

June 30, 2026

Chairman Ho K. Nieh and Fellow Commissioners
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Re: Comments of Connecticut Department of Energy and Environmental Protection on
Modernizing NRC Regulations for Byproduct Material Use

Docket ID: NRC-2025-1205

Dear Chairman Nieh:

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 Parts 30, 31, 32, 34, 39, 40, 70 and 150¹ as part of the NRC's regulatory modernization efforts under Executive Orders 14300.

The State of Connecticut (hereinafter "Connecticut" or "State") 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 Connecticut's 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. DEEP 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, 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 federal and state 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 'Modernizing NRC Regulations for Byproduct Material Use,' 91 FR 28916 (18 May 2026).

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

DEEP supports the comments submitted to the NRC by the Organization of Agreement States Board dated June 24, 2026. (Docket ID NRC-2025-1205-0015)

DEEP respectfully submits its own comments in Attachment A accompanying this letter.

DEEP's comments herein support many aspects of the NRC's efforts to modernize the materials regulatory framework, particularly those that improve regulatory clarity, eliminate unnecessary regulatory burden, and facilitate medical innovation while maintaining adequate protection of public health and safety.

However, DEEP identifies several significant concerns regarding implementation of the proposed Standard General License (SGL) framework and revisions to reciprocity requirements. In particular, DEEP believes the proposed changes could result in unintended consequences by shifting regulatory oversight from pre-licensing review to post-licensing inspection, introducing uncertainty regarding transition from specific licenses to SGLs, and reducing opportunities for prospective inspection of reciprocity activities. In addition to these concerns, DEEP supports several proposed changes, including revisions related to Positron Emission Tomography (PET) radionuclide consortia, decommissioning financial assurance requirements for accelerator-produced radionuclides, and expanded distribution pathways for microsources.

At the same time, the volume and pace of concurrent rulemakings—more than twenty (20) underway, including multiple direct final rules—present significant challenges for Agreement States and other stakeholders. This compressed timeline limits the ability of DEEP to fully evaluate complex technical changes and the potential impacts, increasing the risk that implementation challenges may not be adequately addressed, and may render it pragmatically unfeasible to implement such technical changes within the timeframe prescribed.

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 new technologies.

Given these considerations about the pace of rulemaking, 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 DEEP's comments on this particular rulemaking in Attachment A, DEEP 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,



Emma Cimino
Deputy Commissioner
Connecticut Department of Energy and Environmental Protection

ATTACHMENT A

DEEP appreciates the NRC's request for specific comments in Section V of the Federal Register Notice (FRN) on the proposed "Modernizing NRC Regulations for Byproduct Material Use."² In response to the NRC's questions, DEEP offers the following comments and recommendations. While supporting many aspects of the proposed rulemaking, DEEP identifies several significant implementation, regulatory, and Agreement State concerns that should be addressed before the rule is finalized.

Response to NRC Question #1: The NRC is seeking comments on how many persons that currently possess a specific license for portable gauge activities, fixed gauge activities, limited medical uses, analytical equipment uses, and in vitro testing would transition to a Standard General License (SGL) that is described in the changes to 10 CFR part 31 subpart C. The NRC is also seeking comments on the costs and the benefits of the new SGL. Please provide a basis for your response.

At this time, DEEP cannot determine with confidence how many Connecticut licensees would elect to transition from a specific license to the proposed SGL framework. While the population of potentially eligible licensees can be identified, the decision to transition will depend heavily on the final fee structure, inspection requirements, and associated implementation guidance, none of which are sufficiently developed in the proposed rule or supporting regulatory analysis.

More fundamentally, DEEP questions whether the proposed SGL framework addresses the underlying source of regulatory burden experienced by many materials licensees. For many low-risk license categories, the primary burden licensees have reported to DEEP is not necessarily the specific licensing process itself, but rather the associated licensing and annual fees. The NRC appears to be creating an entirely new licensing framework to address burden concerns without first evaluating whether those concerns could be more directly addressed through adjustments to the fee structure for existing specific licenses.

For example, portable gauge licensees—one of the principal categories proposed for SGL eligibility—are currently subject to a new application fee of \$7,700 under 10 CFR Part 170, Fee Category 3.P, and an annual fee of approximately \$15,600 under 10 CFR Part 171, Fee Category 3.P. For many portable gauge users, these fees represent a significant portion of the overall regulatory burden associated with maintaining a license. It is therefore unclear whether licensees are seeking relief from the licensing process itself or from the costs associated with that process.

The proposed rule states that SGLs would require the submission of a registration, fee, and certification of understanding, yet no proposed fee schedule or associated Agreement State cost analysis has been provided. Without this information, DEEP cannot meaningfully evaluate the

² "Modernizing NRC Regulations for Byproduct Material Use," 91 FR 28916 (18 May 2026).

economic incentives or disincentives associated with transitioning to an SGL, nor can it assess whether the proposed framework would result in net efficiencies for licensees or regulators.

