

September 10, 2026

Chairman Nieh, and Commissioners Wright, Crowell, Marzano, and Weaver
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Re: Comments of the Connecticut Department of Energy and Environmental Protection on NRC
Regulatory Modernization Efforts – Reducing Barriers to Medical Use Licensing

Docket ID: NRC–2025–1237

Dear Chairman Nieh, and Commissioners Wright, Crowell, Marzano, and Weaver:

The Connecticut Department of Energy and Environmental Protection (DEEP) appreciates the opportunity to provide comments on the U.S. Nuclear Regulatory Commission’s (NRC’s) proposed revisions to 10 CFR Part 35¹ as part of the NRC’s regulatory modernization efforts under Executive Order 14300.

DEEP supports the development and utilization of atomic energy in a manner that protects public health and safety, promotes the common defense and security, and preserves the environment. This framework reflects a deliberate balance in State of Connecticut’s (hereinafter “Connecticut” or “State”) state policy: the State is directed to adapt its laws and regulations to evolving conditions in ways that encourage the safe development of industries producing or utilizing atomic energy, while at the same time protecting the public interest. Connecticut remains committed to working with the NRC and to maintaining a regulatory program compatible with the Atomic Energy Act of 1954.

This statutory policy is implemented through a defined governance structure within the State’s government. Pursuant to Section 16a-102 of the Connecticut General Statutes (C.G.S.), the Commissioner of DEEP serves as the State’s lead official responsible for coordinating all atomic energy development and regulatory activities and ensuring consistency across state agencies. The Commissioner’s statutory role encompasses coordination with the federal government, including the NRC, and reinforces DEEP’s responsibility to ensure that regulatory programs are comprehensive, compatible, and effectively implemented.

As the 40th and most recent NRC Agreement State, Connecticut has direct regulatory responsibility for the safe use of radioactive materials within the State. DEEP is a partner with the NRC in the National Materials Program and is responsible for implementing compatible requirements, conducting inspections, and performing licensing and enforcement activities.

¹ “Reducing Barriers to Medical Use Licensing,” (Docket: NRC-2025-1237), 91 FR 47042 (July 27, 2026).

Accordingly, Connecticut has a strong interest in ensuring that NRC rulemakings support effective, consistent, and implementable requirements nationwide.

DEEP generally supports the NRC's efforts to reduce unnecessary regulatory burden and modernize the medical use regulations. DEEP respectfully submits the insights in Attachment A, which identify opportunities to improve flexibility and streamline licensing while highlighting specific provisions where additional clarification, guidance, or implementation considerations are needed to ensure consistent application and continued protection of patients, workers, and the public across the National Materials Program.

At the same time, the volume and pace of concurrent rulemakings—more than twenty (20) underway, including multiple direct final rules—compounds the challenges for Agreement States and other stakeholders. This compressed timeline not only limits the ability of Connecticut to fully evaluate complex technical changes and the potential impacts but also increases the risk that implementation challenges may not be adequately addressed.

It is essential that NRC rulemakings reflect a commitment to rigor, openness, and meaningful stakeholder engagement. Advancing significant regulatory changes without sufficient opportunity for review risks undermining public confidence—not only in existing programs, but also in the successful deployment of advanced nuclear technologies.

Given these considerations, DEEP respectfully recommends that the NRC:

- Provide public comment periods that are sufficiently long to allow Agreement States and other stakeholders to thoroughly review, analyze, and assess the technical, legal, operational, and implementation impacts of proposed rulemakings, particularly where changes are complex, far-reaching, or issued concurrently with other major regulatory actions;
- Sequence and pace rulemakings to provide meaningful spacing between significant regulatory changes and avoid requiring Agreement States to review and implement multiple complex rulemakings simultaneously; and
- Limit the use of direct final rules to truly non-controversial or minor administrative changes, ensuring that substantive or technically complex revisions are subject to full notice-and-comment rulemaking.

In closing, and before turning to the specific comments in the Attachment A, Connecticut remains supportive of the NRC's efforts to modernize its regulatory framework and to fulfill its mission to protect public health and safety and advance the nation's common defense and security by enabling the safe and secure use and deployment of civilian nuclear energy technologies and radioactive materials through efficient and reliable licensing, oversight, and regulation for the benefit of society and the environment. Achieving these objectives while maintaining public trust and strong oversight will require a deliberate, transparent, and inclusive process that fully incorporates the experience and expertise of Agreement States.

Thank you for the opportunity to comment on this important matter.

Sincerely,

A handwritten signature in blue ink that reads "Emma Cimino". The script is fluid and cursive, with the first letters of each name being capitalized and prominent.

