



POLICY ISSUE **(Notation Vote)**

January 13, 2020

SECY-20-0005

FOR: The Commissioners

FROM: Margaret M. Doane
Executive Director for Operations

SUBJECT: RULEMAKING PLAN FOR TRAINING AND EXPERIENCE
REQUIREMENTS FOR UNSEALED BYPRODUCT MATERIAL
(10 CFR PART 35)

PURPOSE:

The purpose of this paper is to request Commission approval to initiate a rulemaking that would revise the training and experience (T&E) requirements for use of unsealed byproduct material in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35, "Medical Use of Byproduct Material."

SUMMARY:

This paper provides rulemaking options and the U.S. Nuclear Regulatory Commission (NRC) staff's recommendation to initiate a rulemaking to remove prescriptive T&E requirements and to eliminate the need for NRC review and approval of authorized users (AUs). The staff's recommended option would require that physicians be certified by an NRC-recognized or Agreement State-recognized medical specialty board to become AUs. As part of this recommended rulemaking, the NRC would revise its board recognition criteria so that certification by specialty boards other than the existing nuclear medicine and radiation oncology boards would be an acceptable T&E pathway for the use of radiopharmaceuticals. The staff's recommended rulemaking option would continue to protect public health and safety, better align

CONTACTS: Sarah Lopas, NMSS/MSST
301-415-6360

Maryann Ayoade, NMSS/MSST
301-415-0862

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the NRC's T&E requirements with the Medical Policy Statement,¹ and position the agency for more effective and efficient regulatory decision making with respect to the expected increase in the number and complexity of emerging radiopharmaceuticals. The recommended option would also alleviate regulatory burden for the NRC, Agreement States, and licensees, resulting in an estimated cost savings of \$2.4 million per year.

BACKGROUND:

The NRC's regulations require that physicians complete T&E criteria to be authorized for medical use of byproduct material and to independently fulfill the radiation safety-related duties of an AU. The current regulatory T&E criteria are prescriptive (viz., set forth a defined number of training hours and patient casework for the range of medical modalities, irrespective of licensee practices; and emerging technologies). In addition, successful completion of the T&E requirements to become an AU does not reflect on a physician's medical competency related to radiopharmaceutical administrations. The regulations in 10 CFR 35.390, "Training for Use of Unsealed Byproduct Material for Which a Written Directive Is Required," provide two pathways² for a physician to satisfy the T&E requirements and be initially approved as an AU for radiopharmaceuticals requiring a written directive:

- (1) approval of a physician who is certified by a medical specialty board that has a certification process recognized by the NRC or an Agreement State as meeting the NRC's requirements for T&E, also known as the "board certification pathway"³
- (2) approval based on an evaluation of a physician's T&E—completion of 200 hours of classroom and laboratory training and 500 hours of supervised work experience (including patient casework) for a total of 700 hours of T&E, plus preceptor⁴ attestation, also known as the "alternate pathway"

The NRC issued T&E requirements for the alternate pathway in 2002.⁵ Since that time, some pharmaceutical industry stakeholders and physicians that do not traditionally use radioactive material in their practice of medicine⁶ (referred to in this document as nonnuclear medicine and nonradiation oncology physicians) have asserted that the current 700-hour T&E requirement in the alternate pathway is overly burdensome for physicians who are not eligible for the board certification pathway, preventing these physicians from becoming AUs, thereby affecting patient access to certain therapeutic radiopharmaceuticals. These stakeholders have suggested that the NRC could address these concerns by providing additional tailored pathways for nonnuclear

¹ "Medical Use of Byproduct Material; Policy Statement, Revision" (65 FR 47654; August 3, 2000).

² In accordance with the regulations in 10 CFR 35.2, "Definitions," section (b)(4) of 35.13, "License Amendments," and section (a) of 35.14, "Notifications," physicians can also satisfy the T&E requirements to be approved as an AU if they have been previously approved and listed as an AU on an existing NRC or Agreement State license or a permit.

³ The procedures for recognizing medical specialty board certifications are available at <https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>. Currently, specialty boards must show that they meet the requirements of the alternate pathway (10 CFR 35.390(b)(1)) to be recognized by the NRC or an Agreement State. Specialty board certifications currently recognized by the NRC under 10 CFR Part 35 are available at <https://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>.

⁴ As defined in 10 CFR 35.2 and for the discussion in this paper, "preceptor" means an individual who provides, directs, or verifies T&E required for a physician to become an AU. Per 10 CFR 35.392(b)(2), a preceptor must attest in writing that the physician to serve as an AU has satisfactorily completed the appropriate T&E requirements and has achieved a level of competency or a level of radiation safety knowledge sufficient to function independently.

