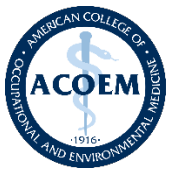

AMERICAN COLLEGE OF
OCCUPATIONAL AND
ENVIRONMENTAL MEDICINE

Submitted electronically via www.regulations.gov

August 28, 2026

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, "Reducing Barriers to Medical Use Licensing"

Docket ID NRC-2025-1237; RIN 3150-AL50; 91 Fed. Reg. 47042 (July 27, 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 Reducing Barriers to Medical Use Licensing. 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). The NRC has proposed five rulemakings related to Executive Order 14300 "Ordering the Reform of the Nuclear Regulatory Commission." ACOEM has submitted extensive comments 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). Since there is an interconnection between that proposed rule and this one, we are submitting our response to this docket regarding the caregiver framework, which also appears in our response to Docket ID NRC-2025-1140. Our response to the question on agreement state compatibility (Docket ID NRC-2025-1140 Section XV) is also relevant here as it also addresses the intersection of 10 CFR Parts 20 and 35.

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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.

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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

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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-

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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.

(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.

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.

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ACOEM respectfully requests a 60-day extension of the comment period. The notice for Docket ID NRC-2025-1140 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. The notice for this docket runs 59 pages. Both were published as part of three draft guidance documents for concurrent comment.

ACOEM also requests a reopening of the comments period once the deferred elements, including 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 and the criterion that a licensee may decline a dose-reduction measure costing more than a "reasonably calculated cost-basis of an averted person-rem". 91 Fed. Reg. at 43469.

Sequencing, the deferred cost basis, and overlapping proceedings.
The Part 35 provisions this letter addresses are simultaneously before the agency in a second proceeding, "Reforming and Modernizing the NRC's Radiation Protection Framework" Docket ID NRC-2025-1140; RIN 3150-AL47; 91 Fed. Reg. 43456 and the two do not account for one another.
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 extend and 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.

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Conclusion
ACOEM supports a radiation protection framework that is clear, objective, and current, along with reducing barriers to medical use licensing when that is appropriate. But the proposed rules 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.

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,

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

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