Emma Cimino
Acting Commissioner
Connecticut Department of Energy and Environmental Protection

ATTACHMENT A

Specific Requests for Comments

DEEP appreciates the NRC's request for specific comments in Section V of the Federal Register Notice (FRN) on the proposed "Reducing Barriers to Medical Use Licensing."² DEEP generally supports the NRC's efforts to reduce unnecessary regulatory burden, modernize the medical use regulations, and provide greater flexibility for licensees. At the same time, DEEP has identified several provisions where additional clarification, guidance, or implementation time are needed to ensure that these changes can be applied consistently across the National Materials Program while maintaining appropriate protection of patients, workers, and the public. In response to the NRC's questions, DEEP offers the following perspectives:

DEEP Response to Question #1: The NRC is proposing to revise the definition of "teletherapy" in § 35.2 to clarify that it refers to external beams of ionizing radiation that are delivered from an external source without stereotactic guidance. However, the NRC is also considering removing the specific reference to stereotactic guidance or adding additional clarifying language to further expand the definition. As such, the NRC is seeking comments on examples of teletherapy uses and whether the NRC would need to further revise the definition of teletherapy to ensure these teletherapy uses are included. Please provide the basis for your response.

Connecticut currently has no teletherapy uses licensed under its Agreement State program. Therefore, the Department does not have direct experience with existing or emerging teletherapy applications that would warrant expanding the proposed definition at this time.

Nevertheless, DEEP recommends that the NRC retain the proposed definition of teletherapy rather than further expanding the definition at this time. The medical community continues to develop and adopt innovative radiation therapy technologies, and overly broad or technology-specific definitions could inadvertently encompass applications that may have substantially different radiation safety characteristics or are more appropriately addressed under another regulatory framework. Maintaining a clear definition will provide regulatory certainty while allowing the NRC to evaluate new technologies based on their specific radiation safety characteristics.

The NRC's existing framework under 10 CFR § 35.1000 provides an effective mechanism for addressing emerging medical technologies that do not fit within the existing provisions of 10 CFR Part 35. Under 10 CFR § 35.1000, the NRC and Agreement States can evaluate the specific characteristics and risks of an emerging technology and establish appropriate licensing requirements, including technology-specific training, facility and equipment specifications, and other radiation safety provisions. The proposed rule itself recognizes that this approach has been

² "Reducing Barriers to Medical Use Licensing," (Docket: NRC-2025-1237), 91 FR 47042 (July 27, 2026).

successfully used for a range of emerging medical technologies, including photon-emitting teletherapy systems.

Given the pace of innovation in medical radiation therapy, DEEP believes preserving this flexibility is preferable to attempting to anticipate and codify every potential future teletherapy application in the definition of 10 CFR § 35.2. Accordingly, DEEP supports retaining the proposed definition and recommends continued use of 10 CFR § 35.1000 when a novel application does not clearly fall within an existing category of medical use.

DEEP Response to Question #2: As part of this rulemaking package, the NRC has developed guidance to clarify that the physical presence of an AU for the medical use of byproduct is not required under § 35.11(b)(1). 10 CFR 35.11(b)(1) permits licensees to allow individuals who are not AUs to perform certain tasks under the supervision of an AU who is named on the license or permit. As indicated, the NRC has developed guidance to clarify that there is no requirement regarding the location of the AU during the use. The current compatibility category of § 35.11(b) is category C, allowing Agreement States to be more restrictive and potentially require the physical presence of an AU. The NRC has received concerns from industry stakeholders that § 35.11(b) raises transboundary concerns as medical networks have grown and many cross state lines, such that the regulation should be compatibility category B. In addition, the industry stakeholders have expressed concerns that requiring an AU to be physically present or within a specified location of the medical use limits access to treatments in rural areas. As such, the NRC is considering changing this regulation to be compatibility category B. The NRC is requesting specific comments on the appropriate compatibility category for § 35.11(b).

DEEP supports changing 10 CFR § 35.11(b) to Compatibility Category B. A uniform national approach to the supervision requirements is appropriate given the increasingly interconnected nature of medical networks and the potential for medical services and personnel to operate across State boundaries. A Category B designation would provide greater consistency among Agreement States while retaining the flexibility contemplated by the NRC's proposed approach. The NRC identifies Category B provisions as those involving jurisdictional boundaries where uniformity is appropriate on a nationwide basis.

DEEP does, however, have some concern regarding the definition and interpretation of the phrase "under the supervision of an authorized user." Similar questions regarding the meaning and practical implementation of supervision requirements have previously arisen in other NRC-regulated activities, including industrial radiography. Without a clear and consistent understanding of what constitutes supervision, Agreement States and licensees could develop differing interpretations of the level of oversight required.

DEEP has a related concern with the proposed use of the term "immediately available" in 10 CFR § 35.615. For example, the proposed requirements for gamma stereotactic radiosurgery would allow an Authorized User (AU) to leave the treatment area after initiation but require the AU to remain immediately available during continuation of treatment. The term "immediately available" could similarly be subject to varying interpretations regarding the AU's location, ability to respond, communications, and expected response time.

Accordingly, if the NRC proceeds with the Category B designation, DEEP recommends that the NRC define “under the supervision of” and “immediately available” in regulation or provide sufficiently specific and nationally applicable guidance addressing these terms. Clear expectations will help ensure that the transition to a uniform national standard does not result in a patchwork of interpretations among Agreement States. Such clarification should address, as appropriate, the AU’s ability to communicate with personnel performing the authorized activity, the AU’s ability to provide timely direction or intervention, and the circumstances under which the AU must be physically present.

