

August 31, 2026

Subject: Breakthrough Institute Comment on Reforming and Modernizing the NRC's Radiation Protection Framework [Docket ID NRC-2025-1140; RIN 3150-AL47].

The Breakthrough Institute (BTI) appreciates the opportunity to comment on the Nuclear Regulatory Commission's (NRC) proposed rule, *Reforming and Modernizing the NRC's Radiation Protection Framework*.¹ BTI is an independent 501(c)(3) global research center 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.

The NRC is proposing to reform its radiation protection standards in response to Section 5(b) of Executive Order 14300, which directed the NRC to reconsider its reliance on the linear no-threshold (LNT) model and on the "as low as reasonably achievable" (ALARA) standard, and to specifically consider adopting determinate radiation limits.² The *Accelerating Deployment of Versatile, Advanced Nuclear for Clean Energy* (ADVANCE) Act supplies independent statutory grounds for the reconsideration.³

BTI supports the direction of the proposed rule. BTI has been engaged extensively on this topic and has commented on two related rulemakings.⁴ BTI has also published analysis of the interagency questions this rulemaking raises under the Clean Air Act (CAA).⁵ Notably, the NRC has issued three draft regulatory guides for comment alongside the rule, but the operative content of the new framework resides largely in the phase-two guidance that will not be published until

¹ *Reforming and Modernizing the NRC's Radiation Protection Framework*, 91 Fed. Reg. 43456 (proposed July 15, 2026) (Docket No. NRC-2025-1140, RIN 3150-AL47).

² Executive Order No. 14300, *Ordering the Reform of the Nuclear Regulatory Commission*, § 5(b), 90 Fed. Reg. 22587 (May 29, 2025).

³ Accelerating Deployment of Versatile, Advanced Nuclear for Clean Energy Act of 2024, Pub. L. No. 118-67, (Hereinafter ADVANCE Act) § 501.

⁴ Breakthrough Institute, Comment on Regulatory Improvements for Microreactors, Docket No. NRC-2025-0379, May 2026 (Hereinafter BTI, Part 57 Comment); Breakthrough Institute, Comment on Modernizing Requirements for Byproduct Material, Docket No. NRC-2025-1205, June 2026.

⁵ PJ Seel, The Breakthrough Institute, *Why Modernization of the Nuclear Regulatory Commission's Radiation Protection Framework Requires Coordination Across Federal Law*, August 7, 2026, <https://thebreakthrough.org/issues/nuclear-energy-innovation/why-modernization-of-the-nuclear-regulatory-commissions-radiation-protection-framework-requires-coordination-across-federal-law>, (Hereinafter Seel, Coordination Across Federal Law).

after this comment period closes, which significantly limits the impact of public comment on the provisions that will decide how the framework actually operates.

The recommendations below rest on the *Atomic Energy Act* (AEA), the CAA, and the ADVANCE Act, and are intended to strengthen the rule's legal durability, administrability, and coordination with related rulemakings. This comment addresses the codification of the three principles of radiological protection, a de minimis dose criterion, international alignment, the affected population and proposed flexibilities, the graded approach and the role of cost, the effluent constraint at § 20.1101(d), coordination with the Environmental Protection Agency (EPA), and cross-rule, Agreement State, and implementing-guidance questions.

I. SUMMARY OF RECOMMENDATIONS

1. **Codify justification, optimization, and limitation in § 20.1101.** Adopt the three principles as the framework the graded approach implements, including an express justification gate, state that the principles impose no obligation independent of the requirements of Subpart C and the graded approach, and state in the final rule where cost operates relative to the adequate-protection determination.
2. **Codify a de minimis annual dose criterion in § 20.1101.** Establish the criterion on individual-agency and non-distinguishability grounds with stated boundary conditions. Section IV sets out three levels the NRC could adopt and identifies what each requires of the interagency record. A codified criterion is also what bounds the monetized test the implementing guidance would apply, which is otherwise linear to zero. The final rule should also state why a determinate lower bound on the optimization obligation was not separately considered.
3. **State the objective the graded approach serves and the variable it grades against.** Resolve whether the graded approach is the optimization mechanism or compliance-assurance, and state the consequence for the international-alignment finding. State what bounds the obligation below the thresholds, including on the occupational side, and whether compliance through ALARA practice remains acceptable indefinitely.
4. **Bound each proposed flexibility.** Establish a numerical ceiling in § 20.1301(d), publish criteria for the § 20.1301(b) controlled-area determination, and justify or remove the five-year lookback in the unplanned-exposure assessment, and require documented worker consent for the planned occupational dose limit extension in § 20.1205.

5. **Ensure the § 20.1101(d) regulatory text and eventual guidance matches the explanation given in the preamble.** State plainly whether the provision requires a licensee to fix the problem or only to evaluate whether a fix is worthwhile, explain where the 25 mrem/yr number comes from, and explain why a mandatory fix is necessary given the reporting and recordkeeping obligations already in place.
6. **Commit to substantive joint work with the EPA.** Address the open dose and risk questions on a stated schedule, through the rulemaking that section 112(d)(9) requires rather than a concurrence letter. Address Section II.D of Appendix I, which this rule leaves unamended, and state whether an applicant electing Section VI still owes that analysis.
7. **State alignment with the international system as a specific benefit.** Add ICRP Publication 158 to the Appendix H incorporations, address units, and address the exemption and clearance provisions of GSR Part 3.
8. **Sequence the remaining implementing guidance ahead of implementation.** Preserve Agreement State stringency by retaining Category C for § 20.1101(d), reconcile the overlapping amendments to Part 61, Part 57, and § 35.75, conform the surviving ALARA references in Appendix I to the discontinuation of the term, and extend the patient release framework to veterinary use through the definitions in § 20.1003.

II. JUSTIFICATION, OPTIMIZATION, AND LIMITATION IN § 20.1101

The proposed rule describes optimization, justification, and limitation as the three guideposts of the NRC's radiation protection framework, but does not codify anything beyond numerical limits themselves. The preamble assigns optimization to the graded approach and other precautionary requirements; justification to the governing statutes, regulations, and licensing process; and limitation to the dose limits in Subpart C.⁶ BTI supports explicit inclusion of these terms in the rule text in § 20.1101, rather than only in the preamble.⁷

The proposed graded approach to dose management should be implemented closer to optimization. The proposed rule defines "graded approach" as: "Graded approach to dose management means an approach whereby progressively increasing radiation protection measures are required as prospective, or actual, radiation doses exceed determinate thresholds to provide reasonable assurance that the applicable regulatory limit is not exceeded." The

⁶ 91 Fed. Reg. at 43465; *Id.* at 43465; *Id.* at 43493.

⁷ *Id.* at 43463.

International Commission on Radiological Protection (ICRP) definition of “optimisation of protection” is: “the likelihood of incurring exposure, the number of people exposed and the magnitude of their individual doses should all be kept as low as reasonably achievable taking into account economic and societal factors. In medical imaging optimisation of protection implies lowest dose for the clinical purpose.” The NRC’s definition for the graded approach, partially fills the removal of ALARA, but then in rule text, does not establish determinate limits or protective action criteria beyond dosimetry and the singular 25 mrem cost-limit. The NRC does not need to adopt ICRP’s exact definition considering the deviations that the U.S. takes on many regulatory decisions. BTI recommends the following definition: “Optimization means the process by which a licensee, having satisfied the applicable justification and dose limits, selects protective measures under the graded approach to dose management so that individual dose is reduced below the applicable regulatory limit to the extent achievable through those measures.”

Justification should be codified and expanded upon in the final rule. The proposed rule explains that NRC-authorized activities are justified through the AEA, NRC regulations, and the licensing process because those activities serve the general welfare. That explains why the NRC may authorize a practice, but it does not fully explain how justification should inform the requirements imposed on that practice. The ADVANCE Act now directs the NRC not only to protect public health and safety, but also to avoid unnecessarily limiting the benefits of nuclear energy to society.⁸ Codifying justification would give that obligation a clear place within the radiation protection framework.

That principle should remain a responsibility of the NRC rather than becoming a new case-by-case burden on licensees. GSR Part 3 similarly places responsibility for determining whether practices are justified on the government or regulatory body.⁹ A licensee that complies with the applicable NRC requirements should not have to independently reestablish the net benefit of the licensed activity or justify individual protective measures. The main measure is that justification can be a tool for exposure assessment without being an official gate, giving licensees a cohesive vocabulary across uses of radioactive materials and one that is internationally recognizable.

⁸ ADVANCE Act, § 501.

⁹ International Atomic Energy Agency, *Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards*, IAEA Safety Standards Series No. GSR Part 3 (2014), Requirement 8, para. 3.10, and Schedule I, paras. I.1–I.2 (Hereinafter GSR Part 3).

Guidance should also address how justification and optimization interrelate within the graded approach, rather than treating justification as a gateway for further action.. The two operate together: justification establishes why an activity or exposure exists, and that basis continues to inform how much optimization effort is warranted at each dose gradation, not merely whether the activity may proceed at all.

A medical exposure is justified by the patient's diagnosis or treatment, but a justified exposure can still be optimized for a lower dose which does not reduce clinical outcomes. A public dose may be justified because some release is impractical or undesirable to eliminate entirely, but the resulting dose may be subject to optimization. A worker's dose is justified by the necessity of the work performed and worker's voluntary participation, but optimization remains sensible within the operational and cost constraints that work allows and in the worker's best interests. In each case justification does not end the inquiry, but rather supplies the basis the graded approach needs for the space between its thresholds, where the applicable degree of optimization effort is otherwise undefined. This treatment is consistent with the ICRP's system, in which justification and optimization operate as distinct, coexisting principles rather than sequential steps, though NRC guidance need not adopt ICRP's terms by name to apply the same structure to its own thresholds.

Section 20.1101 should codify justification, optimization, and limitation as the organizing principles of the radiation protection framework while making it clear that those principles are implemented through the requirements of Subpart C and the graded approach. The rule should also state expressly that the principles create no independent obligation beyond the requirements established by the regulations. This preserves their role in explaining and applying the framework without creating a new basis for open-ended enforcement. By codifying these provisions, and preventing open-ended interpretations using a graded approach, the NRC can create a unifying set of principles that the regulations are based on. The numeric limits are essential for compliance, but having codified principles can make determinations on the margins and appropriate action more straightforward for licensees and keeps the ever-evolving core terms of the international system of radiation protection grounded to the specifics of U.S. implementation. The NRC can remove the historical conservatism of ALARA, while bounding the modern term of optimization, create clear actionable terms and limits without defining new uncertain terms.

