

Nuclear Regulatory Commission (NRC) Updates

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NRC Advisory Committee on Medical Uses of Isotopes (ACMUI)**



- Licenses / regulates *civilian* use of radioactive materials and nuclear energy
 - Regulatory portfolio overwhelmingly devoted to power reactors
 - Radiation protection standards: MPDs
- Does *not* regulate medical and pharmacy practice
 - MPDs apply to staff and general public but *not* to patients



Ongoing Regulatory Changes

- **Executive Order No 14300**
- **Proposed Rule**
- **Radiopharmaceutical extravasation and Medical-Event reporting**
- **Rev 2 of Reg Guide 8.39 (Patient Release)**

Executive Order No 14300

May 2025

“...to reform the Nuclear Regulatory Commission and to reconsider its use of the linear no-threshold (LNT) dose-response model and alternative models for formulation of radiation protection standards.”

Comments: Intent - Ease environmental dose limits surrounding nuclear power reactors and thereby facilitate licensing and construction
DOE discarding ALARA principle for same purpose (Energy Secretary Chris Wright memo, Jan 2025)

Key Points

- **Despite the uncertainties and other limitations of the LNT model, it remains a practical approach to formulation of radiation protection standards.**
 - This does *not* imply endorsement of the LNT model as a valid mechanistic model of radiation action.
- **Given the low occupational effective doses already received by nuclear medicine personnel and the current prevailing practice of *outpatient* radiopharmaceutical therapy, the results of any re-evaluation of the LNT model would likely have modest regulatory impact on nuclear medicine operations.**

**Proposed Rule:
Reforming and Modernizing
NRC's Radiation Protection Framework
10CFR19, 20, 34, 35, 40, 50, 53, 61, 71, and 72
Docket NRC-2025-1140 / RIN3150-AL47
August 2026**

- **Comprehensive revision - the first in decades - to its Standards for Protection Against Radiation in response to Executive Order No 14300 to support national policy objectives (eg expedited licensing of new reactors).**
- **Retire the use of the ALARA concept and replace it with a new "graded approach to dose management," responding to criticisms that radiation protection standards were no longer ALARA, but rather a *"as-low-as-possible"* approach.**

Proposed Rule: Reforming and Modernizing NRC's Radiation Protection Framework “Graded Approach to Dose Management”

Occupational Dose Thresholds

- >100 mrem/year - Expected Dose: Training and instruction required for workers.
- >500 mrem/year - 10% of the Applicable Limit: Monitor doses to workers.
- >5 rem/year- Occupational Dose Limit.
- **Planned Occupational Dose Limit Extension**: New process allowing workers to *exceed* annual occupational dose limits, provided doses remain within specified 5-year limitations - Up to 2X the annual limit in a single year, 10 rem in a single year, and 5X the annual limit over the current year plus preceding 4 years, 25 rem in a single year, *without* cost-benefit analysis.
 - >25 rem in a single year if justified by cost-benefit analysis.

**Proposed Rule:
Reforming and Modernizing
the NRC's Radiation Protection Framework
“Graded Approach to Dose Management”**

Public Dose Thresholds

- **<+25% of public dose limit (<+25 mrem/year, given 100-mrem/year public dose limit) *without* cost-benefit analysis.**
- **>+25% of public dose limit (>+25 mrem/year, given 100-mrem/year public dose limit) *with* cost-benefit analysis.**

**Proposed Rule:
Reforming and Modernizing
NRC's Radiation Protection Framework
“Graded Approach to Dose Management”**

- **Dose thresholds for radiopharmaceutical therapy:**
 - **2 rem/administration regimen**
for *caregivers*.
 - **5 rem/administration regimen**
for *consenting, trained caregivers*

vs current limit of
0.5 rem/administration
 - **0.5 rem/administration regimen**
for *non-caregivers*.
- 
- vs current limit of
0.1 rem/administration

Key Points

- Endorsement of NRC's re-affirmation of LNT model as a practical approach to formulation of radiation protection standards.
- Elimination of ALARA principle is ultimately less important in practice than the actual radiation protection standards.
- Explicit guidance (eg regulatory guides) on practical implementation of the radiation protection standards is required as soon as possible.
- Recommend adoption of SI system of quantities and units in regulations - with SI unit followed parenthetically by conventional unit.

Key Points cont

- **The Society endorses the flexibility for MPDs in the proposed Graded Approach to Dose Management.**
 - **“One-time exceptions” (up to 25 rem) to annual occupational MPDs - eg for cyclotron, radiochemistry, and radiopharmacy personnel - without a demonstrable increase in excess lifetime cancer risk.**

Key Points cont

- Endorsement of the higher MPDs *per administration regimen*, 2 or 5 rem, for caregivers and non-caregivers, 0.5 rem, for outpatient radiopharmaceutical therapy.
 - The Society nevertheless recommends that such MPDs should be formulated on a *per-administration* basis for practical considerations.
eg A patient is treated at *different* facilities over the course of a multi-administration regimen.
A patient cannot complete all fraction of a multi-administration regimen.

Key Points cont

- Relevant regulations in the Proposed Rule should *not* prohibit disposal of radioactive waste directly from the patient's home in the general waste stream and associated guidance should *not* be overly prescriptive to the point of disallowing or discouraging such disposal.
 - Following administration of 200 mCi PLUVICTO™, effective dose to a member of patient's household is 33 mrem from radioactive waste if such waste were held for complete decay in storage in patient's home but ten-fold lower, 3.6 mrem, if disposed of immediately in the general waste stream – and that to maximally exposed sanitation workers collecting such waste is only 1.0 mrem (Graves SA. J Nucl Med. 64:1567-1569, 2023.)
 - The Society recommends specific regulatory guidance for setting of lower limit of detectable activities by radiation detectors monitoring waste-transporting vehicles at local waste-transfer stations - to avoid setting of unnecessarily low detectable activity limits.

Release of Patients Administered Radioactive Material

Revision 2 - Regulatory Guide 8.39, August 2026 (Draft Regulatory Guide DG-8070)

- Adopts approach in NCRP Report No 155 (Management of Radionuclide Therapy Patients) for *individualized* releasability
- Retains Default Tables: Radionuclide-specific thresholds for *non-individualized* patient releasability
 - Activity - A_{rel} in Table 1
 - Dose rate @1 m - M_{rel} in Table 2

But now assumes
Occupancy Factor, F_o , of 1

**Release of Patients
Administered Radioactive Material
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 - 2 rem/administration regimen
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 - 5 rem/administration regimen
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**Release of Patients
Administered Radioactive Material
Revision 2 - Regulatory Guide 8.39, August 2026
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- ***Default* Occupancy Factor, F_o , of 1 versus historical standard value of 0.25 *decreases* releasable activities 4-fold → Requires hospitalization of PLUVICTO/LUTATHERA therapy (Administration regimen of 4-6 x 200 mCi)**
- **BUT Occupancy Factor, F_o , of 0.25 may be stipulated *without justification***
 - $F_o < 0.25$ requires justification
- **The Society recommends a *default* Occupancy Factor, F_o , of 0.25**