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Draft Regulatory Guide: Release of Patients Administered Radioactive Material

Comment On: NRC-2026-3730-0001

Draft Regulatory Guide: Release of Patients Administered Radioactive Material

Document: NRC-2026-3730-DRAFT-0011

Comment on FR Doc # 2026-16344, NRC-2026-3730-0001, from Society of Nuclear Medicine and Molecular Imaging

Submitter Information

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General Comment

See attached file(s)

Attachments

SNMMI Comment Patient Release

September 10, 2026

The Honorable Ho Nieh
United States Nuclear Regulatory Commission
Washington, DC 20555-0001

Re: "Release of Patients Administered Radioactive Material" (91 FR 51749, Docket NRC-2026-3730)

Dear Chairman Nieh:

The Society of Nuclear Medicine and Molecular Imaging (hereafter, the Society), appreciates the opportunity to submit comments on the Nuclear Regulatory Commission's (NRC) proposed revisions to Draft Regulatory Guide 8.39, "Release of Patients Administered Radioactive Material."

About SNMMI

The Society is an international nonprofit medical society dedicated to advancing nuclear medicine, molecular imaging, and theranostics. Founded in 1954, the Society represents more than 15,000 physicians, technologists, scientists, and other healthcare professionals worldwide.

The Society's members develop and apply advanced imaging technologies and targeted radiopharmaceutical therapies that enable earlier disease detection, more precise treatment planning, and improved patient outcomes. The Society establishes clinical practice guidelines, publishes leading scientific journals, convenes scientific meetings, and advocates for policies that support innovation and patient access in molecular imaging and precision medicine.

Comments

Proposed Revision 2 defines the limits in 10 CFR 35.75 on a per-administration-regimen basis and provides separate baseline release criteria for bystanders and caregivers. For caregivers, Table 3 uses a total effective dose equivalent (TEDE) limit of 50 mSv (5 rem) and assumes 100 percent occupancy at 1 m. The Society supports the 50 mSv (5 rem) limit for a consenting, appropriately instructed caregiver, but is concerned that the default 100 percent occupancy assumption is unnecessarily conservative for routine outpatient radiopharmaceutical therapy (RPT) and may impose avoidable administrative burden without a commensurate radiation-safety benefit.

Table 3 lists baseline caregiver release thresholds of 3.2 GBq (86 mCi) for ^{131}I and 41 GBq (1,100 mCi) for ^{177}Lu . These values are conservative activity-only thresholds, not absolute outpatient-release limits. For example, a six-administration course of ^{177}Lu -vipivotide tetraxetan at 7.4 GBq per administration totals 44.4 GBq and therefore exceeds the Table 3 baseline threshold; commonly used ^{131}I therapeutic activities may also exceed the corresponding baseline threshold, depending on the indication and prescribed activity. Under DG-8070, exceeding Table 3 does not itself preclude outpatient treatment. Rather, the licensee must use another permitted release demonstration, such as

measured dose rate, screening criteria, patient-specific calculations, or a hold until release criteria are met. The Society is concerned that routinely requiring these additional demonstrations when a realistic occupancy assumption would already show compliance creates unnecessary complexity. Historically, RG 8.39 used an occupancy factor of 0.25 at 1 m for radionuclides with physical half-lives greater than one day. Applying an occupancy factor of 0.25 to the caregiver baseline increases the corresponding activity thresholds fourfold, to 12.8 GBq (344 mCi) for ^{131}I and 164 GBq (4,400 mCi) for ^{177}Lu . The Society therefore strongly recommends that NRC use 0.25 as the default caregiver occupancy factor for the baseline activity tables, with a higher or patient-specific factor when anticipated caregiver contact warrants it. This approach would preserve the proposed 50 mSv (5 rem) caregiver dose limit while avoiding unnecessary disruption of established outpatient RPT practice.

Separately, the Society recommends that the proposed 20 mSv (2 rem) per-administration-regimen limit in 10 CFR 20.1301(c) for a caregiver visiting a patient who cannot be released under 10 CFR 35.75 be increased to 50 mSv (5 rem), consistent with the post-release caregiver limit. This issue is particularly important for pediatric inpatients, for whom a parent or other caregiver may need sustained close contact as part of necessary support and comfort. The Society recommends that this higher limit remain subject to authorized-user determination, informed consent, appropriate instruction, and reasonable radiation-protection measures.

