NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

[NRC–2025–1237]

RIN 3150–AL50

Reducing Barriers to Medical Use Licensing

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule and guidance; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations to reduce barriers to medical use licensing. This proposed rule responds to Executive Order 14300, ''Ordering the Reform of the Nuclear Regulatory Commission,'' which requires the NRC to conduct a review and wholesale revision of its regulations. This proposed rule, if adopted, would reduce overly prescriptive regulations, increase flexibility, and modernize radiation safety practices for the medical use of byproduct material. It also would enable more efficient and predictable licensing for emerging medical technologies and reduce unnecessary burden in training and experience requirements for medical authorized users. The NRC is revising guidance for this proposed rule. This proposed rule also would incorporate minor editorial corrections.

DATES: Comments must be submitted electronically using *https://www.regulations.gov* by 11:59 p.m. eastern time on September 10, 2026.

ADDRESSES: Submit your comments, identified by Docket ID NRC–2025–1237, at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* call or email the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments are public records; they are publicly displayed exactly as received, and will not be deleted, modified, or redacted. Comments may be submitted anonymously.

Follow the search instructions on *https://www.regulations.gov* to view public comments.

You can read a plain language description of this proposed rule at *https://www.regulations.gov/docket/NRC–2025–1237.* For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Irene Wu, Office of Nuclear Material Safety and Safeguards, telephone: 301–415–1951, email: *Irene.Wu@nrc.gov* and Katie Tapp, Office of Nuclear Material Safety and Safeguards, telephone: 301–415–0236, email: *Katherine.Tapp@nrc.gov.* Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

EXECUTIVE SUMMARY

A. Need for Regulatory Action

On May 23, 2025, President Donald J. Trump signed Executive Order (E.O.) 14300, ''Ordering the Reform of the Nuclear Regulatory Commission.'' E.O. 14300 directs the NRC to conduct a comprehensive review and wholesale revision of its regulations and guidance documents in alignment with objectives outlined in section 2 of the E.O. This rulemaking addresses section 5 of the E.O., focusing on the regulations in title 10 of the *Code of Federal Regulations* (10 CFR) part 35, ''Medical Use of Byproduct Material,'' and guidance documents related to the medical use of byproduct material. The proposed changes would facilitate the licensing of innovative technologies while maintaining the NRC's commitment to public health and safety. The proposed changes also aim to improve efficiency, reduce regulatory burden, and ease administrative burden for the NRC, Agreement States, licensees, and individuals or entities that seek medical use licenses.

B. Major Provisions

The major provisions of this proposed rule include the following:

1. Broadening the definition of ''physician'' to include foreign-trained individuals as long as they are licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice medicine.

2. Replacing the recentness in training requirement (within 7 years) with a performance-based continuing education model and removing specific work experience requirements for generator systems due to changes in industry practice.

3. Eliminating the requirement for license amendments to add authorized users for diagnostic uses, allowing licensees to approve and document these users internally due to the lower risk of these non-therapeutic uses.

4. Removing prescriptive training hours requirements for physicians who have received significant radiation safety and clinical training during the completion of a clinical radiation specialty residency, while retaining the alternative board certification and cross-qualification pathways.

5. Updating work experience categories for ''oral'' and ''parenteral'' administration of any radioactive drug requiring a written directive, allowing flexibility for future radiopharmaceuticals.

6. Moving specialty board certification approval requirements to a new section for clarity and regulatory efficiency, removing specific accrediting body references in residency training requirements, and clarifying that required work experience may be supervised by an authorized user at an NRC or Agreement State licensed medical facility.

7. Codifying provisions for emerging medical technologies (EMTs) currently licensed under subpart K of 10 CFR part 35, by establishing clear licensing pathways, training and experience requirements, and performance-based safety criteria. The EMTs include modern gamma stereotactic radiosurgery (GSR) devices, ophthalmic source/applicator devices, generators, and microsources.

8. Establishing clear requirements for rubidium-82 (Rb–82) generators, including codified definitions for breakthrough, calibration flexibility for dynamic systems, and updated licensing and training provisions to codify enforcement guidance.

9. Removing the written directive requirement for diagnostic administrations of sodium iodide I-131, aligning regulatory oversight with current clinical practice and other diagnostic administrations with comparable risk.

10. Refining written directive and medical event reporting requirements to exclude events caused by emergent patient conditions or real-time clinical decisions, while preserving reporting for events with potential safety significance, such as those involving equipment defects or unintended harm, reducing unnecessary burden and improving regulatory clarity.

11. Refining embryo/fetus dose reporting requirements to exclude cases where pregnancy could not reasonably be determined prior to administration, aligning oversight with clinical realities and reducing unnecessary reporting.

12. Expanding decay-in-storage eligibility by increasing the allowable

half-life from 120 to 275 days, enabling safe, cost-effective onsite disposal of longer-lived materials like lutetium–177 metastable (Lu–177m) and cobalt-57 (Co–57).

13. Eliminating the license amendment requirement for human subject research already approved by an Institutional Review Board (IRB) and covered under existing medical use authorizations, streamlining research initiation while maintaining safety and ethical oversight.

14. Removing duplicative and prescriptive requirements for mobile medical services, aligning them with general radiation safety regulations and providing licensees greater flexibility without compromising protection of patients, workers, or the public.

15. Extending the temporary Radiation Safety Officer (RSO) duration and refining Radiation Safety Committee (RSC) requirements to reflect current clinical practice, reduce administrative burden, and focus oversight on higher-risk therapeutic uses requiring written directives.

16. Removing outdated and redundant provisions across 10 CFR part 35, including prescriptive mobile medical survey requirements, obsolete waiver clauses, and recordkeeping requirements, to modernize the regulatory framework.

C. Costs and Benefits

This proposed rule is considered a deregulatory action and is expected to reduce barriers to medical use licensing by enabling more efficient and predictable licensing, increasing flexibility, and easing administrative burden for the NRC, Agreement States, licensees and individuals or entities that seek medical use licenses. Over the 5-year analysis period (2027–2031), the proposed revisions are estimated to generate net savings of $39.1 million (savings minus costs), undiscounted. Using 2024 as the base year, the net present value (NPV) of these net savings is $35.6 million, discounted at 3 percent, or $31.7 million, discounted at 7 percent. The licensees, accounting for the largest share of net savings, would save about $30.5 million over 5 years, undiscounted, with an NPV of $27.8 million discounted at 3 percent, or $24.8 million discounted at 7 percent. Overall, the projected annualized cost savings would be $7.2 million discounted at 3 percent, or $6.4 million discounted at 7 percent. Although this proposed rule would reduce barriers to medical-use licensing (including new technologies) and generate net savings, some costs would still be incurred over the 5-year period, primarily due to small increases in recordkeeping requirements from the proposed new regulations for new technologies and aligning with other modalities contained in 10 CFR part 35, as well as implementation costs. The additional recordkeeping costs, which represent operational costs for licensees, are estimated at $2.4 million (undiscounted), $2.2 million (discounted at 3 percent), and $2.0 million (discounted at 7 percent) over this 5-year period. Implementation costs for both NRC and industry stakeholders are estimated at about $2.9 million (undiscounted), $2.8 million (discounted at 3 percent), and $2.7 million (discounted at 7 percent). When compared with the projected savings, the operational (expanded recordkeeping requirements) costs account for a small share, about 6 percent of the projected net savings.

For more information, please see the regulatory analysis included later in this notice.

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I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2025–1237 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2025–1237.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin ADAMS Public Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the ''Availability of Documents'' section.
- *Public Meeting:* The NRC plans to conduct a public meeting to describe the proposed amendments and answer questions from the public on the proposed rule. The NRC will publish a notice of the location, time, and agenda of the meeting on the NRC's public meeting website within 10 calendar days of the meeting. Stakeholders should monitor the NRC's public meeting website for information about the public meeting at: *https://www.nrc.gov/public-involve/public-meetings/index.cfm.*
- *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open

by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time, Monday through Friday, except Federal holidays.

B. Submitting Comments

Comments must be submitted electronically using *https://www.regulations.gov* no later than 11:59 p.m. eastern time on September 10, 2026. Please include Docket ID NRC–2025–1237 in your comment submission.

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

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

II. Executive Order 14300: Ordering the Reform of the Nuclear Regulatory Commission

On May 23, 2025, President Donald J. Trump signed Executive Order (E.O.) 14300. Section 5, ''Reforming and Modernizing the NRC's Regulations,'' requires the NRC to undertake a review and wholesale revision of its regulations and guidance documents as guided by the policies set forth in section 2 of the E.O. This rulemaking addresses section 5 with a focus on the regulations and guidance documents pertaining to the medical use of byproduct material.

III. Background

Since 1946, physicians have used byproduct material in the diagnosis, treatment, and research of medical conditions. Over the decades, the medical use of byproduct material has evolved significantly, driven by advances in isotopes, procedural complexity, and medical technologies. Today, more than 20 million patients undergo procedures involving byproduct material each year in the United States, a number expected to grow as new medical devices and radiopharmaceuticals are developed, researched, and approved by the U.S. Food and Drug Administration (FDA).

As part of its ongoing efforts to modernize the regulatory framework in accordance with E.O. 14300, the NRC has reviewed its regulations governing the medical use of byproduct material under 10 CFR part 35. This review has led the NRC to propose changes to the training and experience requirements to ensure they are risk-informed, reduce unnecessary burden on physicians who already receive substantial radiation safety training as part of their medical education, and enhance regulatory clarity. In addition, the NRC proposes to codify certain well-established EMTs and regulatory provisions specific to the use of Rb-82 generators. The NRC uses ''well-established EMTs'' to refer to EMTs with extensive operating experience and widespread clinical use, for which licensing and training practices are stable and supported by NRC and Agreement State experience. In selecting EMTs for codification, the NRC prioritized those with the most extensive history and highest levels of use and with performance-based safety criteria that can be standardized in 10 CFR part 35. These updates aim to improve efficiency and predictability in licensing and oversight. The proposed changes also seek to eliminate outdated or unnecessarily burdensome requirements, allow for flexibility to facilitate licensing of innovative devices and medical uses, align regulations with current clinical practices, and improve clarity for licensees. Nothing in this proposed rule would relieve licensees from complying with applicable FDA, Federal, or State requirements or National Institutes of Health grant compliance obligations related to the use of radioactive drugs or devices. These proposed changes are detailed in Section IV, ''Discussion,'' of this document.

Several key topics addressed in this proposed rule benefit from additional context and relevant background information, as provided in the following sections.

A. Training and Experience

The training and experience requirements in 10 CFR part 35 are designed to ensure that individuals authorized to use byproduct material in medical applications possess the necessary knowledge, skills, and competencies to ensure radiation safety. The regulations in 10 CFR part 35 include provisions related to the training and experience of physicians who use or supervise the medical use of byproduct material, known as authorized users (AUs). The AU training and experience requirements in 10 CFR part 35 have evolved over time in response to changes in medical practice, stakeholder input, and broader shifts in medical education. The current framework includes requirements for classroom and laboratory training and supervised work experience that requires a prescriptive number of hours for all AUs, regardless of whether they completed residency training in a clinical radiation specialty. This is in addition to the individual (1) being a physician licensed to prescribe drugs in the practice of medicine by their respective State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico; (2) either having obtained written attestation that they are able to independently fulfill the radiation safety-related duties as an AU for the medical uses authorized, or having received board certification from a board recognized by the NRC or an Agreement State; and (3), in some cases, having obtained device-specific training. 10 CFR part 35 also contains training and experience requirements for other individuals important to radiation safety, including authorized medical physicists (AMPs), authorized nuclear pharmacists (ANPs), and RSOs.

The NRC last made significant revisions to the training and experience requirements in 2002 and 2005. Since then, stakeholders have raised concerns about the impact of these requirements, particularly the prescriptive number of hours required for unsealed use of byproduct material for therapy contained in § 35.390, ''Training for use of unsealed byproduct material for which a written directive is required.'' From 2015 to 2016, both the NRC staff and the Advisory Committee on the Medical Uses of Isotopes (ACMUI) independently reviewed the training and experience requirements for medical uses authorized under § 35.300, ''Use of unsealed byproduct material for which a written directive is required.'' In its March 2016 report, the ACMUI concluded that no changes to the 700-hour requirement were warranted at that time as they found no evidence that the requirement adversely affected patient access. However, the ACMUI recommended forming a subcommittee to periodically review the training and experience requirements and make recommendations as needed.

In 2016, the ACMUI established a subcommittee to review the training and experience requirements across all modalities regulated under 10 CFR part

35, beginning with § 35.300. In its September 2016 status report, the subcommittee identified several drivers for reevaluation, including ongoing stakeholder concerns about access to radiopharmaceuticals, the development of new radiopharmaceuticals since the 2002 rulemaking, and a shift in medical education from hour-based to competency-based training models.

The subcommittee's draft interim report, discussed in a public meeting on March 1, 2018, expressed concern about the declining number of nuclear medicine physicians and the potential long-term implications for patient access. While the subcommittee acknowledged the difficulty in quantifying the impact of this trend, it noted the absence of data suggesting a surplus of AUs and emphasized the need to consider future workforce needs.

In response to these ongoing concerns, the Commission issued Staff Requirements Memorandum (SRM)–M170817 on August 17, 2017, directing the NRC staff to evaluate whether tailored training and experience requirements should be established for different categories of radiopharmaceuticals, how those categories should be defined (*e.g.,* by risk or delivery method), and whether training and experience requirements should be based on hours or competency. The staff's initial evaluation was documented in SECY–18–0084, ''Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals.'' In that paper, the staff concluded that additional stakeholder outreach was needed.

Following further engagement with stakeholders, including the ACMUI and Agreement States, the NRC staff submitted SECY–20–0005, ''Rulemaking Plan for Training and Experience Requirements for Unsealed Byproduct Material (10 CFR part 35),'' to the Commission on January 13, 2020. On January 27, 2022, the Commission issued SRM–SECY–20–0005, maintaining the existing training and experience requirements and directing staff to continue to obtain stakeholder input on training and experience requirements for EMTs as part of the broader rulemaking effort to update 10 CFR part 35.

At the time E.O. 14300 was issued on May 23, 2025, the NRC staff was actively evaluating training and experience requirements for Rb-82 generators and EMTs. The E.O. directed the NRC to undertake a comprehensive review and modernization of its regulations, including those governing the medical use of byproduct material. The proposed changes to training and experience in this rulemaking are in response to the E.O. and build upon the historical evolution of the training and experience requirements and the extensive body of stakeholder feedback and Commission direction developed over the past two decades.

Specifically, this proposed rulemaking removes prescriptive hours for physicians who have received significant radiation safety and clinical training over years of a clinical radiation specialty residency. In addition, it proposes to remove the requirement for diagnostic AUs to be listed on a license and removes outdated training topics and requirements associated with arbitrary dates of when physicians last received training, allowing licensees to focus training and experience on topics more relevant to clinical practice. Finally, the NRC proposes changes to the training and experience requirements' organization for all authorized individuals (*i.e.,* AUs, AMPs, ANPs, and RSOs) to enhance regulatory clarity.

B. Emerging Medical Technologies

In 2002, the NRC added subpart K, ''Other Medical Uses of Byproduct Material or Radiation from Byproduct Material,'' (§ 35.1000) to 10 CFR part 35 to provide a flexible regulatory framework for licensing new or existing EMTs that do not fit within the existing subparts of 10 CFR part 35. The regulations in § 35.1000 define the process to obtain a license or license amendment for EMTs. EMTs often require unique provisions for training and experience, facility and equipment specifications, or other safety-related considerations that are not addressed in the existing 10 CFR part 35 subparts (subparts D through H). As a result, the NRC and Agreement States evaluate each EMT on a case-by-case basis to determine the specific risks associated with the EMT and any additional regulatory requirements needed for its medical use and may develop model- and vendor-specific licensing guidance to support consistent and safe licensing and use.

Licensing guidance for EMTs is developed with input from the ACMUI, vendors, and regulatory staff, and includes general licensing considerations, radiation safety protocols, and training and experience expectations for individuals authorized to use the technology. While not binding, licensing guidance for EMTs provides applicants with an acceptable means to satisfy the requirements for a license for the EMT. Applicants who commit to following the EMT licensing guidance may have those commitments incorporated as license conditions. Alternatively, applicants may propose other sets of regulations and specific conditions to use the EMT that become binding through license conditions in accordance with § 35.1000.

Since 2002, the NRC and Agreement States have licensed at least 18 EMTs under subpart K, including microspheres, GSR units, photon-emitting teletherapy systems, radiopharmaceutical generator systems, and ophthalmic applicator sources and devices. While subpart K offers a quick path for licensing EMTs with unique radiation safety needs as they are being introduced, continued licensing of well-established EMTs under subpart K offers limited regulatory benefit and can lead to inconsistencies and lack of clarity, as subpart K relies on guidance and the incorporation of license conditions rather than codified rules. This approach also places a resource burden on regulators due to frequent updates of EMT-specific guidance.

On June 27, 2023, the NRC published an associated regulatory basis document, ''Rubidium-82 Generators, Emerging Technologies, and Other Medical Use of Byproduct Material Regulatory Basis Document,'' for public comment. The majority of the comments were in favor of incorporating well-established EMTs into the main body of 10 CFR part 35. However, to meet the timeline established in E.O. 14300 for publishing this proposed rule, the scope of EMTs addressed in this proposal has been narrowed to focus on some well-established technologies with the most extensive history and highest levels of use, such as modern GSR devices, ophthalmic source/applicator devices, generators, and microsources. Uses and EMTs not included in this rulemaking include intravascular brachytherapy systems, liquid and diffusing brachytherapy sources and devices, and radioactive seed localization. While these technologies currently remain licensed under § 35.1000, and they may be incorporated into the main body of 10 CFR part 35 in a future rulemaking depending on NRC and industry need and available resources.

C. Rubidium-82 Generators

Rb-82 generators produce Rb-82 chloride, a positron-emitting radiopharmaceutical used for cardiac imaging. These generators differ from other generators licensed under § 35.200, ''Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required,'' due to the short 75

second half-life of Rb-82 and the generator's automated elution and direct patient infusion. Because of both the short half-life and direct infusion after elution, as well as the absence of nationally recognized standards or specific instrument calibration procedures, Rb-82 generator licensees are unable to calibrate instruments or measure dosage prior to administration. As such, these licensees are unable to meet the requirements in § 35.60, ''Possession, use, and calibration of instruments used to measure the activity of unsealed byproduct material,'' for the calibration of radiation detector instruments associated with medical use, or § 35.63, ''Determination of dosages of unsealed byproduct material for medical use,'' to determine the activity of each dosage administered before medical use. In recognition of these challenges, the NRC issued Enforcement Guidance Memorandum (EGM) 13–003, ''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, to provide interim enforcement discretion for licensees that are unable to fully comply with the applicable calibration and dosage determination requirements. This EGM remains in effect today and continues to provide temporary regulatory relief. Like for EMTs, the majority of public comments received on the June 27, 2023, regulatory basis document were in favor of resolving the Rb-82 generator compliance issue by rulemaking.

D. Written Directives for Diagnostic Sodium Iodide I-131

A written directive is the AU's written order for administration of byproduct material or radiation from byproduct material to a specific patient or human research subject. Section 35.40, ''Written directives,'' establishes requirements for which medical uses of byproduct material require written directives. Under the current regulations, a written directive is required for diagnostic administrations of sodium iodide I-131 in quantities greater than 1.11 megabecquerels (30 microcuries), even when the administration is solely for diagnostic purposes. This is the only diagnostic use that currently requires a written directive; all other uses requiring a written directive are therapeutic in nature and are subject to more stringent requirements commensurate with their higher risk. Because diagnostic sodium iodide I-131 currently requires a written directive, it is licensed under subpart E of 10 CFR part 35, which otherwise applies exclusively to therapeutic uses. In contrast, all other diagnostic uses of unsealed byproduct material are regulated under subpart D of 10 CFR part 35, which does not require a written directive and reflects the lower risk associated with diagnostic procedures.

The requirement for a written directive for diagnostic sodium iodide I-131 was established by rule on April 24, 2002. At that time, the radiation safety considerations associated with the diagnostic use of millicurie quantities of sodium iodide I-131 were considered to be more similar to therapeutic uses than to other diagnostic procedures, such as those involving technetium-99m (Tc–99m). However, the practice of nuclear medicine has evolved significantly since 2002. On October 1, 2007, the NRC published a final rule to amend 10 CFR part 35 to implement provisions of the Energy Policy Act of 2005 requiring the NRC to license medical use of accelerator-produced radioactive material, including positron emission tomography (PET) (72 FR 55864). This introduced diagnostic procedures involving higher radiation exposure risk and more complex safety considerations. As a result, the relative risk profile of diagnostic sodium iodide I-131 use has shifted.

Today, diagnostic sodium iodide I-131 is typically administered in unit dosages, often in capsule form, rather than as liquid preparations compounded onsite. This change has reduced the radiation safety risks associated with handling and administering radioactive material. Additionally, the training and expertise of diagnostic nuclear medicine staff have increased in parallel with the broader use of PET and other advanced imaging modalities. These developments have brought radiation safety considerations for diagnostic sodium iodide I-131 in line with those of other diagnostic procedures regulated under subpart D of 10 CFR part 35. There are also now over 50 years of operating experience using diagnostic dosages of sodium iodide I-131, contributing to a better understanding of diagnostic sodium iodide I-131 and safety considerations surrounding its use. For the foregoing reasons, this proposed rule would remove the requirement that diagnostic sodium iodide I-131 administrations need a written directive, moving its authorization from subpart E to subpart D of 10 CFR part 35.

E. Reductions in Event Reporting

Sections 35.3045, ''Report and notification of a medical event,'' and 35.3047, ''Report and notification of a dose to an embryo/fetus or a nursing child,'' establish the criteria for reporting medical events and dose to embryo/fetus from the administration of byproduct material or radiation from byproduct material. These events represent unintended deviations from the AU's planned administration of radioactive materials that may result in doses exceeding specified thresholds. Medical event reporting is consistent with item number 3 in the NRC's risk-informed, performance-based Medical Use Policy Statement, which states the NRC will, when justified by the risk to patients, regulate the radiation safety of patients primarily to assure the use of radionuclides is in accordance with the physician's directions. These reports enable the NRC to investigate safety concerns, ensure corrective actions are taken at a licensee level, and take action such as providing communication to the industry or working with the manufacturer and the FDA to prevent recurrence at the national level.

The NRC first required reporting of medical use errors, then termed ''misadministrations,'' in 1980. In 2002, the NRC comprehensively revised 10 CFR part 35, renaming ''misadministrations'' as ''medical events'' and refining the reporting criteria to focus on outcomes with potential radiation safety significance. The revised rule introduced a dose-based threshold to exclude events associated with most diagnostic procedures from reporting, recognizing their low risk. Despite these improvements, stakeholders have raised concerns that the current criteria may still result in the reporting of events that do not reflect licensee error, such as those caused by emergent patient conditions (*e.g.,* vascular spasms or seizures) or real-time clinical decisions made in the interest of patient care. The NRC is proposing changes to medical event reporting requirements to avoid unnecessary reporting of these events while maintaining oversight of significant occurrences that could impact radiation safety.

F. Decay-in-Storage

On April 24, 2002, § 35.92, ''Decay-in-storage,'' was revised to allow medical licensees to dispose of short-lived radioactive waste ''without regard to its radioactivity'' once they can confirm the waste has become indistinguishable from background. This provides medical licensees with a practical and cost-

effective option for managing short-lived radioactive waste commonly used in medicine while avoiding triggering additional regulatory requirements under the Environmental Protection Agency's hazardous waste rules (40 CFR part 261), and the Department of Transportation's transportation regulations (49 CFR parts 171–178), which would otherwise apply if the waste retained measurable radioactivity. If licensees would prefer to dispose of waste sooner, they can continue to use disposal pathways available to all licensees in 10 CFR part 20, subpart K. The NRC is proposing a change to this rule to reflect the increasing use of longer-lived medical isotopes, such as Lu–177m, in clinical practice. Expanding the eligibility for decay-in-storage disposal would reduce waste disposal costs while maintaining safety.

IV. Discussion

This discussion section has been divided into multiple sections (Training and Experience, Emerging Medical Technologies, Rubidium-82 Generators, and Other Topics) and subsections to better present information on the major topics impacted by this proposed rule. Each section will discuss what action the NRC is proposing, why the action is being proposed, and who the action affects and how.

The NRC prepared an unofficial redline strikeout version of the proposed changes to regulatory text that is intended to help the reader identify the changes. The NRC is providing the unofficial redline as a reader tool only. Comments on the rule text should be made in this proposed rule.

A. Training and Experience

1. Flexible Physician Training Pathways

The current definition of physician in § 35.2, ''Definitions,'' means a medical doctor (MD) or doctor of osteopathy (DO) licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine. The NRC is proposing to change this definition to remove the specific requirement for the individual to be an MD or DO. This change is intended to expand eligibility for foreign-trained physicians whose primary medical qualifications may not be titled MD or DO, but who are fully licensed to practice medicine in the United States, to become AUs. AUs must still meet the training and experience requirements in the applicable subparts of 10 CFR part 35.

In addition, the NRC is proposing to remove from regulations the listing of specific accrediting bodies for residency programs under the training and experience requirements for AU physicians in §§ 35.190. 35.290, 35.390, 35.392, 35.394, 35.396, 35.490, and 35.690. Over time, both residency programs and their accrediting bodies have evolved to incorporate NRC requirements into their curricula. As a result, the NRC no longer finds it necessary to specify accrediting bodies in the regulations. Under this proposed rule, the residency programs would be required to include the proposed classroom and work experience topics to ensure that physicians receive training as part of a structured educational program. This approach allows for greater flexibility by permitting any accredited program, regardless of the accrediting body, to qualify, provided it includes the specified training topics.

2. Physician Residency Pathways

The NRC is proposing to revise its regulations to recognize the structured and comprehensive nature of accredited residency programs in certain medical specialties that inherently include radiation safety training and experience as part of the clinical specialty. Specifically, the NRC proposes to remove the prescriptive requirements in §§ 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.490, and 35.690 for specific numbers of classroom, laboratory, and work experience hours for physicians who have completed residency training in specialties where radiation safety and the clinical use of byproduct material are inherently integrated into the curriculum. This proposed change acknowledges that the depth and scope of training provided in these accredited residency programs are tailored to the clinical application of byproduct materials. The NRC believes that successful completion of such a residency program along with written attestation from a preceptor or residency program director, provides sufficient assurance of an individual's competency to serve as an AU, without the need for fixed hour requirements.

To implement this change, the NRC is proposing to add a residency-based training and work experience pathway for the medical use of unsealed byproduct material in §§ 35.190, 35.290, 35.390, 35.392, 35.394, and 35.396. This new pathway would apply to §§ 35.190 (Training for uptake, dilution, and excretion studies), 35.290 (Training for imaging and localization studies), 35.390, and 35.396 (Training for the parenteral administration of unsealed byproduct material requiring a written directive), where current regulations do not explicitly reference residency training. For §§ 35.490 (Training for use of manual brachytherapy sources) and 35.690 (Training for use of remote afterloader units, teletherapy units, and GSR units), no new pathway would be created as the regulations already require completion of a residency. For all applicable sections, the NRC would remove the prescriptive hour requirements for classroom, laboratory, and work experience for individuals who have completed an accredited residency in specified specialties. This change would not amend the topics that must be covered for classroom and laboratory training and work experience that must be completed in a structured educational program. The topics listed in the regulations are essential to ensuring radiation safety. Individuals completing a residency-based pathway would still need to receive training and experience in all required topic areas during their residency. The written attestation from a preceptor or residency program director should confirm that the individual has completed the required training and experience as required and is able to independently fulfill the radiation safety-related duties as an AU for the medical use the individual is requesting.

The NRC would retain the NRC-approved specialty board pathway and alternate pathway with specified hours for individuals who have not completed residency training in specialties identified in regulations. Finally, the proposed regulations would retain the equivalent qualification pathways where an AU who is qualified for § 35.290 also is qualified for § 35.190, an AU who is qualified for § 35.390 also is qualified for §§ 35.290 and 35.190, and an AU who is qualified for 35.490 also is qualified for § 35.491, ''Training for ophthalmic use of strontium-90.''

3. Device and Use Specific Training

Currently, §§ 35.300, 35.392, 35.394, 35.396, and 35.491 require physicians to complete a prescribed number of cases to qualify as an AU. This fixed case requirement does not allow flexibility for physicians who can complete the required work experience and demonstrate the knowledge and competency in radiation safety-related duties through other means than a prescriptive number of cases for the medical use for which they are requesting AU status.

This proposed rule would replace the specified number of cases to qualify as an AU in the NRC's regulations with a requirement that the physician receive sufficient experience in casework during either their residency or the

required training and experience hours for the medical use in question. This experience must be sufficient for the supervising AU to evaluate and document the physician's competency in independently performing radiation safety-related duties for the requested medical use. This proposed change would allow flexibility based on the needs of the physician to ensure they have the knowledge necessary to ensure radiation safety for the patient, public, other workers, and themselves for their requested medical use.

In addition, §§ 35.300, 35.392, 35.394, and 35.396 currently state that the physician must have experience in administering dosages of radioactive drugs in their respective categories. However, the physical act of administering dosages of radioactive drugs is a practice of medicine and is not always performed by the physician seeking AU status. The purpose of training and experience for AUs is to ensure radiation safety rather than medical competency; this proposed rule revises this requirement to focus on preparing written directives and observing or performing the administration of dosages. While the AUs do not need to physically perform the administration, they must participate in the entire process, gaining experience in all required topics, to ensure they can independently perform all radiation safety-related duties for the medical use for which they are requesting AU status.

In addition, currently, § 35.59, ''Recentness of training,'' requires individuals to demonstrate related continuing education and experience if their required training and experience was obtained more than 7 years prior to the date of application. However, as the medical use of byproduct material continues to evolve at a quick pace, particularly with the expansion of radiopharmaceutical therapies, experience gained even a few years ago does not ensure that authorized individuals, such as AUs, possess current training or experience in the specific uses for which they are applying. In many cases, the uses for which individuals were originally trained differ significantly from current or emerging practices.

Inadequate training of staff, including AUs, before treating the first patient has been identified as a root cause of a significant number of events, including those described in NRC Information Notice 2024–04, ''Recent Medical Events involving Administration of Therapeutic Radiopharmaceuticals.'' Similarly, as documented in Information Notice 2019–07, ''Methods to Prevent Medical Events,'' NRC staff determined that several additional medical events were linked to insufficient training following the introduction of new equipment or software. The ACMUI has also concluded that many medical events involve users who perform treatments infrequently and recommended refresher training for AUs. These findings underscore the need for a performance-based continuing education requirement to ensure that authorized individuals maintain current knowledge and skills as practices and technologies evolve, particularly as the NRC proposes to remove the outdated recentness requirement in § 35.59.

The ACMUI and other stakeholders have recommended that licensees receive additional application-specific training for existing and future EMTs. This includes the potential for future radiopharmaceutical therapies to be licensed under 10 CFR part 35, subpart H. Stakeholders also have expressed concern that the current § 35.59 lacks clarity regarding what constitutes acceptable training and experience to meet the recentness requirement. This has led to uncertainty about what documentation should be submitted with license applications. To address these concerns, the NRC this proposed rule would revise § 35.59 to remove the prescriptive requirement to demonstrate recent training and experience at the time of application and would introduce a performance-based continuing education requirement. This would ensure authorized individuals maintain the necessary education and experience to support radiation safety and regulatory compliance for the uses they are authorized.

