POLICY ISSUE
(Notation Vote)

February 9, 2021 SECY-21-0013

FOR: The Commissioners

FROM: Margaret M. Doane
Executive Director for Operations

SUBJECT: RULEMAKING PLAN TO ESTABLISH REQUIREMENTS FOR RUBIDIUM-82 GENERATORS AND EMERGING MEDICAL TECHNOLOGIES

PURPOSE:

The purpose of this paper is to request Commission approval to initiate a rulemaking that would add requirements to address calibration and dosage measurement for rubidium-82 (Rb-82) generators and establish performance-based requirements for existing and future emerging medical technologies (EMTs). By revising outdated, prescriptive quality assurance regulations with risk-informed, performance-based quality assurance programs, the rulemaking would improve the overall flexibility of the U.S. Nuclear Regulatory Commission's (NRC's) medical regulations in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35, "Medical use of byproduct material," and would better accommodate future EMTs.

SUMMARY:

The NRC uses the term "EMT" to describe any medical technology licensed under 10 CFR 35.1000, "Other medical uses of byproduct material or radiation from byproduct material." Based on close to 20 years of operational experience with EMTs, the staff has identified opportunities for improving the regulatory framework for these other medical uses across the National Materials Program (NMP). The staff evaluated the regulatory issues

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associated with continued licensing of commonly used and well-established EMTs under 10 CFR 35.1000. The staff also evaluated a separate need to establish calibration and dosage measurement requirements for Rb-82 generators, because the design of Rb-82 generators means they cannot meet some detailed aspects of the current regulations. To address potential compliance issues under the current regulations, the staff developed temporary enforcement guidance until a more appropriate and permanent regulatory resolution was implemented.

Based on this evaluation, the staff is providing the Commission with three rulemaking options: (1) address the medical use of Rb-82 generators only; (2) address Rb-82 generators along with a subset of current, well-established EMTs; or (3) address Rb-82 generators along with all current, well-established EMTs, plus create added flexibility throughout 10 CFR Part 35 to accommodate future EMTs.

The staff recommends the third option. In addition to establishing performance-based requirements for Rb-82 generators and all current, well-established EMTs, Option 3 would also broadly examine 10 CFR Part 35 to determine where other outdated, prescriptive requirements could be revised to be more performance-based. The staff's recommended rulemaking option would make 10 CFR Part 35 more inclusive of future EMTs and improve the effectiveness and consistency of medical use licensing across the NMP. It would result in an estimated benefit to the NRC, Agreement States, and licensees of $1.8 million over 10 years after full implementation of the rule.[1]

BACKGROUND:

Rubidium-82 Generators

Rb-82 generators[2] came under the NRC's regulatory jurisdiction after passage of the Energy Policy Act of 2005, which expanded the definition of byproduct material to cover naturally occurring and accelerator-produced radioactive materials.[3] Rb-82 generators produce rubidium-82 chloride, an imaging radiopharmaceutical. The elution, measurement, and administration of Rb-82 are fully automated. However, the short half-life of Rb-82 (76 seconds) and the method of production and administration make its use for imaging significantly different from other imaging products that the NRC currently regulates under Subpart D of 10 CFR Part 35, "Unsealed Byproduct Material—Written Directive Not Required."

Automation prevents licensees from meeting parts of 10 CFR Part 35, Subpart C, "General Technical Requirements"; specifically, (1) the medical use calibration requirements in 10 CFR 35.60, "Possession, use, and calibration of instruments used to measure the activity of unsealed byproduct material," for radiation detectors associated with generator systems and (2) the requirement in 10 CFR 35.63, "Determination of dosages of unsealed byproduct material for medical use," to determine the activity of each dosage administered before medical use.

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1 Benefit-cost values in this paper are net present value, calculated using a real discount rate of 7 percent in accordance with Office of Management and Budget Circular A-94, "Guidelines and Discount Rates for Benefit-Cost Analysis of Federal Programs," issued February 2018, available at https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A94/a094.pdf.

2 A radionuclide generator is a self-contained device housing a parent/daughter radionuclide mixture in equilibrium. All generators have a method of removing the daughter radionuclide and leaving the parent behind to regenerate more daughter activity.

3 See the Energy Policy Act of 2005, Pub. L. 109-58, 42 U.S.C. 15801 et seq. (2005). On October 1, 2007, the NRC published a final rule in Volume 72 of the *Federal Register* (FR), page 55864 (72 FR 55864) amending its regulations to address naturally occurring and accelerator-produced radioactive materials.

Because the design of Rb-82 generators means they cannot meet these current NRC regulatory requirements, the NRC staff may exercise enforcement discretion in certain circumstances. These circumstances are outlined in Enforcement Guidance Memorandum (EGM) 13-003, "Enforcement Guidance Memorandum—Interim Guidance for Dispositioning Violations Involving 10 CFR 35.60 and 10 CFR 35.63 for the Calibration of Instrumentation To Measure the Activity of Rubidium-82 and the Determination of Rubidium-82 Patient Dosages," dated April 18, 2013 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML13101A318). However, because EGMs are considered temporary enforcement guidance under the NRC's Enforcement Policy,[4] EGM 13-003 states that it will "remain effective until the underlying technical issue is dispositioned through rulemaking or other regulatory action." The staff estimates that about 160 NRC and Agreement State licensees are authorized to use Rb-82 generators.