⁵ "10 CFR 20, 32, and 35, Medical Use of Byproduct Material; Final Rule" (67 FR 20249; April 24, 2002).

⁶ Typically, physicians who complete the T&E requirements under 10 CFR 35.390 are trained in nuclear medicine or radiation oncology and are certified by one of the NRC-recognized specialty boards (American Board of Nuclear Medicine, American Board of Radiology, or American Osteopathic Board of Radiology).

medicine and nonradiation oncology physicians to be authorized to use specific types of radiopharmaceuticals.

In Staff Requirements Memorandum (SRM)-M170817,⁷ the Commission directed the staff to evaluate (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals, (2) how those categories should be determined (such as based on the risks posed by groups of radionuclides or by delivery method), (3) the appropriate T&E requirements for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. The staff's initial response to the Commission's direction was to analyze the radiation safety knowledge topics needed for safe administration of radiopharmaceuticals. In SECY-18-0084,⁸ the staff concluded that, while it may be feasible to establish tailored T&E requirements for different categories of radiopharmaceuticals, additional and more extensive outreach to the medical community was needed to determine whether and how to tailor the T&E requirements. Enclosure 1 provides additional background information, including past stakeholder feedback and a summary of prior T&E activities by the NRC and the Advisory Committee on the Medical Uses of Isotopes (ACMUI).

To support this rulemaking plan, the staff continued its evaluation of tailored T&E requirements by seeking additional feedback from a broad range of medical and regulatory stakeholders through two public comment periods and coordination with the Agreement States and the ACMUI. Enclosure 2 provides additional detail on these two public comment periods and summarizes the results of these efforts. Additionally, the staff evaluated the NRC's regulatory framework for T&E more broadly, including whether: (1) the T&E requirements for radiopharmaceuticals could be better aligned with the NRC's Medical Policy Statement, (2) the current requirements are inappropriately affecting patient access to radiopharmaceuticals, (3) changes are needed to position the NRC to more efficiently regulate emerging and future radiopharmaceuticals, and (4) the requirements could be more risk-informed while continuing to ensure the safe and secure medical use of byproduct material. The staff also considered the regulatory approaches of international counterparts and evaluated medical event data to determine whether T&E requirements have resulted in medical events. Enclosure 3 discusses the staff's evaluation of the current T&E regulatory framework. Further, during these two public comment periods, in response to the Commission's direction in SRM-M170817, the staff also evaluated maintaining the status quo and several rulemaking options. Four options (the status quo, tailored requirements, National Materials Program-recognized specialty board credentialing, and maintaining the alternate pathway with National Materials Program-recognized specialty board credentialing) are discussed below.

DISCUSSION:

In the SRM for SECY-15-0129, "Commission Involvement in Early Stages of Rulemaking," dated February 3, 2016 (ADAMS Accession No. ML16034A441), the Commission directed the staff to provide a streamlined rulemaking plan in the form of a SECY paper that would request Commission approval to initiate all rulemakings not already explicitly delegated to the staff.

⁷ SRM-M170817, "Staff Requirements—Affirmation Session, 10:30 A.M., Thursday, August 17, 2017, Commissioners' Conference Room, One White Flint North, Rockville, Maryland (Open to Public Attendance)," dated August 17, 2017 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML17229B283).

⁸ SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817," dated August 28, 2018 (ADAMS Accession No. ML18135A276).

Accordingly, a rulemaking plan that follows the Commission-approved template (ADAMS Accession No. ML19032A609, nonpublic) is presented below.

Title

"Training and Experience Requirements for Unsealed Byproduct Material."

Regulation

10 CFR Part 35.

Regulatory Issue

In response to SRM-M170817, the NRC staff evaluated stakeholder concerns regarding the perceived burden of the T&E requirements in 10 CFR 35.390 and whether to address those concerns by tailoring the T&E requirements to create limited AU pathways for different categories of radiopharmaceuticals. While the staff does not recommend tailoring the T&E requirements, the staff did identify areas for transformation in the existing T&E regulatory framework that could also address stakeholder concerns.

The NRC's Medical Policy Statement says, in part, that the NRC will not intrude into medical judgments affecting patients except as necessary to provide for the radiation safety of workers and the general public; the NRC will regulate the radiation safety of patients to assure that medical uses are in accordance with physician directions; and, when developing regulatory approaches, the NRC will consider industry and professional standards that define acceptable approaches for achieving radiation safety. The NRC staff, some members of the medical community, the Organization of Agreement States (OAS) Executive Board, and some Agreement States have questioned whether the T&E regulatory framework could be better aligned with these policies. Specifically, the existing prescriptive T&E criteria and the requirement that the NRC and Agreement States review and approve physician T&E before a physician can prescribe radiopharmaceuticals is viewed by some as encroaching on the practice of medicine.

