by either an RSO or ARSO. The requirement now would be only applicable to RSOs or ARSOs using the alternate pathway. The language that is

required in the written attestation would be amended to state that the individual "is able to independently fulfill the radiation safety-related duties as an RSO or ARSO," rather than that the individual "has achieved a level of radiation safety knowledge to function independently" as an RSO or ARSO.

Paragraph (c)(1). This paragraph would be modified to allow medical physicists who have been certified by a specialty board whose process has been recognized by the Commission or Agreement State under § 35.51(a) to be named as ARSOs. Additionally, the requirement for a written attestation for these medical physicists is removed. Medical physicists seeking to be named as RSO's or ARSOs would still need to meet the training requirements in paragraph (d) of this section.

Paragraph (c)(2). This paragraph would be modified to allow AUs, AMPs, and ANPs identified on a Commission or Agreement State medical license or permit to be an RSO or ARSO on any Commission or 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 RSO only on the license they are listed on.

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

Paragraph (c)(3). This new paragraph would allow an individual who is not named as an AU on a medical license or permit but is qualified to be an AU to be named simultaneously as the RSO and the AU on the same new medical license. Current regulations, under

§ 35.50(c)(2), allow an AU on a medical license or permit to be named as the RSO for the same byproduct material for which the AU is authorized. An individual may meet the qualifications of an AU via the board certification or alternate pathway and must have the experience with the radiation safety aspects of the byproduct material for which the license is sought.

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

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

Section 35.51 Training for an authorized medical physicist.

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

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

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

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

Section 35.55 Training for an authorized nuclear pharmacist.

Paragraph (a). The requirement for individuals seeking to be named as an ANP to obtain a written attestation would be removed for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or Agreement State. Individuals seeking to be named as an ANP via the certification pathway would still need to meet the training requirements in paragraph (c) of this section.

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

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

Multiple changes to this section are proposed. Most of the proposed changes are to the T& E requirements in response to the requested amendments in the Ritenour petition. This includes recognizing the board certifications of individuals certified by boards recognized under

Subpart J, which was removed from 10 CFR part 35 in a rulemaking dated March 30, 2005 (70 FR 16336), and making administrative clarifications. Additional information on the Ritenour petition as it relates to this rulemaking is located in Section IV, Discussion, of this document.

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

However, under the proposed rule, RSOs and AMPs identified by this paragraph would have to meet the training requirements in §§ 35.50(e) or 35.51(c) as appropriate, for any new material or new medical use. This is not a new training requirement. Current regulations require individuals qualifying under §§ 35.50 and 35.51 as RSOs and AMPs to meet the training requirements in § 35.50(e) and § 35.51(c). Individuals excepted by this paragraph would still need to meet the recentness of training requirements in § 35.59.

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

Paragraph (a)(3). This paragraph would recognize individuals certified by the named boards in the now removed subpart J of 10 CFR part 35 on or before October 24, 2005, who would not need to comply with the training requirements of § 35.51 to be identified as a AMP on a Commission or Agreement State license or Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005. Removal of subpart J from 10 CFR part 35 was effective on October 24, 2005. Training requirements excepted under this paragraph would be limited to those materials and uses these individuals performed on or before October, 24, 2005. Individuals excepted by this paragraph would still need to meet the recentness of training requirements in § 35.59 and for new materials and uses, the training requirements in § 35.51(c).

Paragraph (a)(4). This paragraph would renumber from current paragraph (a)(3) and has not been revised.

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

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

Paragraph (b)(2). This paragraph would be restructured and expanded to recognize physicians, dentists, or podiatrists who were certified by the named boards in the now removed subpart J of 10 CFR part 35 on or before October 24, 2005, who would not need to comply with the training requirements of subparts D through H of this part to be identified as an AU on a Commission or 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. Individuals excepted from the T&E requirements by this paragraph would still need to meet the recentness of training requirements in § 35.59.

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

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

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

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

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). The requirement for physicians seeking to be named as an AU of unsealed byproduct material for uses authorized under § 35.100 to obtain a written attestation would be removed for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or Agreement State. Further discussion on removing the written attestation requirement can be found in Section IV, Discussion, of this document.

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

The residency program directors who provide written attestations do not have to be AUs who meet the requirements in §§ 35.57, 35.190, 35.290, or 35.390, 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, 35.190, 35.290, or 35.390, or equivalent Agreement State requirements and that the AU concurs with the attestation.

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

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

Paragraph (b). The current requirement to measure the Mo-99 concentration after the first eluate would be changed to require that the Mo-99 concentration be measured in each eluate. A generator can be eluted several times to obtain Tc-99m for formulating radiopharmaceuticals for human use. Current regulations require licensees to measure the Mo-99 concentration only the first time a generator is eluted.