Emerging Medical Technologies

In 2002, the NRC amended 10 CFR Part 35, in part, to add generic requirements for new medical uses of byproduct material or radiation from byproduct material.[5] Subpart K, "Other Medical Uses of Byproduct Material or Radiation from Byproduct Material," or 10 CFR 35.1000, defines the process to obtain a license or license amendment for EMTs. Subpart K allows the NRC and Agreement States to regulate medical uses that are not otherwise addressed in 10 CFR Part 35 in a timely manner and on a case-by-case basis. Under Subpart K, the NRC has the ability to license EMTs using detailed licensing guidance that is specific to the EMT device model, vendor, and use (herein referred to as "EMT licensing guidance"). When sufficient operating experience is acquired and an EMT is no longer considered "emerging," the NRC can establish regulations for the technology elsewhere in 10 CFR Part 35.

A given EMT may need unique provisions for training and experience (T&E) of authorized users, facilities and equipment, or other safety-related considerations that the NRC does not capture in the existing 10 CFR Part 35 subparts.[6] Therefore, the NRC or Agreement States evaluate each radioactive materials license application for an EMT on a case-by-case basis, with input from the Advisory Committee on the Medical Uses of Isotopes (ACMUI), EMT vendors, and the medical community, as appropriate, to determine the specific risks associated with the EMT and any additional regulatory requirements needed for its medical use. EMT licensing guidance can be informed by vendor documents but does not endorse vendor documents. EMT licensing guidance consists of general licensing considerations, specific radiation safety aspects of the EMT, and T&E expectations for those authorized to use the technology.

EMT licensing guidance is often prescriptive, covering a broad range of medical use issues and scenarios, and, depending on the technology and uses proposed by the licensee, may include detail beyond what the provisions in other 10 CFR Part 35 subparts might prescribe for those existing medical uses. EMT licensing guidance provides applicants with an acceptable means to satisfy the requirements for a license for the EMT, but the NRC does not intend that guidance to be the only means for satisfying the requirements, and the guidance is not binding on licensees. Therefore, during licensing to approve use of an EMT, the NRC issues license

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4 "NRC Enforcement Policy," dated January 15, 2020 (ADAMS Accession No. ML19352E921).

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

6 10 CFR Part 35, Subpart D, as well as Subpart E, "Unsealed Byproduct Material—Written Directive Required"; Subpart F, "Manual Brachytherapy"; Subpart G, "Sealed Sources for Diagnosis"; Subpart H, "Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units."

conditions for applicants who commit to following the EMT licensing guidance, making the guidance a requirement for licensees.

Since its issuance in 2002, the Subpart K regulatory framework has enabled the NRC and Agreement States to conduct timely licensing of 14 EMTs. Some EMTs, such as yttrium-90 (Y-90) microspheres and newer generations of gamma stereotactic radiosurgery (GSR) units, are frequently licensed and widely used in the medical community, whereas other EMTs are less commonly used. The NRC is currently developing EMT licensing guidance for two EMTs, and the staff expects to develop EMT licensing guidance for several additional EMTs in the near term. As described above, each of these new EMTs will be individually reviewed for its specific safety considerations, and the NRC or Agreement States will develop model- and vendor-specific EMT licensing guidance to assist applicants and license reviewers in authorizing use of the EMTs. The NRC has issued EMT licensing guidance more than two dozen times since 2002, including revisions to address small changes in the devices, administrations, and T&E requirements. The Medical Uses Licensee Toolkit[7] on the NRC Web site lists EMTs the agency has previously evaluated and licensed and their associated licensing guidance.

Gamma Stereotactic Radiosurgery Units

The NRC developed regulations in 10 CFR Part 35, Subpart H (10 CFR 35.600, "Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit"), in 2002 for the Leksell Gamma Knife® model in use at that time, a GSR unit that treats the brain using stationary sources, helmet collimators, and a head frame. Since then, newer generation GSR units have been manufactured with engineering changes not addressed by Subpart H, and the basis for some requirements, such as "physical presence" of the authorized user, no longer applies. Very few GSR units currently installed in the United States are licensed under 10 CFR 35.600, and the staff expects that, in the near term, it will need to license all installed GSR units under 10 CFR 35.1000. Since 2007, the staff has developed EMT licensing guidance specific to the model and vendor of four GSR units. The staff is currently developing guidance for another model and vendor and is aware of three more vendors in various developmental stages, for which additional EMT licensing guidance would need to be developed.[8]

Y-90 Microspheres

Y-90 microspheres are used for permanent implantation therapy. They have unique hybrid[9] properties—including their small size, the large number of microspheres used in a treatment, and the route of administration (injection through tubing)—that prevent them from fitting under the requirements of either 10 CFR Part 35, Subpart F (manual brachytherapy) or Subpart E (radiopharmaceutical therapy). The NRC staff first developed licensing guidance for Y-90 microspheres in 2002 and has issued 10 revisions to the guidance. The staff is aware of three new microsphere vendors whose technologies would need to be licensed under 10 CFR 35.1000.

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7 The NRC's Medical Uses Licensee Toolkit is designed to help medical licensees easily find key information and submit medical-related inquiries: https://www.nrc.gov/materials/miau/med-use-toolkit/emerg-licensed-med-tech.html.

8 The NRC has issued licensing guidance for the Viewray™ System, Leksell Gamma Knife® Perfexion™, Leksell Gamma Knife® Icon™, and Xcision® GammaPod™. The NRC staff is currently developing EMT licensing guidance for the MASEP Infini®.

9 "Hybrid EMTs" refers to EMTs that have essential characteristics of two or more medical uses as described in the current 10 CFR Part 35 medical use subparts.

