

September 10, 2026

Subject: Breakthrough Institute Comment on Reducing Barriers to Medical Use Licensing [Docket ID NRC-2025-1237; RIN 3150-AL50].

The Breakthrough Institute (BTI) appreciates the opportunity to comment on the Nuclear Regulatory Commission's proposed rule, *Reducing Barriers to Medical Use Licensing* (Docket ID NRC-2025-1237, RIN 3150-AL50), published at 91 Fed. Reg. 47042 (July 27, 2026).¹ BTI is an independent 501(c)(3) research organization that advocates for appropriate regulation and oversight of nuclear reactors and radioactive materials to enable the new and continued use of safe and clean nuclear energy. BTI acts in the public interest and does not receive funding from industry.

BTI has participated in the related rulemakings the NRC is promulgating in response to Executive Order 14300,² including its comment on the modernization of the byproduct material framework and its concurrent comment on the NRC's proposed reforms to the radiation protection framework in 10 CFR part 20.^{3,4} BTI supports the NRC's effort to reduce administrative barriers to medical use licensing while preserving the risk-informed, performance-based aspects of the existing framework, and several of the proposed changes should be finalized as drafted. The recommendations below concern a smaller set of issues where the final rule's administrability, documentation basis, and consistency with related rulemakings would benefit from clarification.⁵ This comment addresses practitioner eligibility and supervision, medical event and embryo/fetus reporting, decay-in-storage verification methodology, and cross-rulemaking coordination.

Several of the recommendations below could be addressed through the final rule preamble, the interim frequently-asked-questions guidance issued alongside this proposed rule, or the

¹ Nuclear Regulatory Commission, *Reducing Barriers to Medical Use Licensing*, Proposed Rule, 91 Fed. Reg. 47042 (July 27, 2026) (Docket ID NRC-2025-1237; RIN 3150-AL50) (hereinafter Proposed Rule).

² Executive Order No. 14300, *Ordering the Reform of the Nuclear Regulatory Commission*, 90 Fed. Reg. 22587 (May 29, 2025).

³ PJ Seel, The Breakthrough Institute, *Comment on Modernizing NRC Regulations for Byproduct Material Use*, Comment ID NRC-2025-1205-0019, June 29, 2026 (hereinafter Byproduct Comment).

⁴ PJ Seel and Adam Stein, The Breakthrough Institute, *Comment on Reforming and Modernizing the NRC's Radiation Protection Framework*, Comment ID NRC-2025-1140-2078, Aug. 31, 2026 (hereinafter RP Framework Comment).

⁵ NRC, *Public Meeting on Proposed Rule: Reducing Barriers to Medical Use Licensing*, Docket ID NRC-2025-1237 (Aug. 20, 2026) (hereinafter Public Meeting).

forthcoming update to NUREG-1556, Volume 9, rather than through regulatory text. Where BTI recommends a guidance clarification, the NRC should preserve the relevant performance expectation in the final rule record.

I. SUMMARY OF RECOMMENDATIONS

1. **Address practitioner eligibility and supervision together.** Reconsider the Compatibility Category D designation for the § 35.2 physician definition and the Category C designation for § 35.11(b) authorized-user physical presence in light of the rule's own anti-competitive-barriers rationale, and pair any change to § 35.11(b) with a performance-based description of adequate supervision under § 35.27, including which categories of non-authorized-user personnel may administer byproduct material under a written directive. Given the NRC's new mission statement, explain why the NRC did not consider additional authorized-user eligibility criteria alongside the § 35.11(b) compatibility change.
2. **Preserve a documented basis for reporting exclusions.** Require licensees to document the basis for invoking the emergent-patient-condition exclusion under § 35.3045(a) and the pregnancy reasonable-effort exclusion under § 35.3047(a)(2) in an inspectable record, without reinstating the reporting obligation the proposed rule removes.
3. **Address isotopic verification alongside the decay-in-storage half-life ceiling.** Specify that decay-in-storage release determinations under § 35.92 account for isotopic composition rather than gross count rate alone, and clarify whether and how decay-in-storage-eligible waste generated at mobile or satellite locations may be consolidated at a primary storage facility.
4. **Coordinate this rulemaking with the concurrent Part 35 amendments in Docket NRC-2025-1140.** State in the final rule how the two rulemakings' non-overlapping amendments to Part 35 will be reconciled, and confirm that the § 32.72/74 distributor-population question BTI raised in the byproduct material rulemaking applies to the new microsource sourcing requirement in § 35.700.

