American College of Radiology

September 9, 2026

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

Re: (Docket ID NRC-2025-1237), Reducing Barriers to Medical Use Licensing; Comments of the American College of Radiology

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) proposed rule (NPRM), *Reducing Barriers to Medical Use Licensing* (NRC-2025-1237), published in the July 27, 2026, *Federal Register*.

General Comments

ACR generally supports NRC's efforts to reduce unnecessary administrative burden in 10 CFR Part 35 where safe and appropriate, and to improve efficiency, licensing predictability, and patient access to beneficial technologies. We urge the agency to continue to ensure appropriate physician-Authorized User (AU) qualifications, radiation protections, and patient access to NRC-regulated diagnostic and therapeutic modalities. Additionally, we encourage NRC to advance nationwide uniformity wherever feasible by increasing Agreement State compatibility for any substantially revised subjects.

ACR understands the challenges associated with implementing the Executive Order 14300 rulemaking agenda within compressed timeframes. However, ACR is concerned that the overlapping comment periods for multiple NRC reform initiatives have limited the ability of many stakeholders to fully evaluate their cumulative impact and identify potential unintended consequences, particularly given the significant implications these initiatives may have for patients, providers, and healthcare facilities. As a general recommendation, ACR encourages NRC to establish a transparent mechanism for stakeholders to provide ongoing feedback on implementation issues identified after publication of the final rule and be prepared to provide guidance and clarification, or issue correction notices, where appropriate.

§35.2, "Physician" definition revision

NRC Proposal – "*Physician*" would be changed to "*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*." The proposal is intended to enable foreign-trained physicians without an MD or DO to become AU-eligible if the corresponding AU training and experience (T&E) criteria are also satisfied.

ACR Comments – ACR strongly opposes the proposed revision to the "physician" definition in the NPRM and, if change is pursued, recommends significant refinements in the final rule version of this language to target NRC's intended narrow purpose without creating new concerns. Basing the definition of "physician" on State-granted prescribing authority would be imprecise, as physician is a distinct professional licensure category whereas prescribing authority is a function granted to multiple categories of healthcare practitioners. Laws and regulations governing the authority to prescribe drugs vary across states and jurisdictions, and states grant prescribing authority to nonphysician practitioners such as physician assistants and nurse practitioners in varying arrangements. As a result, the proposed definition would create significant ambiguity regarding eligibility for physician-based AU pathways and could lead to inconsistent implementation of Part 35 requirements across jurisdictions.

Additionally, ACR notes that many foreign-trained physicians in radiation-related specialties already have viable pathways to AU eligibility through existing NRC regulations, including American Board of Medical Specialties' (ABMS) member board certification pathways, completion of US-based residency or fellowship training, and satisfaction of applicable NRC T&E requirements.

Achieving NRC's stated objective of accommodating foreign-trained physicians whose primary medical degree is not titled MD or DO does not require eliminating physician-level qualification requirements from the definition of physician. NRC should instead recognize a foreign medical degree that is equivalent to an MD or DO as a criterion, combined with state licensure to practice medicine. Such an approach would be broadly consistent with how federal healthcare programs administered by HHS agencies and the Department of Veterans Affairs commonly distinguish physicians from other practitioners. We recommend:

> §35.2 "*Physician means a medical doctor, doctor of osteopathy, or holder of a foreign-equivalent medical degree, who is licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice medicine, and who is acting within the scope of their medical license.*"

§35.190/290/390-92-94-96/490-91/590/690, Revisions to existing AU T&E to add radiation specialty residency-based pathway

NRC Proposal – To establish residency-based pathways to AU eligibility for physicians who complete specified radiation-related specialty residencies, thereby reducing the need to separately document certain training hours and work experience requirements. Under the proposal, radiation oncology residency training would be recognized for diagnostic uses under §35.200, while nuclear medicine residency training would provide eligibility across the unsealed byproduct material uses. The proposal would retain existing board-certification and alternate T&E pathways, while making conforming revisions to the existing AU T&E framework.

ACR Comments – The T&E requirements for AUs and other authorized personnel are foundational to NRC's ability to protect public health and safety. To that end, ACR generally supports NRC's proposed residency-based pathways to AU eligibility, provided these recognitions remain restricted to appropriate physician radiation specialties with inherent training relevant to the respective authorized use.