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

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

Section 35.290 Training for imaging and localization studies.

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

Paragraph (c)(1)(ii). This paragraph would be amended to allow an ANP who meets the requirements in §§ 35.55 or 35.57 to provide the supervised work experience specified in paragraph (c)(1)(ii)(G) of this section for individuals seeking to be named as an AU of unsealed byproduct material for uses authorized under § 35.200. Paragraph (c)(1)(ii)(G) of this section

covers eluting generator systems. Many medical facilities no longer elute generators and receive unit doses from centralized pharmacies, therefore, training on eluting generators is not available at these facilities. ANPs have the T&E to provide the supervised work experience for AUs on the elution of generators.

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

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

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

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

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

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

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

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

radionuclides that are primarily used for their alpha radiation characteristics.

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

Current regulations require that 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. This requirement would be retained in the proposed rule with regard to all categories in this paragraph.

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

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

categories as the physicians requesting AU status and that the AU concurs with the attestation.

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

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

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

The residency program directors who provide written attestations do not have to be AUs

who meet the requirements in §§ 35.57, 35.390, 35.392, 35.394, or equivalent Agreement State requirements or have experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(1) or 35.390(b)(1)(ii)(G)(*2*). However, they must affirm in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an AU who meets the requirements in §§ 35.57, 35.390, 35.392, 35.394, or equivalent Agreement State requirements and has experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(1) or 35.390(b)(1)(ii)(G)(*2*) and that the AU concurs with the attestation.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 35.400 Use of sources for manual brachytherapy.

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

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

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

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

Paragraph (a). This paragraph would be amended and expanded to allow certain

individuals who are not AMPs to calculate the activity of strontium-90 sources that is used to determine the treatment times for ophthalmic treatments. These individuals who are not AMPs would have to meet the T&E requirements detailed in the new paragraph (a)(2) of this section in order to perform the specified activities. These requirements are similar to the T&E requirements for an AMP but include only the requirements related to brachytherapy programs.

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

Paragraph (b). This new paragraph would establish the tasks that individuals qualified in paragraph (a) of this section would be required to perform in supporting ophthalmic treatments with strontium-90. The first task is based upon the requirements in § 35.432 for calculating the activity of each strontium-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 are included in this proposed rule to ensure the safe use of strontium-90 for ophthalmic treatments. Both the AMP and the individuals identified under paragraph (a)(2) of this section would be required to assist the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the dose administration is in accordance with the WD. Under this paragraph, the licensee would have to modify their procedures required under § 35.41 to include the frequencies that the AMP and/or the individual identified under paragraph (a)(2) of this section would observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the treatment was administered in

accordance with the WD.

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

Section 35.490 Training for use of manual brachytherapy sources.

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

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

Paragraph (c)(3). This paragraph would be restructured and expanded to allow certain residency program directors to provide written attestations for physicians seeking to be named as an AU of a manual brachytherapy source for the uses authorized under § 35.400. The residency program directors must represent a residency training program approved by the

Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association. The residency training program must include T&E specified in § 35.400.

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

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

Section 35.491 Training for ophthalmic use of strontium-90.

Paragraph (b)(3). This paragraph would be amended to incorporate the new language that the written attestation would verify that the physician is able to independently fulfill the radiation safety-related duties, rather than has achieved a level of competency to function independently, as an AU.

Section 35.500 Use of sealed sources for diagnosis.

The section would be restructured and expanded to include the use of medical devices, to allow sealed sources and medical devices that are listed in the SSDR for diagnostic medical uses to be used for diagnostic medical uses that are not explicitly listed in the SSDR, and to

allow sealed sources and medical devices to be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA. The section title would be modified to add "and medical devices" as the use of medical devices is added to this section.

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

Paragraph (b). This paragraph would be added to allow diagnostic devices containing sealed sources 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 apply to include storage, handling, sterilization, conditions of use, and leak testing of radiation sources.

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

Section 35.590 Training for use of sealed sources for diagnosis.

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

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

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

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

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

Paragraph (b). This paragraph would continue to require that licensees only use photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units approved in the SSDR or in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of § 35.49(a) are

met. However, this paragraph would be amended to provide that these units may be used for medical uses that are not explicitly provided for in the SSDR, provided that these units are used in accordance with the radiation safety conditions and limitations described in the SSDR.

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

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

Currently, § 35.610 (d) requires that individuals who operate these units be provided safety instructions initially, and at least annually; however, there is no requirement for these individuals to receive instructions when the unit is upgraded. In addition, the proposed amendment would require individuals who operate these units to receive training prior to first use for patient treatment of the new or upgraded unit.