DEEP also strongly supports the proposed provision in 10 CFR § 35.615(e)(3)(iv) addressing unexpected interruptions of gamma stereotactic radiosurgery treatments. The proposal requires that, when an unexpected interruption requires operator re-initiation, an AU and Authorized Medical Physicist (AMP) evaluate the situation to ensure treatment is being delivered in accordance with the treatment plan and written directive before treatment is re-initiated. DEEP considers this provision an important and much-needed patient safety measure. Requiring both the AU and AMP to evaluate the circumstances before re-initiation provides an appropriate independent check that the treatment can safely resume and that the patient will receive the intended treatment in accordance with the treatment plan and written directive.

Overall, DEEP supports the proposed change to Compatibility Category B for 10 CFR § 35.11(b), provided that the NRC establishes clear and consistent expectations for the terms “under the supervision of” and “immediately available.” DEEP further supports the proposed treatment-interruption provision in 10 CFR § 35.615(e)(3)(iv) as an important enhancement to patient safety.

DEEP Response to Question #3: The NRC is proposing to establish specific criteria in § 35.63 to allow incremental administrations to be performed using direct infusion systems, including a criterion that calls for the administered radioisotope to have a half-life of less than three minutes. These provisions are designed to accommodate the unique characteristics of isotopes such as Rb-82, which cannot be practically measured using traditional methods due to their rapid decay and automated delivery systems. The NRC is seeking feedback on whether the proposed three-minute timeframe is appropriate or if a higher threshold would be beneficial for a current or expected future medical use and if so, what length half-life would be appropriate (for example, 5 minutes or 10 minutes). Please provide the basis for your response.

The proposed three-minute half-life criterion appears to be based primarily on the characteristics of the radionuclides and systems currently being considered by the NRC, particularly Rb-82. The proposed rule explains that Rb-82 presents unique challenges because of its short half-life and automated delivery directly to the patient, making traditional measurement of the activity impractical. However, the NRC does not appear to have provided a specific safety case supporting three minutes as the appropriate regulatory threshold.

DEEP recommends that the NRC develop and clearly articulate the safety basis for the proposed three-minute limit before establishing a fixed half-life threshold in regulation. Such an analysis

should consider, at a minimum, the potential for additional activity to be handled as a result of the time required to measure or otherwise establish the administered activity while the radionuclide is decaying. The analysis should also consider the potential detriment to the patient resulting from a malfunction of the direct infusion system, including the maximum potential unintended or excessive administration that could occur based on the design and controls of the system.

If the NRC's safety analysis demonstrates that a longer half-life can be accommodated while maintaining adequate protection of patients, DEEP would support establishing a higher threshold than three minutes. DEEP would also support eliminating a prescriptive half-life restriction altogether if the safety case demonstrates that the risks associated with incremental administration can be adequately controlled through isotope- and system-specific requirements.

An alternative approach would be to retain the proposed three-minute criterion as the general regulatory standard while providing a pathway under 10 CFR § 35.63 for an applicant to propose the use of an isotope with a longer half-life through an isotope- and system-specific safety analysis. Under this approach, the applicant would demonstrate that the radionuclide, delivery system, system controls, measurement methodology, and maximum potential patient dose provide adequate assurance of patient safety. The NRC could review and approve the analysis as part of the licensing process.

This approach would provide a predictable baseline for currently established technologies while preserving sufficient regulatory flexibility to accommodate future medical technologies. Given the pace of innovation in radiopharmaceuticals and delivery systems, DEEP believes that a performance-based pathway supported by an appropriate safety analysis would be preferable to establishing a fixed half-life limit that could unnecessarily constrain future technologies.

DEEP Response to Question #4: The NRC is proposing to change § 35.92(a) to allow licensees to hold byproduct material with a physical half-life of less than or equal to 275 days, instead of 120 days, to allow licensees to hold Lu-177m and Co-57 flood sources for decay-in-storage. The NRC is seeking feedback on whether an even longer half-life limit would be beneficial for medical use in this context. Specifically, the NRC is considering increasing the physical half-life beyond 275 days if there is a radioisotope used in medicine that could benefit from such an increase without causing a significant increase in risk. Please comment on whether increasing the half-life limit beyond 275 days would provide a meaningful benefit to medical licensees. If you believe a longer limit would be appropriate, indicate what specific half-life (for example, 300 days or 365 days) you recommend and explain the medical use which would benefit from your recommendation. In addition, describe any safety or operational considerations the NRC should evaluate if the limit is extended further.

DEEP supports the NRC's proposed expansion of eligibility for decay-in-storage. The proposed change would increase the maximum half-life from 120 days to 275 days and is intended to accommodate longer-lived medical isotopes, including Lu-177m and Co-57. DEEP agrees that the change is appropriate for the isotopes of concern currently identified by the NRC.

However, DEEP believes that the ultimate consideration should not be solely the half-life of the isotope, but rather the amount of time and activity that material may remain in decay-in-storage before the storage area begins to function as a de facto radioactive waste storage facility. Extending the eligibility period for decay-in-storage could result in accumulation of radioactive material over extended periods, particularly where longer-lived isotopes are involved. The NRC should consider this potential accumulation as part of the safety and regulatory basis for the proposed change.