DISCUSSION:

Title

"Establishment of Requirements for Rubidium-82 Generators and Emerging Medical Technologies."

Regulation

10 CFR Part 35.

Regulatory Issue

Rubidium-82 Generators

As discussed in the "Background" section, the NRC staff may exercise enforcement discretion in certain circumstances through EGM 13-003 because it is not possible for Rb-82 generators to meet the current requirements in 10 CFR 35.60 and 10 CFR 35.63.

Emerging Medical Technologies

As discussed above in the "Background" section, because EMTs are not addressed in the other medical use subparts of 10 CFR Part 35, EMT licensing guidance is developed by the NRC or Agreement States and is relied upon to assist licensees and applicants in their submission of licensing information required by 10 CFR 35.12(d).[10] While 10 CFR 35.1000 has proven to be a flexible way to timely review and license new EMTs, the continued licensing of well-established EMTs under 10 CFR 35.1000 provides no regulatory benefit. Furthermore, the basis for licensing EMTs is established through license conditions rather than regulations, which was identified as a problem and addressed for other well-established EMTs in the 10 CFR Part 35 final rulemaking in 2002.[11] With sufficient operating experience, EMTs that are no longer considered "emerging" can be moved out of 10 CFR 35.1000 and their regulations can be established in existing or new medical use subparts in 10 CFR Part 35. Continued licensing of commonly used and now well-established EMTs under 10 CFR 35.1000 could create the following regulatory issues:

- Implementation of EMT licensing guidance is subject to individual interpretation by regulators, and the EMT licensing guidance is not legally binding until it is incorporated into a license through a condition. Furthermore, EMT licensing guidance is Compatibility Category C, which could create inconsistency in applying some program elements—such as T&E requirements for authorized users and medical event reporting, which are Compatibility Category B for technologies licensed under the other subparts of

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10 10 CFR 35.12, "Application for license, amendment, or renewal."

11 The final regulatory analysis for the 2002 rulemaking for 10 CFR Part 35 states, "NRC has identified the following six problems require revisions to 10 CFR Part 35…[R]evisions are needed to place the basis for regulation of certain well-established technologies into 10 CFR Part 35. Specifically, the regulations in 10 CFR Part 35 currently do not address high dose-rate remote brachytherapy, low dose-rate remote brachytherapy, pulsed dose-rate remote brachytherapy, and gamma stereotactic radiosurgery. The regulatory basis for these technologies is currently established by license conditions rather than regulations." (SECY-00-0118, Final Rules – 10 CFR Part 35, "Medical Use of Byproduct Material" and 10 CFR Part 20, "Standards for Protection Against Radiation," May 31, 2000).

10 CFR Part 35.[12] This compatibility issue has already been raised by Agreement States, and the NRC recently responded to a request from the Organization of Agreement States for clarification on two regulatory topics addressed in EMT licensing guidance: (1) T&E for Y-90 microspheres, and (2) use of safety evaluation reports as license conditions for the Radiogenix™ generator system.[13] While less regulatory certainty is acceptable for licensing new EMTs under 10 CFR 35.1000, establishing regulations for well-established EMTs would promote consistency, compatibility, and efficiency across NMP licensing and inspection, and would improve clarity.

- The current 10 CFR 35.1000 licensing process facilitates timely review of new EMTs to support patient care, but it is not set up to incorporate public feedback once sufficient operating experience exists.[14] This rulemaking would include opportunities for public feedback, including the notice-and-comment period required by the Administrative Procedure Act, on the EMTs that are now well understood.

- Developing and frequently updating EMT licensing guidance can be time- and resource-intensive for the NRC and Agreement States. EMT licensing guidance is model- and vendor-specific, so each new model or vendor of even a similar type of technology needs a new guidance document. For example, as noted above, the staff is aware of several new models and vendors of GSR units and microsphere EMTs on the horizon that would each require new EMT licensing guidance given the specificity in the current guidance. Furthermore, EMT licensing guidance is updated more frequently than other medical use guidance documents (e.g., the generic regulatory guidance in NUREG-1556, Volume 9).[15] The NRC has revised the original guidance documents for some EMTs several times to adopt small changes in the devices, administrations, and T&E requirements. Performance-based regulations that focus on the essential safety-related elements of EMT licensing guidance would obviate the need to write new EMT licensing guidance for new models or vendors of existing EMTs and the need to update outdated EMT licensing guidance.

Future Emerging Medical Technologies

The NRC defined the existing medical uses in 10 CFR Part 35, Subparts D through H, in 2002, and now almost 20 years later, some aspects are outdated or even obsolete. The staff is aware of several new EMTs, including hybrid EMTs, under various stages of development. The NRC would likely need to license these future EMTs under 10 CFR 35.1000 given their unique characteristics, special safety considerations, and T&E expectations. Revising the requirements in the existing medical use subparts of 10 CFR Part 35 to be less prescriptive and more performance-based could allow the NRC to license many of these new EMTs with less reliance

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12 Compatibility Category C means that Agreement States should adopt the essential objectives of the provisions in the EMT licensing guidance, but they do *not* have to adopt them "essentially as written." Compatibility Category B means that Agreement States must adopt these requirements in an essentially identical manner. Management Directive 5.9, "Adequacy and Compatibility of Program Elements for Agreement State Programs," dated April 26, 2018 (ADAMS Accession No. ML18081A070), describes compatibility categories.

