RULEMAKING ISSUE

Affirmation

June 17, 2016 SECY16-0080

FOR: The Commissioners

FROM: Victor M. McCree
Executive Director for Operations

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

PURPOSE:

To request Commission approval to publish a final rule in the *Federal Register* that will amend Parts 30, 32, and 35 of Title 10 of the *Code of Federal Regulations* (10 CFR).

SUMMARY:

The final rule will amend the U.S. Nuclear Regulatory Commission (NRC) regulations related to the medical use of byproduct material. This rule amends the medical event (ME)[1] definition for reporting and notification requirements for permanent implant brachytherapy. This rule also amends the training and experience (T&E) requirements to (1) remove the requirement to obtain a written attestation for an individual who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State in multiple sections; and (2) address a request filed in a petition for rulemaking (PRM), PRM-35-20, to exempt certain board-certified individuals from certain T&E requirements (i.e., "grandfather" these individuals). Additionally, this rule (1) amends the requirements for measuring molybdenum contamination; (2) adds a new requirement for the reporting of failed technetium and rubidium generators; and (3) allows licensees to name associate radiation safety officers (ARSOs) on a medical license.

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[1] The terms ME criteria, ME reporting criteria, and ME definitions are used interchangeably throughout this paper.

BACKGROUND:

In the Staff Requirements Memorandum (SRM) for SECY-13-0084, "Proposed Rule: Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments (RIN 3150-AI63)," dated January 6, 2014 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML14007A044), the Commission approved publication of the proposed rule. On July 21, 2014, the NRC published the proposed rule (79 FR 42410) for a 120-day comment period that ended on November 18, 2014. The NRC received 69 comment letters containing over 100 individual comments. The commenters included several professional societies including the American Brachytherapy Society, the American College of Radiology, the Health Physics Society, the American Society for Radiation Oncology, the American Association of Physicists in Medicine (AAPM), and the Council on Radionuclides and Radiopharmaceuticals. The NRC also received comments from the Organization of Agreement States (OAS), the Conference of Radiation Control Program Directors (CRCPD), individual States, practicing physicians, medical physicists, radiation safety officers (RSOs), nuclear pharmacists, individual members of the public, and a member of the U.S. House of Representatives. The comments and associated responses are discussed in Section V of the *Federal Register* notice (FRN) for the final rule (Enclosure 1).

DISCUSSION:

Part 35 of Title 10 of the *Code of Federal Regulations* (10 CFR Part 35) was revised in its entirety in 2002 (67 FR 20250, April 24, 2002), and the T&E requirements were further revised in 2005 (70 FR 16336, March 30, 2005). In implementing the regulations, the NRC staff, stakeholders, and the Advisory Committee on the Medical Uses of Isotopes (ACMUI) identified numerous issues that should be addressed through the rulemaking process. The final rule addresses these issues. The major issues addressed in the final rule are:

ME reporting criteria for permanent implant brachytherapy

The ME rulemaking has a long history. In 2008, the NRC published a proposed rule for public comment in the *Federal Register* on August 6, 2008 (73 FR 45635) to revise ME criteria for permanent implant brachytherapy. This proposed rule would have changed the ME criteria from absorbed dose delivered (dose-based) to total source strength administered (activity-based). However, during late summer and fall of 2008, a substantial number of MEs involving permanent implant brachytherapy were reported to the NRC. In response, the staff re-evaluated the proposed rule and submitted a reproposed rule to the Commission in SECY-10-0062, "Reproposed Rule: Medical Use of Byproduct Material – Amendments/Medical Event Definitions," dated May 18, 2010 (ADAMS Accession No. ML100890121).

In the SRM for SECY-10-0062, dated August 10, 2010 (ADAMS Accession No. ML102220233), the Commission disapproved the publication of the reproposed rule. The Commission directed the staff to:

> …work closely with the Advisory Committee on the Medical Uses of Isotopes and the broader medical and stakeholder community to develop event definitions that will protect the interests of patients, allow physicians the flexibility to take actions that they deem medically necessary, while continuing to enable the agency to detect failures in process,

procedure, and training as well as any misapplication of byproduct materials by authorized users.

The SRM also directed the staff to hold a series of public stakeholder workshops to discuss issues associated with the ME criteria.

