



January 30, 2025

To Whom It May Concern:

I am contacting you regarding the Nuclear Regulatory Commission (NRC) [Draft Regulatory Guide DG-8062](#) for radiopharmaceutical extravasation reporting.

We are [Patients for Safer Nuclear Medicine \(PSNM\)](#), a coalition of 30 non-profit patient advocacy organizations, representing thousands of patients across every state. We are fortunate to be advised by leading global experts in radiology, nuclear medicine, physics, radiation protection, and vascular access. PSNM has one primary objective: ensure that NRC requires reporting of large extravasations similar to any other accidental exposure of radiation.

We appreciate the comments from the NIH regarding this issue, including the [Winter 2023 newsletter article](#) which encouraged clinical areas that administer radiopharmaceuticals to prepare for the upcoming changes. This letter is intended to update you on the status of the proposed rule change, highlight issues with the proposed changes, and to respectfully urge NIH to take the next step on extravasation policy by supporting a legislative solution, the Nuclear Medicine Clarification Act.

This proposed legislation is the exact suggestion proposed by the NIH Radiation Safety Officer Catherine Ribaudo in her [August 2023 letter to the NRC](#). In this letter, Ms. Ribaudo states, "It would be preferable for the NRC to adopt the medical event reporting criteria already established in 10 CFR 35.3045(a) and (b) to define extravasation risk."

NRC's proposed rule, as highlighted in your newsletter, uses injury for the first time in the history of NRC medical event reporting and utterly fails to deliver a workable solution that protects patients. That proposed criterion for reporting was widely criticized for its subjectivity by patients, Ms. Ribaudo, and other professionals. As a result, the NRC medical staff added another subjective criterion and in August of 2024 proposed Draft Regulatory Guide DG-8062 for radiopharmaceutical extravasation reporting.

The NRC in an attempt to placate an increasingly angry and frustrated patient population that has seen no favorable action on this critical issue after years of committed outreach, added the potential radiation injury as a criterion to the draft guide. Unfortunately, this revised proposal still falls far short.

The draft guide fails to require dosimetry to quantify the potential impact of extravasations and to ensure appropriate patient follow-up care. The application of objective, dose-based and risk-informed standards is an absolute must to determine whether an extravasation should be reported as a medical event. We are pleased that the NIH Radiation Safety Officer agrees with us that objective standards need to be incorporated in updated extravasation policy.

There is another reason patients regard NRC's proposed subjective rule with suspicion: the agency relied on conflicted advisers in the development of extravasation policy. In March 2024, a U.S. NRC Office of the Inspector General (OIG) report concluded that two members of the NRC Advisory Committee on the Medical Uses of Isotopes (ACMUI) were also top members of the Society of Nuclear Medicine and Molecular Imaging (SNMMI), who violated federal ethics rules in how they addressed the petition for rulemaking regarding extravasations. The published report can be found at this link: <https://bit.ly/NRCOIG>.

PSNM filed a separate complaint with the OIG in October 2023 with five evidence-backed examples of how NRC disregarded vital clinical data, cultivated factual errors in NRC documents, and more. We understand this matter remains under investigation. You can view the complaint at www.safernuclearmedicine.org/position-statements-recommendations.html.

While the OIG investigations illustrate the troubling relationships that NRC has with the industry it is supposed to regulate, there is no requirement of any follow-up action. With this in mind, we now believe the best course of action to protect patients is via Congressional action.

Members of Congress who agree with NIH Radiation Safety Officer Ribaudo's statements in principle attempted to advance legislation and are reintroducing the Nuclear Medicine Clarification Act (HR 6815 in the previous session) in the new session. The legislation would require NRC to treat large extravasations (irradiation above the existing dose-based limit) just like any other medical event - the same suggestion made by the NIH Radiation Safety Officer.

Crucially, this measure would give NRC a way to encourage providers to proactively lower the risk of extravasation. We will endeavor to keep you informed of this legislation once it is reintroduced, and hope that you will seriously consider doing all you can to support this bill.

Countless patients rely on radiopharmaceuticals to help extend their lives. PSNM remains in this fight because the threat of patient harm is very real. We appreciate your words of support and urge you to remain committed to supporting this common-sense revision in federal extravasation policy.

Our global expert advisers would be happy to answer any of your questions or meet at your convenience to discuss this matter further. Thank you for your time and attention.

Respectfully,

Simon Davies
Executive Director, Teen Cancer America
Representing the [membership](#) of the Patients for Safer Nuclear Medicine Coalition

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