Recommendations

Affected Provision	Recommendation
§ 20.1003 (Definitions) and § 20.1101	Define justification in § 20.1003 as the NRC's determination (made under authority from the AEA, NRC regulations, and the licensing process) that a licensed practice serves the general welfare, including the societal benefit of the activity consistent with the ADVANCE Act. State in § 20.1101 that licensed activities satisfy justification by virtue of that determination having already been made.
§ 20.1003 (Definitions)	Define optimization as: "the process by which a licensee, having satisfied the applicable justification and dose limits, selects protective measures under the graded approach to dose management so that individual dose is reduced below the applicable regulatory limit to the extent achievable through those measures." State in § 20.1101 that the graded approach implements this obligation.
§ 20.1003 (Definitions)	Define limitation as the dose limits established throughout 10 CFR Part 20.
§ 20.1101	State expressly that the justification, optimization, and limitation framework creates no obligation independent of the requirements already established by Subpart C and the graded approach.
Guidance	State that justification and optimization operate together rather than sequentially: a justified activity remains subject to optimization per the approach, and justification's basis for an exposure informs how much optimization effort is warranted at each gradation between the graded approach's thresholds.

III. ALIGNMENT WITH THE INTERNATIONAL SYSTEM OF RADIOLOGICAL PROTECTION

The proposed rule relies on international radiation protection standards in several important respects, including its conclusion that the graded approach satisfies the optimization requirement in IAEA GSR Part 3. BTI supports greater alignment with the international system where it can improve regulatory consistency without compromising the NRC's statutory

responsibilities. The final rule should state that objective directly and identify material areas where the NRC has chosen to diverge. Greater transparency on alignment would also allow the NRC to distinguish departures based on genuine scientific or regulatory differences from differences that simply impose an additional framework on entities operating across jurisdictions.

The NRC proposes to allow applicants and licensees to use updated dosimetry methodologies, including methods based on ICRP Publication 103, but the proposed list does not include ICRP Publication 158. Publication 158 is the first part of a series replacing the Publication 56 series and updating data from Publication 119, so it should be added rather than substituted for publications already proposed for inclusion.¹⁰ Its implementation of the Publication 103 tissue weighting factors engages the additivity rules in proposed § 20.1004(e), governing whether quantities determined under different dosimetry methods may be summed. The final rule should formalize official adoption of SI units for dose, exposure, and radioactive material quantities with an appropriate implementation timeline, to reduce the burden of dual unit reporting, and one of the most straightforward fixes to reduce friction with the international community.

The exemption and clearance question is the more consequential omission. The rule invokes Requirement 11 of GSR Part 3 to establish that the graded approach satisfies the optimization requirement. The same instrument pairs optimization with Requirement 8, which directs the government or regulatory body to determine which practices or sources are exempted or may be cleared from regulatory control, supplying criteria in Schedule I: risks sufficiently low as not to warrant regulatory control, or regulatory control yielding no net benefit, with an effective dose of the order of 10 μ Sv or less in a year sufficient for exemption without further consideration.¹¹ Adopting the optimization half of the instrument while declining the exemption half is partial alignment, and the final rule should address the omission on the record. This is the route into Section IV.

¹⁰ International Commission on Radiological Protection, *Dose Coefficients for Intakes of Radionuclides by Members of the Public: Part 1*, ICRP Publication 158, Ann. ICRP 53 (4-5) (July 2024), <https://doi.org/10.1177/01466453241248329>. The Appendix H list proposed at 91 Fed. Reg. at 43498–99 does not include it. On the tissue weighting factors, see International Commission on Radiological Protection, *The 2007 Recommendations of the International Commission on Radiological Protection*, ICRP Publication 103, Ann. ICRP 37 (2-4) (2007); the NRC describes the corresponding occupational recommendation at 91 Fed. Reg. at 43459.

¹¹ GSR Part 3, Requirement 8, paras. 3.10–3.12, and Schedule I, paras. I.1–I.2.

The occupational structure BTI has previously recommended, a five- year average limit of 20 mSv with a single-year ceiling of 50 mSv, is the structure of ICRP Publication 103, so adopting it would advance the alignment objective rather than depart from it.¹²

Recommendations

Affected Provision	Recommendation
Appendix H	Add ICRP Publication 158 to the approved methodologies and establish a process for considering subsequent publications in the series.
§ 20.1004	Formal adoption of SI units for dose, activity, and quantities of radioactive materials.
Preamble	State alignment with the international system of radiological protection as an objective of the rule and explain material departures from international standards, including the treatment of exemption and clearance.
Regulatory Analysis	Evaluate, as best as possible, what the costs of deviations from international standards might cost to companies that wish to export or otherwise be considered, in international markets.

IV. DETERMINATE THRESHOLDS AND A DE MINIMIS DOSE CRITERION

The NRC correctly identifies the absence of a reasonable stopping point as a principal defect in the current implementation of ALARA, and the proposed rule appropriately uses determinate thresholds to reduce subjectivity about when additional radiation protection measures are required. The proposed framework does not apply that same logic to the point at which the obligation to further reduce dose should end. When considering determinate limits for stochastic effects, the NRC asks whether the scientific evidence can establish a biological threshold below which stochastic health effects do not occur. Because no such threshold has been established, the NRC declines to adopt determinate limits for stochastic effects.

¹² International Commission on Radiological Protection, *The 2007 Recommendations of the International Commission on Radiological Protection*, ICRP Publication 103, Ann. ICRP 37 (2-4) (2007). The NRC describes the corresponding occupational recommendation at 91 Fed. Reg. at 43459.

BTI believes that the analysis asks the wrong question. A biological threshold and a regulatory lower bound serve different purposes. A biological threshold would establish a dose below which stochastic effects do not occur. A de minimis regulatory criterion would instead establish a dose below which any residual risk is sufficiently small that further dose-reduction requirements are not warranted. The NRC does not need to conclude that risk is zero to establish such a boundary.

The NRC should codify a de minimis annual dose criterion in § 20.1101, with stated boundary conditions. The NRC approached this with its 25 mrem cost-limit but did not pursue a full limit, despite that being the primary flaw with the implementation of ALARA. The NRC should address this as the fundamental reason for applying a graded approach, and should use the most effective remedy to the problem of unbounded dose reduction. BTI's recommendation differs from proposals elsewhere on this docket through asking the NRC to make a regulatory judgment about when residual risk has become too small to justify a continuing obligation to reduce dose.

A Determinate Floor Refused on the Wrong Test

The NRC's analysis treats the absence of a scientifically established no-effect threshold as a reason not to establish a determinate boundary for stochastic effects.¹³ That reasoning makes biological certainty a prerequisite for deciding when additional regulation is no longer warranted. Scientific evidence informs the magnitude and uncertainty of radiation risk, but the point at which a residual risk becomes too small to justify further regulatory intervention is ultimately a regulatory judgment.

The NRC has already stated the premise a de minimis criterion rests on. The preamble explains that there is a difference between eliminating all risks and recognizing when a risk exists but is extremely small, or even within the margin of error that includes zero risk, and that further risk reduction is not reasonable. That is precisely the judgment BTI asks the NRC to codify. The notice does not carry it into the rule. Neither the phrase de minimis nor the phrase below regulatory concern appears anywhere in the notice, and the draft regulatory analysis evaluates only two alternatives, the no-action baseline and the rule as proposed. A determinate lower bound on the optimization obligation was therefore not analyzed at all, notwithstanding that Executive Order 14300 directed reconsideration of the ALARA standard and that the absence of a stopping point is the defect this rulemaking identifies. Of all of the determinate limits that the NRC could have

¹³ 91 Fed. Reg. at 43464.

considered, setting a hard floor was within the scope of the executive order and within the NRC's regulatory authority. It maintains adequate protection while acknowledging an appropriate minimum of risk.

The Supreme Court's reasoning in *Industrial Union Department, AFL-CIO v. American Petroleum Institute* illustrates that regulatory judgement. In considering what level of risk could be treated as "safe" under the Occupational Safety and Health Act, the plurality rejected the premise that safety requires the elimination of all risk. As the Court explained, "safe" is not equivalent to "risk-free."¹⁴ BTI does not rely on *Benzene* as establishing a particular radiation dose or as directly governing the NRC's authority under the AEA. The case supports that a health and safety regulator may identify a level of residual risk that does not warrant additional regulation without first establishing that the underlying risk is zero.

The NRC has already determined that the existing dose limits provide reasonable assurance of adequate protection. The proposed graded approach operates below those limits to prescribe additional precautionary measures and maintain margin to them. A lower bound on that optimization obligation would not change the dose limits or alter the level the NRC has determined provides adequate protection. It would identify the point below those limits at which the regulatory obligation to pursue additional dose reduction ends.

Section 501 of the ADVANCE Act requires the Commission to carry out its licensing and regulatory functions in a manner that protects public health and safety while also enabling the safe and beneficial use of nuclear energy and avoiding unnecessary limitations on those benefits.¹⁵ These are two separate tests, not one goal: the NRC can fail the first by passively missing an available benefit, and fail the second by actively choosing a more restrictive design than necessary, and satisfying one doesn't excuse failing the other. Where more than one regulatory approach provides adequate protection, those statutory responsibilities require the NRC to consider whether one approach imposes unnecessary burdens without a commensurate safety benefit. A determinate lower bound presents that question directly because it could reduce an acknowledged source of regulatory burden without relaxing the dose limits that provide adequate protection. The proposed rule does not separately analyze that alternative. Doing so

¹⁴ *Industrial Union Dep't, AFL-CIO v. American Petroleum Institute*, 448 U.S. 607, 642 (1980) (plurality opinion).

¹⁵ ADVANCE Act§ 501(a).

would provide a clearer record that the NRC considered an alternative directly responsive to the problem this rulemaking is intended to solve.¹⁶

Low-Dose Uncertainty Does Not Require Open-Ended Obligation

The scientific uncertainty the NRC identifies at low doses does not resolve whether the optimization obligation should have a regulatory lower bound. The proposed rule acknowledges that epidemiological evidence becomes increasingly uninformative as dose declines and quotes ICRP Publication 103 for the proposition that, at exposures of a few tens of millisieverts and below, epidemiological evidence generally cannot determine whether an increased cancer risk exists.¹⁷ The NRC treats the absence of evidence as a reason not to adopt a determinate boundary for stochastic effects.