The staff's proposed rulemaking would revise the current prescriptive T&E regulations under 10 CFR Part 35, Subpart D, "Unsealed Byproduct Material—Written Directive Not Required," and Subpart E, "Unsealed Byproduct Material—Written Directive Required," to require that AUs be physicians certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State as having met certain high-level, performance-based radiation safety training requirements. This proposed rulemaking would better align the T&E regulatory framework with the Medical Policy Statement by increasing the medical community's involvement in setting specific T&E requirements in accordance with the NRC and Agreement State criteria and in credentialing physicians as AUs. Additionally, the high-level radiation safety training criteria would better prepare the NRC for the expected increase in the number and complexity of emerging and future radiopharmaceuticals, and better address nonnuclear medicine and nonradiation oncology physicians wishing to use radiopharmaceuticals.

Another regulatory issue identified by NRC staff, the OAS Executive Board, and several Agreement States is AU supervision of individuals responsible for the day-to-day handling and administration of radiopharmaceuticals, e.g., nuclear medicine technologists. Some Agreement States questioned whether the T&E requirements should focus on these non-AU individuals.

Because AUs are ultimately responsible for ensuring that radiopharmaceuticals they prescribe are administered in accordance with their signed written directive, the staff does not recommend revising the T&E requirements to focus on non-AU individuals at this time. However, the proposed rulemaking would consider revisions to the NRC's regulations at 10 CFR 35.27, "Supervision," which address the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an AU.

Existing Regulatory Framework

Regulations

The current regulations in 10 CFR 35.190, "Training for Uptake, Dilution, and Excretion Studies," 10 CFR 35.290, "Training for Imaging and Localization Studies," and 10 CFR 35.390 require that physicians complete a certain amount of radiation safety training before their certification as an AU for the medical use of unsealed byproduct material. For each modality, this training can be approved through the board certification pathway or the alternate pathway.

Guidance

The primary guidance document for medical uses of byproduct material is NUREG-1556, Volume 9, Revision 3, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses, Final Report," issued September 2019 (ADAMS Accession No. ML19256C219). A list of applicable guidance documents and inspection procedures is included as Enclosure 4.

Additionally, the list of medical specialty boards recognized by the NRC and the Agreement States, procedures to apply for board recognition, and the NRC 313A series of forms and guidance on T&E for authorized individuals⁹ are all maintained on the NRC's Medical Uses Licensee Toolkit.¹⁰

Explanation of Why Rulemaking Is the Preferred Solution

In its evaluation of the current T&E requirements, the staff considered maintaining the status quo and several rulemaking options. Four options are discussed below, and other options the staff evaluated but does not recommend for Commission consideration are documented in Enclosure 5.

All rulemaking options could include variations that the staff would finalize with stakeholder input during the early stages of rulemaking. For example, these variations could include incorporation of a formal radiation safety competency evaluation (e.g., preceptor attestation, examination), changes to written directive requirements, or additional oversight of the specialty board recognition process. Additionally, as discussed above in the "Regulatory Issue" section, each rulemaking option would consider revisions to the NRC's supervision regulations (10 CFR 35.27) to address potential issues regarding supervision by AUs.

⁹ The NRC 313A series of forms provide a suitable format for licensees to document required T&E for authorized individuals (AUs, authorized medical physicists, ophthalmic physicists, authorized nuclear pharmacists, Radiation Safety Officers, and Associate Radiation Safety Officers). The NRC and Agreement States review the information provided in the 313A to determine whether the applicant meets the required T&E to be authorized and listed on a license.

¹⁰ The NRC's Medical Uses Licensee Toolkit is available at <https://www.nrc.gov/materials/miau/med-use-toolkit.html>.

Option 1, "Status Quo," would make no changes to the NRC's T&E requirements.

Pros:

- Since their promulgation in 2002, the current T&E requirements have proven to protect radiation safety for the general public, workers, and patients.
- The NRC, Agreement States, and licensees have experience applying the existing T&E regulations and accompanying guidance, and the medical community has a good understanding of the existing regulations and guidance.
- Radionuclide categories in 10 CFR 35.300 can accommodate most emerging and future radiopharmaceuticals, and 10 CFR 35.1000, "Other Medical Uses of Byproduct Material or Radiation from Byproduct Material," would be available for radiopharmaceuticals that do not fit under 10 CFR 35.300.
- This is the only option that would not require rulemaking resources.
- The ACMUI, some Agreement States, and the nuclear medicine and radiation oncology medical communities support maintaining the status quo, stating that the current requirements are protective of public health and safety, there is no evidence of an AU shortage, and the radionuclide categories in 10 CFR 35.300 are inclusive of emerging radiopharmaceuticals.