Following Commission direction, in the summer of 2011 the staff conducted two workshops in New York, New York and Houston, Texas. The meeting summaries are available in ADAMS at Accession Nos. ML111930470 and ML112510385, respectively. The staff also requested the ACMUI prepare a report providing recommendations on ME definitions for permanent implant brachytherapy. In February 2012, the ACMUI submitted its final revised report (ADAMS Accession No. ML12038A279) to the NRC. The staff used the recommendations in the ACMUI report and input from stakeholders to develop revised ME definitions, which the staff provided to the Commission in SECY-12-0053, "Recommendations on Regulatory Changes for Permanent Implant Brachytherapy Programs," dated April 5, 2012 (ADAMS Accession No. ML12072A306). The staff recommended a hybrid ME definition for permanent implant brachytherapy that used both activity-based and dose-based criteria. In the August 13, 2012, SRM for SECY-12-0053 (ADAMS Accession No. ML122260211), the Commission approved the staff recommendations. Accordingly, the proposed rule contained both activity-based and dose-based ME criteria. The dose-based criteria related to the dose to 5 contiguous cubic centimeters of normal tissue, located outside and within the treatment site.

In public comments on the proposed rule, the medical community expressed concern that the dose-based ME criteria are not practical and may create confusion. Many commenters also indicated that regulators may not be able to inspect these criteria and that these criteria may discourage licensees from using this treatment modality. In response to public comments, the staff made a number of changes to the ME reporting criteria for permanent implant brachytherapy. One of the major changes is the removal of the dose-based ME criteria.

This final rule would amend the written directive requirements in § 35.40 and amend the ME reporting requirements in § 35.3045 to establish separate ME reporting criteria for permanent implant brachytherapy. The ME criteria would be activity-based rather than dose-based for permanent implant brachytherapy. The final rule also adds a requirement in § 35.41 for licensees to establish procedures to determine if an ME has occurred and to make certain that assessments related to the permanent implant brachytherapy implantation are conducted within 60 days after the procedure is completed. The final rule amendments are based on the staff recommendations contained in SECY-12-0053 and the comments received on the proposed rule.

Amending preceptor attestation requirements

The final rule eliminates the requirement in multiple sections for written preceptor attestations for individuals who are certified by a board that is recognized by the NRC or an Agreement State. The final rule modifies the text of the written attestation and allows a residency program director to provide the written attestation, which is still required for individuals who are not board certified. These changes are based on recommendations approved by the Commission in the January 16, 2009, SRM for SECY-08-0179, "Recommendations on Amending Preceptor Attestation Requirements in 10 CFR Part 35, Medical Use of Byproduct Material" (ADAMS

Accession No. ML090160275). The commenters on the proposed rule generally supported the proposed changes to the written attestation requirements.

Issues raised by Petition for Rulemaking PRM-35-20

The final rule addresses issues that were raised in PRM-35-20 (ADAMS Accession No. ML062620129), which was filed by E. Russell Ritenour, Ph.D., on behalf of the AAPM in September 2006. The petition requested that the training requirements in § 35.57 for experienced RSOs and medical physicists be amended to recognize board certified physicists and RSOs as "grandfathered" for the modalities that they practiced on or before October 24, 2005, although they were not named on a license. The NRC reviewed the petitioner's request and comments received on the petition and published the resolution in the *Federal Register* on May 14, 2008 (73 FR 27773), concluding that the revisions made to the regulations in 2005 may have inadvertently affected a group of board certified medical professionals. The final rule addresses the issues raised in this petition and amends the regulations to allow all individuals previously certified as RSOs, teletherapy or medical physicists, authorized medical physicists, authorized users (AUs), and authorized nuclear pharmacists by boards recognized under the previous 10 CFR Part 35, subpart J, to use byproduct material for the modalities they practiced on or before October 24, 2005. The commenters on the proposed rule generally supported this proposed grandfathering provision.

Requiring increased frequency of testing to measure Mo-99 breakthrough

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

From October 2006 through January 2008, medical licensees reported to the NRC that numerous generators had failed 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. In response to the numerous reports of failed Mo-99 breakthrough tests, in elutions, subsequent to the initial elution, this final rule amends the requirement to measure the Mo-99 concentration from requiring measurement only on the first elution, to requiring licensees to measure the concentration for each elution. The commenters on the proposed rule supported the change to measure Mo-99 for each elution.

Requiring reporting of failed technetium and rubidium generators

This final rule adds a new requirement that licensees report a generator eluate that exceeds the permissible concentration of Mo-99, strontium-82 (Sr-82), or strontium-85 (Sr-85). This new reporting requirement in § 35.3204(a) requires a licensee to report to the NRC and the manufacturer or distributor of medical generators, within 7 calendar days, any measurement that exceeds the limits in 10 CFR 35.204(a), at the time of generator elution. The staff believes that requiring licensees to report each incidence of a failed generator will ensure that the

patients are administered radiopharmaceuticals that meet the regulatory limit defined in § 35.204(a). This reporting requirement will also provide the NRC the opportunity to receive all the necessary information to evaluate these instances and take prompt actions as needed to prevent unnecessary radiation exposure to patients.

