

**U.S. Nuclear Regulatory Commission
Advisory Committee on the Medical Uses of Isotopes**

Subcommittee on Reducing Barriers to Medical Use Licensing

Draft Report

Submitted on August 25th, 2026

Subcommittee Members:

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Subcommittee Charge:

The Subcommittee on the Reducing Barriers to Medical Use Licensing Proposed Rule was first initiated by NRC staff on November 21st, 2025. The subcommittee was charged with reviewing and commenting on the proposed rule to amend 10 CFR 35 in response to Executive Order 14300 entitled “Reducing Barriers to Medical Use Licensing Rulemaking.”

Background:

On July 27th, 2026, the U.S. Nuclear Regulatory Commission (NRC) published the proposed rulemaking package entitled “Reducing Barriers to Medical Use Licensing Rulemaking” for public comment (91 FR 47042). The proposal is to amend the NRC regulations contained in 10 CFR Part 35 to modernize and streamline rules regarding the medical use of radioactive materials to improve licensing flexibility and efficiency, including such regulations that incorporate microspheres and gamma stereotactic radiosurgery systems (GSRs) into traditional Part 35, training and experience, decay-in-storage provisions, medical event reporting, and other related items. The rulemaking is in response to Executive Order 14300, which initiated an NRC staff review of the 10 CFR part 35 requirements.

The ACMUI Subcommittee first met with NRC staff working group that developed the draft proposed rule on January 7th, 2026 to discuss the proposed regulatory changes, draft Federal Register Notice (FRN), and guidance to prepare for ACMUI review and comments. Of note, during this period, due to the timeline of this rule, the ACMUI did not provide recommendations or report to the NRC on the draft proposed rule. Therefore, the September 9th, 2026 ACMUI meeting will be the first time ACMUI is providing its review and comments on this proposed rule.

Discussion:

The members of the subcommittee appreciate the efforts of the NRC to perform this extensive overhaul of existing regulations, and for the care and attention that NRC staff put into reviewing the many and diverse changes proposed. The members of the subcommittee performed a line by line review of the proposed rule language and Frequently Asked Questions (FAQ) with the NRC staff.

The specific comments and recommendations of the subcommittee are organized by the major provisions of the proposed rule:

Physician training:

The proposed rule would broaden the definition for “physicians” eligible to become Authorized Users (AUs) by removing the requirement for medical doctor (MD) or doctor of osteopathy (DO) title; the understanding is that the intent of this is to allow foreign-trained physicians holding degrees such as MBBS and MBBSCh (*Bachelor of Medicine, Bachelor of Surgery* and Latin version: *Baccalaureus Medicinae, Baccalaureus Chirurgiae*) to become AUs so long as they are fully licensed to practice medicine independently in the United States and its defined territories. In the proposed rule, however, it defines physicians as anyone licensed to prescribe drugs in the practice of medicine. This could be interpreted too broadly, potentially including nurse practitioners and other non-physician practitioners licensed to prescribe drugs. The subcommittee recommends that rather than removing MD and DO examples from the definition of Physician, that these remain in place and that the definition also include practitioners with MBBS, MBBSCh, and other physicians with equivalent licensure who are board certified or board eligible to practice medicine.

- The subcommittee disagreed with the changes as written, and recommends rather than removing MD, DO, explicitly mention MD, DO, as well as MBBS, MBBSCh, or other physicians with equivalent license; board certified or board eligible for practice.

In the proposed rule, the “recentness of training” requirement specified in 35.59 will be replaced with a performance-based continuing education model. The current 7 year rule specified in 35.59 is vague, and allows for exceptions to be made if the prospective AU had completed continuing education relevant to clinical practice with radioactive byproduct material without providing guidance on training content. Under 35.2059 “records of continuing education and training,” licensees are responsible for maintaining record of the continuing education and training.

- The subcommittee agreed with these changes. In keeping with prior recommendations by the Training and Experience Subcommittee for All Modalities, ACMUI recommends NRC partnering with professional societies to generate and administer that content, and it will be important for the continuing education material/content to have a mechanism for review by the NRC to establish whether it sufficiently covers required knowledge base information to meet NRC requirements.¹

Generator training work experience requirements were removed from 35.290. This is tied to changes in 35.63, recognizing that for generation of isotopes with $T_{1/2} < 3$ min used for diagnostic applications not requiring a written directive, as long as the equipment is calibrated

and the manufacturer's guidelines and procedures are followed, the need for enforcement discretion is eliminated.

- The subcommittee agreed with these changes, which were felt to be appropriate for simplification and efficiency without compromising safety.