Cons:

- The prescriptive knowledge topics and supervised work experience requirements in the current T&E regulations may be unnecessary for certain radiopharmaceuticals, or conversely, they may not adequately address safety-related characteristics of more complex, future radiopharmaceuticals.
- The prescriptive nature of the current T&E regulatory framework and the required role of the NRC and Agreement States in approving AUs to practice nuclear medicine (i.e., physicians must be credentialed as AUs by the NRC or an Agreement State in order to prescribe radiopharmaceuticals) are viewed by some as encroaching on the practice of medicine.
- The OAS Executive Board and some Agreement States do not support the status quo, contending that it may not ensure adequate supervision of radiopharmaceutical administration, and regulatory focus may be better placed on the non-AU individuals who most often handle and administer radiopharmaceuticals.

Option 2, "Tailored Requirements," would tailor and likely reduce T&E requirements to create additional AU pathways for administration of specific categories of radiopharmaceuticals. The existing AU pathways would remain unchanged. Examples of tailored T&E categories could include patient-specific, unit-dose, nonradioligand¹¹ alpha emitters (e.g., radium-223 dichloride); *any* patient-specific, unit-dose radiopharmaceutical; or *any one* parenteral radiopharmaceutical.

Pros:

- This option would risk-inform the T&E requirements for certain radiopharmaceuticals while continuing to protect radiation safety for the general public, workers, and patients.
- This option would provide additional, more flexible pathways for nonnuclear medicine and nonradiation oncology physicians to become AUs for specific radiopharmaceuticals.

¹¹ Radioligand therapies involve attaching a radioactive isotope to a ligand-signaling molecule that binds only to a specific cancer-related molecule on a tumor cell to deliver therapeutic radiation doses (additional information available at <https://endocyte.com/pipeline/advanced-prostate-cancer-treatment/>).

Cons:

- Definitive categories may entirely exclude emerging and future radiopharmaceuticals, or may not adequately capture safety-related characteristics of future radiopharmaceuticals (such as energy level, dose, half-lives, or administration protocol).
- This option may require rulemakings or exemption requests if additional radiopharmaceuticals merited tailored T&E in the future, would add complexity to already complicated T&E regulations with multiple AU pathways, could increase AU documentation errors, and would require additional licensing resources.
- The ACMUI, Agreement States, the OAS Executive Board, and the nuclear medicine and radiation oncology medical communities oppose tailored requirements, citing concerns about the safety of limited-trained AUs and increasing regulatory complexity.

Option 3, “National Materials Program-Recognized Specialty Board Credentialing,” is a performance-based approach that would remove the NRC and Agreement States from review and approval of T&E for AUs, and instead would require that physicians be certified by a medical specialty board recognized by the NRC or an Agreement State. During the rulemaking process, the NRC, in coordination with the ACMUI and the Agreement States and with input from the medical community, would evaluate the board recognition criteria and determine if less prescriptive criteria could provide equivalent radiation safety competency as the current criteria, while also being more encompassing of the safety-related characteristics of emerging radiopharmaceuticals. The specialty board criteria could ensure appropriate didactic education and hands-on T&E to provide reasonable assurance of adequate protection of public health and safety. This option provides an opportunity to critically assess the specific requirements in 10 CFR 35.390. Medical specialty boards seeking NRC or Agreement State recognition would develop radiation safety training programs specific to their medical program objectives and in accordance with the board recognition criteria. Certification by a recognized medical specialty board would credential a physician to be an AU for the medical uses authorized to the specialty board, and ongoing AU status would be tied to the physician's maintenance of board certification. The NRC and Agreement States would periodically audit recognized boards to ensure their continued compliance with the radiation safety training criteria.

AUs would continue to be responsible for ensuring that the radiopharmaceuticals they prescribe are administered in accordance with their signed written directive, and regulatory emphasis would continue to be on performance-based inspection of a licensee's radiation safety program to ensure safe and secure handling, storage, and use of radiopharmaceuticals. To allow time for physicians planning on using the alternate pathway to become AUs, the staff would first implement the new board recognition criteria, followed by later removal of the alternate pathway.

Pros:

- This option would continue to protect radiation safety for the general public, workers, and patients.
- This option would better align with the Medical Policy Statement than the existing T&E framework: the less prescriptive nature of the board recognition criteria and increased medical community involvement in setting T&E requirements and credentialing AUs would encroach less on the practice of medicine and better consider industry and professional standards.
- The NRC, Agreement States, and licensees would require fewer licensing resources because the NRC and Agreement States would no longer review and approve T&E for AUs, licensees would no longer submit those licensing documents, and AUs would no longer be listed on licenses.