Recognizing the differing risk profiles between diagnostic and therapeutic uses, the NRC is proposing a change that would require AUs for diagnostic uses to maintain education or experience in the type of use. For uses requiring a written directive, AUs must maintain education and experience in the specific source, microsource, device, or radioactive drug. This proposed rule also would require instruction on changes to applicable regulations, license conditions, and the licensee's written radiation protection and written directive procedures. This is particularly important because AUs are responsible for supervising others under § 35.27, ''Supervision,'' and ensuring safe use of byproduct material. As part of this performance-based approach, licensees would no longer be required to submit documentation of recent training and experience with a license application. Instead, a new recordkeeping requirement would be added in a new section, § 35.2059, ''Records of continuing education and training,'' to ensure that licensees maintain appropriate documentation of continuing education and experience.

The NRC also is proposing to remove the specific work experience requirement for eluting generator systems, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs. Changes in industry practice have resulted in a limited number of generators in use at medical facilities, creating challenges for AU trainees to meet this portion of the experience requirement. The NRC believes that the classroom portion of the requirements for the chemistry of byproduct material could adequately cover the topics previously addressed through hands-on experience. This change would provide the necessary radiation safety information as an alternative to direct work experience.

4. Authorized User Approval for Non-Therapeutic Uses of Unsealed Byproduct Material

The NRC is proposing to amend its regulations to eliminate the requirement for licensees to submit a license amendment before allowing an individual to serve as an AU for medical uses authorized under § 35.100, ''Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required,'' or § 35.200, ''Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.'' Under this proposed rule, licensees would be permitted to approve individuals as AUs for these non-therapeutic uses of unsealed byproduct material without prior NRC review and approval, provided the individual meets the applicable training and experience requirements specified in subpart D. Licensees would be required to maintain documentation of their internal review and approval process, including verification that the individual satisfies the relevant training and experience criteria. This documentation would be subject to NRC inspection.

This proposed change reflects the NRC's risk-informed, performance-based regulatory approach and acknowledges that the medical uses authorized under §§ 35.100 and 35.200, such as diagnostic imaging and localization studies, do not require a written directive and are considered lower-risk activities. By removing the license amendment

requirement for these uses, the NRC aims to reduce unnecessary regulatory burden on licensees while maintaining appropriate oversight. The approval of AUs for these uses would be evaluated as part of the NRC's routine inspection program, ensuring AUs have the necessary training and experience to support radiation safety without requiring pre-approval through the licensing process.

5. Training and Experience Categories of Therapeutic Uses of Unsealed Byproduct Material

The NRC is proposing to amend §§ 35.390(b)(1)(ii)(G) and 35.14(a) to remove the prescriptive requirement that individuals seeking AU status must have experience with both low-dose (less than or equal to 1.22 gigabecquerels or 33 millicuries) and high-dose (greater than 1.22 gigabecquerels or 33 millicuries) oral administrations of sodium iodide I-131. Under the current regulation, applicants must document a minimum of three cases in each of these two categories. This rigid structure may not reflect the evolving landscape of radiopharmaceuticals. The proposed change would consolidate these two categories into a single, broader category: oral administration of any radioactive drug for which a written directive is required. This proposed revision eliminates the specific dose-based thresholds for sodium iodide I-131 and instead focuses on the route of administration and the requirement for a written directive. This approach is more risk-informed and performance-based. This proposed change preserves the integrity of the training and experience requirements while allowing for greater flexibility in how those requirements are met. It also would ensure that the regulation remains adaptable to future developments in radiopharmaceuticals that may be administered orally and require a written directive. This proposed amendment would only apply to the categories in § 35.390 for physicians seeking full authorization and does not remove or change the existing work experience requirements for those who desire the limited scope pathway provided in §§ 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),'' and 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).'' These limited pathways would remain available for physicians who seek authorization for these specific uses without completing the training and experience requirements for all therapeutic uses of unsealed byproduct material authorized under § 35.390.

The NRC also is proposing to remove unnecessary limitations in the current § 35.390(b)(1)(ii)(G)(*3*), which requires AU applicants to have work experience with a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 kilo-electron volt (keV). This proposed rule would amend § 35.390(b)(1)(ii)(G)(*2*) to require parenteral administration of any radioactive drug for which a written directive is required, replacing the removed requirement with a broader, more flexible requirement while still ensuring safety. This proposed change would allow training involving any future radiopharmaceuticals delivered by a parenteral route to be included under this regulation. These revisions provide flexibility for future individuals seeking AU status while ensuring such individuals continue to demonstrate the foundational knowledge and clinical experience necessary to support radiation safety. In conjunction with the proposed changes to § 35.59, these updates also would ensure that individuals maintain current knowledge specific to the uses they are authorized to perform.

6. Authorized User Pathway To Become a Radiation Safety Officer

Under the current regulations, § 35.50(c)(3) allows physicians to be simultaneously approved as both the RSO and AU on a new medical use license or permit, provided they also meet the requirements of § 35.50(d). The NRC is proposing to amend this regulation to allow individuals to seek this pathway on an existing license or permit. There is no safety basis for limiting this pathway solely to new licenses or permits, and this change would provide greater flexibility for an AU to become an RSO on a license at any time without compromising safety.

7. Regulatory Clarification of Training and Experience Regulations

To improve clarity, the NRC is proposing to restructure the training and experience requirements in 10 CFR part 35 by consolidating the specialty board certification approval process into a new section, § 35.58, ''Specialty board certification approval.'' Currently, the specialty board certification requirements for AUs, RSOs, AMPs, and ANPs are embedded within multiple subparts throughout 10 CFR part 35. When a licensee is reviewing the requirements needed to complete a licensing application for approval as an AU, the requirements of a specialty board certification process is not needed to support the application. Therefore, the NRC is proposing a separation to clarify the training and experience requirements for AUs and to simplify the approval process for specialty boards.

The proposed amendment moves the specialty board approval process from §§ 35.50(a), 35.51(a), 35.55(a), 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), and 35.690(a) to proposed new § 35.58.

In addition, this proposed rule would clarify that work experience required under each subpart may be obtained under the supervision of an AU at a medical facility authorized to use byproduct materials under that subpart. Under the proposed change, licensees would not be required to verify the training and experience of supervising individuals, as they are already authorized to use the material. This regulatory change would clarify who can supervise required work experience.

B. Emerging Medical Technologies

1. Expansion of Medical Use Generators

The NRC is proposing amendments to 10 CFR part 35 to modernize and expand the regulatory framework for medical use generators. Currently, § 35.204, ''Permissible molybdenum-99, strontium-82, and strontium-85 concentrations,'' provides specific concentration limits for parent radionuclides for molybdenum-99 (Mo-99)/Tc-99m and Rb-82 generators to limit such exposure, but provides no such limit for Germanium-68/Gallium-68 (Ge-68/Ga-68) generators or flexibility for other new or emerging generators. In addition, generator regulations are contained within subpart D, which are limited to diagnostic uses. As a result of this narrow regulatory framework, generator systems such as the Ge-68/Ga-68 generators have been regulated under § 35.1000. Additionally, the current regulatory requirements for breakthrough testing and effluent limits are prescriptive and located within the diagnostic subpart, which would not be appropriate for future therapeutic applications. As generator technologies become more common and new therapeutic generators are developed, reliance on § 35.1000 would create unnecessary delays in licensing and implementation because each new generator type would need to undergo case-by-case review and approval under

the EMT review process rather than following a standardized regulatory pathway.

To address these issues, the NRC is proposing to revise and expand the regulatory provisions applicable to medical use generators to accommodate both diagnostic and therapeutic applications and to reduce reliance on § 35.1000 for licensing new generator systems. Specifically, the NRC is proposing to—

a. Revise § 35.2 to add a definition for ''breakthrough'' to reflect current industry practices and terminology.

b. Move generator breakthrough testing requirements contained in §§ 35.204 and 35.2204, ''Records of molybdenum-99, strontium-82, and strontium-85 concentrations,'' to new sections §§ 35.93, ''Permissible concentrations for generator-produced radionuclides,'' and 35.2093, ''Records of generator breakthrough testing,'' respectively. The proposed new § 35.93 would be located in subpart C (General Technical Requirements) as opposed to subpart D (Unsealed Byproduct Material—Written Directive Not Required) where the current generator breakthrough testing requirements in § 35.204 are contained. This move would support the anticipated licensing of therapeutic generators, which may not fall under the current scope of subpart D. In addition, the proposed § 35.93 would remove prescriptive requirements limited to specific generators and replace them with a more flexible approach that allows licensees to develop and implement written procedures to define acceptable breakthrough limits and testing frequencies that are consistent with generator labeling as set forth in its FDA product approval or nationally recognized standards. To ensure safety and regulatory alignment, the proposed changes would require that the limits and testing frequency be consistent with generator labeling as set forth in its FDA product approval or nationally recognized standards, such as those published by the United States Pharmacopeia (USP). These proposed changes align with the current recommendations outlined in the § 35.1000 licensing guidance for the Ge-68/Ga-68 generators and would ensure that breakthrough testing practices remain current with evolving safety and performance standards and allow flexibility for emerging generators. These proposed changes also would allow licensing of emerging generators without further rulemaking or a separate case-by-case licensing evaluation and guidance development under § 35.1000.

c. Include a requirement in § 35.93(a)(2) that licensees must ensure individuals using generator systems have received operational and safety training specific to the generator model. This codifies expectations that were previously addressed only in guidance (*e.g.,* EGM–13–003), and expands them to apply to all radionuclide generators, not just rubidium-based generator systems, enhancing regulatory clarity and stability. In addition, § 35.93(b) would require that licensees provide instruction in their generator procedures to individuals involved in generator use, particularly when procedures are first implemented or significantly changed. Because the NRC is proposing to require training on the specific generator model and procedures being used, the NRC is also able to propose the removal of broader training and experience requirements for all physicians seeking authorization under § 35.200 described above. This approach is informed by operational experience, where untrained users used the wrong eluant without understanding the associated risks leading to generator breakthrough events and unnecessary radiation exposure to patients. Ensuring that users are trained on the specific systems they operate mitigates these risks. Overall, this proposed change would represent a significant reduction in regulatory burden, particularly since most physicians do not directly use or supervise generator systems in clinical settings, while still maintaining a high standard of safety in generator operation. Proposed conforming changes also would be made to the associated recordkeeping requirement contained in § 35.2310, ''Records of safety instruction,'' to add the proposed new § 35.93.

d. Similar to § 35.204, the proposed § 35.93(a)(3) would prohibit the administration of generator eluate to patients or human research subjects if breakthrough measurements exceed the licensee's established limits. Section 35.93(c) would retain the requirement to report any such exceedance at the time of generator elution, but reference new proposed § 35.3093, ''Report and notification for an eluate exceeding breakthrough limits,'' instead of § 35.3204, ''Report and notification for an eluate exceeding permissible molybdenum-99, strontium-82, and strontium-85 concentrations.'' Section 35.93(d) would require licensees to retain records of each breakthrough test in accordance with § 35.2093, replacing the previous reference to § 35.2204.

e. Confirming changes would be made to information collections contained in § 35.8, ''Information collection requirements: OMB approval,'' and recordkeeping requirements would be moved from § 35.2204 to § 35.2093.

These proposed changes are intended to remove the need for licensing emerging generators under § 35.1000 in order to increase licensing efficiency, eliminate unnecessary prescriptiveness, align regulatory requirements with current standards, and ensure that the NRC's regulations remain adaptable to future innovations. By relocating generator requirements out of the diagnostic subpart and into a more general framework, the NRC aims to facilitate broader adoption of generator-based technologies commensurate with the NRC's role in maintaining appropriate oversight and safety assurance.

2. Ophthalmic Applicator Sources and Devices

The NRC is proposing to amend subpart F to replace references to ''strontium-90 sources'' with ''beta-emitting sources,'' to reflect the broader range of beta-emitting isotopes that may be used in superficial ophthalmic treatments and remove the outdated assumption that only strontium-90 (Sr-90) is applicable. The proposed revised language would ensure that the regulation remains relevant as new technologies and isotopes are introduced into clinical use, reducing reliance on § 35.1000 licensing, such as what is currently done for the NeoVista Inc's Epi-Rad90 Sr-90 Ophthalmic System and Liberty Vision (LV) Yttrium-90 (Y-90) Disc and iWand®, by allowing these technologies to be licensed under subpart F instead. While § 35.400, ''Use of sources for manual brachytherapy,'' allows AUs who meet training and experience requirements under § 35.490 to currently use beta-emitting sources for superficial ophthalmic procedures, these proposed amendments would reduce training and experience criteria contained in § 35.491 for superficial ophthalmic procedures for all beta-emitting sources. These amendments aim to modernize regulatory language, support innovation in treatment methods, and align with the NRC's risk-informed, performance-based regulatory framework.

Specifically, the NRC is proposing to amend § 35.491 to modernize and clarify the training and experience requirements for physicians authorized for superficial beta emitter ophthalmic treatments, currently licensed under § 35.1000, and any new innovative superficial ophthalmic treatments. The section title would be amended to read, ''Training for superficial ophthalmic use of beta-emitting sources,'' and

references to ''strontium-90'' would be replaced with ''beta-emitting sources,'' recognizing that ophthalmic radiotherapy may involve a broader range of isotopes.

As the proposed amendment would allow use of a broader range of isotopes instead of just one, the NRC is proposing to introduce device-specific training for the applicable AUs authorized via §§ 35.490 and 35.491. The applicable AUs would be able to satisfy this training either through a vendor-provided program for new users or through supervised instruction by an AU or AMP authorized to use the same device. This aligns with the current recommendations outlined in the § 35.1000 licensing guidance for Liberty Vision, ensuring that AUs are not only trained in radiation safety and clinical application but also are proficient in the specific operational and safety features of the device they will use.

In addition, confirming changes would be made to expand § 35.433, ''Strontium-90 sources for ophthalmic treatments,'' to allow for any beta-emitting source, not just Sr-90, to be used for ophthalmic treatments. This proposed rule also would make conforming changes to the recordkeeping requirement in § 35.2433, ''Records of decay of strontium-90 sources for ophthalmic treatments,'' to reflect the broader terminology, requiring licensees to retain records of the activity of each beta-emitting source. This proposed change does not alter the intent or scope of the recordkeeping requirement but instead updates the terminology to reflect current and future clinical practices.

3. Remote Afterloader, Teletherapy, and Gamma Stereotactic Radiosurgery

Subpart H of 10 CFR part 35 establishes requirements for the use of sealed sources in photon-emitting remote afterloader units, teletherapy units, and GSR units. These requirements were originally developed based on the operational characteristics of the devices available at the time. For example, regulations for GSR units were developed in 2002 and calibration and spot check regulations contained in §§ 35.635, ''Full calibration measurements on gamma stereotactic radiosurgery units,'' and 35.645, ''Periodic spot-checks for gamma stereotactic radiosurgery units,'' were based on the NRC's review of units and clinical practice used in 1995. In 1995, the units used stationary sources, helmet collimators that needed to be changed manually, trunnions, and head frames drilled into the skull. However, the evolution of medical technology has introduced new units with design and engineering elements that make their operation significantly different than these previous units, resulting in their inability to be licensed under 10 CFR part 35 subpart H. As a result, modern GSR units are currently licensed under § 35.1000.

To support licensing these units under § 35.1000, the NRC developed several licensing guidance documents, including for Akesis Galaxy Rti, Leksell Gamma Knife® Perfexion™, Leksell Gamma Knife® Icon™, Elekta Esprit, Xcision® GammaPod™, and ViewRay™ System for Radiation Therapy. In addition, the NRC expects more EMTs would be licensed under § 35.1000 if subpart H to 10 CFR part 35 is not changed. As licensing under subpart K can increase burden on licensees and regulators and lead to inconsistencies, this proposed rule would eliminate the need to use subpart K for licensing for modern GSR units. In addition, the NRC is proposing additional amendments to support the broader goals of E.O.s 14300 and 14267 to align regulations with current clinical practices and reduce unnecessary requirements that may limit innovation.

To reduce unnecessary regulatory burdens that may hinder innovation, the NRC is proposing to amend:

a. Section 35.2 to include a definition for ''gamma stereotactic radiosurgery'' and revise the existing definition of ''teletherapy.'' These changes are part of a broader initiative to modernize and clarify terminology used in 10 CFR part 35, improve consistency in regulatory language, and better reflect current clinical practices and medical community standards;

b. Section 35.610(a)(1) to allow flexibility in securing either the console or its keys, rather than requiring both, while still maintaining the requirement to secure the unit and treatment room when not in use; and

c. Sections 35.615(a) and (b) to remove the prescriptive requirement for a physical door to control access, while preserving the requirement that access to each treatment room entrance must be controlled using an electronic interlock.

These proposed changes preserve the core safety principles of the current regulations while allowing for alternative, modern mechanisms to ensure therapeutic units remain secure and controlled.

As GSR technology advances, the differences between units impacting radiation safety are increasing. With the proposal to allow more unit types to be licensed under subpart H, it is essential that AUs, operators, and calibrators receive training specific to the units they will use. To address this, the NRC is proposing to amend § 35.610(d)(1) to require vendor-provided operational and safety training for all individuals who will operate or calibrate the unit, including the AU, prior to the first use of a new or upgraded unit. Unlike traditional units for which subpart H was originally written, modern units may incorporate various types of immobilization devices, and in the event of an emergency, it is critical that responders are trained to safely release a patient from the specific device in use. Therefore, the NRC is proposing to revise § 35.610(e) to add a requirement to ensure emergency training includes instruction on the specific immobilization devices used with the unit. These amendments would ensure safety is maintained while subpart H is expanded to include different types of units, minimizing the need for future subpart K licensing.

GSR units have advanced along with their safety systems, which help ensure patients are treated accurately and as prescribed. This advancement is detailed in the ACMUI subcommittee report titled ''Physical Presence Requirements for the Leksell Gamma Knife® Icon™.'' Currently, § 35.615(f)(3) requires both an AU and an AMP to be physically present throughout the entire GSR treatment. However, due to the enhanced safety features of modern GSR units, the NRC is proposing to reduce this physical presence requirement by amending § 35.615(f)(3), now proposed § 35.615(e)(3):

a. The AU and AMP would still be required to be physically present at the initiation of treatment to ensure proper setup and confirm that the patient receives the intended dose to the correct location.

b. After initiation, the AU may leave the treatment area but must remain immediately available in case of an emergency or treatment interruption that requires a medical decision.

c. Given the high dose rates involved in GSR treatments, the AMP would still be required to remain physically present during the continuation of treatment.

d. The licensee would have the flexibility to designate other appropriate personnel to be physically present to respond to emergencies and remove the patient from the radiation field if necessary.

e. In the event of an unexpected interruption, both the AU and the AMP would be required to evaluate the situation before treatment re-initiation.

This proposed amendment reduces the amount of time the AU must be physically present during GSR

treatments compared to both current regulations and licensing conditions described in § 35.1000 licensing guidance documents, reflecting the reliability of modern safety systems. Additionally, the proposed amendment does not require the AU to return in the event of an unexpected interruption. However, to ensure treatments are delivered according to the treatment plan and written directive, the AU must evaluate the situation before the operator resumes treatment. Overall, this proposed amendment reduces prescriptive requirements regarding the AU's location while maintaining safety as qualified personnel remain available to respond to emergencies and unexpected conditions.

To allow modern and future radiation therapy units, including GSRs, to be licensed under 10 CFR part 35, subpart H, the NRC is proposing to modify or remove prescriptive spot check and full calibration requirements. These proposed changes would eliminate outdated, redundant, or overly prescriptive provisions, better accommodate modern equipment designs, and align with the NRC's risk-informed, performance-based regulatory framework.

Specifically, for GSRs, the NRC is proposing to amend the following full calibration requirements contained within § 35.635:

a. Remove all references to helmet factors in paragraphs (a)(3) and throughout (b). These references are obsolete because newer GSR technologies do not rely on physical helmets or use integrated collimation systems. Removing all references to helmet factors eliminates unnecessary specificity that no longer reflects current practice and equipment design.

b. Revise paragraph (a)(2)(iii) to include collimation components in required post-repair calibrations aligning with the current recommendations outlined in § 35.1000 licensing guidance for modern GSR units. The current language limits the calibration trigger to repairs involving source removal or source assembly components. This proposed rule includes ''major repair of component(s) associated with the source assembly or collimation,'' ensuring calibrations are conducted when critical components that affect dose distribution are modified. This clarification improves regulatory clarity without increasing burden.

c. Replace outdated and device-specific calibration checks in paragraph (b) with a more performance-based set of criteria. The list includes references to obsolete components (*e.g.,* helmet microswitches, trunnion centricity) that are no longer applicable to modern units. The proposed revised calibration elements focus on broad system functions such as accuracy of positioning, localization, attenuation, and collimation devices; isocenter coincidence; timer linearity and on-off error; function of system interlocks; and availability of backup power systems. These revisions would provide licensees with greater flexibility in meeting calibration requirements, while aligning with the current recommendations outlined in § 35.1000 licensing guidance for modern GSR units.

d. Add a requirement for full calibration to verify the operability and availability of emergency response equipment required under § 35.610. This change would account for modern and future gamma stereotactic radiosurgery (GSR) units, which incorporate varied emergency response equipment that licensees must ensure is available and operational to respond in the event of an emergency, such as a stuck shutter. Although rare, such events have been reported to the NRC and resulted in sources continuing to be exposed following treatment where licensees have had to use emergency equipment. This requirement would not be expected to increase burden because licensees are already required to have emergency response equipment operational and available to implement emergency procedures specified in § 35.610 and perform full calibration of the unit in accordance with § 35.635.

Next, the NRC is proposing to amend § 35.645 to eliminate redundant and overly prescriptive requirements for periodic spot-checks of GSR units that are already addressed through nationally recognized standards or manufacturer protocols. Specifically, the NRC is proposing to—

a. Remove prescriptive specific spot checks for the GSR units contained in § 35.645(c)(1)–(2) and (d)(1)–(6), such as helmet microswitches, trunnion centricity, emergency timing circuits, and intercom systems. The prescriptive list of outdated requirements for modern GSR units would be replaced with a performance-based approach allowing licensees to follow written procedures established by the AMP and to rely on nationally recognized standards or NRC-accepted manufacturer instructions. NRC-accepted manufacturer instructions would be listed on the NRC's medical use toolkit on the emerging medical technology page after the NRC confirms the instructions to check the necessary systems and components as required per regulation and contain clear tolerance limits for licensee use. This change provides flexibility while maintaining safety and quality assurance.

b. Restructure § 35.645 to clearly define the frequency of required spot checks, aligning with the current recommendations outlined in § 35.1000 licensing guidance for modern GSR units.

c. Revise the current § 35.645(e) into proposed §§ 35.645(d) and (e) to permit the licensee to continue using the unit, provided that any system or device identified as not functioning properly is not used for treatment. The requirement in § 35.645(e) that a licensee must not use a unit if a malfunction is found in a system necessary for treatment would be retained.

d. For remote afterloader units, the NRC is proposing to amend § 35.643 to eliminate redundant and overly prescriptive requirements for periodic spot-checks that are already addressed through nationally recognized protocols or NRC-accepted manufacturer procedures. These changes are intended to streamline regulatory requirements, reduce unnecessary burden on licensees, and align with the NRC's risk-informed, performance-based regulatory framework. Specifically, the NRC is proposing to remove prescriptive specific spot checks for the high dose rate (HDR) units contained in § 35.643(d)(1)–(8), such as electrical interlocks, source exposure indicator lights, viewing and intercom systems, emergency response equipment, and computer clock settings. These requirements would be replaced with a performance-based approach allowing licensees to follow written procedures established by the AMP and to rely on nationally recognized standards or NRC-accepted manufacturer instructions, as described in § 35.643(b). NRC-accepted manufacturer instructions would be listed on the NRC's medical use toolkit on the EMT page after NRC confirms the instructions contain procedures and acceptable tolerance limits for necessary spot checks and calibrations. This shift would align required checks with standards and allow licensees to use innovative or emerging technologies while maintaining safety.

As very few teletherapy units currently exist in the U.S., the NRC is not proposing additional changes to remove prescriptive spot-check or full calibration requirements for these units, as was done for HDR and GSR. However, for consistency with the updates to HDR and GSR regulations, the NRC is proposing to amend spot check requirements contained within §§ 35.632(d) for teletherapy units. This amendment would allow licensees to

follow NRC-approved manufacturer procedures in the absence of nationally recognized protocols if a new teletherapy unit is developed.

4. Establishment of Subpart I for Microsource Brachytherapy

The NRC is proposing to establish a dedicated regulatory framework for microsource brachytherapy by developing a new subpart I under 10 CFR part 35 and making other conforming changes. These changes are intended to incorporate microsources, such as Y-90 microspheres, into traditional medical-use subparts in a way that reflects their unique characteristics. Due to microspheres' unique characteristics, they are currently licensed under § 35.1000. To support licensing these units under subpart K, the NRC developed two licensing guidance documents for 3 types of microspheres, TheraSphere®, SIR-Spheres®, and Eye90®. The use of microspheres for permanent implant manual brachytherapy has grown significantly over the past two decades, and the NRC anticipates continued growth and innovation in this area, including the development of new microsource systems. This proposed rule would eliminate the need to use subpart K for licensing microspheres, while still ensuring proper radiation safety oversight.

The new subpart I of 10 CFR part 35 mirrors the structure of existing subparts F and H but specific requirements would be tailored to the specific operational and safety considerations of microsource brachytherapy based on current licensing conditions contained in § 35.1000 licensing guidance to include microsources. The NRC is proposing to amend § 35.2 to add definitions for ''microsource,'' ''microsource brachytherapy,'' and ''shunting,'' and revise the definition of ''prescribed dosage'' to include microsources. Adding these definitions is part of a broader effort to modernize and clarify terminology used in 10 CFR part 35 to improve consistency in regulatory language and better reflect current clinical practices and medical community standards.

The NRC is proposing to amend written directive requirements in § 35.40 to include microsource brachytherapy. Specifically, the proposed amendments would—

a. Revise § 35.40(b)(5) to explicitly include ''microsource brachytherapy'' alongside permanent manual brachytherapy, ensuring that written directives for microsource treatments document the treatment site, radionuclide, and either total source strength or prescribed dosage before administration.

b. Update §§ 35.40(a)(2) and (b)(5) to include microsource brachytherapy with manual brachytherapy to allow changes to the written directive after administration but before the patient leaves the post-treatment recovery area.

c. Modernize terminology to reflect current clinical practice, replacing ''permanent implant brachytherapy'' with ''permanent manual or microsource brachytherapy,'' and allowing for documentation of either total source strength, prescribed dosage, or administered activity, which is particularly relevant for microsphere therapies.

Additionally, the proposed subpart I would introduce the following provisions:

a. Section 35.700 would establish the conditions under which microsources may be used, including sourcing from licensed manufacturers or use under an FDA-accepted investigational device exemption (IDE). This provision would ensure that microsources are obtained and used in a manner consistent with existing safety and quality standards.

b. Section 35.710 would outline safety procedures and instruction requirements. Specifically, § 35.710(a) would mandate that microsource administration devices be used in accordance with the Sealed Source and Device Registry, consistent with current licensing guidance. In addition, § 35.710(b) would require licensees to develop, implement, and maintain written procedures for responding to abnormal situations (*e.g.,* spills, equipment failures, or emergent conditions that could affect the administration of microsources). This is a new requirement that is not currently addressed in the current § 35.1000 microsphere licensing guidance and which is not expected to increase regulatory burden. The addition would be necessary for safety to ensure that applicants have documented procedures to manage abnormal situations that may periodically occur during microsource use, enhancing safety and preparedness and reducing risk. Section 35.710(c) also would require initial operational and safety training for individuals handling microsources, including training provided by the manufacturer or certified trainers, in line with current § 35.1000 licensing guidance. Further, to align with regulations in other subparts for other therapeutic modalities that may involve patients who cannot be released under § 35.75, radiation safety instructions are proposed to be added for personnel caring for such patients or human research subjects in § 35.710(d). These instructions emphasize patient control, contamination prevention, and emergency response. This change is not expected to increase the burden for current yttrium-90 microsphere licensees, as patients are typically released under current clinical practice. However, it is essential to ensure personnel have clear and consistent safety instructions in the event that future microsource administrations require inpatient care. Recordkeeping requirements are proposed to be added for training and procedures to ensure accountability and compliance.

c. Proposed new § 35.790 would define the training and experience requirements for AUs of microsources in line with current § 35.1000 licensing guidance and changes described in Section IV.A., ''Training and Experience,'' of this document. Specifically, the proposed amendment would require:

i. Completion of a diagnostic and interventional radiology residency, along with classroom and laboratory training in radiation safety fundamentals.

ii. Supervised clinical experience involving at least three microsource cases, including hands-on work with ordering, preparing, administering, and evaluating treatments. Unlike the proposed changes that remove specific case requirements for unsealed byproduct material and superficial ophthalmic use of beta-emitting sources, this proposed rule retains a minimum of three microsource cases currently contained in the § 35.1000 licensing guidance for Y-90 microspheres and is being retained to ensure practitioners have sufficient experience to maintain safety given the continued high number of reported events and the unique delivery systems used for each microsource type.

iii. Written attestation from a qualified preceptor or residency program director confirming the individual's readiness to independently perform radiation safety duties.

Alternatively, prior authorization under § 35.390, 35.396, or 35.490 with supplemental microsource-specific training and attestation would meet the training and experience requirement. The addition of § 35.396 would allow for additional physicians to be licensed based on their prior training and experience under § 35.396, reducing burden from past § 35.1000 licensing guidance recommendations.

a. The regulations in § 35.2310 would establish the recordkeeping requirements for safety instruction provided under §§ 35.93, 35.310,

35.410, 35.610, and now also § 35.710, which would address safety procedures for microsource brachytherapy systems. This revision would expand the scope of required records to include operational and safety instruction related to microsource use. The update would align microsource recordkeeping requirements for operational and safety instructions with the other therapeutic technologies contained in 10 CFR part 35.

b. The regulations in § 35.2710 is a proposed new section that would establish the recordkeeping requirements associated with safety procedures and instruction for microsource use. This section would ensure that licensees maintain documentation of written procedures for managing abnormal situations involving microsource administration, aligning microsource recordkeeping requirement for procedures with other modalities contained in 10 CFR part 35 while adding minimal burden. The NRC is proposing these requirements to support accountability and reinforce safe clinical practice in the use of microsource brachytherapy systems.

5. Increasing Flexibility for Safety Precautions Regarding Exposure From Patients

The NRC is proposing to amend its regulations to reduce regulatory burden and increase flexibility for licensees in managing patients or human research subjects who cannot be released under § 35.75. Specifically, the NRC is proposing to combine safety precautions from individual modality subparts into a new section, § 35.76 contained in subpart C, which would be applicable to all uses. By combining the safety precautions, licensees would have flexibility to house individuals who cannot be released under § 35.75 in the same room, regardless of whether they received the same type of administration. This change would allow, for example, a patient who received radiopharmaceutical administration under subpart E to be roomed with a patient who received microsource administration under subpart I, provided the licensee can do so in accordance with 10 CFR part 20 dose limits. This would increase flexibility in patient management and facility use without compromising radiation safety.