This comment focuses on the specific requests for comment where BTI can add regulatory-design and documentation value. It does not address the clinically specific requests (Specific Requests for Comment 1, 3, and 6 through 8), which are better answered by practicing authorized users,

medical physicists, and specialty societies, several of whom raised related questions directly at the NRC's public meeting on this docket.

II. PRACTITIONER ELIGIBILITY AND SUPERVISION

The NRC should treat the § 35.2 physician definition, the compatibility category for § 35.11(b), and the scope of adequate supervision under § 35.27 as one coordinated eligibility question.

Addressed separately, each risks reproducing the jurisdictional inconsistency that the rule's anti-competitive-barriers rationale is meant to eliminate.

The § 35.2 Physician Definition and Its Compatibility Category

The NRC should either elevate the compatibility category of the § 35.2 physician definition or explain in the final rule why Category D is consistent with removing barriers to market participation under Executive Order 14267.

The proposed rule removes the requirement that a physician hold an MD or DO degree, tying authorized-user eligibility instead to state licensure to prescribe drugs in the practice of medicine.⁶ It is the only professional-eligibility term the rule amends; the authorized-user categories (physician, dentist, and podiatrist) are unchanged, and the rule does not extend eligibility to other licensed practitioners. The NRC identifies this definition as an anti-competitive barrier under Executive Order 14267, finding that it “creates a barrier to market participation by limiting the pool of eligible employees.”⁷

The Adequacy and Compatibility Table lists the § 35.2 physician definition as Compatibility Category D both before and after the amendment.⁸ An Agreement State may therefore retain its existing MD/DO-only definition without falling out of compliance. A category that permits non-adoption reproduces the same jurisdictional patchwork the amendment is designed to eliminate: a foreign-trained physician who qualifies as an authorized user in one jurisdiction may not qualify in an adjoining Agreement State that has not updated its own regulation.

⁶ Proposed Rule, 91 Fed. Reg. at 47047.

⁷ Proposed Rule, 91 Fed. Reg. at 47076.

⁸ Proposed Rule, 91 Fed. Reg. at 47078 (Adequacy and Compatibility Table, § 35.2 row).

The same gap appears in the byproduct material rulemaking, where a provision establishing a national eligibility or licensing baseline was left in a compatibility category that permits non-adoption by default; BTI has recommended aligning the category there with the degree of uniformity the underlying policy requires.⁹ That reasoning applies here with more force, because the FRN itself identifies the anti-competitive rationale for the change.

Physical Presence Under § 35.11(b)

BTI recommends Category B for § 35.11(b), paired with the performance-based supervision standard below, so a national compatibility category does not on its own leave open-ended discretion over what adequate supervision requires.

The NRC is separately requesting comment on whether § 35.11(b), which the agency has clarified does not require an authorized user's physical presence for supervision of certain tasks, should move from Compatibility Category C to Category B.¹⁰ The same anti-competitive-barriers rationale that supports elevating the § 35.2 physician definition supports Category B here, consistent with the request the NRC itself is soliciting, and industry stakeholders have raised the same transboundary-network and rural-access concerns motivating that change.¹¹

A compatibility change would not resolve a concern raised at the NRC's August 20, 2026 public meeting on this docket. A commenter from Johns Hopkins Hospital, speaking on behalf of the American Association of Physicists in Medicine, asked whether the NRC would define a proximity or capacity limit on supervision, noting that an authorized user could otherwise nominally supervise procedures at a large number of geographically dispersed sites.¹² NRC staff confirmed that Part 35 has never imposed a physical-presence requirement for authorized users supervising radiopharmaceutical administrations—only for high-dose-rate afterloaders, teletherapy, and gamma stereotactic radiosurgery units under § 35.600—and that adequate supervision under § 35.27 may be discharged through presence, written procedures, trained staff, or Radiation Safety Officer availability, at the licensee's discretion.¹³

⁹ Byproduct Comment, § II.