- This option could provide a pathway for additional medical specialty boards—more knowledgeable of the medical expertise of their community—to seek NRC or Agreement State recognition, which would allow more physicians to become AUs. Based on NRC performance-based requirements, medical specialty boards could develop radiation safety training programs tailored to their practice of medicine and specific use of radiopharmaceuticals.
- This option is agile and transformative in that it offers the flexibility needed to accommodate emerging and future radiopharmaceuticals—medical specialty boards could revise their T&E requirements as new radiopharmaceuticals are developed, while continuing to meet the radiation safety training criteria required by the NRC and the Agreement States.
- This option would tie ongoing AU status to maintenance of board certification, and AUs may be subject to continuing education requirements by their board, both of which could provide institutional checks on AU status.
- The OAS Executive Board and some Agreement States support the NRC and the Agreement States no longer reviewing and approving T&E for AUs; the OAS Executive Board specifically supports this option.¹²

Cons:

- This option would remove the alternate pathway, leaving only the board certification pathway. Until they are board certified, new physicians who have not been certified would need to work under the supervision of another AU and would be unable to sign written directives.
- Newly recognized board programs would need to address whether and how to provide a pathway for their existing certified physicians (i.e., board diplomates) who are not AUs to become AUs.
- This option relies on nonnuclear medicine and nonradiation oncology medical specialty boards to apply to the NRC or an Agreement State for recognition in order for new AU pathways to be realized.
- The nuclear medicine and radiation oncology medical communities oppose any changes to the current T&E requirements, including this option. Without specific information for new board criteria, the ACMUI supports the current T&E requirements. The ACMUI acknowledges there is room for a comprehensive review of the specific requirements in 10 CFR 35.390 and welcomes the opportunity to critically assess these details.

Option 4, “Alternate Pathway with National Materials Program-Recognized Specialty Board Credentialing,” would implement Option 3 while maintaining the alternate pathway. The alternate pathway would remain prescriptive to ensure consistency in the review and approval of T&E by regulators across the National Materials Program.

Pros:

- This option features pros similar to Option 3.
- In addition, this option would maintain the alternate pathway, which would continue to allow physicians to obtain AU status without specialty board certification.
- This option offers flexibility to support timely certification of new AUs.

¹² Comment submissions from the OAS Executive Board and the States of North Carolina, Wisconsin, and Colorado are available at ADAMS (ADAMS Accession Nos. ML19184A590, ML19290H493, ML19170A073, ML19184A593, and ML19177A330, respectively).

Cons:

- This option features cons similar to Option 3 (with exception of the con associated with removal of the alternate pathway).
- This option requires continued review and approval of T&E by the NRC and Agreement States and does not address issues associated with the prescriptive nature of the alternate pathway, making it less transformative than Option 3 and resulting in a smaller reduction in licensing resources for the NRC, Agreement States, and licensees.
- AUs credentialed by medical specialty boards would be subject to institutional checks on their AU status by maintenance of board certification and continuing education requirements; there will continue to be no checks on AUs approved using the alternate pathway.
- Maintaining the prescriptive alternate pathway requirements alongside high-level board recognition criteria would reduce clarity, efficiency, and reliability of the T&E requirements, and may result in differing standards for credentialing between the two pathways.

Description of Rulemaking: Scope

The staff is recommending the Option 3 rulemaking, which would revise the T&E requirements under Subparts D and E of 10 CFR Part 35 to include one pathway for a physician to become an AU: certification by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State as meeting the NRC and Agreement State requirements for T&E. The alternate T&E pathways under these subparts would be removed from the regulations some years after implementation of the rule and the new board recognition criteria. To support this regulatory framework of relying solely on certification by medical specialty boards, the NRC would revise the board recognition criteria under these subparts to be less prescriptive, focused on radiation safety competency, and more encompassing of emerging radiopharmaceuticals. The criteria would also require training on written directives, medical event reporting, and patient release criteria. The NRC and Agreement States would periodically audit recognized boards to ensure their continued compliance with the radiation safety training criteria.

The rulemaking would require physicians seeking AU status to be certified by a National Materials Program-recognized medical specialty board—there would be no alternate pathways. Therefore, physicians awaiting board certification would need to work under the supervision of an existing AU until they are board certified. After an AU is initially credentialed, ongoing AU status would be tied to the physician's maintenance of board certification.

Medical specialty boards seeking NRC or Agreement State recognition would need to demonstrate that their training programs meet the revised radiation safety training criteria that would be determined by the NRC (in coordination with the ACMUI and the Agreement States and with input from external stakeholders) during the rulemaking. As part of the rulemaking, the NRC would publish guidance to assist medical specialty boards in developing radiation safety programs that meet the revised board recognition criteria. Because the board certification pathway addresses future physicians, the NRC plans to develop guidance assisting newly recognized specialty board programs in determining whether and how to provide a pathway for their existing board diplomates to become AUs. Existing AUs and recognized medical specialty boards would be grandfathered.