Specifically, the absence of fee information prevents DEEP from evaluating:

- Whether SGLs would provide a lower-cost alternative relative to maintaining a specific license;
- Whether equivalent burden reduction could be achieved through targeted revisions to NRC licensing and annual fee schedules without creating a new licensing framework that properly reflects the anticipated regulatory workload for standard specific licenses;
- The potential fiscal impacts on Agreement State programs whose fee structures are based on NRC fees;
- Whether the proposed SGL framework will require equivalent or greater staff resources to verify qualifications, training, radiation safety program, and other information that are currently reviewed during licensing actions. The proposed rule does not contain detailed inspection guidance, and DEEP cannot, therefore, determine whether or how inspection efficiencies could be realized. Based on the proposed framework, DEEP anticipates that most licensing effort will simply be shifted to inspections, with the potential for increased demands depending on how licensees maintain and document required records;
- The increased enforcement workload that will result from identification of deficiencies discovered after licensed activities have commenced. Such deficiencies will be cited during inspections rather than resolved during licensing; and
- The extent to which implementation of SGLs could create new unfunded mandates for Agreement States from shifting regulatory burden while disproportionately reducing fee revenue.

The proposed SGL framework will simply shift a substantial portion of regulatory oversight from pre-licensing review to post-licensing inspection activities. Under the current specific licensing framework, DEEP reviews and verifies training, radiation safety programs, authorized uses, credentialing information, and, where appropriate, the legitimacy and qualifications of applicants before a license or license amendment is issued. This process allows errors, omissions, or deficiencies to be identified and corrected before licensed activities begin, providing reasonable assurance that only qualified individuals and organizations conduct licensed activities.

Under the proposed SGL framework, many of these determinations would instead be made by the licensee through self-certification and internal review, with regulatory verification occurring during routine inspections after licensed activities have commenced. While this approach may reduce upfront licensing burden for some applicants, it also transfers responsibility and risk to the licensee, reduces regulatory certainty, and may increase the complexity and resource demands associated with inspection activities.

Medical qualification self-certification risk

For example, under proposed 10 CFR § 31.16, entities conducting certain medical uses under an SGL would be responsible for independently determining whether Radiation Safety Officers (RSOs) and Authorized Users (AUs) satisfy applicable training and experience requirements.

Under the current specific licensing framework, these qualifications are reviewed and approved by the regulatory authority before an individual is authorized to perform licensed activities. This independent review provides an important verification function that helps ensure personnel possess the knowledge, training, and experience necessary to safely conduct licensed activities.

Under the proposed SGL framework, however, the licensee may determine that an individual is qualified to serve as the RSO without prior regulatory review. That individual, once designated as the RSO, may then be responsible for evaluating and approving the qualifications of AUs and other personnel. As a result, qualification determinations that are currently subject to independent regulatory review will instead rely upon a chain of self-certifications performed entirely within the organization. This could readily result in an individual with limited practical experience being responsible for evaluating the qualifications of others who will conduct or direct activities involving radioactive material.

Credentialing errors under such a framework may not be identified until a subsequent inspection. If a licensee incorrectly determines that an RSO or AU satisfies applicable training and experience requirements, that individual would be directing or conducting activities involving radioactive material without the qualifications necessary to ensure safe operations. In medical applications, this could affect the safe administration of radioactive material to patients. In industrial applications, it could affect the safe use of radioactive sources and increase risks to workers and the public. In either case, deficiencies would be identified only after licensed activities have occurred, thereby increasing both public health and safety risks and the likelihood of enforcement actions, which could include penalties.

The proposed framework therefore shifts the regulatory approach from one that identifies and corrects qualification deficiencies before licensed activities begin to one that may identify such deficiencies only after operations are underway. While this may reduce licensing workload, it increases the potential consequences of credentialing errors and exposes licensees to greater enforcement risk if inspectors later determine that personnel did not satisfy applicable requirements.

MQSA model

DEEP's experience implementing the FDA Mammography Quality Standards Act (MQSA) inspection program illustrates the practical implications of this approach. Verification of personnel qualifications and medical physicist credentials during inspections is substantially more resource-intensive than review during licensing because inspectors must independently reconstruct, validate, and document credentialing records in the field rather than relying on previously reviewed licensing documentation. Similar challenges are expected under the proposed SGL framework, where inspectors will be required to evaluate after-the-fact determinations that are currently reviewed and approved during the licensing process.

Reduction in oversight

DEEP is also concerned that the proposed framework may lessen regulatory oversight of categories of licensees, such as portable gauge users, that have historically accounted for a significant number of lost, abandoned, or stolen radioactive material events. Reducing pre-

licensing review and increasing reliance on self-certification will diminish opportunities to identify programmatic weaknesses before radioactive material is possessed or used.

Accordingly, while the proposed SGL framework may reduce licensing workload at the front end of the process, DEEP does not believe, based on its experience, that creation of an entirely new licensing framework is the most effective means of reducing regulatory burden. The NRC should first evaluate whether targeted modifications to licensing and annual fee structures for low-risk license categories could achieve many of the same objectives while preserving the benefits of pre-licensing review and regulatory approval. Until the impacts, implementation costs, inspection frequencies, fee structures, and Agreement State resource implications are more fully developed, DEEP cannot reliably estimate how many Connecticut licensees would elect to transition to an SGL.

Response to NRC Question #2: The NRC is seeking comments on possible impacts to small entities. The regulations in [10 CFR] § 2.810, “NRC size standards,” provide specific size standards to determine whether a licensee qualifies as a small entity in its regulatory programs.

