



AMERICAN COLLEGE OF
OCCUPATIONAL AND
ENVIRONMENTAL MEDICINE

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Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
ATTN: Rulemakings and Adjudications Staff

RE: Comments of the American College of Occupational and Environmental Medicine on the Proposed Rule, "Reforming and Modernizing the NRC's Radiation Protection Framework"

Docket ID NRC-2025-1140; RIN 3150-AL47; 91 Fed. Reg. 43456 (July 15, 2026)

Dear Secretary:

The American College of Occupational and Environmental Medicine (ACOEM) appreciates the opportunity to comment on the U.S. Nuclear Regulatory Commission's (NRC) proposed rule reforming and modernizing its radiation protection framework. Founded in 1916, ACOEM is the nation's largest medical society dedicated to promoting the health of workers through preventive medicine, clinical care, research, and education, and represents more than 3,000 physicians and other health care professionals specializing in occupational and environmental medicine (OEM). Our members are the physicians who conduct medical surveillance of radiation workers, evaluate individuals after suspected overexposures, counsel patients and their families about radiation risk, and perform the causation analyses on which occupational illness compensation depends. We comment from that clinical vantage point.

Exposure to radiation can cause cancer, reproductive health effects, and other conditions. To reduce risk from radiation, exposures should be as low as reasonably achievable (ALARA). ACOEM supports the elements of this rulemaking that genuinely modernize the framework — principally the optional use of contemporary dosimetry methods under proposed § 20.1010 and Appendix H, and the elimination of duplicative respiratory-protection reviews. We oppose the provisions that reduce protection for workers, patients' caregivers, and members of the public, and we oppose them primarily on the basis of the NRC's own record in this notice.

Summary of ACOEM's Position

The scientific premise of this rulemaking does not support its principal action. In this same notice the NRC states that it "finds that no consensus-supported, regulation-ready alternative model to the LNT model exists at this time;" "reaffirms its position that the linear dose response model is the most appropriate available consensus model for formulating radiation protection standards;" and concludes

that establishing a determinate regulatory dose limit for both stochastic and nonstochastic health effects, with a corresponding go/no-go regulatory approach, "is not currently supported by scientific evidence." 91 Fed. Reg. at 43462, 43464. Having reaffirmed a linear no-threshold (LNT) model, the NRC proposes to remove that model's operational corollary — the requirement to reduce dose below the limits where it is reasonable to do so. That is the central inconsistency in the proposal, and most of our specific objections follow from it.

The NRC further identifies the problem it seeks to solve as one of implementation rather than principle. It reaffirms its 2021 characterization of ALARA compliance as turning on "whether the licensee has incorporated reasonable measures to track and, if necessary, to reduce exposures — not whether exposures and doses represent an absolute minimum," and states that this description of the ALARA requirement "remains true today". 91 Fed. Reg. at 43461 (describing the denial at 86 Fed. Reg. 45923). The Commission then rejects clarification as a remedy because it "would not be effective in achieving an enduring resolution" of the issues associated with the current implementation of the principle. 91 Fed. Reg. at 43463. A remedy that repeals a correctly stated principle in order to correct its misapplication is broader than the defect identified and not appropriate.

A summary of ACOEM's positions on the nine major provisions of the proposed rule is provided below, followed by a more detailed explanation of our positions, and then responses to the NRC's specific requests for comments in Section V.

Summary of ACOEM Positions

1. Removal of ALARA; graded approach to dose management — Oppose. The replacement requirement contains no thresholds in rule text, and its operative content is deferred to guidance not issued for comment. ACOEM cannot support a framework it has not been permitted to read.

2. Planned occupational dose limit extension (§ 20.1205) — Oppose as structured. Adopts multiyear averaging without the reduced annual limit that makes averaging protective, and without any lifetime cap.

3. Reporting threshold for monitoring results (§ 20.2106(a)(7)) — Oppose. Degrades the individual dose record in precisely the dose range the NRC says is scientifically unresolved.

4. Replacement of overexposure reporting with a 5-year assessment (§ 20.2203) — Oppose. A retrospective assessment cannot perform the clinical or regulatory function of a contemporaneous overexposure report.

5. Case-by-case variances in public dose limits and accessible dose rates — Oppose. Removes the numerical ceiling on requested limits, deletes the short-term dose rate limit, and addresses caregiver dose at the occupational limit without stating an operative ceiling in the rule text and without any retained record of the individual dose evaluation for the released-patient caregiver.

6. Optional use of modern dose modeling and calculation methods — Support with one condition: record the dosimetry method used for each dose of record.

7. 10-rem design-basis accident acceptance criterion — Oppose. Raises the public-facing criterion by a factor of 1.6 to 4 on a rationale that conflates deterministic and stochastic endpoints and is implemented through guidance not issued for comment.

8. Referenced approvals for respiratory protection devices and deviations — Support in concept; oppose self-certification without notification to the NRC and oppose any amendment that leaves the engineering-control hierarchy in §§ 20.1701, 20.1702, and 20.1704 without an operative standard.

9. Revised effluent constraint (10 to 25 mrem per year) — Oppose. Departs from the Clean Air Act record on which the 10 mrem value was set, carries forward no counterpart to EPA's separate limit for iodine, and permits a licensee-proposed higher constraint bounded only by the public dose limit itself. ACOEM also urges the NRC to extend the comment period and reopen it for comments once the deferred guidance is issued, to reconsider the Agreement State compatibility reclassifications in Section XV, and to republish the operative portions of this rule together with the implementing guidance that contains its thresholds. Those requests are addressed at the end of this letter.

Explanation of ACOEM Positions

1. Removal of ALARA and Substitution of a Graded Approach to Dose Management

ACOEM opposes this provision. Proposed § 20.1101(b) requires that licensees "use procedures, engineering controls, and a graded approach to dose management based upon sound radiation protection principles to maintain occupational doses and doses to members of the public within the limits specified in this part." The graded approach to dose management is the operative addition, and the rule text supplies none of its content: no thresholds, no dose management actions, and no criterion beyond compliance with the limits themselves. Every operative element sits in guidance that the NRC has expressly deferred. Until and unless NRC provides a satisfactory alternative approach to dose management ACOEM recommends that ALARA remains the appropriate approach.

The rule text contains none of the substance the preamble describes.

The preamble offers examples of "progressively increasing, threshold doses" — 100 mrem per year, 500 mrem per year, and 5 rem per year. 91 Fed. Reg. at 43469. Each of these merely restates a requirement that already exists: worker instruction under § 19.12, individual monitoring under § 20.1502, and the annual limit itself under § 20.1201. The NRC acknowledges this, stating that the threshold doses and dose management actions "would generally correspond to existing requirements in 10 CFR part 20 or other regulations and, therefore, should already be incorporated within the radiation protection programs of existing licensees" to a degree "commensurate with the scope and extent of licensed activities" as § 20.1101 currently requires. *Id.* The qualifier the NRC invokes is drawn from the very section this rulemaking amends. The graded approach, as it appears in the proposed regulatory text, credits requirements that are already in force and adds nothing operative below the limits. What it removes — the obligation to reduce dose below the limits where reduction is reasonable — is not replaced.

The one genuinely new element is not available for comment.

The single new decision rule the NRC describes is a monetary criterion: that a licensee may decline a dose-reduction measure costing more than a "reasonably calculated cost-basis of an averted person-rem," with NUREG-1530 offered as an acceptable standard at a nominal value of \$5,200 per person-rem

in 2014 dollars. 91 Fed. Reg. at 43469. The NRC then states that this guidance "would be issued subsequent to this rulemaking as part of the NRC's planned two-phased approach" to issuing guidance associated with this rulemaking. Id. The public is therefore asked to comment on a requirement whose only substantive content will be written after the comment period closes. ACOEM requests that the NRC either (a) issue the graded-approach guidance and reopen the comment period on the rule and guidance together, or (b) place the thresholds and the decision criterion in the regulatory text where they are subject to notice and comment.

ACOEM states its position on the deferred content plainly: we cannot support the graded approach to dose management, because we have not been permitted to see it. That is not a rhetorical objection. The thresholds, the corresponding radiation protection measures, and the cost basis by which a licensee would decide whether a protective measure is required are the entire operative content of the replacement requirement, and none of it has been published. A commenter cannot endorse a requirement whose substance is unwritten, and the agency cannot fairly treat the absence of objection to unpublished content as acquiescence in it.

We want to be precise about what we are and are not saying. ACOEM does not assert that no acceptable graded approach could be constructed. What we cannot do is state a position on a framework that does not yet exist in reviewable form. ACOEM therefore withholds support for the graded approach as proposed and reserves its position until the implementing guidance is issued and available for comment. We ask that the record reflect that ACOEM has had no opportunity to evaluate the operative content of this provision.

The proposed definition makes the gap explicit. The rule would define a graded approach to dose management as 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." Proposed § 20.1003, 91 Fed. Reg. at 43493; see also id. at 43465. The definition thus promises determinate thresholds as the operative mechanism, and no such threshold appears anywhere in the proposed regulatory text. The closing purpose clause confirms the character of the replacement: the graded approach is directed to reasonable assurance that the limit is not exceeded, not to the reduction of dose below it. The thresholds exist only as preamble examples and in guidance not yet written.

There is a further difficulty with the substitution itself. The NRC states that the graded approach is essentially an application of the concept of optimization, and it supplies the definition of optimization on which it relies, taken from the 2022 IAEA Nuclear Safety and Security Glossary: the process of determining what level of protection and safety would result in the magnitude of individual doses, the number of individuals exposed, and the likelihood of exposure being as low as reasonably achievable, economic and social factors being taken into account. The glossary entry closes with the parenthetical "ALARA." Id. at 43468. The agency proposes to retire a term from its regulations while resting the replacement on a definition in which that same term is the operative content. ACOEM does not raise this as wordplay. If optimization as the NRC defines it is ALARA, then the substance of the requirement is unchanged and the rulemaking is a relabeling; if it is not, the agency should say what the difference is, because that difference is the actual regulatory change and it is nowhere described.