The Commission, in the SRM for SECY-13-0084, directed the staff to change the notification deadline from 24 hours to 30 days. After considering public comments, the staff determined that a shorter notification period would be more effective to evaluate failures considering the short half-life of the generators. In this final rule, the staff lowered the reporting deadline of failed generators from the proposed 30 calendar days to 7 calendar days. Also, the deadline for a written report of a failed generator is lowered from the proposed 45 days to 30 days.

Naming Associate Radiation Safety Officers on a medical use license

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

The commenters on the proposed rule generally supported the change to allow ARSOs to be named on a medical license. However, several commenters asked for clarifications on the newly created position of the ARSO, which the staff provided in its responses to comments.

Coordination with the Advisory Committee on the Medical Uses of Isotopes

In accordance with the Office of Nuclear Material Safety and Safeguards (NMSS) Policy & Procedure 2-5, “NMSS Procedure for Interfacing with the Advisory Committee on the Medical Uses of Isotopes during Development of Major Medical Issues,” the staff consults with the ACMUI when the NRC is revising its medical use regulations. Accordingly, staff provided the draft proposed rule (ADAMS Accession No. ML13014A487) to the ACMUI for a 90-day review. The ACMUI discussed its review at two publicly-held teleconferences on March 5 and March 12, 2013. The teleconference transcripts are available in ADAMS under Accession Nos. ML13087A474 and ML13087A477, respectively. The ACMUI provided a final report on the draft proposed rule to the NRC staff on April 5, 2013 (ADAMS Accession No. ML13099A459). In its report, the ACMUI supported the majority of the proposed amendments, although the ACMUI expressed concerns on some issues and provided recommendations. The staff considered all of ACMUI’s recommendations and revised the rule text and Statement of Considerations in the FRN accordingly to incorporate many of ACMUI’s comments. However, the staff did not accept all of the ACMUI recommendations. Enclosure 5 to SECY-13-0084 (ADAMS Accession No. ML13178A124) provides the staff’s response to each of the ACMUI recommendations.

The staff also provided the draft final rule (ADAMS Accession No. ML15278A469) to the ACMUI for a 90-day review. The ACMUI discussed its review of the draft final rule during its public teleconference held on January 6, 2016 (ADAMS Accession No. ML16074A271). The ACMUI submitted its final report on the draft final rule to the NRC staff on January 6, 2016 (ADAMS Accession No. ML16007A771).

The ACMUI final report is provided in Enclosure 4 and the staff's response to ACMUI's recommendations is provided in Enclosure 5. In summary, the ACMUI provided 13 recommendations. Six of these recommendations endorsed portions of the draft final rule, so no change to the draft final rule is needed in response to these recommendations. The staff accepted two recommendations in full and one recommendation in part. The staff did not accept four recommendations from the ACMUI.

Three recommendations from the ACMUI warrant highlighting to the Commission. First, the ACMUI continues to support its previous recommendations that alpha-emitting radiopharmaceuticals do not differ significantly from currently approved radiopharmaceuticals in terms of clinical use and management, radiation safety, and logistics. Physicians already authorized to use therapeutic radiopharmaceuticals under § 35.390 or § 35.396 have the requisite education, training, and experience to safely and effectively use alpha-emitting radiopharmaceuticals. The staff agrees with this part of the recommendation and has included alpha-emitting radiopharmaceuticals within the category for the parenteral administration of radioactive drugs, which is provided in § 35.390(b)(1)(ii)(G)*(3)*. Further discussion of this issue is provided in the staff response to the ACMUI's recommendations.

Second, the ACMUI endorsed the component of the draft final rule that will change the ME criteria from dose-based to activity-based for permanent implant brachytherapy.

Third, the ACMUI endorsed, with reservations, designating the ME reporting criteria for permanent implant brachytherapy as Compatibility Category C, "with activity-based medical event metrics defined as an essential program element." The ACMUI stated that "[t]he ACMUI and its Rulemaking sub-Committee strongly advise that Agreement States *not* also adopt dose-based criteria for medical events." The ACMUI indicated that if such problematic multiplicity of criteria in different jurisdictions were to occur, the ACMUI's compatibility recommendation would have to be reconsidered.

Agreement State Issues

Agreement States were represented in the development of the proposed and final rule. The staff provided the draft final rule to the Agreement States for an opportunity for review. The OAS and 12 Agreement States submitted comments on the draft final rule. Nine of these Agreement States supported the OAS comments with no additional comments.

