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U.S. Nuclear Regulatory Commission
Office of the Secretary
ATTN: Rulemakings and Adjudications Staff
Washington, DC 20555

Subject: "Reducing Barriers to Medical Use Licensing" [NRC-2025-1237]

To all concerned:

The State of New York appreciates the opportunity to comment on the U.S. Nuclear Regulatory Commission's (NRC) proposed rule "Reducing Barriers to Medical Use Licensing" (NRC-2025-1237), published in the Federal Register on July 27, 2026.

The proposed rule was developed in response to Executive Order 14300, "Ordering the Reform of the Nuclear Regulatory Commission," which directs the NRC to conduct a review and wholesale revision of its regulations and guidance. The rule amends 10 C.F.R. part 35, "Medical Use of Byproduct Material," and is accompanied by revised guidance. Among its principal components, the proposed rule would:

- Broaden the definition of "physician" to include foreign-trained individuals who 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 of medicine.
- Replace the seven-year recentness-of-training requirement in § 35.59 with a performance-based continuing-education model and remove specific work-experience requirements for generator systems.
- Eliminate the license-amendment requirement to add authorized users for diagnostic uses, allowing licensees to approve and document these users internally.
- Remove prescriptive pathways and requirements for physicians who complete a clinical radiation specialty residency, while retaining the board-certification and

cross-qualification pathways, and remove specific accrediting-body references in residency training requirements.

- Update the work-experience categories for "oral" and "parenteral" administration of any radioactive drug requiring a written directive.
- Codify licensing pathways, training and experience, and performance-based safety criteria for emerging medical technologies (EMTs) currently licensed under subpart K and establish clear requirements for rubidium-82 (Rb-82) generators.
- Remove the written-directive requirement for diagnostic administrations of sodium iodide I-131.[1]
- Refine written-directive and medical-event reporting to exclude events caused by emergent patient conditions or real-time clinical decisions and refine embryo/fetus dose reporting to exclude cases where pregnancy could not reasonably be determined before administration.
- Expand decay-in-storage eligibility by increasing the allowable half-life from 120 to 275 days; eliminate the license-amendment requirement for Institutional Review Board (IRB) approved human-subject research already covered under existing authorizations; remove duplicative requirements for mobile medical services; and extend the temporary Radiation Safety Officer (RSO) duration while refining Radiation Safety Committee (RSC) requirements.

New York's Interest in the Proposed Rule

New York, as an Agreement State under Section 274b of the Atomic Energy Act of 1954, as amended, appreciates the opportunity to comment on this rulemaking and its associated guidance. New York shares the NRC's objective of a safe, effective, and efficient national materials program and supports several elements of the proposed rule. The comments below, which reflect the review of the New York State Department of Health (NYSDOH) and the New York City Department of Health and Mental Hygiene (NYCDOHMH) as the New York's Agreement State radioactive materials licensing program agencies, are offered in the cooperative spirit of the National Materials Program and identify provisions the State supports, provisions the State opposes, as well as recommendations intended to strengthen the final rule and its implementation.

[1]As described in the proposed rule, a written directive is currently required for administration of sodium iodide I-131 in quantities greater than 1.11 megabecquerels (30 microcuries). 91 Fed. Reg. 47042.

Provisions the State Supports

New York supports several changes that reflect sound, risk-informed regulation:

- Broadened definition of "physician." The State supports this change, which more formally recognizes the New York State Education Department (NYSED) licensing process and promotes inclusivity for physicians licensed and registered by NYSED.
- Removal of generator systems from training and experience. The State supports removing generator systems as a required training-and-experience element. In revised guidance such as NUREG-1556, Volume 9, the State recommends that the NRC note that authorized users who continue to supervise this activity should retain training, experience, and familiarity with the elution and utilization of generators, as applicable.
- Codification of emerging medical technologies. The State supports codifying provisions for EMTs currently licensed under subpart K of 10 CFR Part 35. This change reinforces existing publications and positions that are widely accepted by Agreement States and enhances the State's ability to evaluate compliance against regulatory requirements rather than guidance.
- Requirements for Rb-82 generators. The State supports establishing clear requirements for Rb-82 generators. A significant gap currently exists that the State and many Agreement States address through licensing or state-specific requirements, and codifying these requirements enhances national consistency and the clinical use of these generators.
- Expanded decay-in-storage eligibility. The State supports increasing the allowable half-life from 120 to 275 days, provided the associated financial-assurance requirements are aligned, as discussed under Principal Concerns and Recommendations below.
- Elimination of the IRB license-amendment requirement. The State supports eliminating the license-amendment requirement under § 35.6 for investigational new drugs and investigational device exemptions, provided that an IRB report is maintained on site and available for review during inspections, as discussed below.
- Streamlined mobile medical services. The State supports removing duplicative and prescriptive requirements for mobile medical services, subject to the compatibility considerations discussed below.