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

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

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

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

Paragraph (a). This paragraph would be amended to change the requirement for fully inspecting and servicing intervals for gamma stereotactic radiosurgery units from not to exceed 5 years to not to exceed 7 years. The inspecting and servicing of teletherapy units intervals would remain the same (not to exceed 5 years). Additionally, the paragraph would require that the full inspection and servicing of these units would be required during each source replacement regardless of the last time the units were inspected and serviced.

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

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

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

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

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

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 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 for which the individual is requesting AU status and that the AU concurs with the attestation.

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

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

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

Section 35.2310 Records of safety instruction.

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

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

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

Section 35.3045 Report and notification of a medical event.

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

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

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

Paragraph (a)(2). This new paragraph would be added to establish separate criteria for reporting MEs involving permanent implant brachytherapy. These new criteria are designed to identify 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 this criterion would identify would be if the sealed sources, which were implanted, had a different source strength than what was intended. This could occur from ordering, or a vendor shipping, sealed sources with the wrong radiation 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 this criterion would identify would be if sealed sources are unintentionally implanted outside of the treatment site. This would be identified by the licensee when determinations related to § 35.41 of this part are made;

3) An absorbed dose to the maximally exposed 5 contiguous cubic centimeters of normal tissue located outside of the treatment site that exceeds by 150 percent or more the absorbed dose prescribed to the treatment site by an AU in the pre-implantation portion of the

WD. The ACMUI recommended that for this criterion the absorbed dose to normal tissue should be measured in a volume large enough such that small fluctuations, such as a single source out of place, would not result in a ME. The 5 contiguous cubic centimeters proposed is the largest volume related to organ at risk toxicity in the literature.

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

4) An absorbed dose to the maximally exposed 5 contiguous cubic centimeters of normal tissue located within the treatment site that exceeds by 150 percent or more the absorbed dose to that tissue based on the pre-implantation dose distribution approved by an AU. The ACMUI recommended with regard to this criterion that the absorbed dose to normal tissue should be measured in a volume large enough such that small fluctuations, such as a single source out of place, would not result in a ME. The 5 contiguous cubic centimeters proposed is the largest volume related to organ at risk toxicity in the literature.

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

5) An administration that includes the wrong radionuclide; the wrong individual or human research subject; sealed sources directly delivered to the wrong treatment site; a leaking sealed source; or a 20 percent or more error in calculating the total source strength documented

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

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

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

Paragraph (a). This new section would require a licensee to notify both the NRC Operations Center and the manufacturer/distributer of the generator by telephone no later than the next calendar day after discovery that an eluate exceeds the permissible concentration listed in § 35.204(a). This notification would include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects, whether the manufacturer/distributor was notified, and the action taken.

Paragraph (b). This new section would require licensees to submit a written report to the appropriate NRC Regional Office listed in § 30.6 within 15 days after discovery of an eluate exceeding the permissible concentration. The report would have to be submitted by an appropriate method listed in § 30.6(a). The report would include the action taken by the licensee, patient dose assessments, and the methodology used in making the patient dose

assessment if the eluate was administered to patients or human research subjects, and the information in the telephone report as required by paragraph (a) of this section.

VI. Criminal Penalties

For the purpose of Section 223 of the Atomic Energy Act (AEA), the Commission is proposing to amend 10 CFR Part 30, 32, and 35 under one or more of Sections 161b, 161i, or 161o of the AEA. Willful violations of the rule would be subject to criminal enforcement.

VII. Coordination with NRC Agreement States

The Agreement States were involved throughout the rulemaking process. Agreement State representatives served on the Working Group that developed the proposed amendments to 10 CFR part 35 and on the Steering Committee.

Through an All Agreement State Letter (FSME-11-044, dated May 20, 2011) Agreement States were notified of the availability of preliminary rule text for comments posted at the Federal Rulemaking Website at www.regulations.gov and noticed in the Federal Register (76 FR 29171, May 20, 2011). The FRN also invited the Agreement States to participate at the two public workshops that were held in New York City, New York, and Houston, Texas during the summer of 2011. Finally, in preparing the proposed amendments, the rulemaking working group considered the comments provided by the Agreement States.

VIII. Agreement State Compatibility

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" approved by the Commission on June 30, 1997, and published in the Federal Register (62 FR 46517; September 3, 1997), this proposed rule would be a matter of compatibility between the NRC and the Agreement States, thereby providing consistency among the Agreement States and the NRC requirements. The NRC staff analyzed the proposed rule in accordance with the procedure established within Part III, "Categorization Process for NRC Program Elements," of Handbook 5.9 to Management Directive 5.9, "Adequacy and Compatibility of Agreement State Programs" (a copy of which may be viewed at http://www.nrc.gov/reading-rm/doc-collections/management-directives/).