13 State and Tribal Communication 20-049, "Responses to the Organization of Agreement States Requests Regarding Clarification of Compatibility Categories for Medical Licensing Guidance Documents; and Use of Safety Evaluation Reports as a Legally Binding Requirement," dated June 30, 2020 (ADAMS Accession No. ML20178A610).

14 The NRC staff provides draft licensing guidance to the Agreement States and the ACMUI for comment.

15 NUREG 1556, "Consolidated Guidance About Materials Licenses," Volume 9, "Program Specific Guidance About Medical Use Licenses," Revision 3, issued September 2019 (ADAMS Accession No. ML19256C219).

on 10 CFR 35.1000, and would improve the overall applicability of 10 CFR Part 35 for expected future medical uses of byproduct material. The following are examples of new EMTs that currently would require licensing under 10 CFR 35.1000:

- novel designs within manual brachytherapy, such as "unsealed" sealed sources like Radiogel™, which uses insoluble Y-90 in a gel form delivered by needle into solid tumors, and AlphaDaRT seeds, which are implanted in the tumor and leak short-lived alpha particles; new ophthalmic and dermatologic sources either superficially applied or temporarily implanted; and resurgence of intravascular brachytherapy technologies;

- "radiotheranostics" that merge molecular-targeted diagnostic imaging agents with molecular-targeted radiopharmaceutical therapy;[16]

- internally applied, sealed sources for diagnosis, such as the Check-Cap C-Scan technology, an ingestible capsule containing byproduct material that screens for colorectal cancer; and

- generator systems using novel radionuclides (e.g., titanium-44/scandium-44 and zinc-62/copper-62) or novel methods for separation of parent/daughter radionuclides.

Existing Regulatory Framework

Rubidium-82 Generators

Rb-82 generators are licensed under 10 CFR 35.200, "Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required," and are subject to the requirements in 10 CFR 35.204, "Permissible molybdenum-99, strontium-82, and strontium-85 concentrations." Under these requirements, Rb-82 generator licensees must measure for permissible concentrations of strontium-82 and strontium-85 in generator eluant and report any measurement that exceeds the permissible concentrations. Rb-82 generators are inspected at 5-year intervals.[17]

EGM 13-003 addresses how the NRC staff could disposition violations of 10 CFR 35.60 and 10 CFR 35.63 requirements by Rb-82 generator licensees, if certain criteria are met. Accordingly, the staff may exercise enforcement discretion if licensees meet three criteria detailed in the EGM: (1) the licensee has written test procedures for the radiation detector, (2) all authorized users and radiation safety officers complete specific training, and (3) the licensee records the activity for each administered dosage. If the licensee does not meet all three criteria, the staff will follow the normal enforcement process. This EGM is applicable for both initial and subsequent inspections provided that all the criteria continue to be met.

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16 Radiotheranostics is a rapidly evolving field that likely will involve additional radiation safety considerations, including higher radiation doses, more complex dose calculations that may require the involvement of an authorized medical physicist before and during the treatment, shielded facilities and equipment, whether certain extravasations should be reported as medical events, and special patient release instructions.

17 Inspection frequency is documented in Inspection Manual Chapter 2800, "Materials Inspection Program," issued September 2017 (ADAMS Accession No. ML17186A204).

Emerging Medical Technologies

The regulatory requirements and licensing process for EMTs are in 10 CFR 35.1000, while 10 CFR 35.12(d) includes the specific information licensees and applicants must provide to the NRC in support of an application for use under 10 CFR 35.1000. Under 10 CFR 35.1000, they must also submit the information required by 10 CFR 35.12(b) and (c).

Model- and vendor-specific EMT licensing guidance assists licensees and applicants in their submission of licensing information required by 10 CFR 35.12(d). EMT licensing guidance also guides the NRC and Agreement State staff in their reviews of EMT license applications and amendments. NUREG-1556, Volume 9, also assists licensees and applicants in submitting the information to support an application or amendment for an EMT. Licensees and applicants can use NRC Form 313, "Application for Materials License," and the NRC Form 313A series for authorized individual T&E to list information related to T&E, facilities and equipment, radiation safety programs, and waste management.[18]

When licensing guidance, rather than regulations, is used to inform licensing of EMTs, licenses and license amendments authorizing use of EMTs contain license conditions to make referenced guidance legally binding. EMTs are inspected at 2 year intervals, while diagnostic uses under 10 CFR 35.1000 are inspected at 5 year intervals.

Explanation of Why Rulemaking Is the Preferred Solution

In its evaluation of the current 10 CFR Part 35 regulatory framework, the staff considered maintaining the status quo and several rulemaking options. The following factors apply to each of the three rulemaking options listed below: (1) 10 CFR Part 35 would be revised to address Rb-82 generators; (2) the costs associated with processing exemptions for Rb-82 generators (required absent EGM 13-003) would be avoided; (3) NUREG-1556, Volume 9, and other applicable generic guidance documents would be updated as needed; and (4) 10 CFR 35.1000 would remain unchanged and available to address future EMTs as needed. In addition, the staff would ensure that newly established performance-based requirements provide appropriate flexibility to address evolutions in approved EMTs over time.