DEEP recommends consideration of a graded, performance-based approach that would allow longer-lived radionuclides to be managed under decay-in-storage provided the quantity or activity of material remains below an appropriate threshold. For example, the NRC could establish graduated criteria based on half-life, such as:

- radionuclides with half-lives of less than 120 days;
- radionuclides with half-lives of 120 to 270 days; and
- radionuclides with half-lives of 270 to 365 days.

As the half-life increases, the allowable activity eligible for decay-in-storage could decrease. This approach would provide greater flexibility for emerging medical isotopes while reducing the potential for accumulation of significant quantities of longer half-life byproduct material in decay-in-storage areas. It would also better align the regulatory allowance with the underlying concern—preventing decay-in-storage areas from becoming de facto waste storage sites—rather than relying solely on a fixed half-life criterion.

DEEP also recommends that the NRC consider additional performance-based controls associated with extended decay-in-storage periods. These could include requirements addressing the location, access controls, accounting, and inventory management of material held for decay. Such controls could provide assurance that material remains appropriately managed and that licensees can demonstrate the quantity and activity of material accumulated in storage.

A graded approach could also help limit potential financial assurance implications associated with accumulating larger quantities of radioactive material onsite. By limiting the activity that may be retained for increasingly long periods, the NRC could provide flexibility for longer-lived medical isotopes without creating substantial inventories that could raise questions regarding long-term waste management or financial assurance.

DEEP therefore supports the proposed change to accommodate the longer-lived isotopes currently identified by the NRC, but recommends that the final rule incorporate a graded, performance-based approach that considers both half-life and activity. This would provide a more adaptable framework for future medical isotopes while ensuring that decay-in-storage remains a waste-management option and does not become a de facto radioactive waste storage facility.

DEEP Response to Question #5: The NRC is proposing to change the definition of “physician” in § 35.2 to expand eligibility for individuals to become AUs. This change is intended to allow those who meet training and experience requirements and are fully

licensed to practice medicine in the United States, but whose primary medical qualification is not titled MD or DO, such as foreign-trained physicians, to be eligible to become AUs. The NRC is considering whether the clause specific to prescribing drugs should be removed or additional qualifying language should be added to this definition in the final rule. In particular, the NRC is seeking feedback on whether removing additional language or adding additional qualifying language, such as “fully licensed to practice medicine independently,” is needed in this definition to ensure individuals defined as physicians have adequate training and experience to perform tasks allowed under 10 CFR part 35. Please provide the basis for your response.

DEEP supports the proposed realignment of the definition of “physician” to allow physicians who were trained outside the United States and subsequently licensed by a State to be named as AUs. This change would provide greater flexibility while appropriately recognizing State medical licensure as the basis for determining an individual’s authority to practice medicine.

DEEP supports retaining the existing requirement that an individual be licensed to prescribe drugs as part of the definition of “physician.” Authorization to safely use byproduct material in medical applications carries responsibilities that are analogous in important respects to the responsibilities associated with safely prescribing and administering medications. Both activities require an understanding of the appropriate use of the medical product or material, applicable protocols, and the potential consequences of an inappropriate administration. Retaining the prescribing requirement therefore provides an additional assurance that an individual serving as an AU has the appropriate understanding of the responsibilities associated with safely directing the medical use of byproduct material.

At the same time, DEEP recognizes that the proposed definition could inadvertently create differences in eligibility among States because the scope of prescribing authority varies by jurisdiction and among different categories of health care practitioners. For example, Connecticut does not authorize naturopathic doctors to prescribe drugs, while other States provide naturopathic doctors with some degree of prescribing authority. Similarly, the scope of practice and prescribing authority of advanced practice registered nurses (APRNs) and other non-physician practitioners varies significantly among States. Consequently, an individual could meet the literal definition of “physician” in one jurisdiction based on that jurisdiction’s prescribing authority while an individual with similar education, training, and clinical responsibilities may not meet the definition in another jurisdiction.

DEEP therefore supports adding language clarifying that the individual must be fully licensed to practice medicine independently. This would provide greater assurance that an individual seeking AU status has satisfied the applicable State or jurisdictional requirements to independently practice medicine and perform the responsibilities associated with an AU. Such a requirement would also help avoid ambiguity regarding individuals who may be licensed in a limited capacity, under supervision, or subject to other restrictions on their practice. DEEP believes this clarification is particularly important if the NRC retains prescribing authority as a criterion, because prescribing authority alone may not adequately distinguish among practitioners with substantially different scopes of practice.

DEEP recognizes that retaining the prescribing requirement and adding an independent-licensure provision may create additional complexity, particularly because the qualifications and scope of authority to prescribe medications can vary among States and jurisdictions. These differences could create challenges for Agreement States when evaluating the qualifications of an individual who received medical training or licensure in another jurisdiction, particularly where the requirements applicable to prescribing differ from those in the jurisdiction where the AU will practice.