The NRC would no longer review and approve T&E for AUs, and AUs would no longer be listed on licenses. Licensees would no longer submit license amendments regarding AUs; instead, they would be required to maintain a list of their credentialed AUs, a list of the authorized uses by these AUs, and copies of medical specialty board certificates. These items could be subject to review during routine inspections of licensees.

For the Option 3 rulemaking, the NRC would revise the following regulations: 10 CFR 35.190; 35.290; 35.390; 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)"; 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)"; and 35.396, "Training for the Parenteral Administration of Unsealed Byproduct Material Requiring a Written Directive."

Stakeholder feedback during the early stages of rulemaking will determine whether enhancements are needed to 10 CFR 35.27; 35.40, "Written Directives"; 35.41, "Procedures for Administrations Requiring a Written Directive"; and 35.59, "Recentness of Training."

Administrative changes would likely be required for 10 CFR 35.2, "Definitions"; 35.8, "Information Collection Requirements: OMB Approval"; 35.12, "Application for License, Amendment, or Renewal"; 35.13, "License Amendments"; 35.14, "Notifications"; 35.57, "Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Medical Physicist, Authorized User, Nuclear Pharmacist, and Authorized Nuclear Pharmacist"; and 10 CFR Part 35, Subpart L, "Records."

Conforming changes would likely be required for 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," and 10 CFR Part 32, "Specific Domestic Licenses To Manufacture or Transfer Certain Items Containing Byproduct Material."

Description of Rulemaking: Preliminary Backfitting and Issue Finality Analysis

The Commission's backfitting provisions in 10 CFR Parts 50, 70, 72, and 76 and issue finality provisions in 10 CFR Part 52 do not apply to the licensees or proposed AUs that would be affected by this rulemaking amending 10 CFR Part 35. However, under the NRC's Principles of Good Regulation,¹³ the proposed rulemaking change would further promote efficiency, clarity, reliability, and openness. The staff would consider the costs and benefits of the rule as part of the regulatory analysis associated with the rulemaking, as further discussed in the "Description of Rulemaking: Estimate of Resources" section below.

Description of Rulemaking: Estimated Schedule

- Publish advance notice of proposed rulemaking (ANPR)—3 months after decision to initiate rulemaking.
- Publish regulatory basis for comment—12 months after ANPR.
- Publish proposed rule (considering comments on regulatory basis)—12 months after regulatory basis comment period closes.
- Publish final rule—12 months after proposed rule comment period closes.

¹³ The NRC's Principles of Good Regulation are available at <https://www.nrc.gov/about-nrc/values.html#principles>.

All schedules include time to coordinate reviews with the Agreement States and the ACMUI.¹⁴ The staff will continue to look for opportunities to compress these schedules as the work proceeds.

The staff would publish an ANPR to solicit early stakeholder input on certain regulatory issues, such as the high-level board recognition criteria and removal of the alternate pathway, or retention of the current specialty board recognition criteria. While the proposed and final rule would come to the Commission for approval, the staff is recommending that the Commission specifically delegate signature authority for the ANPR to the Executive Director for Operations.

Description of Rulemaking: Preliminary Recommendation on Priority

Based on the Common Prioritization of Rulemaking methodology, updated September 2018 (ADAMS Accession No. ML18263A070), the preliminary priority for the Option 3 rulemaking is medium. The staff determined that the rulemaking will (1) be a moderate contributor towards attaining the NRC's Safety Strategic Goal of ensuring the safe use of radioactive materials, (2) significantly support the NRC's Principles of Good Regulation by increasing efficiency, clarity, reliability, and openness, (3) provide a future regulatory benefit and consider Commission and congressional interest in patient access to radiopharmaceuticals, (4) reduce regulatory burden for licensees and Agreement States, and (5) consider substantial public interest and participation to date in the staff's evaluation of the T&E requirements for radiopharmaceuticals.

Description of Rulemaking: Estimate of Resources

Option 3, as recommended in this paper, is estimated to achieve substantial savings. The savings (averted costs) would be approximately \$2.4 million per year to Agreement States, the NRC, and licensees. The staff estimates that implementation of this rulemaking, including updates to guidance and inspection procedures, recognition of new medical specialty boards, and auditing medical specialty boards, would cost the NRC, the Agreement States, licensees, and medical specialty boards approximately \$7.8 million over several years. The costs for this rulemaking would be significantly offset by the savings (averted costs) to the licensees, Agreement States, and the NRC. Based on this early estimate (subject to further evaluation in the regulatory analysis for the rulemaking), Option 3 is cost-justified.