The consequence reaches beyond domestic practice. The NRC states that the graded approach meets the description of optimization in Requirement 11 of GSR Part 3 and therefore also satisfies Article 15 of the Convention on Nuclear Safety. *Id.* at 43465. A conclusion about compliance with a treaty obligation is thus made to rest on a framework whose thresholds, dose management actions, and decision criterion have not been published. ACOEM asks the NRC to substantiate that conclusion against the text of the requirement it proposes to adopt, rather than against guidance the public has not seen.

For public dose, the graded approach has a single threshold, and it is the same number as the new effluent constraint.

The preamble treats public dose separately, and the structure there is thinner still. The NRC states that one acceptable way of managing dose below the public dose limit would be to perform a cost-benefit analysis on the assumptions of NUREG-1530 for projected public doses at or above 25 percent of the limit, that is, 25 mrem per year, and that it would be acceptable to comply with the requirement by not analyzing projected public doses below that value. 91 Fed. Reg. at 43470. For members of the public the graded approach therefore has one threshold rather than three, it appears only in guidance that has not been issued, and below it no analysis of any kind is required.

That number is the same one this rulemaking adopts as the new effluent constraint. Provision 9 would raise the constraint in § 20.1101(d) from 10 mrem per year to 25 mrem per year, and a licensee demonstrating effluents below 25 mrem per year would retain data for inspection rather than report it. A licensee operating just under the new constraint would therefore sit just under the analysis floor as well: no report to the agency, and no obligation to consider whether the dose could reasonably be reduced. Under the current framework that same licensee is at two and one-half times its constraint and squarely within the range where analysis is expected. ACOEM asks the NRC to state whether this alignment is intended, and to place the public-dose threshold and the analysis it triggers in the regulatory text rather than in deferred guidance.

A monetary criterion of this kind requires scrutiny that deferral prevents.

If a dollar-per-person-rem test is to govern dose reduction, its construction matters. The NUREG-1530 value is derived from a statistical-life coefficient multiplied by a cancer mortality risk coefficient. It therefore monetizes fatal cancer alone. It does not account for nonfatal cancer, heritable effects, cataract and other tissue effects, or the documented psychological burden that radiation workers and their families carry. It is also asymmetric in incidence: the cost savings accrue to the licensee, while the dose accrues to the individual worker. For the same reason given above, ACOEM cannot support a monetary decision rule it has not seen and would only support a rule that provides sufficient protection for workers and their families. If the NRC nonetheless seeks to adopt a monetary decision rule, it should be available for review and comment. For any proposed rule, ACOEM recommends at minimum that the criterion be stated in rule text, be expressed in current dollars with a defined escalation method and be accompanied by a requirement that the analysis be documented and retained.

Compliance should not be treated as conclusive evidence of optimization.

The NRC proposes that "compliance with the NRC's regulations would be taken as evidence of the application of those principles in the United States." The principles are justification, limitation, and optimization under IAEA GSR Part 3 Requirement 11. 91 Fed. Reg. at 43463. Optimization as defined in the international framework is an ongoing process of examining whether further reduction is warranted,

not a status conferred by meeting a limit. Treating compliance as conclusive evidence of optimization does not implement the principle; it retires it while retaining its name.

The clinical consequence is a change in practice, notwithstanding the NRC's assurance.

The NRC states repeatedly that the rule "will not require any changes to licensees' current practices" and that licensees are not precluded "from choosing to do more." 91 Fed. Reg. at 43463. In our members' experience, radiation protection programs are staffed, budgeted, and audited to what is required. Removing the term from the regulations and from all implementing guidance will, over a licensing cycle, remove the internal justification for dose-reduction expenditures, for the radiation safety committee's review of dose trends, and for the occupational physician's participation in work planning. ACOEM recommends that the NRC retain an affirmative obligation to reduce dose below the limits where reduction is reasonable, however that obligation is labeled.

Recommendation. Retain an affirmative obligation to reduce dose below the limits where reduction is reasonable, however that obligation is labeled. If the NRC proceeds with a graded approach to dose management, place the thresholds, the corresponding dose management actions, and the monetary decision criterion in the regulatory text rather than in deferred guidance; state the cost basis in current dollars with a defined escalation method and require that the analysis be documented and retained; place the public-dose threshold and the analysis it triggers in the regulatory text as well; and state whether the alignment between that threshold and the new effluent constraint is intended. ACOEM reserves its position on the graded approach until the implementing guidance is issued and available for comment.

2. Planned Occupational Dose Limit Extension (Proposed § 20.1205)

ACOEM opposes this provision as structured. We do not object in principle to multiyear dose management. We object to the adoption of multiyear flexibility without the constraints that make multiyear averaging protective in the frameworks from which it is borrowed.

The proposal takes the flexibility of ICRP Publication 60 without its limit.

ICRP Publication 60 recommended multiyear averaging as part of a package: 2 rem per year averaged over five years, not to exceed 5 rem in any single year. The NRC declined the reduced limit in 1991 and does not propose it now. 91 Fed. Reg. at 43459. The result is that the five-year envelope under the ICRP recommendation is 10 rem, while the five-year envelope under proposed § 20.1205(d)(1) is 25 rem — two and one-half times greater. The averaging mechanism is imported; the constraint that justified it is not. If the NRC wishes to adopt multiyear dose management, ACOEM recommends it adopt the corresponding annual limit as well.

There is no lifetime cap and no lifetime accounting.

The only lifetime accounting anywhere in Part 20 is § 20.1206(e), whose subparagraph (e)(2) caps dose from all planned special exposures and all doses in excess of the limits at five times the annual limits over the individual's lifetime. Paragraph (e) opens "Subject to § 20.1201(b)," and current § 20.1201(b) requires doses received in excess of the annual limits to be subtracted from the planned special exposure allowances for the current year and for the lifetime.

Proposed § 20.1205(f) provides that dose from planned occupational dose limit extensions "is not to be considered in controlling future occupational dose of the individual under § 20.1201(a) but is to be included in evaluations required by §§ 20.1205 (c) and (d) and 20.1206 (d) and (e)." Read alone, that folds extension dose into the lifetime cap.

Proposed § 20.1201(b) does the opposite. It provides that doses received in excess of the annual limits, "with the exception of doses received under § 20.1205," must be subtracted from the planned special exposure allowances. Because § 20.1206(e) operates only as § 20.1201(b) permits, the exception in § 20.1201(b) removes extension dose from the very evaluations that § 20.1205(f) directs it into.

The two provisions cannot both be given effect, and the choice between them is consequential. On the § 20.1205(f) reading, extension dose counts against the 25 rem lifetime ceiling. On the § 20.1201(b) reading, a worker may exhaust a 25 rem rolling five-year extension allowance in every five-year period while retaining the full 25 rem planned special exposure allowance untouched, and no lifetime accounting of extension dose exists at all. Over a forty-year working life the second reading admits an outer bound on the order of 200 rem, against the 25 rem lifetime ceiling that governs the same worker under § 20.1206.

ACOEM does not suggest that this bound describes expected practice. We state it because bounding the outlier is the function a limit performs, and because the record does not disclose which reading the Commission intends. ACOEM asks the NRC to resolve the conflict expressly in the final rule and recommends the resolution that gives § 20.1205(f) its stated effect: extension dose should count toward a lifetime ceiling, the lifetime dose determination required by § 20.2104(b)(2) for planned special exposures should be extended to dose limit extensions, and extension dose should count toward the individual's dose of record for all purposes.

Unused dose is not a bank.

The NRC's safety rationale is that where a worker received less than the limit, "there often exists unused retrospective dose that could be safely used." 91 Fed. Reg. at 43472. Under the LNT model the NRC reaffirms in this same notice, dose not received is risk not incurred. It does not create an entitlement to future dose. The NRC's better argument — that annual limits are "essentially fractionated lifetime totals," *id.* — supports averaging only if a lifetime total is actually enforced. Under this proposal none is.

The magnitudes involved warrant medical involvement.

Section 20.1205(d)(2) permits, in a single year, twice the limits in § 20.1201(a)(1) and (a)(2)(ii): 10 rem total effective dose equivalent, 100 rem to an individual organ or tissue, and 100 rem shallow-dose equivalent to the skin. These are not routine exposures. ACOEM recommends that the rule require, before authorization: documented consultation with a physician qualified in occupational medicine or radiation medicine; documented informed consent that records the estimated doses and their associated risks in terms the worker can act on; and confirmation that the individual is neither a declared pregnant woman nor a minor. ACOEM supports the exclusion of declared pregnant women and minors, which the opening sentence of proposed § 20.1205 accomplishes. ACOEM also supports the treatment of the lens, which proposed § 20.1205(d)(3) accomplishes not by excluding the lens from the process but by capping lens dose equivalent at 15 rem in any one year, so that the annual lens limit itself cannot be extended. That treatment is discussed further in the following paragraph.

The approach to the lens of the eye illustrates the inconsistency in the treatment of uncertainty.

The NRC excludes the lens from the occupational dose limit extension (DLE) process because of "the uncertainty associated with the health risks of lens dose." 91 Fed. Reg. at 43472-73. In the same rulemaking it declines to reduce the occupational lens limit, characterizing the recommendation of NCRP Commentary No. 26 as a reduction from 15 rem per year to 5 rem per year and the underlying findings as "preliminary" and the recommendations as "conservative in nature". 91 Fed. Reg. at 43460. And it deletes cataracts from the definition of "nonstochastic effect" in § 20.1003 "in consideration of recent research that indicates that this health effect may be stochastic in nature." 91 Fed. Reg. at 43465; see proposed § 20.1003, id. at 43493 (defining "nonstochastic effect" without the cataract example). These three positions cannot all stand. If cataract is stochastic, there is no threshold, and the case for dose management is stronger, not weaker.

ACOEM recommends that the NRC adopt the recommendation of NCRP Commentary No. 26 as NCRP actually made it. NCRP recommends reducing the annual occupational lens limit from an equivalent dose of 150 mSv to an absorbed dose of 50 mGy, together with the use of relative biological effectiveness values for high-LET radiation. The change of dose quantity is deliberate and substantive: NCRP now recommends absorbed dose when addressing tissue reactions, and the distinction matters in mixed and high-LET fields where equivalent dose and absorbed dose diverge. The notice renders the recommendation as a reduction from 15 rem per year to 5 rem per year expressed in equivalent dose. 91 Fed. Reg. at 43460. That is not what NCRP recommended, and the final rule should state it accurately.