Additional Approaches Evaluated but Not Included for Further Consideration

The staff evaluated maintaining the status quo, which would mean using a non-rulemaking option for addressing Rb-82 generators. However, longstanding reliance on temporary enforcement guidance to exercise enforcement discretion is inconsistent with NRC Enforcement Policy and is not a substitute for resolving the underlying technical issues associated with calibration and dosage measurement for Rb-82 generators. Without rulemaking, about 160 NRC and Agreement State licensees would need to apply for exemptions from 10 CFR 35.60 and 10 CFR 35.63 to continue use of these generators after the EGM is retired. Processing exemptions would cost Agreement States, the NRC, and licensees approximately $600,000 over 3 years (the expected implementation period for all existing generators). The staff did not include this option for Commission consideration because continuous and widespread use of exemptions or temporary enforcement guidance would not be an effective means of implementing the authority provided under the Energy Policy Act of 2005 for Rb-82 generators.

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[18] The 313 and 313A series of NRC forms provide a suitable format for licensees and applicants to document required licensing information and T&E for authorized individuals. The NRC maintains these forms on its "Forms" Web site at https://www.nrc.gov/reading-rm/doc-collections/forms/.

Rather, the establishment of appropriate regulatory requirements for Rb-82 generators would eliminate the inherent compliance issues that exist today, and would provide a more efficient, clear, and reliable regulatory framework for these generators.

In addition, considering the rapidly advancing field of nuclear medicine, the staff contemplated a transformative rulemaking that would replace the entire 10 CFR Part 35 framework—which is based on medical uses that were defined in 2002 and prescriptive T&E requirements—with a new framework that could better position the NMP for future medical uses of byproduct material. However, the staff did not include this option for Commission consideration because (1) there is no external driver or known support from the stakeholder community for a restructuring of 10 CFR Part 35, and (2) it would be a lengthy, resource-intensive, and potentially controversial rulemaking that would delay addressing the more immediate regulatory needs for Rb-82 generators and certain EMTs.

Finally, the staff considered ways that it could make the current EMT licensing guidance process less prescriptive, without the need for a rulemaking to change 10 CFR Part 35. For example, license conditions could be focused on the essential safety elements of the EMT licensing guidance. While this approach would make the licensing requirements less prescriptive, it would continue to necessitate model- and vendor-specific EMT licensing guidance for each new EMT and would not represent a resource savings. In addition, the EMT licensing guidance for well-established technologies (i.e., Y-90 microspheres and GSR units) could be revised to be less prescriptive, more performance-based, and applicable to the technology generally rather than to a specific EMT model and vendor. However, the resources needed to generalize existing EMT licensing guidance and develop this type of generalized guidance going forward would likely surpass the resources needed to continue to update existing EMT licensing guidance and develop new model- and vendor-specific EMT licensing guidance. More importantly, neither of these potential approaches would address the underlying regulatory issues associated with continued licensing of well-established EMTs under 10 CFR 35.1000, nor the staff's recommendation to revise 10 CFR Part 35 to be less prescriptive, more performance-based, and thus inclusive of future medical uses.

Option 1—Rulemaking Only for Rb-82 Generators

This rulemaking would solely address calibration and dosage measurement requirements for Rb-82 generators. It would not result in any changes related to EMTs. The staff considered whether this rulemaking could be accomplished through a direct final rule; however, because the revisions would expand on criteria in EGM 13-003, there could be public interest such that the standard notice-and-comment rulemaking process more appropriate.

Pros:

- A rulemaking for Rb-82 generators would remove the need for licensees to submit exemption requests for 10 CFR 35.60 and 10 CFR 35.63 (which would be required absent EGM 13-003). This change would avert the associated application and exemption review costs; however, the staff did not quantify these averted costs because they are common to all three options.

- A rulemaking would provide opportunity for public comment on calibration and dosage measurement requirements for Rb-82 generators, and would improve regulatory openness, efficiency, clarity, and reliability for these generators.

- By focusing only on the immediate regulatory needs of Rb-82 generators, this rulemaking would be comparatively less resource intensive and could be completed in less time than the other options.

Cons:

- The NRC would continue to license EMTs with extensive operating experience using guidance, without the benefit of public feedback on these established technologies.

- Compatibility issues and inconsistency in guidance implementation for EMTs would continue across the NMP.

- Regulators and licensees would need continued resources to develop, maintain, and use 10 CFR 35.1000 licensing guidance, which is updated more frequently than other medical use guidance.

- Option 1 has a one-time cost of $3.2 million for the NRC and Agreement States to conduct the rulemaking and implement the new rule, and the lowest long-term operational savings.

Option 2—Limited Scope Rulemaking to Establish Requirements for Rb-82 Generators and Certain Emerging Medical Technologies

In addition to Rb-82 generators, this limited-scope rulemaking would address GSR units and microspheres. These EMTs are well established and commonly used. Option 2 would amend 10 CFR Part 35 such that current and future GSR units could be licensed under 10 CFR 35.600 (Subpart H), and the NRC would develop a new subpart for current and future microsphere technologies.[19] Rule language would be performance-based, focusing on intended functions and outcomes rather than prescriptive requirements. For example, outdated requirements to test helmet microswitches and trunnions that no longer exist in newer generation GSRs would be replaced with testing requirements for functional items (e.g., dose delivery accuracy and positional accuracy). Risk-informed requirements would be consistent with nationally recognized standards and recommendations by medical professional societies such as the American Association of Physicists in Medicine. The rule would accommodate device updates and T&E changes for GSR units and microspheres as well as the licensing of potential new models and vendors of these technologies.

Pros:

- Option 2 would maintain safety while increasing regulatory openness, consistency, clarity, and reliability for commonly used EMTs and Rb-82 generators.

- This option would focus NRC and Agreement State rulemaking resources on widely used, well-established EMTs with expected continued use. It would also resolve Rb-82 generator issues discussed under Option 1.