Enclosure 6 provides a detailed summary of the major comments from the OAS and Agreement States as well as the NRC staff responses. The staff accepted nine comments and did not accept six comments. One comment did not require a specific response. In summary, the OAS and Agreement States provided comments on the following topics: (1) definition of treatment site; (2) requirements related to written directives and ME criteria; (3) training for Radiation Safety Officer and Associate Radiation Safety Officer; (4) permissible concentrations of Mo-99, Sr-82, and Sr-85; (5) training for the parenteral administration of unsealed byproduct material requiring a written directive; (6) requirements related to strontium-90 sources for ophthalmic treatments and the ophthalmic physicist; (7) reporting and notification of an ME; and (8) clarification of the categorization of radium-223 dichloride.

Two comments warrant highlighting to the Commission. First, the OAS is supportive of the NRC's decision to assign a Compatibility Category C designation for the reporting requirements

found in § 35.3045. Second, one Agreement State indicated that it may retain the dose-based ME criteria as well as adopt the activity-based ME criteria for permanent implant brachytherapy. In the response to Agreement State comments (Enclosure 6) and in the public comment analysis section of the FRN, the staff reiterated the reasons that the NRC has determined that activity-based criteria are the appropriate criteria for ME reporting. The staff also explained why dose-based criteria are not appropriate. The compatibility of ME reporting criteria is discussed in more detail below in the section "Compatibility Category Designation of 10 CFR 35.3045, 'Report and notification of a medical event.'"

The staff has analyzed the final rule in accordance with the procedures established within Part III, "Categorization Process for NRC Program Elements," of the Handbook to Management Directive 5.9 (ADAMS Accession No. ML041770094). The staff assigned compatibility designations to specific sections of the final rule. The compatibility determination for the final rule is addressed in Section XVIII, "Agreement State Compatibility," of the enclosed FRN.

The Standing Committee on Compatibility (SCC) reviewed the final rule and agreed that the amendments to the NRC regulations are a matter of compatibility between the NRC and the Agreement States. The SCC agreed with the compatibility designations assigned to each section of the final rule. The Agreement States must adopt compatible requirements no later than 3 years from the effective date of the final rule, and this has been included in the FRN.

Compatibility Category Designation of 10 CFR 35.3045, "Report and notification of a medical event"

In the SRM for SECY-13-0084 the Commission directed that § 35.3045 be designated as a Compatibility Category B in the proposed rule. Currently, § 35.3045 is designated as a Compatibility Category C. In the FRN for the proposed rule, the Commission specifically requested comments on this topic from external stakeholders. The NRC received 19 comments on this issue. The 10 comments in support of Compatibility Category B were submitted by members of the medical community. The OAS, CRCPD, and the seven Agreement States that submitted comments on the proposed rule submitted comments in support of Compatibility Category C. The staff has determined, after considering the comments received, that Compatibility Category C is the appropriate category for ME reporting, including MEs involving permanent brachytherapy implants. This approach will provide uniformity of practice for all licensees, while still providing the Agreement States some flexibility to include, for example, shorter reporting times.

The medical community expressed concerns that under Compatibility Category C, Agreement States may continue to use dose-based reporting criteria, which would be inconsistent with non-Agreement State regulated entities. As part of the staff's review and incorporation of comments, staff considered the definition of the term "essential objectives" in accordance with Management Directive 5.9, "Adequacy and Compatibility of Agreement State Programs." Staff has determined that ME reporting should be designated as Compatibility Category C. Under Compatibility Category C, the Agreement States must adopt the essential objectives of the requirement to avoid conflicts, duplications, or gaps. The essential objective of § 35.3045 is to maintain a consistent national program for reporting MEs. The staff determined that dose-based criteria would conflict with, and create inconsistencies within, the national ME reporting program, because it would result in the reporting of insignificant events as MEs.

Training and Experience for Parenteral Administration of Alpha and Beta Emitters

The NRC received two public comments during the public comment period and several public comments after the public comment period on the 700-hour T&E requirements at §§ 35.390 and 35.396 for authorization for the parenteral administration of alpha- and beta-emitting radiopharmaceuticals. Several commenters stated that this requirement caused a shortage of AUs, and thus a barrier to patient access to certain radiopharmaceuticals. These commenters recommended reducing the T&E requirement to 80 hours. Several other commenters opposed this recommendation and stated that the NRC and ACMUI would need to carefully consider several radiation health and safety issues before contemplating reducing this T&E requirement.