¹⁰ Proposed Rule, 91 Fed. Reg. at 47058 (Specific Request for Comment 2).

¹¹ Proposed Rule, 91 Fed. Reg. at 47058.

¹² Public Meeting (remarks of a commenter from Johns Hopkins Hospital speaking on behalf of the American Association of Physicists in Medicine).

¹³ Public Meeting (remarks of Katie Tapp, NRC Office of Nuclear Material Safety and Safeguards).

Adequate Supervision Under § 35.27

Section 35.27 should articulate (in regulatory text or in guidance) which categories of non-authorized-user personnel may administer byproduct material under a written directive, and a functional standard for adequate supervisory capacity.

Part 35 does not identify which professional categories, apart from authorized users, may administer byproduct material under an authorized user's supervision and written directive. Section 35.27 requires only that the supervising authorized user instruct the individual performing the task and retain responsibility for adequate supervision.¹⁴ At the same public meeting, a commenter representing a radiopharmaceutical manufacturer described the consequence of that silence: multi-state licensees are adopting conservative interpretations that limit administration to authorized users and nuclear medicine technologists, reducing the number of practitioners who can administer therapies and reducing patient access, particularly in the underserved and rural settings the proposed rule is otherwise intended to reach.¹⁵ NRC staff acknowledged the concern and pointed to draft frequently-asked-questions guidance issued alongside the proposed rule, inviting a comment identifying the clarification needed.¹⁶

A performance-based standard, that is naming who may administer under a written directive and stating a functional capacity requirement, would resolve both concerns without a rigid proximity rule.

Regulatory Analysis on Expanding Authorized User Eligibility

The final rule should explain why authorized user eligibility was not evaluated for the same access-driven flexibility the rule already extends to physical presence under § 35.11(b).

The ADVANCE Act requires that licensing and regulation of the civilian use of radioactive materials and nuclear energy "be conducted in a manner that is efficient and does not unnecessarily limit... the benefits of civilian use of radioactive materials and nuclear energy technology to society." The NRC's resulting mission statement commits the agency to "enabling the safe and secure use and deployment of civilian nuclear energy technologies and radioactive

¹⁴ Proposed Rule, 91 Fed. Reg. at 47084 (§ 35.27).

¹⁵ Public Meeting (remarks of Tom Boyki, Novartis).

¹⁶ Public Meeting (remarks of Katie Tapp, NRC Office of Nuclear Material Safety and Safeguards).

materials through efficient and reliable licensing, oversight, and regulation for the benefit of society."¹⁷

The rule already applies exactly this reasoning once as the NRC's justification for reconsidering § 35.11(b)'s physical-presence requirement is that it limits access to treatments in rural areas. That same logic was available to address the authorized-user eligibility question directly but was not addressed in this rulemaking. If the NRC declines to evaluate a Category D pathway allowing Agreement States to define additional authorized-user eligibility criteria under specified training and supervision conditions, the final rule should state why the § 35.11(b) access rationale does not apply with equal force to authorized-user eligibility itself. BTI supports that this decision be left to individual states on how to address scope-of-practice, but the NRC should not unduly impose a barrier upon such consideration. There are many studies in this contentious area, but one indicative study across 18 randomized trials found that nurse-led primary care "probably leads to similar or better patient health and higher patient satisfaction" than doctor-led care, and "may lead to slightly fewer deaths among certain groups of patients" (low-to-moderate certainty evidence).¹⁸ With appropriate stakeholder input, the NRC should be able to make a decision that includes which options might lead to the greatest benefit to society, without lessening public health and safety.