Accordingly, DEEP recommends that the NRC provide clear guidance for Agreement States and licensees on how to verify that an individual seeking AU status meets the physician definition when the individual's medical licensure or prescribing authority was obtained in another State or jurisdiction. The guidance should address differences in scope of practice among physicians, APRNs, naturopathic doctors, and other practitioners, and should establish a consistent approach for determining whether an individual's licensure and prescribing authority satisfy the federal definition. The guidance should also specifically address how an Agreement State should determine whether an individual qualified as an AU under another Agreement State's requirements meets the applicable requirements when the individual will practice in an NRC jurisdiction, and vice versa.

Overall, DEEP supports the proposed flexibility to recognize physicians trained outside the United States who are appropriately licensed by a State, while recommending that the NRC retain the prescribing-drugs requirement and add a requirement that the individual be fully licensed to practice medicine independently. These provisions provide important assurance that individuals authorized to direct medical uses of byproduct material possess the appropriate medical qualifications and professional authority. At the same time, the NRC should recognize and address the significant differences among States in the scope of practice and prescribing authority of various health care professionals. Clear, nationally consistent NRC guidance will be important to prevent these differences from resulting in inconsistent determinations of AU eligibility across jurisdictions.

DEEP Response to Question #6: The NRC is proposing to remove the requirement for a written directive for a diagnostic administration of sodium iodide I-131 in quantities greater than 1.11 megabecquerels (30 microcuries). The requirement was historically established to reduce the potential for unintended thyroid irradiation associated with irreversible thyroid uptake and to help prevent wrong-patient or wrong-procedure administrations. The NRC is seeking feedback on whether eliminating this written directive requirement could raise any safety concerns or otherwise affect patient protection beyond risks associated with diagnostic administrations. In particular, the NRC seeks input on whether current clinical practices of patient identification, procedure verification, and pregnancy screening provide sufficient assurance that diagnostic administration of sodium iodide I-131 are performed safely without the need for a written directive. The NRC is also seeking feedback on whether the removal of this requirement would reduce unnecessary administrative burden on licensees while maintaining adequate protection of patients. Please provide the technical or operational basis for your response, including any relevant experience, data, examples from clinical practices, or information on current institutional practices used to verify patient identity and the intended procedure.

Based on DEEP's inspection experience, the agency has not identified significant patient safety issues associated with diagnostic administrations of I-131. DEEP has observed some administrative issues with written directives; however, these have not resulted in impacts to patient safety. In DEEP's experience, the written directive requirement can create administrative burden without providing a commensurate patient health benefit.

DEEP also observes that facilities routinely perform diagnostic I-131 administrations below the 30 microcurie threshold and maintain robust patient identification, procedure verification, and other safety practices. These observations support the conclusion that existing clinical safeguards provide adequate protection without the additional written directive requirement.

Accordingly, DEEP supports removal of the written directive requirement for diagnostic administrations of sodium iodide I-131 greater than 30 microcuries.

DEEP Response to Question #7: The NRC is proposing to remove prescriptive requirements for specific numbers of classroom and laboratory training hours and work experience hours for physicians who have completed residency training in specialties where radiation safety and the clinical use of byproduct material are inherently integrated into the curriculum. This proposed rule identifies diagnostic radiology, nuclear medicine, and radiation oncology as specialties that would not need to complete these prescriptive training hours for training related to uptake, dilution, excretion, imaging, and localization studies. The NRC is seeking feedback on whether these residency programs do and would continue to include sufficient training in these areas, without the prescriptive hour requirements, as the NRC considers whether to remove or maintain the current requirements.

DEEP supports a performance-based approach to these training requirements. However, DEEP recognizes the potential risk that residency programs could reduce the amount of radiation safety and clinical training provided if the prescriptive hour requirements are removed. States will necessarily rely on the residency program's training and, ultimately, the preceptor's or residency program director's attestation that the proposed AU has received sufficient training and experience.

DEEP believes that the proposed structure in 10 CFR § 35.190(a), which identifies the specific topics that must be included in the required classroom and laboratory training, provides an appropriate safeguard. Retaining these training topics in the regulation establishes clear minimum subject areas that residency programs must address and should help ensure that the removal of prescriptive hour requirements does not result in the elimination or significant reduction of essential radiation safety training. The performance-based approach can therefore provide flexibility in how the training is delivered and demonstrated while maintaining appropriate expectations regarding the substance of the training.

Accordingly, NRC guidance should clearly establish that the preceptor or residency program director is responsible for evaluating the individual's actual knowledge, skills, and performance and ensuring that the proposed AU has received sufficient training and experience in the

regulatory topics before providing the required attestation. The attestation should represent more than completion of a residency program; it should confirm that the individual has demonstrated the competency necessary to safely and effectively perform the radiation safety-related duties associated with the requested medical use.

DEEP also recommends that the NRC consider recommendations from the Advisory Committee on the Medical Use of Isotopes (ACMUI), which was established to provide the NRC with expert insight on the medical use of byproduct material. ACMUI's expertise should be considered when evaluating whether residency programs provide sufficient training and experience under the performance-based approach and when developing associated guidance for preceptors and residency program directors.

DEEP supports the proposed transition away from rigid hour-based requirements provided that the NRC maintains the substantive training topics in 10 CFR § 35.190(a), establishes clear expectations for evaluating individual competency, and provides sufficient guidance regarding the responsibility of preceptors and residency program directors when attesting to an individual's qualifications. This approach would provide needed flexibility while maintaining reasonable assurance that physicians authorized to use byproduct material possess the knowledge and competency necessary to protect patients, workers, and the public.