The NRC program elements (including regulations) are placed into four compatibility categories (See the Draft Compatibility Table for Proposed Rule in this section). In addition, the NRC program elements can also be identified as having particular health and safety significance or as being reserved solely to the NRC. 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 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 nationwide basis. An Agreement State should adopt the essential objectives of the Category C program elements. Compatibility

Category D are those program elements that do not meet any of the criteria of Category A, B, or C, and, thus, do not need to be adopted by Agreement States for purposes of compatibility.

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

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

Draft Compatibility Table for Proposed Rule

Section	Change	Subject	Compatibility	
			Existing	New
Part 30				
30.34(g)	Amend	Terms and conditions of licenses	B	B
30.50(b)(5)	New	Reporting requirements	-	C
Part 32				
32.72(a)(4)	Amend	Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under 10 CFR part 35	B	B
32.72(b)(5)(i)	Amend	Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under 10 CFR part 35	B	B
32.72(d)	New	Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under 10 CFR part 35	-	B
Part 35				
35.2	New	Definitions – Associate Radiation Safety Officer	-	B
35.12(b)(1)	Amend	Application for license, amendment, or renewal	D	D
35.12(c)(1)	Amend	Application for license, amendment, or renewal	D	D
35.12(c)(1)(ii)	Amend	Application for license, amendment, or renewal	D	D
35.12(d)	Amend	Application for license, amendment, or renewal	D	D
35.12(d)(1)	New	Application for license, amendment, or renewal	-	D
35.12(d)(2)	New	Application for license, amendment, or renewal	-	D
35.12(d)(3)	New	Application for license, amendment, or renewal	-	D
35.12(d)(4)	Amend	Application for license, amendment, or renewal	D	D
35.13(d)	New	License amendments	-	D
35.13(i)	New	License amendments	-	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 program	H&S	H&S
35.24(c)	Amend	Authority and responsibilities for the radiation program	D	D
35.40(b)(6)	Amend	Written Directive	H&S	H&S
35.41(b)(5)	New	Procedures for administrations requiring a written directive.	-	H&S

Section	Change	Subject	Compatibility	
			Existing	New
35.41(b)(6)	New	Procedures for administrations requiring a written directive.	-	H&S
35.50	Amend	Training for Radiation Safety Officer and Associate Radiation Safety Officer	B	B
35.50(a)	Amend	Training for Radiation Safety Officer and Associate Radiation Safety Officer	B	B
35.50(a)(2)(ii)(B)	Amend	Training for Radiation Safety Officer and Associate Radiation Safety Officer	B	B
35.50(b)(1)(ii)	Amend	Training for Radiation Safety Officer and Associate Radiation Safety Officer	B	B
35.50(b)(2)	New	Training for Radiation Safety Officer and Associate Radiation Safety Officer	-	B
35.50(c)(1)	Amend	Training for Radiation Safety Officer and Associate Radiation Safety Officer	B	B
35.50(c)(2)	Amend	Training for Radiation Safety Officer and Associate Radiation Safety Officer	B	B
35.50(c)(3)	New	Training for Radiation Safety Officer and Associate Radiation Safety Officer	-	B
35.50(d)	Amend	Training for Radiation Safety Officer and Associate Radiation Safety Officer	B	B
35.51(a)	Amend	Training for an authorized medical physicist	B	B
35.51(a)(2)(i)	Amend	Training for an authorized medical physicist	B	B
35.51(b)(2)	Amend	Training for an authorized medical physicist	B	B
35.55(a)	Amend	Training for an authorized nuclear pharmacist	B	B
35.55(b)(2)	Amend	Training for an authorized nuclear pharmacist	B	B
35.57(a)(1)	Amend	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist and authorized nuclear pharmacist	B	B
35.57(a)(2)	New	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist and authorized nuclear pharmacist	-	B
35.57(a)(3)	New	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist and authorized nuclear pharmacist	-	B
35.57(b)(1)	Amend	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist and authorized nuclear pharmacist	B	B