Two further points bear on the Commission's treatment of this recommendation. First, NCRP Commentary No. 26 is expressly premised on continued application of ALARA; it states the expectation that actual individual exposures would fall below the recommended limit through application of that principle. The Commission is declining to adopt a recommendation whose stated premise this same rule would delete. Second, the notice states that the NCRP recommendation aligns with international recommendations including those of the ICRP. It does not. The ICRP recommends an equivalent dose limit for the lens of 20 mSv per year averaged over five years, with no single year exceeding 50 mSv. The NCRP value of 50 mGy per year is materially less restrictive than the ICRP value, and the two should not be described as aligned.

ACOEM further recommends that lens dose be monitored in the operational quantity appropriate to the lens where lens dose may approach a substantial fraction of the limit, rather than inferred from whole-body dosimetry placed elsewhere on the body, and that any dose-management obligation retained or created by this rulemaking apply expressly to the lens. This is the one place in the record where the science clearly supports a change in the direction of greater protection, and the proposed rule declines to make it. Additional Comment A below develops this point and states ACOEM's recommendation on the lens limit in full.

Recommendation. Adopt the reduced annual occupational lens dose limit as NCRP Commentary No. 26 actually states it, expressed as an absorbed dose. If the NRC proceeds with the planned occupational dose limit extension, resolve on the record the conflict between proposed §§ 20.1201(b) and 20.1205(f) in favor of the reading that gives § 20.1205(f) its stated effect; adopt the reduced annual limit that accompanies multiyear averaging in ICRP Publication 60; extend the lifetime dose determination

required by § 20.2104(b)(2) to dose limit extensions and count extension dose toward the individual's dose of record for all purposes; and require, before authorization, documented consultation with a physician qualified in occupational or radiation medicine, documented informed consent recording the estimated doses and their associated risks, and confirmation that the individual is neither a declared pregnant woman nor a minor.

3. Reporting Threshold for Required Monitoring Results (Proposed § 20.2106(a)(7))

ACOEM opposes this provision. Proposed § 20.2106(a)(7) would allow a licensee, where monitoring was required under § 20.1502 but the dose "did not exceed 10 percent of the applicable monitoring criteria," to annotate that an occupational dose was received rather than record its numerical value. Because the § 20.1502 monitoring criterion is itself 10 percent of the applicable limit, the provision appears to make numerical recording optional below approximately 50 mrem per year of total effective dose equivalent. ACOEM reads "the applicable monitoring criteria" as referring to the § 20.1502 criteria and asks the NRC to confirm that reading in the final rule so that the threshold is not later construed against the § 20.1201(a) limits, which would raise it tenfold.

The provision is self-defeating on the rule's own premise.

The central scientific argument of this rulemaking is that low-dose epidemiology lacks the statistical power to resolve risk at doses typical of licensed activities — the signal-to-noise problem the NRC describes at 91 Fed. Reg. at 43461, referencing the 20 percent baseline solid cancer mortality in Table 12-4 of BEIR VII. Individual dose records are the input to the studies that would resolve that question. Replacing numeric values with a non-quantitative annotation in the low-dose range reduces the resolving power of future analyses of the U.S. worker population, and does so permanently, since the data cannot be reconstructed later.

The value of complete records is demonstrable. The most recent update to the International Nuclear Workers Study assembled individual monitoring data on 309,932 workers across France, the United Kingdom, and the United States, with 10.7 million person-years of follow-up and 28,089 solid cancer deaths, and estimated an excess relative rate of solid cancer mortality of 52 percent per gray (90% CI, 27% to 77%), lagged ten years; restricting the analysis to the 0-100 mGy range approximately doubled the estimate of association. Richardson DB, Leuraud K, Laurier D, 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. *BMJ*. 2023;382:e074520. That result exists because the underlying dose records were quantitative.

Numeric records serve compensation and clinical functions independent of research.

Individual dose records are relied upon in claims under the Energy Employees Occupational Illness Compensation Program Act, in NIOSH-IREP dose reconstruction, and in workers' compensation causation analysis. Where a numeric value is absent, the analysis defaults to reconstruction assumptions, which are less favorable to the claimant and more contestable. Our members also rely on these records when evaluating a worker years after the fact for a condition of possible radiogenic origin.

Recommendation. Retain numerical recording under § 20.2106. If the NRC wishes to reduce burden, it can do so by simplifying what is reported to the agency while leaving the licensee's individual record

intact. The recordkeeping burden of retaining a number already generated by the dosimetry vendor is minimal.

4. Replacement of Unplanned Overexposure Reporting with a Five-Year Dose Assessment (Proposed § 20.2203)

ACOEM opposes this provision and regards it as the most consequential occupational health change in the rule. Under proposed § 20.2203(a)(2)(i), an unplanned exceedance of the annual total effective dose equivalent limit is reportable "only if the total effective dose equivalent for the current year and the preceding four years exceeds 25 rem." Under § 20.2203(a)(2)(iv), an exceedance of the public dose limit is reportable only if the five-year total exceeds 500 mrem.

A retrospective assessment cannot do the work of an overexposure report.

An overexposure report is not primarily a statistical instrument. It is the event that triggers investigation of the cause, verification of the dosimetry, evaluation for internal deposition, consideration of bioassay and work restriction, corrective action, and — through § 19.13 — notification of the affected individual. Every one of those responses is time-dependent. Bioassay and biodosimetry windows close.

Contaminated equipment is repaired or replaced. Coworkers who shared the exposure disperse. A worker informed five years later that a five-year sum has been exceeded learns something about their record; they learn nothing that permits any clinical or protective action. The proposal converts a real-time safety signal into an accounting reconciliation.

The threshold permits repeated annual exceedances without any report.

Because the trigger is the five-year sum rather than the annual event, a worker may exceed the 5 rem annual limit in one or more years without the NRC ever receiving a report, provided the running five-year total remains at or below 25 rem. The agency loses the ability to detect a failing radiation protection program while the failure is occurring. The same structure applies to public dose, where exceedances of the 100 mrem limit go unreported until a five-year total exceeds 500 mrem.

Recommendation. Retain the existing requirement to report an exceedance of an annual limit within the current timeframes. If the NRC finds value in a five-year retrospective assessment, adopt it as an additional requirement rather than a substitute. ACOEM would not object to a five-year assessment layered on top of contemporaneous reporting.

5. Case-by-Case Variances in Public Dose Limits, Deletion of the Short-Term Dose Rate Limit, and Caregiver Dose

ACOEM opposes these provisions. We address them together because they operate on the same population — individuals who are not radiation workers, who are not monitored, who have received no training under § 19.12, and who have no dose record.

Removal of the numerical ceiling in § 20.1301(d).

The current § 20.1301(d) permits a licensee to request authorization to operate up to 500 mrem per year for an individual member of the public. The proposal removes that ceiling and replaces it with nothing. 91 Fed. Reg. at 43473. The only remaining constraint is the NRC's case-by-case judgment,

applied to an application that need only demonstrate the need for and expected duration of the operations, describe the licensee's program to assess and control dose, and state "[t]he proposed dose limit for an individual member of the public and its supporting basis, including why it remains protective of the public health and safety." Proposed § 20.1301(d)(1)-(3), 91 Fed. Reg. at 43495. The applicant must therefore propose a number, but the rule states no maximum against which that number is measured. Each of the three requirements is procedural; none supplies a numerical ceiling. ACOEM recommends that the existing 500 mrem ceiling be retained in the rule text. If the Commission concludes a different value is warranted, an explanation should be provided, and that value should appear in the regulation itself rather than in preamble or guidance. A limit with no stated maximum is not a limit.

Generic approval of higher controlled-area public dose.

Proposed § 20.1301(b) permits requests for a higher controlled-area public dose limit, and the preamble states that "[s]uch requests may be on a generic basis (e.g., for a design)." 91 Fed. Reg. at 43473. The justification the NRC offers for allowing higher controlled-area dose is entirely site- and population-specific: that members of the public are present temporarily, for tours or deliveries or while accompanying patients, and that most will be adults. A generic, design-based approval severs the authorization from the occupancy assumptions that justify it. ACOEM recommends that any such authorization be site-specific and be conditioned on the occupancy and access assumptions on which it was granted.

Deletion of the 2 mrem in any hour limit.

The proposal deletes § 20.1301(a)(2) and the corresponding reference in § 20.1302(b)(2)(ii) on the reasoning that a member of the public "could receive the full 100 mrem annual public dose instantaneously and this fact in and of itself would have minimal safety impact." 91 Fed. Reg. at 43474. That reasoning addresses the aggregation of stochastic risk. It does not address the two functions the rate limit actually performs: it bounds the dose an unmonitored individual can receive in a single unanticipated encounter, and it provides an operational detection threshold for an uncontrolled or mispositioned source before an annual limit is approached. The NRC's own text concedes the latter, observing that such a source "would most assuredly result in an exceedance of the annual public dose limit in a short period of time." *Id.* Detecting that condition promptly is the point. ACOEM recommends the rate limit be retained.

Caregiver dose under §§ 20.1301(c), 35.75, and 35.2075 —a very concerning change.

The proposal creates two caregiver pathways, in two parts of the regulations, for two different patient states. They should be read together. For a patient who cannot be released, proposed § 20.1301(c)(1) sets 0.5 rem per administration regimen for a member of the public who is not a caregiver and 2 rem per administration regimen for a caregiver, each subject to an authorized user determination before the visit. For a released patient, proposed § 35.75(b) handles the caregiver separately and addresses a dose of 5 rem per administration regimen on the basis of written consent and instruction. The characterization of that figure as the occupational dose limit is the NRC's own. The preamble states that the agency "is proposing to introduce flexibility through the identification of a caregiver, who is eligible to receive up to the occupational dose limit (i.e., 5 rem) per patient administration regimen." 91 Fed. Reg. at 43475. The assumptions that produce that figure, however, do not appear in the rule. The same passage explains that the difference between the caregiver and the general member of the public is

reflected in DG-8061, the proposed Revision 2 to Regulatory Guide 8.39, through an assumed occupancy factor of 0.25 at 1 meter for a member of the public and an assumed occupancy factor of 1 at 1 meter for a caregiver. Id. Proposed § 35.75 footnote 1, by contrast, directs the reader to "[t]he current revision of Regulatory Guide 8.39" for methods of calculating caregiver dose. Id. at 43500. ACOEM asks the NRC to state which document supplies the governing assumptions, and to make that document available for comment together with the rule.