DEEP recognizes the importance of ensuring that NRC regulations appropriately consider impacts on small entities. Connecticut's economy is heavily dependent on small businesses, which constitute the overwhelming majority of businesses operating within the state³ and serve as a critical source of employment, innovation, and economic growth. As a result, regulatory changes affecting radioactive materials licensees should be carefully evaluated to ensure that anticipated burden reductions are realized in practice and do not unintentionally create new compliance obligations, costs, or regulatory uncertainties for smaller organizations.

The NRC has not proposed or published a fee structure for Standard General Licensees. As a result, DEEP does not believe sufficient information is currently available to meaningfully assess the overall impacts of the proposed rule on small entities or determine whether the proposed SGL framework would provide a net benefit to affected licensees.

DEEP supports continued use of the NRC's established small entity standards because they provide a predictable and nationally consistent basis for regulatory administration.

Connecticut currently incorporates NRC fee regulations by reference and utilizes the size standards established in 10 CFR § 2.810 when administering its Agreement State radioactive materials program. This approach promotes consistency between NRC and Agreement State programs and provides a uniform framework for determining eligibility for reduced fees and other regulatory considerations applicable to small entities.

At the same time, definitions of "small business" vary considerably among Federal and State programs. Connecticut law employs multiple small-business definitions depending on the purpose of the program, including thresholds based on employment, annual revenue, and ownership structure. While DEEP supports continued use of the NRC's established standards for purposes of compatibility and consistency, the NRC should also consider a broad definition that

³ https://portal.ct.gov/DECD/Content/Business-Development/01_Type_of_Business/Small-Businesses

allows for some degree of flexibility and variation in recognition that affected small entities may vary substantially in their available administrative, technical, and financial resources.

In addition to the absence of fee information, DEEP is concerned that certain regulatory responsibilities currently performed during licensing reviews may be shifted to licensees under the proposed SGL framework. Smaller organizations often have limited regulatory and technical staff available to interpret requirements, evaluate training and experience qualifications, maintain compliance programs, and document regulatory determinations.

Under the current specific licensing framework, many compliance issues are identified and resolved during the licensing review process before licensed activities begin. Under the proposed SGL framework, licensees may bear greater responsibility for independently determining compliance with regulatory requirements, including qualification and authorization determinations that are currently reviewed by the regulatory authority. While this approach may reduce some licensing activities, it may also reduce regulatory certainty and increase the potential for inadvertent noncompliance, corrective actions, and enforcement exposure if deficiencies are identified during subsequent inspections.

DEEP is also concerned that some costs may be shifted rather than eliminated. For example, reductions in licensing review may be offset by increased internal compliance efforts, recordkeeping, training evaluations, consultant support, preparation for inspections, and corrective actions associated with post-implementation compliance verification. Because these costs have not been quantified, it is difficult to determine whether the proposed framework would produce a net reduction in burden for small entities.

Accordingly, DEEP recommends that the NRC defer conclusions regarding impacts to small entities until a complete fee structure and supporting cost analysis are available. DEEP further recommends that the NRC supplement its small entity analysis with a more detailed evaluation of:

- The expected compliance costs associated with self-implementation of SGL requirements;
- The resources required for small entities to evaluate training, qualification, and programmatic requirements without prior regulatory review;
- Potential enforcement and corrective-action costs arising from post-implementation compliance verification;
- The potential for increased inspection burden associated with verification of determinations that are currently reviewed during licensing actions; and
- The extent to which reduced licensing costs are offset by increased compliance management responsibilities.

Such an evaluation would provide a more complete understanding of the actual impacts of the proposed rule on small entities and would better inform both NRC and Agreement State implementation decisions.

Response to NRC Question #3: The NRC is seeking comments on all event reporting and notification requirements in 10 CFR parts 30–34, 39, 40, and 150 related to the burden, content, and required timeframe associated with each report or notification. Please provide a basis for your response.

DEEP recognizes that the NRC's request encompasses a broad range of reporting and notification requirements across multiple parts of the regulations, each of which serves a different regulatory purpose and addresses different types of radiological, operational, security, and environmental events. As a result, the burden, content, and appropriate reporting timeframe associated with any particular notification requirement will vary significantly depending on the nature and potential consequences of the event being reported.

DEEP agrees that event reporting requirements should be closely tied to an underlying regulatory purpose: providing timely information regarding events, equipment failures, vulnerabilities, or conditions that may represent a threat to public health and safety, occupational safety, security, or the environment. Event reports also serve an important role in identifying emerging operational trends, equipment reliability issues, and potential generic concerns that may warrant broader regulatory attention.

The principal value of reporting and notification requirements is not limited to the evaluation of individual events. Timely reports provide regulators with information that can be used to identify recurring equipment failures, common-cause vulnerabilities, operational weaknesses, or other industry-wide concerns. This information may support the development of generic communications, information notices, inspection focus areas, or other actions that improve safety across the National Materials Program.

