American College of Radiology™

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U.S. Nuclear Regulatory Commission
One White Flint North
11555 Rockville Pike
Rockville, MD 20852-2738

RE: (Docket ID: NRC-2025-1140) Reforming and Modernizing the NRC's Radiation Protection Framework

The American College of Radiology (ACR)—a professional association representing more than 40,000 physicians practicing diagnostic radiology, interventional radiology, radiation oncology, and nuclear medicine, as well as medical physicists—appreciates the opportunity to comment on the U.S. Nuclear Regulatory Commission's (NRC) proposed rule (NPRM), *Reforming and Modernizing the NRC's Radiation Protection Framework* (NRC-2025-1140), published in the July 15, 2026, *Federal Register*.

Radiation safety principles are fundamental to the medical use of radiation in diagnostic and interventional radiology, radiation oncology, nuclear medicine, and the practice of medical physics. Improving the health of patients and ensuring their safety and that of medical professionals and members of the public are among ACR's highest priorities. NRC's role is to regulate the safe use of byproduct material by medical licensees (and not the practice of medicine). To achieve these goals, access to critical health care services must be maintained. In addition, any radiation protection policy must consider the need to reassure the general public and non-radiation trained healthcare providers and alleviate their reservations or fears regarding the medical use of radiation.

General Comments

10 CFR Chapter 1, Nuclear Regulatory Commission – Removal of "ALARA"

NRC Proposal: *References to "As Low As Reasonably Achievable (ALARA)" would be substituted with a graded approach to dose management, defined in 10 CFR 1.2 as "an approach whereby progressively increasing radiation protection measures are required as prospective, or actual, radiation doses exceed determinate dose thresholds to provide reasonable assurance that the applicable regulatory limit is not exceeded." Additionally, NRC proposes that these changes would not affect current licensees who desire to continue using their existing ALARA-based programs.*

ACR Comments: ACR remains committed to the longstanding principles of radiation protection and dose optimization for patients, workers, caregivers, and the public. This guiding principle is not in conflict with the rubric denoted by operative regulations. While the NRC proposes to replace ALARA-based regulatory requirements with a graded approach to dose management, we believe medical practice will continue to be guided by an underlying philosophy of minimizing unnecessary radiation exposure consistent with achieving the intended clinical or operational objective. These principles are reflected in professional society guidance and initiatives such as the Image Wisely® and Image Gently® programs developed by the ACR, as well as in clinical quality and safety programs throughout the imaging and radiation medicine communities.

Additionally, ACR supports NRC's stated objective of ensuring that licensees currently operating under ALARA-based requirements and guidance are not required to substantially revise existing radiation safety programs due to NRC's proposed transition to a graded approach to dose management.

10 CFR Part 35

10 CFR 35.2, Definitions

NRC Proposal: *New definitions would be added to 10 CFR Part 35 to support related proposals. "Administration regimen" would be defined as the course of administrations of a given radiopharmaceutical or brachytherapy source as intended by the authorized user. "Caregiver" would be defined as an adult who provides the patient with support or comfort for non-commercial gains following administration of byproduct material.*

ACR Comments:

***Administration regimen definition*:** ACR opposes the use of "administration regimen" in NRC regulations. Even as defined by NRC, this concept would be unclear in real-world medical practices and does not account for intended regimen modifications or changes in caregiver(s). We recognize that Draft Regulatory Guide DG-8070, *Release of Patients Administered Radioactive Material,* provides additional context for this definition, but we do not believe this sufficiently addresses the clarity concerns. Critical context should be included in the regulatory language to ensure consistent Agreement State and licensee implementation. If the NRC chooses to finalize the administration regimen proposal despite opposition, ACR recommends that the agency consider defining the term "expected administration regimen" instead. This would allow greater flexibility for unanticipated changes in treatment. Additional rationale for ACR's opposition is discussed in the subsections of this comment letter related to patient dose to caregivers and other members of the public.

Caregiver definition: ACR generally supports the definition of "caregiver," and understands this concept is intended by NRC to delineate such an individual from children or other members of the household as well as healthcare workers within the licensed facility. We agree with the NRC's justification that a caregiver - such as a spouse, other family member, or friend - provides emotional and logistical support to the patient. For example, caregivers can enable patients' access to and from the treatment location and assist with patients' understanding of instructions.