Section	Change	Subject	Compatibility	
			Existing	New
35.57(b)(2)	Amend	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist and authorized nuclear pharmacist	B	B
35.57(b)(2)(i)	New	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist and authorized nuclear pharmacist	-	B
35.57(b)(2)(ii)	New	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist and authorized nuclear pharmacist	-	B
35.57(b)(2)(iii)	New	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist and authorized nuclear pharmacist	-	B
35.57(b)(2)(iv)	New	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist and authorized nuclear pharmacist	-	B
35.65(b)	New	Authorization for calibration, transmission, and reference sources	-	D
35.65(b)(1)	New	Authorization for calibration, transmission, and reference sources	-	D
35.65(b)(2)	New	Authorization for calibration, transmission, and reference sources	-	D
35.65(c)	New	Authorization for calibration, transmission, and reference sources	-	D
35.190(a)	Amend	Training for uptake, dilution, and excretion studies	B	B
35.190(c)(2)	Amend	Training for uptake, dilution, and excretion studies	B	B
35.190(c)(2)(i)	New	Training for uptake, dilution, and excretion studies	-	B
35.190(c)(2)(ii)	New	Training for uptake, dilution, and excretion studies	-	B
35.204(b)	Amend	Permissible molybdenum-99, strontium-82, and strontium-85 concentrations	H&S	H&S
35.204(e)	New	Permissible molybdenum-99, strontium-82, and strontium-85 concentrations	-	H&S
35.290(a)	Amend	Training for imaging and localization studies	B	B
35.290(c)(1)(ii)	Amend	Training for imaging and localization studies	B	B
35.290(c)(2)	Amend	Training for imaging and localization studies	B	B

Section	Change	Subject	Compatibility	
			Existing	New
35.290(c)(2)(i)	New	Training for imaging and localization studies	-	B
35.290(c)(2)(ii)	New	Training for imaging and localization studies	-	B
35.300	Amend	Use of unsealed byproduct material for which a written directive is required	B	B
35.390(a)	Amend	Training for use of unsealed byproduct material for which a written directive is required	B	B
35.390(b)(1)(ii)(G)(*3*)	Amend	Training for use of unsealed byproduct material for which a written directive is required	B	B
35.390(b)(1)(ii)(G)(*4*)	New	Training for use of unsealed byproduct material for which a written directive is required	-	B
35.390(b)(1)(ii)(G)(*5*)	New	Training for use of unsealed byproduct material for which a written directive is required	-	B
35.390(b)(2)	Amend	Training for use of unsealed byproduct material for which a written directive is required	B	B
35.390(b)(2)(i)	New	Training for use of unsealed byproduct material for which a written directive is required	-	B
35.390(b)(2)(ii)	New	Training for use of unsealed byproduct material for which a written directive is required	-	B
35.390(c)	New	Training for use of unsealed byproduct material for which a written directive is required	-	B
35.392(a)	Amend	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)	B	B
35.392(c)(3)	Amend	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)	B	B
35.392(c)(3)(i)	New	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)	-	B
35.392(c)(3)(ii)	New	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)	-	B
35.394(a)	Amend	Training for the oral administration of sodium iodide I–131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	B	B

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

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

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

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

The NRC staff consults with the ACMUI whenever it identifies any issues with implementation of the current 10 CFR part 35 regulations. As such, all the proposed amendments have been discussed at the ACMUI meetings spanning over the past nine years. The ACMUI meetings are transcribed. Full transcripts of the ACMUI meetings can be found on the NRC's public website:http://www.nrc.gov/reading-rm/doc-collections/acmui/tr. In addition, in SRM-SECY-10-0062, the Commission specifically directed the staff to engage the ACMUI in developing the ME definition criterion for permanent implant brachytherapy. Further, the proposals to revise T&E requirements to eliminate preceptor attestation for board certified individuals, change the language of the attestation, and allow a residency director to provide preceptor attestations were initiated by the ACMUI in its briefing to the Commission held on April 29, 2008 (discussed in detail in item b in Section IV, Discussion, of this document. Similarly, the issue of naming more than one RSO was initiated by the ACMUI at the June, 2007

ACMUI meeting (discussed in detail in item d in Section IV, Discussion, of this document. Finally, the entire ACMUI meeting held on April 20-21, 2011, was devoted to discussion of the rulemaking issues addressed in this proposed rule, so that the staff would be better able to understand ACMUI's position and views on the issues raised.

(Placeholder for ACMUI's review…..)

X. Plain Language

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

XI. Consistency with Medical Policy Statement

The proposed amendments to 10 CFR part 35 are consistent with the Commission's Medical Use Policy Statement published August 3, 2000 (65 FR 47654). The proposed rule is consistent with this statement because it balances the interests of patients, the flexibility for AUs to take actions that they deem are medically necessary, and continues to enable the agency to detect failures in process, procedures, and training as well as any misapplication of byproduct materials.