DEEP generally supports the use of risk-informed principles when evaluating reporting requirements. However, care should be taken to ensure that efforts to reduce reporting burden do not inadvertently eliminate information that may be valuable for identifying broader safety, reliability, or performance trends. Events that may not present immediate safety consequences can nevertheless provide important operating experience information when evaluated collectively.

DEEP also encourages the NRC to improve regulatory clarity by incorporating key implementation criteria directly into the regulations whenever practical rather than relying on guidance documents or case-by-case interpretation communications. For example, NRC Information Notice 2023-02 clarified that a fixed gauge shutter stuck in the closed (safe) position is not reportable under 10 CFR § 30.50(b)(2) because it continues to perform its intended safety function and does not prevent re-shielding of the source. While DEEP supports this interpretation, the need for a national generic communication to explain the reporting threshold demonstrates that the regulation could be drafted more clearly, reducing ambiguity and promoting a more consistent implementation across the National Materials Program.

At the same time, DEEP recognizes that the circumstances surrounding equipment failures can vary significantly depending on device design, operating environment, accessibility of the source, and other site-specific factors. Consistent with concerns raised by Agreement States, DEEP believes there is value in maintaining reporting requirements for events involving failures

of safety-significant equipment, including fixed gauge shutters stuck in the open position, to ensure regulators have sufficient information to evaluate whether additional corrective actions, inspections, or generic communications may be warranted. Such reporting also supports identification of recurring equipment reliability issues and long-term performance trends across the National Materials Program.

More broadly, DEEP encourages the NRC to review event reporting requirements using a risk-informed framework that distinguishes between:

- Events requiring immediate notification because they present actual or potential significant safety consequences;
- Events warranting delayed written reporting because they provide valuable operating experience or trend information but do not present immediate safety concerns; and
- Events of sufficiently low safety significance that provide little regulatory value.

In conducting such a review, DEEP recommends that the NRC focus on ensuring that reporting requirements maintain a clear nexus to public health and safety, security, environmental protection, and operating experience objectives, while also providing licensees and regulators with clear, predictable, and readily understandable reporting criteria. Where recurring questions regarding reportability have been resolved through Information Notices, Regulatory Issue Summaries, or other guidance documents, the NRC should consider whether corresponding clarifications should be incorporated directly into the regulations to improve transparency and consistency of implementation.

Should the NRC pursue revisions to reporting requirements, DEEP recommends that the regulations continue to emphasize the licensee's responsibility to take immediate corrective action whenever a loss of control or equipment failure creates a potential health or environmental hazard. Similar to § 19-24-11(b)(3) of the Regulations of Connecticut State Agencies, DEEP recommends consideration of language requiring that, in the event of loss of control of a radiation source or a safety-significant equipment failure due to mechanical malfunction or other accidental cause, the licensee shall take immediate actions necessary to prevent or limit any resulting hazard to workers, the public, or the environment. Such a provision would help ensure that any future modifications to reporting requirements reaffirm a licensee's fundamental responsibility to promptly identify, control, and mitigate unsafe conditions.

Accordingly, and to summarize the above recommendations, DEEP recommends that any modifications to reporting requirements be supported by a clear demonstration that the information proposed for elimination is not necessary for effective regulatory oversight, operating experience evaluation, trend analysis, or protection of public health and safety. In the absence of such a demonstration, DEEP believes existing reporting requirements should be retained.

Cumulative Effects of Regulation (CER)

DEEP provides the following responses to the specific request for comments in “Section IX. Cumulative Effects of Regulations” of the FRN:

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 Agreement State that incorporates many NRC requirements by reference, regulatory adoption 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 associated with this rulemaking.

Rather, DEEP's primary implementation concerns relate to the supporting infrastructure, guidance, and administrative processes necessary to ensure consistent implementation across the National Materials Program. While the regulatory requirements themselves may become effective within 30 days, successful implementation will depend on the timely development of licensing guidance, inspection procedures, training materials, administrative processes, and other supporting resources necessary to ensure consistent oversight by both the NRC and Agreement States.

In particular, DEEP believes successful implementation will depend upon:

- Finalization of licensing guidance and inspection procedures;
- Development of training materials for NRC and Agreement State licensing and inspection staff;
- Establishment of appropriate licensing fee structures, program codes, and administrative processes;
- Development of clear procedures for transitioning existing licensees from specific licenses to SGLs;
- Clarification of inspection, enforcement, and compliance expectations under the SGL framework; and
- Coordination of future guidance updates associated with related materials rulemakings.

Transition from Specific Licenses to SGLs

DEEP notes that one of the most significant implementation issues not fully addressed in the proposed rule is the process by which existing specific licensees would transition to an SGL. Current NRC regulations and licensing guidance contain established processes for issuing, amending, renewing, and terminating licenses. However, DEEP is not aware of comparable guidance describing how a licensee converts from a specific license to an SGL.

In practice, a licensee that chooses to transition to the new SGL framework is not merely terminating a license and ceasing licensed activities; rather, the licensee is transitioning from one regulatory framework to another while maintaining possession and use of licensed material. Without a clearly defined process, Agreement States are likely to develop differing approaches regarding the treatment of existing license conditions, commitments, authorizations, inspection

histories, and administrative closure actions. These differing approaches would result in inconsistencies and a resulting in lack of regulatory reliability and predictability across the National Materials Program.