The NRC is also proposing to revise the requirement that patients receiving unsealed byproduct material must have a private sanitary facility. This proposed rule would instead require that such patients have access to a sanitary facility used only by individuals who have received similar administrations, without leaving the controlled area. This change would support more efficient facility design and use while maintaining adequate protection against contamination and exposure in uncontrolled areas.

6. Reduce Barriers for Innovative Emerging Medical Technologies

The NRC is proposing amendments to 10 CFR part 35 to reduce regulatory barriers that may delay or discourage the adoption of innovative EMTs. These changes are part of a broader initiative to modernize the medical use regulations and ensure they remain risk-informed, performance-based, and adaptable to technological advancements.

One set of proposed changes addresses the calibration of dose calibrators and survey instruments. Specifically, § 35.60(c) would be amended to permit licensees to submit written calibration procedures for NRC approval in cases where the instrumentation required under paragraph (a) cannot be calibrated using nationally recognized standards or the manufacturer's instructions. This revision would facilitate the use of innovative instrumentation for emerging and novel radioisotopes in medical applications without the need for licensing under subpart K or exemption as current licensees must calibrate these instruments using nationally recognized standards or manufacturer instructions. The NRC would evaluate the submitted procedures to determine whether they achieve calibration tolerances comparable to those established in nationally recognized standards. Conforming changes would be made to §§ 35.12(b)(2) and (c)(2). This approach is intended to support the safe and effective use of new technologies in nuclear medicine while reducing regulatory barriers that may hinder medical research and the development of future clinical applications involving byproduct material.

Similarly, the proposed revision to § 35.61 would reduce the prescriptiveness of survey instrument calibration requirements, allowing licensees greater flexibility to tailor calibration methods to the energy characteristics of new isotopes. Specifically, the proposed amendments would:

a. Revise § 35.61(a)(1) to require calibration of survey instruments for the radiation type and energy range measured, rather than specifying calibration of all scales up to 10 mSv (1000 mrem) per hour. This change would provide licensees with greater flexibility while ensuring that instruments are appropriately calibrated for their intended use.

b. Additionally, the requirement in § 35.61(a)(2) to calibrate two separate readings on each scale or decade would be removed, as it is overly prescriptive and not necessary to ensure accurate instrument performance. The requirement to conspicuously note the date of calibration on the instrument, currently in § 35.61(a)(3), would be retained as § 35.61(a)(2).

The NRC also is proposing to revise § 35.604, ''Surveys of patients and human research subjects treated with a remote afterloader unit,'' to remove the term ''portable'' from the description of survey instruments. This change would accommodate the use of innovative detection technologies, provided they meet performance and calibration requirements. The revised language would continue to ensure that radiation sources are properly surveyed and returned to a shielded position before the end of the procedure, while allowing licensees to adopt newer technologies within existing regulatory framework.

Another proposed change clarifies the licensing pathway for manual brachytherapy sources. Under current regulations, subpart F governs the use of sealed sources in manual brachytherapy, but the term ''implant'' in §§ 35.404(a) and (b), and 35.2404, ''Records of surveys after source implant and removal,'' has led to confusion regarding whether topically administered sources could be licensed under this subpart. The proposed revisions would clarify that manual brachytherapy sources both topically and inserted within a patient or human research subject are subject to subpart F. This clarification would streamline the licensing process for treatments such as those for skin cancers or post-surgical sites and ensure that licensees can efficiently implement innovative brachytherapy devices without compromising safety.

7. Other Regulatory Clarifications and Implementation Changes for Emerging Medical Technologies

The NRC is proposing amendments to certain regulatory requirements in 10 CFR part 35 to clarify the intent and application of several regulatory provisions related to the medical use of byproduct material. These clarifications are part of the NRC's broader effort to ensure that its regulations remain clear, risk-informed, and aligned with current clinical practices, particularly as new technologies emerge and evolve.

One area of focus is §§ 35.57(b)(4) and 35.1000(c), which address the continued use of medical technologies initially licensed under subpart K. As these technologies become well established and are incorporated into traditional subparts of 10 CFR part 35, the NRC seeks to ensure that licensees and AUs do not need to reapply for approval to continue using them. The proposed changes would establish a clear regulatory pathway to preserve existing authorizations when a § 35.1000 use transitions into a standard subpart use, thereby reducing administrative burden and supporting continuity of care.

The NRC also is proposing to revise § 35.27(a)(1) to replace the phrase ''written directive procedures'' with ''procedures for administrations requiring a written directive.'' This change would align the language with § 35.41, ''Procedures for administrations requiring a written directive,'' and clarify that the regulation applies to the implementation of the written directive, not to the physician's clinical decision-making process. The proposed revision reinforces the NRC's intent to ensure that licensees have procedures in place to verify that the medical use of byproduct material is administered in accordance with the physician's instructions, as documented in the written directive.

Additionally, the NRC is proposing to revise § 35.41(b)(4) to remove prescriptive language that limits the applicability of the requirement for verifying computer-generated dose calculations to specific subparts such as § 35.600 or § 35.1000. This proposed change broadly applies to any modality that uses computer-generated dose calculations, regardless of the subpart under which it is licensed. The proposed revision would ensure that the requirement applies broadly, without inadvertently triggering subpart K licensing for modalities that adopt these technologies in the future.

Together, these proposed changes are intended to clarify regulatory intent, reduce unnecessary burden, support the safe and efficient adoption of EMTs, and ensure that the NRC's medical use regulations remain flexible, forward-looking, and focused on safety outcomes.

C. Rubidium-82 Generators

The proposed revision would include amendments to 10 CFR part 35, subpart A, ''General Information,'' subpart B, ''General Administrative Requirements,'' subpart C, ''General Technical Requirements,'' and subpart D, ''Unsealed Byproduct Material—Written Directive Not Required,'' to resolve outstanding regulatory issues regarding the use of Rb-82 generators that are currently dispositioned through use of enforcement discretion as described in EGM 13–003. To continue regulating Rb-82 generators without the need for enforcement discretion and without impacting safety, changes would be necessary to allow for the currently accepted methods for calibration of radiation detectors in a dynamic mode and to address dosage measurements for Rb-82 generators. These criteria are currently implemented under EGM 13–003 and remain in effect today. The proposed amendments would codify these requirements into regulation, eliminating the need for ongoing enforcement discretion while maintaining the same safety basis. The NRC is proposing to revise § 35.63 to address longstanding challenges associated with determining the activity of radiopharmaceutical dosages in certain clinical scenarios, particularly those involving short-lived isotopes administered via direct infusion systems, which cannot meet the regulations for measuring patient dosages before administration.

1. Specifically, the title of § 35.63 would be revised from ''Determination of dosages of unsealed byproduct material for medical use'' to ''Determination of dosages for medical use'' to reflect the broader applicability of the section. Paragraph (a) to § 35.63 would be amended to exempt incremental administrations that meet the criteria in new paragraph (e) from the requirement to determine and record the activity of each dosage before medical use.

2. Paragraphs (b) and (c), which describe acceptable methods for determining the activity of unit and non-unit dosages, respectively, would be retained but revised to clarify that they do not apply to incremental administrations that meet the criteria in paragraph (e).

3. A new paragraph (d) would be added to allow licensees to determine and record the activity of each incremental dosage administered from a direct infusion system using either a calibrated instrument that is part of the system or a combination of measurement and mathematical calculations.

4. Paragraph (e) would establish specific criteria under which incremental administrations may be performed using direct infusion systems. These criteria include: (1) the administered radioisotope must have a half-life of less than three minutes; (2) a written directive must not be required (for diagnostic use, a written directive would not be required because these administrations involve very short-lived isotopes delivered in small quantities through automated systems, making pre-administration measurement impractical and risk minimal); (3) the radioisotope must be administered directly from the generator or system without additional preparation steps; and (4) the administration must follow the manufacturer's guidelines and procedures. These provisions are designed to accommodate the unique characteristics of isotopes such as Rb-82, which cannot be practically measured before administration using traditional methods due to rapid decay and automated delivery systems.

5. The existing dosage deviation limit in paragraph (d) would be redesignated as paragraph (f) and retained without change, as would the recordkeeping requirement in paragraph (e), which would become paragraph (g). These proposed changes would accommodate the unique characteristics of isotopes such as Rb-82, which cannot be practically measured prior to administration using traditional methods, while maintaining adequate assurance that patients receive the prescribed dosage.

To address direct measurements allowed under the proposed addition of § 35.63(d), § 35.60(d) would be added to require licensees to test the infusion pump flow rate and radiation detectors used by developing, implementing, and maintaining written test procedures. These tests would continue to be required at least every 12 months to ensure continued accuracy and reliability of the infusion systems and associated detectors over time and following any repair that could affect calibration in accordance with EGM 13–003 and the proposed new § 35.60(e). Conforming changes would be made in §§ 35.60(f) and 35.2060, ''Records of calibrations of instruments used to measure the activity of unsealed byproduct material,'' to ensure licensees retain a copy of procedures used to verify the infusion pump flow rate. These criteria, with the exception of the proposed record keeping requirements for testing procedures under § 35.2060(b), are currently implemented under EGM 13–003 and remain in effect today. The new recordkeeping requirement would ensure traceability and regulatory oversight by documenting not only test results but also the approved methods used to obtain those results, while adding minimal burden. This would close a gap in current rules, align with best practices for quality assurance, and

provide inspectors confidence that testing was performed under validated procedures rather than improvised practices.

D. Other Topics

1. Written Directives for Diagnostic Sodium Iodide I-131

The NRC is proposing to amend § 35.40 to remove the requirement that a written directive be prepared for diagnostic administrations of sodium iodide I-131. Currently only diagnostic administrations of sodium iodide I-131 in quantities greater than 1.11 megabecquerels (30 microcuries) require a written directive. This proposed change would reclassify these diagnostic uses under the licensing framework of 10 CFR part 35, subpart D, which governs diagnostic uses of unsealed byproduct material that do not require a written directive. To support this change, §§ 35.100 and 35.200 would be revised to remove the introductory clause referencing § 35.40(b) as a limiting condition. The revision would ensure consistency with the updated written directive requirements in § 35.40.

This revision also would reflect the evolution of clinical practice and radiation safety standards in diagnostic nuclear medicine. In the past decade, only one reported medical event involved a diagnostic administration of sodium iodide I-131 at a dosage level requiring a written directive. This event occurred because the licensee failed to complete the written directive before administration, even though the patient received the correct prescribed dosage. In contrast, there have been three medical events in the same period where patients scheduled for diagnostic administration of sodium iodide I-123 received the wrong radionuclide. Additionally, two older events (both more than 5 years ago) involved patients prescribed doses below the threshold requiring a written directive who instead received higher-than-intended doses of sodium iodide I-131. These examples show that diagnostic administrations of sodium iodide I-131 at dosage levels requiring a written directive have a risk profile comparable to other diagnostic administrations that do not require a written directive. By removing the written directive requirement for these diagnostic administrations, licensees would still be required to report any medical event that occurs, maintaining appropriate safety oversight while eliminating the unnecessary requirement.

2. Reductions in Event Reporting

The NRC is proposing to amend § 35.3045(a) to exclude requiring licensees to report events that result from emergent patient conditions that prevent completion of administration as planned. In addition, the NRC is proposing to add a definition of emergent patient conditions to § 35.2 to clarify that emergent patient conditions are unexpected developments or acute changes in patients' condition, such as vascular spasm or seizure, that occur during the administration which cause a deviation from the planned administration. To ensure the NRC takes appropriate actions to reduce occurrence of significant events, the NRC is also proposing to amend § 35.3045(b) to require reporting of an event under this proposed exclusion if the event is expected to cause unintended permanent functional damage to an organ or physiological system, as determined by a physician. This clarification does not introduce a new reporting category; rather, it aligns emergent patient condition events with existing requirements for events caused by actions of patients, known as patient intervention. This proposed change would be expected to reduce reporting burden by approximately nine events per year while ensuring the NRC is still notified of significant events that could cause unintended significant harm to patients. The proposed changes are intended to reduce unnecessary reporting burden; improve clarity; better align the rule with a risk-informed, performance-based regulatory framework; and continue to ensure significant events that result in unintended permanent functional damage are reported.

In addition, the NRC is proposing to amend § 35.40(a)(2) to allow AUs to revise the written directive during administration for all brachytherapy procedures, except for high dose-rate (HDR) remote afterloader treatments, provided the changes are documented and signed by the AU within 24 hours of the procedure. This change would provide clarity that licensees may use the post-administration portion of the written directive when determining whether a medical event occurred and allows AUs to approve real-time adjustments based on the medical needs of the patient, consistent with their medical judgment. This includes adjusting the written directive if stasis occurs during administration, consistent with the current Y–90 microsphere licensing guidance. However, to ensure leaks or defects in administration device or supplies are reported, the NRC is proposing to add § 35.3045(a)(3) to require reporting if the total dose or dosage delivered differs from the prescribed dose or dosage defined on the written directive before administration by 20 percent, as caused by a leak or defect in administration device or supplies, unless the event resulted from patient intervention or an emergent patient condition. This would ensure the NRC can take appropriate action to prevent reoccurrence of similar events.

Section 35.3047 requires licensees to report any dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent that is a result of an administration of byproduct material or radiation from byproduct material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the AU. Over the years, this has resulted in licensees reporting events where they made reasonable effort to determine pregnancy status but due to early gestational age or other medical conditions of the patient, they were unable to determine the patient's pregnancy status at the time of administration. Because this is a medical issue and there is no action for the NRC to take in these events, the NRC is proposing to amend the regulation to add § 35.3047(a)(2) to exclude requiring licensees to report these events when they made a reasonable effort to determine pregnancy status, but pregnancy could not be reasonably excluded prior to the administration by the licensee.

The NRC has determined that the proposed revisions to § 35.3045 would maintain adequate protection of public health and safety while improving the utility, clarity, and clinical relevance of medical event reporting. By focusing reporting requirements on events that may indicate a breakdown in safety controls, such as those caused by equipment defects or procedural errors, the rule continues to support the NRC's oversight mission while reducing unnecessary administrative burden on licensees.

3. Expanding Use of Decay-in-Storage

The NRC is proposing to amend § 35.92 to increase the allowable physical half-life for byproduct material eligible for decay-in-storage from 120 days to 275 days. This change would allow licensees to use decay-in-storage for longer-lived materials, such as Lu-177m, which is becoming more prevalent in medical facilities as new lutetium-177 (Lu-177) radiopharmaceuticals receive FDA approval. In addition, this amendment

would enable licensees to retain Co-57 flood sources for decay-in-storage as operational experience has demonstrated licensees can store these sources safely.

This proposed amendment would reduce unnecessary disposal costs and regulatory burden for medical licensees while maintaining public health and safety. Under the current rule, licensees must dispose of Lu-177 waste as low-level radioactive waste if it contains Lu-177m, even if the licensee has the space and shielding to safely store the material until it decays to background levels. As medical licensees already maintain secure, shielded storage areas for decay-in-storage, this proposed change would not require new infrastructure or introduce new risks. The proposed change supports the NRC's risk-informed, performance-based regulatory approach by focusing regulatory requirements on materials that pose a greater hazard, while allowing flexibility for low-risk materials.

4. Reduction in License Amendments for Human Subject Research

Under § 35.6(c), licensees currently must seek a license amendment for certain proposed research involving humans even if they are licensed for the type of medical use involved and the research is approved by an institutional review board (IRB). This duplicative requirement has led to delays in research and increased administrative workload for both licensees and the NRC. Therefore, the NRC is proposing to amend § 35.6 to eliminate the requirement for licensees to submit a license amendment before conducting research involving human subjects, provided the licensee is already authorized for the medical use of byproduct material and has obtained IRB approval and informed consent from the research subject. Conforming changes also would be made to § 35.8 as the proposed change would reduce the need for a licensing amendment request. By removing the requirement for an unnecessary license amendment application, the NRC would facilitate timely and efficient research without compromising safety or ethical standards.

5. Reduce Duplication Requirements for Mobile Medical Services

The NRC is proposing to amend regulations specific to mobile medical services contained in § 35.80 to eliminate prescriptive requirements that are redundant to regulations contained in 10 CFR part 20 and other sections of 10 CFR part 35. These changes would ensure regulations for mobile medical licensees are aligned with survey requirements in 10 CFR part 20, and consistent with requirements for transfer of byproduct material for other 10 CFR part 30 licensees. In addition, these proposed changes would reduce unnecessary limitations on licensees and align with the NRC's risk-informed, performance-based regulatory framework.

Specifically, the proposed amendments would remove the following provisions:

a. Section 35.80(a)(2), which requires licensees to check instruments used to measure the activity of byproduct material before use at a client's address. This requirement is overly prescriptive and redundant with § 35.60, which requires that all licensees possess and calibrate instruments used to measure activity of unsealed byproduct material and microsources before administration in accordance with specific requirements. Because § 35.60 provides reasonable assurance that patients receive prescribed dosages for both mobile and non-mobile medical licensees, § 35.80(a)(2) is unnecessary.

b. Section 35.80(a)(3), which requires licensees to check survey instruments for proper operation with a dedicated check source before use at each client's address. This is a standard health physics practice and is already encompassed by the broader requirement in § 20.1501(c) to perform adequate radiation surveys that are necessary to ensure compliance with radiation safety regulations contained in 10 CFR part 20 and are reasonable under the circumstances to evaluate the magnitude and extent of radiation levels, concentrations or quantities of residual radioactivity, and the potential radiological hazards of the radiation levels and residual radioactivity detected. The removal of this provision would eliminate unnecessary regulatory specificity and clarify that there are not different requirements for mobile medical licensees versus non-mobile medical licensees who can also transport survey instruments to different sites.

c. Section 35.80(a)(4), which requires licensees to survey all areas of use to ensure compliance with 10 CFR part 20 before leaving the client's address. Removing this provision would align regulations for mobile medical licensees with regulations for other 10 CFR part 30 licensees who have temporary job sites and would avoid duplicative regulation with § 20.1501 while ensuring radiation safety.

d. Section 35.80(b), which prohibits the delivery of byproduct material to a client unless the client is licensed to receive it. Section 20.1802 requires licensees to control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage, which would already preclude a mobile medical licensee from delivery of byproduct material to a client unless they would be able to safely secure it or the client has a license. Therefore, retaining this provision in § 35.80 is unnecessary.

Conforming changes are being proposed to remove associated survey records as currently required in § 35.2080(b). The proposed amendments would not introduce new risks or reduce the level of protection for workers, patients, or the public. Rather, they would remove outdated or duplicative requirements and provide licensees with greater flexibility in how they meet existing performance-based requirements, consistent with their capabilities.

6. Expand Temporary Radiation Safety Officer and Changes to Radiation Safety Committee

Section 35.24 outlines the authority and responsibilities for licensees' radiation protection programs, including requirements for RSOs and RSCs. The NRC is proposing to revise § 35.24 to increase the allowable service period for temporary RSOs and to revise the required composition and applicability of RSCs to better reflect current clinical practices. This change would reduce regulatory burden on medical use licensees while maintaining appropriate oversight of radiation safety programs.

First, the NRC proposes to amend § 35.24(c) to extend the allowable duration for a qualified individual to serve as a temporary RSO from 60 days to 120 days per calendar year. Under the current rule, licensees may allow a qualified individual to act as a temporary RSO for up to 60 days without submitting a license amendment. However, the NRC has found that this timeframe is often insufficient for licensees to recruit, hire, and onboard a permanent RSO, particularly in specialized or rural medical settings. Extending the temporary RSO period to 120 days would provide licensees with greater flexibility during staffing transitions or extended absences, reduce the need for license amendments, and support continuity of oversight and safety by avoiding the need to designate multiple RSOs during a transition period.

Second, the NRC proposes to revise § 35.24(f) to clarify that an RSC is only required if a licensee is authorized for

two or more different types of uses or units that require written directives. This change would provide clarity that diagnostic uses, which are generally lower risk and do not require written directives, do not trigger the requirement to establish an RSC. In addition, this section would be amended as a conforming change to add subpart I and to clarify that EMTs that require a written directive must be included when a licensee is determining if an RSC is needed. This revision aligns with the NRC's risk-informed approach by focusing regulatory oversight on higher-risk therapeutic uses.

Finally, the NRC proposes to revise the required composition of the RSC by removing the requirement to include a representative of the nursing service. The current rule specifies that the RSC must include an AU for each type of use, the RSO, a representative of management, and a representative of the nursing service. However, in modern medical practice, patients receiving therapeutic byproduct material are often treated on an outpatient basis and are not under the care of nursing staff. As a result, the nursing representative is frequently not involved in the radiation safety aspects of treatment. Removing this requirement would reduce administrative burden on licensees while preserving the core safety oversight functions of the RSC. Licensees may still choose to include a nursing representative or any other clinical staff member on the RSC at their discretion.

These proposed changes are consistent with the NRC's ongoing efforts to modernize its medical use regulations, reduce unnecessary regulatory burden, and align requirements with current clinical practice. The NRC has determined that these proposed amendments would not introduce new risks and would maintain adequate protection of public health and safety for workers, patients, and the public, while providing greater flexibility and clarity.

7. Removal of Redundant Regulations and Addition of Implementation Clauses

As part of the larger response to E.O. 14300, the NRC reviewed 10 CFR part 35 in its entirety to remove redundant regulations. As a result of this review, the NRC is proposing to remove § 35.5 because maintenance of records is already required by § 30.51, which applies to 10 CFR part 35 licensees.

In addition, the NRC reviewed 10 CFR part 35 to remove outdated regulations related to implementation of previous rulemakings. On October 1, 2007, the NRC published a final rule to amend 10 CFR part 35 to implement provisions of the Energy Policy Act of 2005 requiring that the NRC license the medical use of accelerator-produced radioactive material or discrete sources of radium-226 (72 FR 55864). In §§ 35.10(a) and 35.11(c)(1) and (2), the NRC regulations provide waivers for certain entities using this material from requiring a specific license until the entity submitted a medical use license application. As these waivers had end dates of no later than August 8, 2009, for § 35.10(a); December 1, 2008, for § 35.11(c)(1); and August 7, 2009, for § 35.11(c)(2), these paragraphs are outdated and would be removed. In addition, the clause ''on or after October 24, 2002,'' regarding calibration measurements of brachytherapy sources in § 35.432, is outdated and also would be removed.

V. Specific Requests for Comments

The NRC is seeking advice and recommendations from the public on this proposed rule. The NRC is particularly interested in comments and supporting rationale from the public on the following:

1. The NRC is proposing to revise the definition of ''teletherapy'' in § 35.2 to clarify that it refers to external beams of ionizing radiation are delivered from an external source without stereotactic guidance. However, the NRC is also considering removing the specific reference to stereotactic guidance or adding additional clarifying language to further expand the definition. As such, the NRC is seeking comments on examples of teletherapy uses and whether the NRC would need to further revise the definition of teletherapy to ensure these teletherapy uses are included. Please provide the basis for your response.

2. As part of this rulemaking package, the NRC has developed guidance to clarify that the physical presence of an AU for the medical use of byproduct is not required under § 35.11(b)(1). 10 CFR 35.11(b)(1) permits licensees to allow individuals who are not AUs to perform certain tasks under the supervision of an AU who is named on the license or permit. As indicated, the NRC has developed guidance to clarify that there is no requirement regarding the location of the AU during the use. The current compatibility category of § 35.11(b) is category C, allowing Agreement States to be more restrictive and potentially require the physical presence of an AU. The NRC has received concerns from industry stakeholders that § 35.11(b) raises transboundary concerns as medical networks have grown and many cross state lines, such that the regulation should be compatibility category B. In addition, the industry stakeholders have expressed concerns that requiring an AU to be physically present or within a specified location of the medical use limits access to treatments in rural areas. As such, the NRC is considering changing this regulation to be compatibility category B. The NRC is requesting specific comments on the appropriate compatibility category for § 35.11(b).

3. The NRC is proposing to establish specific criteria in § 35.63 to allow incremental administrations to be performed using direct infusion systems, including a criterion that calls for the administered radioisotope to have a half-life of less than three minutes. These provisions are designed to accommodate the unique characteristics of isotopes such as Rb-82, which cannot be practically measured using traditional methods due to their rapid decay and automated delivery systems. The NRC is seeking feedback on whether the proposed three-minute timeframe is appropriate or if a higher threshold would be beneficial for a current or expected future medical use and if so, what length half-life would be appropriate (for example, 5 minutes or 10 minutes). Please provide the basis for your response.

4. The NRC is proposing to change § 35.92(a) to allow licensees to hold byproduct material with a physical half-life of less than or equal to 275 days, instead of 120 days, to allow licensees to hold Lu-177m and Co-57 flood sources for decay-in-storage. The NRC is seeking feedback on whether an even longer half-life limit would be beneficial for medical use in this context. Specifically, the NRC is considering increasing the physical half-life beyond 275 days if there is a radioisotope used in medicine that could benefit from such an increase without causing a significant increase in risk. Please comment on whether increasing the half-life limit beyond 275 days would provide a meaningful benefit to medical licensees. If you believe a longer limit would be appropriate, indicate what specific half-life (for example, 300 days or 365 days) you recommend and explain the medical use which would benefit from your recommendation. In addition, describe any safety or operational considerations the NRC should evaluate if the limit is extended further.

5. The NRC is proposing to change the definition of ''physician'' in § 35.2 to expand eligibility for individuals to become AUs. This change is intended to

allow those who meet training and experience requirements and are fully licensed to practice medicine in the United States, but whose primary medical qualification is not titled MD or DO, such as foreign-trained physicians, to be eligible to become AUs. The NRC is considering whether the clause specific to prescribing drugs should be removed or additional qualifying language should be added to this definition in the final rule. In particular, the NRC is seeking feedback on whether removing additional language or adding additional qualifying language, such as ''fully licensed to practice medicine independently,'' is needed in this definition to ensure individuals defined as physicians have adequate training and experience to perform tasks allowed under 10 CFR part 35. Please provide the basis for your response.

6. The NRC is proposing to remove the requirement for a written directive for a diagnostic administration of sodium iodide I-131 in quantities greater than 1.11 megabecquerels (30 microcuries). The requirement was historically established to reduce the potential for unintended thyroid irradiation associated with irreversible thyroid uptake and to help prevent wrong-patient or wrong-procedure administrations. The NRC is seeking feedback on whether eliminating this written directive requirement could raise any safety concerns or otherwise affect patient protection beyond risks associated with diagnostic administrations. In particular, the NRC seeks input on whether current clinical practices of patient identification, procedure verification, and pregnancy screening provide sufficient assurance that diagnostic administration of sodium iodide I-131 are performed safely without the need for a written directive. The NRC is also seeking feedback on whether the removal of this requirement would reduce unnecessary administrative burden on licensees while maintaining adequate protection of patients. Please provide the technical or operational basis for your response, including any relevant experience, data, examples from clinical practices, or information on current institutional practices used to verify patient identity and the intended procedure.

7. The NRC is proposing to remove prescriptive requirements for specific numbers of classroom and laboratory training hours and work experience hours for physicians who have completed residency training in specialties where radiation safety and the clinical use of byproduct material are inherently integrated into the curriculum. This proposed rule identifies diagnostic radiology, nuclear medicine, and radiation oncology as specialties that would not need to complete these prescriptive training hours for training related to uptake, dilution, excretion, imaging, and localization studies. The NRC is seeking feedback on whether these residency programs do and would continue to include sufficient training in these areas, without the prescriptive hour requirements, as the NRC considers whether to remove or maintain the current requirements.

8. In addition, the NRC is proposing to keep the current training hours requirements for physicians who completed fellowship but is considering removing these training hours requirements provided the fellowship curriculum sufficiently integrates radiation safety and the clinical use of byproduct material to ensure the physician can independently fulfill radiation safety-related duties as an AU for medical use. Thus, the NRC is seeking feedback on whether any fellowship curriculum sufficiently integrates radiation safety and the clinical use of byproduct material to ensure the physician can independently fulfill radiation safety-related duties as an AU for medical use, and on any potential considerations of including fellowship training in addition to residency training for meeting the training and experience requirements in subparts D through H of 10 CFR part 35. Please provide the basis for your response.

VI. Regulatory Flexibility Analysis

The Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), requires that agencies consider the impact of their rulemakings on small entities and, consistent with applicable statutes, consider alternatives to minimize these impacts on the businesses, organizations, and government jurisdictions to which they apply. An agency must prepare an Initial Regulatory Flexibility Analysis unless it determines and certifies that a rule, if promulgated, would not have a significant economic impact on a substantial number of small entities. Because the NRC has not made such a certification for this proposed rule, the NRC has prepared this analysis in accordance with 5 U.S.C. 603.

The NRC has established standards for determining which of its licensees qualify as small entities pursuant to 10 CFR 2.810, ''NRC size standards.'' These standards include an $8 million receipts-based threshold and related employee-based criteria. Approximately 30 percent of 4,250 NRC and Agreement State licensees (or about 1,275 licensees) qualify as small entities. This percentage is derived from the small-entity distribution used in the NRC's annual fee rule (91 FR 36470; June 16, 2026) and is applied here as a general indicator of the proportion of licensees that may qualify as small entities.

The Small Business Regulatory Enforcement Fairness Act requires that the NRC prepare a written compliance guide to assist small entities in complying with each rule for which a regulatory flexibility analysis is prepared. The proposed rule includes both deregulatory provisions and several new or revised recordkeeping requirements. These include updates associated with continuing education, documentation for emerging medical technologies, Rb-82 generator activities, expanded decay in storage provisions, and revised Radiation Safety Committee applicability. As discussed in Sections VII, ''Regulatory Analysis,'' these requirements apply to different subsets of licensees, and together represent a small portion of the overall amendments.

As shown in table 25, licensees would incur approximately $3.8 million in total costs over the five-year analysis period when discounted at 7 percent, consisting of about $1.8 million in implementation costs and about $2.0 million in recordkeeping costs. Applying the NRC's 30-percent small-entity proportion, small entities would experience approximately $1.1 million of this total, or about $0.5 million in implementation costs and $0.6 million in recordkeeping costs, discounted at 7 percent. Based on 1,275 small entities, this equates to roughly $430 to $470 per small entity over five years, or about $90 per year. These impacts are minimal.

Likewise, the estimated annual small-entity burden, discounted at 7 percent, would be $0.2 million, consisting of about $0.1 million in implementation burden and about $0.1 million in recordkeeping burden. Because the individual recordkeeping provisions apply to different subsets of licensees, the number of affected small entities varies by requirement.

The NRC is seeking public comment on the potential impact of this proposed rule on small entities. The NRC particularly desires comment from licensees who qualify as small businesses, specifically as to how the proposed regulation will affect them and how the regulation may be tiered or otherwise modified to impose less stringent requirements on small entities while still adequately protecting the public health and safety and common defense and security. Comments on how

the regulation could be modified to take into account the differing needs of small entities should specifically discuss:

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

(b) How the proposed regulation could be further modified to take into account the business's differing needs or capabilities;

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

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

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

Comments should be submitted as indicated under the **ADDRESSES** caption.