- Temporary RSO and RSC changes. The State supports extending the temporary RSO duration and refining RSC requirements and recommends aligning these provisions with the broad-scope RSC requirements under 10 C.F.R. part 33 for consistency.
- Revisiting the seven-year recentness requirement. The State supports revisiting the recentness-of-training requirement in § 35.59, subject to the guidance concerns discussed below.

Principal Concerns and Recommendations

While the State supports the rule's direction in several respects, the following provisions warrant modification or clarification before the rule is finalized.

Elimination of authorized-user naming for diagnostic uses

The State strongly opposes eliminating the requirement to name authorized users for diagnostic uses. New York and other Agreement States have observed persistent issues with training-and-experience documentation for diagnostic authorized users. Removing diagnostic uses from the license would lengthen inspection times, because inspectors would need to review medical events and training and experience for these users at inspection. Although medical events involving diagnostic agents are rarely reportable at the Federal level, improperly trained diagnostic authorized users would be expected to lead to significant problems, including poor supervision of nuclear medicine technologists and staff, improper study orders, and reduced confidence in healthcare systems. The State's ability to identify improperly trained physicians could be substantially delayed for diagnostic-only facilities, which may be inspected only every five years as a priority-5 facility. The State is concerned that this change would erode public trust in the healthcare system and lead to additional medical events.

> **Recommendation 1.** The State requests that the NRC retain the requirement to name authorized users for diagnostic uses. If the NRC's objective is to reduce administrative delay in adding diagnostic users, the State recommends that the NRC instead consider revising 10 C.F.R. § 35.14 to extend the period within which a licensee must notify its regulator that an authorized user has begun work. Extending that notification period beyond 30 days could mitigate administrative delays in amending licenses while reducing items of noncompliance, medical events, and personnel-training issues associated with improperly trained physicians. The State prefers this approach to removing diagnostic authorized users from the license.

Removal of the written directive for diagnostic sodium iodide I-131

The State opposes removing the written-directive requirement for diagnostic administrations of sodium iodide I-131, particularly in combination with no longer naming or listing diagnostic authorized users, which compounds the concerns described in Section A. The current written-directive threshold for I-131 administrations greater than 30 microcuries provides a well-established standard that helps prevent medical events and inadvertent biological effects on the thyroid. Although diagnostic uses of I-131 above 30 microcuries are rare, the biological risk to the thyroid above those quantities is established and can substantially reduce temporary or permanent thyroid function. Because such administrations are rare, the State believes these orders should be performed by a physician trained in therapeutic doses of I-131, who is best informed of the potential biological effects on the thyroid when weighing patient benefits and risks. In addition, I-123 offers a reasonable diagnostic alternative for uptake scans at higher administered quantities while sparing thyroid tissue.

> **Recommendation 2.** The State requests that the NRC retain the written-directive requirement for diagnostic administrations of sodium iodide I-131 above the current threshold.

Embryo and fetus dose reporting

The State opposes refining the embryo/fetus dose reporting requirements to exclude cases where pregnancy could not reasonably be determined before administration. The early stages of fetal development are especially vulnerable during the pre-implantation and organogenesis stages, up to approximately week eight. Reporting these circumstances remains valuable and necessary given the potential patient implications. Although such cases are rare, the reported information supports localized public-health outreach related to nuclear medicine and radiation therapy and provides useful data for other clinical-care needs, including assessment of adverse patient impacts, non-radiological event reporting, and informed consent.

> **Recommendation 3.** The State requests that the NRC retain the embryo/fetus dose reporting requirement.

Work-experience categories for oral and parenteral administration

The State opposes updating the work-experience categories for “oral” and “parenteral” administration of any radioactive drug requiring a written directive. The State believes this change would not substantially reduce regulatory burden and could dilute the specific training and experience that physicians obtain for particular

radiopharmaceuticals. The current work-experience category methods remain sufficient and appropriate for the activities and duties expected of authorized users.