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[19] Current GSR units include Leksell Gamma Knife® Perfexion™, Leksell Gamma Knife® Icon™, Xcision® GammaPod™, MASEP Infini®, and ViewRay™ System. Current microsphere EMTs include TheraSphere®, SIR-Spheres®, and OncoSil.

- A rulemaking would provide an opportunity for public comment on licensing requirements for these well-established EMTs.

- The establishment of licensing requirements for commonly used EMTs would improve regulatory consistency and resolve compatibility issues for these medical uses across the NMP.

- Option 2 would decrease licensing costs for licensees and regulators, resulting in an estimated net benefit of $1.6 million over 10 years (full implementation of the rule by the NRC and Agreement States). The NRC would no longer develop or update EMT licensing guidance for these technologies because the rule would accommodate device updates, T&E changes, and new models and vendors. Regulators and licensees would realize increased licensing efficiencies for GSR units and microspheres.

Cons:

- The NRC would still require licensing under 10 CFR 35.1000 for other well-established EMTs that are excluded from this option, missing out on the regulatory benefits and efficiencies associated with establishing regulations for these technologies.

- As detailed in the "Estimated Resources" section below, the Option 2 rulemaking would require more time and resources than Option 1.

Option 3—Performance-Based Rulemaking to Increase Regulatory Flexibility

Option 3 is an expanded version of the Option 2 rulemaking. In addition to developing performance-based requirements for Rb-82 generators, GSR units, and microspheres, the staff would evaluate how to make additional sections of 10 CFR Part 35 more flexible. Option 3 would revise specificities in the general requirements, medical uses, records, and reports subparts. The revised requirements would be more generic and more performance-based (focusing on intended functions and outcomes rather than prescriptive requirements) and would enable licensing of all approved EMTs, future updates to currently licensed EMTs, and potentially even new hybrid EMTs. 10 CFR 35.1000 would remain available for EMTs that would not fit under the revised medical use subparts. Similar to Option 2 but on a larger scale, Option 3 would replace outdated, prescriptive quality assurance regulations with risk-informed, performance-based quality assurance programs. These programs would be consistent with nationally recognized standards and current recommendations by medical professional societies, such as the American Association of Physicists in Medicine. The staff would request early stakeholder input by holding public meetings and developing a regulatory basis.

Pros:

- Option 3 has similar pros as Option 2 but on a larger scale: it would maintain safety while increasing regulatory openness, consistency (e.g., from the implementation of regulations across the NMP rather than use of licensing guidance), clarity, reliability, public participation, and efficiency.

- Option 3 would reduce reliance on 10 CFR 35.1000 by developing performance-based requirements for well-established EMTs that would accommodate updated or new EMT models, new vendors, and new hybrid technologies.

- Option 3 would provide the greatest resource savings by decreasing licensing costs for licensees and regulators, resulting in an estimated net benefit of $1.8 million over 10 years (full implementation of the rule by the NRC and Agreement States).

Cons:

- The medical community has a good understanding of the current licensing framework for EMTs; therefore, not all stakeholders may fully support changing this framework significantly under the Option 3 rulemaking.

- As detailed in the "Description of Rulemaking: Estimated Resources" section and in the enclosure (not publicly available), Option 3 would be the most resource-intensive rulemaking and would require the most time to complete of the three options.

The staff recommends Option 3, "Performance-Based Rulemaking to Increase Regulatory Flexibility." The Option 3 rulemaking would provide an opportunity for greater performance-based regulation of existing and potentially new EMTs. Rather than regulating each EMT and use on a case-by-case basis through license conditions that make prescriptive EMT licensing guidance legally binding, the revised regulations and accompanying generic guidance would focus on only the essential performance-based requirements necessary to protect radiation safety for workers, the general public, and patients.

Description of Rulemaking: Scope

The staff would evaluate the existing 10 CFR Part 35 subparts to determine where more performance-based requirements could replace general and specific medical use requirements. The staff also expects to create a new 10 CFR Part 35 subpart to address microspheres. The new subpart would establish requirements to address the essential objectives of the current Y-90 microspheres licensing guidance[20] while accommodating additional microsphere vendors and potentially other microsphere-type EMTs.

This rulemaking could revise many sections of 10 CFR Part 35, including (but not limited to) T&E for authorized individuals, written directives, operating procedures, equipment calibrations, medical event reporting, and radiation protection programs. Performance-based revisions to the applicable subparts, incorporation of risk-informed recommendations by medical professional societies, and creation of a new subpart for microspheres would permit licensing of existing and potentially future EMTs, even those with hybrid-like characteristics, to be completed with less reliance on 10 CFR 35.1000.

Conforming changes may be needed for 10 CFR Part 35, Subpart A, "General Information"; 10 CFR Part 30; 10 CFR Part 32, "Specific domestic licenses to manufacture or transfer certain items containing byproduct material"; 10 CFR Part 40, "Domestic licensing of source material"; and 10 CFR Part 150, "Exemptions and continued regulatory authority in Agreement States and in offshore waters under section 274."

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[20] "Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance," Revision 10.1, dated March 20, 2020 (ADAMS Accession No. ML20080J208).