10 CFR 35.75, Release of individuals containing byproduct material

NRC Proposal: *NRC proposes extensive modifications to patient release criteria. NRC proposes to allow a consenting caregiver who has been educated on the risks of radiation exposure to receive up to 50 mSv (5 rem) per patient administration regimen. The limit for non-caregiver members of the public would remain 5 mSv (0.5 rem). However, the licensee must obtain written consent from the released individual, or parent/guardian or caregiver, and instructions must be provided on radiation risk and management if caregiver dose is likely to exceed 5 mSv (0.5 rem) but remain lower than 50 mSv (5 rem). Patients must continue to be provided release instructions if the dose to another member of the public is likely to exceed 1 mSv (0.1 rem), as well as special instructions specific to nursing mothers and discontinuation/interruption of breastfeeding.*

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ACR Comments:

***Caregiver/released patient*:** ACR supports caregiver dose limits aligned with occupational dose limits, as this would simplify and provide flexibility in patient release determinations by licensees, while enabling the benefits described in ACR's comments on the §35.2 "caregiver" definition proposal.

***Written consent*:** ACR opposes the proposed §35.75(b)(1) "written consent" related requirements, which the NPRM suggests would not be limited to administrations exceeding 5 mSv (0.5 rem). If finalized, such a proposal would create undue compliance and documentation burdens without a risk-based rationale. This new burden would be in direct conflict with NRC's stated goal of ensuring that existing compliance approaches would be interoperable with the proposed changes.

If mandatory written release consent is maintained in the final rule despite opposition, ACR then recommends §35.75(b)(1) be limited exclusively to scenarios in which caregiver dose would likely exceed the non-caregiver public dose limit of 5 mSv (0.5 rem). This would align with the NRC's intent to only require written consent in situations in which a released individual chooses the caregiver pathway, as stated during the August 17, 2026, meeting of the Advisory Committee on the Medical Use of Isotopes (ACMUI). Moreover, NRC should clarify the minimum data elements contained in the authorization as well as acceptable methods (including retention periods) of documenting compliance.

To clarify the written consent requirements, ACR offers the following recommended regulatory language:

§35.75: Release of individuals containing byproduct material.

(b) A licensee may authorize the release from its control of any individual who has been administered byproduct material if –

> *(1) in the case that the released individual identifies a caregiver as defined in* § 35.2*, and the total effective dose equivalent to the caregiver is likely to exceed 5mSv (0.5 rem) and is not likely to exceed 50 mSv (5 rem);*
>
> > *(i) the licensee has obtained written consent from the released individual and the released individual's caregiver, or, as necessary, the released individual's parent or guardian prior to treatment administration; and*
> > *(ii) the released individual's caregiver has been instructed on the radiation risks to the caregiver and methods to manage exposure to the caregiver if the total effective dose equivalent to the caregiver is likely to exceed 5mSv (0.5 rem) and is not likely to exceed 50 mSv (5 rem) per patient expected administration regimen; or*
>
> *(2) the total effective dose equivalent to any other individual who is not a caregiver as defined in* § 35.2*from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem) per release.*

Additionally, if the written consent requirement is finalized despite opposition, ACR recommends clarifying that such consent may be obtained at any time before or after administration and through any reasonable mechanism or authorized licensee representative (e.g., patient portal

acknowledgements, electronic check-in processes, written intake forms, or clinical staff documentation). Absent such clarification, ACR is concerned that licensees could face situations in which a patient who otherwise meets the regulatory release criteria cannot be released merely because the required consent process has not been completed. In many healthcare settings, unplanned hospitalization/holding for this administrative purpose would be operationally impracticable and create unnecessary burdens, including negative financial impact on the already strained inpatient infrastructure, without providing radiation safety benefits. In addition, unnecessary hospitalizations would reduce the availability of hospital beds for patients with a clinical need for inpatient care.

The ACR is also concerned that the proposed regulatory language and draft guidance do not address the potential scenario in which a patient or caregiver withdraws consent after the treatment has been administered. In this scenario, ACR recommends that the NRC allows facilities to establish internal processes for addressing withdrawn consent, such as instructing the patient to follow protocols that restrict dose limits to all members of the household, including the caregiver, to the public dose limit.