Recommendations

Affected Provision	Recommendation
§ 35.2 (Physician Definition)	Elevate the compatibility category of the § 35.2 physician definition, or explain in the final rule why Category D is consistent with removing barriers to market participation under Executive Order 14267.
§ 35.11(b)	Move § 35.11(b) to Compatibility Category B, paired with the performance-based supervision standard in § 35.27, so a national compatibility category does not leave open-ended discretion over adequate supervision.

¹⁷ Nuclear Regulatory Commission, *About the ADVANCE Act* (mission statement adopted Jan. 2025), <https://www.nrc.gov/about-nrc/governing-laws/advance-act/about-advance-act>.

¹⁸ Miranda Laurant et al., "Nurses as Substitutes for Doctors in Primary Care," *Cochrane Database of Systematic Reviews* 2018, Issue 7, Art. No. CD001271, <https://doi.org/10.1002/14651858.CD001271.pub3>.

Affected Provision	Recommendation
§ 35.27	Articulate, in § 35.27 or cross-referenced guidance, (i) which categories of non-authorized-user personnel may administer byproduct material under a written directive, and (ii) a functional standard for adequate supervisory capacity.
§ 35.2 (Authorized User Definition); § 35.11(b); Preamble; Regulatory Analysis	State why the § 35.11(b) access rationale does not apply with equal force to authorized-user eligibility, and evaluate a Category D pathway allowing Agreement States to define additional eligibility criteria under specified training and supervision conditions.

III. MEDICAL EVENT AND EMBRYO/FETUS REPORTING: DOCUMENTATION AND INSPECTION BASIS

The NRC should require licensees to document the basis for invoking the new medical-event and embryo/fetus reporting exclusions in an inspectable record, distinct from and without reinstating the reporting obligation the proposed rule removes.

The proposed rule excludes from medical event reporting an event that results from an “emergent patient condition,” a new term the rule defines as an unexpected development or acute change in a patient's condition causing a deviation from the planned administration.¹⁹ The exclusion does not apply if the deviation would cause unintended permanent functional damage, as determined by a physician.²⁰ The rule separately adds a reporting exclusion for embryo/fetus dose where the licensee made a reasonable effort to determine pregnancy status but could not reasonably exclude it before administration.²¹ Both exclusions remove a reporting obligation, but neither is paired with a requirement that the licensee document, at the time of the event, the basis on which the exclusion was invoked.

That gap matters more here than it would for a simple deregulatory deletion, because both exclusions (together with the new § 35.3045(a)(3) threshold for leaks or device defects) depend on

¹⁹ Proposed Rule, 91 Fed. Reg. at 47056, 47083.

²⁰ Proposed Rule, 91 Fed. Reg. at 47099 (§ 35.3045(a)—(b)).

²¹ Proposed Rule, 91 Fed. Reg. at 47056, 47100 (§ 35.3047(a)(2)).

the licensee's own causal characterization of what happened, rather than a determinate dose trigger.²² A documented basis might be the only way for a treating authorized user or Radiation Safety Officer conducting internal quality assurance, or an NRC or Agreement State inspector conducting a later review, to verify that an exclusion was properly invoked rather than accepted after the fact.²³

A structurally identical issue arises in the byproduct material rulemaking,²⁴ and the same separation applies here: removing the reporting obligation is a reasonable burden reduction, but the underlying record of why the exclusion applied should not disappear along with it. A documentation requirement imposes materially less burden than the reporting obligation.

Recommendations

Affected Provision	Recommendation
§ 35.3045(a); § 35.3047(a)(2)	Require licensees to document, in an inspectable record, the basis for invoking the emergent-patient-condition and pregnancy reasonable-effort exclusions—including the deviation, the physician's permanent-damage determination where applicable, and the pregnancy-status assessment steps—without reinstating the reporting obligation itself.