VII. Regulatory Analysis

This regulatory analysis is prepared in accordance with E.O. 12866, ''Regulatory Planning and Review,'' and E.O. 14215, ''Ensuring Accountability for All Agencies.'' E.O. 14215 requires independent agencies, such as the NRC, to comply with E.O. 12866 and submit significant actions for Office of Information and Regulatory Affairs (OIRA) review. The analysis assesses the costs and savings of the alternatives considered by the NRC and concludes that the proposed deregulation action in this rule is expected to reduce regulatory burden and generate cost savings for licensees, the NRC, and the Agreement States when compared to the no-action baseline. The regulatory analysis is detailed in the following paragraphs of this document. Comments on the analysis may be submitted to the NRC as indicated under the **ADDRESSES** caption of this document.

A. Need for the Rule

The NRC was created by Congress in 1974 to ensure the safe use of radioactive materials for beneficial civilian purposes while protecting people and the environment. The NRC protects public health and safety and advances the Nation's common defense and security by enabling the safe and secure use and deployment of civilian nuclear energy technologies and radioactive materials through efficient and reliable licensing, oversight, and regulation for the benefit of society and the environment. From an economic perspective, common defense and national security are public goods for which the markets cannot maximize net benefits, and markets alone can sometimes create unintended impacts to public health and safety. Consistent with its statutory authority, the NRC provides reasonable assurance of adequate protection of public health and safety.

Section 5 of E.O. 14300 requires the NRC to undertake a review and wholesale revision of its regulations and guidance documents as guided by the policies set forth in section 2 of the E.O. This rulemaking is part of the NRC's response to the direction in section 5 of the E.O. because, in conducting the wholesale review of its regulations, the NRC reexamined the regulations pertaining to the use of certain nuclear material without a license and determined—based on past experience and practice—such uses can be expanded. Rulemaking is the most effective way to achieve this. Licensees may amend their current license for additional radionuclides; however, such amendments impose a cost on licensees and regulators without a proportionate benefit to public health and safety. Expanding the use of certain nuclear material without the need for a license also cannot be accomplished through guidance, as such guidance would conflict with the existing regulatory text. Therefore, amending the NRC's regulations is the most effective way to make this deregulatory change for all intended exempt uses.

B. Analytical Framework

This analysis uses current regulations under 10 CFR part 35 as the no-action baseline (Alternative 1), evaluates the changes proposed in this rule as the regulatory alternative (Alternative 2), and estimates the costs and savings of this proposed rule's implementation. Alternative 2 would revise 10 CFR part 35 to reduce barriers to medical use licensing and address E.O. 14300, section 5, by improving efficiency, predictability, and flexibility, while easing administrative burdens for the NRC, Agreement States, licensees, and applicants. The proposed changes include administrative updates, clarifications, and streamlined requirements that reduce redundancies and support the licensing of innovative technologies, all while maintaining the NRC's commitment to public health and safety.

To estimate the regulatory impact of the proposed changes, the NRC used input from agency subject matter experts, data from three related agency information collection requests approved by the Office of Management and Budget (OMB),[1] through OIRA, and other supporting documents as listed under Section XIX., ''Availability of Documents,'' of this document. Specifically, tables 2, 3, 4, and 7 and tables 9 through 23 rely on current OMB-approved information collection requests included in the paperwork reduction package supporting this proposed rule. Tables 5, 6, and 8 rely on prior NRC regulatory basis analysis listed in the ''Availability of Documents'' section of this document. In all cases, the quantitative and qualitative input used in the analysis were informed by the agency subject matter experts. Where possible, the NRC provides quantitative estimates based on available data. Where data are not available, the NRC relies on judgment from agency subject matter experts to approximate the impact and the level of effort involved. The analysis then monetizes the estimated time impacts for NRC staff, Agreement State staff, and licensees involved in medical use licensing activities. Monetized impacts are calculated by multiplying the estimated labor hours spent by (1) licensees to comply with regulatory requirements and (2) NRC and Agreement State staff to review submissions by the applicable wage rates. Because the monetized impacts are directly proportional to both labor time and wage rates, any change in these inputs would result in a corresponding change in the estimated values. For the NRC staff, the NRC uses its own internal labor rate of $158 per hour.[2] As shown in table 1, wage rates for licensees and Agreement State staff are derived from U.S. Bureau of Labor Statistics (BLS)[3] and adjusted using NRC's standard 2.4 multiplier to account for fringe benefits and overhead costs.

[1] OMB Control Numbers 3150–0010, 3150–0120, and 3150–0178.

[2] This NRC labor rate differs from those developed under the agency's license fee recovery program (10 CFR part 170, ''Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services under the Atomic Energy Act of 1954, as Amended''). NRC labor rates for fee recovery purposes are appropriately designed for full-cost recovery of the services rendered and thus include nonincremental costs (*e.g.,* overhead, administrative, and logistical support costs). *https://www.nrc.gov/about-nrc/regulatory/rulemaking/regulatory-analysis.*

[3] U.S. Bureau of Labor Statistics, Occupational Employment and Wage Statistics, National Industry-Specific Occupational Employment and Wage Statistics, May 2024.

TABLE 1—WAGE RATES USED IN THE ANALYSIS

[2024 U.S. dollars]

Standard occupational classification	Position title	Hourly mean wage	NRC multiplier	Fully loaded hourly mean wage (mean wage rate * 2.4)
Licensees: Wage rates for training and experience requirements				
29–0000	Healthcare Practitioners and Technical Occupations	$52.85	2.4	$126.84
29–1210	Physicians	133.01	2.4	319.22
29–1224	Radiologists	176.61	2.4	423.86
Blended mean wage				289.98
Licensees: Wage rates for EMT, Rb-82 generators, and other related topics requirements				
19–2099	Physical Scientists, All Other	47.40	2.4	113.76
19–2012	Physicists	107.97	2.4	259.13
19–5011	Occupational Health and Safety Specialists	42.64	2.4	102.34
19–5012	Occupational Health and Safety Technicians	28.71	2.4	68.90
29–0000	Healthcare Practitioners and Technical Occupations	52.85	2.4	126.84
29–1210	Physicians	133.01	2.4	319.22
29–1224	Radiologists	176.61	2.4	423.86
43–0000	Office and Administrative Support Occupations	22.77	2.4	54.65
43–1011	First-Line Supervisors of Office and Administrative Support Workers.	32.02	2.4	76.85
Blended mean wage				171.73
29–1140	Registered Nurses	47.21	2.4	113.30
Licensees: Wage rates for written directives for diagnostic sodium iodide I-131 requirements				
29–2033	Nuclear Medicine Technologists	47.98	2.4	115.15
29–1224	Radiologists	176.61	2.4	423.86
Blended mean wage				269.51
Licensees: Wage rates for event reporting requirements				
19–2012	Physicists	107.97	2.4	259.13
29–0000	Healthcare Practitioners and Technical Occupations	52.85	2.4	126.84
29–1210	Physicians	133.01	2.4	319.22
29–1224	Radiologists	176.61	2.4	423.86
Blended mean wage				282.26
Licensees: Wage rates for use of decay in storage				
29–0000	Healthcare Practitioners and Technical Occupations	52.85	2.4	126.84
For all licensees: Average wage rate				
Blended mean wage				228.06
Agreement State: Wage rates				
11–3031	Financial Managers	64.45	2.4	154.68
17–2081	Environmental Engineers	48.66	2.4	116.78
19–5010	Occupational Health and Safety Specialists and Technicians	37.24	2.4	89.38
23–1011	Lawyers	57.44	2.4	137.86
Blended mean wage				124.67

All costs and cost savings are expressed in 2024 dollars. The analysis covers a 5-year period, which provides a reasonable basis for projecting licensee activities. In accordance with OMB Circular A–4, the staff used NPV calculations to estimate the value of future cost savings in constant 2024 dollars, the most recent year for which complete annual data are available. NPV analysis allows for the comparison of costs and benefits that occur at different points in time by discounting them to a common base year. Consistent with OMB guidance, the analysis applies real discount rates of 3 percent and 7 percent. The 3-percent rate reflects the social rate of time preference and approximates the real return on long-term government debt. The 7-percent rate reflects the opportunity cost of capital and approximates the average pretax real rate of return on private-sector investments. The sign convention

used in this analysis is that savings associated with Alternative 2 are positive, while costs are negative. Negative values are shown in parentheses (*e.g.,* negative $500 is displayed as ($500)).

The resulting estimates and underlying calculations are presented in the subsequent sections.

C. Estimated Costs and Savings of This Proposed Rule

The estimated undiscounted costs and savings for major provisions are outlined in this section. These include updates to training and experience requirements, incorporation of certain well-established EMTs, revisions to requirements for the use of Rb-82 generators to codify existing enforcement guidance and provide regulatory clarity, changes to other requirements in different areas of medical use, and costs associated with implementing the rule.

1. Training and Experience

As discussed in Sections III.A and IV.A, ''Training and Experience,'' the proposed changes would modernize and streamline the training and experience requirements for physician AUs. Most physician AUs undergo comprehensive residency programs that include radiation safety as part of the nature of the program that equips them with the necessary knowledge to ensure they can independently fulfill the radiation safety-related duties as an AU for medical use. By removing outdated and prescriptive topics from the regulations, the NRC seeks to reduce unnecessary administrative burdens for applicants while ensuring AUs are adequately prepared for their roles. Past experience has shown that many applicants submit incomplete or inadequate information, which results in additional time needed by the NRC, Agreement States, and applicants to resolve these issues. Because this proposed rule would reduce the complexity of training and experience criteria, it is expected that it would shorten licensing processing times and reduce the need to track incomplete information, some of which would no longer be required. Retaining preceptor statements for non-board-certified individuals and providing alternative pathways would ensure each physician has a pathway to become an AU while ensuring they have the knowledge to independently fulfill radiation safety duties. Finally, changing the definition of physician to include a path for foreign trained medical doctors would remove anti-competitive barriers.

These proposed changes to the training and experience requirements in 10 CFR part 35 would reduce ongoing NRC and Agreement State licensing resources in reviewing and approving requests from applicants and reduce licensee burden in developing license applications to add authorized individuals. Overall, these changes are designed to enhance licensing efficiency and reduce unnecessary burdens, while ensuring that AUs have sufficient training to ensure radiation safety in the medical use of byproduct material.

In addition, by removing the license amendment requirement for certain diagnostic uses of unsealed byproduct material, the NRC aims to reduce unnecessary regulatory burden on licensees while maintaining appropriate oversight. The approval of AUs for these uses would be evaluated as part of the NRC's routine inspection program, ensuring AUs have the necessary training and experience to support radiation safety without requiring pre-approval through the licensing process. As shown in table 2, these proposed changes are expected to reduce paperwork and administrative costs, yielding a reduction of 4,208 hours (or $1.2 million, undiscounted) for the licensees per year.

TABLE 2—AVERTED COSTS FROM PRE-APPROVAL THROUGH THE LICENSING PROCESS

[Licensees]

Type	Reduction in number of amended and renewed applications	Responses per licensee	Burden hours per response	Total burden hours reduced	Fully loaded wage rate	Annual cost savings
Amendments: Authorized user approval for non-therapeutic uses of unsealed byproduct material						
NRC licensees	70	1	4.50	315	$289.98	$91,342
Agreement State licensees	525	1	4.50	2,363	289.98	685,068
Renewal: Authorized user approval for non-therapeutic uses of unsealed byproduct material						
NRC licensees	40	1	4.50	180	289.98	52,196
Agreement State licensees	300	1	4.50	1,350	289.98	391,468
Total				4,208		1,220,074

This proposed rule also would reduce unnecessary burden by eliminating outdated and overly broad training and experience requirements for physicians. Instead of mandating individuals provide documentation at time of licensing that they had training or experience within 7 years in uses and administrations that may no longer be relevant or practiced, sometimes in types of use they never will see in practice, the NRC is proposing to streamline requirements to focus solely on the procedures that licensees actively perform, ensuring more efficient and targeted preparation. These proposed changes are expected to reduce paperwork and associated administrative costs related to training and experience requirements. Under the current requirements, licensees must report the information listed in NRC forms 313 and 313a, by either using these forms or their own format, to document training and experience details. The proposed amendments would streamline reportable data by reducing the number of data fields and clarifying what information must be reported, which is expected to lessen burden. These proposed changes would reduce reporting time by an estimated 1.25 hours per submission. Of this reduction, 0.25 hours comes from less time spent reporting on the recentness of training. The remaining savings result from other burden reductions related to training and experience requirements, excluding the diagnostic AU category

previously shown in table 2. Overall, these proposed changes would yield a saving of 8,177 hours (or $2.4 million, undiscounted) for the licensees per year, as shown in table 3.

TABLE 3—AVERTED COSTS FROM OUTDATED AND BROAD TRAINING REQUIREMENTS

[Licensees]

Type	Number of licensee respondents	Responses per licensee	Reduction in burden hours per response	Total burden hours reduced	Fully loaded wage rate	Annual cost savings
New license applications						
NRC licensees	32	1	1.25	40	$289.98	$11,599
Agreement State licensees	240	1	1.25	300	289.98	86,993
Amendments						
NRC licensees	640	1	1.25	800	289.98	231,981
Agreement State licensees	4,800	1	1.25	6,000	289.98	1,739,856
Renewals						
NRC licensees	122	1	1.00	122	289.98	35,377
Agreement State licensees	915	1	1.00	915	289.98	265,328
Total				8,177		2,371,134

Currently, § 35.59 requires individuals to demonstrate related continuing education and experience if their required training and experience was obtained more than 7 years prior to the date of application. This proposed rule would replace this prescriptive licensing requirement that may not align with uses the physician plans to perform with a performance-based continuing education requirement that ensures authorized individuals maintain the necessary education and experience to support radiation safety and regulatory compliance for the uses they are authorized to perform. Although licensees would incur an increase in recordkeeping cost, it is necessary to ensure physicians have necessary education and experience to support radiation safety and regulatory compliance for the uses they are authorized to perform to ensure safety while decreasing costs overall. As shown in table 4, the recordkeeping burden would increase by 1,063 hours (or $308,100, undiscounted) per year for licensees.

TABLE 4—ADDITIONAL COSTS FROM RECORDKEEPING REQUIREMENTS

[Licensees]

Type	Increase in number of recordkeepers	Records per licensee	Burden hours per record	Total burden hours increase	Fully loaded wage rate	Annual cost
NRC licensees	500	5	0.05	125.0	$289.98	($36,247)
Agreement State licensees	3,750	5	0.05	937.5	289.98	(271,853)
Total				1,062.5		(308,100)

The NRC recognizes that, to realize these ongoing savings, licensees and training providers may need to update continuing education programs and revise recordkeeping practices to reflect the new requirements. The NRC has included an estimate for these activities within the overall implementation costs presented in table 24.

2. Emerging Medical Technologies

As discussed in Sections III.B. and IV.B, ''Emerging Medical Technologies,'' this proposed rule would codify provisions for 13 EMTs, by establishing clear licensing pathways, defined training and experience requirements, and performance-based safety criteria. Codifying these provisions would reduce reliance on EMT-specific guidance and eliminate the recurring burden associated with application reviews and guidance updates. Based on data presented in the regulatory basis, the NRC estimated measurable burden reductions would occur for well-established EMTs across the NRC, Agreement States, and licensees. Due to the timeline established in E.O. 14300 for publishing this proposed rule, the scope of EMTs addressed in this proposed rule has been narrowed to focus on those with the most extensive history and highest levels of use. In addition, the proposed regulations have been updated to align with the NRC's efforts to reduce burden by establishing performance-based requirements compared to current recommendations contained in licensing guidance where possible. To assess burden, the NRC used data from the regulatory basis for the EMTs listed. For EMTs not included in the regulatory basis, the NRC applied the same methodology from the regulatory basis to the updated EMT list, to ensure consistency. The regulatory basis originally presented cumulative burden estimates over a 15-year period, which the NRC converted to annual estimates for purposes of this regulatory

analysis. As shown in table 5, the NRC estimates that 12,867 hours of burden related to EMT licensing guidance would be eliminated on an annual basis across the NRC, Agreement States, and licensees. This total includes 724 hours for NRC licensing staff, 10,380 hours for Agreement States to review and process EMT-related licensing actions, and 1,763 hours for licensees to prepare and submit applications and amendments per year.

TABLE 5—AVERTED TIME SPENT ON EMT-RELATED LICENSING ACTIONS

[NRC, agreement states and licensees]

EMTs	NRC	Agreement states	Licensees
Time spent on submission and review of license applications and amendments in hours per year			
Ge-68/Ga-68 Pharmaceutical Grade Generators	5	76	10
NeoVista, Inc.'s Epi-Rad90 (Sr-90) Ophthalmic System	12	171	23
ViewRay System for Radiation Therapy	6	86	11
LV Liberty Vision Y-90 Disc and Ophthalmic System	7	105	14
Gamma Knife—Elekta Esprit	11	162	22
Akesis Galaxy RTi	11	162	22
Eye90 Microspheres	64	914	122
Gamma Knife—Perfexion	9	133	18
GammaPod	5	76	10
Masep Infini	12	171	23
Sirtex Microspheres	389	5,562	744
Nordion Microspheres	193	2,762	744
Total hours	724	10,380	1,763

In addition to this burden reduction, the NRC would save 437 hours for licensing guidance development. As shown in table 6, the aggregate annual savings for the NRC, Agreement States, and licensees would be 13,304 hours (or $1.8 million, undiscounted). These estimated burden reductions reflect reduced staff time associated with licensing reviews license amendment processing, and related administrative and guidance-development activities for EMTs.

TABLE 6—AVERTED COSTS FROM EMT-RELATED LICENSING ACTIONS

[NRC, agreement states and licensees]

Entities and activities	Averted hours	Fully loaded wage rate	Annual cost savings
NRC: EMT licensing guidance cost	437	$158.00	$68,993
NRC: Review of EMT license applications and amendments	724	158.00	114,392
Agreement States: Review of EMT license applications and amendments	10,380	124.67	1,294,116
Licensees: Submission of EMT license applications and amendments	1,763	171.73	302,756
Total	13,304	.....	1,780,258

Licensees would benefit from the proposed change to codify provisions that reduce reliance on EMT-specific guidance and eliminate the recurring burden associated with application reviews and guidance updates. Specifically:

- Proposed changes that would align with recommended EMT-specific guidance are not expected to impose additional burdens on licensees. The NRC staff determined that no incremental costs are anticipated, and costs for these changes were not included.
- Proposed changes to § 35.60 would allow licensees to use instrumentation that cannot be calibrated according to nationally recognized standards or the manufacturer's instructions. This flexibility is optional and intended to support future innovations, but it is not expected to be used at this time. The NRC subject matter experts determined that no incremental costs are anticipated, and costs for these changes were not included.
- Proposed changes in § 35.41(b)(4) would require licensees to verify computer-generated dose calculations are transferred into a console correctly for all therapeutic uses, not just those authorized by §§ 35.600 and 35.1000. This proposed regulation would not be required for new modalities at this time as they do not currently use computer-driven consoles. The intent of this proposed regulation is to reduce future licensing costs associated with subpart K of 10 CFR part 35 licensing for innovative and emerging medical technologies; NRC subject matter experts determined that cost cannot be estimated at this time because none of these technologies are currently in use.
- Proposed changes in § 35.635(b)(6) would require licensees to determine the operability and availability of emergency response equipment in their full calibration. This requirement is not expected to increase burden because licensees are already required to have emergency response equipment operational and available to implement emergency procedures specified in § 35.610 and perform full calibration of the unit in accordance with § 35.635.

Although the proposed changes to the NRC's microsource regulations would introduce an additional burden on licensees, these changes are intended to make these regulations more flexible and better accommodate both current and future microsource use. The proposed changes that align with

current § 35.1000 licensing guidance criteria and the additional requirement contained in § 35.710(d), which would require radiation safety instructions for personnel caring for such patients or human research subjects who cannot be released in accordance with § 35.75, are not expected to increase the burden. Current Y-90 microsphere regulations allow licensees to release patients under § 35.75 following administration; however, it is uncertain if future microsource administrations could require inpatient care. This proposed rule would require licensees to keep records of safety instructions and develop and maintain procedures for responding to abnormal situations, such as microsource spills, equipment failures, and emergent conditions that may occur during use. Licensees would incur a small increase in costs due to this requirement, but these procedures are necessary to ensure the safe use of microsources. As shown in table 7, the recordkeeping burden associated with this proposed requirement would increase by 183 hours (or $31,427, undiscounted) per year for licensees.

TABLE 7—COSTS FROM RECORDKEEPING REQUIREMENTS ON EMTS

[Licensees]

Type	Increase in number of recordkeepers	Records per licensee	Burden hours per record	Total burden hours increase	Fully loaded wage rate	Annual cost
Amended requirements: Maintain a record of safety instructions						
NRC licensees	40	1	0.1	4.0	$171.73	($687)
Agreement State licensees	300	1	0.1	30.0	171.73	(5,152)
New requirements: Maintain a copy of each procedure						
Amended record maintained	35	1	0.5	17.5	171.73	(3,005)
Agreement State licensees	263	1	0.5	131.5	171.73	(22,582)
Total				183.0		(31,427)

Impacts related to EMT training requirements have already been accounted for in Section VII.B.1, ''Training and Experience,'' of this document.

3. Rubidium-82 Generators

As discussed in Sections III.C. and IV.C, ''Rubidium-82 Generators,'' of this document, this proposed rule would establish formal requirements for Rb-82 generators, including calibration flexibility for radiation detector instrumentation in dynamic use mode and updated licensing and training provisions to replace reliance on enforcement guidance. The proposed regulations are consistent with the criteria required to use enforcement discretion as described in EGM 13–003. Eliminating reliance on enforcement guidance would remove the recurring burden associated with enforcement discretion activities, such as, review of exemption requests and inspections associated with Rb-82 generators. The NRC converted the data presented in the regulatory basis, cumulative burden estimates over a 15-year period, into annual estimates for purposes of this regulatory analysis. As shown in table 8, the NRC estimates 3,145 burden hours (or $435,699, undiscounted) related to enforcement guidance activities would be eliminated on an annual basis across the NRC, Agreement States, and licensees under this proposed rule. These estimated burden reductions reflect reduced staff time associated with licensing, inspection, exemption review, and related administrative activities that would have supported the use of enforcement guidance for Rb-82 generators.

TABLE 8—AVERTED COSTS FROM Rb-82 GENERATORS ENFORCEMENT GUIDANCE

[NRC, agreement states and licensees]

Entities	Enforcement discretion cases		Inspections		Total burden hours reduced	Fully loaded wage rate	Annual cost savings
	Number	Hours	Number	Hours			
NRC	11	36	8.5	6	447	$158.00	$70,626
Agreement States	49.5	36	76.5	4	2,088	124.67	260,319
Licensees	55	8	85	2	610	171.73	104,754
Total					3,145		435,699

Licensees would incur a small increase in costs due to the recordkeeping requirements associated with this proposed rule change but would benefit and save costs overall from the proposed codification of EGM–13–003. As shown in table 9, the recordkeeping burden would increase by 253 hours (or $43,499, undiscounted) per year for licensees.

TABLE 9—COSTS FROM RECORDKEEPING REQUIREMENTS ON RB-82 GENERATORS

[Licensees]

Type	Increase in number of recordkeepers	Records per licensee	Burden hours per record	Total burden hours increase	Fully loaded wage rate	Annual cost
Amended requirements: Maintain a record of each instrument calibration and test						
NRC licensees	5	255	0.02	25.5	$171.73	($4,379)
Agreement State licensees	38	255	0.02	193.8	171.73	(33,281)
New requirements: Retain a copy of each procedure						
NRC licensees	40	1	0.10	4.0	171.73	(687)
Agreement State licensees	300	1	0.10	30.0	171.73	(5,152)
Total				253.3		(43,499)

4. Other Topics

The proposed amendments discussed in this section seek to modify existing requirements in several areas of 10 CFR part 35, including those governing written directives, decay-in-storage requirements, medical event reporting criteria, and other provisions. These changes are intended to reduce regulatory burden, increase flexibility, and modernize radiation safety practices for the medical use of byproduct material.

a. Written Directives for Diagnostic Sodium Iodide I-131

The proposed changes to § 35.40 would remove the requirement that a written directive be prepared for diagnostic administrations of sodium iodide I-131 in quantities greater than 1.11 megabecquerels (30 microcuries). As a result, physicians would no longer need to prepare a written directive prior to these diagnostic administrations and licensees would no longer need to develop, implement, and maintain written procedures in accordance with § 35.41 to use this administration. In addition, physicians who do not perform any other administrations requiring a written directive besides diagnostic administrations of sodium iodide I-131 in quantities greater than 1.11 megabecquerels (30 microcuries) would be able to receive AU status under subpart D. This would reduce the training and experience needed for these physicians to be able to provide this administration as discussed Section VII.A of this document.

As shown in table 10, these proposed changes are expected to reduce paperwork and other administrative costs. A decrease of 15 records per licensee and a one-hour decrease in burden per procedure is estimated to save 6,323 hours (or $1.7 million, undiscounted) annually for licensees performing reporting and recordkeeping for the NRC and Agreement States.

TABLE 10—AVERTED COSTS FROM WRITTEN DIRECTIVES FOR DIAGNOSTIC SODIUM IODIDE I-131

[Licensees]

Type	Number of licensees	Records reduced per licensee	Burden hours reduced per response	Burden hours per record	Total burden hours	Fully loaded wage rate	Annual cost savings
Recordkeeping							
NRC licensees	425	15		0.05	319	$269.51	$85,906
Agreement State licensees	3,188	15		0.05	2,391	269.51	644,394
Following procedure							
NRC licensees	425		1		425	269.51	114,541
Agreement State licensees	3,188		1		3,188	269.51	859,192
Total	7,226				6,323		1,704,032

b. Reductions in Event Reporting

The NRC is proposing to amend § 35.3045(a) to exclude requiring licensees to report events that result from emergent patient conditions that prevent completion of administration as planned unless the administration results or would result in damage as described in § 35.3045(b). In addition, NRC is proposing to amend § 35.40 to allow AUs for microsources to modify written directives after administration. To ensure the NRC continues to receive reports of leaks or defects in administration devices or supplies which can impact multiple licensees in a short time period, the NRC is proposing to add § 35.3045(a)(3). This addition would require reporting when such a leak or defect causes the total dose or dosage delivered to differ from the prescribed dose or dosage specified in the pre-administration portion of the written directive, unless the event results from patient intervention or an emergent patient condition. The cumulative result of these proposed changes would reduce the number of medical events, which would reduce burden in reporting these events to the

NRC or Agreement States as well as the required notification to the patient and referring physician. As shown in table 11, these proposed changes are expected to reduce paperwork burden, resulting in estimated annual savings of about 117 hours (or $33,025, undiscounted) per year for licensees.

TABLE 11—AVERTED COSTS FROM MEDICAL EVENT REPORTING

[Licensees]

Type	Reduction in number of licensees	Responses per licensee	Burden hours per response	Total burden hours	Fully loaded wage rate	Annual cost savings
Notification by telephone to the NRC within 15 days of the discovery of the medical event						
NRC licensees	1	1	0.50	0.50	$282.26	$141
Agreement State licensees	8	1	0.50	4	282.26	1,129
Written report to the NRC within 15 days of the discovery of the medical event						
NRC licensees	1	1	8	8	282.26	2,258
Agreement State licensees	8	1	8	64	282.26	18,065
Annotated copy of the medical event report						
NRC licensees	1	1	0.50	0.50	282.26	141
Agreement State licensees	8	1	0.50	4	282.26	1,129
Notification of medical events to referring physician and individual within 24 hours						
NRC licensees	1	2	2	4	282.26	1,129
Agreement State licensees	8	2	2	32	282.26	9,032
Combined Total	.....	.....	.....	117	.....	33,025

Additionally, the NRC is proposing to amend the regulation to add § 35.3047(a)(2) to exclude reporting of exposure to an embryo/fetus if the licensee made a reasonable effort to determine pregnancy status, but pregnancy could not be reasonably excluded prior to the administration by the licensee. As shown in table 12, the projected reductions related to these events are expected to result in a reduced burden of about 28 hours (or $7,903, undiscounted) per year for licensees.

TABLE 12—AVERTED COSTS FROM MEDICAL EVENT REPORTING

[Licensees]

Type	Reduction in number of licensees	Responses per licensee	Burden hours per response	Total burden hours	Fully loaded wage rate	Annual cost savings
Notification by telephone to the NRC Operations Center no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child						
NRC licensees	1	1	0.50	0.50	$282.26	$141
Agreement State licensees	7	1	0.50	3.50	282.26	988
Written report to the NRC Regional Office no later than 15 days after discovery of a dose to the embryo/fetus or nursing child						
NRC licensees	1	1	0.50	0.50	282.26	141
Agreement State licensees	7	1	0.50	3.50	282.26	988
Notification to referring physicians and to the pregnant individual or mother no later than 24 hours after discovery of an event						
NRC licensees	1	1	2	2	282.26	565
Agreement State licensees	7	1	2	14	282.26	3,952
Annotated copy of the event report						
NRC licensees	1	1	0.50	0.50	282.26	141
Agreement State licensees	7	1	0.50	3.50	282.26	988
Total	.....	.....	.....	28	.....	7,903

In addition, both these changes would reduce burden to both the NRC and Agreement States as it would reduce reactive inspection follow-ups that occur when the NRC receives a medical or fetal/embryo event. As shown in table 13, the projected reduction related to these events would reduce burden by 48 hours per year for the NRC and 120

hours per year for Agreement States. There are also savings on travel and lodging costs for NRC inspectors, with estimated savings of about $800 for each inspection event (or $1,600 per year). For Agreement States, savings on travel and lodging costs are expected to be minimal because most inspection sites are nearby. The combined savings for both the NRC and Agreement States are $25,274, undiscounted, per year.

TABLE 13—AVERTED COSTS FROM MEDICAL EVENT FOLLOW-UPS

[NRC and agreement states]

Entity	Reduction in number of reactive inspections	Burden hours per inspector	Total burden hours reduced	Fully loaded wage rate	Annual cost savings
NRC	2	24	48	$158.00	$7,584
Travel and lodging					1,600
Agreement State	15	8	120	124.67	14,961
Total			168		25,274

In addition, the NRC requires Agreement States to submit reports to the Nuclear Material Events Database (NMED) each time a qualifying medical event occurs at one of their licensee's facilities within their state. With this proposed rule, the number of respondents would decrease resulting in a reduction in reporting obligations to the NRC. As shown in table 14, the projected savings are expected to result in a reduced burden of about 145 hours (or $18,129, undiscounted) per year for Agreement States.