The 5 rem figure is not drafted as a limit. Proposed § 35.75(b)(1) requires written consent and then requires instruction on radiation risks and the management of exposure where the caregiver dose is likely to exceed 0.5 rem and is not likely to exceed 5 rem per administration regimen. The 5 rem value is the upper edge of the band that triggers the instruction duty. It is not stated as a bound on the dose. Proposed § 35.75(b)(2) states a genuine ceiling for individuals who are not caregivers, in the ordinary "not likely to exceed" form. Paragraph (b)(1) states none. Read literally, a caregiver dose likely to exceed 5 rem falls outside the condition in paragraph (b)(1), with the result that no instruction is required and nothing in the paragraph prohibits the release. Proposed paragraph (c) then refers to the limits in paragraphs (b)(1) and (b)(2) as though paragraph (b)(1) contained one.

ACOEM offers this as a reading of the proposed regulatory text and acknowledges that the preamble discussion contemplates a 5 rem ceiling. Whichever the Commission intends, the value it adopts should appear in the operative text as an express limit, in the same form as paragraph (b)(2). A ceiling that exists only in the preamble is not enforceable, and it is not available to the caregiver, to the licensee, or to an Agreement State regulator reading the rule.

The objection to the magnitude follows behind that one. An individual may receive dose at the occupational limit with none of the protections that attach to the same dose in a worker:

- no dosimetry and therefore no knowledge of the dose actually received;
- no training under § 19.12, which applies to workers at one-fiftieth of this dose;
- no medical surveillance and no occupational health provider of record;
- no individual dose record under § 20.2106, and, for the reasons given below, no retained record of the dose evaluation supporting the release;
- no notification under § 19.13 and no reporting pathway if the estimate proves low; and
- no cumulative accounting, since the allowance is stated per administration regimen and the NRC acknowledges that radiopharmaceuticals "are increasingly being administered over a series of administrations as a matter of protocol." 91 Fed. Reg. at 43475.

The two pathways do not combine, and the preamble says so expressly: caregiver dose received before release does not contribute to the dose allowed after release. A single caregiver, in a single administration regimen, may therefore receive 2 rem in the hospital under proposed § 20.1301(c)(1) and a further 5 rem at home under proposed § 35.75(b)(1). ACOEM is aware of no clinical or radiobiological basis for treating those two increments as unrelated. They are received by the same individual, from the same patient, arising out of the same course of treatment.

The record structure is asymmetric in the same direction. The new record requirement at proposed § 20.2107(c) reaches only the caregiver described in § 20.1301(c)(1)(ii), which is the 2 rem case in the

controlled setting. The larger released-patient dose has no counterpart. ACOEM does not suggest that the proposal eliminates release records generally. The current duty in § 35.2075(a) is already conditional, applying where the dose was calculated using retained rather than administered activity, an occupancy factor below 0.25 at one meter, biological or effective half-life, or tissue shielding. That is the point. Those four are precisely the least conservative ways of calculating the dose, and the record obligation attaches to all of them. Republishing § 35.2075 to retain only a written procedure kept for the duration of the license removes the individual estimate in exactly the cases where the estimate is most likely to be optimistic. The proposal separately deletes current § 35.2075(b), the record that instructions were given to a breastfeeding patient.

The contrast sharpens against the NRC's companion medical use proceeding, published twelve days after this notice. There the agency proposes a new § 35.76 governing individuals who cannot be released under § 35.75: a private room, or a room shared only with another individual who also received such an administration; for unsealed byproduct material and microsources, access without leaving the controlled area to a sanitary facility used only by individuals who received similar administrations; a visibly posted radioactive materials sign; and a note on the door or in the chart recording where visitors may be and for how long. 91 Fed. Reg. 47042, 47089 (July 27, 2026). A parallel provision in the proposed new microsource subpart would require radiation safety instruction, initially and at least annually, for personnel caring for individuals who cannot be released, covering patient control, visitor control, contamination control, and waste control. *Id.* at 47097.

Those are the precautions the agency considers appropriate around the caregiver who receives 2 rem in a controlled setting. The caregiver who receives 5 rem at home under proposed § 35.75(b)(1) has none of them, and under the revised § 35.2075 would have no retained record of the dose estimate either. ACOEM does not suggest that a home is a hospital, or that these particular controls could be transplanted to it. We make the narrower point: in the same month, for the same population, and in adjacent dockets, the agency has described what reasonable precaution looks like at 2 rem and has proposed the larger dose with none of it.

We want to be clear about what we are not saying. ACOEM supports the recognition of the caregiver role. Caregiver access is frequently essential to the patient's well-being, and the current framework has forced licensees into exemption requests to accomplish something clinically appropriate. Our objection is to a dose of this magnitude stated without an operative limit and without an individual record, not to the recognition of the role. Additional Comment B below develops the caregiver framework in full, including the consensus values for this population, the treatment of pregnancy and of minors in the household, and the retention of the dose evaluation.

Recommendations. ACOEM recommends that the NRC: (1) state the caregiver value adopted for released patients as an express limit in the operative text of § 35.75(b)(1), in the same form as § 35.75(b)(2), rather than as the upper edge of a condition that triggers an instruction duty; (2) provide that caregiver dose received before release and after release be summed within an administration regimen; (3) retain in § 35.2075 the requirement to record the individual dose evaluation supporting a release involving a designated caregiver, at minimum in those cases where the calculation relies on retained activity, an occupancy factor below 0.25 at one meter, biological or effective half-life, or tissue shielding; (4) establish a cumulative caregiver dose ceiling across administration regimens within a

defined period, rather than an unbounded per-regimen allowance; (5) require that the written instructions include the estimated dose and a means by which the caregiver may obtain a dose estimate on request; (6) expressly exclude pregnant individuals from designation as a caregiver, consistent with the exclusion the NRC applies to workers in § 20.1205, and state an express value for a minor in the household, for the reasons developed in Additional Comment B below; and (7) retain the requirement in current § 35.2075(b) to document instructions provided to breastfeeding patients, which is a clinically significant communication and not a paperwork formality.

6. Optional Use of Modern Dose Modeling and Calculation Methods (Proposed § 20.1010 and Appendix H)

ACOEM supports this provision, as long as it includes one recommended addition. The dosimetric methods underlying the current Part 20 derive from ICRP Publication 26 and Publication 30. The methods proposed for generic approval in Appendix H — including ICRP Publications 116, 130, 134, 137, 141, 144, and 151 — reflect substantially improved biokinetic and dosimetric modeling, and the use of the radiation weighting factor in place of the quality factor better represents dose across an organ. Requiring a case-by-case exemption to use them has been a real and unjustified burden.

Career dose records assembled from multiple systems require method provenance.

Proposed § 20.1004(e) provides that values determined under different dosimetry methods are additive, following ICRP Publication 60 paragraph 31, and the NRC does not propose to correct earlier values. For compliance purposes this is defensible. For longitudinal purposes it is not sufficient without one addition. A worker's career record may come to consist of doses computed under ICRP 26/30 methods, ICRP 60-era methods, and ICRP 103-era methods, with no indication in the record of which applies to which period. Organ dose estimates — the quantity that matters in dose reconstruction and in causation analysis — can differ materially between systems for the same physical exposure.

Recommendation. Amend § 20.2106 to require that the individual dose record identify the dosimetry method or system used to determine each dose of record, and that a licensee changing methods document the effective date of the change. This is a field, not a program. It costs almost nothing and it preserves the interpretability of the record for the several decades during which it will actually be used. ACOEM supports proposed § 20.1004(e)(3), which correctly isolates quantities derived using non-ICRP weighting factors from additivity with ICRP-based quantities.

Reasonable availability of incorporated material.

ACOEM notes that ANSI/ANS-6.1.1-2020 is available in read-only form only during the comment period, and otherwise costs \$97. 91 Fed. Reg. at 43487. Where a standard is incorporated by reference and becomes binding regulatory text, ACOEM encourages the NRC to secure continued no-cost read-only access after promulgation, consistent with the reasonable-availability obligations in 1 CFR part 51.

7. Single 10-Rem Design Basis Accident Acceptance Criterion

ACOEM opposes this provision. The proposal would replace the criteria derived from fractions of the 25 rem maximum hypothetical accident value — which the NRC has interpreted as 2.5 rem for "small fraction of" and 6.3 rem for "well within" — with a single 10 rem total effective dose equivalent criterion, applied at the exclusion area boundary and the low population zone. 91 Fed. Reg. at 43477. That is an increase of 1.6 to 4 times in the dose criterion applied to members of the public.

The stated rationale addresses the wrong endpoint.

The NRC supports the change with "the knowledge that deterministic health effects do not occur below 10 rem and that there is a reasonably [sic] likelihood that stochastic health effects below 10 rem have been overestimated." Id. The first clause is correct and not responsive: these criteria have never been about deterministic effects. They bound stochastic risk to an exposed population under postulated accident conditions. The second clause is a speculation that the NRC elsewhere in this same notice declines to act on, reaffirming the linear dose-response model and finding no regulation-ready alternative. A rationale the agency will not accept as a basis for changing dose limits should not be accepted as a basis for changing accident acceptance criteria.

The change eliminates the frequency-consequence balance the NRC describes.

The NRC explains that it has "historically assigned a lower dose-based criteria value (i.e., lower consequence) for accidents that are more likely to occur," in order to maintain the balance of the risk triplet. Id. Collapsing the graded criteria into a single value removes exactly that balance: the most frequent postulated events receive the largest relative increase in permitted consequence. If the NRC believes the graded structure is no longer warranted, it should explain why the risk-triplet reasoning that produced it is no longer sound.

The change is implemented through guidance not before the public.