The low-dose literature does not support that inference. The 2020 *Issues in Interpreting Epidemiologic Studies of Populations Exposed to Low-Dose, High-Energy Photon Radiation* analysis cited in the proposed rule concludes that, if a threshold for stochastic effects exists, the available evidence suggests that it is unlikely to be above 1 rem, and treats that conclusion as indicating a difficulty with establishing a defensible determinate threshold.¹⁸ That conclusion may constrain claims about where a biological threshold could lie, but it does not establish that a regulatory lower bound below that level is inappropriate. A de minimis criterion does not depend on proving the absence of an effect.

The same information scarcity that prevents the low-dose literature from establishing an effect also prevents it from excluding a sizable effect. In the largest occupational cohort assembled, the stratum below 20 mGy carries 75.8 percent of all solid-cancer deaths yet returns a result that is not statistically significant, and the upper 90 percent confidence bound of 4.06 per Gy is roughly eight

¹⁶ Agency action is arbitrary and capricious where the agency has “entirely failed to consider an important aspect of the problem”, *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

¹⁷ 91 Fed. Reg. at 43462–64.

¹⁸ E. Gilbert et al., *Issues in Interpreting Epidemiologic Studies of Populations Exposed to Low-Dose, High-Energy Photon Radiation*, JNCI Monographs (July 13, 2020), <https://doi.org/10.1093/jncimonographs/lgaa004>, as cited at 91 Fed. Reg. at 43464.

times the nominal linear coefficient.¹⁹ BTI does not assert that effects are absent at low doses but that a regulatory criterion cannot be conditioned on resolving that question.

The limits of low-dose epidemiology reinforce why the NRC should not condition a regulatory stopping point on proof that stochastic effects disappear below a particular dose. Under the linear excess-relative-rate framework commonly used in radiation epidemiology, the statistical information available to estimate a dose-response relationship falls rapidly as dose decreases. On the basis of statistical strength alone, finding a relationship between low-dose radiation and a detectable cancer signal would require (with perfect information):²⁰

- An 11 mGy root-mean-square cumulative dose across the cohort, with a cohort of one million people, and at a cohort of one hundred thousand, about 35 mGy; or,
- A cohort approaching 125 million, more than a third of the United States population with 1 mGy; or,
- Beneath about 0.61 mGy root-mean-square cumulative dose, there is no study of any size up to the entire United States population that can resolve an effect of the magnitude assumed by current radiation protection models.

This result does not establish that any particular candidate criterion is beneath detectability, and this comment does not claim that it does. Sustained across a lifetime, 25 mrem/yr accumulates to roughly 17.5 mGy, which falls within the range detectable at single-site cohort scale, and 10 mrem/yr accumulates to roughly 7 mGy. The absolute limit of 0.61 mGy lifetime corresponds to well under 1 mrem/yr. However, the evidence that such low chronic exposure has the same effects as more acute doses is also up for scientific debate. These estimates assume unusually favorable conditions, including precisely known individual doses and confounders, so actual epidemiological studies would face still greater limitations.

¹⁹ David B. Richardson et al., *Cancer Mortality after Low Dose Exposure to Ionising Radiation in Workers in France, the United Kingdom, and the United States (INWORKS): Cohort Study*, 382 BMJ e074520 (Aug. 16, 2023), <https://doi.org/10.1136/bmj-2022-074520>.

²⁰ These figures assume a nominal linear no-threshold effect size of 0.5 per Gy, a one-sided significance level of 0.05, eighty percent power, and a baseline lifetime solid-cancer mortality of 0.20; a larger true effect would be resolvable at a lower dose. Each of these values is subject to the perfect-information premise described below, and is therefore a minimum rather than an achievable study design; Adam Stein, *The Detectability Frontier of Low-Dose Radiation Epidemiology: A Source-Agnostic Floor in the Linear-ERR Framework*, Research Square preprint (June 18, 2026), <https://doi.org/10.21203/rs.3.rs-10010384/v1> [hereinafter Stein, Detectability Frontier].

Low-dose uncertainty must still inform the level and conservatism of any criterion the NRC adopts. It does not require the optimization obligation to remain open-ended. When the hazard avoided cannot be measured at the doses in question, protection requirements at those doses are not evidence-based optimizations. Once the NRC has determined that the dose limits provide adequate protection, the question below those limits is how much additional regulatory control is warranted in light of residual risk, uncertainty, and the purposes of the graded framework. That is a regulatory judgment the Commission can make without resolving whether a biological threshold exists.

Uncertainty of low-dose exposure is a permanent condition. Awaiting better evidence to pinpoint the upper boundary of risk leaves overly burdensome regulation in place for decades more. For the dose ranges the graded approach handles, its foundation is based on evidence that cannot be supplied. Thus, the framework is leaving its broadest and most important area of regulation mired in uncertainty, in the exact region that the Executive Order directed re-examination.

Even once the assumption of perfect information is relaxed, viability is governed by two independent constraints rather than one: an information constraint (which a larger sample does improve) and a confounding constraint (set by competing individual exposures to the same physical hazard, chiefly per-home indoor radon). Sample size does not appear in the second constraint at all. When comparing an ambitious design against an extreme upper bound (the entire United States population, at the fenceline regulatory maximum dose, with the best achievable per-home radon measurement), the improvement in the ratio of bias to signal is attributable entirely to dose and measurement fidelity. A drastic increase in cohort size contributes nothing, and even that upper bound sits at the edge of viability. The consequence is that the evidence the NRC's reasoning waits on is not merely expensive but unobtainable.²¹

Authority, Existing Practice, and the Basis for the Dose Tiers

The history of the NRC's below-regulatory-concern policy does not foreclose the Commission from establishing a de minimis dose criterion today. Section 2901 of the Energy Policy Act of 1992 rendered the NRC's two BRC policy statements ineffective and preserved state authority over the

²¹ Adam Stein, *Sample Size Is Not the Constraint: A Sample-Size-Invariant Bias Wall in Routine Low-Dose Radiation Epidemiology* (2026), (Preprint) <https://doi.org/10.5281/zenodo.22217294>. The same power-floor result underlies the realistic-information extension in Stein, *Detectability Frontier*, § 4.4.

disposal and off-site incineration of certain low-level radioactive waste that the NRC exempts from regulation.²² It did not eliminate the NRC's underlying exemption authority or establish a general prohibition on future dose-based regulatory boundaries. The statute itself presupposes continued NRC authority to exempt material from regulation by defining the circumstances in which states may regulate waste after such an exemption.²³ Neither provision revoked the underlying exemption authority.

The NRC also already uses dose-based thresholds to determine when further regulatory control is unnecessary or when a different level of control is appropriate. Existing examples include the alternative disposal procedures in § 20.2002, exemptions in Parts 30 and 40, the 25 mrem annual dose criterion for license termination in § 20.1402, and other dose-based provisions that establish regulatory boundaries below the principal Part 20 dose limits.²⁴ These provisions serve different purposes and should not be treated as interchangeable with the criterion BTI recommends here, but they demonstrate that the Commission already makes regulatory judgments about when residual radiological risk warrants additional control.

International and federal environmental standards reflect the same basic approach. GSR Part 3 provides for exemption or clearance where radiological risks are sufficiently low that regulatory control is unwarranted or where continued control would provide no net benefit.²⁵ The EPA has likewise established radionuclide standards that tolerate residual risk after determining that the remaining risk falls within an acceptable range and that additional controls are not warranted.²⁶ Neither example depends on proving that health effects are impossible below the regulatory boundary.

The dose tiers in the existing framework track individual agency and justification. Public dose limits are lower because the exposure is not chosen. Occupational limits are higher because the exposure is knowingly accepted, informed, and monitored. Medical exposure of a patient is not limited in the same way because the exposed person is the beneficiary. The proposed caregiver

²² U.S. Nuclear Regulatory Commission, Public Meeting on Executive Order 14300 Rulemaking - Reforming and Modernizing the NRC's Radiation Protection Framework, Docket No. NRC-2025-1140, ML26197A150 (meeting held Aug. 10, 2026).

²³ Energy Policy Act of 1992, Pub. L. No. 102-486, § 2901, adding Atomic Energy Act § 276 (codified at 42 U.S.C. § 2023). The revoked policy statements are 55 Fed. Reg. 27522 (July 3, 1990) and 51 Fed. Reg. 30839 (Aug. 29, 1986).

²⁴ See, e.g., 10 CFR §§ 20.2002, 20.1402; see also 10 CFR §§ 30.14–30.20.

²⁵ GSR Part 3, Schedule I, para. I.1.

²⁶ National Emission Standards for Hazardous Air Pollutants; Radionuclides, 54 Fed. Reg. 51654, 51666 (Dec. 15, 1989).

allowance works because it has both net benefit and consent after counseling. Agency and justification are the individual and collective halves of one question, which is why the tiers track them together: justification asks whether the practice produces net good at all, and agency governs how the resulting burden may be distributed among the people it reaches.

A de minimis criterion creates a rational level that beneath some level the increment of dose is not distinguishable from ordinary variation in natural background and at levels that are unlikely to ever cause substantive risk. The benefit this recommendation invokes is the allocation of limited regulatory and licensee attention, not cost savings. Framing the benefit in cost terms invites judgments about the social value of particular end uses that the NRC does not need to make and cannot control.

Levels the NRC Could Adopt

While BTI primarily supports a 1 mSv de minimis value, there are considerations at each possible level the NRC has been considering. Regardless of the value chosen, the basis for each one has strong implications on the scientific and legal durability of the final rule.

These alternatives should not be read as three simultaneous recommendations. BTI views 1 mSv (100 mrem) per source as the preferable long-term de minimis level, subject to the broader changes needed to make that level coherent with the public dose framework. If the NRC is unwilling to undertake those changes in this rulemaking, it should not leave the optimization obligation without a floor. The existing record provides a basis to adopt a lower criterion now, with 0.1 mSv (10 mrem) presenting the clearest path within the current NRC-EPA regulatory structure.

1 mSv (100 mrem)

BTI's preferred long-term level is 1 mSv (100 mrem) per source per year as the most appropriate number for a de minimis value.²⁷ 1 mSv (100 mrem) per source, as a background-variation or clearance level is comparable to the change in natural background from moving between regions or from a low elevation to a high elevation. It is not distinguishable from variation people

²⁷ Wilson et al., Stakeholder Support for Regulatory Harmonization and Expanded Nuclear Power: Outcomes of HPS/NCRP Open Forums, 130 Health Physics 598 (2026), <https://doi.org/10.1097/HP.0000000000002056>.

already receive and accept without regulatory attention.²⁸ It also relieves regulatory burden, since most of what ALARA practice reaches falls between 1 and 100 mrem, and it corresponds to the GSR Part 3 Schedule I criterion for low-probability exposure scenarios at paragraph I.1(b), though not to the 10 μ Sv criterion for exemption without further consideration at paragraph I.1(a). Since 1 mSv is the current public dose limit in § 20.1301(a), a per-source criterion at that level is coherent only within a tier structure in which the public limit also moves.