ACR recommends that NRC add recognition of completion of a "diagnostic radiology residency followed by at least a one-year nuclear radiology fellowship" as another eligible residency-based pathway for all applicable §35.300 (unsealed material requiring a written directive) sections. This type of approach would be consistent with NRC's existing proposal for residency/fellowship-based recognition in the new §35.790.

NRC should also consider whether diagnostic radiology residency completion combined with appropriate oral and/or parenteral §35.300 radiopharmaceutical therapy (RPT) work experience should enable their use of the residency pathway for unsealed materials requiring a written directive without documenting all 700 hours, as NRC has similarly proposed for radiation oncology with respect to §35.100/200 imaging modalities. This seems appropriate as an extension, assuming the other criteria have been met, as NRC has also proposed removing minimum case requirements from the RPT-related criteria.

ACR recommends that NRC consider recognizing "completion of" the designated specialty residencies rather than specifying a "minimum" number of years per each residency. Most of the cited radiation-related residency durations identified in the proposed regulatory language of the T&E sections do not align with the typical structure of the corresponding training programs. For example, diagnostic radiology training typically consists of a PGY-1 clinical year followed by four years of specialty training (PGY2-5/R1-4), radiation oncology typically consists of a PGY-1 clinical year followed by four years of specialty training (PGY2-5/R1-4), and nuclear medicine typically consists of a PGY-1 clinical year followed by three years of specialty training (PGY2-4/R1-3). The durations in the regulatory language seem based on nuclear medicine's three years of specialty training rather than incorporating the precise durations of each residency type. We recognize that the proposed language establishes "minimum" residency durations rather than fixed program durations; however, in the interest of simplification, accuracy, and long-term adaptability (as residency durations can technically change with accreditation requirement changes), using "completion of" is preferable to a stated minimum.

Additionally, ACR supports retaining the existing "alternate" T&E pathways, i.e., the 700-hour documentation-based pathways (where applicable or otherwise carried over from cross-qualification pathways). These alternate pathways can continue to provide an important mechanism for physicians who are not graduates of a recognized residency program for a particular use, or who do not hold an NRC-recognized specialty board certification, to demonstrate the qualifications necessary for AU eligibility.

Finally, ACR recommends eliminating the proposed insertion of the word "superficial" before "ophthalmic use of beta-emitting sources" in the proposed revision of §35.491 as this is unnecessarily limiting.

§35.59 and §35.2059, Continuing education (CE) and corresponding record-keeping

NRC Proposal – To replace the "recentness of training" requirement with a "continuing education" (CE) model providing more clarity and removing specific work experience requirements for generator systems due to changes in industry practice.

ACR Comments – ACR acknowledges that the seven-year recentness of training requirement has been applied inconsistently in license amendment reviews, and that this has been an ongoing source of ambiguity and unpredictability during license amendment processes. However, the proposed CE framework does not appear to directly resolve those real-world challenges. For example, NRC proposes to assign compatibility category D to the record-keeping requirements in §35.2059, effectively allowing Agreement States to establish state-specific documentation requirements. This approach could perpetuate variation among jurisdictions and limit the uniformity and predictability for which medical stakeholders have long advocated. While ACR does not oppose the proposed CE framework, we advise NRC to explore additional methods of advancing uniformity, including compatibility category upgrades for relevant sections.

Additionally, as general awareness of disparate generator systems is usually adequate for most practice scenarios, ACR supports the proposed removal of practical work experience requirements for generator system use for AUs. Generator elution is not typically relevant to real-world physician-AU services because, apart from certain academic institutions, the majority of §35.200 licensed imaging facilities do not have onsite generators. Moreover, obtaining this work experience often requires special arrangements with nuclear pharmacies or other facilities.

§35.13, Removing license amendment requirements for adding diagnostic use-only AUs

NRC Proposal – To eliminate license amendments to add AUs for §35.100/200 (diagnostic) uses, allowing licensees to approve and document added AUs internally.

ACR Comments – ACR generally supports NRC's proposal to eliminate license amendment requirements for adding AUs for activities conducted exclusively under §35.100 and §35.200, provided the licensee maintains all AU compliance information onsite for inspection. We also support NRC continuing to require that the Radiation Safety Officer (RSO) be listed on these licenses, including in situations where a diagnostic-exclusive AU also serves as the RSO on the license.