The NRC states that it "would revise Table 7 in RG 1.183," and that this guidance "would be issued subsequent to this rulemaking." Id. As with the graded approach, the operative instrument is not available for comment, and ACOEM takes the same position: we cannot support a revision to Table 7 that has not been published, and we reserve our position on the revised criteria until they are issued for comment.

Recommendation. Retain acceptance criteria graded to the frequency of the postulated event, rather than a single value. If the NRC adopts a single criterion, it should explain why the risk-triplet reasoning that produced the graded structure is no longer sound and should issue the revised Table 7 of Regulatory Guide 1.183 for comment before the criterion is made operative.

8. Referenced Approvals for Respiratory Protection Devices and Assigned Protection Factors

ACOEM supports the concept and opposes the implementation. We agree that the NRC should not repeat a technical review it has already performed. The efficiency gain is real and the safety cost of eliminating duplicative review is low.

The proposal eliminates agency visibility, not just duplicative review.

Under proposed § 20.1703(b) and § 20.1705(c), a licensee may use non-NIOSH-certified equipment, or assigned protection factors exceeding those in Part 20, previously approved for a different licensee, provided the licensee "maintains an evaluation to demonstrate that the bases for the previous NRC approval—as documented in the applicable safety evaluation—are applicable to the licensee's facility," proposed § 20.1703(b), or, for higher assigned protection factors, that the bases for "the previous

Commission approval" are so applicable, proposed § 20.1705(c). 91 Fed. Reg. at 43496. No submission, no notification, and no concurrence is required. The NRC therefore will not know which licensees are operating under which referenced approvals until an inspection occurs.

Applicability is a facility-specific judgment. Whether an assigned protection factor is achieved in practice depends on the contaminant and its form, work rate and duration, the fit-testing program, the medical fitness determination required by § 20.1703(c)(5) and the fit testing required by § 20.1703(c)(6), maintenance and cartridge-change practice, and supervision. These are precisely the variables that differ between the referenced facility and the adopting one, and non-NIOSH devices and elevated protection factors are the categories in which residual risk is greatest.

Recommendation. Require written notification to the NRC before first use, identifying the referenced approval and certifying that the applicability evaluation has been completed, with the evaluation retained as a record subject to inspection. This preserves nearly all of the burden reduction while restoring the agency's ability to know where these devices and factors are in use.

Section 20.1702(b) should remain an affirmative requirement.

The proposal revises § 20.1702(b) by deleting a single word. The paragraph now reads "[i]f the licensee performs an ALARA analysis to determine whether or not respirators should be used"; as proposed it would read "[i]f the licensee performs an analysis." 91 Fed. Reg. at 43496. The analysis was already discretionary. What the amendment removes is the standard that governed the analysis when a licensee chose to perform one. ACOEM Recommends that ALARA be retained as that standard. If it is not retained, there should be an expressed standard. Where respirators are considered for use in lieu of engineering controls an analysis should be required. We recognize that the decision to impose respirator use involves a genuine trade-off: respirators impose physiologic burden, impair communication and vision, and require medical clearance, and in some circumstances the burden of respirator use exceeds the benefits of the dose averted. If it is determined that respirators impose too great a burden under specific circumstances, that is a judgment that should be made deliberately and documented, not left optional. The overall goal needs to remain the reduction of dose, preferably using ALARA.

The amendments leave the hierarchy of controls inconsistent on the face of Part 20.

The engineering-control hierarchy survives the amendments in form. What it loses is the standard that made it operative. Proposed § 20.1101(b) still requires the licensee to use "procedures, engineering controls, and a graded approach to dose management based upon sound radiation protection principles" — but only "to maintain occupational doses and doses to members of the public within the limits specified in this part." The current provision requires those controls to be used to the extent practical to achieve doses as low as is reasonably achievable. Under the proposed text, an engineering control is required only insofar as it is needed to stay under the limit. A licensee already below the limit without one is compliant.

The same standard is withdrawn at each remaining point in the hierarchy. Proposed § 20.1702(a) deletes the requirement that intakes be limited "consistent with maintaining the total effective dose equivalent ALARA," and proposed § 20.1702(b) strikes "ALARA" from the analysis of whether respirators should be used, leaving an analysis with no stated objective. Proposed § 20.1704(a) preserves the Commission's authority to limit substitution of respiratory protection for engineering controls but replaces the standard that authority served with the phrase "within the requirements of this part" — which is to say, with compliance itself. 91 Fed. Reg. at 43496. An authority to require more than the limit, measured against the limit, cannot reach conduct that already satisfies the limit.

Section 20.1701 is not amended. It will continue to require, in terms, that the licensee use process or other engineering controls to the extent practical to control airborne concentrations. The amended Part 20 will therefore retain a practicability standard for engineering controls against airborne radioactive material while withdrawing any comparable standard for external exposure and for the substitution of respiratory protection. ACOEM asks the NRC to state whether that asymmetry is intended.

The hierarchy of controls — elimination and substitution, then engineering controls, then administrative controls, with personal protective equipment last — is foundational to occupational health practice. ACOEM has consistently opposed regulatory structures that permit personal protective equipment (PPE) to substitute for feasible engineering and work-practice controls, most recently in its comments on OSHA's proposed lead standards. Assigned protection factors for PPE are established under controlled test conditions and are not reliably achieved in field use across a full shift. ACOEM recommends that, if the term ALARA is replaced (a proposition we do not support), proposed § 20.1101(b) retain a practicability standard parallel to the one § 20.1701 already carries; that proposed § 20.1702(a) retain an express requirement that intakes be limited beyond bare limit compliance; that proposed § 20.1702(b) restore the analysis as a requirement rather than a condition; and that proposed § 20.1704(a) be given a substantive standard, since an authority defined by reference to the requirements of the part cannot reach conduct that already satisfies them.

9. Revised Effluent Constraint from 10 to 25 Millirem per Year

ACOEM opposes this provision. The proposal raises the air emissions constraint in § 20.1101(d) from 10 mrem per year to 25 mrem per year, with corresponding changes to §§ 50.34a and 50.36a and Appendix I to Part 50.

The NRC's own risk arithmetic states the increment.

Applying the cancer risk coefficient of 5×10^{-4} per rem that the NRC uses, seventy years at 10 mrem per year yields an excess fatal cancer risk of 3.5×10^{-4} ; at 25 mrem per year, 8.7×10^{-4} . 91 Fed. Reg. at 43471. The increment is approximately 5×10^{-4} , or roughly one excess fatal cancer per two thousand persons so exposed. The NRC characterizes this as small by comparison to a 20 percent baseline. That comparison is not the relevant one for an involuntary environmental exposure conferring no benefit on the exposed individual, where risk levels on the order of 10^{-4} to 10^{-6} are conventionally treated as the range of acceptability.

The 10 mrem value is EPA's, set on a Clean Air Act record that is closed.

The 10 mrem per year figure in § 20.1101(d) did not originate with the NRC. EPA set it in 1989, in subpart I of 40 CFR part 61, as the Clean Air Act standard for radionuclide air emissions from facilities licensed by the NRC or an Agreement State and from non-DOE Federal facilities. 54 Fed. Reg. 51654 (Dec. 15, 1989). Subpart I imposed three requirements: an annual effective dose equivalent to any member of the public not exceeding 10 mrem; a separate limit of 3 mrem per year for emissions of iodine; and annual reporting to EPA by any facility whose emissions exceeded 10 percent of the standard, that is, 1 mrem per year. 40 CFR 61.102, 61.104(b).

Section 112(d)(9) of the Clean Air Act permits EPA to decline to regulate radionuclide emissions from NRC-licensed facilities where the Administrator determines, by rule and after consultation with the NRC, that the NRC's program provides an ample margin of safety to protect public health. EPA explained that

determination in the rules promulgating the radionuclide national emission standards. 54 Fed. Reg. 9612; 54 Fed. Reg. 51654. EPA made the determination for nuclear power reactors in 1995. 60 Fed. Reg. 46206 (Sept. 5, 1995). For the remaining NRC and Agreement State licensees, EPA reopened the comment period on its proposed rescission in September 1995 for the stated reason that the NRC had committed to propose a rule constraining air emissions from those licensees to a dose of no more than 10 mrem per year. 60 Fed. Reg. 50161 (Sept. 28, 1995). The NRC adopted that constraint on December 10, 1996, 61 Fed. Reg. 65120, and EPA rescinded subpart I as to those licensees twenty days later. 61 Fed. Reg. 68972 (Dec. 30, 1996). The NRC states the relationship plainly in this notice: in developing the air emissions constraint in § 20.1101(d), the NRC ensured that the value of that constraint would be such that the Administrator of EPA could determine that it provided an ample margin of safety, as section 112(d)(9) requires. 91 Fed. Reg. at 43470. The supporting record was empirical. EPA's studies covered air emissions from 412 NRC and Agreement State facilities and found that most did not result in doses exceeding 1 mrem per year, with a small percentage approaching but none exceeding 10 mrem per year. *Id.* The 10 mrem per year figure was therefore the express condition of the rescission, not an incidental feature of it.

Two consequences follow. First, of subpart I's three requirements, only the 10 mrem per year figure was carried into § 20.1101(d). The separate limit for iodine and the reporting threshold was not. This proposal raises the one value that was carried over, and pairs that increase with a reduction in reporting. Second, the constraint was adopted to implement the requirement this rulemaking removes. The NRC states in this notice that the effluent requirements, § 20.1101(d) among them, were added to ensure that radioactive effluents, and the resulting public doses, would be maintained consistent with the ALARA principle. 91 Fed. Reg. at 43470. The rule text says the same on its face, opening with the words "To implement the ALARA requirements of paragraph (b) of this section". 10 CFR 20.1101(d). This rulemaking deletes the ALARA requirement from § 20.1101(b) while raising the number in § 20.1101(d), and it deletes that lead-in as well. Proposed § 20.1101(d) opens instead, "Notwithstanding the requirements in § 20.1301 of this part." 91 Fed. Reg. at 43493. The constraint is thereby severed in the operative text from the purpose for which it was adopted and repositioned as an exception to the public dose limit. ACOEM asks the NRC to state on the record what purpose the constraint is now understood to serve, and what work the new "notwithstanding" clause is intended to do in relation to § 20.1301. Nothing in section 112(d)(9) obliges EPA to revisit a determination when the NRC changes the program on which that determination was premised. ACOEM therefore does not ask the NRC to seek a new determination from EPA, and our position does not depend on one. It rests on the 1989 record, which is closed and which supports the value now in the rule. A constraint of 25 mrem per year does not follow from that record; the proposed figure sits above the highest dose the record documents and is not appropriate.