TABLE 14—AVERTED COSTS FROM NMED REPORTING

[Agreement states]

Requirements	Reduction in agreement state licensee respondents	Responses per licensee	Burden hours per response	Total burden hours reduced	Fully loaded wage rate	Annual cost savings
Nuclear Material Event Report (Routine Significance)	8	10.77	1.50	129.24	$124.67	$16,113
Nuclear Material Event Report (Higher Significance)	7	0.77	3.00	16.17	124.67	2,016
Total				145.41		18,129

c. Expanding Use of Decay in Storage

The NRC is proposing to amend § 35.92 to increase the allowable physical half-life for byproduct material eligible for decay-in-storage (DIS) from 120 days to 275 days. This proposed change would allow licensees to use DIS for longer-lived materials, such as Lu-177m, which is becoming more prevalent in medical facilities as new Lu-177 radiopharmaceuticals receive FDA approval. By allowing these materials to decay on-site until they are no longer radioactive, rather than requiring disposal as radioactive waste under subpart K of 10 CFR part 20, the proposed amendment would reduce waste disposal costs for licensees. NRC staff has determined this would likely result in fewer low level waste shipments overall, reducing costs associated with packaging, transportation, and disposal fees for the licensees. As shown in table 15, these reductions are estimated to yield annual undiscounted savings of $584,800 for licensees. This value is subject to the use of Lu-177 containing Lu-177m by licensees and savings may vary due to differences in licensee-specific practices.

TABLE 15—AVERTED COSTS FROM LOW LEVEL WATE SHIPMENTS

[Licensees]

Type	Reduction in number of waste shipments	Amount of waste (pound)	Cost per pound of waste	Annual cost savings
NRC licensees	86	100	$8.00	$68,800
Agreement State licensees	645	100	8.00	516,000
Total				584,800

Most licensees that would benefit from this proposed change already operate a DIS program for isotopes with half-lives of 120 days or less and maintain dedicated secured space that complies with regulatory requirements.

However, with this proposed rule change, additional onsite storage may be needed to hold waste from materials with longer half-lives for licensees who opt into expanded DIS rather than continue disposal under current regulations. NRC staff believe most licensees would choose DIS because it is expected to cost less than disposal under current regulations, resulting in potential savings for those who opt in. Although the NRC staff assume that these activities would result in minor costs for facility expansion or operational adjustments, there is uncertainty regarding potential cost impacts because detailed information on licensees' existing storage setup and waste-handling procedures is not available. Additionally, licensees would incur a small increase in costs due to recordkeeping requirements associated with the extended storage period. As shown in table 16, the recordkeeping burden would increase by 833 hours (or $105,658, undiscounted) per year for licensees.

TABLE 16—ADDITIONAL COSTS FROM RECORDKEEPING REQUIREMENTS ON STORAGE

[Licensees]

Type	Increase in number of recordkeepers	Records per licensee	Burden hours per record	Total burden hours	Fully loaded wage rate	Annual cost
NRC licensees	86	57	0.02	98.0	$126.84	($12,435)
Agreement State licensees	645	57	0.02	735.3	126.84	(93,265)
Total				833.3		(105,701)

d. Reduction in License Amendments for Human Subject Research

The NRC is proposing to amend § 35.6 to eliminate the requirement for licensees to submit a license amendment before conducting research involving human subjects, provided the licensee is already authorized for the medical use of byproduct material and has obtained IRB approval and informed consent from the research subject. This would reduce the number of license amendments required. As shown in table 17, the estimated reduction related to the elimination of research application information is expected to result in a reduced burden of 204 hours (or $35,033, undiscounted) per year for licensees.

TABLE 17—AVERTED COSTS FROM RESEARCH APPLICATION INFORMATION

[Licensees]

Type	Reduction in number of licensees	Responses per licensee	Burden hours per response	Total burden hours	Fully loaded wage rate	Annual cost savings
NRC licensees	6	1	4	24	$171.73	$4,121
Agreement State licensees	45	1	4	180	171.73	30,911
Total				204		35,033

In addition, this change would reduce burden to both the NRC and Agreement States as it would reduce license amendment review time. This proposed change would reduce the burden on both the NRC and Agreement States by decreasing the time needed to review license amendments. As shown in table 15, these reductions are estimated to yield annual undiscounted savings of $584,800 for both the NRC and Agreement States.

TABLE 18—AVERTED COSTS ON REVIEWING LICENSE AMENDMENTS RELATED TO RESEARCH

[NRC and agreement states]

Entity	Reduction in number of license reviews	Responses per licensee	Burden hours per response	Total burden hours	Fully loaded wage rate	Annual cost savings
NRC	6	1	8	48	$158.00	$7,584
Agreement State	45	1	8	360	124.67	44,883
Total				408		52,467

e. Reduce Duplication Requirements for Mobile Medical Services

The NRC is proposing to amend regulations specific to mobile medical services contained in § 35.80 to eliminate prescriptive requirements that are redundant to regulations contained in 10 CFR part 20 and other sections of 10 CFR part 35. Conforming changes are being proposed to remove associated survey records as currently required in § 35.2080(b). As shown in table 19, these proposed changes are expected to reduce recordkeeping requirements, resulting in estimated annual savings of about 426 hours (or $73,156, undiscounted) per year for licensees.

TABLE 19—AVERTED COSTS FROM MOBILE MEDICAL SERVICES

[Licensees]

Type	Reduction in number of recordkeepers	Responses per licensee	Burden hours per response	Total burden hours	Fully loaded wage rate	Annual cost savings
NRC licensees	25	20	0.10	50	$171.73	$8,586
Agreement State licensees	188	20	0.10	376	171.73	64,570
Total				426		73,156

f. Expand Temporary Radiation Safety Officer and Changes to Radiation Safety Committee

The NRC proposes to amend § 35.24(c) to extend the allowable duration for a qualified individual to serve as a temporary RSO from 60 days to 120 days per calendar year. This would reduce the number of license amendments required. As shown in table 20, these proposed changes are expected to reduce paperwork burden, resulting in estimated annual savings of about 18 hours ($2,919, undiscounted) per year for licensees.

TABLE 20—AVERTED COSTS FROM EXTENDING ALLOWABLE DURATION FOR RSO

[Licensees]

Type	Reduction in number of license amendments	Responses per licensee	Burden hours per response	Total burden hours	Fully loaded wage rate	Annual cost savings
NRC licensees	2	1	1	2	$171.73	$343
Agreement State licensees	15	1	1	15	171.73	2,576
Total				17		2,919

Similarly, the NRC and Agreement States would realize an estimated annual savings of 17 hours (or $2,186, undiscounted) per year for reduced requirements regarding reviewing and processing RSOs. This reduction is based on eliminating two RSO reviews per year for the NRC (at 1 hour per review) and 15 RSO reviews per year for the Agreement States (at 1 hour per review), as shown in table 21.

TABLE 21—AVERTED COSTS FROM REDUCED RSO REVIEWS

[NRC and agreement]

Entity	Reduction in number of license amendments to review	Responses per licensee	Burden hours per response	Total burden hours	Fully loaded wage rate	Annual cost savings
NRC	2	1	1	2	$158.00	$316
Agreement State	15	1	1	15	124.67	1,870
Total				17		2,186

In addition, the NRC proposes to revise the requirements to the RSC contained in § 35.24(f). First, with the addition of microsources, this proposed rule is updated to include subpart I and K and clarifies that an RSC is only required if a licensee is authorized for two or more different types of uses or units that require written directives. As shown in table 22, the projected increase in burden is estimated at 42.5 hours (or $7,298, undiscounted) annually for licensees. This estimate is based on expanded reporting requirements due to the inclusion of microsources under subparts I and K of 10 CFR part 35.

TABLE 22—AVERTED COSTS FROM RSC REQUIREMENTS

[Licensees]

Type	Increase in number of respondents	Responses per licensee	Burden hours per response	Total burden hours	Fully loaded wage rate	Annual cost savings
NRC licensees	10	1	0.5	5.0	$171.73	$859
Agreement State licensees	75	1	0.5	37.5	171.73	6,440
Total				42.5		7,298

In addition, this proposed rule would remove the requirements for a representative of the nursing service to be part of an RSC. This would reduce an average of 4 hours of a nurse's time for all licensees who are required to have an RSC. As shown in table 23, this elimination is estimated to yield 4,640 hours savings (or $525,731, undiscounted) annually for licensees.

TABLE 23—AVERTED COSTS FROM NURSING SERVICE

[Licensees]

Type	Reduction of nursing service under RSC	Nurse's time in hours	Total burden hours	Fully loaded wage rate	Annual cost savings
NRC licensees	232	4	928	$113.30	$105,146
Agreement State licensees	928	4	3,712	113.30	420,584
Total			4,640		525,731

D. Rulemaking and Implementation Costs

For the purposes of this analysis, rulemaking costs consist of non-recurring expenses incurred by the NRC to complete the rulemaking process and transition to compliance with the final requirements. Implementation costs consist of non-recurring expenses incurred by the NRC, Agreement States, and affected licensees to transition to compliance with the final rule, including updates to guidance, procedures, and internal processes. Proposed provisions that would result in recurring costs are discussed in Sections VII.B.1 through VII.B.4 of this document and are therefore not included in this section. The NRC would incur about 1,000 hours of effort (or $158,000, undiscounted) to implement this rule, if finalized.

Agreement States would need to assess compatibility with the NRC's final rule, update state regulations and procedures as necessary, and inform affected licensees. While the rule is deregulatory, existing stringent requirements remain consistent with safety mandates. The NRC estimates that, if this proposed rule were to become final, Agreement States implementing this rule with respect to EMTs and Rb-82 generators, would incur an estimated cost of $760,000, undiscounted, as they would need to update their regulatory framework to reflect changes introduced by the NRC's final rule and ensure compatibility for licensing and oversight of these technologies. This effort ensures compliance with compatibility standards and provides the necessary authority for Agreement States to issue licenses for EMTs and Rb-82 generators. For the other changes associated with this proposed rule, because the effect of the rule would be deregulatory, the more stringent requirements currently required by Agreement States would be consistent with the mandate to adequately administer safety regulations. However, Agreement States would be likely to expend resources to amend state regulations and guidance documents to be consistent with this rule, if finalized. The NRC staff did not quantify these costs due to the expectation that the costs would be minor relative to the net benefits and are difficult to quantify.

Licensees and industry stakeholders would need to update compliance programs and internal procedures on the new requirements, if finalized. Because this would be a deregulatory rule, the implementation burden would be minimal and occur only during the initial period. The largest implementation burden would come from the revision to § 35.59 to replace the prescriptive recentness of training and experience requirement with a performance-based continuing education requirement. On average, each licensee is anticipated to spend 2 hours on implementation activities with licensees that have a greater number of AUs requiring more time than those with fewer AUs. In addition, there may be some implementation burden associated with appropriate licensees establishing a process to authorize diagnostic AUs without submitting a license amendment. However, this burden is expected to be small because licensees already maintain a process for preparing license applications to demonstrate that these individuals meet the authorized user training and experience requirements; the only change is that this information would no longer need to be submitted to the NRC. The remaining implementation burden would be relatively minor or would occur during the licensing process and due to the deregulatory action of the rule, would result in net burden reduction as already reflected above. As shown in table 24, the licensees implementing this rule would incur about 8,500 hours of effort, or an estimated cost of $1.9 million, undiscounted.

TABLE 24—IMPLEMENTATION COSTS

[Licensees]

Type	Number of licensees	Estimated hours to implement rule	Total hours	Fully loaded wage rate	One-time cost
NRC licensees	500	2	1,000	$228.06	($228,063)
Agreement State licensees	3,750	2	7,500	228.06	(1,710,474)
Total			8,500		(1,938,537)

Summary of Costs, Cost Savings, and Net Cost Savings

Overall, this proposed rule is considered a deregulatory action and would be expected to reduce barriers to medical use licensing by enabling more efficient and predictable licensing, increasing flexibility, and easing administrative burden for the NRC, Agreement States, licensees, and individuals or entities that seek medical use licenses. Over the 5-year analysis period (2027–2031), the proposed revisions are estimated to generate net savings of $39.1 million (savings minus costs), undiscounted. As shown in table 25, the NPV of these net savings would be $35.6 million, discounted at 3 percent, or $31.7 million, discounted at 7 percent. The projected annualized cost savings would be $7.2 million discounted at 3 percent, or $6.4 million discounted at 7 percent. Although this proposed rule would reduce barriers to medical use licensing and generate savings, some costs would still be incurred over the 5-year period, primarily due to expanded recordkeeping requirements and implementation costs. The additional recordkeeping costs, which represent operational costs for licensees, are estimated at $2.4 million (undiscounted), $2.2 million (discounted at 3 percent), and $2.0 million (discounted at 7 percent) over this 5-year period. Implementation costs for both NRC and industry stakeholders are estimated at about $2.9 million (undiscounted), $2.8 million (discounted at 3 percent), and $2.7 million (discounted at 7 percent). The combined implementation and compliance costs for both NRC and industry stakeholders, as well as expanded recordkeeping requirements in some areas for licensees, are estimated at about $5.3 million (undiscounted), $5.0 million (discounted at 3 percent), and $4.7 million (discounted at 7 percent).

The licensees, accounting for the largest share of net cost savings, would save about $30.5 million over the 5-year analysis horizon, undiscounted, with an NPV of $27.8 million discounted at 3 percent, or $24.8 million discounted at 7 percent. The Agreement States would realize net cost savings of about $7.4 million over 5 years, undiscounted, with an NPV of $6.7 million discounted at 3 percent, or $6.0 million discounted at 7 percent. During the same period, the NRC would save about $1.2 million over 5 years, undiscounted, with an NPV of $1.1 million discounted at 3 percent, or $964,000 discounted at 7 percent.

The annualized costs are approximately $970,000 per year at a 3 percent discount rate, and $865,000 per year at a 7 percent discount rate. The annualized cost savings are approximately $8.1 million per year at a 3 percent discount rate, and $7.2 million per year at a 7 percent discount rate. Therefore, the annualized net cost savings are estimated at $7.2 million per year at a 3 percent discount rate and $6.4 million per year at a 7 percent discount rate.

TABLE 25—TOTAL 5-YEAR COSTS, SAVINGS, AND NET SAVINGS

[NRC, agreement states and licensees] [4]

Attribute	Costs (2024 dollars)		
	Undiscounted	3% NPV	7% NPV
NRC Total	$158,000	$153,000	$148,000
Agreement States Total	760,000	738,000	710,000
Licensee Total	4,382,000	4,120,000	3,816,000
Net	5,300,000	5,012,000	4,674,000
Annualized		970,000	865,000
	Cost Savings (2024 Dollars)		
NRC Total	(1,355,000)	(1,242,000)	(1,112,000)
Agreement States Total	(8,171,000)	(7,485,000)	(6,701,000)
Licensee Total	(34,863,000)	(31,933,000)	(28,589,000)
Net	(44,390,000)	(40,659,000)	(36,402,000)
Annualized		(8,125,000)	(7,247,000)
	Net Cost Savings (2024 Dollars)		
Net NRC	(1,197,000)	(1,089,000)	(964,000)
Net Agreement States	(7,411,000)	(6,747,000)	(5,991,000)
Net Licensees	(30,481,000)	(27,813,000)	(24,773,000)
Net Total	(39,089,000)	(35,649,000)	(31,728,000)
Annualized Net		(7,155,000)	(6,382,000)
Qualitative Factors	Regulatory Clarity, Predictability, Flexibility, and Promoting Technological Advances		

In addition to the quantified savings, the NRC notes that this proposed rule would be expected to provide qualitative benefits to medical use licensees by enhancing regulatory clarity and predictability. By consolidating and modernizing requirements, the rule reduces ambiguity that has historically led to inconsistent interpretations and delays. Clearer, performance-based standards for training, experience, and emerging technologies will foster greater confidence in compliance and reduce the need for repeated consultations with regulators. This improved transparency would support a more streamlined licensing process and strengthen trust between licensees and regulators.

This proposed rule also promotes innovation and adaptability in medical use licensing. Codifying pathways for emerging medical technologies and updating requirements for generator systems ensures that licensees can adopt new devices and therapies without prolonged reliance on case-by-case guidance. This forward-looking approach positions the regulatory framework to accommodate future

[4] Values rounded to the nearest 1,000 dollars.

advancements in nuclear medicine, reducing barriers that could otherwise slow patient access to cutting-edge treatments. These benefits extend beyond cost savings by creating an environment that encourages technological progress while maintaining safety.

Finally, updates to training and experience requirements would allow licensees to receive authorization more quickly for future users and uses under § 35.300, which is critical given the anticipated growth in therapeutic radiopharmaceuticals. By recognizing accredited residency programs and introducing continuing education provisions, the rule aligns regulatory expectations with modern medical education practices. This flexibility helps address workforce challenges and supports timely onboarding of qualified practitioners, ensuring that patients benefit from expanded access to specialized care without unnecessary administrative delays.

VIII. Backfitting and Issue Finality

The NRC's backfitting provisions (which are found in the regulations at §§ 50.109, 70.76, 72.62, and 76.76) and issue finality provisions of 10 CFR part 52 do not apply to this rule. The regulations in 10 CFR part 35 do not contain a backfitting provision, and this rulemaking would not impact activities authorized by 10 CFR parts 50, 52, 70, 72, or 76. As a result, this rulemaking would not constitute ''backfitting'' as defined in 10 CFR chapter I or otherwise affect the issue finality of a 10 CFR part 52 approval.

IX. Cumulative Effects of Regulation

The NRC seeks to minimize potential negative consequences resulting from the cumulative effects of regulation (CER). The NRC believes that the de-regulatory impacts of this rulemaking activity are unlikely to cause implementation challenges for stakeholders. In addition, during the pendency of this rulemaking, the NRC is deprioritizing issuance of regulatory actions that might influence the implementation date for the new rule requirements (*e.g.,* orders, generic communications, license amendment requests, and inspection findings of a generic nature).

To fully understand any potential CER implications that could result from this rulemaking, the NRC is asking the following questions. Response to these questions is voluntary and any input will be considered during development of the final rule.

1. The NRC is proposing an effective date that will be 30 days after the date of publication of a final rule. Does this provide sufficient time to implement the proposed requirements? Please provide a rationale for your response.

2. Are there unintended consequences related to this rulemaking and how should they be addressed? Please provide a rationale for your response.

3. Please comment on the NRC's cost and benefit estimates in the regulatory analysis that supports this proposed rule.

X. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111–274) requires Federal agencies to write documents in a clear, concise, and well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, ''Plain Language in Government Writing,'' published June 10, 1998 (63 FR 31885). The NRC requests comment on this document with respect to the clarity and effectiveness of the language used.

XI. National Environmental Policy Act

A. Introduction

The NRC has prepared this environmental assessment (EA) of this proposed rule amending regulations to reduce barriers to medical use licensing to determine the significance of the environmental effects of the proposed agency action in accordance with the National Environmental Policy Act of 1969, as amended (NEPA) and NRC's NEPA implementing regulations in 10 CFR part 51, ''Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions.'' As explained below, the NRC has determined that the proposed agency action to modernize NRC regulations for medical use licensing would have no significant effect on the quality of the human environment.

B. Environmental Impacts of the Proposed Agency Action

Proposed rule changes would occur in 10 CFR part 35. Conforming changes would be made to guidance at a later date consistent with changes to regulations. Table 26 lists the sections of the regulations being changed and affected guidance.

TABLE 26—REGULATIONS AND GUIDANCE UNDER CONSIDERATION IN THE REDUCING BARRIERS TO MEDICAL USE LICENSING RULEMAKING

Regulations	Guidance
35.2, 35.5, 35.6, 35.8, 35.10, 35.11, 35.12, 35.13, 35.14, 35.24, 35.27, 35.40, 35.41, 35.50, 35.51, 35.55, 35.57, 35.58, 35.59, 35.60, 35.61, 35.63, 35.67, 35.69, 35.70, 35.76, 35.80, 35.92, 35.93, 35.100, 35.190, 35.200, 35.204, 35.290, 35.315, 35.390, 35.392, 35.394, 35.396, 35.404, 35.415, 35.432, 35.433, 35.490, 35.491, 35.590, 35.604, 35.610, 35.615, 35.632, 35.633, 35.635, 35.643, 35.645, 35.690, 35.700, 35.710, 35.790, 35.1000, 35.2059, 35.2060, 35.2063, 35.2080, 35.2093, 35.2204, 35.2310, 35.2404, 35.2406, 35.2433, 35.2642, 35.2643, 35.2645, 35.2710, 35.3045, 35.3047, 35.3093, 35.3204.	NUREG–1556, Volume 9.

Conforming changes are administrative actions with no physical environmental effect and provide for the appropriate administrative and regulatory framework for byproduct material use under title 10 of the CFR. An example would be adding a reference to a newly created subsection in an existing regulation. All amendments to NRC regulations in this proposed rule occur within the affected regulation.

1. Rule Amendments Addressed Under Categorical Exclusion

The NRC has determined that some of the changes to the regulations identified in this proposed rule meet criteria for categorical exclusion under § 51.22, ''Categorical exclusions.'' Categorical exclusions provide a mechanism to identify Federal actions that normally do not have a significant environmental effect on the human environment and for which neither an environmental assessment nor environmental impact statement is normally required. This ensures that resources are not expended on the environmental analysis of proposed actions that do not present the potential for significant environmental effects. Rule amendments with applicable categorical exclusions are presented in table 27 and no further NEPA analysis is required.

These proposed rule amendments belong to categories of actions that the

Commission, by rule or regulation, has declared to be a categorical exclusion, after first finding that the actions within the category do not individually or cumulatively have a significant effect on the human environment. In reviewing the list of regulations in table 26, the NRC staff have determined that several of the rule amendments are actions eligible for categorical exclusion under § 51.22(a)(1) or (2). Examples of eligible actions include amendments to the regulations in this chapter that are corrective or of a minor or nonpolicy nature and do not substantially modify existing regulations, and actions on petitions for rulemaking relating to these amendments. Additional examples of eligible actions include amendments to 10 CFR part 35, which include the issuance of or changes to procedures for filing and reviewing applications, recordkeeping or reporting requirements, and administrative procedures or requirements. Actions under § 51.22(a)(2) include the issuance of or changes to education, training, experience, qualification or other employment suitability requirements.

The following rulemaking actions meet the criterion for categorical exclusion under § 51.22(a)(1) or (2):

TABLE 27—RULE AMENDMENTS COVERED BY CATEGORICAL EXCLUSION

Rule amendments	Categorical exclusion	Reason
35.6; 35.12; 35.13	§ 51.22(a)(1)	Example (i). Amendments are administrative, procedural, or solely financial in nature. They would amend procedures for filing and reviewing applications.
35.5; 35.8; 35.14; 35.40; 35.2060; 35.2063; 35.2080; 35.2093; 35.2204; 35.2310; 35.2406; 35.2642; 35.2643; 35.2645; 35.2710; 35.3045; 35.3047; 35.3093; 35.3204.	§ 51.22(a)(1)	Example (ii). Amends recordkeeping or reporting requirements.
35.2; 35.10; 35.11; 35.27; 35.41; 35.60; 35.61; 35.63; 35.67; 35.69; 35.70; 35.76; 35.80; 35.93; 35.100; 35.200; 35.204; 35.315; 35.404; 35.415; 35.432; 35.604; 35.615; 35.632; 35.633; 35.635; 35.643; 35.645; 35.700; 35.710; 35.2404.	§ 51.22(a)(1)	Examples (iv) and (vi). Amendments are administrative, corrective or of a minor or nonpolicy nature, and do not substantially modify existing regulations. Amendments would be procedural—taking place in an office setting, relying on paper or electronic (*e.g.*, computer) screen to demonstrate compliance with revised regulations. Amendments would modernize and clarify terminology used in 10 CFR part 35, improve consistency in regulatory language, and better reflect current clinical practices and medical community standards. Amendments do not authorize any site-specific action on the part of the NRC or licensee.
35.24; 35.50; 35.51; 35.55; 35.57; 35.58; 35.59; 35.190; 35.290; 35.390; 35.392; 35.394; 35.396; 35.433; 35.490; 35.491; 35.590; 35.610; 35.690; 35.790; 35.2059; 35.2433.	§ 51.22(a)(2)	Amends education, training, experience, qualification, or other employment suitability requirements.

These proposed rule amendments include administrative and procedural changes—taking place in an office setting, relying on paper or electronic (*e.g.,* computer) screen to demonstrate compliance with revised regulations, and would not authorize any site-specific action on the part of the NRC or licensee. They clarify NRC regulations and would not change radiation protection and emergency preparedness requirements while continuing to provide reasonable assurance of adequate protection of public health and safety.

2. Rule Amendments Requiring Environmental Assessment

The NRC also evaluated rule amendments that have the potential to affect the human environment and determined that the proposed agency action (rulemaking) would not have a significant environmental effect. These rule amendments would clarify NRC regulations, would not change existing radiation protection and emergency preparedness requirements or overall risk, would continue to provide reasonable assurance of adequate protection of public health and safety, and would result in no new or different environmental effects. The following table presents the basis for why these proposed rule amendments would have no significant environmental effects.

TABLE 28—BASIS FOR NO SIGNIFICANT ENVIRONMENTAL EFFECTS DETERMINATION FOR RULE AMENDMENTS NOT COVERED BY A CATEGORICAL EXCLUSION

Rule amendments	Basis for no significant environmental effects
35.92 Decay-in-storage	Proposed amendment would increase the half-life from 120 to 275 days for decay-in-storage, which would reduce costs for medical licensees who have been required to dispose of Lu-177 waste as low level waste when they have space to safely store it. Expanding the scope of radioisotopes for which licensees are permitted to use decay-in-storage would not have any significant environmental effect because § 35.92 requires licensees to store the waste until its radioactivity cannot be distinguished from background.

These proposed rule amendments would modernize existing NRC regulations while ensuring the continued safe, effective, and efficient medical use licensing to provide reasonable assurance of adequate protection of public health and safety. As noted in table 28, these amendments consist of administrative and procedural changes and would not authorize any site-specific action on the part of the NRC or licensee. Implementation of these amendments would have no significantly different environmental effects than those from the current regulatory framework.

C. Summary of the Environmental Impacts of the Proposed Agency Action

Implementation of this rule, if finalized, would result in no physical changes to the environment, and, therefore, the NRC has determined that this proposed agency action will not have a significant effect on the quality of the human environment. Proposed rule amendments are administrative in application, matters of procedure, clarify record keeping and reporting requirements, and would provide an equivalent level of safety and security as current NRC regulations.

Since no physical changes would occur in the human environment, the proposed agency action (rulemaking) would not affect any threatened or endangered species or historic properties. Accordingly, the NRC finds that this proposed rulemaking would have no significant environmental impact.

D. Environmental Impacts of the Alternative to the Proposed Agency Action

Under the no-action alternative (the status quo), NRC regulations would remain unchanged. As stated in Section B of this EA, this proposed rule would not have a significant effect on the quality of the human environment. Therefore, the no-action alternative and the proposed agency action (proposed rulemaking) would have the same environmental effect, although there would be costs attributable to reviewing the environmental effects of exemption and license amendment requests under the no-action alternative. Licensees would continue to comply with existing NRC regulations or request regulatory relief (exemption) from the regulations. The NRC would continue to evaluate the environmental effects of exemption and license amendment requests. The averted costs (benefits) of the rulemaking would not occur. The regulatory analysis for this proposed rule provides information about the costs and benefits of the no-action alternative and the proposed agency action, as discussed in Section VII., of this document, ''Regulatory Analysis.''

E. Agencies and Persons Consulted

The NRC is requesting public comment on this draft EA. Comments on this draft EA may be submitted to the NRC as indicated under the **ADDRESSES** caption of this document. The NRC will consider public comments in the development of the final rule, EA, and finding of no significant impact. The NRC will issue the final EA when it publishes the final rule. This proposed rule is one step in the rulemaking process.

As discussed in Section B of this EA, these proposed rule provisions would not have a significant effect on the quality of the human environment. For this reason, this proposed rule would not impact threatened or endangered species or critical habitat, and the NRC has determined that section 7 consultation under the Endangered Species Act of 1973, as amended, is not necessary. These proposed regulatory changes do not involve any ground disturbing activities or visual effects that would adversely affect historic properties. Therefore, the NRC has determined that consultation is not required under section 106 of the National Historic Preservation Act of 1966, as amended.

F. Draft Finding of No Significant Impact

The NRC has prepared this EA to determine the environmental effects of the proposed agency action (rulemaking). Proposed rule amendments are primarily administrative or procedural in nature and thus would not have any physical environmental effect. As explained in the EA, the NRC has determined this proposed rulemaking would not change radiation protection and emergency preparedness requirements or overall risk, would continue to provide reasonable assurance of adequate protection of public health and safety, and would result in no new or different environmental effects. Therefore, the NRC concludes that the proposed regulatory changes would not have a significant effect on the quality of the human environment. Based on this conclusion, the NRC has determined there is no need to prepare an environmental impact statement. Accordingly, the NRC finds the proposed agency action would have no significant environmental impact. This environmental assessment and finding of no significant impact can be tracked with identification number NEPA ID EAXX–429–00–000–1770620320.

XII. Paperwork Reduction Act

This proposed rule contains new and amended collections of information subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq). This proposed rule has been submitted to the Office of Management and Budget for review and approval of the information collections.

Type of submission: New.

The title of the information collection: Reducing Barriers to Medical Use Licensing.

OMB Approval Number(s): 3150–0010, 3150–0120, and 3150–0178.

The form number if applicable: NRC Form 313A (RSO), 313A (AMP), 313A (ANP), 313A (AUD), 313A (AUT), 313A (AUS), 313A (AUM).

How often the collection is required or requested: Some information must be submitted once at application or amendment (*e.g.,* NRC Form 313, training attestations, procedures), while other collections are required on a recurring basis, such as continuing education and experience documentation (preceding first use), annual or periodic instrument calibrations and spot-checks (every 12 months, monthly, or before each use), semi-annual inventories, daily or per-use surveys, and periodic safety instructions (initially and annually). Most records must be kept for three years (*e.g.,* instrument calibrations, safety instructions, dosages, spot-checks, generator breakthrough tests, mobile medical service letters), while some records (such as activity records for beta-emitting ophthalmic sources) must be retained for the life of the source, and certain procedures or authorizations must be retained for the duration of the license or until superseded by updated records.

Who will be required or asked to respond: Applicants and licensees who use byproduct materials for medical uses.

An estimate of the number of annual responses:

10 CFR part 35: 4,360 (−122 reporting responses + 4,500 recordkeepers + −18 third party disclosure responses)

Form 313 and Form 313A Series: −990 (−990 reporting responses + 0 recordkeepers + 0 third party disclosure responses)

NMED: −92 (−92 reporting responses + 0 recordkeepers + 0 third party disclosure responses)

The estimated number of annual respondents:

10 CFR part 35: 4,369 respondents

Form 313 and Form 313A Series: −990 respondents

NMED: −15 respondents

An estimate of the total number of hours needed annually to comply with the information collection requirement or request:

10 CFR part 35: −220 (−334 reporting + 150 recordkeeping + −36 third party disclosure responses)

Form 313 and Form 313A Series: −12,915 (−12,915 reporting + 0 recordkeeping + 0 third party disclosure responses)

NMED: −145 (−145 reporting + 0 recordkeeping + 0 third party disclosure responses)

Abstract:

The NRC is proposing to amend its regulations to reduce barriers to medical use licensing. This proposed rule would reduce overly prescriptive requirements, increase regulatory flexibility, and modernize radiation safety practices for the medical use of byproduct material. It also would enable more efficient and predictable licensing for emerging medical technologies and reduce unnecessary burden associated with training and experience requirements for medical authorized users. This effort is consistent with, and implements, the direction in Executive Order 14300, ''Ordering the Reform of the Nuclear Regulatory Commission,'' which directs the NRC to conduct a comprehensive review and revision of its regulations.