XII. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995 (Pub. L. 104-113) requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this proposed rule, the NRC would amend its medical use regulations related to ME definitions for permanent implant brachytherapy; T&E requirements for AUs, medical physicists, RSOs, and nuclear pharmacists; consideration of the Ritenour Petition (PRM-35-20) to "grandfather" certain experienced individuals; measuring molybdenum contamination for each elution and reporting of failed breakthrough tests; naming ARSOs on a medical license; and several minor clarifications.

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

XIII. Environmental Impact: Categorical Exclusion

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

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

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

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

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

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

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

XIV. Finding of No Significant Environmental Impact: Availability

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in subpart A of 10 CFR part 51, not to prepare an environmental impact statement for this proposed rule because the Commission has concluded on the basis of an environmental assessment that this proposed rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment. The amendments would relax certain requirements and eliminate other procedural restrictions associated with the medical use of byproduct material. The Commission believes these amendments would provide greater flexibility in the medical use of byproduct material while continuing to adequately protect public health and safety. It is expected that this rule, if adopted, would not cause any significant increase in radiation exposure to the public or radiation release

to the environment beyond the exposures or releases currently resulting from the medical use of byproduct material.

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

The NRC has sent a copy of the Environmental Assessment and this proposed rule to every State Liaison Officer and requested their comments on the Environmental Assessment. The Environmental Assessment is available in ADAMS under Accession No. MLXXXXXXXX (to be added) and may be examined at the NRC's Public Document Room (PDR), O-1F21, 11555 Rockville Pike, Rockville, MD 20852.

XV. Paperwork Reduction Act Statement

This proposed 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 by the Office of Management and Budget (OMB), approval numbers 3150-0010 and 3150-0120. (to be sent to OMB for clearance)

Public Protection Notification

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

XVI. Regulatory Analysis

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

The Commission requests public comment on the draft regulatory analysis. The draft regulatory analysis is available in ADAMS under Accession No. MLXXXXXXXX (to be added) and available for inspection in the NRC's PDR, 11555 Rockville Pike, Rockville, MD 20852.

XVII. Regulatory Flexibility Certification

(This section will be revised after the Regulatory Analysis is completed). In accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this rule would not, if promulgated, have a significant economic impact on a substantial number of small entities. The majority of the licensees do not fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act or the size standards established by the NRC (10 CFR 2.810). The NRC is seeking public comment on the potential impact of the proposed rule on small entities. The NRC particularly desires comment from licensees who qualify as small businesses, specifically as to how the proposed regulation will affect them and how the regulation may be tiered or otherwise modified to impose less stringent requirements on small entities while still adequately protecting the public health and safety and common defense and security. Comments on how the regulation could be modified to take into account the differing needs of small entities should specifically discuss–

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

b) How the proposed regulation could be further modified to take into account the

business's differing needs or capabilities;

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

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

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

XVIII. Backfit Analysis

The NRC has determined that the backfit rule, which is found in the regulations at §§ 50.109, 70.76, 72.62, 76.76, and in 10 CFR part 52, does not apply to this proposed rule because this amendment would not involve any provisions that would impose backfits as defined in 10 CFR chapter I. Therefore, a backfit analysis is not required.

List of Subjects

10 CFR Part 30

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

10 CFR Part 32

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

10 CFR Part 35

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

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974; and 5 U.S.C. 553, the NRC is proposing to adopt the following amendments to 10 CFR parts 30, 32, and 35.

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

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

Authority: Atomic Energy Act secs. 81, 82, 161, 181, 182, 183, 186, 223, 234 (42 U.S.C. 2111, 2112, 2201, 2231, 2232, 2233, 2236, 2273, 2282); Energy Reorganization Act secs. 201, 202, 206 (42 U.S.C. 5841, 5842, 5846); Government Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note); Energy Policy Act of 2005, Pub. L. No. 109-58, 119 Stat. 549 (2005).

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

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

§ 30.34 Terms and conditions of licenses.

* * * * *

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

* * * * *

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

§ 30.50 Reporting requirements.

* * * * *

(b) * * *

(5) For manufacturers or distributers of medical generators, receipt of a notification required by § 35.3204(a).

* * * * *

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

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

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

5. In § 32.72, revise paragraphs (a)(4) and (b)(5)(i), redesignate paragraph (d) as

paragraph (e), and add a new paragraph (d) to read as follows:

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

(a) * * *

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

* * * * *

(b) * * *

(5) Shall provide to the Commission:

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

* * * * *

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

* * * * *

PART 35—MEDICAL USE OF BYPRODUCT MATERIAL

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

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

7. In § 35.2, modify the definition for *Preceptor*, and add, in alphabetical order, the definition for *Associate Radiation Safety Officer* 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 Agreement State; or

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

* * * * *

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

* * * * *

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

§ 35.12 Application for license, amendment, or renewal.