The rulemaking action is estimated to provide the following benefits:

- *Protection of Public Health and Safety:* Rulemaking would continue to provide for the radiation safety of the general public, workers, and patients in accordance with the NRC's Medical Policy Statement. Requiring AUs to be certified by recognized medical specialty boards and periodic auditing of the boards' radiation safety training programs would continue to ensure appropriate T&E for the safe and secure use of radiopharmaceuticals.
- *Licensing Reviews of AU T&E:* Rulemaking would relieve the NRC and Agreement States of the time and effort required to perform licensing reviews of AU T&E. Using NRC licensee data from the Web-Based Licensing system, it is estimated that the NRC receives about 240 amendment requests related to AU T&E for unsealed byproduct

¹⁴ The Agreement States typically receive 30-90 days to review the draft regulatory basis, proposed rule, and final rule; the ACMUI receives 90 days to review the proposed rule and final rule.

modalities per year, and spends 10 to 100 hours per amendment request (staff used an estimated average of 15 hours per amendment for this early analysis). Because the T&E regulations are Compatibility Category B,¹⁵ the Agreement States' regulatory actions related to T&E likely mirror the NRC's actions. Considering that the NRC regulates 9.5 percent of all medical licensees and Agreement States regulate the remaining 90.5 percent,¹⁶ savings by Agreement States would be significant.

- *Potential New AU Pathways:* Rulemaking would revise the medical specialty board recognition criteria to broaden the radiation safety training topics and better align them with the current practice of diagnostic and therapeutic nuclear medicine, including emerging radiopharmaceuticals. It is expected that revising the board recognition criteria would result in boards outside the fields of nuclear medicine and radiation oncology applying for NRC or Agreement State recognition, providing additional pathways for new types of physicians to become AUs upon completion of their board certificate programs. To date, medical specialties that have expressed interest in radiopharmaceutical therapies targeted to their practice of medicine include urology, hematology, and medical oncology. Recognition of new medical specialty boards could expand the number of AUs and potentially increase the availability of radiopharmaceuticals.
- *Reduction of Regulatory Burden for Licensees:* Rulemaking would relieve 10 CFR 35.100, "Use of Unsealed Byproduct Material for Uptake, Dilution, and Excretion Studies for Which a Written Directive Is Not Required," 35.200, "Use of Unsealed Byproduct Material for Imaging and Localization Studies for Which a Written Directive Is Not Required," and 35.300 licensees of the time and effort required to develop and submit license amendment requests related to AUs. Using NRC licensee data from the Web-Based Licensing system, the staff estimated that these licensees submit an average of 2,500 AU-related amendments for 10 CFR 35.100, 35.200, and 35.300 materials per year. The staff estimated 4.5 hours per amendment to calculate the savings to licensees.

One-time costs associated with Option 3 include notice-and-comment rulemaking and updates to guidance (see Enclosure 6 for estimates); Agreement State implementation of compatible regulations and corresponding NRC regulatory review; licensee implementation of new or updated licensing guidance; medical specialty boards development of radiation safety training programs and application for NRC or Agreement State recognition; and NRC and Agreement State review of new medical specialty boards for recognition. One smaller, ongoing cost for the NRC, Agreement States, and medical specialty boards includes periodic auditing of the specialty boards. The staff also expects that the rulemaking would result in small changes to inspection procedures for nuclear medicine licensees, but these changes would have a marginal impact on NRC and Agreement State inspection resources.

¹⁵ Compatibility Category B— Program elements in Compatibility Category B are those that apply to activities that cross jurisdictional boundaries. These program elements have a particular impact on public health and safety and need to be adopted in an essentially identical manner to ensure uniformity of regulation on a nationwide basis. (Management Directive 5.9, "Adequacy and Compatibility of Program Elements for Agreement State Programs," dated April 26, 2018 (ADAMS Accession No. ML18081A070)).

¹⁶ NRC and Agreement State licensee count data obtained from "Annual Count of Active Radioactive Materials Licenses in the National Materials Program (STC-19-069)," dated October 21, 2019 (ADAMS Accession No. ML19290E330).

The staff also considered the costs and benefits associated with the other options identified in this paper. Option 1, status quo, would have no costs and no savings (averted costs). Option 2, tailored requirements, would entail an additional burden of approximately \$7.5 million to licensees, Agreement States, and the NRC relative to the status quo. There are no savings (averted costs) associated with tailored requirements. Option 4, which is similar to Option 3 but would maintain the alternate pathway, would result in approximately \$500,000 per year in savings (averted costs) to Agreement States, the NRC, and licensees.