DEEP therefore recommends that the NRC develop standardized guidance describing the conversion process before implementation of the final rule. Such guidance should address how existing license conditions and commitments are evaluated, transferred, modified, or otherwise incorporated into the SGL framework, as well as the documentation and regulatory actions necessary to formally complete the conversion.

Effective Date and Compatibility Period

Consistent with the concerns raised by the OAS, DEEP believes that effective implementation should be tied to the availability of clear NRC guidance and an appropriate transition period for Agreement States. Guidance addressing license conversion processes, inspection expectations, administrative implementation, and related operational issues should be available prior to the effective date of the final rule.

In addition, DEEP recommends that Agreement States be afforded the standard three-year compatibility period to adopt and implement any compatible requirements associated with this rulemaking. Sufficient transition time is necessary to develop state procedures, update administrative systems, train staff, and ensure consistent implementation across the National Materials Program.

Accordingly, and to summarize the above comments, DEEP recommends that the NRC either issue the necessary implementation guidance concurrently with the final rule or provide an implementation schedule that allows adequate time for guidance development, dissemination, and Agreement State adoption activities.

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 that several potential unintended consequences could arise from the proposed rulemaking, including those associated with implementation of the SGL framework, modifications to reciprocity provisions, and the interaction of this rulemaking with several concurrent NRC materials rulemakings.

DEEP also believes that the cumulative impacts of these changes should be evaluated in the broader context of the National Materials Program. The proposed rulemaking includes significant modifications to licensing, oversight, inspection, and reciprocity provisions that individually appear manageable, but which will create implementation challenges when considered collectively.

Shift from Pre-Licensing Review to Post-Licensing Inspection

As discussed in DEEP's response to NRC Question #1, the proposed SGL framework represents a major shift in regulatory oversight from pre-licensing review and approval to licensee self-certification and post-implementation inspection. DEEP is concerned that this shift will create

unintended consequences by reducing regulatory certainty, increasing inspection burden, transferring greater responsibility and risk to licensees, and increasing the likelihood that credentialing, training, radiation safety program, or qualification deficiencies will not be identified until after licensed activities have commenced.

DEEP is particularly concerned that, under the proposed framework, qualification determinations that are currently independently reviewed and approved by regulatory authorities will instead rely upon internal self-certification processes. In medical applications, errors involving RSO or AU qualifications would have implications not only for patient safety and radiological protection, but also for professional licensure, accreditation status, reimbursement eligibility, and oversight by other regulatory or accrediting organizations. In industrial applications, improperly qualified personnel would increase risks to workers, members of the public, or the environment.

DEEP also notes that verification of training, experience, and credentialing requirements during inspections is generally more resource-intensive than review during licensing actions. As discussed in DEEP's response to Question #1, the proposed framework will shift, and likely increase, regulatory workload from licensing functions to inspection and compliance activities without a corresponding reduction in overall regulatory effort.

Accordingly, DEEP recommends that the NRC more fully evaluate the implications of replacing pre-approval review with post-implementation compliance verification, including impacts on public health and safety, enforcement exposure, inspection resources, regulatory certainty, and overall effectiveness of the National Materials Program.

Concurrent Rulemaking

DEEP believes that a primary potential unintended consequence of the proposed rule arises from its interaction with several concurrent NRC materials rulemakings, including revisions to 10 CFR Parts 20, 30, 31, 35, 37, and related regulatory initiatives. While each rulemaking addresses distinct elements of the NRC regulatory framework, many of the provisions are closely interrelated in practice, particularly with respect to radiation protection standards, licensing processes, security requirements, decommissioning obligations, financial assurance, inspection programs, and waste management.

Because these rulemakings are proceeding on parallel schedules, there is a risk that individual regulatory changes will be developed or implemented without sufficient integration across the broader materials program framework. This would result in unintended inconsistencies, duplicative or overlapping requirements, and uncertainty regarding how revised provisions are intended to function together. For example, modifications to licensing or oversight requirements in one rulemaking may have downstream implications for compliance expectations, inspection practices, or implementation assumptions embedded in other parts of the regulatory system. Likewise, revisions in radiation protection, security, decommissioning, or financial assurance requirements may have broader cross-cutting effects not fully addressed within a single rulemaking package.

DEEP therefore recommends that the NRC strengthen coordination across related rulemakings through structured integration of regulatory and guidance development, alignment of

implementation schedules, and clear communication regarding how overlapping requirements are intended to operate within the National Materials Program. DEEP further recommends that the NRC consider providing appropriate spacing between finalization and implementation of interrelated rulemakings to allow Agreement States, licensees, and other stakeholders sufficient time to evaluate, implement, and integrate each set of changes before additional interconnected requirements take effect.

Reciprocity Notification Timeframe (10 CFR § 150.20(b)(1))

DEEP also notes a specific unintended consequence associated with the proposed revision to 10 CFR § 150.20(b)(1), which would reduce the advance notification period for initial reciprocity filings from three days to same-day submission and eliminate the current provisions allowing shortened submittals for emergent circumstances.