A 100 mrem criterion cannot simply be inserted into the framework proposed in this rulemaking. Section 20.1301(a) currently limits public dose to 100 mrem per year, so a 100 mrem per-source de minimis criterion would only be coherent within a broader tiered structure in which the public dose limit is also reconsidered. It would also require coordination with the EPA, as discussed in Section VIII, because it would depart from the dose levels underlying EPA's existing Clean Air Act determinations.

0.25 mSv (25 mrem)

25 mrem is used at four points in this rulemaking: the guidance analysis trigger, the § 20.1101(d) constraint, the elective design objective in proposed Section VI of Appendix I, and the § 72.104 criterion. It is also the 40 CFR part 190 value and the § 20.1402 license-termination criterion. Adopting it as a codified criterion requires no new numerology, only the stated basis the rule currently omits. Part 190 was issued in 1977, and its limits were derived principally from doses reasonably achievable with available effluent-control technology rather than a health determination, so it corroborates a health-based basis without supplying one.²⁹ And Part 190 does not reach the hospitals, radiopharmaceutical manufacturers, and laboratories that make up most of the § 20.1101(d) population. It remains unclear what level of analysis is required to determine the 25 mrem dose and whether only further protective actions fall within the cost limitation. Adoption at this level would still require the interagency work discussed in Section VIII.

²⁸ PJ Seel and Adam Stein, The Breakthrough Institute, *Drawing the Line: The Linear No-Threshold Model, and When are Doses Too Small to Matter?*, July 16, 2025, <https://thebreakthrough.org/issues/energy/drawing-the-line> [hereinafter Seel and Stein, *Drawing the Line*], § 8.2.

²⁹ 40 CFR pt. 190; *Environmental Radiation Protection Standards for Nuclear Power Operations*, 42 Fed. Reg. 2858 (Jan. 13, 1977).

0.1 mSv (10 mrem)

A 10 mrem (0.1 mSv) per source criterion has the strongest basis for immediate adoption within the existing federal framework. 10 mrem was the individual level in the 1990 below-regulatory-concern policy statement, the prior § 20.1101(d) constraint, and the value the EPA identified in 1996 as the NRC's authoritative conclusion about what ALARA consistently requires, accepted as providing an ample margin of safety.³⁰ A criterion at this level does not disturb the CAA Section 112(d)(9) record, because it codifies the level that record already rests on, so the NRC could pursue this level without the interagency step the other two require.

Recommendations

Affected Provision	Recommendation
§ 20.1101	Codify a de minimis annual dose criterion, set at one of the three levels discussed above. BTI recommends 100 mrem as the most durable and technically coherent de minimis; 10 mrem is the strongest immediate option if NRC is not prepared to make the broader changes required for 100 mrem. The criterion should: apply per source rather than per person in total; be expressly inapplicable to medical exposure of patients, the deliberate addition of radioactive material to consumer products, and accident sequences and dose-independent obligations (security, safeguards, criticality); and terminate only the optimization obligation, leaving monitoring, reporting, and recordkeeping requirements in place.
Preamble	State why a determinate lower bound on the optimization obligation was not separately evaluated, as Executive Order 14300 directed for the ALARA standard generally, or evaluate it directly. State the two disciplines that should govern benefit-weighting under the ADVANCE Act: that it occurs at the level of rulemaking, on a published record, rather than case-by-case in individual licensing actions, and that the NRC explains the weighing it performed.
Appendix I	Address the convergence between the elective design objective and the § 20.1101(d) constraint, both currently set at 25 mrem/yr, since a design objective is ordinarily set beneath the constraint it provides margin to.

³⁰ *Withdrawal of Subpart I of 40 CFR Part 61*, 61 Fed. Reg. 68972, 68979 (Dec. 30, 1996). The NRC recites the same history at 91 Fed. Reg. at 43481.

V. DOSE LIMITS, FLEXIBILITIES, AND AFFECTED POPULATIONS

BTI supports the proposed rule's effort to provide greater flexibility where existing radiation protection requirements impose burdens without commensurate safety benefits. Those flexibilities should remain predictable and bounded. The final rule should identify the circumstances in which each flexibility is available, preserve a numerical ceiling where one is necessary to prevent open-ended discretion, and explain the benefit the flexibility is intended to provide.

The Occupational Dose Distribution

Request for Comment 2 asks for the expected benefits and drawbacks of the proposed flexibilities, for specific use cases, and for quantitative information. The provisions are strongest where the rule defines both the circumstances that justify additional flexibility and the maximum exposure that may result. Where either is left to case-by-case judgment, the final rule should provide clearer boundaries.

Planned occupational dose limit extension (PODLE), § 20.1205

On a scientific basis, BTI does not oppose a planned occupational dose extension of up to 100 mSv in a year, as proposed in § 20.1205. With documented worker consent, and a clear justification for the exposure (whether challenging crew rotations, impractical shielding requirements for essential work, etc), then this can be a reasonable assumption of risk. However, the NRC should acknowledge three challenges inherent to this category. First, planned special exposures have historically gone almost entirely unused despite not being significantly more burdensome. Second, imperfect dose histories and tracking can make the five-year lookback difficult to calculate reliably for every worker. Lastly, the extension appears designed for an unclear population, since nearly every worker's dose already falls well short of even the current annual limit.

The proposed text does not require that consent. Proposed § 20.1205(a) requires the licensee, and the employer where the employer is not the licensee, to authorize the extension in writing, and proposed § 20.1205(b) requires only that the individual be informed of the purpose of the operation, the estimated doses and associated potential risks, and the measures to be taken. There is no consent requirement and no stated right of refusal. Proposed § 35.75(b)(1), by contrast,

conditions the caregiver allowance on written consent after instruction as to the risks. The occupational tier sits above the public tier because the exposure is knowingly accepted, informed, and monitored, so a provision that doubles the annual limit is the place where informed acceptance should be codified rather than assumed. BTI recommends that § 20.1205(b) require documented consent from the individual worker. This is a condition on a new flexibility BTI supports rather than a freestanding new obligation: the extension is available only where a licensee elects to use it.

The NRC's occupational exposure reporting in the NUREG-0713 series shows that the flexible dose regimes created in this rulemaking are working at the top end of a dose distribution that almost no worker ever gets close to. In 2024, the transient-corrected light-water reactor distribution of the 81,608 individuals monitored, 357 received between 1 and 2 rem, 17 received between 2 and 3 rem, and none exceeded 3 rem.³¹ More than 99.5 percent of the monitored reactor workforce fell below one-fifth of the occupational limit. Even with the new graded approach, the higher end of this range would still warrant optimization procedures, which should be further constraining on higher exposures.

Across an estimated nine million medically exposed workers worldwide, the average annual effective dose is approximately 0.5 mSv, with a reported uncertainty interval of roughly 0.26 to 1.0 mSv/yr. U.S. nuclear medicine technologists generally sit higher with an average of 2.70 mSv, with three percent above 10 mSv. U.S. interventional radiology has shown approximately 5.0 mSv for physicians and 1.8 mSv for other staff. A broader five-year national registry analysis found comparable subspecialty means, with individual maxima reaching 8 to 9 mSv.³²

BTI supports offering flexibility at the higher end of the dose range to increase essential work. However, it is not clear what population this is really meant to serve. It could be said that these

³¹ U.S. Nuclear Regulatory Commission, *Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities*, NUREG-0713, Vol. 46 (CY 2024), ML26069A604, Abstract. The notice cites Volume 45 at 91 Fed. Reg. at 43489; Volume 46 issued after the proposed rule was signed.

³² United Nations Scientific Committee on the Effects of Atomic Radiation, *Evaluation of Occupational Exposure to Ionizing Radiation*, UNSCEAR 2020/2021 Report, Annex D (estimates for 2010–2014); *A U.S. Multi-Center Study of Occupational Radiation Doses in Nuclear Medicine*, 58 J. Nucl. Med. 202 (Supp. 1 2017) (208 technologists, 2,618 annual records, nine institutions); *Collar Badge Lens Dose Equivalent Values Among U.S. Physicians Performing Fluoroscopically-Guided Interventional Procedures* (77 physicians, 455 non-physicians, three institutions); *Assessment of Occupational Radiation Exposure Among Various Medical Professions in Interventional Cardiology: A Five-Year Study (2018-2022)*, Radioprotection (2025), <https://doi.org/10.1051/radiopro/2025003>.

doses are lower because of ALARA practices, but in these ranges, optimization procedures would still be warranted. This part of the rule requires better justification.

National Dose Registry

The NRC should support the creation of a national dose registry that can supplement REIRS. The lack of any sort of cohesive dose tracking in the United States is a distinct limitation in the implementation of the PODLE, especially outside of reactor applications. The five-year lookback § 20.1205 depends on is only as reliable as the dose history data feeding it, and workers that work between licensees could easily lose critical dosimetric data. The NRC is likely not the best place to house such a registry, but could be a driving force in the creation of one alongside dosimetry vendors, other federal agencies, and other stakeholders.

Public Dose Limits

§ 20.1301(a)

Request for Comment 6 asks what level would be appropriate if § 20.1301(a) were increased, and asks for a technical basis. Request 1(B)(iii) asks the narrower version of the same question for members of the public within the controlled area.

The position published in *Drawing the Line* is a four-tier graded approach, with action limits performing the work that fixed annual limits perform today.³³ The first tier is a background-variation or clearance level up to 1 mSv, exempt from further regulatory attention. The second is a public action limit up to 10 mSv, within which doses are optimized. The third is an occupational action limit of 20 mSv averaged across five years, consistent with the ICRP recommendation. The fourth is an overall occupational limit of 50 mSv in any single year. As stated earlier, when polled, most health physics professionals find 1 mSv to be appropriate as a de minimis dose, so if that is the case, then raising the public dose would be sensible.

Using the EPA acceptable risk threshold (10^{-4}) and a conservative application of LNT yields a public dose of approximately 1.7 mSv (170 mrem).³⁴ The basis for the ranges provided in *Drawing the Line* were based on NCRP 160 and the range of background doses in the United States.³⁵ It follows that, given that a non-negligible portion of the U.S. population can receive doses up to 10

³³ Seel and Stein, *Drawing the Line*, § 8.2.