This final rule would not amend this T&E requirement. The NRC did not intend to propose any change to this T&E requirement and thus has not developed a regulatory basis to change to this requirement.[2]

The staff referred these commenters' AU availability and patient access concerns to the ACMUI. In a public teleconference held on June 16, 2015, the Florida Cancer Specialists & Research Institute presented to the ACMUI its assertion that this T&E requirement caused a shortage of AUs and thus a barrier to patient access to certain radiopharmaceuticals. The ACMUI established a subcommittee to assess these concerns. At its meetings on October 8-9, 2015 and March 10, 2016 (ADAMS Accession Nos. ML15294A461 and ML16095A356, respectively), the ACMUI discussed this issue and unanimously approved the subcommittee's two reports on this issue (ADAMS Accession Nos. ML15271A124 and ML16089A271). As stated in its reports, the ACMUI was unable to substantiate these assertions (a shortage of AUs and thus a barrier to patient access to certain radiopharmaceuticals), and therefore recommended against reducing this T&E requirement. However, because of the introduction of new radioactive drugs since the requirements were established 15 years ago and the educational paradigm shift from prescriptive curricula to competency-based education, the ACMUI established a standing subcommittee to conduct a thorough review of the T&E requirements across all modalities.

Cumulative Effects of Regulation and Implementation

The staff is recommending that the final rule be effective 180 days after publication in the *Federal Register*. This would provide sufficient time for licensees to develop procedures, and conduct training on the new requirements. The Agreement States will be required to issue compatible regulations within 3 years of the effective date of the final rule.

COMMITMENTS:

The staff will publish the implementing guidance concurrently with the final rule (ADAMS Accession No. ML16126A441). NUREG-1556, Volume 9, "Program-Specific Guidance about Medical Use Licenses," Revision 2 and NUREG-1556, Volume 13, "Program Specific Guidance about Commercial Radiopharmacy Licenses," Revision 1 will be revised at a later date to

[2] In the proposed rule, the word "or" appeared between the rule text in § 35.396(c) and (d). This administrative error could have been interpreted to require that a physician complete only 80 hours of T&E for parenteral administration of unsealed byproduct material requiring a written directive. The NRC is correcting the error by removing the word "or" in the final rule text.

incorporate the implementing guidance. Staff will update Inspection Procedure 87132, "Brachytherapy Programs" at a later date.

RECOMMENDATIONS:

That the Commission:

1. Approve for publication in the *Federal Register* the attached notice of final rule (Enclosure 1).

2. To satisfy the requirement of the Regulatory Flexibility Act, 5 U.S.C. 605 (b), certify that this rule, if promulgated, will not have significant impact on a substantial number of small entities. This certification is included in the attached *Federal Register* notice.

3. Note:

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

   b. That a final Regulatory Analysis has been prepared for the final rule (Enclosure 2);

   c. That an Environmental Assessment has been prepared for the final rule (Enclosure 3);

   d. The NRC staff has determined that this action is not a major rule, as defined in the Congressional Review Act (CRA) of 1996 [5 U.S.C 804(2)] and has confirmed this determination with the Office of Management and Budget (OMB). The appropriate Congressional and Government Accountability Office contacts will be informed;

   e. The appropriate Congressional committees will be informed;

   f. A press release will be issued by the Office of Public Affairs when the NRC publishes the rule in the *Federal Register*; and

   g. The final rule contains amended and new information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, et seq) that must be submitted to the OMB for its review and approval before publication of the final rule in the Federal Register.

RESOURCES:

The 10 CFR Part 35 Final Rulemaking, "Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments," will require resources in Fiscal Years (FY) 2016 and 2017 under the Nuclear Materials Users Business Line/Rulemaking Product Line/Rulemaking Product. The resources needed to complete the rulemaking are included in the FY 2016 Enacted Budget and the FY 2017 President's Budget.

COORDINATION:

The Office of the General Counsel has no legal objection to the enclosed final rule. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections.

/RA by Glenn M. Tracy for/

Victor M. McCree
Executive Director
for Operations

Enclosures:
1. *Federal Register* notice
2. Regulatory Analysis
3. Environmental Assessment
4. ACMUI Report on Part 35 draft final rule
5. Staff response to ACMUI report
6. Summary of Specific Agreement State and OAS comments and staff response

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2. Regulatory Analysis
3. Environmental Assessment
4. ACMUI Report on Part 35 draft final rule
5. Staff response to ACMUI report
6. Summary of Specific Agreement State and OAS comments and staff response

ADAMS Accession Number: ML16123A342 NMSS2014337

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