Under the existing framework and NRC Inspection Manual Chapter 2800⁴, reciprocity oversight is implemented through a risk-informed, performance-based approach that relies on timely submission of NRC Form 241 or Agreement State equivalent form to support prospective evaluation of whether a reciprocity inspection should be conducted. This framework depends on both NRC and Agreement State inspectors applying a shared risk-informed methodology, considering factors such as risk significance, inspection priority, duration of work, and licensee performance history. The reciprocity model described in IMC 2800 depends not only on risk characterization but also on sufficient lead time to evaluate incoming submissions, assess inspection priorities, and coordinate field deployment. This includes logistical feasibility considerations such as travel to temporary job sites and, where appropriate, the ability to conduct announced inspections of higher-risk activities in progress.

Reducing the notification period to same-day submission would significantly constrain the ability of both NRC regional offices and Agreement State inspection programs to apply this framework in practice. In many cases, work will commence before the regulator has sufficient opportunity to review reciprocity notifications, evaluate risk factors, and determine whether inspection resources should be deployed. This is particularly relevant for activities initiated during off-hours, weekends, or at geographically dispersed temporary job sites.

As a result, the proposed change would effectively diminish the ability of both NRC and Agreement State programs to make prospective, risk-informed inspection determinations, shifting oversight toward a more retrospective awareness model. This shift will reduce the ability to observe higher-risk, non-routine activities—such as source exchanges or maintenance on high-activity irradiators—while they are in progress, which is a key objective of the current reciprocity inspection approach.

Importantly, the compressed notification timeframe would also create a circumstance in which licensees may be able to utilize same-day submissions in a manner that effectively precludes meaningful opportunity for either NRC or Agreement State inspectors to deploy to temporary job sites, whether intentionally or as a practical consequence of scheduling flexibility. In such cases, the timing of submission relative to the initiation of work would have the unintended effect of

⁴ <https://www.nrc.gov/docs/ML2310/ML23102A025.pdf>

limiting or avoiding the possibility of contemporaneous inspection oversight, despite the activity occurring under reciprocity.

Additionally, the elimination of the existing provisions allowing shortened-notice submissions for emergent circumstances removes a structured regulatory mechanism that currently helps distinguish between legitimate emergent work and routine last-minute planning. Replacing this mechanism with universal same-day submission does not enhance regulatory clarity and reduces the ability of both NRC and Agreement State programs to assess whether expedited work is justified or whether inspection resources should be allocated.

DEEP therefore believes that, absent sufficient lead time for review and coordination, the proposed revision would unintentionally limit the effectiveness of the reciprocity inspection program and reduce alignment with the NRC's stated risk-informed and performance-based inspection philosophy. This proposed change would likely necessitate revisions to NRC Inspection Manual Chapter 2800 and corresponding Agreement State coordination practices to acknowledge that reciprocity inspections will no longer be feasible in a prospective manner for a subset of activities. This represents a substantive shift away from the current shared risk-informed, performance-based oversight model that relies on timely notification to support both NRC and Agreement State inspection decision-making.

Transition from Specific Licenses to Standard General Licenses

As discussed in DEEP's response to CER Question #1, the proposed rule does not fully address the administrative and regulatory process for transitioning an existing specific license to an SGL. While NRC regulations and guidance provide established mechanisms for issuance, amendment, renewal, and termination of specific licenses, a comparable framework for conversion to an SGL is not currently defined.

In practice, conversion to an SGL would not constitute a simple termination of licensed activities, but rather a transition from one regulatory structure to another while maintaining possession and use of radioactive material. Absent a clearly defined process, there is a potential for inconsistent implementation among Agreement States regarding the treatment of existing license conditions, commitments, and authorizations.

DEEP recommends that the NRC develop standardized guidance describing the conversion process. Such guidance should, at a minimum, address:

- a. A standardized mechanism for requesting conversion or registration under an SGL, including explicit identification of applicable inspection and oversight provisions;
- b. A regulatory review process to determine whether existing license conditions require preservation through alternative enforceable mechanisms; and
- c. A defined process for administrative closure of the specific license following confirmation that all applicable regulatory obligations have been transferred or otherwise satisfied under the SGL framework.

A uniform conversion process would enhance regulatory consistency, reduce implementation uncertainty, and support efficient administration across the National Materials Program.

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 believes the NRC’s regulatory analysis may not fully capture the actual costs associated with implementing this rulemaking, particularly for Agreement State programs responsible for administering compatible regulatory requirements.

The underlying 2025 data identified Connecticut as a non-Agreement State. However, Connecticut became an Agreement State effective September 30, 2025, resulting in the transfer of approximately 101 radioactive materials licenses from NRC jurisdiction to DEEP. According to the *Annual Count of Active Radioactive Material Licenses in the National Materials Program (STC-26-005)*⁵ published in January 2026, there were 15,081 Agreement State licenses and 1,969 NRC licenses. These figures are notably different from those cited in the regulatory analysis supporting this rulemaking. As a result, the current Agreement State license population is larger and the NRC license population smaller than reflected in the analysis. Because estimates of implementation costs, burden reduction, transition rates, and regulatory impacts are dependent upon the number and distribution of affected licensees, this fundamental error raises questions regarding the quantitative assumptions and conclusions used to support the rulemaking.

