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

Subcommittee on Modernizing Regulations for Byproduct Material Use Rulemaking

Draft Report
Submitted on May 18, 2026

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Charge: The subcommittee on the Modernizing NRC Regulations for Byproduct Material Use proposed rule was established by NRC staff on November 11, 2025. The subcommittee was to provide ACMUI review and comments on the modernizing regulations for byproduct material use proposed rule.

Background: The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations for the licensing of byproduct material, some source material, and some special nuclear material. The NRC's goal in amending these regulations is to modernize the safe, effective, and efficient use of licensed material. This action would reduce the burden of the NRC's licensing process, eliminate the need for certain exemptions from existing regulations, and eliminate unnecessary requirements. The ACMUI subcommittee met with NRC staff working group that developed the draft proposed rule to walk through the proposed regulatory changes that could impact medical licensees, draft federal register notice, and guidance.

Discussion: The staff's proposed rule introduces several significant updates that streamline regulatory oversight for medical licensees while continuing to ensure robust radiation safety controls. Overall, these changes are intended to modernize outdated processes, remove anti-competitive barriers, and reduce unnecessary regulatory burden for medical institutions, radiopharmacies, and device manufacturers, all while maintaining the long-standing commitment to patient, public, and worker safety. Below provides more background on proposed changes which could impact medical licensees.

1. Standard General Licensing (SGL) for Nuclear Medicine

A cornerstone of the proposed rule is the creation of the option of a Standard General Licenses (SGLs) for certain nuclear medicine activities under 10 CFR Part 31 Subpart C. These SGLs establish a low-burden, regulatory-by-rule pathway for common, low-risk medical uses of byproduct material.

- In 10 CFR 31.16, the NRC proposes the SGL for diagnostic medical uses described in 10 CFR 35.100 and 200 for which written directive is not required. Specifically referenced are Tc-99m, Ga-67, In-111, I-123, I-125, I-131, Tl-201, and Xe-133, along

with Mo-99/Tc-99m generators. These uses correspond to routine uptake, imaging, dilution, and localization procedures, none of which require a written directive.

- Importantly, the NRC excluded PET radionuclides from the SGL option, which would then continue to require specific licensing, reflecting their higher complexity and need for NRC to evaluate facility design.
- The SGL program will reduce medical facility licensing burden as they would no longer need to submit detailed license applications, amendments, or renewals for these standard diagnostic procedures. A facility instead submits a one-time registration using NRC Form 1003, certifies compliance with the SGL requirements, and pays reduced fees. License amendments are replaced by simple notifications, vastly reducing administrative delays for modifications such as changes in radiation safety officers, authorized users, or locations.
- Because SGL activities are limited to low risk, standardized uses, the NRC concluded that no increase in radiological risk results from shifting these activities out of specific licensing.
- Proposed 10 CFR 31.16 establishes the core regulatory framework that Standard General Licensees (SGLs) must follow, ensuring the safe use of byproduct material in routine diagnostic nuclear medicine. Under this framework, SGL holders would no longer need to submit documentation of training and experience for Radiation Safety Officers (RSOs) and Authorized Users (AUs) as part of a license application or amendment; instead, these qualifications would be verified during inspection, significantly reducing administrative burden while maintaining safety oversight. Importantly, AU and RSO minimum training and experience requirements remain aligned with the applicable provisions of 10 CFR Part 35, and SGLs continue to require robust radiological safety programs, including survey instrumentation, sealed-source leak testing, radiation protection procedures consistent with 10 CFR Part 20, and adherence to relevant medical-use requirements.

This modernization creates a more predictable and streamlined licensing environment for medical institutions by replacing repetitive licensing correspondence with standardized commitments and inspection-based oversight, without reducing the level of safety expected of medical-use licensees. The ACMUI subcommittee supports this proposed rule.

2. Inclusion of Microsources and New Flexibility in Distribution Pathways

The proposed rule also addresses emerging clinical practices by expanding microsource distribution options as described below.

- § 32.72 is expanded to allow commercial radiopharmacies to prepare and distribute microsources, aligning NRC licensing with how these materials are handled under USP <825> and FDA regulations.
- § 32.74 is clarified so manufacturers may also distribute microsources under that pathway, ensuring both radiopharmacies and device manufacturers have appropriate options.

- These changes provide the medical community with timelier access to microsources, reduce licensing inconsistencies, and support personalization of therapy, all while requiring compliant preparation and labeling consistent with NRC safety standards.

The ACMUI subcommittee supports this proposed rulemaking.

3. Updated Definitions: Removal of "Physician" from Part 30

The proposed rule removes the definition of physician from 10 CFR 30.4 because the term is already fully defined in 10 CFR 35.2, as described below.

- Maintaining a single definition avoids conflicting interpretations between Parts 30 and 35.
- The change increases regulatory clarity without affecting who may serve as an Authorized User in medical licensing.
- The NRC notes this also prevents future divergence as medical use rules evolve.

The ACMUI subcommittee supports this proposed rulemaking.

4. ACMUI Financial Assurance (FA) Recommendations for Category 1–3 Sealed Sources

The proposed rule revises the radionuclide activity values in Appendix B to 10 CFR Part 30, which determines when licensees must provide decommissioning financial assurance (DFA). These revisions modernize DFA thresholds by incorporating updated radionuclide values, adding isotopes not previously listed such as for gallium/germanium generators, and resolving overly conservative default values that have created licensing inefficiencies for medical and industrial users. The ACMUI previously reviewed a draft regulatory basis document for this rulemaking and provided its recommendations in its final report dated August 29, 2024 (ML24254A315). The ACMUI subcommittee supports the NRC's continued efforts in this area and endorses moving forward with updates to financial assurance regulations.

Subcommittee Recommendations: The ACMUI subcommittee on the Modernizing NRC Regulations for Byproduct Material Use rulemaking recommends that the proposed rule be made final as proposed.

Respectfully Submitted May 18, 2026
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U.S. Nuclear Regulatory Commission (NRC)