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, "Licenses, certifications, and approvals for nuclear power plants," do not apply to the applicants or licensees that would be affected by this rulemaking amending 10 CFR Part 35. However, according to the NRC's Principles of Good Regulation, the proposed rulemaking would further promote openness, efficiency, clarity, and reliability by providing a flexible regulatory framework for licensing actions currently addressed through detailed guidance documents, as well as by resolving the Rb-82 issue that is currently addressed through enforcement discretion. 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 for Option 3

The staff estimates the following schedule for Option 3:

- Publish the regulatory basis for comment—approximately 14 months after the Commission issued its decision, if it approves the rulemaking.[21]

- Submit the proposed rule and draft guidance documents (with consideration of comments on the regulatory basis) to the Commission—14 months after the regulatory basis comment period closes.

- Submit the final rule and final guidance documents (with consideration of comments on the proposed rule and draft guidance) to the Commission—14 months after the proposed rule comment period closes.

This schedule includes time to coordinate reviews with the Agreement States and the ACMUI. The Agreement States typically receive 30 to 90 days to review the regulatory basis and proposed and final rule packages (including guidance documents). The ACMUI receives at least 60 days to review the regulatory basis and 90 days to review the proposed and final rule packages. Consistent with its plans for rulemaking innovation,[22] the staff will continue to look for opportunities to increase efficiency as the work proceeds.

Description of Rulemaking: Preliminary Recommendation on Priority

Based on the Common Prioritization of Rulemaking methodology, updated in September 2018 (ADAMS Accession No. ML18263A070), the preliminary priority for the Option 3 rulemaking is medium (30 points). The staff evaluated the rulemaking's impacts as follows:

- medium contributor toward the NRC's strategic plan goals by implementing the following four safety goal strategies: (1) maintain and enhance the NRC's medical uses regulatory program, using information gained from operating experience, lessons learned, and advances in nuclear medicine, (2) further risk-inform the current medical regulatory framework in response to advances in nuclear medicine and prioritize efforts

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21 The tracked action will be transmittal of the regulatory basis to the Commission for awareness; after 10 days, the staff would publish the regulatory basis for comment.

22 "Rulemaking Process Innovation at the U.S. Nuclear Regulatory Commission," issued July 2020 (ADAMS Accession No. ML20198M408).

to focus on the most safety-significant issues, (3) maintain effective and consistent oversight of medical uses licensees with a focus on the most safety-significant issues, and (4) maintain material safety through the NMP in partnership with the Agreement States;

- high contributor toward the NRC's Principles of Good Regulation by implementing four principles: increased openness through public comment on the rulemaking setting Rb-82 and EMT requirements, and increased efficiency, clarity, and reliability by establishing performance-based requirements for EMTs and addressing regulatory issues for Rb-82 generators;

- medium contributor toward the governmental priority by (1) addressing regulatory issues for Rb-82 generators, (2) supporting the NRC's risk-informed licensing initiative, and (3) creating a future regulatory benefit for EMTs; and

- medium contributor toward the public priority, because it would likely garner considerable interest from the medical community given the increased licensing efficiencies and reduced regulatory burden.

Description of Rulemaking: Estimate of Resources

The staff developed a preliminary cost-benefit analysis to support the weighing of options in this paper. Option 3, as recommended in this paper, is estimated to achieve a net benefit of $1.8 million considering the costs and averted costs. Based on this preliminary estimate (subject to further evaluation in the regulatory analysis for rulemaking), Option 3 is cost justified.

The NRC, Agreement States, applicants, and licensees would save approximately $6.3 million over 10 years (full implementation of the rule by the NRC and Agreement States), realizing a 25- to 50-percent reduction in the resources needed to complete EMT licensing actions. In addition, the Option 3 rulemaking action would provide the following qualitative benefits:

- *Protection of Public Health and Safety*: The rulemaking would continue to provide for the radiation safety of the general public, workers, and patients in accordance with the NRC's Medical Use Policy Statement.[23] Increased regulatory openness, consistency, clarity, and reliability would improve oversight of medical licensees across the NMP. Consideration of industry and professional standards that define acceptable approaches for achieving radiation safety would risk-inform the revised regulations.

- *Increased Regulatory Effectiveness and Efficiency*: The rulemaking would close existing regulatory gaps, increase the overall effectiveness and efficiency of licensing requirements for Rb-82 generators and well-established EMTs, and improve the quality and timeliness of license application or amendment reviews.

- *Future Regulatory Benefit*: The NRC could license updates to existing EMTs, including new models and vendors, and possibly future new EMTs, under the revised regulations with less reliance on 10 CFR 35.1000.

One-time costs associated with Option 3 include the rulemaking process and revising generic guidance documents such as NUREG-1556, Volume 9, and inspection procedures (as outlined

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

in the enclosure to this paper), adoption of the new regulations by the Agreement States, and the NRC staff's regulatory review of revised Agreement State regulations. The staff estimates these activities would cost the NRC, Agreement States, and licensees approximately $4.5 million.

The staff also considered the costs and benefits associated with Options 1 and 2. Option 1, a rulemaking just for Rb-82 generators, would involve one-time costs for the NRC, Agreement States, and licensees associated with rulemaking and implementing the new rule of approximately $3.2 million. Beyond avoiding the costs associated with processing exemptions if the status quo is maintained (which is an averted cost common to all three rulemaking options and therefore not included in the estimates in this section as a decisionmaking criterion), no additional savings are associated with Option 1 because it does not address EMTs. The Option 2 rulemaking, limited to addressing Rb-82 generators, GSR units, and microspheres, would involve one-time costs of approximately $3.7 million for the NRC, Agreement States, and licensees associated with rulemaking and implementing the new rule. However, Option 2 would result in approximately $5.3 million in savings to the Agreement States, the NRC, and licensees over 10 years (full implementation of the rule). Based on the staff's preliminary estimate, Option 2 would also be cost justified. Options 2 and 3 provide similar benefits; however, the benefits associated with Option 3 extend to other existing EMTs and potential future EMTs.