DEEP Response to Question #8: In addition, the NRC is proposing to keep the current training hours requirements for physicians who completed fellowship but is considering removing these training hours requirements provided the fellowship curriculum sufficiently integrates radiation safety and the clinical use of byproduct material to ensure the physician can independently fulfill radiation safety-related duties as an AU for medical use. Thus, the NRC is seeking feedback on whether any fellowship curriculum sufficiently integrates radiation safety and the clinical use of byproduct material to ensure the physician can independently fulfill radiation safety-related duties as an AU for medical use, and on any potential considerations of including fellowship training in addition to residency training for meeting the training and experience requirements in subparts D through H of 10 CFR part 35. Please provide the basis for your response.

DEEP supports a performance-based approach that would allow qualifying fellowship training to satisfy the training and experience requirements, including the fellowship provisions in 10 CFR § 35.790(a), where the curriculum sufficiently integrates radiation safety and the clinical use of byproduct material. As discussed in DEEP's responses to Question #7, reliance on the training program and the preceptor's evaluation and attestation can provide appropriate assurance of competency while reducing unnecessary prescriptive requirements.

For the proposed training and experience requirements in 10 CFR § 35.790(a)(1), however, it is unclear whether the required three years of diagnostic radiology residency training and one year of interventional radiology training in a residency or fellowship program may be obtained concurrently, or whether these must be completed as separate and distinct training programs. DEEP therefore recommends that NRC provide clarification that this requirement can be obtained concurrently to ensure consistent implementation by licensees and Agreement States.

DEEP also recommends that NRC consider recommendations from ACMUI when evaluating fellowship curricula and developing associated guidance, consistent with DEEP's response to Question #7.

Cumulative Effects of Regulation (CER)

DEEP provides the following responses to the specific request for comments in Section XI. Cumulative Effects of Regulations of the FRN. DEEP's primary concern is the cumulative impact of the proposed changes on the National Materials Program, particularly where reductions in licensing activities may shift regulatory workload to inspections, compliance, and enforcement. DEEP believes these potential resource impacts, as well as the need for consistent implementation across the NRC and Agreement States, should be considered when evaluating the overall effects of the rulemaking.

DEEP Response to CER Question #1: The NRC is proposing an effective date that will be 30 days after the date of publication of a final rule. Does this provide sufficient time to implement the proposed requirements? Please provide a rationale for your response.

DEEP recognizes that, as an NRC Agreement State that incorporates many NRC requirements by reference, implementation of compatible regulations can often occur more efficiently than in States that must undertake extensive independent rulemaking processes. Accordingly, DEEP does not view the regulatory adoption process itself as the primary implementation challenge for Connecticut.

DEEP's primary concern is that the 30-day effective date would effectively require compliance before the necessary implementation infrastructure is in place. Successful implementation will require timely development of licensing and inspection guidance, enforcement guidance, training materials, administrative processes, and other supporting resources to ensure consistent implementation across the National Materials Program (NMP).

This need is particularly significant because the proposed rule would revise long-established radiation protection and medical-use requirements that are reflected throughout NRC regulations, guidance, NUREGs, inspection procedures, licensing review guidance, standard review plans, and training materials. Clear NRC guidance should be available before the requirements become effective to avoid inconsistent implementation by the NRC and Agreement States.

For example, consistent guidance will be particularly important for provisions that rely on performance-based determinations, such as AU training and experience, where licensees, preceptors, and regulatory authorities will need a common understanding of how competency is to be evaluated.

Accordingly, DEEP strongly recommends that the NRC establish an implementation period of at least one year, and preferably two years, between publication of the final rule and its effective date. This would provide sufficient time for the NRC to develop and issue necessary guidance, update supporting program materials, train NRC and Agreement State staff, and allow licensees and regulatory authorities to prepare for implementation. A more reasonable effective date would also reduce the risk of guidance being developed after the rule is already legally effective, which could result in inconsistent interpretation and implementation across the NMP.

DEEP Response to CER Question #2: Are there unintended consequences related to this rulemaking and how should they be addressed? Please provide a rationale for your response.

DEEP believes several potential unintended consequences could arise from the proposed rulemaking, particularly from the shift of certain licensing determinations to post-licensing inspection and the interaction of this rulemaking with other concurrent NRC materials rulemakings.

The proposed removal of certain pre-approval requirements, including the licensing of diagnostic authorized users under 10 CFR §§ 35.100 and 35.200, will shift a significant portion of the regulatory burden from the licensing space to the inspection and enforcement space. Rather than independently verifying AU qualifications during licensing, regulators will increasingly need to verify training, experience, and competency during inspections. DEEP believes this will increase inspection time and potentially result in deficiencies being identified only after an individual has begun performing medical procedures. Inadequately qualified AUs could therefore become not only a radiation safety concern, but potentially a patient-care, accreditation, or reimbursement concern.