The continuing expansion of radiopharmaceutical therapy, administered predominantly on an outpatient basis, raises the practical issue of managing potentially contaminated household waste, such as adult diapers, generated after treatment. Management options include return to the treating facility where feasible; temporary storage in the patient's home until the activity has decayed sufficiently for ordinary disposal; or prompt disposal in the general waste stream where permitted by applicable law and supported by a radiation-safety assessment. The Society recommends that NRC guidance allow the latter approach rather than prescriptively favoring decay-in-storage at home. In the peer-reviewed analysis by Graves (Graves SA. Radiation safety considerations of household waste disposal after release of patients who have received ^{177}Lu]Lu-PSMA-617. *J Nucl Med.* 2023 Oct;64(10):1567-1569. doi: 10.2967/jnumed.123.265750. PMID: 37442601), following administration of 7.4 GBq (200 mCi) of ^{177}Lu -vipivotide tetraxetan (PLUVICTO), the conservatively estimated effective dose to a member of the patient's household was 330 μSv (33 mrem) if the waste were retained in the home for decay, versus approximately 36 μSv (3.6 mrem) with prompt disposal in the general waste stream; the estimated dose to the maximally exposed sanitation worker was approximately 10 μSv (1.0 mrem). These data support a risk-informed approach in which prompt household disposal is not prohibited or discouraged solely because low-level radioactivity remains detectable.

An ancillary but important issue is the setting of radiation portal-monitor alarm setpoints and associated response criteria for waste-transporting vehicles at local transfer stations and disposal facilities. Section 6.2.2(b)(7) of DG-8070 notes that landfills may detect radiation and decline such waste; however, detectability alone is not a surrogate for health risk. Alarm setpoints and response practices may vary substantially among jurisdictions, including Agreement States. The Society therefore recommends that NRC, in coordination with Agreement States and appropriate waste-management authorities, develop risk-informed guidance for portal-monitor alarm setpoints and response criteria based on potential dose consequence rather than detector sensitivity alone.

The Society welcomes Regulatory Guide 8.39 but cautions that the final guidance should not be so prescriptive that it unnecessarily constrains medical practice. Radiation-safety approaches may legitimately vary among institutions, patient populations, and treatment protocols; alternative methods that satisfy the applicable regulatory dose limits should remain available.

Given the broader modernization of the NRC radiation-protection framework, the Society encourages NRC to use the International System of Units (SI) as the primary system for activity and radiation-dose quantities in the final guidance and related rulemaking, with conventional units shown parenthetically during an appropriate transition. SI is the internationally standardized system and is widely used in scientific and medical practice, including by the Journal of Nuclear Medicine. As the underlying regulations are modernized, the Society also recommends use of effective dose rather than TEDE where legally and technically appropriate, with activity, absorbed dose, equivalent dose, and effective dose expressed in becquerels (Bq), gray (Gy), sieverts (Sv), and sieverts (Sv), respectively.

Note: In comments on the proposed rule, “Reforming and Modernizing the NRC’s Radiation Protection Framework” (Docket ID NRC-2025-1140), the Society addressed the use of “deterministic” in discussing low-dose regulatory limits. The Society recommends avoiding “deterministic” as a descriptor of such limits because, for example, the 5 rem per year occupational limit is well below threshold doses for tissue reactions, historically termed deterministic effects. The term remains appropriate when referring to threshold-type tissue reactions.

Conclusion

Concerning the proposed patient-release requirements, the Society strongly recommends a 0.25 default caregiver occupancy factor in the baseline activity tables, with higher or patient-specific factors when warranted by anticipated contact. The Society also recommends increasing the caregiver visitor limit in 10 CFR 20.1301(c) from 20 mSv (2 rem) to 50 mSv (5 rem) per administration regimen; permitting risk-informed prompt household-waste disposal where otherwise allowed; and using SI as the primary measurement system, with conventional units shown parenthetically during transition.

The Society appreciates the opportunity to comment on the proposed guidance.

Please contact the Society’s Director of Health Policy and Regulatory Affairs, Julia Bellinger, MPP (jbellinger@snmmi.org), if we can provide additional information.

Sincerely,



Heather Jacene, MD, FSNMMI
President, Society of Nuclear Medicine and Molecular Imaging