Subpart I's separate limit for iodine has no counterpart in part 20.

Subpart I limited emissions of iodine separately, at an annual effective dose equivalent of 3 mrem, in addition to the 10 mrem limit applicable to all radionuclides together. 40 CFR 61.102. Section 20.1101(d) contains no equivalent sublimit. Against a 10 mrem constraint, the absence of one has modest practical consequence. Against a 25 mrem constraint, it has more. Medical licensees administering iodine-131 for thyroid carcinoma and hyperthyroidism are among the licensees to which § 20.1101(d) applies, and iodine is the emission for which subpart I set a separate and lower limit. If the NRC raises the general constraint, it should carry forward a sublimit for iodine consistent with the value EPA set.

The alternative-constraint provision states no numerical bound in the rule text.

ACOEM acknowledges that proposed § 20.1101(d) retains, without change, the requirement that a licensee exceeding the constraint "report the exceedance as provided in § 20.2203 and promptly take appropriate corrective action to ensure against recurrence." That duty is preserved in the rule text, and ACOEM supports its retention.

Our concern is with what the rule text adds. Proposed § 20.1101(d) permits a licensee or applicant to request prior NRC authorization to establish a higher constraint, subject only to the condition that the proposed constraint "provides an ample margin of safety to protect public health." Proposed § 20.1101(d), 91 Fed. Reg. at 43493-94. The preamble describes the operative mechanism more plainly: where a cost analysis shows corrective action is not justified, the licensee could propose a new constraint supporting continued operations in a cost-justified manner, subject only to the requirement that it be below the public dose limit. 91 Fed. Reg. at 43471. A constraint exists to preserve margin to the limit. A bound set at the limit itself is not a margin. A constraint that may be raised on a showing of cost, against a criterion the rule text does not quantify, does less of that work than one fixed in the regulation. Combined with the reporting structure, under which data below 25 mrem per year are retained and inspectable but not submitted, the agency's visibility declines as the permitted release increases.

Recommendation. Retain the 10 mrem per year constraint. That figure is EPA's, set in 1989 on a Clean Air Act record that is closed, and it is the value the NRC adopted in 1996, 61 Fed. Reg. 65120 (Dec. 10, 1996), to support EPA's determination that the NRC program provides an ample margin of safety. ACOEM does not ask the NRC to seek a new determination from EPA; section 112(d)(9) does not require one, and the adequacy of the existing constraint does not depend on one. Should the NRC nonetheless proceed with an increase, it should carry forward a separate sublimit for emissions of iodine consistent with the 3 mrem per year value in subpart I; state in rule text a numerical ceiling on any licensee-proposed alternative constraint, substantially below the public dose limit, rather than leaving the bound to the ample-margin criterion alone; and retain annual reporting to the NRC regardless of the constraint in use. ACOEM supports retention of the prompt corrective-action obligation in proposed § 20.1101(d) without regard to the value ultimately adopted.

Additional Comment A: The Occupational Dose Limit for the Lens of the Eye

ACOEM recommends that the NRC adopt the reduced occupational lens dose limit recommended in NCRP Commentary No. 26, expressed as an absorbed dose, and retain an affirmative obligation to manage lens dose below the limit.

This is the one area in which the notice's own record supports a change in the direction of greater protection, and the rule declines to make it. ACOEM raises it because the affected populations, principally interventional cardiology and interventional radiology staff, nuclear medicine personnel, and industrial radiographers, are cared for by ACOEM members, and because radiation cataract is a clinically consequential outcome that is monitored, if at all, in occupational health practice.

The notice's conclusions about the lens are in tension

The notice proposes to delete cataracts from the examples of a nonstochastic effect in § 20.1003 and records the NCRP observation that vision-impairing cataracts might be better characterized as a

stochastic effect than as a tissue reaction. In the same document it declines to reduce the lens limit, characterizing the supporting findings as preliminary. If the effect is stochastic, then by the notice's own framework there is no threshold below which it does not occur, and the case for managing lens dose below the limit is stronger rather than weaker. The rule simultaneously removes the ALARA obligation under which lens dose below the limit has been managed. The three positions are contradictory.

The threshold comparison in the notice compares unlike quantities

The notice reasons that the current annual limit is already less than half of the 50 rad (0.5 Gy) nominal threshold identified in ICRP Publication 118. That comparison sets an annual limit against a threshold for a chronic or cumulative exposure. A worker at the current annual limit of 15 rem accrues 150 rem over ten years, three times the nominal threshold. For the low linear energy transfer fields in which the annual limit ordinarily governs, the absorbed and equivalent dose quantities are numerically equal, so the comparison is not an artifact of units. An annual limit set at less than half a cumulative threshold provides no margin at all against a cumulative effect.

Two characterizations of NCRP Commentary No. 26 require correction

First, NCRP Commentary No. 26 recommends reducing the annual occupational lens limit from an equivalent dose of 150 mSv to an absorbed dose of 50 mGy. The change of quantity was deliberate. NCRP now recommends the use of absorbed dose, in milligrays, when addressing tissue reactions, and pairs the recommendation with the use of a relative biological effectiveness value for high linear energy transfer radiation. The notice renders the recommendation as a change from 15 rem/year (150 mSv/year) to 5 rem/year (50 mSv/year), expressed throughout in equivalent dose. That is not what NCRP recommended. The difference is immaterial in a pure photon field and material in mixed or high linear energy transfer fields, which is precisely where the quantity chosen determines the answer. ACOEM notes that NCRP carried the change forward into NCRP Report No. 180, the report on which the notice relies elsewhere in this rulemaking, adopting 50 mGy per year absorbed dose for workers and 15 mGy per year absorbed dose for members of the public, in each case replacing an equivalent dose value, and specifying that for high linear energy transfer radiation the quantity is a radiation-weighted absorbed dose using the biological effectiveness values of NCRP Report No. 132 rather than radiation weighting factors.

Second, the notice states that the NCRP recommendation aligns with international recommendations, including those from the ICRP. The ICRP recommends an equivalent dose limit for the lens of 20 mSv per year averaged over defined five-year periods, with no single year exceeding 50 mSv. The NCRP value of 50 mGy per year is materially less restrictive than the ICRP value. The two should not be described as aligned, and the final rule should state each accurately.

Recommendation. ACOEM recommends that the NRC adopt the NCRP Commentary No. 26 value, expressed as absorbed dose; that it require monitoring in the operational quantity appropriate to the lens where lens dose may approach a substantial fraction of the limit, rather than inferring lens dose from whole-body dosimetry placed elsewhere on the body; that any dose-management obligation retained or created by this rulemaking apply expressly to the lens; and that the lens ceiling in proposed § 20.1205(d)(3) be conformed to whatever limit is adopted.

Additional Comment B: The Caregiver Framework in 10 CFR Parts 20 and 35

ACOEM supports establishing a defined pathway for caregivers of patients administered radioactive material. ACOEM asks that the released-patient caregiver value be stated as an express limit in the regulatory text, that it be set materially below the occupational dose limit, and that the final rule provide for cumulative accounting across regimens and across the pre-release and post-release periods, for caregivers who are or may be pregnant, and for retention of the dose evaluation.

The proposal establishes two caregiver pathways, in two parts, for two different patient states. For a patient who cannot be released, proposed § 20.1301(c)(1) would permit a member of the public who is not a caregiver to receive up to 0.5 rem, and a caregiver as defined in 10 CFR part 35 to receive up to 2 rem, in each case per administration regimen, subject to a determination by the authorized user before the visit that the visit is appropriate. That value codifies the exemption practice described in RIS 2006-18. For a released patient, proposed § 35.75(b) addresses the caregiver separately, and the treatment there is new.

The released-patient caregiver value does not appear in the regulatory text

Proposed § 35.75(b)(1) requires written consent from the released individual and, where applicable, the caregiver, and requires that both be instructed on the radiation risks to the caregiver and on methods to manage that exposure, if the total effective dose equivalent to the caregiver is likely to exceed 0.5 rem and is not likely to exceed 5 rem per patient administration regimen. In the preamble the NRC describes this change as allowing a consenting caregiver to receive up to 5 rem, which it identifies as the occupational dose limit of § 20.1201. The regulatory text does not say that.

Paragraph (b)(2) states a ceiling in the conventional form: dose to any other individual who is not a caregiver is not likely to exceed 0.5 rem per administration regimen. Paragraph (b)(1) states no caregiver ceiling at all. It conditions the consent and instruction requirement on the projected dose falling within a band, with the consequence that a caregiver dose likely to exceed 5 rem falls outside the condition, triggers no instruction obligation, and encounters no prohibition on release. Paragraph (c) then requires instructions sufficient to maintain doses below the limits in paragraphs (b)(1) and (b)(2), treating paragraph (b)(1) as containing a limit that it does not contain.

ACOEM's first recommendation on this provision is therefore a drafting matter rather than a policy disagreement. Whatever caregiver value the NRC adopts should appear in the operative text as an express limit, in the same form as paragraph (b)(2). A ceiling that exists only in the preamble is not enforceable, and it is not available to the caregiver, the licensee, or the Agreement State regulator who reads the rule.

ACOEM supports the concept of a defined caregiver pathway. Caregivers receive dose, and an exemption process ill-suited to household caregiving serves no one. ACOEM also supports the consent and instruction requirements in § 35.75(b)(1), which it would otherwise have recommended. The objections that follow concern the magnitude of the released-patient value, the absence of aggregation, the absence of any provision for pregnancy, and the loss of the record.

