

June 30, 2026

U.S. Nuclear Regulatory Commission  
One White Flint North  
11555 Rockville Pike  
Rockville, MD 20852-2738

**RE: (Docket ID: NRC-2025-1205) Modernizing NRC Regulations for Byproduct Material Use**

The American College of Radiology (ACR) - a professional association representing more than 40,000 physicians practicing diagnostic radiology, interventional radiology, radiation oncology, and nuclear medicine, as well as medical physicists - appreciates the opportunity to comment on the U.S. Nuclear Regulatory Commission's (NRC) notice of proposed rulemaking (NPRM), *Modernizing NRC Regulations for Byproduct Material Use (NRC-2025-1205)*, published in the May 18, 2026 *Federal Register*.

The NRC is proposing a new "Standard General License (SGL) for Certain Medical Uses" to reduce reliance on multiple specific licenses and amendments while maintaining compliance with applicable regulatory requirements. This framework would shift NRC/Agreement State oversight toward inspections and reactive enforcement, rather than the proactive application and amendment reviews currently required for specific licenses. The SGL would apply to certain diagnostic uses under § 35.100 (*Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required*) and § 35.200 (*Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required*). However, the ACR is concerned that the precise scope and limits of §§ 35.100 and 35.200 uses that could be authorized under the SGL mechanism remain unclear.

The ACR generally supports easing administrative burdens for medical licensees while maintaining appropriate safety and oversight. We also recognize that SGLs have the potential – independently and/or in combination with conventional specific licenses – to reduce administrative burden and associated costs for certain imaging centers, community hospitals, and other facilities. This flexibility should be limited to facilities with appropriately qualified Authorized Users (AUs) who meet the existing training and experience (T&E) requirements set forth in §§ 35.190 and/or 35.290, and to sites that would otherwise be eligible to obtain specific licenses for §§ 35.100 or 35.200 uses today. The SGL framework should not expand access beyond well-established qualifications or permit use in healthcare settings that do not meet current regulatory standards.

The NRC is planning a separate, yet-to-be-published NPRM, *Reducing Barriers to Medical Use Licensing*. This NPRM may propose revisions throughout 10 CFR Part 35, including potential changes to AU T&E requirements under §§ 35.190 and 35.290. If such proposals substantially

reduced current AU T&E criteria, the resulting broadening of AU eligibility - when combined with the proposed SGL flexibility - could create gaps in licensee oversight and raise new safety concerns. Accordingly, ACR's support for the SGL proposal is contingent on maintaining AU T&E requirements that ensure sufficient physician-AU expertise in the safe use of byproduct material.

The ACR appreciates the NRC's consideration of these comments and welcomes further discussion on these matters. For questions or additional information, please contact Mike Peters, ACR Senior Director, Government Affairs at [mpeters@acr.org](mailto:mpeters@acr.org), or Lindsay Robbins, Regulatory Policy Specialist, at [lmrobbins@acr.org](mailto:lmrobbins@acr.org).

Sincerely,

A handwritten signature in black ink that reads "D Smetherman". The letter "D" is large and stylized, followed by the first name "Smetherman" in a cursive script.

Dana H. Smetherman, MD, MPH, MBA, FACR  
Chief Executive Officer  
American College of Radiology