RULEMAKING ISSUE
NOTATION VOTE

August 8, 2013 SECY-13-0084

FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

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

PURPOSE:

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

SUMMARY:

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

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medical license. Third, the rule proposes changes to address a request filed in a petition for rulemaking (PRM) (PRM-35-20) to exempt certain board-certified individuals from certain T&E requirements (i.e., "grandfather" these individuals) so that they may be identified on a license or permit for materials and uses that they performed on or before October 24, 2005, the expiration date of the former Subpart J of Part 35 which contained the prior T&E requirements.

BACKGROUND:

Part 35 was revised in its entirety in 2002 (67 FR 20250), and the T&E requirements were further revised in 2005 (70 FR 16336). In implementing the current regulations, the NRC staff, stakeholders, and the Advisory Committee on the Medical Uses of Isotopes (ACMUI) have identified numerous issues that need to be addressed through the rulemaking process. These issues would be addressed in this proposed rule.

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

The proposed rule would also address issues that were raised in PRM-35-20 (ADAMS Accession No. ML062620129) filed by E. Russell Ritenour, Ph.D., on behalf of the American Association of Physicists in Medicine (AAPM) in September 2006. The petition requested that experienced board-certified RSOs and medical physicists not named on a license who had practiced certain modalities prior to October 24, 2005, be exempt from the specific T&E requirements in 10 CFR 35.50, and 35.51, respectively. In effect, they would be "grandfathered" for these training requirements for the modalities that they practiced as of October 24, 2005.

DISCUSSION:

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

ME definitions for permanent implant brachytherapy.

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

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

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

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

Preceptor attestation requirements.

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

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

Petition for Rulemaking PRM-35-20

The petition requested that experienced board-certified RSOs and medical physicists not named on a license who had practiced certain modalities prior to October 24, 2005, be exempted from the specific T&E requirements in 10 CFR 35.50, and 35.51, respectively. In effect, they would be "grandfathered" for these training requirements for the modalities that they practiced as of October 24, 2005. The petitioner was concerned that as a result of the amendments to the T&E regulations in 2005, an individual could become authorized on a license only if he or she had been certified by a specialty board whose certification process was recognized under the new regulations by the NRC or an Agreement State or was already identified on an existing NRC or Agreement State license. If the individual had been certified prior to the effective date for recognition of the certifying board but had not been listed on a license, he or she would not be "grandfathered," and would have to obtain training through the so-called "alternate pathway" which establishes the specific training requirements for the non-certified individuals. The petitioner did not believe that it was the intent of the Commission to deny recognition to individuals currently practicing or to minimize the importance of certification by a certifying board.

The NRC reviewed the petitioner's request and comments received on the petition (73 FR 27773, May 14, 2008) and concluded that the revisions made to the regulations in 2005 may have inadvertently affected a group of medical professionals. The proposed rule would resolve the issues raised in this petition and amend the regulations to recognize all individuals previously certified by boards recognized under the previous 10 CFR Part 35, subpart J, as

RSOs, teletherapy or medical physicists, AMPs, AUs, nuclear pharmacists, and ANPs for modalities they practiced on or prior to October 24, 2005.

Increased frequency of testing to measure molybdenum-99 breakthrough.

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

From October 2006 through January 2008, medical licensees reported to the NRC that numerous generators had failed the Mo-99 breakthrough tests. Some licensees reported the failed tests in the first elution, while some reported an acceptable first elution but failed subsequent elutions. One generator manufacturer voluntarily reported 116 total elution test failures in 2008. Based upon the numerous reports of failed Mo-99 breakthrough measurements noted in the subsequent elutions, the proposed rule would amend the requirement to measure the Mo-99 concentration of the first eluate to return to a pre-2002 performance standard in the regulations which had required licensees to measure the Mo-99 concentration for each elution of the Mo-99/Tc-99m generator.

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

Reporting of failed technetium and rubidium generators.

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

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

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

Naming Associate Radiation Safety Officers on a medical use license.

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

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

Coordination with the Advisory Committee on the Medical Uses of Isotopes

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

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

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

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

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

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

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

Cumulative Effects of Regulation

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

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

AGREEMENT STATE ISSUES:

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

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

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

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

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

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

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

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

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

COMMITMENTS:

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

RECOMMENDATIONS:

That the Commission:

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

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

Note:

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

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

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

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

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

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

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

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

COORDINATION:

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

/RA by Michael F. Weber for/

R. W. Borchardt
Executive Director
for Operations

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

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

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

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

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

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

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4. ACMUI Report on Part 35 Draft Proposed Rule
5. Staff Response to ACMUI Report on Part 35 Draft Proposed Rule
6. Summary of Major Agreement State Comments and Staff Responses
7. Resources for Part 35 Rulemaking

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