* * * * *

(b) * * *

(1) Filing an original NRC Form 313, “Application for Material License,” that includes the facility diagram, equipment, and training and experience qualifications of the Radiation Safety

Officer, Associate Radiation Safety Officer(s), authorized user(s), authorized medical physicist(s), and authorized nuclear pharmacist(s); and

* * * * *

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

(1) Submitting an original of either—

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

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

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

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

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

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

(3) Any additional specific information on--

(i) Radiation safety precautions and instructions;

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

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

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

* * * * *

9. In § 35.13, redesignate paragraphs (d), (e), (f), and (g) as paragraphs (e), (f), (g), and (h), respectively, revise newly redesignated paragraphs (g) and (h), and add new paragraphs (d) and (i) to read as follows:

§ 35.13 License amendments.

* * * * *

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

* * * * *

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

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

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

10. In § 35.14, revise paragraph (b) to read as follows:

§ 35.14 Notifications.

* * * * *

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

(1) An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer, an Associate Radiation Safety Officer, an authorized medical physicist, or an individual identified in § 35.433(a)(2) permanently discontinues performance of duties under the license or has a name change;

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

(3) The licensee's mailing address changes;

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

(5) The licensee has added to or changed the areas of use identified in the application or on the license where byproduct material is used in accordance with either § 35.100 or § 35.200 if the change does not include addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide/PET radioactive drug production area; or

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

* * * * *

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

§ 35.24 Authority and responsibilities for the radiation protection program.

* * * * *

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

(c) For up to 60 days each year, a licensee may permit an individual qualified to be a Radiation Safety Officer, under §§ 35.50 and 35.59, to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in paragraph (g) of this section, if the licensee takes the actions required in paragraphs (b), (e), (g), and (h) of this section and notifies the Commission in accordance with § 35.14(b).

* * * * *

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

§ 35.40 Written directives.

* * * * *

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

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

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

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

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

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

(6) For permanent implant brachytherapy:

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

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

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

(i) Before implantation: treatment site, the radionuclide, and dose; and

(ii) After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).

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

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

* * * * *

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

§ 35.41 Procedures for administrations requiring a written directive.

* * * * *

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

(1) Verifying the identity of the patient or human research subject;

(2) Verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;

(3) Checking both manual and computer-generated dose calculations;

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

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

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

unavailability:

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

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

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

* * * * *

14. Revise § 35.50 to read as follows:

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

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

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

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

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

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

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

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

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

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

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

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

(i) 200 hours of classroom and laboratory training in the following areas-

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Radiation biology; and

(E) Radiation dosimetry; and

(ii) One year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on a Commission or 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 Agreement State license or permit issued by a Commission master material licensee. The full-time radiation safety experience must involve the following—

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

(C) Securing and controlling byproduct material;

(D) Using administrative controls to avoid mistakes in the administration of byproduct material;

(E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

(F) Using emergency procedures to control byproduct material;

(G) Disposing of byproduct material; and

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

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

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

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

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

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

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

§ 35.51 Training for an authorized medical physicist.

* * * * *

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

* * * * *

(2) * * *

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

* * * * *

(b) * * *

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

* * * * *

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

§ 35.55 Training for an authorized nuclear pharmacist.

* * * * *

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

* * * * *

(b) * * *

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

17. Revise § 35.57 to read as follows:

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

(a)(1) An individual identified on a Commission or Agreement State license or a permit issued by a Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope as a Radiation Safety Officer, a teletherapy or medical physicist, an authorized medical physicist, a nuclear pharmacist or an authorized nuclear pharmacist on or before October 24, 2005, need not comply with the training requirements of §§ 35.50, 35.51, or 35.55, respectively. After **[DATE THAT IS 90 DAYS AFTER THE DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**, Radiation Safety Officers and authorized medical physicists identified in this paragraph must meet the training

requirements in § 35.50(d) or § 35.51(c), as appropriate, for any new material or new medical use.

(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 on a Commission or Agreement State license or Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005.

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

(4) A Radiation Safety Officer, a medical physicist, or a nuclear pharmacist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses or in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of § 35.50, § 35.51 or § 35.55, respectively, when performing the same uses. A nuclear pharmacist, who prepared only radioactive drugs containing accelerator-produced

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

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

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

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

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

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

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

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

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

18. Revise § 35.65 to read as follows:

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

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

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

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

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

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

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

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

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

requirements in § 35.500; or

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

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

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

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

* * * * *

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

* * * * *

(c) * * *

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

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

(ii) A residency program director who affirms in writing that the attestation represents

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

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

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

* * * * *

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

* * * * *

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

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

§ 35.290 Training for imaging and localization studies.