Eliminating the need for license amendments to add diagnostic AUs would reduce administrative burdens on licensees and improve the efficiency of onboarding §35.100/200 AUs. Nonetheless, the proposal would effectively shift NRC oversight from proactive regulatory review to inspections. Therefore, the NRC should provide sufficient guidance to ensure licensees are compliant and that inspectors can reliably and predictably review/confirm compliance.

ACR also recommends "registration" of these AUs be maintained by the regulator to enable interjurisdictional reciprocity. Requirements for continuing AU eligibility across disparate states and licenses currently necessitate documentation of AU status on a prior license. This would not be available in the proposed revision of §35.13 without some manner of recognized documentation.

ACR is also concerned that NRC's continued assignment of compatibility category D to §35.13 may limit the proposal's intended benefits. Given the relatively novel approach of this proposal, implementation seems likely to vary by jurisdiction, reducing nationwide consistency and regulatory predictability for licensees. We recommend upgrading the compatibility category to promote nationwide uniformity.

§35.11(b)(1), Clarification of AU supervision requirements

NRC Proposal – To clarify that unless otherwise specified by regulation or license conditions, the AU is not required to be physically present or onsite during the administration, provided that the supervised individual is able to follow the AU's instructions in accordance with §35.27. NRC is requesting comments on whether this interpretation should be compatibility category B, effectively prohibiting Agreement States from establishing AU presence requirements.

ACR Comments – ACR generally supports NRC's objective of promoting consistency in the implementation of Part 35 requirements across NRC and Agreement State jurisdictions. The rationale for elevating this specific clarification to compatibility category B, while other important proposals remain at lower compatibility, is not well established in the preamble, however. If an exception to NRC's categorization approaches can be made for §35.27, we recommend extending similar exceptions to other subjects impacted by state-to-state nonconformity.

Additionally, ACR encourages NRC to consider how the proposed clarification may be applied in unconventional practice arrangements, particularly for RPTs under §35.300. While remote supervision may be appropriate in certain RPT settings, safety depends on the qualifications of the supervised individual, the availability of the AU, and the ability of personnel to recognize and appropriately respond to risk-graded radiation safety, patient care, or administration-related issues.

ACR recognizes that the clarification in the NPRM reflects NRC's prior interpretation of §35.27. Nevertheless, while remote supervision can help alleviate some patient access issues in conventional radiation-related provider settings, experience suggests that widely varying RPT supervision models and loopholes may evolve under this flexibility due to other incentives. NRC should therefore ensure that guidance and inspection activities emphasize the AU's responsibility to continue to provide effective oversight and be reasonably and expeditiously available to address clinical and radiation safety issues that may arise during RPT administrations.

§35.3045(a), "Medical event" reporting reductions

NRC Proposal – NRC proposes to explicitly exclude the requirement for licensees to report §35.3045(a) events that result from emergent patient conditions and prevent completion of administration as planned unless the administration results or would result in damage as described in §35.3045(b). NRC also proposes a new §35.3045(a)(3) medical event type that requires 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. Additionally, NRC proposes to codify several microsource brachytherapy provisions relevant to medical events with those modalities.

ACR Comments – With respect to proposed § 35.3045(a)(3), ACR recommends that NRC not finalize this provision currently and instead evaluate these issues within a harm-based framework. The discussion in the preamble appears to focus on concerns involving leaks or defects associated with administration devices or supplies. However, the proposed regulatory language would apply broadly to medical uses requiring a written directive, including unsealed therapeutic administrations. As a result, ACR is concerned that the proposal would establish a new medical event category based on a fixed percentage deviation without demonstrating that the associated burden of measuring, documenting, and reporting such deviations is justified by a corresponding radiation safety benefit. Additionally, depending on the unsealed agent, treatment regimen, and whether therapy is delivered over multiple fractions, a deviation of 20 percent during an individual administration may not necessarily represent an unintended occurrence or an NRC radiation safety concern. Accordingly, ACR recommends that NRC focus new medical event reporting on cases associated with significant patient harm rather than fixed deviation thresholds that require new measurement processes for demonstrating compliance.

