American College of Radiology™

September 9, 2026

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

RE: (Docket ID: NRC-2026-3730) Draft Regulatory Guide: Release of Patients Administered Radioactive Material; Comments of the American College of Radiology

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) draft Regulatory Guide (DG), "*DG-8070, Release of Patients Administered Radioactive Material,"* announced in the August 11, 2026, *Federal Register*.

Background – Proposed Rule and Corresponding Draft Guidance:
The NRC recently proposed extensive modifications to patient release criteria at 10 CFR 35.75 as part of a broader proposed rule (NPRM), *Reforming and Modernizing the NRC's Radiation Protection Framework*. ACR previously filed comments on the NPRM on August 31, 2026. DG-8070 would revise NRC's existing Regulatory Guide, RG 8.39, "*Release of Patients Administered Radioactive Materials,"* to provide updated guidance to licensees on the NPRM's proposed version of §35.75, including patient instructions content and calculational methodologies.

In the NPRM, NRC proposed 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. New definitions would be added to §35.75 to underlay these proposed changes. "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*.

Additionally, the dose limit (from a patient administered byproduct material) for non-caregiver members of the public would remain 5 mSv (0.5 rem). However, NRC proposes that the licensee must obtain written consent from the released individual, parent/guardian, or caregiver, and that the caregiver must be instructed on radiation risk and management if the caregiver's dose is likely to exceed 5 mSv (0.5 rem) but remain lower than 50 mSv (5 rem). Patients must also continue to be provided release instructions if the dose to another member of the public is likely to exceed 1 mSv (0.1 rem) with special instructions specific to nursing mothers and discontinuation/interruption of breastfeeding.

Recommendation 1: Re-propose DG for comment after publication of the final rule
The NPRM and DG-8070 both require key refinements prior to finalization. After NRC publishes the future final rule, ACR recommends that NRC issue an updated version of this DG with a comment period to enable stakeholders to provide feedback with knowledge of the finalized §35.75 regulatory

text. Alternatively, NRC could publish the revised RG 8.39 with comment period and rapidly resolve the issues identified during that comment period with a corrected revision.

Recommendation 2: Resolve inconsistencies in the DG that may lead to hospitalization
ACR recommends that NRC resolve various inconsistencies and technical errors in the document that warrant additional review. For example, a full lutetium Lu-177 vipivotide tetraxetan course exceeds the total allowance outlined in Table 1 and Table 3. As a result, the table look up method cannot be used and every patient will require a patient specific calculation. These patients also cannot be released based on measured exposure rate outlined in Table 4. Therefore, nearly every patient receiving this treatment would need to be held by the licensee using appropriate radiation controls. This change would result in a major patient access barrier as most healthcare facilities do not have the capacity to hold nuclear medicine patients who do not need inpatient care. In addition, this type of medically unnecessary hospitalization would likely not be covered under existing payment policies.

Recommendation 3: Implement ACMUI recommendations on the DG
The NRC provided an early draft of DG-8070 to the NRC Advisory Committee on the Medical Uses of Isotopes (ACMUI). The ACMUI Subcommittee on RG 8.39 provided recommendations to NRC staff during the August 17, 2026, ACMUI meeting. The Subcommittee offered the following recommendations, among others:

- Remove the requirement that caregivers must be unpaid from the definition.
- Provide threshold tables with additional occupancy factors, such as .67 (close contact for the entire day) or .25 (following standard precautions).
- Replace the term "administration regimen" with "expected administration regimen" or retain the current per-release radiation dose limit for caregivers and members of the public.
- Maintain the requirement for patient specific record keeping for written instructions and release, particularly with respect to breast-feeding patients.
- Create additional radiopharmaceutical-specific patient instructions based on typical example calculations.

ACR generally agrees with the ACMUI Subcommittee's recommendations on the DG and offers the following additional comments:

a) ***Caregiver definition****:* ACR generally agrees with the ACMUI's rationale for recommending removal of the proposed requirement that caregivers must be "unpaid" from the proposed definition of caregiver at §35.2. Section 6.2.1 suggests licensees ask whether a patient is going to a group home, nursing home, or detention facility following treatment, but does not provide further guidance on how to address these scenarios with respect to caregiver dose limits. The NRC should clarify in regulation that "caregiver" excludes licensee employees who care for patients within the scope of their employment and may be subject to occupational dose limits. The NRC should also revise DG-8070 to include examples of acceptable paid caregivers, such as home health aides or nursing home staff.