³⁴ *Id.* § 7; Clean Air Act Amendments of 1990, Pub. L. No. 101-549, § 112.

³⁵ *Ionizing Radiation Exposure of the Population of the United States*, NCRP Report No. 160, 2009.

mSv regularly each year, that it acts as a natural bound for radiation exposure, anthropogenic or otherwise. Further, even the INWORKS study, with its conservative assumptions, loses statistical significance at this level, so it can be construed to be scientifically valid to set a limit around where proof cannot be established. If setting a hard limit, using the historic standard of 5 mSv would also be sufficiently protective, and has legal precedence.

§ 20.1301(a)(2)

Deleting the 2 mrem in any hour dose rate limit in the unrestricted area is correct for the reason the rule gives: the annual limit governs, and a source capable of delivering a dose rate that high would breach the annual limit in short order, which is the condition that warrants corrective action. Licensees remain free to adopt short-term rate limits as an internal dose management or investigation tool.³⁶ The NRC could address that, as with packaging, the dose rate is sometimes used to set cordons or other protective measures, and provide guidance on appropriate measures for easy reference.

Controlled area, § 20.1301(b).

Proposed § 20.1301(b) would allow the NRC to authorize higher doses for members of the public within a controlled area. This is bounded, but the benefit is not quantified in the proposal. BTI supports the provision on the condition that the NRC publish the criteria staff will apply to the case-by-case determination, so that determinations are consistent and reviewable. A major weakness of the proposed text is that there are but no guidelines for even the broad categories of considerations.

Case-by-case allowance, § 20.1301(d).

BTI supports retaining case-specific flexibility, but not an authorization with no stated upper bound. This provision is unbounded, as the existing 500 mrem cap would be removed. The final rule should retain a numerical ceiling in the regulatory text or establish a replacement ceiling with a stated technical basis. The NRC should also define 'variance', since staff clarified at the August 10 public meeting that these are not new exemptions but a term for the same case-by-case flexibilities. Further, the staff in the public meeting noted factors like population density, adjacency to farmland or urban areas, and site access as examples that could be included in the assessment of a definition. While specific factors should be placed in guidance, overall

³⁶ 91 Fed. Reg. at 43474 (deletion of § 20.1301(a)(2) and the reference in § 20.1302(b)(2)(ii)).

philosophy could be illustrated in the rule preamble or even listed as general considerations in the rule text.

Caregiver Dose Limits

The rule establishes two separate caregiver allowances based on a comprehensive background.³⁷ Proposed § 20.1301(c)(1)(ii) permits 2 rem (20 mSv) per administration regimen to a caregiver visiting a patient who cannot be released, and proposed § 35.75(b)(1) permits up to 5 rem (50 mSv) per administration regimen to a consenting caregiver of a released patient who has been instructed on the risks.³⁸ Each is bounded, each rests on benefit and consent after counseling, and each sits one to two orders of magnitude above observed caregiver doses. BTI supports both § 20.1301(c)(1)(ii) and § 35.75(b)(1).

The two are expressly decoupled, and the final rule should address that. The preamble states that caregiver doses received before release do not contribute to the 5 rem allowed under § 35.75 following release. A single caregiver supporting one patient through one administration regimen could then be authorized for 20 mSv before release and 50 mSv after it, for 70 mSv across the regimen. The final rule should state the basis for the cumulative exposure. The observed dose distribution makes the situation unlikely but not impossible. However, caregiver doses are also poorly tracked, so guidance should lean towards conservative assumptions in occupancy factors.

³⁷ Measured doses to household caregivers following radiopharmaceutical therapy are generally low. Reported values include a mean of 0.12 mSv across 29 caregivers of iodine-131 thyroid cancer patients, 0.15 mSv for caregivers in non-malignant iodine-131 therapy, a median of 0.038 mSv among adult family members after lutetium-177 DOTATATE treatment, and 0.245 mSv in the more intensive pediatric caregiving setting. The highest value reported in this literature, from lutetium-177 PSMA therapy, is 1.17 mSv. See *Measurement of the Dose to the Family Members Taking Care of Thyroid Cancer Patients Undergoing I-131 Therapy* (29 caregivers, thermoluminescent dosimeters worn approximately 24 days); *Radiation Dose Assessment to Family Members Taking Care of Non-Cancerous Thyroid Patients Treated with I-131 Therapy*; *Radiation Exposure to Families of Patients Following Administration of 177Lu-DOTATATE*, EJNMMI Physics (2025), <https://doi.org/10.1186/s40658-025-00776-x>; *Radiation Exposure to Patients and Others During Therapy for Pediatric Neuroblastoma with Lu-177-DOTATATE*; *Evaluation of External Radiation Exposure in Patients Treated with 177Lu-PSMA and Radiation Safety Assessment of the Patient Caregivers*, 201 Radiation Protection Dosimetry 633 (2025).

³⁸ Proposed 10 CFR § 20.1301(c)(1)(ii), 91 Fed. Reg. at 43495; proposed 10 CFR § 35.75(b)(1), *id.* at 43499. The decoupling is stated at *id.* at 43476.

Veterinary Use and the Caregiver Definition

The NRC should define caregiver and administration regimen in § 20.1003 without limiting them to human medical use, and should revise the § 20.1301(c) predicate so that the allowance is available where a licensee retains control of a treated individual.

Request for Comment 4 asks about barriers to treatment access. One such barrier is that the patient release framework, including the proposed caregiver allowance, is available only for human medical use. Proposed § 20.1301(c) is keyed to an individual who cannot be released under § 35.75 and to a caregiver as defined in part 35, and there is no part 35 analog for animals receiving therapeutic radiopharmaceuticals. The owner's dose is a public dose under § 20.1301(a) with no release criterion, no instruction threshold, and no consent structure.

The agency and benefit pairing that supports the human caregiver tier is at least as strong here. The benefit is real and privately valued, the consent is entirely voluntary because no one is compelled to seek treatment for an animal, and the person accepting the dose is the decision-maker rather than a third party absorbing another person's dose.

The adjustment required is to the exposure scenario rather than to the dose level. The obvious difficulty is that an animal cannot be instructed, and the answer is that the constraint stays at the same value while the assumptions change: no instruction-dependent behaviors credited, occupancy and proximity assumptions appropriate to the species and the treatment, and internal exposure pathways treated as material rather than incidental, since waste handling makes ingestion and inhalation live in a way that most human caregiver scenarios do not. Those assumptions belong in guidance rather than in the regulatory text, alongside the occupancy factor tables in draft revision 2 of RG 8.39. The recommendation is definitional and does not require a veterinary release regime.

Recommendations

Affected Provision	Recommendation
§ 20.1205	Justify the planned occupational dose limit extension against an unclear target population, and address the reliability of the five-year lookback given imperfect dose-history tracking, or simplify the provision accordingly.
§ 20.1205	Require documented consent from the individual worker as a condition of a planned occupational dose limit extension, consistent with the informed acceptance that supports the higher occupational dose tier.
§ 20.1301(b) and Guidance	Publish the criteria staff will apply to the controlled-area case-by-case determination. Consider including broad consideration points in rule text.
§ 20.1301(d)	Establish a numerical ceiling in the regulatory text, since removing the existing 500 mrem cap leaves the allowance unbounded.
Definitions	The NRC should officially define the meaning of a “variance”
§ 20.1301(c) and § 35.75	The NRC should support the creation of a national dose registry beyond REIRS.
§ 20.1301(c) and § 35.75	State the basis for why the in-hospital and post-release caretaker doses are decoupled and why there isn’t analysis on the potential cumulative dose of 70 mSv.
§ 20.1003 and § 20.1301(c)	Define caregiver and administration regimen in § 20.1003 without limiting them to human medical use, and revise the § 20.1301(c) predicate to cover any licensee-controlled treated individual. Species-appropriate exposure assumptions belong in guidance, not the regulatory text.
§ 20.1301(a)	NRC should be willing to raise the public dose limit. The graded approach limits should be changed if the public doses changes. We support an all-source 10 mSv action limit for the public. If a hard limit is preferred over an action limit, 5 mSv is a historically precedented alternative.

VI. THE GRADED APPROACH AND COST AS A DIAGNOSTIC RATHER THAN A CRITERION

The NRC's proposed graded approach is a substantial improvement over an open-ended ALARA obligation because it ties additional radiation protection measures to determinate dose thresholds. Those thresholds establish in advance when additional measures are required, reducing the subjectivity that the NRC identifies as a central problem with current ALARA implementation. The final rule should retain that structure and state more clearly what the graded approach is intended to accomplish.

The use of determinate action thresholds is the best portion of the graded approach. They are boundaries above which an action is required and below which the requirement is inapplicable, with no subjectivity as to when a measure is triggered. The rule uses the same instrument elsewhere in this same notice, replacing the qualitative "well within" and "small fraction of" formulations for design-basis-accident acceptance criteria (historically 25 percent and 10 percent of the 25 rem maximum hypothetical accident value, or 6.3 rem and 2.5 rem) with a single determinate criterion of 10 rem TEDE.³⁹ However, the use of mostly administrative limits does not meet the requirements of Executive Order 14300, which calls for the NRC to set determinate dose limits.

A graded approach should scale effort to hazard: protective measures intensifying as risk grows and relaxing as it recedes, so attention concentrates where the hazard is largest instead of spreading evenly regardless of it. This is the same reasoning the IAEA's GSR Part 3 builds into its own system of requirements and relates to the codification of optimization alongside the determinate limit analysis previously discussed. Yet in the rule text, without either of them written explicitly, the grades do little to ensure safety or reduce regulatory burden. Its three occupational triggers are administrative rather than actionably protective: 100 mrem/year requires worker instruction, 500 mrem/year requires individual dose monitoring, and 5 rem/year is the annual limit itself.⁴⁰ None reduces the dose nor says where a licensee's obligation to reduce dose stops. The NRC's draft regulatory analysis illustrates this gap: its entire quantified savings figure comes from averted reporting and recordkeeping labor, not from any estimated change in

³⁹ 91 Fed. Reg. at 43476–77.

⁴⁰ 91 Fed. Reg. 43470–71

actual dose, cost, or construction practice. The analysis states directly that the NRC lacks reliable data on how doses would change as a result of the rule.⁴¹ BTI's analysis to bound the cost effects of a comparable change (modifying ALARA and raising the public dose limit, for new nuclear construction alone) produced a first-order estimate ranging from \$200 million to \$40 billion, a range BTI attributes to uncertain deployment outcomes and industry implementation.⁴² The graded approach as proposed cannot capture savings of that scale, because it changes reporting and recordkeeping rather than the underlying practice. Guidance is not a sufficient vehicle for that kind of change. Realizing savings closer to BTI's estimated range would depend on the codified de minimis criterion and public dose limit this comment recommends, not on administrative adjustments alone, and without increasing risk to the public.