IV. DECAY-IN-STORAGE: VERIFICATION METHODOLOGY AND SITE LOGISTICS

The NRC should specify that decay-in-storage release determinations under § 35.92 account for isotopic composition rather than gross count rate alone, and should clarify how decay-in-storage-eligible waste generated away from a licensee's primary facility may be consolidated for the extended hold period.

²² Proposed Rule, 91 Fed. Reg. at 47056 (§ 35.3045(a)(3)).

²³ Proposed Rule, 91 Fed. Reg. at 47059 (Specific Request for Comment 6).

²⁴ The NRC is eliminating a real-time reporting obligation for abandoned downhole sources in the byproduct proposed rule. BTI has recommended preserving the accounting function there through a lower-burden, after-the-fact record rather than eliminating it outright; Byproduct Comment, § III.

Isotopic Composition and Decay-in-Storage Verification

The proposed rule increases the physical half-life eligible for decay-in-storage from 120 to 275 days, principally to accommodate lutetium-177 metastable (Lu-177m) and cobalt-57 flood sources.²⁵ Section 35.92 requires a licensee to confirm that stored waste has become indistinguishable from background before disposing of it without regard to its radioactivity;²⁶ the rule does not specify how that determination should be made for a waste stream that may carry a longer-lived isotopic impurity alongside the clinically dominant, shorter-lived isotope.

The amendment's own target isotope illustrates the problem: reactor-produced Lu-177 ($T_{1/2} = 6.65$ days) can carry Lu-177m ($T_{1/2} \approx 160$ days) as a co-produced isomeric impurity when produced by direct irradiation of Lu-176.²⁷ A licensee relying on gross count rate cannot distinguish a batch in which the Lu-177 has decayed from one still holding a detectable Lu-177m residual, and most clinical users have no basis to know which production route supplied a given lot. NRC staff have confirmed that isotopic impurities associated with Yttrium-90 microspheres have been observed extending multiple years past the current 120-day threshold, and that impurities associated with materials in clinical trials are known to extend similarly.²⁸ Staff also noted that licensees have appropriate space to handle the waste streams they wish to have decay-in-storage as part of the provisions. This is a necessary and sensible limitation, but consideration should be given to whether a production batch were to have an impurity issue, which might not become apparent until the end of the decay period, and bursts of treatments, which can happen spontaneously in clinical care. These are resolvable issues, but the NRC and licensees should be aware and have contingencies in place for such scenarios.

The environmental assessment finds no significant effect from the amendment on the premise that § 35.92 requires storage until its radioactivity cannot be distinguished from background.²⁹ The same gap bears on the rule's cost basis: the regulatory analysis projects \$584,800 in annual

²⁵ Proposed Rule, 91 Fed. Reg. at 47043, 47046, 47089 (§ 35.92(a)).

²⁶ Proposed Rule, 91 Fed. Reg. at 47046.

²⁷ Philip E. Harris and Konstantin Zhernosekov, "The Evolution of PRRT for the Treatment of Neuroendocrine Tumors; What Comes Next?," *Frontiers in Endocrinology* 13 (2022): 941832, <https://doi.org/10.3389/fendo.2022.941832>.

²⁸ Public Meeting (remarks of Katie Tapp, NRC Office of Nuclear Material Safety and Safeguards, responding to a question from PJ Seel, The Breakthrough Institute).

²⁹ Proposed Rule, 91 Fed. Reg. at 47074 (Table 28, Basis for No Significant Environmental Effects Determination for Rule Amendments Not Covered by a Categorical Exclusion).

disposal-cost savings from the amendment on the assumption that decay-in-storage releases proceed on the schedule the extended ceiling contemplates.³⁰ BTI supports this as a reasonable cost estimate, and that the expansion of decay-in-storage to licensees is an effective burden reduction without many environmental concerns. These factors are primarily logistical, but forethought on the NRC's part prevents issues that licensees could bear the cost of.