This proposed rule addresses a wide range of topics, including the following areas that result in new or revised recordkeeping and reporting requirements involving:

- Research applications,
- Applications,
- Temporary RSOs,
- Instrument calibrations,
- Medical events,
- Dose to an embryo/fetus or a nursing child,
- Generator elutions,
- Radiation Safety Committees,
- Mobile medical services,
- Radiation safety,
- Continuing education,
- Decay-in-storage,
- Permissible concentrations for generator-produced radionuclides,
- Microsource brachytherapy, and
- Safety precautions for patients not eligible for release.

This supporting statement includes the burden associated with new and revised information collections in 10 CFR part 35, the Nuclear Material Events Database (NMED), and NRC Forms 313A (RSO), 313A (AMP), 313A (ANP), 313A (AUD), 313A (AUT), and 313A (AUS). It also includes burden associated with new information collection in proposed Form 313A (AUM).

The NRC is seeking public comment on the potential impact of the information collections contained in this proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility? Please explain your response.

2. Is the estimate of the burden of the proposed information collection accurate? Please explain your response.

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected? Please explain your response.

4. How can the burden of the proposed information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology? Please explain your response.

A copy of the OMB clearance package and proposed rule are available in the ''Availability of Documents'' section of this document or may be viewed free of charge by contacting the NRC's Public Document Room reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* You may obtain information and comment on submissions related to the OMB clearance package by searching on *https://www.regulations.gov* under Docket ID NRC–2025–1237.

You may submit comments on any aspect of these proposed information collection(s), including suggestions for reducing the burden and on the above issues, by the following method:

Federal rulemaking website: Go to *https://www.regulations.gov* and search for Docket ID NRC–2025–1237.

Submit comments by August 26, 2026.

Public Protection Notification

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

XIII. Executive Orders

The following are Executive orders that are related to this proposed rule:

A. Executive Order 12866: Regulatory Planning and Review (As Amended by Executive Order 14215, Ensuring Accountability for All Agencies)

The Office of Information and Regulatory Affairs (OIRA) has determined that this proposed rule is a significant regulatory action under section 3(f) of E.O. 12866; though not economically significant under section 3(f)(1). Accordingly, the NRC submitted this proposed rule to OIRA for review. The NRC is required to conduct an economic analysis in accordance with section 6(a)(3)(B) of E.O. 12866. More can be found in Section VII of this document, ''Regulatory Analysis.''

B. Executive Order 14154: Unleashing American Energy

The NRC has examined this proposed rule and has determined that it is consistent with the policies and directives outlined in E.O. 14154.

C. Executive Order 14192: Unleashing Prosperity Through Deregulation

This action is tentatively determined to be a deregulatory action as defined by E.O. 14192. Details on the estimated costs of this proposed rule can be found in Section VII, of this document, ''Regulatory Analysis.''

D. Executive Order 14267: Reducing Anti-Competitive Regulatory Barriers

E.O. 14267 requires the NRC to identify anti-competitive regulations for rescission or modification. The NRC identified the definition of physician listed in § 35.2 because the regulation creates a barrier to market participation by limiting the pool of eligible employees to work in this role. The proposed modification of the regulation supports the objectives of E.O. 14267 by removing regulatory requirements that could create unnecessary barriers to entry for new market participants. In addition, the NRC identified that training and qualification requirements contained in 10 CFR part 35 create a barrier to entry and restrict the flexibility of training pathways by favoring existing qualification certifying organizations and specialty boards. The proposed modification of the regulation to expand flexible training options supports the objectives of E.O. 14267 by removing unnecessary barriers to entry for new market participants.

E. Executive Order 14270: Zero-Based Regulatory Budgeting To Unleash American Energy

E.O. 14270, ''Zero-Based Regulatory Budgeting to Unleash American Energy,'' requires the NRC to insert a conditional sunset date into all new or amended NRC regulations provided the regulations are (1) promulgated under the Atomic Energy Act (AEA), the Energy Reorganization Act of 1974, as amended (ERA), or the Nuclear Waste Policy Act of 1982, as amended; (2) not statutorily required; and (3) not part of the NRC's permitting regime. The NRC determined that the regulatory changes proposed in this rule are required because they would be necessary for providing reasonable assurance of adequate protection of public health and safety and provide for the common defense and security and would be part of the NRC's permitting regime authorized by the AEA. Therefore, the NRC views this rulemaking to be

outside the scope of E.O. 14270 and did not insert conditional sunset dates for the regulatory changes in this proposed rule.

F. Executive Order 14294: Fighting Overcriminalization in Federal Regulations

This proposed rule includes Federal regulations that, if adopted, would be enforceable by criminal penalty, as authorized by section 223 of the AEA. Therefore, per E.O. 14294, those regulations constitute ''criminal regulatory offenses.''

For the purposes of section 223 of the AEA, the NRC is issuing this proposed rule that would amend 10 CFR part 35 under one or more of sections 161b, 161i, or 161o of the AEA, except as noted in § 35.4002(b). The applicability of criminal penalties to regulations in 10 CFR part 35 is set forth in § 35.4002(a). Willful violations of the 10 CFR part 35 regulations, other than those listed in § 35.4002(b), would be subject to criminal enforcement.

XIV. Coordination With NRC Agreement States

The working group that prepared this proposed rule included a representative from the Organization of Agreement States. Comments from the Agreement States representative were taken into consideration during the development of this proposed rule.

XV. Compatibility of Agreement State Regulations

On the basis of the ''Agreement State Program Policy Statement'' approved by the Commission on October 2, 2017, and published in the **Federal Register** (82 FR 48535; October 18, 2017), NRC program elements can be placed into six categories (A, B, C, D, NRC, or health and safety (H&S)) to form the basis for evaluating and classifying the program elements. Under the Policy Statement, a program element means any component or function of a radiation control regulatory program, including regulations and other legally binding requirements imposed on regulated persons, which contributes to implementation of that program.

Compatibility Category A are those program elements that include basic radiation protection standards and scientific terms and definitions that are necessary to understand radiation protection concepts. Compatibility Category A program elements adopted by an Agreement State should be essentially identical to those of the NRC to provide uniformity in the regulation of agreement material on a nationwide basis.

Compatibility Category B pertains to a limited number of program elements that cross jurisdictional boundaries and should be addressed to ensure uniformity of regulation on a nationwide basis. For Compatibility Category B, the Agreement State program element shall be essentially identical to that of NRC.

Program elements in Compatibility Category C include those program elements that are important for an Agreement State to have in order to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a national basis. An Agreement State program shall embody the essential objectives of the Category C program elements. Under Category C, Agreement State program elements may be more restrictive than NRC program elements; however, they should not be so restrictive as to prohibit a practice authorized by the AEA, as amended, and in the national interest without an adequate public health and safety or environmental basis related to radiation protection.

Compatibility Category D are those program elements that do not meet any of the criteria of Category A, B, or C, above, and are not required to be adopted by Agreement States for purposes of compatibility. An Agreement State has the flexibility to adopt and implement program elements within the State's jurisdiction that are not addressed by the NRC or that are not required for compatibility (*i.e.,* Compatibility Category D). However, such program elements of an Agreement State relating to agreement material shall (1) not create conflicts, duplications, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis; (2) not preclude a practice authorized by the AEA and in the national interest; and (3) not preclude the ability of the NRC to evaluate the effectiveness of Agreement State programs for agreement material with respect to protection of public health and safety.

Compatibility Category NRC are those program elements that address areas of regulation that cannot be relinquished to the Agreement States under the AEA, or provisions of 10 CFR. The NRC maintains regulatory authority over these program elements and the Agreement States must not adopt these NRC program elements. However, an Agreement State may inform its licensees of these NRC requirements through a mechanism under the State's administrative procedure laws, as long as the State adopts these provisions solely for the purposes of notification and does not exercise any regulatory authority as a result.

Category H&S program elements embody the basic health and safety aspects of the NRC's program elements. Although H&S program elements are not required for purposes of compatibility, they do have particular health and safety significance. The Agreement State must adopt the essential objectives of such program elements to maintain an adequate program.

This proposed rule is a matter of compatibility between the NRC and the Agreement States, thereby providing consistency among Agreement State and NRC requirements. For amended and redesignated requirements, the NRC is not proposing any changes to the current compatibility designations for those requirements. However, for § 35.300, which would not be revised as part of this proposed rulemaking, the NRC is proposing to change its compatibility designation as it was identified to have been erroneously assigned as Category B the last time the section was revised. Since § 35.300 does not have cross jurisdictional impacts, the NRC is proposing the compatibility category revert to its original designation of Category H&S (67 FR 20250; April 24, 2002). There are also several requirements pertaining to outdated regulations needed for implementation of previous rulemakings and duplicative requirements being removed. Agreement States are encouraged, but not required to, also remove those regulations. Agreement States keeping their equivalent to those outdated and duplicative requirements would not lead to a disorderly pattern of regulation on a nationwide basis.

The compatibility (A, B, C, D, and NRC) and adequacy (H&S) categories are designated in the following table:

ADEQUACY AND COMPATIBILITY TABLE

Section	Change	Subject	Adequacy or compatibility	
			Existing	New
35.2	Amend	Definition: Authorized user	B	B.
35.2	New	Definition: Breakthrough		D.
35.2	New	Definition: Emergent patient condition		H&S.
35.2	New	Definition: Gamma stereotactic radiosurgery.		D.
35.2	Amend	Definition: Manual brachytherapy	D	D.
35.2	New	Definition: Microsource		D.
35.2	New	Definition: Microsource brachytherapy		D.
35.2	Amend	Definition: Physician	D	D.
35.2	Amend	Definition: Prescribed dosage	C	C.
35.2	New	Definition: Shunting		H&S.
35.2	Remove	Definition: Stereotactic radiosurgery	D.	
35.2	Amend	Definition: Teletherapy	D	D.
35.5	Remove	Maintenance of records	D.	
35.6(b)	Amend	Provisions for the protection of human research subjects.	C	C.
35.6(c)	Remove	Provisions for the protection of human research subjects.	C.	
35.6(d)	Redesignate	Provisions for the protection of human research subjects.	C	C.
35.8(b)	Amend	Information collection requirements: OMB approval.	D	D.
35.10(a)	Remove	Implementation	D.	
35.11(a)	Amend	License required	C	C.
35.11(c)	Remove	License required	NRC/D.	
35.12(b) & (c)(2)	Amend	Application for license, amendment, or renewal.	D	D.
35.13(a)	Remove	License amendments	NRC/D.	
35.13(b) & (h)	Amend	License amendments	D	D.
35.14(a)(1)(ii)	Amend	Notifications	D	D.
35.24(c)	Amend	Authority and responsibilities for the radiation protection program.	D	D.
35.24(f)	Amend	Authority and responsibilities for the radiation protection program.	H&S	H&S.
35.24(g)(3) & (4)	Amend	Authority and responsibilities for the radiation protection program.	H&S	H&S.
35.24(g)(5)	New	Authority and responsibilities for the radiation protection program.		H&S.
35.27(a)(1)	Amend	Supervision	H&S	H&S.
35.40(a) & (b)	Amend	Written directives	H&S	H&S.
35.40(d)	Amend	Written directives	D	D.
35.41(b)	Amend	Procedures for administrations requiring a written directive.	H&S	H&S.
35.50(a)(c)	Amend/Redesignate.	Training for radiation safety officer and associate radiation safety officer.	B	B.
35.51(a)(b)	Amend/Redesignate.	Training for an authorized medical physicist.	B	B.
35.55(a)(b)	Amend/Redesignate.	Training for an authorized nuclear pharmacist.	B	B.
35.57(b)(4)	New	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist.		B.
35.58	New	Specialty board certification approval		B.
35.59	Amended in its entirety.	Continuing education		B.
35.60(a) & (b)	Amend	Possession, use, and calibration of instruments used to measure the activity of unsealed byproduct material and microsources.	H&S	H&S.
35.60(c), (d) & (e)	New	Possession, use, and calibration of instruments used to measure the activity of unsealed byproduct material and microsources.		H&S.
35.60(f)	Amend/Redesignate (previously 35.60(c)).	Possession, use, and calibration of instruments used to measure the activity of unsealed byproduct material and microsources.	D	D.
35.61(a)(1)	Amend	Calibration of survey instruments	H&S	H&S.
35.61(a)(2)	Redesignate	Calibration of survey instruments	D	D.
35.63(a), (b), (c)	Amend	Determination of dosages for medical use.	H&S	H&S.
35.63(d) & (e)	New	Determination of dosages for medical use.		H&S.
35.63(f)	Redesignate (previously 35.63(d)).	Determination of dosages for medical use.	H&S	H&S.

ADEQUACY AND COMPATIBILITY TABLE—Continued

Section	Change	Subject	Adequacy or compatibility	
			Existing	New
35.63(g)	Amend/Redesignate (previously 35.63(e)).	Determination of dosages for medical use.	D	D.
35.67(b) & (g)	Amend	Requirements for possession of sealed sources and brachytherapy sources.	H&S	H&S.
35.69	Amend	Labeling of vials and syringes	H&S	H&S.
35.70(a)	Amend	Surveys for ambient radiation exposure rate.	H&S	H&S.
35.76	New	Safety precautions for individuals not eligible for release under § 35.75.		H&S.
35.80(a)(2)(4), (b), & (c).	Remove	Provision of mobile medical service	H&S/D.	
35.92(a)	Amend	Decay-in-storage	H&S—for those States which authorize this activity D for States that do not.	H&S—for those States which authorize this activity D for States that do not.
35.93(a) & (b)	Amend/Redesignate (previously 35.204(a)).	Permissible concentrations for generatorproduced radionuclides.	H&S	H&S.
35.93(b)	New	Permissible concentrations for generatorproduced radionuclides.		H&S.
35.93(c)	Amend/Redesignate (previously 35.204(b)).	Permissible concentrations for generatorproduced radionuclides.	H&S	H&S.
35.93(d)	Amend/Redesignate (previously 35.204(c)).	Permissible concentrations for generatorproduced radionuclides.	D	D.
35.93(e)	New	Permissible concentrations for generatorproduced radionuclides.		D.
35.100	Amend	Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.	H&S	H&S.
35.190	Amend/Redesignate.	Training for uptake, dilution, and excretion studies.	B	B.
35.200	Amend	Use of unsealed byproduct material for imaging and localization studies.	H&S	H&S.
35.204	Remove	Permissible molybdenum-99, strontium-82, and strontium-85 concentrations.	H&S/D.	
35.290	Amend/Redesignate.	Training for imaging and localization studies.	B	B.
35.300	Category designation change.	Use of unsealed byproduct material for which a written directive is required.	B	H&S.
35.315	Remove	Safety precautions	H&S.	
35.390	Amend/Redesignate.	Training for use of unsealed byproduct material for which a written directive is required.	B	B.
35.392	Amend/Redesignate.	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries).	B	B.
35.394	Amend/Redesignate.	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries).	B	B.
35.396	Amend/Redesignate.	Training for the parenteral administration of unsealed byproduct material requiring a written directive.	B	B.
35.404(a) & (b)	Amend	Surveys after source implant and removal.	H&S	H&S.
35.415(a) & (c)	Remove	Safety precautions	H&S.	
35.415	Redesignate (previously 35.415(b)).	Safety precautions	H&S	H&S.
35.432(a)	Amend	Calibration measurements of brachytherapy sources.	H&S	H&S.
35.433(a)	Amend	Decay of strontium-90 sources for ophthalmic treatments.	B	B.
35.433(b)(1)	Amend	Decay of strontium-90 sources for ophthalmic treatments.	H&S	H&S.
35.433(c)	Amend	Decay of strontium-90 sources for ophthalmic treatments.	D	D.
35.490(a) & (b)	Amend/Redesignate.	Training for use of manual brachytherapy sources.	B	B.

ADEQUACY AND COMPATIBILITY TABLE—Continued

Section	Change	Subject	Adequacy or compatibility	
			Existing	New
35.490(c)	New	Training for use of manual brachytherapy sources.		B.
35.491(a) & (b)	Amend	Training for ophthalmic use of strontium-90.	B	B.
35.491(c)	New	Training for ophthalmic use of strontium-90.		B.
35.590	Amend/Redesignate.	Training for use of sealed sources and medical devices for diagnosis.	B	B.
35.604(a)	Amend	Surveys of patients and human research subjects treated with a remote afterloader unit.	H&S	H&S.
35.610(a)(1), (d)(1) & (e).	Amend	Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.	H&S	H&S.
35.615	Amend	Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.	H&S	H&S.
35.632(a), (c), (d) & (e).	Amend	Full calibration measurements on teletherapy units.	H&S	H&S.
35.632(g)	Amend	Full calibration measurements on teletherapy units.	D	D.
35.633(a), (c), (d), (e), (g).	Amend	Full calibration measurements on remote afterloader units.	H&S	H&S.
35.633(i)	Amend	Full calibration measurements on remote afterloader units.	D	D.
35.635(a)(e)	Amend	Full calibration measurements on gamma stereotactic radiosurgery units.	H&S	H&S.
35.635(g)	Amend	Full calibration measurements on gamma stereotactic radiosurgery units.	D	D.
35.643(a)(e)	Amend	Periodic spotchecks for remote afterloader units.	H&S	H&S.
35.643(f)	Amend	Periodic spotchecks for remote afterloader units.	D	D.
35.645(a)–(e)	Amend/Redesignate.	Periodic spotchecks for gamma stereotactic radiosurgery units.	H&S	H&S.
35.645(f)	Amend/Redesignate (previously 35.645(g)).	Periodic spotchecks for gamma stereotactic radiosurgery units.	D	D.
35.690	Amend/Redesignate.	Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.	B	B.
35.700	New	Use of microsources for microsource brachytherapy.		H&S.
35.710(a)	New	Safety procedures and instruction		C.
35.710(b)(d) & (f)	New	Safety procedures and instruction		H&S.
35.710(e)	New	Safety procedures and instruction		D.
35.790	New	Training for use of microsources		B.
35.1000	Amend	Other medical uses of byproduct material or radiation from byproduct material.	D	D.
35.2059	New	Records of Continuing Education and Training.		D.
35.2060	Amend	Records of calibrations of instruments used to measure the activity of unsealed byproduct material.	D	D.
35.2063	Amend	Records of dosages for medical use	D	D.
35.2080(b)	Remove	Records of mobile medical services	D.	
35.2093	Amend/Redesignate (previously 35.2204).	Records of generator breakthrough testing.	D	D.
35.2204	Remove	Records of molybdenum-99, strontium-82, and strontium-85 concentrations.	D.	
35.2310	Amend	Records of safety instruction	D	D.
35.2404	Amend	Records of surveys after source administration and removal.	D	D.
35.2406	Amend	Records of brachytherapy sealed source accountability.	D	D.
35.2433	Amend	Records of decay of betaemitting sources for ophthalmic treatments.	D	D.
35.2642	Amend	Records of periodic spotchecks for teletherapy units.	D	D.
35.2643	Amend	Records of periodic spotchecks for remote afterloader units.	D	D.

ADEQUACY AND COMPATIBILITY TABLE—Continued

Section	Change	Subject	Adequacy or compatibility	
			Existing	New
35.2645	Amend	Records of periodic spotchecks for gamma stereotactic radiosurgery units.	D	D.
35.2710	New	Records of safety procedures and instruction.		D.
35.3045	Amend	Report and notification of a medical event.	C	C.
35.3047(a)(1) & (2)	New/Redesignate.	Report and notification of a dose to an embryo/fetus or a nursing child.		C.
35.3093	New	Report and notification for an eluate exceeding breakthrough limits.		C.
35.3204	Remove (has been incorporated into 35.3093).	Report and notification for an eluate exceeding permissible molybdenum-99, strontium-82, and strontium-85 concentrations.	C.	

XVI. Coordination With the Advisory Committee on the Medical Uses of Isotopes

The ACMUI established a subcommittee to review and comment on the draft proposed rule. The subcommittee will make its recommendations on this proposed rule at a publicly held teleconference with the full committee during the public comment period.

XVII. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Public Law 104–113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this proposed rule, the NRC would revise the NRC requirements in 10 CFR part 35 to reduce overly prescriptive regulations, increase flexibility, and modernize radiation safety practices for the medical use of byproduct material. This action also would enable more efficient and predictable licensing for emerging medical technologies and reduce unnecessary burden in training and experience requirements for medical authorized users. This action does not constitute the establishment of a standard that contains generally applicable requirements.

XVIII. Availability of Guidance

The NRC expects to update NUREG–1556, Volume 9, ''Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses,'' to make changes to conform with this rulemaking effort. To support an accelerated development schedule for this proposed rule, the updates will be made in a future revision of the guidance, rather than concurrently with this rulemaking. The NRC is issuing interim guidance, in the form of frequently asked questions, for implementation of the requirements in this rulemaking, as finalized. The draft guidance is available in ADAMS under Accession No. ML26167A223 and in the docket for this proposed rule (NRC–2025–1237). You may submit comments on the draft regulatory guidance by the methods outlined in the **ADDRESSES** section of this document.

XIX. Availability of Documents

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated.

Document	ADAMS Accession No./**Federal Register** citation
Proposed Rule: Reducing Barriers to Medical Use Licensing—Frequently Asked Questions, July 2026.	ML26167A223.
Unofficial Redline of the NRC's Proposed Rule: Reducing Barriers to Medical Use Licensing, July 2026.	ML25349A081.
Proposed Rule Supporting Statement, ''Reducing Barriers to Medical Use Licensing''.	ML25349A079.
Proposed Rule: Reducing Barriers to Medical Use Licensing Burden Tables	ML25349A082.
NRC Form 313A (RSO), Radiation Safety Officer or Associate Radiation Safety Officer, Training, Experience and Preceptor Attestation.	ML26064A071.
NRC Form 313A (ANP), Authorized Nuclear Pharmacist, Training, Experience and Preceptor Attestation.	ML26065A073.
NRC Form 313A (AMP), Authorized Medical Physicist or Ophthalmic Physicist, Training, Experience and Preceptor Attestation.	ML26065A074.
NRC Form 313A (AUT), Authorized User Training, Experience and Preceptor Attestation (for uses defined under 35.300).	ML26078A320.
NRC Form 313A (AUS), Authorized User Training, Experience and Preceptor Attestation (for uses defined under 35.400 and 35.600).	ML26078A321.
NRC Form 313A (AUD), Authorized User Training, Experience and Preceptor Attestation (for uses defined under 35.100, 35.200, and 35.500).	ML26084A017.
NRC Form 313A (AUM), Authorized User Training, Experience and Preceptor Attestation (for uses defined under 35.700).	ML26085A524.
Final Rule—Medical Use of Byproduct Material, April 24, 2002	67 FR 20250.
Final Rule—Medical Use of Byproduct Material—Recognition of Specialty Boards, March 30, 2005.	70 FR 16336.
Final Rule—Requirements for Expanded Definition of Byproduct Material, October 1, 2007.	72 FR 55864.

Document	ADAMS Accession No./**Federal Register** citation
NRC Information Notice 2024–04, Recent Medical Events involving Administration of Therapeutic Radiopharmaceuticals, August 9, 2024.	ML24138A129.
NRC Information Notice 2019–07, Methods to Prevent Medical Events, August 26, 2019.	ML19240A450.
ACMUI Subcommittee on Patient Intervention Report, Final Report, April 6, 2020	ML20097F476.
ACMUI Subcommittee on Training & Experience for Authorized Users of Alpha and Beta Emitters under 10 CFR 35.390, Final Report, March 16, 2016.	ML16089A271.
ACMUI Standing Subcommittee on Training and Experience Requirements, Status Report, September 16, 2016.	ML17066A442.
ACMUI Subcommittee on Training and Experience Requirements for All Modalities, Interim Report, February 19, 2018.	ML18051A725.
ACMUI Subcommittee on Training and Experience, Final Report, April 7, 2025	ML25177A059.
Policy Statement—Medical Use of Byproduct Material Policy Statement, August 3, 2000.	65 FR 47654.
Final Rule—Misadministration Reporting Requirements, May 14, 1980	45 FR 31701.
SRM–M170817M—Affirmation Session, 10:30 A.M., Thursday, August 17, 2017, Commissioners' Conference Room, One White Flint North, Rockville, Maryland (Open to Public Attendance).	ML17229B284.
SECY–18–0084, Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM–M170817, August 28, 2018.	ML18135A276 (Package).
SECY–20–0005, Rulemaking Plan for Training and Experience Requirements for Unsealed Byproduct Material (10 CFR Part 35), January 13, 2020.	ML19217A318 (Package).
SRM–SECY–20–0005, Rulemaking Plan for Training and Experience Requirements for Unsealed Byproduct Material (10 CFR Part 35), January 27, 2022.	ML22027A519.
Regulatory Basis—Rubidium-82 Generators, Emerging Technologies, and Other Medical Use of Byproduct Material, July 3, 2023.	88 FR 42654.
Regulatory Basis—Rubidium-82 Generators, Emerging Technologies, and Other Medical Use of Byproduct Material, June 2023.	ML23122A356.
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, EGM–13–003, April 18, 2013.	ML13101A318.
ACMUI Subcommittee on Training and Experience for All Modalities, Draft Report, March 10, 2025.	ML25084A178.
Agreement State Program Policy Statement, October 18, 2017	82 FR 48535.
Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses, Final Report (NUREG–1556, Volume 9, Revision 3), September 2019.	ML19256C219.
SECY–21–0013, Rulemaking Plan to Establish Requirements for Rubidium-82 Generators and Emerging Medical Technologies, February 9, 2021.	ML20261H562.
ACMUI Subcommittee on ''Physical Presence Requirements for the Leksell Gamma Knife® Icon™,'' Final Report, February 27, 2018.	ML18071A413.
Final Rule—Fee Schedules; Fee Recovery for Fiscal Year 2026, June 16, 2026 ..	91 FR 36470.
Presidential Memorandum, ''Plain Language in Government Writing,'' June 10, 1998.	63 FR 31885.
NRC Website: Regulatory Analysis	*https://www.nrc.gov/about-nrc/regulatory/rulemaking/regulatory-analysis*.
Executive Order 12866, ''Regulatory Planning and Review,'' October 4, 1993	58 FR 51735.
Executive Order 14154, ''Unleashing American Energy,'' January 29, 2025	90 FR 8353.
Executive Order 14192, ''Unleashing Prosperity Through Deregulation,'' February 6, 2025.	90 FR 9065.
Executive Order 14215, ''Ensuring Accountability for All Agencies,'' February 24, 2025.	90 FR 10447.
Executive Order 14267, ''Reducing Anti-Competitive Regulatory Barriers,'' April 15, 2025.	90 FR 15629.
Executive Order 14270, ''Zero-Based Regulatory Budgeting to Unleash American Energy,'' April 15, 2025.	90 FR 15643.
Executive Order 14294, ''Fighting Overcriminalization in Federal Regulations,'' May 14, 2025.	90 FR 20363.
Executive Order 14300, ''Ordering the Reform of the Nuclear Regulatory Commission,'' May 29, 2025.	90 FR 22587.

The NRC may post materials related to this document, including public comments, on the Federal rulemaking website at *https://www.regulations.gov* under Docket ID NRC–2025–1237. In addition, the Federal rulemaking website allows members of the public to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) navigate to the docket folder (NRC–2025–1237); (2) click the ''Subscribe'' button; and (3) enter an email address and click on the ''Subscribe'' button.

List of Subjects in 10 CFR Part 35

Biologics, Byproduct material, Criminal penalties, Drugs, Health facilities, Health professions, Labeling, Medical devices, Nuclear energy, Nuclear materials, Occupational safety and health, Penalties, Radiation

protection, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is proposing to amend 10 CFR part 35.

PART 35—MEDICAL USE OF BYPRODUCT MATERIAL

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

Authority: Atomic Energy Act secs. 81, 161, 181, 182, 183, 223, 234, 274 (42 U.S.C. 2111, 2201, 2231, 2232, 2233, 2273, 2282, 2021); Energy Reorganization Act sec. 201, 206 (42 U.S.C. 5841, 5846); 44 U.S.C. 3504 note.

■ 2. In § 35.2:
■ a. Revise the definition for ''Authorized user'';
■ b. Add in alphabetical order the definitions for ''Breakthrough'', ''Emergent patient condition'', and ''Gamma stereotactic radiosurgery'';
■ c. Revise the definition for ''Manual brachytherapy'';
■ d. Add in alphabetical order the definitions for ''Microsource'' and ''Microsource brachytherapy'';
■ e. Revise the definitions for ''Physician'' and ''Prescribed dosage'';
■ f. Add in alphabetical order the definition for ''Shunting'';
■ g. Remove the definition for ''Stereotactic radiosurgery''; and
■ h. Revise the definition for ''Teletherapy''.

The revisions and additions read as follows:

§ 35.2 Definitions.

* * * * *

Authorized user means a physician, dentist, or podiatrist who—

(1) Meets the requirements in §§ 35.59 and 35.190, 35.290, 35.390(b), 35.392(b), 35.394(b), 35.490(b), 35.590(b), or 35.690(b); or

(2) Is identified as an authorized user on—

(i) A Commission or Agreement State license that authorizes the medical use of byproduct material;

(ii) A permit issued by a Commission master material licensee that is authorized to permit the medical use of byproduct material;

(iii) A permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of byproduct material; or

(iv) A permit issued by a Commission master material license broad scope permittee that is authorized to permit the medical use of byproduct material.

* * * * *

Breakthrough, as used in this part, means the unintended presence of the parent radionuclide impurity, expressed as a percentage of the total activity of the intended daughter radionuclide, at the time of elution.

* * * * *

Emergent patient condition means an unexpected development or acute change in a patient's condition that occurs during the administration which causes a deviation from the planned administration.

* * * * *

Gamma stereotactic radiosurgery, as used in this part, means a method of radiation therapy in which collimated external beams of ionizing radiation are delivered from an external source to a patient or human research subject using stereotactic guidance to deliver a localized therapeutic dose to a treatment site.

* * * * *

Manual brachytherapy, as used in this part, means a type of brachytherapy, other than microsource brachytherapy, in which the brachytherapy sources (*e.g.,* seeds, ribbons, and embedded mesh) are manually placed topically on or inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume.

* * * * *

Microsource means inert solid microspheres or microparticles containing radioactive material and dispersed in a carrier solution designed to deliver targeted therapeutic dose to a treatment site.

Microsource brachytherapy means a type of brachytherapy in which microsources are administered through parenteral methods, to deliver targeted therapeutic dose to a treatment site. Microsource brachytherapy is not a form of manual brachytherapy.

* * * * *

Physician means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine.

* * * * *

Prescribed dosage means the specified activity or range of activity of unsealed byproduct material or microsource as documented—

(1) In a written directive; or

(2) In accordance with the directions of the authorized user for procedures performed pursuant to §§ 35.100 and 35.200.

* * * * *

Shunting means blood flow through pathway or bypass due to patient vasculature causing microsources to flow to an unwanted location.

* * * * *

Teletherapy, as used in this part, means a method of radiation therapy in which collimated external beams of ionizing radiation are delivered from an external source to a patient or human research subject without stereotactic guidance to deliver a therapeutic dose to a treatment site.