The final rule should ensure that the graded approach implements optimization through discrete, dose-based requirements within the range below the dose limits. Individual dose should be the principal variable against which regulatory effort is graded, and the applicable requirements should become more stringent as dose increases. This provides licensees and NRC staff an ascertainable framework for determining what level of protection is required without returning to a continuous inquiry into whether further dose reduction is "reasonable."

That structure also reinforces the need for the lower bound discussed in Section IV. A graded framework requires both points at which additional requirements begin and a point below which the optimization obligation ends. Baseline requirements such as monitoring, training, posting, reporting, and recordkeeping may continue below that point, but additional dose-reduction measures should not remain subject to an open-ended optimization requirement.

Cost Should Inform Optimization, Not Define the Safety Standard

The proposed framework also needs a clearer explanation of the role of cost. Cost has no role in determining the level necessary to provide adequate protection, and it should not determine the de minimis criterion that establishes the lower boundary of optimization. Those boundaries

⁴¹ U.S. Nuclear Regulatory Commission, Draft Regulatory Analysis for the Proposed Rule: Reforming and Modernizing the NRC's Radiation Protection Framework, RIN No. 3150-AL47, Docket No. NRC-2025-1140, ML26180A025 (Mar. 2026).

⁴² The Breakthrough Institute, *Estimation of Cost Reduction From Risk-Informed Radiation Standards*, Dec. 18, 2025, <https://thebreakthrough.org/issues/nuclear-energy-innovation/estimation-of-cost-reductions-from-risk-informed-radiation-standards>.

should be established by the NRC through regulation based on health, risk, and the other considerations discussed in Sections II and IV. Once those boundaries are established, cost can appropriately inform whether particular additional measures within the optimization range provide benefits commensurate with the burdens they impose.

Adequate protection is a threshold set on health grounds with no cost term in the AEA, and the rule states that protection is adequate at all doses below the public dose limit and that reduction below it serves to create margin. That distinction matters because a monetized cost-benefit test should not become a substitute for a regulatory lower bound. If every incremental reduction below the dose limits remains subject to a case-specific calculation of dollars spent per unit of dose avoided, the endpoint of optimization continues to depend on changing costs, technologies, and assumptions. The NRC would have removed ALARA terminology without fully resolving the open-ended feature of ALARA that prompted this rulemaking. A codified *de minimis* criterion establishes that endpoint independently; cost-benefit analysis can then operate within the bounded range where optimization remains required.

Within that range, the relevant inquiry should not be limited to the monetary cost of a protective measure compared with the dose it avoids. The ADVANCE Act requires the NRC to consider the broader benefits of nuclear energy, and regulatory requirements can impose consequences beyond their immediate compliance costs. Where the NRC evaluates whether an additional margin-of-safety requirement is warranted, it should consider the actual safety benefit of the measure alongside the operational and societal burdens the requirement may impose. This analysis applies only after the NRC has established adequate protection and cannot be used to justify noncompliance with a dose limit or other determinate requirement.

Two invariants bound any lawful use of cost in the guidance, and the final rule should state both so that the recommendation is actionable when the guidance issues. Cost may never deny or burden a licensee that satisfies the applicable threshold on the ground that further reduction was not cost-justified. And cost may never excuse a failure to satisfy a threshold on the ground that compliance is expensive. Any analysis honoring both operates above the threshold, on the benefit side; any analysis breaching either prices the threshold itself.

The final rule and phase-two guidance should preserve these distinctions: adequate protection and determinate regulatory boundaries are established independently of cost; cost does not

excuse failure to comply with those boundaries; and cost-benefit considerations may inform the additional measures required within the optimization range.

The Monetized Test the Guidance Would Apply

The instrument that would perform this analysis is already described. The preamble states that the NRC's guidance would explain that radiation protection measures under the graded approach may be supported by comparing the cost of the measure to a reasonably calculated cost basis of an averted person-rem, that NUREG-1530 supplies one acceptable basis at \$5,200 per person-rem in 2014 dollars, and that a licensee whose candidate measure costs more than that figure per person-rem averted would have an acceptable cost-justified basis for not implementing it and instead accruing the dose. The preamble describes this as replacing the subjectivity of the current ALARA-based regulations with objective cost-benefit analyses. Draft Regulatory Guide 8064, issued for comment with the proposed rule as Revision 1 to Regulatory Guide 8.37, already applies that approach to effluents at materials facilities.

That instrument cannot supply the endpoint the preceding section describes. The conversion factor is derived in NUREG-1530 as the product of a value of statistical life and a cancer mortality risk coefficient for stochastic effects, applied to collective dose. It is therefore linear to zero by construction: any nonzero dose multiplied by any nonzero population yields a nonzero monetized benefit, so the comparison can be performed at any dose, without end. Adopting it as the operative test would carry forward the very feature of ALARA implementation that this rulemaking identifies as the problem, in a different unit of account. That is the concrete reason the lower bound must be codified in the rule rather than left to the guidance.

The concern is not that a dollar-per-dose figure is used to make optimization decisions actionable. Some such figure is necessary, and comparable values are used by other nuclear regulators. The concern is that a cost figure adopted for that limited purpose is often broadened as an estimate of actual risk. The ICRP's distinction preserves that line in how collective dose and the cost figures derived from it are legitimate instruments for comparing protective measures against one another. However, at the trivial per-capita doses its utility fails for individual epidemiologic analysis.⁴³

⁴³ International Commission on Radiological Protection, *The 2007 Recommendations of the International Commission on Radiological Protection*, ICRP Publication 103, Ann. ICRP 37(2-4), ¶ 161 (2007).

The asymmetry between the public and occupational sides should also be addressed. The 25 mrem per year analysis convention is a public-dose scoping convention with no occupational counterpart, so on the occupational side the graded approach as described retains no lower bound at all and the comparison would run to arbitrarily small doses. The final rule should state what bounds the obligation there, or explain why no bound is required.

NUREG-1530 also does not present \$5,200 as a single value or as a compliance criterion. It reports low, best, and high values of \$2,600, \$5,200, and \$7,800 in 2014 dollars, prescribes the higher figure for high dose-rate and high dose scenarios, establishes a method for keeping the values current, and identifies its applications as regulatory analyses, backfit analyses, and environmental analyses, agency-side analyses whose conclusions and recommendations it describes as neither final nor binding. Converting an agency decision-support input into a licensee compliance test is a substantive change that the rulemaking record does not analyze. The final rule should state which value applies, whether the escalation method travels with it, and on what basis a figure derived for agency use is appropriate as a criterion for licensee compliance.

ALARA Practice as an Accepted Means of Compliance

Two of the three draft guides issued with the proposed rule state that compliance with regulations implementing the current ALARA terminology would also be sufficient to satisfy the revised regulations implementing the graded approach to dose management, and that a licensee's election to follow the referenced ALARA guidance would continue to be an acceptable means of demonstrating compliance. BTI does not object to a transition provision of this kind; some safe harbor is necessary while the second phase of guidance is developed. The difficulty is that the safe harbor is unbounded in time, rests in guidance rather than in rule text, and is not reconciled with the rest of the framework.

If ALARA practice satisfies the graded approach, then the open-ended obligation this rulemaking was convened to address survives for every licensee that continues its current program, and the burden reduction the regulatory analysis projects may not materialize. The finding that the graded approach satisfies the optimization requirement of GSR Part 3 then rests substantially on a change in terminology. And Agreement States would be required to delete the ALARA requirement from their own regulations to conform to a Category A provision, as discussed in

Section X, while NRC licensees remain free to demonstrate compliance by following ALARA guidance.

This also bears on a concern raised from the opposite direction, that determinate thresholds will invite doses to rise toward them with nothing in the framework pushing lower. The preamble answers that concern by observing that occupationally exposed individuals rarely approach even small fractions of the applicable dose limits because of licensees' existing dose management efforts, which are generally founded on ALARA practices. That answer holds only because those practices persist, and they persist because the guidance preserves them. The two concerns share a single cause: the rule states where protective effort attaches without stating what it is for or where it ends. The final rule should also state whether performance achieved below a threshold creates any expectation going forward, since Draft Regulatory Guide 8064 provides that release goals may be adjusted up or down on annual review. Establishing a goal in guidance can lead to a precedent or a de facto limit.

Recommendations

Affected Provision	Recommendation
§ 20.1003 - Definition of "Graded Approach"	State in the final rule what grading is for: the objective (effort proportional to individual dose), the variable graded against (individual dose, not collective dose or cost), and why discrete triggers rather than continuous optimization.
§ 20.1003 - Definition of "Graded Approach"	State that the graded approach specifically applies to the principles of radiation dose control and include optimization in the definition.
Guidance	State two invariants on the use of cost: it may never deny or burden a licensee that satisfies a threshold, and may never excuse a failure to satisfy one. Cost governing an obligation should be no less disciplined than the NRC's own backfit rule, which requires more than cost justification alone.
Guidance	Within the bounded optimization range, cost analysis should weigh the broader societal benefit and operational burden of a requirement, not only the cost estimation of avoided dose.
§ 20.1101 and Guidance	Codify the determinate dose below which no monetized analysis of

Affected Provision	Recommendation
	additional protective measures is required. The \$5,200 per person-rem comparison described in the preamble is linear to zero and cannot supply that endpoint from within.
Guidance	State which of the NUREG-1530 values applies, whether the escalation method travels with it, and the basis for using a factor derived for agency-side regulatory, backfit, and environmental analyses as a criterion for licensee compliance.
Guidance	State what bounds the graded approach on the occupational side, where the 25 mrem per year analysis convention has no counterpart, or explain why no bound is required there.
Preamble and Guidance	State whether compliance through ALARA practice remains an accepted means of satisfying the graded approach indefinitely, and whether performance achieved below a threshold creates any expectation going forward.

VII. THE EFFLUENT DOSE CONSTRAINT AT § 20.1101(d)

The proposed revision to § 20.1101(d) raises related issues. The regulatory text requires a licensee that exceeds the 25 mrem constraint to report the exceedance and “promptly take corrective action to ensure against recurrence,” while the preamble describes the requirement as evaluating and considering cost-justified corrective actions. The final rule should make the regulatory text and preamble consistent and clearly state what the NRC expects after an exceedance.