This shift is particularly significant for Agreement States because differences in how States implement and interpret these performance-based requirements could result in inconsistent oversight across the NMP. DEEP recommends that the NRC provides clear implementation and inspection guidance establishing how AU training, experience, and competency are to be verified during inspections, particularly where those determinations are no longer subject to prior NRC or Agreement State review. As discussed in DEEP's response to CER Question #1, DEEP recommends a longer implementation period to allow the NRC to develop and issue this guidance, train NRC and Agreement State inspectors, and allow licensees sufficient time to understand and implement the new requirements. This would help ensure that the transition to post-licensing verification does not result in inconsistent oversight or place an undue burden on licensees and regulatory authorities.

DEEP also notes that replacing prescriptive requirements with references to “nationally recognized protocols” may create additional inspection and enforcement challenges. For example, elimination of specific periodic spot-check requirements for High Dose Rate (HDR) units in favor of nationally recognized protocols could require inspectors to determine which protocols apply to a particular unit, manufacturer, or model and remain current as standards and equipment evolve. While DEEP supports appropriate use of performance-based requirements, the NRC should ensure that sufficient specificity remains to allow inspectors to consistently determine compliance and support enforcement when necessary. Therefore, DEEP recommends that the NRC provide clear guidance identifying the applicable protocols and establishing how inspectors should evaluate compliance when protocols or equipment-specific standards change. This guidance should be issued before the requirements take effect and should support consistent implementation and enforcement across the NMP.

Finally, DEEP is concerned about the interaction of this rulemaking with the proposed Standard General License (SGL) framework in other concurrent materials rulemakings. In particular,

proposed 10 CFR § 35.13(b) would eliminate the requirement to obtain a license amendment before permitting individuals to work as AUs for certain 10 CFR §§ 35.100 and 35.200 uses. This appears to be related to the proposed SGL framework; however, not all AUs performing 10 CFR § 35.200 uses would fall under that framework. For example, AUs for positron emission tomography (PET) and mobile medical licensees could fall into a regulatory gray area, where they would neither be covered by the SGL framework nor required to be listed on the license. Therefore, DEEP recommends that the NRC clarify these provisions to ensure that licensees and regulators can readily determine which AUs are subject to licensing, notification, or other regulatory requirements.

More generally, DEEP recommends that the NRC evaluate these cumulative impacts across the NMP rather than considering each provision independently. The NRC should coordinate the implementation of this rulemaking with related materials rulemakings, provide clear and consistent inspection and enforcement guidance, and ensure that regulatory changes do not inadvertently shift workload and risk from licensing to inspection without adequately accounting for the resulting impacts on regulatory resources and patient and public health and safety.

DEEP Response to CER Question #3: Please comment on the NRC's cost and benefit estimates in the regulatory analysis that supports this proposed rule.

DEEP generally agrees that the NRC's regulatory analysis appropriately recognizes the potential reduction in licensing workload and associated savings for Agreement States. If anything, DEEP believes the analysis may underestimate the current effort associated with resolving incomplete or deficient licensing actions, the number of license amendment requests requiring regulatory review, and the staff time associated with follow-up of medical events and other compliance issues.

However, as discussed in DEEP's response to CER Question #2, DEEP is concerned that the analysis does not appear to fully capture the potential increase in regulatory burden resulting from shifting activities from the licensing function to inspection and enforcement. Verification of AU qualifications, training and experience, and other requirements during inspections can be significantly more resource-intensive than reviewing these matters during a licensing action. The additional inspection time, follow-up, and potential enforcement activities should therefore be more fully considered in the cost-benefit analysis.

DEEP recommends that the NRC further evaluate the net regulatory workload impact, including the potential transfer of workload from licensing to inspection and enforcement functions.

Additional DEEP Comments

In addition to its responses to the NRC's specific requests for comment, DEEP has identified several additional issues related to regulatory clarity, implementation, and consistency within the proposed amendments to 10 CFR Part 35. DEEP submits the following comments to identify areas where clarification or revision would improve the effectiveness and consistency of the proposed regulations, particularly for Agreement States and their licensees.

DEEP Comment #1 - Incorporation of emerging medical technologies (EMTs)

DEEP supports the proposed changes to incorporate established EMTs into the appropriate provisions of 10 CFR Part 35. These technologies have been regulated under 10 CFR § 35.1000 for multiple years, are well understood by users and regulators, and have well-characterized radiation risks. Doing so will provide greater clarity for licensees and regulators and promote a more consistent approach across the NMP.

DEEP also supports the proposed removal and revision of provisions for technologies that are no longer widely used or have evolved substantially, such as the proposed revisions to requirements for gamma stereotactic radiosurgery. Updating these provisions to reflect current clinical practice will reduce reliance on enforcement discretion and provide clearer expectations for compliance with newer technologies.

Overall, DEEP supports the proposed changes which reflect evolving medical technology while providing clear, risk-informed, and nationally consistent requirements for licensees and regulators.

DEEP Comment #2 – Removal of the prescriptive requirement that the Radiation Safety Committee (RSC) include a member of the nursing staff

DEEP supports the proposed clarification to 10 CFR §35.24(f) regarding applicability of the RSC requirements and supports removal of the prescriptive requirement that the RSC include a member of the nursing staff.