Separately, ACR supports NRC's specific proposal on emergent medical conditions and believes it is consistent with the agency's longstanding approach to circumstances outside licensee control, including patient intervention, extravasation/infiltration occurrences subject to the NRC's current enforcement policy, shunting, and similar phenomena. ACR agrees that reporting should remain required in extremely rare cases that meet the significant harm criterion at §35.3045(b). ACR further notes that the definition of patient intervention in §35.2 already encompasses unintentional patient actions. As such, the proposal appears to clarify NRC's existing requirements rather than propose a major change in direction.

Additionally, ACR continues to recommend that NRC revise §35.3045 to eliminate the requirement for initial 24-hour or next-calendar-day notifications except in circumstances involving urgent public health, safety, or security concerns that require immediate NRC involvement. In most medical event cases, the detailed written report required under §35.3045(d) within 15 days provides NRC with sufficient information for oversight, trend analysis, and programmatic review. By contrast, the accelerated (24 hour/next calendar day) notification often occurs before the licensee has completed the appropriate patient management and investigation and may provide limited regulatory value. As medical event reporting is intended to exclusively inform NRC's oversight activities rather than patient care, ACR believes the agency should reevaluate whether the expedited notification requirement continues to provide NRC with meaningful benefit, or if the 15-day complete report contains all information necessary for NRC's narrow use case.

Finally, ACR recommends that proposed §35.3045(a)(2) (with respect to microsource brachytherapy) be revised to remove the phrase "if shunting was evaluated in accordance with the manufacturer's instructions as set forth in its FDA product approval prior to administration." NRC regulations should not limit physician evaluation of shunting to manufacturer-recommended methodologies, as doing so could unnecessarily constrain clinical judgment and implicate the practice of medicine. Corresponding with the same concern, ACR also recommends removing the proposed definition of "shunting" from §35.2 as this clinical terminology is understood by physicians, and an NRC definition may prove unnecessarily restrictive.

§35.24(f), Radiation Safety Committee composition

NRC Proposal – To eliminate the requirement for a nursing representative on the licensee's Radiation Safety Committee (RSC).

ACR Comments – ACR supports the proposed removal of the requirement for a nursing representative on the licensee's RSC. Nursing personnel are not typically involved in the radiation safety-specific aspects of licensee activities in outpatient/freestanding settings. This proposal would provide licensees with greater flexibility to include individuals whose expertise is more directly aligned with radiation protection, regulatory compliance, and the specific uses authorized under the license. ACR also notes that licensees frequently implement institutional governance policies beyond NRC's minimum RSC requirements. Therefore, this proposal will not prevent licensees from including nursing personnel on their RSC if they believe doing so would enhance the group and its oversight functions and responsibilities.

§35.61, Survey meter calibration

NRC Proposal – To make limited technical and conforming updates to survey instrument calibration requirements as part of the broader modernization of instrument and measurement provisions.

ACR Comments – ACR recommends replacing the proposed energy-range criterion with a requirement that survey meters be calibrated across the range of exposure or dose rates reasonably expected to be encountered during licensed activities. ACR also recommends extending the calibration interval from annually to once every two years to align more closely with calibration frequencies applicable to certain therapy dosimetry systems.

§35.700 (Subpart I), Microsource brachytherapy licensing codification

NRC Proposal – To codify components of Y-90 microsphere brachytherapy licensing guidance into a new "Subpart I" in Part 35 regulations (§35.700) with minimal change, including application of the residency-based pathway to diagnostic radiology with one-year interventional radiology residency or fellowship.

ACR Comments – ACR has long supported transitioning Y-90 microsphere brachytherapy from oversight by guidance (i.e., via reference in §35.1000) to the normal subparts of 10 CFR 35 in a manner that codifies established approaches with minimal changes, including preserving the current methods of satisfying cases in the AU work experience requirements. As recommended to NRC in our prior comment letters, ACR believes that the NPRM's proposals with respect to the §35.790 AU T&E criteria are appropriate and generally aligned with the current licensing guidance. We also support the cross-qualification pathway for those not in the residency-based pathway.

As with the other AU T&E sections, we again note that the minimum duration in the NRC proposed §35.790 language for DR/IR residencies/fellowships does not reflect actual duration of the training. For reasons previously mentioned, ACR recommends that NRC use the language "completion of"

the residency/fellowship, rather than specifying a minimum number of years in the residency/fellowship.