b) ***Occupancy Factor:*** ACR agrees with the ACMUI that tables 3 and 4 in DG-8070, which were calculated using a 1.0 occupancy factor as a conservative upper limit, will create unrealistic default activity and dose rates. As a result, these tables are unlikely to be useful

to licensees and will require the use of patient-specific calculations with modifying factors for certain therapies. The NRC should provide activity threshold tables demonstrating compliance for caregivers using more realistic values, such as 0.25 (which would assume the patient follows standard instructions) and 0.67 (which would assume the patient has close contact with the caregiver throughout the day with no co-sleeping). These more accurate underlying assumptions would help licensees and patients avoid unnecessary hospitalization.

c) ***Administration Regimen*:** As stated in ACR's comments on the proposed rule, ACR opposes the proposed change for evaluating doses to caregivers and non-caregiver members of the public from a "per release" to a "per patient administration regimen" framework. Related treatment regimens can be modified based on patient response, disease progression, or other clinical factors. The proposed rule and DG-8070 do 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. The NRC provides some explanatory text regarding how to determine an administration regimen on page 10 of DG-8070, which states that:

"For example, if a given therapeutic radiopharmaceutical is prescribed to be delivered via multiple infusions over several months, then the administration regimen includes all of those infusions but does not include any diagnostic use of byproduct material or subsequent therapies using byproduct material."

Importantly, limiting factors such as those above and any other information intended to provide basic regulatory clarity should be explicitly described in regulatory language at §35.2 - not merely limited to guidance - to ensure consistent Agreement State and licensee implementation.

ACR continues to strongly recommend that NRC retain the existing per-release compliance framework in §35.75(b) and in particular (b)(2). If NRC chooses to finalize the "per administration regimen" patient release framework, however, ACR recommends implementing the ACMUI's recommendation to use the term "expected administration regimen," and to limit this approach exclusively to caregiver dose. Additionally, the NRC should make corresponding revisions to DG-8070 to include voluntary recommendations for determining the expected administration regimen to caregivers. We stress the importance of maintaining the "per release" approach for non-caregiver members of the public or it may influence practice of medicine such that patients of fractionated radiopharmaceutical therapies receive lower than optimal therapeutic doses over the regimen out of compliance necessity.

d) ***Recordkeeping:*** ACR agrees with the ACMUI that recordkeeping is necessary to ensure licensees following procedures for releasing patients. However, the DG provides unclear guidance on recordkeeping requirements. Section 4 of the DG refers to section 5.1 for guidance on recordkeeping with the use of patient-specific thresholds. However, section 5.1 does not exist within the document. NRC should revise the DG accordingly.

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Recommendation 4: Resolve technical errors and computational issues
ACR observed the following errors that do not align with clinical practice:

- Example F.3 recommends holding patients treated with lutetium Lu-177 vipivotide tetraxetan for three hours following administration, during which time the patient receives amino acids as part of standard drug protocol. However, Lu-177 does not include amino acid co-infusion.
- Example G provides screening criteria for patients with temporary brachytherapy implants using I-125 seed localization as an example. This is inaccurate as localization using I-125 seeds is not considered brachytherapy according to the definition at 10 CFR 35.2
- The guide provides inconsistent instructions regarding use of public transportation following treatment. NRC should make edits throughout for consistency.
- In example H, NRC departs from ICRP 106 by recommending an interruption time from breast feeding of 3.4 hours. The NRC should provide further explanation if it intends to depart from ICRP 106.
- DG-8070 Appendix B defines F_B as total disintegrations in the patient. F.2 and F.3 use the blood half-life. These are two different measurements, and blood kinetics should not be used as whole body retention.
- ACR's Appendix A to this comment letter (below) provides possible computational errors identified by the Government Relations Committee of the ACR Commission on Medical Physics.