The proposed rule centralizes specialty board certification approval requirements under section 35.58, and notes that the names of recognized board certifications will be maintained on the NRC's Medical Uses Licensee Toolkit web page. (<https://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert>)

In the proposed rule, most physician residency pathways would no longer require prescriptive training hour requirements, but instead must be accredited and include core information/knowledge topics required by the NRC in their training.

Under 35.190, "training for uptake, dilution, and excretion studies," the proposed rule explicitly lists a minimum of 3 years of training in nuclear medicine, diagnostic radiology, or radiation oncology with appropriate training and experience topics as eligible for AU status for 35.100 applications.

Under 35.290, "training for imaging and localization studies," the proposed rule explicitly lists a minimum of 3 years of training in nuclear medicine, diagnostic radiology, or radiation oncology with appropriate training and experience topics as eligible for AU status for 35.200 applications.

Under 35.390, "training for use of unsealed byproduct material for which a written directive is required," the proposed rule explicitly lists a minimum 3 years of training in nuclear medicine or radiation oncology with appropriate training and experience topics as eligible for AU status for 35.300 applications.

Under 35.392 and 35.394, "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 "training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)," respectively, the proposed rule explicitly lists a minimum 3 years of training in nuclear medicine or radiation oncology with appropriate training and experience topics as eligible for AU status for sodium iodide I-131 applications.

Under 35.490, "training for use of manual brachytherapy sources," the proposed rule explicitly lists a minimum of 3 years of training in radiation oncology with appropriate training and experience topics as eligible for AU status for 35.400 applications.

Under 35.690, "training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units," the proposed rule explicitly lists a minimum of 3 years of training in radiation oncology with appropriate training and experience topics as eligible for AU status for 35.600 applications.

- The subcommittee could not reach agreement on the subject of removing prescriptive training hours for physician residency pathways. Concerns were raised that removing the minimum hour requirements completely for those who completed 3 years of residency in certain fields would overly reduce training program accountability. Additionally, minimum hours remain present in other sections, such as 24 hours for an authorized user for superficial ophthalmic use of beta emitters in 35.491 and 8 hours for an authorized user for use of sealed sources and medical devices for diagnosis in 35.590. Maintaining

prescriptive hours for classroom and laboratory training does help ensure that trainees have protected time for education outside of work experience on the required core knowledge topics; consensus could not be reached on the need for prescriptive work experience hours requirements.

- The subcommittee does recommend retaining the prescriptive requirement for 80 hours of classroom and laboratory training in 35.290 and 200 hours of classroom and laboratory training in 35.390, 35.490, and 35.690.
- Opinions varied on whether completion of 3 years in an accredited program would suffice as a surrogate benchmark for sufficient work experience hours (total of 700 hours of training including classroom and laboratory training and relevant work experience); some agreed with the proposed changes above, with others recommending that the work experience hours requirement should be for specific accredited programs in which the majority of the training fulfills the core knowledge base requirements (i.e., the training program should exceed the existing minimum 700 hour requirement). Specifically:
 - Nuclear Medicine residency for 35.190, 35.290, and 35.390.
 - Radiation Oncology residency for 35.490 and 35.690.

The proposed rule retains alternative and cross-qualification pathways. Under 35.396, “Training for the parenteral administration of unsealed byproduct material requiring a written directive,” the proposed rule explicitly lists a minimum of 3 years of training in nuclear medicine or radiation oncology with appropriate training and experience topics as eligible for AU status for parenteral administration or unsealed byproduct material requiring a written directive. It retains the prescriptive 80 hours of classroom and laboratory training requirement.

- The subcommittee was overall in agreement with these changes. Retaining the alternative pathway/cross-qualification pathways was felt to be appropriate to maintain flexibility.

The proposed rule removes prescriptive case numbers for “oral” and “parenteral” procedures under 35.390, 35.392, 35.394, and 35.396, transitioning to a “sufficient experience” model instead. Guidance will provide more detail, but the responsibility for assessing sufficient experience will be placed on the supervising authorized user (preceptor). Of note, under the proposed 35.790 “training for use of microsources,” three hands on cases will still be required.

- The subcommittee did not reach consensus on the removal of a specific number of cases required for training.
- Under the existing pathway, the supervising AU was required to sign off on each individual case, and should only have done so if the trainee had been substantially involved in that case; thus, supervising authorized users already had the responsibility for knowledge assessment. Moving to a “sufficient experience” model could avoid fragmentation of training experience and a more global assessment of trainee understanding, but some members of the subcommittee felt that retaining the current case minimums is needed to ensure proper training.