The value the NRC intends places an untrained household member at the occupational dose limit

A caregiver is not an occupationally exposed individual. Caregivers receive no radiation worker training, no individual monitoring, no medical surveillance, and no periodic dose accounting. The occupational limit was derived from an occupational risk comparison among adults in monitored employment, with a program of controls, records, and oversight attached to it. Applying the same number to an unmonitored, untrained, self-selected household member takes the value and leaves the basis behind. The consensus bodies have already set a figure, and it is not this one. NCRP Report No. 180, on which the notice relies elsewhere in this rulemaking, places comforters and caregivers within the medical exposure category rather than the occupational category and recommends an effective dose not exceeding 5 mSv, that is 0.5 rem, per episode for a caregiver aged 18 or over. ICRP Publication 103 recommends the same value. The 2 rem value in § 20.1301(c) reflects a judgment the NRC has already made and defended, and the notice offers no basis for the released-patient value being two and one-half times higher again.

The NCRP unit of account is the episode, and it spans exactly what the proposal separates

The comparison is closer than the numbers alone suggest, because NCRP defines the denominator to cover the whole course of care. An episode, as NCRP uses the term, comprises the dose a caregiver receives from visits to or stays at the medical facility during the patient's diagnosis and treatment together with the dose received at home after the patient is discharged. That is precisely the span the proposal divides between § 20.1301(c) and § 35.75 and expressly declines to aggregate. Measured on the unit NCRP uses, a single caregiver attending one patient through one administration regimen could receive up to 7 rem where NCRP recommends 0.5 rem, a factor of fourteen.

ACOEM notes that NCRP designates this figure a numeric protection criterion rather than a value suitable for use as a regulatory dose limit, on the ground that the source is neither stable nor subject to an advance control program. That distinction does not favor the proposal. It means NCRP regards 0.5 rem per episode as the value toward which a caregiver's dose should be managed under optimization, in a setting NCRP considers unsuited to a fixed limit at all. The NRC proposes a fixed allowance an order of magnitude higher in that same setting, while withdrawing the optimization requirement that would otherwise operate beneath it.

There is no cumulative accounting across regimens

Both values are expressed per administration regimen, and the proposed definition of administration regimen in § 35.2 is the course of administrations of a given radiopharmaceutical or brachytherapy source as intended by the authorized user. A patient may undergo successive regimens, and radiopharmaceutical therapy is increasingly delivered in repeat courses and across sequential agents. The same spouse or parent is likely to serve as caregiver each time. Nothing in the proposal aggregates caregiver dose across regimens, across agents, or across a calendar year. A caregiver could receive the occupational limit more than once in a year without any provision being exceeded.

The two pathways also do not aggregate with one another. The notice states that caregiver doses received before the patient's release do not contribute to the 5 rem allowed under § 35.75 following release. A caregiver who attends a patient during hospitalization and then continues at home may therefore receive 2 rem under § 20.1301(c)(1)(ii) and a further 5 rem under § 35.75 within a single administration regimen, with the agency stating expressly that the two do not combine.

ACOEM notes that the shift from a per-administration to a per-regimen basis is, for members of the public, more restrictive rather than less, since a regimen may comprise several administrations. The gap is not the denominator. It is the absence of any ceiling above the denominator.

There is no provision for a caregiver who is or may be pregnant

The proposed definition of caregiver in § 35.2 is an adult, which excludes minors from the caregiver role. This is insufficient. NCRP Report No. 180 does not exclude minors; it recommends a separate and lower criterion of 1 mSv, that is 0.1 rem, per episode for a caregiver under 18. Under the proposal a minor in the household is not a caregiver and therefore falls to the non-caregiver value in § 35.75(b)(2), which is 0.5 rem, or 5 mSv, per administration regimen. That is five times the value NCRP recommends for a minor who is actually providing care, and it applies without consent, instruction, or any determination that the arrangement is appropriate. Defining minors out of the caregiver category does not remove them from the household.

Neither the definition nor § 35.75(b) addresses pregnancy. For a worker, § 20.1208 limits the dose to the embryo or fetus of a declared pregnant woman to 500 mrem over the entire pregnancy. A pregnant spouse serving as a caregiver under § 35.75(b) is subject to no stated ceiling in the operative text and, on the value the NRC intends, to ten times the § 20.1208 figure per regimen, with no counseling requirement directed to pregnancy and no lower value. ACOEM regards this as a significant gap in the framework.

The record of the dose is not retained

Proposed § 35.2075 would be republished to retain only the written release procedure. ACOEM notes that the existing requirement is narrower than it may appear: current § 35.2075(a) obliges a licensee to retain the basis for authorizing a release only where the dose was calculated using retained rather than administered activity, an occupancy factor below 0.25 at one meter, the biological or effective half-life, or shielding by tissue. Those are, however, precisely the calculations that are least conservative and most dependent on assumptions, and they are the cases in which a retained basis matters most. The proposal removes the requirement in all of them. It also deletes current § 35.2075(b), the record that instructions were provided to a breastfeeding patient.

Proposed § 20.2107(c) requires a record of the justification for a caregiver dose under § 20.1301(c)(1)(ii), retained for three years, but that provision reaches only the non-releasable patient case at 2 rem. The larger released-patient dose would generate no retained record of the estimate. A caregiver who later develops a relevant condition, or who serves across successive regimens, has no dose history and no means of constructing one.

Recommendation. ACOEM recommends that the final rule: (i) state the released-patient caregiver value as an express limit in the operative text of § 35.75(b), in the same form as paragraph (b)(2); (ii) set that value materially below the occupational limit, and explain any departure from the 0.5 rem per episode recommended by both NCRP Report No. 180 and ICRP Publication 103; (iii) provide a cumulative ceiling that aggregates caregiver dose across administration regimens, across agents, and across the pre-release and post-release periods for the same regimen; (iv) establish a substantially lower value for a caregiver who is or may be pregnant, with counseling offered before consent is obtained, and require that the consent process under § 35.75(b)(1) address pregnancy expressly; (v) require that the

estimated caregiver dose be recorded and retained, on the model of proposed § 20.2107(c) and (d), for both the released and non-released cases, and retain the record required by current § 35.2075(b); and (vi) require that the written instructions under § 35.75(c) address dose-reduction practices in the home and identify a knowledgeable person the caregiver may contact with questions.

Responses to the NRC's Specific Requests for Comments (Section V)

ACOEM responds to each of the six questions below. The supporting rationale appears in the corresponding provision sections above.

Question 1 — Higher dose limits for members of the public accessing the controlled area.

(A)(i) A performance-based method may be acceptable as a supplement, but not as the sole justification. Any such method should rest on measured occupancy and measured area dose rates rather than assumed values and should be verified by area monitoring after authorization rather than only at application. (ii) The NRC should require the applicant to carry the burden of demonstrating that the affected individuals will not exceed the generally applicable limit, using site-specific occupancy data and habit assumptions that are representative rather than favorable. (iii) Health risk should be dispositive, not one factor among many. Undue hardship, cost, energy reliability, and national security are legitimate considerations in siting and licensing generally, but they are not health-protective factors and should not be weighed against dose received by an identified individual in a determination of adequate protection. ACOEM specifically opposes prioritizing them alongside health risk in this determination. (iv) Posting alone is not sufficient where the authorized dose exceeds the general public limit. ACOEM recommends access control, an instruction analogous in content to § 19.12, area monitoring, an occupancy log, and express exclusion of minors, pregnant individuals, and nursing individuals from the affected areas. Transient workers who are not the licensee's employees should be treated as workers for training and monitoring purposes if their expected dose approaches the occupational monitoring criterion.

(B) ACOEM opposes a generic increase to the annual public dose limit within the controlled area. Implementation through a licensee's radiation protection program subject to inspection is not an adequate substitute for prior authorization, because it removes the case-specific evaluation that is the only justification the NRC offers for the higher limit. If the NRC nonetheless proceeds, ACOEM does not support any value above the present 100 mrem per year for individuals who are not monitored, trained, or dose-tracked.

Question 2 — Benefits and drawbacks of higher public dose limits.

ACOEM is not positioned to quantify design or construction benefits and does not attempt to. We observe that the benefits identified by the NRC — simplified design, reduced construction cost, operational efficiency — accrue to the applicant, while the drawbacks accrue to individuals who are not parties to the licensing action. Where benefits and burdens fall on different parties, the burden of demonstration properly rests with the party receiving the benefit, and the demonstration should be specific rather than categorical.

Question 3 — Case-by-case higher public dose limits under § 20.1301(d).

(A) The factors should be limited to those bearing on dose and its control: the magnitude and duration of the proposed exposure, the size and composition of the affected population, the

reliability of the dose control measures, and the availability of alternatives. As above, ACOEM opposes weighing cost, energy reliability, or national security against individual dose in this determination.

- (B) Yes. Three scientific considerations bear directly. First, the NRC has reaffirmed in this notice that no threshold has been established for stochastic effects; there is therefore no dose above which the incremental risk becomes categorically acceptable, only a judgment about magnitude. Second, because stochastic risk aggregates across the exposed population, the size of that population is a determinant of collective detriment and should be an explicit element of the analysis — as the NRC itself recognizes at 91 Fed. Reg. at 43473. Third, the tissue weighting factors underlying effective dose are derived for a reference population of both sexes across a wide age range; children are more radiosensitive than that reference for several relevant sites, and an authorization affecting a population with meaningful pediatric presence should account for that rather than rely on the reference values.
- (C) Flexibility should be bounded in rule text by a numerical ceiling and by a stated maximum duration, with renewal requiring fresh demonstration. ACOEM is not aware of a practical use case that requires an unbounded limit; a bounded one preserves the flexibility the NRC seeks while retaining a floor of protection.

Question 4 — Per-regimen versus per-administration basis for patient release.

For members of the public who are not caregivers, ACOEM recommends retaining the per-administration basis. The per-regimen basis is a real simplification for multi-administration protocols, but applied to bystanders it permits accumulation across administrations with no individual accounting. For designated caregivers, ACOEM could support a per-regimen basis if, and only if, it is paired with a cumulative ceiling across regimens within a defined period and with retention of the individual dose evaluation under § 35.2075. We do not believe retaining that record creates a barrier to treatment access; it is a calculation the licensee already performs to authorize the release, and the only change is whether it is retained.

Question 5 — Alternative approaches to the effluent constraint and reporting.

ACOEM's strongly recommends retaining the 10 mrem per year constraint. Of the alternatives the NRC identifies, increasing the constraint while retaining existing reporting practices is preferable to the proposal, because it does not compound a numerical relaxation with a reduction in agency visibility. The least defensible combination is the one proposed: a higher constraint, a licensee-adjustable constraint above it, and reduced reporting below it.