While the analysis identifies potential reductions in licensing workload associated with the proposed SGL framework, DEEP believes additional consideration should be given to implementation costs, inspection resource requirements, administrative system changes, and other downstream impacts that may offset some of the anticipated efficiencies.

Specifically, the analysis should address:

- The development and implementation of SGL fee categories, program codes, and associated administrative systems;
- State regulatory costs associated with transitioning existing specific licensees to SGLs;
- Development of guidance, procedures, forms, and administrative processes necessary to support implementation;
- Staff training needs for NRC and Agreement State licensing, inspection, and administrative personnel;
- Increased inspection resource demands associated with verification of qualifications, training, compliance determinations, and other activities that are currently reviewed during the licensing process;
- Potential increases in enforcement, compliance assistance, and corrective-action activities resulting from greater reliance on self-certification and post-implementation verification; and,
- The potential fiscal impacts on Agreement State programs whose fee structures and resource allocations are currently based on specific licensing activities.

Because the NRC has not yet established an SGL fee structure, neither licensees nor Agreement States have sufficient information to fully evaluate the economic incentives associated with

⁵ <https://scp.nrc.gov/asletters/program/sp26005.pdf>

transitioning from a specific license to an SGL or to determine whether the anticipated burden reductions will result in net cost savings.

In addition, the proposed framework will shift regulatory effort rather than eliminate it. Activities currently performed during pre-licensing review—including evaluation of qualifications, training and experience requirements, authorized uses, and other compliance determinations—will instead be performed during inspections after licensed activities have commenced. While this may reduce licensing actions, it will increase inspection complexity, inspection duration, and associated resource requirements.

DEEP therefore recommends that the NRC supplement its regulatory analysis with a more comprehensive evaluation of Agreement State implementation costs, inspection resource impacts, training needs, administrative system modifications, and transition costs associated with converting existing licensees to the SGL framework. DEEP further recommends that the NRC develop proposed SGL fee structures and incorporate those costs into the final regulatory analysis before reaching conclusions regarding the overall costs and benefits of the rulemaking.

DEEP supports several provisions of the proposed rule that appropriately modernize the NRC's regulatory framework through risk-informed and performance-based approaches. These revisions eliminate unnecessary regulatory barriers, improve regulatory clarity, support medical innovation, and facilitate the safe use of byproduct material for important medical, research, and industrial applications while maintaining adequate protection of public health and safety. DEEP therefore submits the following comments in support of these specific changes.

DEEP Comment #1 - Proposed Revision to the Definition of "Consortium" in 10 CFR § 30.4

DEEP supports the NRC's proposed revision to the definition of "consortium" in 10 CFR § 30.4 and agrees with the removal of the requirement that participating medical use licensees and Positron Emission Tomography (PET) radionuclide production facilities be located within the same geographical area.

DEEP agrees with the NRC's conclusion that the existing geographic limitation lacks a clear safety basis and may unnecessarily restrict collaborative arrangements for the production and distribution of PET radionuclides used in medical diagnosis, research, and patient care. The original geographic limitation appears to have been driven primarily by practical supply-chain considerations associated with the short half-lives of PET radionuclides rather than by radiological safety concerns. Because all transfers of radioactive material would remain subject to applicable NRC and Department of Transportation requirements, DEEP does not believe the geographic location of consortium members, by itself, presents a safety concern warranting regulatory restriction.

Advances in radiopharmaceutical development, transportation logistics, and radionuclide production have expanded the range of PET isotopes available for medical use, including radionuclides with longer half-lives than those commonly available when the original provision was adopted. As a result, the existing geographic limitation may unnecessarily constrain efficient and innovative production and distribution arrangements without providing a corresponding safety benefit.

The proposed change is particularly important for supporting medical innovation, clinical research, and radiopharmaceutical development in Connecticut. Access to PET radionuclides has become a limiting factor for some research programs and smaller medical or academic users that lack the resources or demand necessary to support dedicated radionuclide production capabilities. In some instances, limited commercial availability, production schedules, transportation constraints, or economic considerations have restricted access to PET radionuclides needed for research and development activities.

By allowing greater flexibility in the formation of consortium arrangements, the proposed revision will improve access to PET radionuclides for smaller research institutions, academic medical centers, and emerging radiopharmaceutical development programs. This flexibility will help facilitate collaborative research efforts, support clinical trials involving novel radiopharmaceuticals, and promote the development of new diagnostic and therapeutic applications that ultimately benefit patients.

DEEP also agrees that removal of the phrase "same geographical area" improves regulatory clarity. The term is not clearly defined and may lead to inconsistent interpretations regarding when consortium relief applies. Eliminating this ambiguity will provide greater regulatory certainty for licensees while reducing the potential for inconsistent implementation among NRC regions and Agreement States.

Finally, DEEP believes that the short half-lives of many PET radionuclides continue to serve as a practical and economic limitation on distribution distance. For many PET radionuclides, transportation time directly affects product usability and economic viability, creating a natural market-driven constraint on distribution without the need for an additional regulatory geographic restriction. As a result, DEEP believes the proposed revision appropriately removes an unnecessary regulatory barrier while preserving all existing safety, security, transportation, and radiation protection requirements applicable to the production and transfer of PET radionuclides.