Cumulative Effects of Regulation

The staff's preliminary assessment of the cumulative effects of regulation concludes that (1) the rulemaking will reduce regulatory burden for Agreement States and licensees, (2) there are no known activities or affected entities that will significantly impact the implementation of the proposed changes, and (3) the staff will build on the extensive stakeholder engagement conducted as part of the T&E evaluation conducted in response to SRM-M170817 and plans to hold additional public meetings at each step in the rulemaking process.

The staff is currently developing a rulemaking plan for another 10 CFR Part 35 rulemaking effort, "Updates for Emerging Medical Technologies" (Docket ID NRC-2018-0297, which is likely to be proposed to the Commission as a high-priority rulemaking). These efforts are being coordinated, and if the Commission authorizes both rulemaking activities, the staff will evaluate areas of overlap and will optimize application of staff resources and opportunities for stakeholder participation. Combination of the rulemaking activities will be considered, but narrowly scoped rulemakings conducted separately may be more timely, efficient, and effective.

Agreement State Considerations

The staff expects that regulations revised through this rulemaking will be classified as Compatibility Category B. The staff has coordinated with the Agreement States throughout its evaluation of the T&E requirements (see Enclosures 1 and 2), and the staff will continue to work closely with the Agreement States in accordance with SA-801A, "Agreement State Participation in Rulemaking Working Groups," dated January 16, 2019 (ADAMS Accession No. ML18263A239), throughout all stages of rule development.

Guidance

The staff expects that the following documents will be updated in parallel with the rulemaking: (1) NUREG-1556, Volume 9, Revision 3; (2) NRC Form 313A, "Authorized User Training, Experience, and Preceptor Attestation"; (3) Inspection Procedures 87130 and 87131;¹⁷ and (4) guidance available through the NRC's Medical Uses Licensee Toolkit for medical specialty board recognition criteria and procedures for applying for NRC recognition.

Advisory Committee on Reactor Safeguards Review

This review is not required for medical rulemakings.

¹⁷ Inspection Procedure 87130, "Nuclear Medicine Programs, Written Directive Not Required," dated October 24, 2002 (ADAMS Accession No. ML023370121); and "Inspection Procedure 87131, "Nuclear Medicine Programs, Written Directive Required," dated August 24, 2011 (ADAMS Accession No. ML111610509).

Committee to Review Generic Requirements Review

This review is not necessary because the backfit regulations do not apply, as described in the "Backfitting and Issue Finality" section of this rulemaking plan.

Advisory Committee on the Medical Use of Isotopes Review

The staff will continue to coordinate with the ACMUI on this rulemaking. Enclosures 1 and 2 document the ACMUI's engagement and input to date on the staff's evaluation of T&E for radiopharmaceuticals. The ACMUI will review and comment on the staff's regulatory basis, draft proposed rule, and draft final rule. A series of public meetings will be held to discuss the ACMUI's comments and recommendations.

Analysis of Legal Matters

The Office of the General Counsel has reviewed this rulemaking plan and has not identified any issues necessitating a separate legal analysis at this time.

COMMITMENT:

If the Commission approves initiation of the proposed rulemaking, in accordance with SECY-16-0042, "Recommended Improvements for Rulemaking Tracking and Reporting," dated April 4, 2016 (ADAMS Accession No. ML16075A070), the staff will add the rulemaking activity to the agency's rulemaking tracking tool. The staff may include this rulemaking in the fiscal year 2022 common prioritization of rulemaking for planning and tracking purposes only—resources would not be applied to this rule until Commission direction is received.

This paper serves as the periodic Commissioners' Assistant note on the T&E evaluation that is due February 28, 2020, per SRM-M170817.

RECOMMENDATION:

For the reasons provided above, the staff recommends that the Commission approve rulemaking to amend 10 CFR Part 35. Specifically, the staff recommends **Option 3, "National Materials Program-Recognized Specialty Board Credentialing."**

The staff also recommends that the Commission approve its recommendation to delegate signature authority for the ANPR to the Executive Director for Operations.

RESOURCES:

Enclosure 6 includes an estimate of the NRC resources needed to complete this rulemaking. Resource estimates in Enclosure 6 are not publicly available.

COORDINATION:

The Office of the General Counsel has no legal objection to this action. The Office of the Chief Financial Officer has reviewed this paper and has no concerns with the estimated resources in Enclosure 6.



Margaret M. Doane
Executive Director
for Operations

Enclosures:

1. Background Information
2. Summary of Outreach
and Coordination
3. Staff Evaluation
4. Guidance Documents and
Procedures
5. Other Options Considered
6. Estimated Rulemaking
Resources (not publicly available)

RULEMAKING PLAN FOR TRAINING AND EXPERIENCE REQUIREMENTS FOR UNSEALED BYPRODUCT MATERIAL DATED

Ticket Number: OEDO-20-00003

ADAMS Package Accession No.: ML19217A318 *Via e-mail SECY-20-0XX

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