Question 6 — Whether the public dose limit in § 20.1301(a) should be increased.

No. ACOEM does not support any increase to the 100 mrem per year public dose limit, and we note that the NRC does not propose one. The technical basis runs the other way. The most recent international worker cohort data estimate an excess relative rate of solid cancer mortality of 52 percent per gray at protracted low dose rates, with the association approximately doubling when restricted to the 0-100 mGy range. Richardson DB, et al. BMJ. 2023;382:e074520. The systematic bias assessment and meta-analysis published as part of the same monograph the NRC cites in this notice concluded that, after excluding studies potentially biased away from the null, the majority of remaining studies still reported

positive risk estimates, and that these studies directly support excess cancer risk from low-dose ionizing radiation at magnitudes statistically compatible with the atomic bomb survivor data. Hauptmann M, Daniels RD, Cardis E, et al. Epidemiological studies of low-dose ionizing radiation and cancer: summary bias assessment and meta-analysis. JNCI Monogr. 2020;2020(56):188-200. ACOEM notes that the NRC cites Gilbert et al. from this monograph, 91 Fed. Reg. at 43489, but does not address the monograph's summary conclusion. We respectfully suggest the final rule engage with it.

Agreement State Compatibility (Section XV)

The NRC invites comment on the compatibility category designations. 91 Fed. Reg. at 43488. ACOEM offers one observation that we believe has received insufficient attention.

Several provisions central to this rulemaking are proposed to move into categories that require Agreement State provisions to be essentially identical to the NRC's: § 20.1101(b) from Category H&S to Category A; § 20.1101(d) from Category C to Category A; § 20.1301(d) from Category C to Category A; new § 20.1205 to Category A; and § 35.75(b), together with the new definitions of "caregiver" and "administration regimen," to Category B. Under Category C, an Agreement State program must embody the essential objectives of the NRC provision but may be more restrictive. Under Categories A and B it may not.

The practical consequence is that a State could not retain an ALARA requirement, could not retain a ceiling on authorized public dose, and could not retain a lower caregiver dose allowance, even if its own legislature or radiation control program concluded that doing so was warranted for its population. The NRC states this outcome directly with respect to ALARA: Agreement States "would be required to revise their equivalent 10 CFR 20.1101(b) regulation to be essentially identical to the NRC's and remove the ALARA requirement," and would also remove ALARA references from equivalent regulations. Id. at 43481.

A deregulatory judgment by the NRC is one thing. Converting that judgment into a national ceiling on protection that the States may not exceed is a different and larger step, and the notice does not explain why uniformity requires it here. The Agreement States regulate the majority of materials licensees in this country, including the medical licensees to whom the caregiver provisions apply. ACOEM recommends that § 20.1101(b), § 20.1101(d), and § 20.1301(d) retain Category C designation, which preserves national coherence in essential objectives while allowing a State to be more protective.

Procedural Requests

Extension and reopening of the comment period.

Republication of the operative provisions with their implementing guidance.

The operative content of Provisions 1 and 7 is not in this notice. The thresholds, the dose management actions, and the cost-basis criterion that constitute the graded approach to dose management, and the revised Table 7 of Regulatory Guide 1.183 that carries the 10 rem design-basis accident acceptance criterion, are each deferred to guidance the NRC has stated will issue after this rulemaking. ACOEM therefore requests, in the alternative to the extension sought above, that the NRC republish those provisions for comment together with the guidance that supplies their substance, or place the thresholds and the decision criterion in the regulatory text where they are subject to notice and comment. ACOEM does not ask the Commission to delay the provisions it has published in full. We ask

only that the two provisions whose substance is unwritten not be made final on a record that does not contain them.

ACOEM respectfully requests a 60-day extension of the comment period. The notice spans 49 pages of the Federal Register, amends ten parts of Title 10, was published with three draft guidance documents for concurrent comment, and provides 47 days for response. Those three are DG-8063, proposed Revision 3 to Regulatory Guide 8.18, on radiation dose management at medical institutions; DG-8064, proposed Revision 1 to Regulatory Guide 8.37, on effluent release programs at materials facilities; and DG-8067, proposed Revision 2 to Regulatory Guide 8.31, on radiation protection programs at uranium recovery facilities. None of the three is the graded-approach guidance that carries the operative content of Provision 1, and none is the revised Table 7 of RG 1.183 that carries the operative content of Provision 7. Nor is DG-8061, the proposed Revision 2 to Regulatory Guide 8.39, on which the preamble relies for the occupancy assumptions underlying the caregiver dose values addressed in Provision 5; it is cited at 91 Fed. Reg. at 43475 but does not appear among the guidance documents issued with this notice. More importantly, the operative content of two major provisions — the graded approach thresholds and cost criterion, and the revised Table 7 of RG 1.183 — is expressly deferred to a second phase of guidance that will issue after the comment period closes. Commenters cannot evaluate a requirement whose substance has not been written. ACOEM also notes that the notice provides for a public meeting to be announced on the NRC's website within ten calendar days of the meeting, *id.* at 43457, which leaves open the possibility that the meeting will occur at or after the close of the comment period. An extension would allow the public meeting to inform the comments it is presumably intended to inform. ACOEM therefore also requests a reopening of the comment period once the deferred guidance has been issued.

Sequencing, the deferred cost basis, and overlapping proceedings.

Three features of the NRC's own published rulemaking schedule bear on the requests above. All three are drawn from the agency's active rulemaking data, accessed August 5, 2026.

First, the agency lists the target final rule publication date for this proceeding as December 31, 2026, approximately four months after this comment period closes. The graded-approach guidance that carries the operative content of Provision 1, and the revised Table 7 of RG 1.183 that carries the operative content of Provision 7, are both deferred to a second phase of guidance issuing after this rulemaking. On the schedule the agency has published, that guidance would follow the final rule rather than precede it. ACOEM asks the NRC to take no action on this rulemaking until the graded-approach guidance has been published and an appropriate comment period provided.

Second, the single objective criterion in the graded approach is a dollar-per-person-rem cost basis, and the derivation of that value is itself the subject of a separate open proceeding. "Cost-Benefit Analysis for Power Reactor Radwaste Systems," Docket NRC-2022-0048, RIN 3150-AK75, would replace the fixed dollar value in Appendix I to 10 CFR part 50 with a requirement to calculate and use an updated conversion factor, with a proposed rule listed for November 2026. This rulemaking also amends Appendix I. A requirement whose only objective criterion is a monetary value should not be finalized while the derivation of that value is under revision in another docket.

Third, and most consequentially, the Part 35 provisions this letter addresses are simultaneously before the agency in a second proceeding, and the two do not account for one another. Part 20 is also within the scope of "Regulatory Enhancements for Reactor Licensing, Decommissioning, and Operational Oversight," Docket NRC-2025-1138, RIN 3150-AL45. More directly, "Reducing Barriers to Medical Use Licensing," Docket NRC-2025-1237, RIN 3150-AL50, was published at 91 Fed. Reg. 47042 on July 27, 2026, twelve days after this notice, with a comment period closing September 10, 2026, ten days after this one closes.

That proceeding would add a new § 35.76, "Safety precautions for individuals not eligible for release under § 35.75," consolidating into subpart C precautions that now sit in modality-specific sections. 91 Fed. Reg. at 47089. In the same proceeding § 35.315 would be removed and reserved, id. at 47090, and § 35.415 would be narrowed to the requirement that emergency response equipment be available near each treatment room, id. at 47093. That new section is built on the provisions this rulemaking would rewrite. Its subject is the patient who cannot be released under § 35.75, and the companion provision at proposed § 35.710(d)(2) keys visitor control expressly to § 20.1301(a)(1) and to visitation authorized under § 20.1301(c). Id. at 47097. Paragraph (c) of § 20.1301 is the same paragraph this rulemaking would rewrite to establish the caregiver dose values addressed in Provision 5 above. The medical use proceeding was drafted against the current text of that paragraph.

The consequence for a commenter is concrete. ACOEM must state its position on the caregiver dose values in § 20.1301(c) and § 35.75 by August 31, while the framework that will govern how those individuals are handled at the bedside remains open for comment until September 10 in a docket that assumes the current values. The medical use notice does not reference this proceeding, its docket, or its regulation identifier number at any point, including in its discussion of the cumulative effects of regulation. ACOEM asks the NRC to address the interaction on the record of both dockets and, at minimum, to align the two comment periods so that the public may comment on the combined effect rather than on each provision in isolation. A licensee, and a physician advising one, will have to comply with the result of both at the same time.

Information collection comments.

ACOEM notes that comments on the information collections under the Paperwork Reduction Act are due August 14, 2026 — earlier than the comment period on the rule itself. 91 Fed. Reg. at 43480. To the extent our comments on proposed § 20.2106(a)(7), § 20.2203, § 35.2075, and § 20.2107 bear on the information collections, we ask that they be considered for that purpose as well. We further observe that the burden table reports zero annual burden hours for Parts 50 and 72 while reporting 300 and 170 annual responses respectively. 91 Fed. Reg. at 43479. That appears to be an error, and it should be corrected before the estimates are relied upon.

Conclusion

ACOEM supports a radiation protection framework that is clear, objective, and current. Several elements of this proposal advance that goal, and we say so above without qualification. But the rule as a whole reduces protection for workers, for caregivers, and for members of the public on a scientific record that the NRC itself describes as supporting the opposite conclusion. Where the record does clearly support a change — reducing the occupational dose limit for the lens of the eye — the proposal declines to make it.

We appreciate the Commission's consideration of these comments. ACOEM and its members are available to serve as a resource to the NRC on the occupational and environmental medicine aspects of this rulemaking, including the medical surveillance, worker notification, and dose reconstruction issues discussed above. Please contact Julie Ording, MPH, Director of Scientific Affairs, at (224) 265-6782 with any questions.

Sincerely,

A handwritten signature in black ink that reads "Jill Rosenthal". The signature is written in a cursive, flowing style.

Jill Rosenthal, MD, MPH, MA, MSQM, FACOEM
President, ACOEM