* * * * *

§ 35.5 [Removed and Reserved]

■ 3. Remove and reserve § 35.5.
■ 4. Revise § 35.6 to read as follows:

§ 35.6 Provisions for the protection of human research subjects.

* * * * *

(b) Before conducting research, the licensee must—

(1) Obtain review and approval of the research from an ''Institutional Review Board,'' as defined and described in the Federal Policy for the Protection of Human Subjects (Federal Policy); and

(2) Obtain ''informed consent,'' as defined and described in the Federal Policy, from the human research subject.

(c) Nothing in this section relieves licensees from complying with the other requirements in this part.

■ 5. In § 35.8:
■ a. Remove the reference ''3501*et* seq.'' and add in its place the reference ''3501 *et seq.*'' wherever it appears; and
■ b. Revise paragraph (b).

The revision reads as follows:

§ 35.8 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 35.12, 35.13, 35.14, 35.19, 35.24, 35.26, 35.27, 35.40, 35.41, 35.50, 35.51, 35.55, 35.59, 35.60, 35.61, 35.63, 35.67, 35.69, 35.70, 35.75, 35.76, 35.80, 35.92, 35.93, 35.190, 35.204, 35.290, 35.310, 35.315, 35.390, 35.392, 35.394, 35.396, 35.404, 35.406, 35.410, 35.415, 35.432, 35.433, 35.490, 35.491, 35.590, 35.604, 35.605, 35.610, 35.615, 35.630, 35.632, 35.633, 35.635, 35.642, 35.643, 35.645, 35.647, 35.652, 35.655, 35.690, 35.710, 35.1000, 35.2024, 35.2026, 35.2040, 35.2041, 35.2059, 35.2060, 35.2061, 35.2063, 35.2067, 35.2070, 35.2075, 35.2080, 35.2092, 35.2093, 35.2310, 35.2404, 35.2406, 35.2432, 35.2433, 35.2605, 35.2610, 35.2630, 35.2632, 35.2642,

35.2643, 35.2645, 35.2647, 35.2652, 35.2655, 35.2710, 35.3045, 35.3047, 35.3067, and 35.3093.

§ 35.10 [Amended]

■ 6. In § 35.10, remove and reserve paragraph (a).

■ 7. In § 35.11:

■ a. Revise and republish paragraph (a); and

■ b. Remove and reserve paragraph (c).

The revisions read as follows:

§ 35.11 License required.

(a) A person may manufacture, produce, acquire, receive, possess, prepare, use, or transfer byproduct material for medical use only in accordance with a specific license issued by the Commission or an Agreement State, or as allowed in paragraph (b) of this section.

* * * * *

■ 8. In § 35.12, revise and republish paragraphs (b) through (d) to read as follows:

§ 35.12 Application for license, amendment, or renewal.

* * * * *

(b) An application for a license for medical use of byproduct material must be made by—

(1) Filing an original NRC Form 313, ''Application for Material License,'' that includes the facility diagram, equipment, and training and experience qualifications of the Radiation Safety Officer, Associate Radiation Safety Officer(s), authorized user(s), authorized medical physicist(s), ophthalmic physicist(s), and authorized nuclear pharmacist(s); and

(2) Submitting procedures required by §§ 35.60, 35.610, 35.642, 35.643, and 35.645, as applicable.

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

(1) Submitting an original of either—

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

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

(2) Submitting procedures required by §§ 35.60, 35.610, 35.642, 35.643, and 35.645, as applicable.

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

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

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

(3) Any additional specific information on—

(i) Radiation safety precautions and instructions;

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

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

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

* * * * *

■ 9. In § 35.13:

■ a. Revise the introductory text to § 35.13;

■ b. Remove and reserve paragraph (a);

■ c. Revise the introductory text to paragraph (b) and paragraph (b)(1);

■ d. Revise paragraph (f) by removing the references ''or § 35.200'' and adding in its place the references to ''or 35.200'' wherever it may appear; and

■ e. Revise paragraph (h).

The revisions read as follows:

§ 35.13 License amendments.

A licensee must apply for and must receive a license amendment—

* * * * *

(b) Before it permits anyone to work as an authorized user for medical use of byproduct material as described in §§ 35.300, 35.400, 35.600, 35.700, and 35.1000, authorized medical physicist, ophthalmic physicist, or authorized nuclear pharmacist under the license, except—

(1) For an authorized user, an individual who meets the requirements in §§ 35.59 and 35.390(b), 35.392(b), 35.394(b), 35.490(b), 35.590(b), and 35.690(b);

* * * * *

(f) Before it adds to or changes the areas of use identified in the application or on the license, including areas used in accordance with either § 35.100 or 35.200 if the change includes addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide/PET radioactive drug production area. Other areas of use where byproduct material is used only in accordance with either § 35.100 or 35.200 are exempt;

* * * * *

(h) Before it revises procedures required by §§ 35.60, 35.610, 35.642, 35.643, 35.645, and 35.710, as applicable, where such revision reduces radiation safety; and

* * * * *

§ 35.14 [Amended]

■ 10. In § 35.14:

■ a. In paragraph (a)(1)(ii), remove the reference ''§ 35.390(b)(1)(ii)(G)'' and add in its place the reference ''§ 35.390(a)(2)(ii)(G)''; and

■ b. In paragraph (b)(5), remove the reference ''§ 35.200'' and add in its place the reference ''35.200''.

■ 11. In § 35.24:

■ a. Remove the time period ''60 days'' and add in its place the time period ''120 days'' wherever it may appear; and

■ b. Revise paragraphs (a)(3), (f), and (g).

The addition and revision read as follows:

§ 35.24 Authority and responsibilities for the radiation protection program.

(a) * * *

(3) Radiation protection program changes that do not require a license amendment and are permitted under § 35.26.

* * * * *

(f) Licensees that are authorized for two or more different types of uses of byproduct material under subparts E, F, H, I, and K of this part which require a written directive, or two or more types of units under subpart H of this part, must establish a Radiation Safety Committee to oversee all uses of byproduct material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. The Committee may include other members the licensee considers appropriate.

(g) A licensee must provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative, to—

(1) Identify radiation safety problems;

(2) Initiate, recommend, or provide corrective actions;

(3) Stop unsafe operations;

(4) Verify implementation of corrective actions; and

(5) Verify the training and experience of an individual meets § 35.190 prior to authorizing use under §§ 35.100 and 35.290 prior to authorizing use under § 35.200.

* * * * *

■ 12. In § 35.27, revise paragraph (a)(1) to read as follows:

§ 35.27 Supervision.

(a) * * *

(1) In addition to the requirements in § 19.12 of this chapter, instruct the supervised individual in the licensee's written radiation protection procedures, procedures for administrations requiring a written directive, regulations of this chapter, and license conditions with respect to the use of byproduct material; and

* * * * *

■ 13. In § 35.40, revise and republish paragraphs (a), (b), and (d) to read as follows:

§ 35.40 Written directives.

(a) A written directive must be dated and signed by an authorized user before the administration of any therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material.

(1) If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within 48 hours of the oral directive.

(2) After administration, the portion of the written directive described in (5)(ii) and (6)(ii) of this part must be signed and dated by an authorized user within 24 hours if the treatment site, total source strength, dose or activity administered changes.

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

(1) For an administration of a therapeutic dosage of unsealed byproduct material: the radioactive drug, dosage, and route of administration;

(2) For gamma stereotactic radiosurgery: the total dose for each treatment site(s); dose per fraction and the number of fractions for treatment plan with multiple fractions; and geometry settings;

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

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

(5) For permanent manual or microsource brachytherapy:

(i) Before administration: The treatment site, the radionuclide, and the total source strength or prescribed dosage; and

(ii) After administration but before the patient leaves the post-treatment recovery area: The treatment site, the number of sources and total source strength or activity administered, and the date; or

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

(i) Before administration: The treatment site, radionuclide, and dose; and

(ii) After administration but before completion of the procedure: The treatment site; number of sources; total source strength and exposure time (or the total dose); and date.

* * * * *

(d) The licensee must retain a copy of the written directive in accordance with § 35.2040.

■ 14. In § 35.41, revise the introductory text to paragraph (b) and paragraphs (b)(4) and (6) to read as follows:

§ 35.41 Procedures for administrations requiring a written directive.

* * * * *

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

* * * * *

(4) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units;

* * * * *

(6) Determining, for permanent manual brachytherapy, within 60 calendar days from the date the administration was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-administration portion of the written directive, unless a written justification of patient unavailability is documented.

* * * * *

■ 15. In § 35.50:

■ a. Remove paragraph (a) and redesignate paragraphs (b) and (c) as paragraphs (a) and (b), respectively;

■ b. In newly redesignated paragraph (a)(2), remove the reference ''paragraphs (b)(1) and (d) of this section'' and add in its place the reference ''paragraphs (a)(1) and (d) of this section'';

■ c. Revise newly redesignated paragraphs (b)(1) and (3);

■ d. Add new paragraph (c); and

■ e. Revise paragraph (d).

The revisions and additions read as follows:

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

* * * * *

(b)(1) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State under § 35.58(l), has experience with the radiation safety aspects of similar types of use of byproduct material for which the licensee seeks the approval of the individual as Radiation Safety Officer or an Associate Radiation Safety Officer, and meets the requirements in paragraph (d) of this section; or

* * * * *

(3) Has experience with the radiation safety aspects of types of use of byproduct material for which the individual is seeking approval both as the Radiation Safety Officer and the authorized user on the same medical use license or medical use permit issued by a Commission master material licensee. The individual must also meet the requirements in paragraph (d) of this section; or

(c) Is certified by a medical specialty board whose certification process has been recognized under § 35.58(k); and

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

* * * * *

■ 16. In § 35.51:

■ a. Remove paragraph (a) and redesignate paragraph (b) as paragraph (a);

■ b. Revise newly redesignated paragraph (a)(2); and

■ c. Add new paragraph (b).

The revision and addition read as follows:

§ 35.51 Training for an authorized medical physicist.

* * * * *

(a) * * *

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

35.57, or equivalent Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; or

(b) Is certified by a medical specialty board whose certification process has been recognized under § 35.58(l); and

* * * * *

■ 17. In § 35.55:

■ a. Remove paragraph (a) and redesignate paragraph (b) as paragraph (a);

■ b. Revise newly redesignated paragraph (a)(2); and

■ c. Add new paragraph (b).

The revision and addition read as follows:

§ 35.55 Training for an authorized nuclear pharmacist.

* * * * *

(a) * * *

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

(b) Is certified by a medical specialty board whose certification process has been recognized under § 35.58(m).

■ 18. In § 35.57:

■ a. In paragraph (a)(1), remove the phrase ''§ 35.50, § 35.51, or § 35.55, respectively, except the Radiation Safety Officers and authorized medical physicists identified in this paragraph must meet the training requirements in § 35.50(d) or § 35.51(c)'' and add in its place the phrase ''§ 35.50, 35.51, or 35.55, respectively, except the Radiation Safety Officers and authorized medical physicists identified in this paragraph must meet the training requirements in § 35.50(d) or 35.51(c)'';

■ b. In paragraph (a)(4), remove the phrase ''the training requirements of § 35.50, § 35.51 or § 35.55'' and add in its place the phrase ''the training requirements of § 35.50, 35.51 or 35.55'';

■ c. Revise paragraph (b)(2)(i);

■ d. In paragraph (b)(2)(iii), remove the reference ''§ 35.600'' and add in its place the reference ''35.600''; and

■ e. Add paragraph (b)(4).

The addition and revisions read as follows:

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

* * * * *

(b) * * *

(2) * * *

(i) For uses authorized under § 35.100 or 35.200, a physician who was certified on or before October 24, 2005, in nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology by the American Board of Radiology; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or American Osteopathic Board of Nuclear Medicine in nuclear medicine;

* * * * *

(4) Physicians identified as authorized users for the medical use of byproduct material under § 35.1000 on a license issued by the Commission or an Agreement State, a permit issued by a Commission master material licensee, a permit issued by a Commission or an Agreement State broad scope licensee, or a permit issued in accordance with a Commission master material broad scope license on or before [DATE 30 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**], need not comply with the training requirements for which the physician was authorized, as follows:

(i) For uses authorized under § 35.400 for ophthalmic treatments, need not comply with training requirements of § 35.491 except for device-specific training under § 35.491(c) for any devices for which they were not authorized prior to this date.

(ii) For uses authorized under § 35.600, need not comply with training requirements under § 35.690 except for device-specific training under § 35.690(c) for any devices for which they were not authorized prior to this date; and

(iii) For uses authorized under § 35.700, need not comply with training requirements of § 35.790 except for microsource training under § 35.790(c) for any microsources for which they were not authorized prior to this date.

* * * * *

■ 19. Add § 35.58 to read as follows:

§ 35.58 Specialty board certification approval.

The names of board certification that have been recognized by the Commission or an Agreement State to confirm a physician has adequate training and experience for medical use of byproduct material are posted on the NRC's Medical Uses Licensee Toolkit web page.

(a) To have its certification process recognized for unsealed byproduct material uses authorized under § 35.100, a specialty board must require all candidates for certification to:

(1) Successfully complete an accredited residency training program as described in § 35.190(a)(1); or

(2) Successfully complete 60 hours of training and experience as described in § 35.190(a)(2); and

(3) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control.

(b) To have its certification process recognized for unsealed byproduct material uses authorized under § 35.200, a specialty board must require all candidates for certification to:

(1) Successfully complete an accredited residency training program as described in § 35.290(a)(1); or

(2) Successfully complete 700 hours of training and experience as described in § 35.290(a)(2); and

(3) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control.

(c) To have its certification process recognized for unsealed byproduct material uses authorized under § 35.300, a specialty board must require all candidates for certification to:

(1) Successfully complete an accredited residency training program in nuclear medicine or radiation oncology as described in § 35.390(a)(1); or

(2) Successfully complete an accredited residency training program in a related medical specialty and complete 700 hours of training and experience as described in § 35.390(a)(2); and

(3) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed byproduct material for which a written directive is required.

(d) To have its certification process recognized under § 35.300 for oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries), a specialty board must require all candidates for certification to:

(1) Successfully complete an accredited residency training program in nuclear medicine or radiation oncology as described in § 35.392(a)(1); or

(2) Successfully complete an accredited residency training program

in a related medical specialty and complete 80 hours of training and experience as described in § 35.392(a)(2)(i) through (a)(2)(ii)(E); and

(3) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed byproduct material for which a written directive is required.

(e) To have its certification process recognized under § 35.300 for oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries), a specialty board must require all candidates for certification to:

(1) Successfully complete an accredited residency training program in nuclear medicine or radiation oncology as described in § 35.394(a)(1); or

(2) Successfully complete an accredited residency training program in a related medical specialty and complete 80 hours of training and experience as described in § 35.394(a)(2)(i) through (a)(2)(ii)(E); and

(3) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed byproduct material for which a written directive is required.

(f) To have its certification process recognized for unsealed byproduct material uses authorized under § 35.300 for parenteral administration requiring a written directive, a specialty board must require all candidates for certification to:

(1) Successfully complete an accredited residency training program in nuclear medicine or radiation oncology as described in § 35.396(a)(1); or

(2) Successfully complete an accredited residency training program in a related medical specialty and complete 80 hours of training and experience as described in § 35.396(a)(2)(i) through (a)(2)(ii)(E); and

(3) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed byproduct material for which a written directive is required.

(g) To have its certification process recognized for unsealed byproduct material uses authorized under § 35.400, a specialty board must require all candidates for certification to:

(1) Successfully complete an accredited residency training program in radiation oncology and training and experience as described in § 35.490(a)(1) and (2); and

(2) Pass an examination, administered by diplomates of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy;

(h) To have its certification process recognized for unsealed byproduct material uses authorized under § 35.500, a specialty board must require all candidates for certification to obtain training and experience described in § 35.590.

(i) To have its certification process recognized for unsealed byproduct material uses authorized under § 35.600, a specialty board must require all candidates for certification to:

(1) Successfully complete an accredited residency training program in radiation oncology and training and experience as described in § 35.690(a)(1) and (2); and

(2) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy;

(j) [Reserved]

(k) To have its certification process recognized for individuals fulfilling the responsibilities of the Radiation Safety Officer or an individual's assigned duties and tasks as an Associate Radiation Safety Officer, a specialty board must require all candidates for certification to:

(1)

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

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

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

(2)

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

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

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

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

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

(l) To have its certification process recognized for individuals fulfilling the responsibilities of an authorized medical physicist, a specialty board must require all candidates for certification to:

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

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

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

(ii) In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements in § 35.57, 35.490, or 35.690; and

(3) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery;

(m) To have its certification process recognized for individuals fulfilling the responsibilities of an authorized nuclear pharmacist, a specialty board must require all candidates for certification to:

(1) Have graduated from a pharmacy program accredited by the Accreditation

Council for Pharmacy Education (ACPE) (previously named the American Council on Pharmaceutical Education) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

(2) Hold a current, active license to practice pharmacy;

(3) Provide evidence of having acquired at least 4000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2000 hours of the required training and experience; and

(4) Pass an examination in nuclear pharmacy administered by diplomates of the specialty board, that assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, and research and development.

■ 20. Revise and republish § 35.59 to read as follows:

§ 35.59 Continuing education.

(a) The licensee must ensure an authorized user has continuing education and experience preceding the medical use of a source, microsource, device, or radioactive drug for administrations requiring a written directive. This must include, at a minimum—

(1) Education or experience in the administration of the source, microsource, device, or radioactive drug within the 7 years preceding administration; and

(2) Instruction on the regulations and licensee's written radiation protection procedures, written directive procedures, and license conditions with respect to the use.

(b) The licensee must ensure an authorized user has continuing education and experience preceding the medical use of a source, device, or radioactive drug for administrations not requiring a written directive. This must include, at a minimum—

(1) Education or experience in the type of use within the 7 years preceding administration; and

(2) Instruction on the regulations and licensee's written radiation protection procedures and license conditions with respect to the use.

(c) The training and experience specified in subpart B for Radiation Safety Officers, Associate Radiation Safety Officers, Authorized Medical Physicist, and Authorized Nuclear Pharmacists of this part must have been obtained within the 7 years preceding the date of use or the individual must have had related continuing education and experience since the required training and experience was completed.

(d) The licensee must retain a record of individuals' continuing education and experience and instruction required by paragraphs (a), (b), and (c) in accordance with § 35.2059.

■ 21. Revise and republish § 35.60 to read as follows:

§ 35.60 Possession, use, and calibration of instruments used to measure the activity of unsealed byproduct material and microsources.

(a) For direct measurements performed in accordance with § 35.63, a licensee must possess and use instrumentation to measure the activity of unsealed byproduct material and microsources before it is administered to each patient or human research subject.

(b) A licensee must calibrate the instrumentation required in paragraph (a) of this section in accordance with nationally recognized standards or the manufacturer's instructions.

(c) Except for direct measurement described in paragraph (d) of this section, if instrumentation required in paragraph (a) cannot be calibrated in accordance with nationally recognized standards or the manufacturer's instructions required in paragraph (b), the licensee must submit written procedures for approval used to calibrate the instrumentation required in paragraph (a) of this section.

(d) For direct measurements performed in accordance with § 35.63(d), if radiation detector instrumentation cannot be calibrated in dynamic use mode in accordance with paragraph (b) of this section, a licensee must develop, implement, and maintain written test procedures to ensure that—

(1) The infusion pump flow rate is consistent and accurate; and

(2) The radiation detector meets the manufacturer's specifications.

(e) A licensee must perform the tests required in paragraph (d) of this section at least every 12 months and following repair that affects the calibration.

(f) A licensee must retain a record of each instrument calibration, test, and procedure required by this section in accordance with § 35.2060.

■ 22. In § 35.61:

■ a. Revise paragraph (a)(1); and

■ b. Remove paragraph (a)(2) and redesignate paragraph (a)(3) as paragraph (a)(2).

The revision reads as follows:

§ 35.61 Calibration of survey instruments.

* * * * *

(a) * * *

(1) Calibrate for the radiation type and energy range measured; and

* * * * *

■ 23. Revise and republish § 35.63 to read as follows:

§ 35.63 Determination of dosages for medical use.

(a) A licensee must determine and record the activity of each dosage before medical use of unsealed byproduct material and microsources, except for incremental administrations that meet the criteria in paragraph (d) of this section.

(b) For a unit dosage, this determination must be made by—

(1) Direct measurement of radioactivity; or

(2) A decay correction, based on the activity or activity concentration determined by—

(i) A manufacturer or preparer licensed under § 32.72 or distributor licensed under § 32.74 of this chapter or equivalent Agreement State requirements; or

(ii) An NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(iii) A PET radioactive drug producer and except for incremental administrations that meet the criteria in paragraph (d) of this section, licensed under § 30.32(j) of this chapter or equivalent Agreement State requirements.

(c) For other than unit dosages, this determination must be made by—

(1) Direct measurement of radioactivity;

(2) Combination of measurement of radioactivity and mathematical calculations; or

(3) Combination of volumetric measurements and mathematical calculations, based on the radioactivity measurement made by:

(i) A manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or

(ii) A PET radioactive drug producer licensed under § 30.32(j) of this chapter or equivalent Agreement State requirements.

(d) For incremental administrations from a direct infusion system that meet the criteria in paragraph (e) of this section, a licensee must determine and record the activity of each administered dosage by—

(1) Measurement of radioactivity using a calibrated instrument that is part of the direct infusion system or

(2) A combination of measurement of radioactivity and mathematical calculations.

(e) A licensee may perform incremental administrations as direct infusions only when the following criteria are met—

(1) The administered radioisotope has a half-life of less than three minutes.

(2) A written directive is not required.

(3) The radioisotope is administered through direct infusion from the generator or system without additional preparation steps.

(4) The administration is performed in accordance with the manufacturer's guidelines and procedures.

(f) Unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent.

(g) A licensee must retain a record of the dosage determination required by this section in accordance with § 35.2063.

■ 24. In § 35.67, revise the introductory text to paragraph (b) paragraph (g) to read as follows:

§ 35.67 Requirements for possession of sealed sources and brachytherapy sources.

* * * * *

(b) A licensee in possession of a sealed source, excluding microsources, must—

* * * * *

(g) A licensee in possession of sealed sources or brachytherapy sources, except for gamma stereotactic radiosurgery sources and microsources, must conduct a semi-annual physical inventory of all such sources in its possession. The licensee must retain each inventory record in accordance with § 35.2067(b).

■ 25. Revise § 35.69 to read as follows:

§ 35.69 Labeling of vials and syringes.

Each syringe and vial that contains unsealed byproduct material must be labeled to identify the radioactive drug, microsource, or device. Each syringe shield and vial shield must also be labeled unless the label on the syringe or vial is visible when shielded.

■ 26. In § 35.70, revise paragraph (a) to read as follows:

§ 35.70 Surveys of ambient radiation exposure rate.

(a) In addition to the surveys required by Part 20 of this chapter, a licensee must survey with a radiation detection survey instrument at the end of each day of use in all restricted areas and after each use in all non-restricted areas. A licensee must survey all areas where unsealed byproduct material or microsources requiring a written directive was prepared for use or administered.

* * * * *

■ 27. Add § 35.76 to read as follows:

§ 35.76 Safety precautions for individuals not eligible for release under § 35.75.

(a) For each patient or human research subject who cannot be released under § 35.75, a licensee must:

(1) Maintain the individual in a private room or in a room with another individual who also received such administration and cannot be released under § 35.75.

(2) For administrations involving unsealed byproduct material or microsources:

(i) Provide access for the individual, without leaving the controlled area, to a sanitary facility used only by individuals who have received such administrations; and

(ii) Handle contaminated materials and items removed from the room as radioactive waste, as appropriate; and

(3) Visibly post the individual's room with a ''Radioactive Materials'' sign; and

(4) Note on the door or in the individual's chart the location and duration visitors may stay in the patient's or human research subject's room.

(b) A licensee must notify the Radiation Safety Officer, or his or her designee, and an authorized user for the type of administration, as soon as possible if the patient or human research subject has a medical emergency or dies.

■ 28. Revise and republish § 35.80 to read as follows:

§ 35.80 Provision of mobile medical service.

A licensee providing mobile medical service must obtain a letter signed by the management of each client for which services are rendered that permits the use of byproduct material at the client's address and clearly delineates the authority and responsibility of the licensee and the client, and retain this letter in accordance with § 35.2080.

§ 35.92 [Amended]

■ 29. In § 35.92, in the introductory text to paragraph (a), remove the time period ''120 days'' and add in its place the time period ''275 days''.

■ 30. Add § 35.93 to read as follows:

§ 35.93 Permissible concentrations for generator-produced radionuclides.

(a) A licensee that uses a radionuclide generator for preparing a radiopharmaceutical must:

(1) Develop, implement, and maintain written procedures to define acceptable breakthrough limits and breakthrough testing frequency consistent with manufacturer's generator labeling as set forth in its FDA product approval or nationally recognized standard.

(2) Prior to the first use for preparation of radioactive drugs of a new generator or existing generator with an upgrade that affects the operation and safety, provide operational and safety training to measure and test the eluate for breakthrough to all individuals who will elute the generator and training to process the eluate with reagent kits to all individuals who prepare radioactive drugs; and

(3) Not administer an eluate to patients or human research subjects if the breakthrough measurements exceed the limits established in paragraph (a) of this section.

(b) In addition to the requirements of § 19.12 of this chapter, the licensee must initially or when there are significant changes to the licensee's procedures, provide instruction in the licensee's procedures identified in paragraph (a) of this section to individuals involved in the use of generator systems, as appropriate to the individual's assigned duties.

(c) The licensee must report any measurement that exceeds the limits in paragraph (a) of this section at the time of generator elution, in accordance with § 35.3093.

(d) The licensee must retain a record of each breakthrough test in accordance with § 35.2093.

(e) A licensee must retain a record of individuals receiving instruction required by paragraphs (a) and (b) of this section, in accordance with § 35.2310.

■ 31. In § 35.100, revise the section heading and the introductory text to read as follows:

§ 35.100 Use of unsealed byproduct material for uptake, dilution, and excretion studies.

A licensee may use any unsealed byproduct material prepared for medical use for uptake, dilution, or excretion studies that is—

* * * * *

■ 32. Revise and republish § 35.190 to read as follows:

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

Except as provided in § 35.57, the licensee must require an authorized user of unsealed byproduct material for the uses authorized under § 35.100 to be a physician who—

(a)(1) Has successfully completed a minimum of 3 years of residency

training in a nuclear medicine, diagnostic radiology, or radiation oncology accredited program which includes training and experience topic areas as described in § 35.190(a)(2); or

(2) Has completed 60 hours of training and experience, including a minimum of 8 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies. The training and experience must include, at a minimum—

(i) Classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

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

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user for the use of byproduct materials under § 35.100 or equivalent Agreement State requirements, at a medical facility. The work experience must involve—

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

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

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

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

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

(F) Administering dosages of radioactive drugs to patients or human research subjects; and

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

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

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in § 35.57, 35.190, 35.290, or 35.390, or equivalent Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be accredited and must include training and experience specified in the topic areas in paragraph (a)(2) of this section; or

(b) Is certified by a medical specialty board whose certification process has been recognized under § 35.58(a); or

(c) Is an authorized user under § 35.290, 35.390, 35.396, or equivalent Agreement State requirements.

■ 33. In § 35.200, revise the section heading and the introductory text to read as follows:

§ 35.200 Use of unsealed byproduct material for imaging and localization studies.

A licensee may use any unsealed byproduct material prepared for medical use for imaging and localization studies that is—

* * * * *

§ 35.204 [Amended]

■ 34. Remove § 35.204.

■ 35. Revise and republish § 35.290 to read as follows:

§ 35.290 Training for imaging and localization studies.

Except as provided in § 35.57, the licensee must require an authorized user of unsealed byproduct material for the uses authorized under § 35.200 to be a physician who—

(a)(1) Has successfully completed a minimum of 3 years of residency training in a nuclear medicine, diagnostic radiology, or radiation oncology accredited program which includes training and experience topic areas as described in § 35.290(a)(2); or

(2) Has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. The training and experience must include, at a minimum—

(i) Classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

(D) Chemistry of byproduct material for medical use;

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user for the use of byproduct materials under § 35.200 or equivalent Agreement State requirements, at a medical facility. The work experience must involve—

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

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

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

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

(E) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures; and

(F) Administering dosages of radioactive drugs to patients or human research subjects; and

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

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

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in § 35.57, 35.290, or 35.390, or equivalent Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be accredited and must include training and experience specified in the topic areas in paragraph (a)(2) of this section; or

(b) Is certified by a medical specialty board whose certification process has been recognized under § 35.58(b); or

(c) Is an authorized user under § 35.390, 35.396, or equivalent Agreement State requirements.

§ 35.315 [Removed and Reserved]

■ 36. Remove and reserve § 35.315.

■ 37. Revise and republish § 35.390 to read as follows:

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

Except as provided in § 35.57, the licensee must require an authorized user of unsealed byproduct material for the uses authorized under § 35.300 to be a physician who—

(a)(1) Has successfully completed a minimum of 3 years of accredited residency training in a nuclear medicine or radiation oncology which includes training and experience topics as described in § 35.390(a)(2); or

(2) Has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive. The training and experience must include, at a minimum—

(i) Classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

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

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user for the use of byproduct materials under § 35.300 or equivalent Agreement State requirements, at a medical facility. A supervising authorized user must have experience in administering dosages in the same dosage category or categories (*i.e.,* § 35.390(a)(2)(ii)(G)) as the individual requesting authorized user status. The work experience must involve—

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

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

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

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

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

(F) [Reserved]

(G) Preparing written directives and observing or performing administration of dosages of radioactive drugs to patients or human research subjects from the two categories in this paragraph under the supervision of an authorized user for the use. Radioactive drugs containing radionuclides in categories not included in this paragraph are regulated under § 35.1000. This supervised work experience must involve sufficient experience in each of the following categories to allow the supervising authorized user to evaluate the individual's ability to independently perform radiation safety related duties for the medical use for which the individual is requesting authorized user status—

(*1*) Oral administration of any radioactive drug for which a written directive is required;

(*2*) Parenteral administration of any radioactive drug for which a written directive is required; and

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

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

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in § 35.57, 35.390, or equivalent Agreement State requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be accredited and must include training and experience specified in the topic areas in paragraph (a)(2) of this section; or

(b) Is certified by a medical specialty board whose certification process has been recognized under § 35.58(c).