* * * * *

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State. (The names of board certifications

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

* * * * *

(c)(1) * * *

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

* * * * *

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

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

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

experience specified in § 35.290.

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

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

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

* * * * *

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

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

* * * * *

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

* * * * *

(b)(1) * * *

(ii) * * *

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

status—

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

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

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

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

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

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

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

Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association and must include training and experience specified in § 35.390; or

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

* * * * *

[2] Experience with at least 3 cases in Category (G)(*2*) also satisfies the requirement in Category (G)(*1*).

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

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

* * * * *

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

* * * * *

(c) * * *

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section, and is able to independently fulfill

the radiation safety-related duties as an authorized user for oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under § 35.300. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in §§ 35.57, 35.390, 35.392, 35.394, or equivalent Agreement State requirements and has experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(*1*) or 35.390(b)(1)(ii)(G)(*2*); or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in §§ 35.57, 35.390, 35.392, 35.394, or equivalent Agreement State requirements 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 concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association and must include training and experience specified in § 35.392.

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

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

* * * * *

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

Web page.); or

* * * * *

(c) * * *

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

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

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

26. Revise § 35.396 to read as follows:

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

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

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

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

(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.

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

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of byproduct material for medical use; and

(v) Radiation biology; and

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

requesting authorized user status. The work experience must involve—

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

(ii) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

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

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

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

(vi) Administering dosages to patients or human research subjects, that include at least 3 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 paragraphs (c) or (d), and paragraphs (e)(1) and (e)(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 and has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association and must include training and experience specified in § 35.396.

27. Revise § 35.400 to read as follows:

§ 35.400 Use of sources for manual brachytherapy.

A licensee must use only brachytherapy sources:

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

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

28. Revise § 35.433 to read as follows:

§ 35.433 Strontium-90 sources for ophthalmic treatments.

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

(1) An authorized medical physicist; or

(2) An individual who holds a master's or doctor's degree in physics, medical physics, other physical sciences, engineering, or applied mathematics from an accredited college or university and 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;

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

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

29. In § 35.490, revise the introductory text of paragraphs (a) and (b)(1)(ii), and

paragraph (b)(3) to read as follows:

§ 35.490 Training for use of manual brachytherapy sources.

* * * * *

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

(b)(1) * * *

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

* * * * *

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

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

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

Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association and must include training and experience specified in § 35.490.

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

§ 35.491 Training for ophthalmic use of strontium-90.

* * * * *

(b) * * *

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

31. Revise § 35.500 to read as follows:

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

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

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

Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

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

32. Revise § 35.590 to read as follows:

§ 35.590 Training for use of sealed sources for diagnosis.

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

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

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

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

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity; and

(4) Radiation biology; and

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

33. Revise § 35.600 to read as follows:

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

(a) A licensee must only use sealed sources:

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

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

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

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

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

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

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

* * * * *

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

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

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

(ii) The operating procedures for the unit.

* * * * *

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

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

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

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

* * * * *

36. In § 35.690, revise the introductory text of paragraphs (a) and (b)(1)(ii), and

paragraph (b)(3) to read as follows:

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

* * * * *

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

* * * * *

(b)(1) * * *

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

* * * * *

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

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

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an

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

* * * * *

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

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

* * * * *

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

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

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

38. Revise § 35.2310 to read as follows:

§ 35.2310 Records of safety instruction.

A licensee shall maintain a record of safety instructions required by §§ 35.310, 35.410, and the operational and safety instructions required by § 35.610 for 3 years. The record must

include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

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

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

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

* * * * *

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

§ 35.3045 Report and notification of a medical event.

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

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

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

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

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

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

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

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

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

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

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

(E) A leaking sealed source.

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

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

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

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

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

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

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

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

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

(A) The wrong radionuclide;

(B) The wrong individual or human research subject;

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

(D) A leaking sealed source; or

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

* * * * *

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

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

(a) The licensee shall notify by telephone the NRC Operations Center and the manufacturer/distributor of the generator no later than the next calendar day after discovery that an eluate exceeded the permissible concentration listed in § 35.204(a). The telephone report to the NRC must include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages

were administered to patients or human research subjects, whether the manufacturer/distributor was notified, and the action taken.

(b) By an appropriate method listed in § 30.6(a) of this chapter, the licensee shall submit a written report to the appropriate NRC Regional Office listed in § 30.6 of this chapter within 15 days after discovery of an eluate exceeding the permissible concentration. The written report must include the action taken by the licensee, patient dose assessment, and the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects, and the information in the telephone report as required by paragraph (a) of this section.

Dated at Rockville, Maryland, this_____day of_____, 2013.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,
Secretary of the Commission.