- The proposed rule appears to remove the distinction between low- and high- dose sodium iodide I-131 procedures for 35.390; however low- and high-dose procedures have different release criteria and, in some clinics, release instructions. Addressing these training issues with the separate 35.392 and 35.394 pathways continues to be advisable.
- The proposed rule increases flexibility for new/emerging radiopharmaceutical applications with novel pathways and/or mechanisms of introduction.
- The subcommittee notes that “sufficient experience” will need further detail in guidance. Training and experience in a specific parenteral radiopharmaceutical should generally be considered transferable to other parenteral radiopharmaceuticals.
- Further clarification of “in-person” and “hands-on” training should also be provided in guidance; as many administrations are performed with the AU supervising a trained staff member (certified nuclear medicine technologist (CNMT)), training should also not specifically require each individual trainee to personally deliver an oral dose to a patient, or personally push the parental radiopharmaceutical via IV. Experience with these applications should involve the trainee substantively in as much of the case as possible, from acceptance, to dose calibration, to delivery, to post-treatment management, although all aspects of this may not be seen on the same patient.

License Amendments: (35.13)

The proposal to remove the requirement for radioactive materials license amendments to add AUs for diagnostic uses (35.100 and 35.200 applications) was felt to be appropriate, as these are low-risk procedures that are best managed at a program level.

- This is consistent with prior ACMUI recommendations (Subcommittee on ADVANCE Act)².

Proposals to integrate 35.1000 applications into traditional regulations and refine safety criteria:

A number of radioactive byproduct material applications have been managed under 35.1000 emerging medical technology guidance, and the proposed rule would result in these being formally integrated into traditional 10 CFR Part 35 processes. These include but are not limited to microsources/microspheres, gamma stereotactic radiosurgery systems (GSRs), generators, and newer ophthalmic devices. 35.57 will note that AUs already approved for those applications currently under 35.1000 will not need to undergo additional training requirements under applicable 35.491, 35.690, or proposed 35.790 pathways except for new devices or applications for which they were not authorized previously.

In the proposed rule, microsources/microspheres would be integrated into a new 35.700 pathway with some similarities to the existing 35.400 pathway for manual brachytherapy. This aligns microsources/microspheres with other forms of permanent manual brachytherapy, with consistent written directive (WD) requirements, and allows adaptation/change to clinical scenarios so the WD can be updated after administration but before the patient is discharged. Of note, these microsources are defined as solid carriers of radioactive material delivered via parenteral methods to a treatment site, and include a very wide range of potential technologies

and delivery methods beyond the current widespread practice utilizing glass or resin microspheres incorporating Yttrium-90 in liver radioembolization. Other emerging applications include instillation of microspheres into the cerebrospinal fluid (CSF) for treatment of leptomeningeal disease, or distilled into a surgical cavity to deliver peritoneal radiation for carcinomatosis.

- The subcommittee notes that the core training pathway (35.790) is focused on interventional radiology (IR) despite the long history of radiation oncology (RO) and nuclear medicine (NM) involvement in these procedures. While RO and NM physicians may obtain authorization for 35.700 applications via training under 35.390, 35.396, and 35.490, or equivalent Agreement State requirements, attestation would still come from an AU under 35.790, which would primarily be an IR AU. This has the potential for reducing the already diminishing role of RO and NM in microsphere therapies by raising perceived barriers to authorization for those specialties.
- The subcommittee recommends adding RO and NM explicitly into the 35.790 training pathway as in other training pathways due to their established role in existing microsphere/microsphere procedures, as well as the increasing number and range of microsphere applications and avenues for administration potentially entering into the clinic.
 - o Change 35.790(a)(1) to: “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) or a minimum of 3 years of accredited residency training in nuclear medicine or radiation oncology, and,”

GSRs would have updated physical presence requirements, notably, removing the requirement that AUs and AMPs must be physically present throughout the treatment, but only during the initiation of treatments; AUs must be immediately available in case of an emergency or treatment interruption, and available the continuation of treatments (re-initiation after a treatment interruption). AMPs and staff trained for emergency response would be physically present at the machine. (35.615) Of note, no changes were recommended for physical presence requirements for high dose rate (HDR) remote afterloading brachytherapy applications.

The proposed rule recommends a number of changes to calibration and quality assurance regulations that address the incremental improvements in medical technology used in these systems and remove outdated requirements.