■ 38. Revise and republish § 35.392 to read as follows:

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

Except as provided in § 35.57, the licensee must require an authorized user 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), to be a physician who—

(a)(1) Has successfully completed a minimum of 3 years of residency training in a nuclear medicine or radiation oncology accredited program which includes training and experience topic areas as described in § 35.392(a)(2); or

(2) Has completed training and experience, including 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training and experience must include, at a minimum—

(i) Classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

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

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user for the use of byproduct materials under § 35.300, or equivalent Agreement State requirements, for oral administration of sodium iodide I-131 in quantities less than or equal to 1.22 gigabecquerels (33 millicuries) at a medical facility. A supervising authorized user who meets the requirements in § 35.390(a)(2) must also have experience in administering dosages as specified in § 35.390(a)(2)(ii)(G)(*1*). The work experience must involve—

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

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

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

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

(E) Using procedures to contain spilled byproduct material safely and

using proper decontamination procedures; and

(F) Preparing written directives and observing or performing administration of dosages of radioactive drugs to patients or human research subjects for the oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 under the supervision of an authorized user for the use. This supervised work experience must involve sufficient experience to allow the supervising authorized user to evaluate the individual's ability to independently perform radiation safety related duties for the medical use for which the individual is requesting authorized user status; and

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

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

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in § 35.57, 35.390, 35.392, 35.394, or equivalent Agreement State requirements, has experience in administering dosages as specified in § 35.390(a)(2)(ii)(G)(*1*), and concurs with the attestation provided by the residency program director. The residency training program must be accredited and must include training and experience specified in the topic areas in paragraph (a)(2) of this section; or

(b) Is certified by a medical specialty board whose certification process has been recognized under § 35.58(d).

■ 39. Revise and republish § 35.394 to read as follows:

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

Except as provided in § 35.57, the licensee must require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries), to be a physician who—

(a)(1) Has successfully completed a minimum of 3 years of residency training in a nuclear medicine or radiation oncology accredited program which includes training and experience topic areas as described in § 35.394(a)(2); or

(2) Has completed training and experience, including 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training and experience must include, at a minimum—

(i) Classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation on protection;

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

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

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user for the use of byproduct materials under § 35.300, or equivalent Agreement State requirements, for oral administration of sodium iodide I-131 in quantities greater than 1.22 gigabecquerels (33 millicuries) at a medical facility. A supervising authorized user who meets the requirements in § 35.390(b) must also have experience in administering dosages as specified in § 35.390(a)(2)(ii)(G)(*1*). The work experience must involve—

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

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

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

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

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

(F) Preparing written directives and observing or performing administration of dosages of radioactive drugs to patients or human research subjects for the oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 under the supervision of an authorized user for the use. This supervised work experience must involve sufficient experience to allow the supervising authorized user to evaluate the individual's ability to independently perform radiation safety related duties for the medical use for which the individual is requesting authorized user status; and

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

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

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in § 35.57, 35.390, 35.394, or equivalent Agreement State requirements, has experience in administering dosages as specified in § 35.390(a)(2)(ii)(G)(*1*), and concurs with the attestation provided by the residency program director. The residency training program must be accredited and must include training and experience specified in the topic areas in paragraph (a)(2) of this section; or

(b) Is certified by a medical specialty board whose certification process has been recognized under § 35.58(e).

■ 40. Revise and republish § 35.396 to read as follows:

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

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

(a)(1) Has successfully completed a minimum of 3 years of residency training in a nuclear medicine or radiation oncology accredited program which includes training and experience topic areas as described in § 35.396(a)(2); or

(2) Has completed training and experience, including 80 hours of classroom and laboratory training,

applicable to the medical use of the parenteral administration of unsealed byproduct material requiring a written directive listed in § 35.390(a)(2)(ii)(G)(*2*). The training must include, at a minimum—

(i) Classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

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

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user for the use of byproduct materials under § 35.300, or equivalent Agreement State requirements, for parenteral administrations at a medical facility. A supervising authorized user who meets the requirements in § 35.390(a)(2) must also have experience in administering dosages as specified in §§ 35.390(a)(2)(ii)(G)(*2*). The work experience must involve—

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

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

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

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

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

(F) Preparing written directives and observing or performing administration of dosages of radioactive drugs to patients or human research subjects for the parenteral administration of unsealed byproduct material under the supervision of an authorized user for the use. This supervised work experience must involve sufficient experience to allow the supervising authorized user to evaluate the individual's ability to independently perform radiation safety related duties for the medical use for which the individual is requesting authorized user status; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (a)(1) or (2) of this section and is able to independently fulfill the radiation safety-related duties as an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in § 35.57, 35.390, 35.396, or equivalent Agreement State requirements. A preceptor authorized user who meets the requirements in § 35.390, 35.396, or equivalent Agreement State requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in § 35.57, 35.390, 35.396, or equivalent Agreement State requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be accredited and must include training and experience specified in the topic areas in paragraph (a)(2) of this section; or

(b) Is an authorized user under § 35.390 for uses listed in § 35.390(a)(2)(ii)(G)(*2*), or equivalent Agreement State requirements; or

(c) Is an authorized user under § 35.490, 35.690, or equivalent Agreement State requirements, and who meets the requirements in paragraph (a)(2) of this section; or

(d) Is certified by a medical specialty board whose certification process has been recognized under § 35.58(f).

■ 41. In § 35.404, revise the section heading, and revise and republish paragraphs (a) and (b) to read as follows:

§ 35.404 Surveys after source administration and removal.

(a) Immediately after administering sources, topically or inserted within a patient or a human research subject, the licensee must conduct a survey to locate and account for all sources that have not been administered.

(b) Immediately after removing the last temporary source from a patient or a human research subject, the licensee must make a survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed.

* * * * *

■ 42. Revise § 35.415 to read as follows:

§ 35.415 Safety precautions.

A licensee must have applicable emergency response equipment available near each treatment room to respond to a source—

(1) Dislodged from the patient; and

(2) Lodged within the patient following removal of the source applicators.

§ 35.432 [Amended]

■ 43. In § 35.432:

■ a. In the introductory text to paragraph (a), remove the phrase ''on or after October 24, 2002''; and

■ b. In paragraph (a)(3), remove the reference ''(a)(2)'' and add in its place the reference ''(2)''.

■ 44. In § 35.433, revise the section heading, and revise and republish the introductory text to paragraph (a) and paragraphs (b)(1) and (c).

The revisions read as follows:

§ 35.433 Beta-emitting sources for ophthalmic treatments.

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

* * * * *

(b) * * *

(1) Calculate the activity of each beta-emitting source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under § 35.432; and

* * * * *

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

■ 45. Revise § 35.490 to read as follows:

§ 35.490 Training for use of manual brachytherapy sources.

Except as provided in § 35.57, the licensee must require an authorized user of a manual brachytherapy source for the uses authorized under § 35.400 to be a physician who—

(a)(1) Has successfully completed a minimum of 3 years of residency training in a radiation oncology accredited program, and

(2) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes—

(i) Classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

(D) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user for the use of byproduct materials under § 35.400, or equivalent Agreement State requirements, at a medical facility. The work experience must involve—

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

(B) Checking survey meters for proper operation;

(C) Preparing, implanting, and removing brachytherapy sources;

(D) Maintaining running inventories of material on hand;

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

(F) Using emergency procedures to control byproduct material; and

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

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

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in § 35.57, 35.490, or equivalent Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be accredited and must include training and experience specified in paragraph (a)(2) of this section; or

(b) Is certified by a medical specialty board whose certification process has been recognized under § 35.58(g).

(c) For authorized use of beta-emitting sources for superficial ophthalmic radiotherapy, has received training required in § 35.491(c) of this part.

■ 46. Revise and republish § 35.491 to read as follows:

§ 35.491 Training for superficial ophthalmic use of beta-emitting sources.

Except as provided in § 35.57, the licensee must require the authorized user of beta-emitting sources for superficial ophthalmic radiotherapy to be a physician who—

(a)

(1) Has completed training and experience, including 24 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of beta-emitting sources for superficial ophthalmic radiotherapy. The training and experience must include, at a minimum—

(i) Classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

(D) Radiation biology; and

(ii) Supervised clinical training in superficial ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of beta-emitting sources for the superficial ophthalmic treatment. This supervised work experience must involve sufficient experience to allow the supervising authorized user to evaluate the individual's ability to independently perform radiation safety related duties for the medical use for which the individual is requesting authorized user status. This supervised clinical training must involve—

(A) Examination of each individual to be treated;

(B) Calculation of the dose to be administered;

(C) Administration of the dose; and

(D) Follow up and review of each individual's case history; and

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

(b) Is an authorized user under § 35.490, or equivalent Agreement State requirements; and

(c) Has received training in device operation, safety procedures, and clinical use of the device. This training requirement may be satisfied by completing a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for use of the same device for which the individual is seeking authorization.

■ 47. Revise and republish § 35.590 to read as follows:

§ 35.590 Training for use of sealed sources and medical devices for diagnosis.

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

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

(1) Radiation physics and instrumentation;

(2) Radiation protection;

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

(4) Radiation biology; or

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

(c) Is certified by a medical specialty board whose certification process has been recognized under § 35.58(h); and

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

§ 35.604 [Amended]

■ 48. In § 35.604, in paragraph (a), remove the word ''portable'' from the phrase ''portable radiation detection survey instrument''.

■ 49. In § 35.610, revise paragraphs (a)(1), (d)(1), and (e) to read as follows:

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

(a) * * *

(1) Secure the unit, the console or the console keys, and the treatment room when not in use or unattended;

* * * * *

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

* * * * *

(e) A licensee must ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, prior to first use of a unit, type of immobilization device, or revised procedure, and at least annually.

* * * * *

■ 50. Revise § 35.615 to read as follows:

§ 35.615 Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

(a) A licensee must control access to each entrance to the treatment room with an electrical interlock system that will—

(1) Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is secured;

(2) Cause the source(s) to be shielded in case of unauthorized entry or interlock interruption; and

(3) Prevent the source(s) from being exposed following an interlock interruption until the electrical interlock system is restored and access is controlled to each entrance and the source(s) on-off control is reset at the console.

(b) A licensee must require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.

(c) Except for low-dose remote afterloader units, a licensee must construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

(d) For licensed activities where sources are placed within the patient's or human research subject's body, a licensee must only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

(e) In addition to the requirements specified in paragraphs (a) through (e) of this section, a licensee must—

(1) For medium dose-rate and pulsed dose-rate remote afterloader units, require—

(i) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and

(ii) An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.

(2) For high dose-rate remote afterloader units, require—

(i) An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and

(ii) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.

(3) For gamma stereotactic radiosurgery units, require—

(i) An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments;

(ii) An authorized user to be immediately available during continuation of patient treatments;

(iii) An authorized medical physicist and appropriate staff who are trained in emergency response and are necessary in accordance with written procedures pursuant to § 35.610(a)(4) to be physically present for the continuation of treatment; and

(iv) If there is an unexpected interruption of treatment requiring operator re-initiation, an authorized user and authorized medical physicist will evaluate the situation to ensure treatment is being delivered in accordance with the treatment plan and written directive prior to re-initiation of the treatment.

(4) Notify the Radiation Safety Officer, or his/her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

(f) A licensee must have applicable emergency response equipment available near each treatment room to respond to a source—

(1) Remaining in the unshielded position; or

(2) Lodged within the patient following completion of the treatment.

■ 51. In § 35.632, revise paragraphs (a), (c) through (e), and (g) to read as follows:

§ 35.632 Full calibration measurements on teletherapy units.

(a) A licensee authorized to use a teletherapy unit for medical use must perform full calibration measurements on each teletherapy unit—

* * * * *

(c) A licensee must use the dosimetry system described in § 35.630(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph (b)(1) of this section may be made using a dosimetry system that indicates relative dose rates.

(d) A licensee must make full calibration measurements required by paragraph (a) of this section in accordance with published protocols accepted by nationally recognized bodies. In absence of such protocols, a licensee must make full calibration measurements required by paragraph (a) in accordance with NRC-approved or Agreement State-approved manufacturer procedures.

(e) A licensee must mathematically correct the outputs determined in paragraph (b)(1) of this section for physical decay for intervals not exceeding 1 month for cobalt-60, 6 months for cesium-137, or at intervals consistent with 1 percent decay for all other nuclides.

* * * * *

(g) A licensee must retain a record of each calibration in accordance with § 35.2632.

■ 52. In § 35.633, revise paragraphs (a), (c) through (e), (g), and (i) to read as follows:

§ 35.633 Full calibration measurements on remote afterloader units.

(a) A licensee authorized to use a remote afterloader unit for medical use must perform full calibration measurements on each unit—

* * * * *

(c) A licensee must use the dosimetry system described in § 35.630(a) to measure the output.

(d) A licensee must make full calibration measurements required by paragraph (a) of this section in accordance with published protocols accepted by nationally recognized bodies. In absence of such protocols, a licensee must make full calibration measurements required by paragraph (a) of this section in accordance with NRC-approved or Agreement State-approved manufacturer procedures.

(e) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in paragraph (b) of this section, a licensee must perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding 1 quarter.

* * * * *

(g) A licensee must mathematically correct the outputs determined in paragraph (b)(1) of this section for physical decay at intervals consistent with 1 percent physical decay.

* * * * *

(i) A licensee must retain a record of each calibration in accordance with § 35.2632.

■ 53. In § 35.635, revise paragraphs (a) through (e) and (g) to read as follows:

§ 35.635 Full calibration measurements on gamma stereotactic radiosurgery units.

(a) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use must perform full calibration measurements on each unit—

* * * * *

(2) * * *

(iii) Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the source(s) or major repair of component(s) associated with the source assembly or collimation; and

(3) At intervals not exceeding 1 year.

(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include determination of—

(1) The output within ±3 percent;

(2) Condition, function, and accuracy of source(s), collimator(s), and treatment couch positioning and localizing, attenuation, and collimation devices;

(3) Isocenter coincidence;

(4) Timer accuracy and linearity over the range of use;

(5) On-off error;

(6) The operability and availability of retraction devices and emergency response equipment required per procedures required in § 35.610;

(7) System interlocks necessary to ensure pause in treatment in abnormal operations;

(8) Emergency timing circuits;

(9) The operability and availability of backup power devices or systems; and

(10) Operability of source(s), collimator(s), and treatment couch movement during treatment, as applicable.

(c) A licensee must use the dosimetry system described in § 35.630(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph (b)(1) of this section may be made using a dosimetry system that indicates relative dose rates.

(d) A licensee must make full calibration measurements required by paragraph (a) of this section in accordance with published protocols accepted by nationally recognized bodies. In absence of such protocols, licensee must make full calibration measurements required by paragraph (a) in accordance with NRC-approved or Agreement State-approved manufacturer procedures.

(e) A licensee must mathematically correct the outputs determined in paragraph (b)(1) of this section at intervals not exceeding 1 month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.

* * * * *

(g) A licensee must retain a record of each calibration in accordance with § 35.2632.

■ 54. Revise and republish § 35.643 to read as follows:

§ 35.643 Periodic spot-checks for remote afterloader units.

(a) A licensee authorized to use a remote afterloader unit for medical use must perform spot-checks of each remote afterloader facility and on each unit—

(1) Before the first use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit on a given day;

(2) Before each patient treatment with a low dose-rate remote afterloader unit; and

(3) After each source installation.

(b) A licensee must perform the measurements required by paragraph (a) of this section in accordance with written procedures established by the authorized medical physicist and in accordance with:

(1) Nationally recognized standards or published protocols accepted by nationally recognized bodies; or

(2) Manufacturer instructions accepted by the NRC, if nationally recognized standards or published protocols accepted by nationally recognized bodies do not exist.

(c) A licensee must have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist must notify the licensee as soon as possible in writing of the results of each spot-check.

(d) To satisfy the requirements of paragraph (a) of this section, spot-checks must, at a minimum, verify the performance of the following systems and functions:

(1) Emergency and safety systems;

(2) Computer systems controlling source output and timing; and

(3) Dosimetric and geometry accuracy.

(e) If the results of the checks required in paragraph (d) of this section indicate the malfunction of any system, a licensee must lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(f) A licensee must retain a record of each check required by paragraph (d) of this section and a copy of the procedures required by paragraph (b) of this section in accordance with § 35.2643.

■ 55.. Revise and republish § 35.645 to read as follows:

§ 35.645 Periodic spot-checks for gamma stereotactic radiosurgery units.

(a) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use must perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit in accordance with written procedures established by the authorized medical physicist and—

(1) Nationally recognized standards or published protocols accepted by nationally recognized bodies, or

(2) Manufacturer instructions accepted by the NRC, if nationally recognized standards or published protocols accepted by nationally recognized bodies do not exist.

(b) To satisfy the requirement of paragraph (a) of this section, spot-checks must—

(1) Before each patient use, confirm patient immobilization devices and localization systems, and any adaptors, are functional and fit appropriately.

(2) Before the first use of the unit on a given day and after each source installations:

(i) Verify systems and components that provide for safe termination of treatment and prevention of exposure to individuals other than the patient, and ensure that real-time monitoring and communication during administration are functional;

(ii) Confirm date and time of computer systems necessary for operation are correct; and

(3) On a monthly basis, spot-checks must verify:

(i) Systems and components to ensure accurate image guidance, as applicable, and geometric and dosimetry accuracy; and

(ii) Output for one typical set of operating conditions measured with the dosimetry system described in § 35.630(b) is within range specified by the procedure required in paragraph (a) of this section.

(c) Have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist must notify the licensee as soon as possible in writing of the results of each spot-check.

(d) A licensee must not use a system or device for medical use if the system is identified in paragraph (b)(1) of this section as not functioning appropriately.

(e) If the results of the checks required in paragraphs (b)(2) and (3) of this section indicate the malfunction of any system, a licensee must lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(f) A licensee must retain a record of each check required by paragraph (b) and a copy of the procedures required by paragraph (b) of this section in accordance with § 35.2645.

■ 56. Revise and republish § 35.690 to read as follows:

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

Except as provided in § 35.57, the licensee must require an authorized user of a sealed source for a use authorized under § 35.600 to be a physician who—

(a)(1) Has successfully completed a minimum of 3 years of residency training in a radiation oncology accredited program; and

(2) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes—

(i) Classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

(D) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user for the use of byproduct materials under § 35.600 or equivalent Agreement State requirements, at a medical facility, involving—

(A) Reviewing full calibration measurements and periodic spot-checks;

(B) Preparing treatment plans and calculating treatment doses and times;

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

(D) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

(E) Checking and using survey meters; and

(F) Selecting the proper dose and how it is to be administered; and

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

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

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in § 35.57, 35.690, or equivalent Agreement State requirements, for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be accredited and must include training and experience specified in paragraph (a)(2) of this section; or

(b) Is certified by a medical specialty board whose certification process has been recognized under § 35.58(i); and

* * * * *

§§ 35.700 through 35.799 [Designated as Subpart I of 10 CFR Part 35]

■ 57. Designate §§ 35.700 through 35.799 as subpart I and add a heading for newly created subpart I to read as follows:

Subpart I—Microsource Brachytherapy

■ 58. Add § 35.700 to read as follows:

§ 35.700 Use of microsources for microsource brachytherapy.

A licensee must only use microsources:

(a) Obtained from a manufacturer or preparer licensed under § 32.72 or 32.74 of this chapter or equivalent Agreement State requirements; or

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

■ 59. Add § 35.710 to read as follows:

§ 35.710 Safety procedures and instruction.

(a) Microsource administration devices that use microsources for brachytherapy and are listed in the Sealed Source and Device Registry must be used in accordance with radiation safety conditions and limitations described in the Sealed Source and Device Registry.

(b) A licensee must develop, implement, and maintain written procedures for responding to abnormal situations including microsource spills, equipment failures, and emergent conditions that affect the administration of microsources.

(c)(1) Prior to the first use for patient treatment of a new type of microsource or an existing type with a manufacturer upgrade to the delivery kit that affects the operation and safety of administration, a licensee must ensure that operational and safety training is provided to all individuals who operate the system and authorized user.

(2) A licensee must provide operational and safety instructions initially to all individuals who prepare or transfer microsources for administration and operate the unit at the facility, as appropriate to the individual's assigned duties. The instructions must include instruction in—

(i) The procedures identified in § 35.41; and

(ii) The operating procedures for the unit.

(d) In addition to the requirements of § 19.12, a licensee must provide radiation safety instruction, initially, and at least annually, to personnel caring for patients or human research subjects that cannot be released under § 35.75. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include—

(1) Patient or human research subject control;

(2) Visitor control, including—

(i) Routine visitation to hospitalized individuals in accordance with § 20.1301(a)(1) of this chapter; and

(ii) Visitation authorized in accordance with § 20.1301(c) of this chapter;

(1) Contamination control;

(2) Waste control; and

(3) Notification of the Radiation Safety Officer, or his or her designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.

(e) A licensee must retain a record of individuals receiving instruction required by paragraphs (c) and (d) of this section, in accordance with § 35.2310.

(f) A licensee must retain a copy of the procedures required by paragraph (b) of this section in accordance with § 35.2710.

■ 60. Add § 35.790 to read as follows:

§ 35.790 Training for use of microsources.

Except as provided in § 35.57, the licensee must require an authorized user of microsources authorized under § 35.700 to be a physician who—

(a)(1) Has successfully completed a minimum of 3 years of residency training in diagnostic radiology and 1 year of interventional radiology in a residency or fellowship program(s), and

(2) Has completed the training and experience requirements that include—

(i) Classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

(D) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user at a medical facility that is authorized to use byproduct materials in § 35.700, or training provided by a microsource manufacturer. The work experience or training must involve—

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

(B) Performing quality control procedures on instruments used to determine the activity of microsource doses and performing checks for proper operation of survey meters;

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

(D) Using procedures to contain spilled microsources safely using decontamination procedures; and

(iii) Work experience, under the supervision of an authorized user for the use of byproduct materials under § 35.700 or equivalent Agreement State requirements, at a medical facility. The work experience must involve—

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

(B) Preparing written directives and observing or performing administration of microsource brachytherapy; and

(C) Evaluation of patient or research subject's treatments to determine whether the administered dosage was in accordance with the written directive or if a medical event occurred; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (a)(1) and (2); and is able to independently fulfill the radiation safety-related duties as an authorized user for microsource brachytherapy. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in § 35.57, 35.790, or equivalent Agreement State requirements; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in § 35.57, 35.790, or equivalent Agreement State requirements and concurs with the attestation provided by the residency program director. The residency training program must be accredited and must include training and experience specified in paragraph (a)(2) of this section; or

(b) [Reserved]

(c) Is an authorized user under § 35.390, 35.396, 35.490, or equivalent Agreement State requirements, and

(d)(1) Has received training and work experience in device operation, safety procedures, and clinical use for the type(s) of microsource for which authorization is sought. This training must include three hands on cases including work experience as described in paragraphs (a)(2)(ii) and (iii) for the type of microsource for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user who is authorized for the type(s) of microsources for which the individual is seeking authorization, and

(2) Has obtained written attestation that the individual has satisfactorily completed these requirements.

The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in § 35.57, 35.790, or equivalent Agreement State requirements for the type(s) of microsources for which the individual is requesting authorized status; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in § 35.57, 35.790, or equivalent Agreement State requirements, for the type(s) of microsources for which the individual is requesting authorized status, and concurs with the attestation provided by the residency program director. The residency training program must be accredited and must include training and experience specified in paragraph (d)(1) of this section.

Subpart J [Reserved]

■ 61. Reserve subpart J.

■ 62. Revise § 35.1000 to read as follows:

§ 35.1000 Other medical uses of byproduct material or radiation from byproduct material.

(a) A licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in subparts D through I of this part if—

(1) The applicant or licensee has submitted the information required by § 35.12(b) through (d); and

(2) The applicant or licensee has received written approval from the Commission in a license or license amendment and uses the material in accordance with the regulations and specific conditions the Commission considers necessary for the medical use of the material.

(b) A licensee may use byproduct material or a radiation source approved for medical use in accordance with the written approval from the Commission in a license or license amendment if the licensee obtained approval under § 35.1000 prior to [DATE 30 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE **Federal Register**].

■ 63. Add § 35.2059 to read as follows:

§ 35.2059 Records of continuing education and training.

A licensee must maintain a record of continuing education and training required by § 35.59 until the individual is no longer authorized for medical use or listed on the license. The record must include a list of the topics covered, the date of the training, and the name(s) of the individual(s) who provided the training.

■ 64. Revise and republish § 35.2060 to read as follows:

§ 35.2060 Records of calibrations of instruments used to measure the activity of unsealed byproduct material and microsources.

(a) A licensee must maintain a record of each instrument calibration and test required by § 35.60 for 3 years. The records must include the model and serial number of the instrument, if applicable; the date of, the results of, and the name of the individual who performed each calibration and test.

(b) A licensee must retain a copy of each procedure required by § 35.60(d) until the licensee no longer possesses the instrument.

■ 65. In § 35.2063, revise the section heading and paragraph (a) to read as follows:

§ 35.2063 Records of dosages for medical use.

(a) A licensee must maintain a record of dosage determinations required by § 35.63 for 3 years.

* * * * *

■ 66. Revise § 35.2080 to read as follows:

§ 35.2080 Records of mobile medical services.

A licensee must retain a copy of each letter that permits the use of byproduct

material at a client's address, as required by § 35.80(a)(1). Each letter must clearly delineate the authority and responsibility of the licensee and the client and must be retained for 3 years after the last provision of service.

■ 67. Add § 35.2093 to read as follows:

§ 35.2093 Records of generator breakthrough testing.

A licensee must maintain a record of results of the breakthrough tests required by § 35.93(a) for 3 years. The record must include the eluate concentrations of the parent and daughter, the time and date of the measurement, and the name of the individual who made the measurement.

§ 35.2204 [Removed and Reserved]

■ 68. Remove and reserve § 35.2204.

■ 69. Revise § 35.2310 to read as follows:

§ 35.2310 Records of safety instruction.

A licensee must maintain a record of safety instructions required by §§ 35.93, 35.310, and 35.410 and the operational and safety instructions required by § 35.610 and § 35.710 for 3 years. The record must include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

■ 79. In § 35.2404, revise the section heading and the first sentence in the section to read as follows:

§ 35.2404 Records of surveys after source administration and removal.

A licensee must maintain a record of the surveys required by §§ 35.404 and 35.604 for 3 years. * * *

■ 71. In § 35.2406, revise the section heading, paragraph (a), and the introductory text to paragraphs (b) and (c) to read as follows:

§ 35.2406 Records of manual brachytherapy source accountability.

(a) A licensee must maintain a record of brachytherapy source accountability required by § 35.406 for 3 years.

(b) For temporary manual brachytherapy sources, the record must include—

* * * * *

(c) For permanent manual brachytherapy sources, the record must include—

* * * * *

■ 72. In § 35.2433, revise the section heading and paragraph (a) to read as follows:

§ 35.2433 Records of decay of beta-emitting sources for ophthalmic treatments.

(a) A licensee must maintain a record of the activity of a beta-emitting source required by § 35.433 for the life of the source.

* * * * *

§ 35.2642 [Amended]

■ 73. In § 35.2642:

■ a. In paragraph (a), remove the word ''shall'' and add in its place the word '' ■ must'';

b. In paragraph (b)(9), remove the word ''signature'' and add in its place the phrase ''dated signature''; and

■ c. In paragraph (c), remove the word ''shall'' and add in its place the word ''must''.

■ 74. Revise and republish § 35.2643 to read as follows:

§ 35.2643 Records of periodic spot-checks for remote afterloader units.

(a) A licensee must retain a record of each periodic spot-check for remote afterloader units required by § 35.643 for 3 years.

(b) The record must include, as applicable—

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number for the remote afterloader unit and source;

(3) The equipment and systems checked, including—

(i) Emergency and safety systems;

(ii) Computer systems controlling source output and timing; and

(iii) Dosimetric and geometric accuracy.

(4) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(c) A licensee must retain a copy of the procedures required by § 35.643(b) until the licensee no longer possesses the remote afterloader unit.

■ 75. Revise and republish § 35.2645 to read as follows:

§ 35.2645 Records of periodic spot-checks for gamma stereotactic radiosurgery units.

(a) A licensee must retain a record of each periodic spot-check for gamma stereotactic radiosurgery units required by § 35.645 for 3 years.

(b) The record must include—

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;

(3) The systems and components checked, including—

(i) Patient immobilization devices and localization systems;

(ii) Emergency and safety systems;

(iii) Real-time monitoring and communication systems;

(iv) Computer systems necessary for operation (including date and time settings); and

(v) Image guidance;

(4) The calculated on-off error;

(5) A determination of trunnion centricity;

(6) The difference between the anticipated output and the measured output;

(7) An assessment of source output against computer calculations;

(8) Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and

(9) The name of the individual who performed the periodic spot-check and the dated signature of the authorized medical physicist who reviewed the record of the spot-check.

(c) A licensee must retain a copy of the procedures required by § 35.645(b) until the licensee no longer possesses the gamma stereotactic radiosurgery unit.

■ 76. Add § 35.2710 to read as follows:

§ 35.2710 Records of safety procedures and instruction.

A licensee must retain a copy of the procedures required by § 35.710(b) until the licensee is no longer authorized for the type of microsource.

■ 77. In § 35.3045:

■ a. Revise paragraphs (a) and (b);

■ b. In paragraph (c), redesignate footnote 3 as footnote 1.

The revisions read as follows:

§ 35.3045 Report and notification of a medical event.

(a) A licensee must report any event as a medical event, except for an event that results from patient intervention or emergent patient condition that prevents completion of administration as planned, in which—

(1) The administration of byproduct material or radiation from byproduct material, except permanent manual or microsource brachytherapy, results in—

* * * * *

(2) For permanent manual or microsource brachytherapy, the administration of byproduct material or radiation from byproduct material (excluding sources that were implanted in the correct site but migrated outside the treatment site or microsources administered at the correct site but shunted to a site other than the treatment site if shunting was evaluated

in accordance with the manufacturer's instructions as set forth in its FDA product approval prior to administration) that results in—

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

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

(iii) An administration that includes any of the following:

(A) The wrong radionuclide;

(B) The wrong individual or human research subject;

(C) Sealed source(s) implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the written directive;

(D) A leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue; or

(3) The total dose or dosage that exceeds or results in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue delivered and differs from the prescribed dose or dosage defined on the written directive before administration by 20 percent caused by a leak or defect in administration device or supplies.

(b) A licensee must report any event resulting from patient intervention or emergent patient condition in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

* * * * *

■ 78. In § 35.3047, revise paragraph (a) to read as follows:

§ 35.3047 Report and notification of a dose to an embryo/fetus or a nursing child.

(a) A licensee must report any dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent that is a result of an administration of byproduct material or radiation from byproduct material to a pregnant individual unless;

(1) The dose to the embryo/fetus was specifically approved, in advance, by the authorized user, or

(2) The licensee made a reasonable effort to determine pregnancy status but pregnancy could not be reasonably excluded prior to the administration by the licensee.

* * * * *

■ 79. Add § 35.3093 to read as follows:

§ 35.3093 Report and notification for an eluate exceeding breakthrough limits.

(a) The licensee must notify by telephone the NRC Operations Center and the distributor of the generator within 7 calendar days after discovery that an eluate exceeded the permissible concentration listed in § 35.93(a) at the time of generator elution. The telephone report to the NRC must include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects; when the distributor was notified; and the action taken.

(b) By an appropriate method listed in § 30.6(a) of this chapter, the licensee must submit a written report to the appropriate NRC Regional Office listed in § 30.6 of this chapter within 30 calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report must include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; and the probable cause and an assessment of failure in the licensee's equipment, procedures or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination; and the information in the telephone report as required by paragraph (a) of this section.

§ 35.3204 [Removed and Reserved]

■ 80. Remove and reserve § 35.3204.

For the Nuclear Regulatory Commission.

Dated: July 23, 2026.

Jody Martin,

Secretary of the Commission.

[FR Doc. 2026–15080 Filed 7–24–26; 8:45 am]

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