***Per administration regimen/released patient*:** ACR opposes the proposed change from a "per release" to a "per patient administration regimen" framework for evaluating doses to caregivers and non-caregiver members of the public. Related treatment regimens can be modified based on patient response, disease progression, or other clinical factors. The proposed rule does not clearly address whether such modifications would remain part of the original administration regimen or constitute a new regimen for purposes of compliance with the revised release criteria. This ambiguity would create uncertainty for licensees and unnecessarily complicate patient release determinations. As stated in ACR's comments on the §35.2 definition proposal, additional guidance provided in DG-8070 regarding "administration regimen" should be clearly stated in regulation and in the regulatory definition at §35.2. Moreover, implementation of a "per administration regimen"-based regulatory compliance approach applied to non-caregiver members of the public would require substantial changes to existing workflows, documentation systems, and compliance processes and could influence treatment decisions for reasons unrelated to radiation safety or optimal care delivery. Such outcomes would be inconsistent with the NPRM's stated objectives of reducing unnecessary administrative burden and allowing licensees to continue their existing regulatory compliance strategies.

ACR recommends that the NRC retain the existing per-release compliance framework in §35.75(b). If NRC wishes to encourage consideration of cumulative exposures associated with fractionated radiopharmaceutical therapies and theranostics, ACR recommends implementing the ACMUI's recommendation to use the term "expected administration regimen". This change would allow flexibility for situations in which a patient's treatment regimen or caregiving circumstances change. If a "per expected administration regimen" framework is implemented, the NRC should provide nonbinding/voluntary recommendations or informational notices developed with stakeholder input, including consultation with the NRC ACMUI. However, any such recommendations should be limited to caregiver dose considerations and should not be extended to non-caregiver members of the public, as the latter could effectively restrict existing release criteria without justification.

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10 CFR Part 20

10 CFR 20.1301(a)(1), Dose limits for individual members of the public

NRC Proposal: *To maintain existing public dose limit that the total effective dose equivalent to individual members of the public from the licensed operation does not exceed 0.1 rem (1 mSv) in a year, exclusive of the dose contributions from medical and other listed sources.*

ACR Comments: ACR generally supports maintaining the current base-level public dose limit in §20.1301(a)(1) and agrees there is no apparent safety need to revise this value.

10 CFR 20.1301(b), Short-term dose rate limit in the unrestricted area

NRC Proposal: *NRC is proposing to delete the existing short-term dose rate limit in the unrestricted area of 0.002 rem in any hour in § 20.1301(b).*

ACR Comments: ACR generally supports this proposed removal. Additionally, ACR recommends that NRC ensure that the "Therapy and Equipment" section of DG-8063 is consistent with this regulatory change.

10 CFR 20.1301(c), Public dose limits for those visiting an unreleased patient

NRC Proposal: *NRC proposes keeping a 0.5 rem (5 mSv) dose limit from an unreleased patient for a member of the public and proposes adding a new 2 rem (20 mSv) dose limit for a caregiver exposed to an unreleased patient. Any caregiver dose in excess of 2 rem would continue to require an exemption request and prior NRC approval as outlined in Regulatory Issues Summary (RIS) 2006-18.*

ACR Comments:

***Member of public/unreleased patient*:** ACR supports maintaining a 0.5 rem (5 mSv) dose limit from an unreleased patient for a visitor/member of the public who is not a caregiver.

***Caregiver/unreleased patient*:** ACR generally supports the proposed new caregiver framework to simplify adherence to patient release criteria at §35.75; however, it is questionable whether the proposed 2 rem (20 mSv) dose limit for a caregiver visiting a patient under active licensee control adds useful flexibility. Typically, hospital visitor restrictions are not a major barrier to treatment compared to other, more practical considerations related to hospitalizations.

Per administration regimen/unreleased patient: ACR recommends that all NRC regulatory requirements be "per administration" or "per release," not per "administration regimen," as compliance with the latter would present significant documentation and recordkeeping challenges for licensees. Healthcare institutions evaluate and manage family member doses from patients of fractionated radiopharmaceutical therapies, but this can be complicated by caregiver changes or AU-intended variations or modifications to treatment plans. Instead, "per administration regimen" planning for caregiver dose would be better addressed by NRC as non-regulatory recommendations for fractionated radiopharmaceutical therapies and theranostics, while "per administration" or "per release" should be explicitly required by regulatory text at §20.1301(c)(1)(ii). As stated above, the

NRC could alternatively consider the ACMUI recommendation of "per expected administration regimen" to allow greater flexibility for licensees when treatment regimens change.

Correction: Finally, ACR recommends that NRC remove the word "either" from proposed § 20.1301(c)(1). As drafted, the CFR text could be read to require compliance with one annual limit to the exclusion of the other.