> **Recommendation 4.** The State requests that the NRC retain the current work-experience categories for oral and parenteral administration.

Reporting exclusions for emergent conditions and real-time clinical decisions

The State supports revisiting the reporting exclusions for events caused by emergent patient conditions or real-time clinical decisions, but its support depends on how "real-time clinical decisions" is defined and how independently that determination can be evaluated by inspectors. While the State agrees with the intent of the revision, the ambiguity in these exclusions could create significant potential for underreporting or for unsupported justifications that an event is not reportable. Under current requirements, some facilities attempt to characterize events as non-reportable using unsupported conclusions in root-cause or failure analyses.

> **Recommendation 5.** The State strongly recommends that the NRC establish specific criteria that must be met for these exclusions to apply and provide specific examples in guidance to convey the intent and standards of the exclusionary provisions.

Guidance for continuing education, residency pathways, and accrediting-body references

Several provisions turn on guidance that the State believes must be clarified. With respect to replacing the seven-year recentness requirement with a performance-based continuing-education model, the State's principal concern is existing ambiguity regarding which types of continuing education (CE) are acceptable and how they should be documented; the current inconsistency in what is deemed acceptable does not appear to be resolved by the proposed change. With respect to removing prescriptive training-hour requirements for clinical specialty residency and the cross-qualification pathways and removing specific accrediting-body references in residency training requirements, the State does not have a definitive position on these matters but requests clearer guidance on acceptable methods, references, and pathways, updated on a routine basis, to ensure consistency among licensees and users.

> **Recommendation 6.** The State recommends that, for any modification of these requirements, the NRC provide clear and regularly updated guidance identifying acceptable continuing education, training pathways, and references, in order to reduce regulatory burden and ensure consistent implementation.

Decay-in-storage and decommissioning financial assurance.

The State supports expanding decay-in-storage eligibility to materials with half-lives up to 275 days, provided that the associated financial-assurance requirements under 10 C.F.R. § 30.35 are aligned with the same half-life threshold. If the half-life thresholds do not coincide, licensees could accept and store on site materials that are not accounted for in financial-assurance estimates, creating an interpretation and implementation problem that would increase burden on licensees and regulators alike.

> **Recommendation 7.** The State requests that the NRC align the decommissioning financial-assurance provisions of § 30.35 with the expanded 275-day decay-in-storage threshold.

Implementation, guidance, and Agreement State compatibility

Because Agreement States regulate the large majority of medical-use licensees, much of the practical burden of implementation will fall on the States, and the compatibility category assigned to each amended provision will determine the scope of required State action. New York asks the NRC to address the following:

- Mobile medical services. Certain Agreement States may bar or restrict mobile medical service companies from performing human-use administration of radioactive material based on other State laws and requirements. For this reason, the mobile-medical provisions should be assigned a compatibility category (for example, Category C or D) that preserves existing State-specific restrictions relative to the 10 C.F.R. requirements.
- IRB documentation at inspection. For the elimination of the § 35.6 license-amendment requirement, the State recommends that the NRC enhance guidance on how the § 35.6 requirements should be met so that sufficient information remains available at inspection, commensurate with applicable FDA requirements.
- Radiation Safety Committee consistency. The State recommends aligning the refined RSC requirements with the broad-scope RSC requirements under 10 C.F.R. part 33.
- Generator supervision. As noted above, revised guidance such as NUREG-1556, Volume 9 should reflect that authorized users supervising generator activities retain appropriate training and experience.

> **Recommendation 8.** The State requests that the NRC clearly identify and explain the compatibility category assigned to each amended provision, consistent with Section XV of the notice, and issue final implementation guidance concurrent with the final rule.

Conclusion

New York supports the NRC's effort to modernize and risk-inform its medical-use regulations, and it particularly welcomes the broadened definition of "physician," the codification of emerging medical technologies, and the clear requirements for Rb-82 generators. The State asks the NRC to reconsider the elimination of authorized-user naming for diagnostic uses, the removal of the written directive for diagnostic sodium iodide I-131, the embryo/fetus dose reporting exclusion, and the changes to the oral and parenteral work-experience categories, and to provide the guidance, financial-assurance alignment, and compatibility clarity described above. New York appreciates the NRC's continued partnership in the National Materials Program and welcomes the opportunity to discuss these comments further.

Thank you for the opportunity to comment. If you have any questions, please contact me.

Sincerely,

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