Accordingly, DEEP supports the proposed revision to the definition of "consortium" and believes the change will improve regulatory clarity, reduce unnecessary barriers to collaboration, and enhance access to PET radionuclides for medical, academic, and research institutions without adversely affecting public health and safety.

DEEP Comment #2 - Proposed Revisions to Appendix B to 10 CFR Part 30 and Related Decommissioning Financial Assurance Requirements

DEEP supports the NRC's proposed revisions to Appendix B to 10 CFR Part 30 and related changes to decommissioning financial assurance (DFA) requirements. DEEP believes these changes appropriately modernize the regulatory framework, align financial assurance requirements more closely with actual decommissioning risk, and eliminate unnecessary regulatory burdens that have hindered the use and development of important medical and industrial radionuclides.

In particular, DEEP supports the NRC's proposal to incorporate radionuclide-specific values from Appendix C to 10 CFR Part 20 for radionuclides that are currently absent from Appendix B to 10 CFR Part 30. This change addresses a long-standing concern identified by the Organization of Agreement States (OAS), Agreement State programs, medical licensees, and the Advisory Committee on the Medical Uses of Isotopes (ACMUI).

DEEP agrees that reliance on the current default values in Appendix B has, in certain cases, resulted in decommissioning financial assurance requirements that are not commensurate with the actual radiological risk presented by the radionuclides involved. The most notable example involves germanium-68/gallium-68 generator systems. For many years, the application of default Appendix B values to Ge-68 has created unnecessarily restrictive DFA requirements that have required exemptions, increased regulatory burden, and complicated access to emerging diagnostic technologies utilizing Ga-68.

DEEP believes the proposed rule appropriately resolves a regulatory issue that has persisted since the NRC assumed authority over accelerator-produced radioactive material under the Energy Policy Act of 2005. The NRC's continued reliance on default values for radionuclides not specifically listed in Appendix B has created regulatory obstacles that were never intended to

reflect the actual decommissioning risks associated with these materials. By establishing radionuclide-specific values through rulemaking, the NRC provides a more stable, predictable, and transparent regulatory framework for licensees and regulators alike.

DEEP supports the NRC's proposal to remove radionuclides with half-lives of 120 days or less from Appendix B and to clarify in 10 CFR § 70.25 that decommissioning financial assurance calculations apply to unsealed special nuclear material with half-lives greater than 120 days. These changes appropriately recognize that short-lived radionuclides generally decay to negligible levels before significant decommissioning activities would be required and therefore do not warrant the same financial assurance considerations as longer-lived materials.

DEEP also supports the proposed revision to the title of Appendix B. The current title, "Quantities of Licensed Material Requiring Labeling," does not accurately reflect the appendix's regulatory purpose. Because Appendix B is used to determine decommissioning financial assurance thresholds rather than labeling requirements, renaming the appendix to "Quantities of Licensed Material Used to Assess Financial Assurance for Decommissioning" improves regulatory clarity and will help prevent confusion among applicants, licensees, and regulators.

Finally, DEEP encourages the NRC to periodically review and update Appendix B as new radionuclides, radiopharmaceuticals, production technologies, and industrial applications emerge. The history of Ge-68/Ga-68 generators demonstrates how regulatory frameworks can inadvertently create barriers to innovation when radionuclide-specific values do not keep pace with technological advancement. As novel medical isotopes, theranostic agents, accelerator-produced radionuclides, and other emerging applications continue to be developed, DEEP recommends that the NRC establish a mechanism for timely review of radionuclides not specifically addressed in Appendix B.

DEEP further recommends that the NRC consider establishing a streamlined process through which applicants, licensees, Agreement States, or other stakeholders may request NRC review of radionuclides not specifically listed in Appendix B where application of default values would produce DFA requirements that are not commensurate with actual decommissioning risk. Such a process could include authority for the NRC to approve alternative radionuclide-specific values or grant exemptions where appropriate while longer-term rulemaking solutions are considered. This would help ensure that future innovations are not delayed by unintended regulatory barriers similar to those experienced with Ge-68/Ga-68 generator technologies.

Accordingly, DEEP supports the proposed revisions to Appendix B to 10 CFR Part 30, the related changes to decommissioning financial assurance requirements, and the clarification of the appendix's purpose. DEEP believes these changes appropriately reduce unnecessary regulatory burden, improve consistency between NRC regulations, support medical innovation, and maintain adequate protection of public health and safety.

DEEP Comment #3 - Proposed Changes Expanding Distribution Pathways for Microsources

DEEP supports the proposed revisions to 10 CFR §§ 32.72 and 32.74. The changes improve regulatory clarity, reduce unnecessary regulatory burden, and provide additional flexibility for

the preparation and distribution of radioactive microsources while maintaining appropriate health and safety protections.

DEEP also supports the flexibility provided by allowing multiple licensing pathways for microsource distribution. This approach recognizes the evolving nature of nuclear medicine and radiopharmaceutical practice and helps ensure that regulatory requirements do not unnecessarily constrain patient access to emerging diagnostic and therapeutic technologies.

Accordingly, DEEP supports the proposed amendments and believes they will improve regulatory clarity, promote consistency, and support continued innovation in nuclear medicine while maintaining adequate protection of public health and safety.