10 CFR 20.1201, Occupational dose limits for adults

NRC Proposal: *NRC proposes to maintain the current annual occupational dose limit of the total effective dose equivalent being equal to 5 rems (0.05 Sv); or the sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 50 rems (0.5 Sv). The annual limits to the lens of the eye would continue to be the lens dose equivalent of 15 rems (0.15 Sv). And the annual limit to the skin of the whole body, and to the skin of the extremities, would continue to be a shallow-dose equivalent of 50 rem (0.5 Sv) to the skin of the whole body or to the skin of any extremity. Effectively, these annual limits would not substantially change.*

ACR Comments: ACR generally supports maintaining the current occupational dose limits in §20.1201, including the lens of the eye limit at §20.1201(a)(2)(i), and agrees that there is no immediate safety need to revise these values.

10 CFR 20.1205, Planned occupational dose limit extension (DLE)

NRC Proposal: *NRC proposes a new planned occupational dose limit extension (DLE) process in § 20.1205 that would allow a licensee to authorize a worker to receive doses above applicable annual occupational dose limits, provided certain conditions are met, including that the worker's total occupational dose over the current year and the preceding four years does not exceed 25 rem total effective dose equivalent and that the worker does not receive more than twice the annual limit in any one year. The proposed DLE would allow licensees to use previously "unused" occupational dose allowances from prior years while maintaining the specified five-year dose constraint. Lens of the eye dose is exempted from the DLE process.*

ACR Comments:

DLE/occupational health: ACR is concerned that implementation of the proposed occupational dose limit extension (DLE) framework may require additional guidance and oversight to ensure consistent and appropriate application across regulated sectors. While ACR recognizes the NRC's objective of providing flexibility in limited circumstances, the agency should work closely with occupational medicine and radiation safety experts to ensure that DLE uses are supported by appropriate justifications and do not create unintended loopholes and economic incentives for exceeding these limits within various NRC-regulated industries.

***DLE/lens of the eye exemption*:** ACR supports NRC's proposal to exclude the lens of the eye dose limit from the DLE flexibility and to retain the existing annual limit. As 10 CFR Chapter 1 revisions are implemented by Agreement States with jurisdiction that extends beyond NRC's byproduct material limitations, preserving a clear distinction for lens dose may help avoid unintended downstream adoption of DLE-equivalent concepts in other radiation modalities, such as

fluoroscopically guided procedures. Lens exposures have been a key occupational health consideration for interventional radiologists and other healthcare professionals.

Additional Comments: Graded Approach to Dose Management Implementation

NRC Proposal: *The NRC states that it is developing guidance to further explain and provide acceptable approaches for implementing the graded approach to dose management, such as performing a "cost-benefit analyses using the assumptions of NUREG-1530, or equivalent assumptions, for any doses to members of the public that are projected to be greater than or equal to 25 percent of the public dose limit (i.e., 25 mrem/year)."*

ACR Comments:

The NRC-provided example for implementing a graded approach to dose management does not adequately consider current shielding practices in medical facilities. Performing an analysis of the costs and benefits of shielding to reduce doses below the public dose limit would add significant additional burden for medical licensees. Current shielding practices in medical imaging and therapy ensure that the dose to individuals in uncontrolled areas remains at or below the public dose limit of 100 mrem (1 mSv) per year. In certain medical suites, such as positron emission tomography (PET) suites, shielding requires substantial amounts of lead to maintain dose levels below the public dose limit, and any additional shielding would incur significant costs for the licensee with little additional radiation safety benefit.

As mentioned in the general comments of this letter, ACR members are committed to maintaining public exposure below the public dose limit of 100 mrem per year, and ACR acknowledges and supports the NRC's stated objective of ensuring that licensees currently operating under ALARA-based requirements and guidance are not required to substantially revise existing radiation safety programs based on this rulemaking. ACR recommends that the final rule and any future NRC guidance on implementing a graded approach to dose management clearly states that licensees will remain in compliance with NRC regulations by using current ALARA-based dose management processes. Such clarification would recognize current effective radiation protection programs and avoid imposing unnecessary regulatory burdens without a commensurate safety benefit.

ACR appreciates the NRC's consideration of these recommendations, and we welcome further discussion. For questions, please contact Mike Peters, ACR Senior Director, Government Affairs at mpeters@acr.org, or Lindsay Robbins, Regulatory Policy Specialist, at lmrobbins@acr.org.

Sincerely,

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