The provision is a mandatory safety-improvement requirement located far beneath the level the rule identifies as the point of adequate protection. If a less-limiting design (the reporting and data-retention obligations the rule imposes below the constraint without the mandate) secures the same protection, then the mandate limits a covered benefit beyond what the NRC's non-compensable obligations require.

The Risk Basis

The preamble estimates an excess fatal cancer risk of 3.5×10^{-4} at 10 mrem/yr and 8.7×10^{-4} at 25 mrem/yr, each computed over 70 years of exposure against the roughly 20 percent baseline in Table 12-4 of the BEIR VII report.⁴⁴ The proposed rule text requires a licensee to fix any exceedance within the first year, so no individual could accumulate 70 years of exposure at that level under this framework. For a rulemaking undertaken in response to a direction to consider credible, realistic risk, the NRC should also give figures on realistic assumptions or explain why bounding assumptions are appropriate here. The radiation safety field is prone to conservative assumptions, and those can be informative, but this rulemaking should also endeavor to provide the likely exposure scenarios as well.

The record also lacks an affirmative basis for 25 mrem. The preamble contextualizes its risk estimates against lifetime fatal cancer risk from natural background, including radon. The EPA historically considered and rejected that comparison in the rulemaking that established the standard now at issue, holding that a source does not present an acceptable risk simply by being less than natural background.⁴⁵ This is still an appropriate means of grounding unavoidable risk, but to specifically address the difference with the EPA, the NRC should derive its risk basis in the true statistical uncertainty mentioned above and the need to set appropriate limits based on sound regulatory judgment. Since effluents have joint responsibility, this is a basis that requires collective action.

The reporting and retention structure should be preserved, and the final rule should say why: it mirrors Subpart I, with annual reporting above ten percent of the standard and annual self-check with five-year retention below it, preserving the evidentiary basis the EPA relied on and keeping available the measured performance data that makes a renewed determination possible. Request for Comment 5 asks about alternatives including raising the constraint while retaining existing reporting practices.

⁴⁴ 91 Fed. Reg. at 43470–71. The notice applies a cancer risk coefficient of 0.0005 per rem, citing NCRP Report No. 180, § 4.1.

⁴⁵ 54 Fed. Reg. at 51659.

Recommendations

Affected Provision	Recommendation
§ 20.1101(d) and Guidance	State whether the provision mandates corrective action or requires only an evaluation. The codified text and preamble currently describe different obligations.
§ 20.1101(d) and Guidance	State why the mandate, rather than the reporting and data-retention obligations already imposed below the constraint, was necessary to secure the same protection.
§ 20.1101(d) and Preamble	State the affirmative derivation basis for 25 mrem/yr. There does not seem to be a defensible record being established for the 25 mrem limits despite historic and partner agency similarities.
Preamble	Provide additional justification for the comparison to natural background risk.
§ 20.1101(d)	Preserve the Subpart I-derived reporting and retention structure, and state why: it keeps the EPA's evidentiary basis intact and preserves the data a renewed determination would need.

VIII. COORDINATION WITH THE EPA UNDER CLEAN AIR ACT SECTION 112(D)(9)

The proposed rule changes elements of the NRC radiation protection framework that EPA relied on when it withdrew separate radionuclide emission standards for NRC-licensed facilities under CAA § 112(d)(9). That provision allows the EPA to forgo separate standards only after determining, by rule and in consultation with the NRC, that the NRC regulatory program provides an ample margin of safety. BTI appreciates the NRC addressing these factors in the rule preamble, but the NRC should not assume that those determinations remain unaffected while materially revising the underlying program. The lack of engagement on the EPA's primary concerns from their statutory basis creates an argumentative gap in the NRC's creating rationale for diverging from the current EPA-approved values. BTI has published a full analysis of the interagency questions.⁴⁶ The considerations in this section relate to specific statutory changes tied to the Subpart I rescission decisions.

⁴⁶ Seel, *Coordination Across Federal Law*.

The 1995 reactor determination included three substantive sections that are changed in the proposed rule: Appendix I to part 50, whose title invoked ALARA and which the EPA calculated as limiting total effective dose equivalent to approximately 6 mrem/yr; the enforceability of technical specifications implementing those design objectives; and the resulting assurance that reactor doses remained below 10 mrem/yr.

On the numerical envelope, Sections I through III of Appendix I are not amended, so the existing design objectives stand for licensees that make no changes. The proposed Section VI offers an elective alternative under which the calculated total quantity of radioactive material released from each reactor to the unrestricted area would not exceed 25 mrem/yr, with an investigation and corrective-action obligation triggered in any calendar quarter in which releases would exceed half that design objective. A licensee electing Section VI thus moves from the envelope the EPA relied on to one roughly four times larger, in the same instrument the EPA relied on and will likely trigger public action to encourage an EPA response.⁴⁷

On enforceability, proposed Section VI.B.3 would permit the operative content, including controls for specific equipment, applicability statements, actions, and surveillance requirements, to move out of technical specifications and into licensee-controlled documents managed under a § 50.36(c)(5) administrative control.⁴⁸ The EPA cited the enforceability of technical specifications by name so this likely needs direct attention in the proposed rule.

On terminology, the rule would retitle Appendix I, removing the reference to the ALARA criterion that the EPA quoted in full when explaining what it relied on. Since the 1995 determination was explicitly tied to “ALARA”, by deleting the word, that finding can be reopened. Section VI supplies functional features to key a renewed determination to a numerical objective, a quarterly trigger at half that objective, a mandatory investigation and corrective-action program, and continuing annual reports until conformity is restored. Building a renewed determination of acceptability from the EPA based on this trigger-and-response architecture is more durable than terminology-based determinations, especially when the EPA and NRC often have different definitions.

One drafting question should be resolved on the record. Proposed § 20.1101(d) does not reach power reactors, which are excepted as licensees subject to § 50.34a or § 53.260, so the question is

⁴⁷ 61 Fed. Reg. at 68978.

⁴⁸ Proposed Appendix I, Sections VI.A and VI.B.3, 91 Fed. Reg. at 43502.

one of interaction with part 190 rather than with that constraint. Since 25 mrem/yr is also the part 190 limit for the entire uranium fuel cycle, a per-reactor effluent design objective at the same value leaves no headroom for the rest of the fuel cycle. Both are questions about intended interaction and the NRC should answer them in the preamble or in guidance.

Executive Order 14300 instructed only the NRC to make reforms, but it cannot complete the reform alone. Absent a legislative fix, it is incumbent on both agencies (plus partner agencies) to reach a mutually agreed framework. In addition to the broader reforms needed to align the EPA and the NRC, specific to this rulemaking, there are several provisions that should be better tailored to the EPA's concerns.

The Cost-Benefit Provision in Section II.D of Appendix I

The amendatory scope should also be stated precisely. The instructions revise only the appendix title and Section IV.C and add Section VI, so Sections I, II, III, and V and the remainder of Section IV are unamended. Among them is Section II.D, which requires:

In addition to the provisions of paragraphs A, B, and C above, the applicant shall include in the radwaste system all items of reasonably demonstrated technology that, when added to the system sequentially and in order of diminishing cost-benefit return, can for a favorable cost-benefit ratio effect reductions in dose to the population reasonably expected to be within 50 miles of the reactor. As an interim measure and until establishment and adoption of better values (or other appropriate criteria), the values \$1000 per total body man-rem and \$1000 per man-thyroid-rem (or such lesser values as may be demonstrated to be suitable in a particular case) shall be used in this cost-benefit analysis.⁴⁹

It is the only mandatory, quantified cost-benefit requirement applicable to reactor effluents, and it is graded against collective population dose (the limitation of which are previously discussed).

The figure has not been revised since 1975 and is applied as stated. NUREG-1530 confirms that applicants and NRC staff remain required to use it until it is changed by rulemaking, and states that deletion of the existing \$1,000 and \$2,000 per person-rem references in regulations and guidance is planned. This rulemaking is the vehicle that would accomplish that, and it does not.

⁴⁹ 10 CFR § 50.34a, Appendix I to Part 50, § II.D.

Expressed in matched dollars the two figures are not far apart: \$1,000 in 1975 dollars is roughly \$4,400 in 2014 dollars, within about twenty percent of the NUREG-1530 best estimate. The divergence is therefore one of maintenance rather than derivation. The NUREG-1530 value carries a method for keeping it current and the Appendix I value does not, and Section II.D permits only lesser values to be substituted, never greater ones, so a reactor applicant today applies \$1,000 nominal against a guidance figure that escalation places above \$7,000, a gap that widens every year. The NRC should resolve the conversion factor across Section II.D, the draft implementing guidance, and NUREG-1530 in this rulemaking.

The interaction with proposed Section VI should be resolved on the record. Section VI is stated as an alternative to the approach described in Sections I through V, but that alternative is framed as one for establishing technical specifications under § 50.36a, while Section II.D is a radwaste design obligation running to an applicant under § 50.34a. Whether an applicant electing Section VI still owes the Section II.D analysis is therefore unclear on the face of the text. If it does not, the election removes the only mandatory, quantified cost-benefit requirement applicable to reactor effluents, in addition to enlarging the envelope four-fold. That consequence is not analyzed in the proposed rule, and it is material to a renewed EPA determination under section 112(d)(9), because Section II.D is the provision within Appendix I that most nearly performs the function the EPA described when it relied on the appendix as an ALARA instrument.

A related drafting problem should be corrected, whatever the two agencies decide. The rule strikes § 50.34a(a) in its entirety, and the struck text contains the definition of the term as low as is reasonably achievable for all of part 50; the definition in § 20.1003 is removed as well. But Section II of Appendix I is not amended, and the term survives in Sections I, II.B.2(b), IV and V of the appendix, including in Section II.B.2(b), under which a higher gaseous release quantity will be deemed to meet the requirements for keeping levels of radioactive material in gaseous effluents as low as is reasonably achievable. A codified compliance test would therefore turn on a term with no definition anywhere in part 20 or part 50, and whose deleted definition supplied the only textual limit on it. The NRC should conform those sections to the stated discontinuation of ALARA terminology, or state that they retain the criterion deliberately and restore a definition for it. Because those sections are unchanged, the terminology concern raised above operates with most force as to Section VI electees; that does not reduce what section 112(d)(9) requires, since this rule reaches each of the three pillars of the 1995 determination.

One further provision warrants attention for the same reason. The replacement text of § 50.34a(a) provides that the guides in Appendix I supply acceptable design objectives and that alternative design objectives approved by the NRC are also acceptable. That is a second and broader flexibility alongside Section VI, with no stated criteria and no ceiling, and the EPA's determination rested on the numerical guides. The final rule should state the criteria that would govern approval of an alternative design objective.