Consolidation of Decay-in-Storage Waste From Satellite Sites

Section 35.92 assumes storage in place at the facility where the material was used. The proposed rule simultaneously removes several prescriptive requirements for mobile medical services,³¹ increasing the likelihood that a licensee will generate decay-in-storage-eligible waste at a satellite infusion site or mobile operation without dedicated storage capacity and will need to consolidate that waste at a primary facility for the extended hold period. Waste transported before it reaches background is a shipment of radioactive material subject to Part 71 and Department of Transportation requirements.³² The proposed rule does not address whether cross-site consolidation is contemplated. The final rule should clarify whether decay-in-storage-eligible waste generated at a mobile or satellite location may be consolidated at a licensee's primary storage facility, and if so, the transport framework that applies to material that has not yet decayed to background at the time of consolidation. Transportation regulations are clear, but guidance should provide straightforward information for licensees.

Recommendations

Affected Provision	Recommendation
§ 35.92 and Guidance	Specify in guidance that a decay-in-storage release determination account for isotopic composition (through survey methodology or by accounting for the production route's impurity fraction, for example) rather than gross count rate alone.
§ 35.92; Part 71	Clarify whether decay-in-storage-eligible waste generated at a mobile or satellite location may be consolidated at a primary storage facility.

³⁰ Proposed Rule, 91 Fed. Reg. at 47068 (Table 15, Averted Costs from Low Level Waste Shipments).

³¹ Proposed Rule, 91 Fed. Reg. at 47057 (§ 35.80 discussion).

³² 10 C.F.R. pt. 71; 49 C.F.R. pts. 171–178.

V. CROSS-RULEMAKING COORDINATION

This proposed rule should be understood as one component of a broader NRC effort to revise the medical use framework under Executive Order 14300, and should not be finalized as though its Part 35 amendments can be cleanly separated from the concurrent radiation protection framework rulemaking or from BTI's related recommendations on the byproduct material rule.³³ Four areas of coordination across dockets directly impact this final rule.

First, this proposed rule and the NRC's concurrent proposal in Docket NRC-2025-1140 amend non-overlapping provisions of Part 35: this rule addresses training, emerging medical technologies, generators, event reporting, and decay-in-storage, while the radiation protection framework rulemaking addresses patient release and caregiver dose under § 35.75 and breastfeeding recordkeeping under § 35.2075.³⁴ The final rule should state how the two dockets' amendments will be reconciled into a single, consolidated regulatory text, consistent with the approach BTI has recommended for the overlapping Part 61, Part 57, and § 35.75 amendments in its comment on the radiation protection framework docket.³⁵ NRC staff indicated at the public meeting that the update to NUREG-1556, Volume 9 is being held until the concurrent Part 35 rulemakings finalize for the same reason; BTI supports that sequencing and recommends the final rule commit to a schedule for the guidance update.³⁶ That update should also state how the existing ALARA-based framing of medical licensees' occupational and public dose management will be conformed to the graded-approach terminology the companion docket proposes, distinct from patient dose optimization, which the Medical Use Policy Statement governs independently of Part 20.

Second, Section 35.76 would let a licensee house patients who received different types of administrations in the same room, provided the arrangement satisfies Part 20 dose limits. BTI's radiation protection framework comment raised concerns about the interaction between the administration regimen concept and § 35.76 but deferred to this docket.³⁷ The caregiver dose allowances proposed in the companion docket, § 20.1301(c)(1)(ii) and § 35.75(b)(1), are each scoped

³³ Byproduct Comment, § V; RP Framework Comment.

³⁴ RP Framework Comment (discussing § 35.75 patient release, caregiver dose, and § 35.2075 breastfeeding recordkeeping).

³⁵ RP Framework Comment (discussing reconciliation of concurrent amendments to Part 61, Part 57, and § 35.75).

³⁶ Public Meeting (remarks of Katie Tapp, NRC Office of Nuclear Material Safety and Safeguards).