ACR strongly encourages the NRC to issue a new patient release DG following the radiation protection framework final rule. 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,

D Smetherman

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Appendix A: Technical and Computational Corrections

Location	Issue	Recommended Solution
Page 9	Incorrect regulatory citation.	The sentence "the written procedure required under 10 CFR 37.5(a)" should state "The written procedure required under 10 CFR 35.75(a)".
Section 6.1	Incorrect regulatory citation.	The sentence "In accordance with 10 CFR 35.75(c), licensees must give instructions to released patients, including written instructions, on actions recommended to reduce contamination and maintain doses to bystanders and caregivers," should instead refer to 10 CFR 35.75(b)
Table 8	Radiopharmaceutical name and dose errors.	NRC should review for accuracy.
Section 4	Equations 5 and 6 are missing "n" to denote number of administrations.	NRC should revise equations.
Section 4.1	Section 4.1 cites section 5.1 However, the document does not contain a section 5.1.	NRC should revise the citation or add section 5.1.
Section 6.1	Section 6.1 cites section 2.3, which does not exist.	NRC should revise the citation or add section 2.3.
Sections 2.1 and 3.1	Sections 2.1 and 3.1 cite section B.6 that does not exist.	NRC should revise the citation or add section B.6
Appendix B	Appendix B has two consecutive sections numbered B.4 and skips Figure B-3.	NRC should revise as needed.
Appendix C	Appendix C skips C.3.	Appendix C skips C.3.
Appendix E	The figure in Appendix E is labeled Figure C-1 and cites Table 3 for breastfeeding thresholds that are in Table 7.	NRC should revise as needed

Appendix D	Incorrect citation	Appendix D cites equation C-1. This should be changed to D-1.
Reference 16	Reference 16 uses Management Directive 8.4's superseded title.	This should be changed to the current title, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests," September 20, 2019, which is used in Section D.
Table 1, column 2	Ru-106 instruction threshold reads 14 GBq against 3,900 mCi in the next cell. 3,900 mCi = 144 GBq;	This should be changed to 144 GBq instead of 146.
Table 3; Table 5, column 2	The Xe-133 caregiver row duplicates the Tl-201 row (12 GBq / 320 mCi and 0.24 GBq / 6.4 mCi are the computed Tl-201 values). Table 5 col. 1 and Table 4 for Xe-133 are correct.	This should be changed to 22 GBq (580 mCi) release; 0.43 GBq (12 mCi) instruction
Example F.2	"275 mCi is greater than the administered activity of 41 GBq" — 41 GBq is the table value, not the administered activity.	This should be changed to 1.0 GBq; recomputed Q' = 7.9 GBq (conclusion unchanged)
Example G	n_s stated as 0.12	6 d ÷ 59.4 d = 0.10. The downstream 0.068 is consistent with 0.10. n_s should be changed to 0.10
Appendix D, Equation D-2	Computational error. 0.693 × 96 ÷ (160 × |ln 0.19|) = 0.2504.	0.24 should instead be 0.25
Appendix C.5	The text of the table states that the patient will abstain from co-sleeping for 3 half-lives, but the value in the table does not represent 3 half-lives.	NRC should reconcile the text with the table.
Table 3, Column 2	Computational error.	The table indicates 1.4 GBq = 36 mCi. Sm-153 reads 1.4 GBq / 36 mCi — mutually inconsistent; computed 1.3 GBq.
Tables 7 and 8	Tc-99m HAM shows no 5 mSv interruption, though 0.30 GBq exceeds the 0.2 GBq record threshold, while DISIDA with	The NRC should ensure that the tables are consistent with the stated logic and methods.

	identical numbers shows 1 h. C-11 shows none at 0.93 GBq against a 0.5 GBq threshold.	
Table 7	I-125 NaI row reads "<1 μCi" in GBq but "0.002" mCi (2 μCi) alongside. Every other sub-μCi row shows "<1 μCi" in all four cells.	NRC should correct the anomalous cell that says 0.002 mCi.
Footnotes and Tables 1, 3 and 5.	Er-169 carries the "thresholds do not apply" marker while showing values; Tables 2/4/6 correctly flag it for bremsstrahlung. Ho-166's bremsstrahlung flag is inconsistent across tables.	Er-169 should carry note a.
Table 3 header and Table 6	Table 3's header cites footnotes d and e but only a–d exist. Table 6 marks C-14 with note e (alpha emitters) where d is meant. In addition, C-14 is a beta emitter, not an alpha emitter.	NRC should correct the footnote references and revise the table to refer to C-14 as a beta emitter.
Tables 2, 4, and 6	Kr-81m appears in Tables 1, 3, 5 but is absent from Tables 2, 4, 6.	NRC should revise as needed.
All Tables	Sr-90 (28.8 y) carries full thresholds although note c to Table A-1 bars the method above 10 years — the basis for excluding C-14. It is unclear why the same logic is not applied to both Sr-90 and C-14.	NRC should revise as needed.