- These were felt to be reasonable by the Subcommittee due to the significant advancements in safety features built into modern GSRs. Treatments would still have the AU immediately available (although not necessarily at the GSR console), with the authorized medical physicist (AMP) at the machine; both AU and AMP would present at start of treatment and the AU must be available to determine whether re-initiation can be done after a treatment interruption, but does not need to be physically at the console.
 - o Immediate availability is defined 10 CFR 35.615 and the FAQ further described this as meaning the AU must be able to respond without delay, but does not need to respond in person; the AU must be able to evaluate the situation to provide supervision and support. This is consistent with prior ACMUI recommendations.

The proposed rule provides clearer information for generators (including Rubidium-82 (Rb-82) generators), including determination of dosages for medical use (35.63), permissible concentrations for generator-produced radionuclides (35.93), records of generator breakthrough testing (35.2093) and reporting and notification for an eluate exceeding breakthrough limits (35.3093), and removes outdated regulations such as 35.204 (permissible molybdenum-99, strontium-82, and strontium-85 concentrations), 35.2204 (records of molybdenum-99, strontium-82, and strontium-85 concentrations), and 35.3204 (report and notification for an eluate exceeding permissible molybdenum-99, strontium-82, and strontium-85 concentrations).

- The subcommittee felt these changes improved clarity of the regulations. It allows greater flexibility for new generator technologies and integration into standard regulations rather than relying on 35.1000 pathways.

The proposed rule makes changes throughout regulations on the use of ophthalmic devices, replacing overly specific devices (strontium-90) with the more general term, “beta-emitting sources.” (35.433, 35.491, 35.2433) It removes the case requirement (5 treatments) and replaces it with a similar “sufficient experience” supervised work requirement.

- The subcommittee is in agreement with these changes. They make the regulations more generalizable and allow flexibility as new devices come into use.

Written directives: (35.40)

The proposed rule removes the written directive (WD) requirement for diagnostic administrations of sodium iodide I-131, specifying that it only applies to therapeutic doses. Therapeutic doses are loosely defined as dosages of unsealed byproduct material that are intended to deliver radiation dose for palliative or curative treatments.

- The subcommittee disagreed with this change, and did not feel that removal of the WD for sodium iodide I-131 for diagnostic activity ranges suggested as safe is appropriate. In many cases a diagnostic dose of sodium iodide I-131 could still lead to significant end-organ damage if given to the wrong patient (i.e., young patient with an intact thyroid). For example, the dose of sodium iodide I-131 used to survey patients with metastatic functioning thyroid cancer can vary from 0.2 mCi to 30 mCi.³ A 5 mCi total body dose intended for a patient with a surgically absent thyroid inadvertently given to a patient with an intact thyroid would result in total ablation of the thyroid organ and end organ failure.
- Elimination of WD in this setting would also go against prior recommendations by ACMUI regarding inclusion not just of WD but a checklist in administrations to improve safety.⁴

For permanent implant/microsource brachytherapy (35.400 and proposed 35.700 applications), the subcommittee recommends that the treatment site should be specific; i.e., for liver microsphere radioembolization, should specify right lobe vs left lobe. The subcommittee notes that there have been many medical events resulting from the incorrect lobe of liver was treated, resulting in no therapeutic benefit and real or potential harm to patients.

Additionally, the subcommittee recommended that the WD for high dose rate (HDR) remote afterloading brachytherapy (35.600 applications) which currently includes the radionuclide, treatment site, dose per fraction, number of fractions, and total dose, should change “treatment site” to “specific site with complete description and dosimetric goals.”

- For example, with HDR treatments such as vaginal cylinders, the radiation prescription generally includes the length of treatment and the depth of treatment from the applicator surface (i.e, prescribed to surface, 3 mm or 5 mm depth). Similarly, surface/skin applicators (such as Leipzig, Valencia, or Freiburg Flap) should have a stated depth of treatment.

Event reporting: (35.3045)

The proposed changes to medical event reporting would allow physicians to respond appropriately to emergent patient conditions without the need to report it as a medical event. This would allow medical event reporting to focus on events with a potential safety significance.

(35.3045) This also harmonizes dose/activity-related event reporting between microsource brachytherapy (proposed 35.700) and traditional manual brachytherapy (35.400).

Additionally, the changes in embryo/fetus dose reporting requirements would exempt cases where pregnancy could not be reasonably excluded prior to administration, as long as the institution was following their approved policies and procedures and a reasonable effort was made to determine pregnancy status or the dose to the embryo/fetus was specifically approved by the AU. (35.3047)

- The subcommittee is in agreement with these changes, as they accommodate clinical realities and help to reduce unnecessary reporting. The ability to adapt to unexpected developments allows appropriate medical decision making to be performed.