Nursing staff can provide valuable clinical and operational perspectives to an RSC and should remain eligible to serve when appropriate. However, DEEP recognizes that requiring a specific nursing representative can create unnecessary administrative burden for licensees, particularly given existing workload and staffing constraints within nursing organizations. The proposed change would provide licensees greater flexibility to establish an RSC with members who have the appropriate expertise and responsibilities for the scope of the medical uses being conducted.

DEEP believes this approach is consistent with the NRC's broader effort to establish more performance-based and risk-informed requirements while maintaining the RSC's fundamental oversight responsibilities. Removing the prescriptive membership requirement does not preclude nursing representation; rather, it allows the RSC and licensee to determine whether nursing representation is appropriate based on the facility's activities and organizational structure.

DEEP therefore supports the proposed clarification and removal of the mandatory nursing staff membership requirement.

DEEP Comment #3 – Extension of the temporary Radiation Safety Officer (RSO) duration to 120 days will allow additional time for licensees to hire efficiently

DEEP supports the proposed extension of the temporary RSO authorization period from 60 days to 120 days. The additional time will provide licensees with greater flexibility to identify, evaluate, and hire a qualified permanent RSO without creating unnecessary pressure to make a hiring decision within an overly compressed timeframe.

During DEEP's relatively brief experience as an NRC Agreement State, the Department has already observed challenges associated with licensees identifying and obtaining qualified RSOs within the existing timeframe. Extending the period to 120 days would provide a more practical timeframe for licensees to conduct an appropriate search, particularly for positions requiring specialized qualifications or experience.

DEEP also believes that the existing regulatory requirements applicable to temporary RSOs provide appropriate safeguards to ensure that the individual serving in this capacity is qualified to oversee the licensee's radiation protection program. The extension therefore provides additional administrative flexibility for licensees without diminishing radiation safety oversight.

DEEP supports the proposed 120-day temporary RSO period as a reasonable balance between providing licensees sufficient time to identify a permanent RSO and maintaining appropriate regulatory assurance that the radiation protection program remains under the oversight of a qualified individual.

DEEP Comment #4 – Align compatibility for breakthrough definition and reporting regulations

DEEP recommends that the NRC align the compatibility categories for the proposed definition of "breakthrough" in 10 CFR § 35.2 and the associated reporting requirement in § 35.3093. The proposed definition is identified as Category D, while the reporting requirement for exceeding breakthrough is Category C. Similarly, the proposed permissible concentrations for generator-produced radionuclides in § 35.93(d) are identified as Health and Safety (H&S).

DEEP believes these provisions should have consistent compatibility designations because they address closely related requirements and will otherwise create unnecessary differences in implementation among Agreement States. The NRC should either establish the same compatibility category for these related provisions or clearly explain the basis for assigning different categories.

DEEP Comment #5 – "Microsource" definition

DEEP recommends revising the proposed definition of "microsource" in 10 CFR § 35.2 to use the term "byproduct material" rather than "radioactive material." The scope of 10 CFR Part 35 is

specifically limited to the medical use of byproduct material. Using the broader term “radioactive material” could create ambiguity regarding the intended regulatory scope of the definition and its applicability under 10 CFR Part 35.

DEEP recommends that the NRC revise the definition to state “microspheres or microparticles containing byproduct material and dispersed...” to maintain consistency with the scope and terminology of Part 35.

DEEP Comment #6 – End-of-Day Surveys

DEEP recommends that the NRC clarify the scope of the survey requirement in 10 CFR § 35.70. The first sentence requires a licensee, in addition to the surveys required by 10 CFR Part 20, to survey with a radiation detection survey instrument at the end of each day of use. However, the second sentence specifies that the licensee must survey areas where unsealed byproduct material requiring a written directive was prepared for use or administered.

This creates ambiguity as to whether the end-of-day survey requirement in the first sentence applies to all uses of unsealed byproduct material, including uses that do not require a written directive, or whether the requirement is intended to apply only to the uses identified in the second sentence.

If the NRC’s intent is for the end-of-day survey requirement to apply to all uses of unsealed byproduct material, DEEP recommends that the first sentence be revised to state this explicitly. Clear language would avoid differing interpretations by licensees and Agreement States regarding the scope of the required surveys.

DEEP recommends that the NRC ensure the two sentences clearly establish the intended scope of the requirement and, in particular, clarify whether uses authorized under 10 CFR §§ 35.100 and 35.200 are subject to the additional end-of-day survey requirement.

DEEP Comment #7 – Agreement State Approved Procedures for Spot Checks

DEEP recommends that 10 CFR §§ 35.643(b)(2) and 35.645(a)(2) be revised to recognize manufacturer instructions accepted by an Agreement State, in addition to those accepted by the NRC. 10 CFR §§ 35.633(d) and 35.635(d) appropriately recognize both NRC- and Agreement State-approved manufacturer procedures for full calibration measurements; however, the corresponding periodic spot-check provisions reference only manufacturer instructions accepted by the NRC. The regulations should be consistent and should not imply that a licensee under Agreement State jurisdiction must obtain NRC acceptance of manufacturer instructions when the Agreement State has jurisdiction over the licensee.