³⁷ RP Framework Comment, § X.

per administration regimen; the final rule should state whether and how that scoping applies where § 35.76 gives a caregiver access to a room housing more than one regimen at once, and confirm that § 35.76's co-housing flexibility was evaluated against the combined caregiver dose such an arrangement could produce. Separately, BTI's comment on the radiation protection rule identified the pre-release and post-release caregiver allowances as expressly decoupled, potentially combining to 70 mSv across a single regimen without a stated basis.³⁸ The final rule for this docket should confirm that the basis the companion docket adopts for the combined figure governs § 35.75(b)(1) as § 35.75(b)(1) is the Part 35 half of that pairing.

Third, new § 35.700 requires that microsources be obtained from a manufacturer or preparer licensed under § 32.72 or § 32.74.³⁹ The byproduct material rulemaking expanded § 32.72 and § 32.74 distribution eligibility to include microsources without describing the population of distributors that expansion would newly authorize.⁴⁰ That gap impacts this rule directly because § 35.700's sourcing requirement depends on the same distributor population. The final rule for this docket should confirm that the byproduct material rulemaking's distributor characterization will be completed, and that it will be sufficient to support § 35.700 as finalized.

Fourth, the byproduct material rulemaking's revised consortium definition authorizes noncommercial transfers of positron emission tomography (PET) radionuclides under § 30.32(j) without a separate § 32.72 distribution license.⁴¹ This docket does not address whether an entity participating in the medical-use framework, such as a consortium production facility supplying a microsource user under new subpart I, could rely on the same consortium exception rather than the § 32.72/74 distributor pathway the § 35.700 sourcing requirement otherwise assumes. The final rule should state whether the consortium exception is available for material used under Part 35 and, if so, how it interacts with the distributor characterization discussed above.

³⁸ RP Framework Comment, § V (discussing the § 20.1301(c)(1)(ii) and § 35.75(b)(1) caregiver dose allowances).

³⁹ Proposed Rule, 91 Fed. Reg. at 47097 (§ 35.700).

⁴⁰ Byproduct Comment, § IV.

⁴¹ Byproduct Comment, § V (identifying the § 30.32(j) consortium exception's interaction with § 32.72 distribution licensing as a boundary the Part 35 medical use rulemaking may also affect).

Recommendations

Affected Provision	Recommendation
§ 35.76; § 20.1301(c)(1)(ii); § 35.75(b)(1)	State whether the per-regimen caregiver dose allowance applies per-room or per-patient once § 35.76 permits co-housing patients from different administration regimens, confirm § 35.76 was evaluated against the combined caregiver dose such co-housing could produce, and confirm that § 35.75(b)(1) is governed by whatever basis the companion docket adopts for the combined pre/post-release caregiver dose figure.
§ 35.700; NRC-2025-1140	State how the Part 35 amendments in this docket and in Docket NRC-2025-1140 will be reconciled, commit to a schedule for the NUREG-1556, Volume 9 update, and confirm the § 32.72/74 distributor-population characterization supports the § 35.700 microsource sourcing requirement.
§ 30.32(j); § 32.72; § 32.74; § 35.700	State whether the § 30.32(j) consortium exception for noncommercial transfers is available for material used under Part 35, and if so, how it interacts with the § 32.72/74 distributor characterization requested above.

VI. CONCLUSION

BTI supports the NRC's effort to reduce administrative barriers to medical use licensing while preserving the risk-informed, performance-based character of the existing framework. The recommendations above address a common thread running through several of the rule's provisions: the rule removes prescriptive requirements and reporting obligations on the premise that a national, uniform standard will apply in their place, but several of the replacement standards are not yet defined precisely enough to guarantee that uniformity. The points highlighted in this comment leave room for outcomes to vary by state, by licensee, and by production batch. Closing those gaps in the final rule would let the rule's administrative burden reductions operate as designed without reintroducing the jurisdictional and practice-level inconsistency the rule is meant to eliminate.

BTI appreciates the opportunity to comment and welcomes further engagement with NRC staff on the issues raised in this letter.

Sincerely,

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