Recommendations

Affected Provision	Recommendation
Preamble	Commit to substantive joint work with the EPA on the open dose and risk questions, on a stated schedule, through the section 112(d)(9) rulemaking rather than a concurrence letter.
Proposed Section VI, Appendix I	Directly address the fourfold increase over the effluent envelope the EPA's 1995 determination used.
Proposed Section VI.B.3	Address the independent effect of moving operative content out of enforceable technical specifications and into licensee-controlled documents
Appendix I retitling	Build the renewed EPA determination on Section VI's functional features (numerical objective, quarterly trigger, investigation program, annual reporting) rather than on the ALARA terminology being deleted, so the determination survives future terminology changes.
Proposed Section VI.A / 40 CFR part 190	Resolve on the record whether a per-reactor 25 mrem/yr design objective leaves headroom under the part 190 fuel-cycle limit, and how the objective aggregates at a multi-unit site.
Appendix I, Section II.D	Address Section II.D, which this rule leaves unamended, and resolve the conversion factor across Section II.D, the draft implementing guidance, and NUREG-1530 in this rulemaking.
Proposed Section VI and Section II.D	State whether an applicant electing Section VI still owes the Section II.D analysis, and analyze the consequence for the renewed Section 112(d)(9) determination if it does not.
Appendix I and § 50.34a	Conform Sections I, II, IV and V of Appendix I to the discontinuation

Affected Provision	Recommendation
	of ALARA terminology, or restore a definition for the term, which the deletion of § 50.34a(a) and of the § 20.1003 definition would otherwise leave undefined in codified text.
§ 50.34a(a)	State the criteria that would govern NRC approval of an alternative design objective under the new provision that alternative design objectives approved by the NRC are also acceptable.

IX. IMPLEMENTING GUIDANCE

The NRC must issue the remaining implementing guidance for comment. The public is commenting on a framework whose operative content is not yet published: definitions of optimization practices, the monetized justification test, the criteria for case-by-case determinations, and the analysis triggers. The lack of accompanying guidance for the primary measures in this proposed rule further increases uncertainty in the application of these provisions.

The Draft Revision to Regulatory Guide 8.39

BTI supports finalizing the draft revision to Regulatory Guide 8.39 with the adoption of the recommendations presented by the ACMUI with one adjustment.

The subcommittee's recommendations on occupancy factors, per-regimen framework concerns, patient-specific recordkeeping, iodine-131 contamination precautions, and additional calculational tools and reference tables should be adopted.⁵⁰ The adjustment concerns the caregiver definition.

BTI agrees with the subcommittee's objective that paid family caregivers should not be excluded from the allowance. However, removing "unpaid" without a replacement structure, since removing the qualifier alone would create ambiguity about whether a paid caregiver is a member of the public or an occupationally exposed individual. The final guidance should instead retain the distinction and handle it through differentiated provisions on how dose and risk

⁵⁰ Advisory Committee on the Medical Uses of Isotopes, Subcommittee Report on the Draft Revision to Regulatory Guide 8.39, approved August 17, 2026.

information is conveyed to each category: paid and unpaid caregivers differ in the information channel available to them, in whether an employer holds independent obligations, and in the manner of their consent. Differentiated communication preserves those differences without excluding paid caregivers from the allowance.

On occupancy factors, the draft guide's tables assume a factor of 1.0 at one meter for a caregiver and 0.25 for a bystander. The caregiver value presumes continuous presence at the reference distance for the full decay period. The subcommittee's recommendation for additional tabulated values, with examples at 0.67 for close contact without co-sleeping and 0.25 for standard precautions, is the right instrument. The final guidance should state that the 1.0 default is bounding and supply tabulated alternatives, so a licensee without the capacity for a patient-specific calculation is not confined to the most conservative assumption.

On breastfeeding, the NRC should retain the requirement to document each instance in which instructions are given to a breastfeeding patient. The proposed amendment to § 35.2075 would remove that requirement and rely instead on the written procedure required by proposed § 35.75(a).⁵¹

Patient education should be treated as a continuous obligation across the release process. Informed consent is what makes the caregiver dose tier defensible in the first place, and proposed § 35.75(b)(1) makes that explicit by conditioning the caregiver allowance on written consent and instruction as to the risks.

Recommendations

Affected Provision	Recommendation
RG 8.39 Rev 2	Adopt the amendments suggested by the ACMUI Subcommittee generally as suggested.
RG 8.39 Rev 2	Unpaid and paid caregivers should be separated in guidance with distinct provisions and instructions given the different populations in both groups and differing levels of consent and expectation.

⁵¹ Proposed 10 CFR § 35.2075, 91 Fed. Reg. at 43500; the basis is stated at *id.* at 43475–76.

X. CROSS-RULE COORDINATION AND AGREEMENT STATE COMPATIBILITY

The NRC should reconcile overlapping amendments before finalizing. This proposed rule is one component of a broader NRC effort to revise its regulations under Executive Order 14300, and it should not be finalized as though it can be cleanly separated from the adjacent reforms, because finalizing first risks locking in a mechanism whose assumptions a later rule invalidates. Three interactions warrant coordination language in the final rule.

Sections 61.41 and 61.43 are amended both in this rulemaking and in the integrated low-level radioactive waste disposal rulemaking. That rulemaking restructures those sections into subsections and replaces the current ALARA sentence with a cross-reference to revised § 20.1101(b), while this rulemaking deletes the same ALARA sentence without inserting replacement text. Each rule assumes a coordination step the other does not perform, so depending on the order of finalization, those sections could be left without any provision addressing dose optimization. The final rule should state which text governs.⁵²

The Subpart E license-termination criteria this rule touches are the foundation for a partial-site-release provision BTI recommended in the Part 57 rulemaking.⁵³ There, BTI recommended adapting §§ 50.83 and 53.1080 to allow partial site release and individual-unit license termination before termination of an entire plant or site license. That flexibility is particularly important for staged, multi-unit, manufactured, and transportable deployments, where individual units may be deployed, removed, replaced, refurbished, or retired on different schedules. BTI recommended conditioning partial release on a demonstration that the released area or unit satisfies Part 20, Subpart E, while shared structures, systems, components, and radiological areas remain under appropriate license control and decommissioning and funding obligations continue for the remaining units and facilities. Because Subpart E supplies the release standard for that framework, amendments finalized in this rulemaking will directly affect how a future Part 57 partial-release provision operates. The NRC should ensure that the two rulemakings use the same final Subpart E criteria and do not inadvertently foreclose partial

⁵² *Integrated Low-Level Radioactive Waste Disposal*, Docket No. NRC-2011-0012. The amendments proposed here appear at 91 Fed. Reg. at 43503.

⁵³ BTI, Part 57 Comment, at 103.

release or create conflicting standards for demonstrating that an individual unit or portion of a site is eligible for unrestricted release.

The comment period for the medical use licensing rulemaking closes after this one, so the interaction between the administration regimen concept and § 35.76 is best addressed in that docket.⁵⁴

Agreement State Compatibility

This rulemaking has one of the largest impacts across all Agreement States due to its implications across all of radiation protection. The use of Category A for most provisions is sensible, but the implementation timeline should be considerate of the substantial impact that will be had across Agreement States. Further, in coordinating with the EPA on joint rulemaking endeavors, the Organization of Agreement States and the Conference of Radiation Control and Program Directors should be close partners due to the numerous points of overlap on effluent limits and the complexities of federal and state oversight with mixed statutory bases.

The NRC proposes to move § 20.1101(b) from Category H&S to Category A, and § 20.1101(d) from Category C to Category A. Because Category A requires an essentially identical State provision, the first would require Agreement States to remove the ALARA requirement from their own regulations, and the second would remove their ability to retain the existing 10 mrem per year constraint on air emissions. The NRC observes in the same discussion that the Clean Air Act does not preclude a State from adopting more restrictive emissions standards for radionuclides.

Category A is the right designation for the definitions, dose limits, and other basic standards that must be uniform, as stated above. It is not the right designation for § 20.1101(d). BTI recommends that § 20.1101(d) remain Category C, or that the NRC state on the record why uniformity at 25 mrem per year is necessary to the adequacy of the national program. The provision exists to give the EPA assurance for purposes of section 112(d)(9), and State stringency above the federal level has not been treated as inconsistent with that purpose. Requiring States to relax an existing constraint is a different act from harmonizing definitions or dose limits, and it should be justified as such. The point applies with added force given that the draft implementing guidance would allow NRC licensees to continue demonstrating compliance through ALARA practice, as

⁵⁴ *Reducing Barriers to Medical Use Licensing*, Docket No. NRC-2025-1237, RIN 3150-AL50 (comment period closing September 10, 2026).

discussed in Section VI. States would be required to remove the requirement from their own regulations while the NRC's guidance preserves it as an accepted compliance path.

Recommendations

Affected Provision	Recommendation
§ 20.1101(d)	Retain Category C, or state on the record why uniformity at 25 mrem per year is necessary to the adequacy of the national program, given that the Clean Air Act does not preclude a State from adopting more restrictive radionuclide emissions standards.
§ 20.1101(b)	Address the effect of requiring Agreement States to remove the ALARA requirement from their regulations while the draft implementing guidance would allow NRC licensees to continue demonstrating compliance through ALARA practice.
Implementation	Set an implementation timeline proportionate to the scale of the change across Agreement State programs, developed with the Organization of Agreement States and the Conference of Radiation Control Program Directors.

XI. CONCLUSION

There are two major defects of the proposed rule: the framework leaves the obligation to reduce dose without any stopping point; and its determinate thresholds will invite doses to rise toward them, with nothing in the framework pushing lower. Both occur because the proposed rule states where protective effort attaches without stating what it is for or where it ends. The recommendations in this comment are not a compromise between those positions. They offer structural answers with a codified floor that bounds the obligation from below and a codified optimization principle that gives it direction between the floor and the limit. These recommendations also give the framework a clearer structure: codified radiation protection principles, a defined basis for international alignment, a rationale for the different exposure tiers, a stated purpose for the graded approach, clear bounds for each flexibility, a de minimis floor for optimization, and a path for completing the reform through interagency coordination.

There is substantial opportunity to change the paradigm around radiation protection without losing public support or throwing regulatory certainty away. By adopting bold solutions to the known issues in radiation safety, the NRC will better meet this moment of significant regulatory reform, setting up the U.S. to better regulate advanced nuclear technology.

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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