Storage: (35.92)

The expanding use of decay in storage, increasing allowable half life from 120 days to 275 days, will allow the safe and cost-effective onsite decay and disposal of clinically relevant long-lived materials like Lu-177m (metastable lutetium-177).

- The subcommittee is in agreement with these changes and is consistent with prior ACMUI recommendations. (Subcommittee on ADVANCE Act)².

Human Subjects Research Streamlining: (35.6)

The proposed rule eliminates NRC medical use license amendment requirement for Institutional Review Board (IRB) approved human subjects research.

- The subcommittee is in agreement with these changes. Relevant human subjects research would still have ethical oversight from IRB, reducing administrative requirements without compromising patient safety.

Radiation Safety Officers (RSO)/Associate Radiation Safety Officers (ARSOs) (35.50)

The proposed rule eliminates redundant language regarding specialty board requirements, relevant educational degree, work experience, and examination requirements for RSOs and those assigned duties and tasks as an Associate Radiation Safety Officer (ARSO), and incorporated the medical specialty board pathway under 35.58(k). This is also done for training of an authorized medical physicist (AMP) in 35.51 and authorized nuclear pharmacist (ANP) in 35.55 (referring to 35.58(l) and 35.58(m), respectively).

The duration for temporary RSO status was increased from 60 to 120 days each year.

- The duration for temporary RSO increase will allow greater flexibility, and limiting the need for an RSC to focus on more complex programs with WD applications will reduce the burden on programs that are focused on low-risk diagnostic applications.

Radiation Safety Committee (RSC) requirements: (35.24)

The Radiation Safety Committee (RSC) would only be required for programs with more complex radioactive byproduct materials programs and would no longer require representation from nursing.

- The subcommittee supports the proposed rule but wants to express support for licensees to have representation from a wide range of nursing/allied health related disciplines (nursing, medical assistants/medical office assistants (MA/MOA), advanced practice providers (APP) such as nurse practitioners (NP) and physician assistants/associates (PA)) involved with the administration of radioactive byproduct material at the licensee's institution if possible.

General Cleanup of Redundant Language:

The proposed rule removes duplicative/redundant provisions throughout 10 CFR Part 35, such as those for mobile medical services, obsolete waiver clauses, and recordkeeping requirements. No concerns were noted from the members of the subcommittee.

Subcommittee Recommendations:

The ACMUI Subcommittee on the Reducing Barriers to Medical Use Licensing Proposed Rule does **not** recommend that the proposed rule be finalized as submitted without addressing the following key reservations:

- Definition of physician; the subcommittee would recommend rather than removing MD, DO, explicitly mention MD, DO, as well as MBBS, MBBCh, or other physicians with equivalent license; board certified or board eligible for independent practice.
- For both diagnostic and therapeutic applications of sodium iodide I-131, a written directive should still be required due to the potential for significant harm with administration of even relatively low diagnostic to the wrong patient (patient with intact thyroid receiving a dose intended for a patient with previously ablated metastatic disease); this is in keeping with other recommendations from the ACMUI emphasizing the importance of the written directive and use of checklists to improve patient safety.

- For the proposed 35.790 training for use of microsources pathway, nuclear medicine (NM) and radiation oncology (RO) should be explicitly included under 35.790 (a)(1).
- As the subcommittee could not reach consensus on the topics of prescriptive training hours for physician residency pathways or prescriptive case numbers for oral and parenteral procedures under 35.390, 35.392, 35.394, and 35.396, we recommend further public discussion during our meeting before a recommendation is developed.

References:

1. Subcommittee on Training and Experience for All Modalities Report;
<https://www.nrc.gov/docs/ML2606/ML26061A112.pdf>
2. Subcommittee on ADVANCE Act Report;
<https://www.nrc.gov/docs/ML2613/ML26138A232.pdf>
3. Arnstein NB et al, "Determination of Iodine-131 Diagnostic Dose for Imaging Metastatic Thyroid Cancer," Journal of Nuclear Medicine Nov 1986, 27 (11) 1764-1769.
4. Subcommittee on Development of a Generic Process Checklist to Help Reduce Medical Events Report; <https://www.nrc.gov/docs/ML2606/ML26061A110.pdf>

Respectfully submitted on August 25th, 2026,

**Subcommittee on the Reducing Barriers to Medical Use Licensing Proposed Rule
Advisory Committee on the Medical Uses of Isotopes (ACMUI)
U.S. Nuclear Regulatory Commission (NRC)**