ACR supports NRC's approach in the proposed §35.700 of continuing to require device-specific microsource cases. Historically, most §35.3045(a) "medical events" in Y-90 microsource brachytherapy have been created or exacerbated by issues with components of the unique delivery devices/components. It is therefore appropriate from a radiation safety perspective to require AUs to gain experience in each unique delivery system they are authorized for with respect to §35.700 microsources. Additionally, we note this requirement is consistent with current guidance requirements.

NRC Requests for Comment

Q1. ***(Summary) NRC requests feedback on whether the proposed teletherapy definition appropriately captures all intended teletherapy uses and technologies.***
A1. ACR believes the proposed definition of teletherapy may unnecessarily conflate two distinct concepts: the source of radiation delivery and the method used to localize or guide treatment. Historically, teletherapy has referred to radiation therapy delivered from an external source located outside the patient, in contrast to brachytherapy, where the source is placed within or in close proximity to the treatment site. By comparison, stereotactic guidance describes a treatment localization and targeting methodology rather than a separate category of radiation delivery. Accordingly, ACR recommends that NRC ensure the definition of teletherapy remains sufficiently broad to encompass current and future forms of external beam radiation therapy without creating unnecessary distinctions based on the specific guidance or targeting techniques employed.

Q2. ***(Summary) NRC requests comment on whether §35.11(b) should be assigned compatibility category B instead of category C to ensure nationally consistent AU supervision requirements.***
A2. This subtopic was addressed previously in this comment letter.

Q3. ***(Summary) NRC requests comment on whether the proposed < 3-minute radionuclide half-life threshold for direct infusion systems is appropriate or should be increased to accommodate current or future medical uses.***
A3. ACR recommends consideration of a 10-minute half-life threshold. This would facilitate the use of N-13, currently used for cardiac PET imaging in certain institutions.

Q4. (Summary) NRC requests comment on whether the proposed increase in the decay-in-storage half-life limit from 120 to 275 days is sufficient or should be extended further to accommodate additional medical isotopes.
A4. The NRC's proposed update is sufficient.

Q5. ***(Summary) NRC requests comment on whether the proposed "physician" definition should include additional qualifying language, such as requiring independent medical licensure, to appropriately accommodate foreign-trained physicians while ensuring adequate qualifications for Part 35 activities.***

A5. The NPRM's proposed definition is inherently problematic due to a lack of differentiation between the profession and the prescribing function, which is not limited to physicians across all states. This critical subtopic, including an ACR-recommended language proposal, is discussed in the above comment letter.

Q7. ***(Summary) NRC requests comment on whether diagnostic radiology, nuclear medicine, and radiation oncology residencies provide sufficient radiation safety and clinical training to support removal of the current prescriptive AU training-hour requirements.***
A7. ACR agrees that the prescriptive hour-based requirements can be reserved for non-radiological physician specialties without intrinsic byproduct material expertise obtained via their usual specialty training. The core priority is demonstration of requisite skills and knowledge to the appropriate radiation-related issues, as demonstrated by appropriate eligibility for initial certification and participation in continuous certification programs of the appropriate specialty boards. Specific comments on the residency-pathways are provided in the above comment letter, including use of "completion of" the recognized residency/fellowship rather than specifying a minimum number of years, which may be misaligned with real program durations.

Q8. ***(Summary) NRC requests comment on whether certain fellowship programs provide sufficient integrated radiation safety and clinical training to serve as an alternative to the current prescriptive AU training-hour requirements.***
A8. This subtopic was addressed previously in this comment letter (i.e., ACR supports DR/IR in §35.790, and recommends the addition of DR/NR and DR for those who meet all other T&E criteria, for the relevant §35.300 uses). It is critical that all recognized residencies in Part 35 be limited to radiation specialties, and that non-radiation specialties use the available alternate/T&E documentation pathways. We also recommend "completion of" rather than "minimum" years in a recognized residency as the NRC's minimums do not correspond with real world durations for the recognized residencies other than nuclear medicine.

ACR appreciates the NRC's consideration of these recommendations, and we welcome further discussion. For questions, please contact Mike Peters, ACR Senior Director, Government Affairs at mpeters@acr.org, or Lindsay Robbins, Regulatory Policy Specialist, at lmrobbins@acr.org.

Sincerely,

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