Cumulative Effects of Regulation

The staff's preliminary assessment of the cumulative effects of regulation concludes that no known activities or affected entities will be significantly impacted by implementing the proposed changes. To ensure adequate identification of potential effects not currently foreseen, the staff plans to solicit medical community, Agreement State, and ACMUI input on this issue during the regulatory basis, proposed rule, and final rule phases of this rulemaking. The staff has identified two additional potential rulemakings for 10 CFR Part 35:

(1) On January 13, 2020, the staff submitted for Commission consideration SECY-20-0005, "Rulemaking Plan for Training and Experience Requirements for Unsealed Byproduct Material (10 CFR Part 35)" (ADAMS Accession No. ML19217A318).

(2) On June 5, 2020, the staff docketed Petition for Rulemaking-35-22 (ADAMS Accession No. ML20157A266), requesting that the NRC revise its regulations to require reporting of certain nuclear medicine injection extravasations as medical events. The staff is currently evaluating this petition and plans to provide a recommendation to the Commission on its merits no later than calendar year 2022.

The NRC staff is coordinating these efforts related to 10 CFR Part 35. If the Commission authorizes more than one 10 CFR Part 35 rulemaking activity, the staff will evaluate areas of overlap and optimize application of staff resources and opportunities for stakeholder participation. Combining rulemaking activities may be more timely, efficient, and effective.

Agreement State Considerations

Agreement States would need to adopt compatible regulations for the revised or new subparts that would be affected by this proposed rulemaking. The staff has coordinated with the Agreement States in the development of this rulemaking plan. An Agreement State representative participated in the rulemaking plan working group. The staff provided the Agreement States 45 days to review and comment on a draft of the plan, and the NRC has

considered their comments in finalizing the contents.[24] If the Commission approves the rulemaking, the staff would continue to work with the Agreement States throughout all stages of rule development, in accordance with SA-801A, "Agreement State Participation in Rulemaking Working Groups," dated January 16, 2019 (ADAMS Accession No. ML18263A239).

Guidance

The staff expects that it would update the following documents in parallel with the rulemaking: (1) NUREG-1556, Volume 9, Revision 3, and (2) Inspection Manual Chapter 2800 and associated inspection procedures applicable to medical use licensees. The staff would also evaluate the need to revise NUREG-1757, "Consolidated Decommissioning Guidance," Volume 3, "Financial Assurance, Recordkeeping, and Timeliness," Revision 1, issued February 2012 (ADAMS Accession No. ML12048A683).

Advisory Committee on Reactor Safeguards Review

This review is not required for medical rulemakings.

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 coordinate with the ACMUI on this rulemaking. The ACMUI will review and comment on the staff's regulatory basis, draft proposed rule, and draft final rule. The staff will hold a series of public meetings 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 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 use the resources allocated in the fiscal year 2021 and fiscal year 2022 budgets. If the Commission does not approve the rulemaking, the resources will be reallocated to other approved rulemaking actions in accordance with the planning, budgeting, and performance management process.

RECOMMENDATION:

For the reasons provided above, the staff recommends that the Commission approve the rulemaking to amend 10 CFR Part 35 under Option 3.

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[24] Comment letters from the Organization of Agreement States and the State of Wisconsin are available at ADAMS Accession Nos. ML20324A745 and ML20324A743, respectively.

RESOURCES:

The enclosure includes an estimate of the NRC resources needed to complete this rulemaking. The enclosure is not publicly available because it provides nonpublic budget information for fiscal year 2021 and beyond.

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 the enclosure.

Margaret M. Doane

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Date: 2021.02.09 16:46:45 -05'00'

Margaret M. Doane
Executive Director
for Operations

Enclosure:
Estimated Rulemaking Resources
(Non-publicly available)

RULEMAKING PLAN TO ESTABLISH REQUIREMENTS FOR RUBIDIUM-82 GENERATORS AND EMERGING MEDICAL TECHNOLOGIES DATED February 9, 2021

ADAMS Package Accession No. ML20337A401 *Via e-mail SECY-21-0013

OFFICE	REFS/MRPB:PM*	REFS/MRPB:RS*	MSST/MSEB:TL*	MSST/MSEB:BC*
NAME	CKenny	ALoveBlair	LDimmick	CEinberg
DATE	9/3/2020	9/2/2020	9/3/2020	9/4/2020
OFFICE	NMSS/RASB:BC*	NMSS/MRPB:BC*	NMSS/MSST:D*	NMSS/REFS:D*
NAME	CBladey	JCai	TClark	KCoyne
DATE	9/14/2020	9/10/2020	10/2/2020	10/2/2020
OFFICE	Region I/DNMS*	Region III/DNMS*	Region IV/DNMS*	OCFO*
NAME	BWelling	DPelton	BTharakan	JJohnson
DATE	10/2/2020	09/30/2020	10/2/2020	10/26/2020
OFFICE	OCIO*	OGC*	QTE*	MSST/MSEB:PM*
NAME	DCullison	MSegarnick	JDougherty	SLopas
DATE	10/26/2020	1/29/2020	11/2/2020	1/29/2020
OFFICE	OE*	NMSS*	EDO	
NAME	JPeralta	RLewis	MDoane	
DATE	12/2/2020	12/8/2020	02/09/21	

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