



Information Quality Coordinator  
U.S. Nuclear Regulatory Commission  
TWFN-6B29  
Washington, DC 20555

Delivered on June 2, 2022 via email to [info.quality@nrc.gov](mailto:info.quality@nrc.gov)

To Whom it May Concern:

I am writing today, on behalf of myself, thousands of patients represented by the Patients for Safer Nuclear Medicine Coalition, and the 620 individual signatories, to respectfully request that the Nuclear Regulatory Commission (NRC) correct inaccurate information that was published in the Federal Register on May 14, 1980 regarding nuclear medicine extravasations. While the incorrect information was published more than 40 years ago, it has been recently questioned since it is relied upon as an official government policy.<sup>1</sup> Additionally, this information that was adopted in 1980 by the Commission has been endorsed and used to support a Commission position since October 1, 2002, that affects thousands of licensees, even when evidence has been presented that the information is incorrect. Furthermore, the effects of this incorrect information and its impact to Commission policy have a clear and substantial impact every day by patients who undergo nuclear medicine treatments with inadequate oversight by the NRC. For that reason, it is urgent that the NRC consider and grant this request to protect patients from unnecessary radiation exposure. This request, submitted in accordance with the NRC's Information Quality Guidelines, seeks to correct the longstanding falsehood that nuclear medicine extravasations are "virtually impossible to avoid."

### Information that is in Error and Requires Correction

During rulemaking on misadministration of nuclear medicine injections in 1980, the NRC stated that extravasations are "virtually impossible to avoid."<sup>2</sup> As a result, the NRC exempted all extravasations from medical event reporting requirements, regardless of the resulting radiation dose that was misadministered to the patient. The substance of this information is inaccurate. We now know that extravasations are avoidable.<sup>3</sup> For example, a recent study demonstrated that the use of quality improvement methodologies can result in a statistically significant reduction in the rate of nuclear medicine extravasations.<sup>4</sup> Additionally, medical professionals have drastically lowered the rate of other types of extravasation using quality control programs. As a result, extravasation rates for contrast media are as low as 0.24% of injections,<sup>5</sup> compared to nuclear medicine extravasation rates that can be as high as 16% of injections.<sup>6</sup> This data demonstrates that extravasations are, in fact, avoidable – making the NRC's 1980 statements inaccurate and in need of correction.

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<sup>1</sup> Petition for Rulemaking PRM-35-22, available at: <https://www.regulations.gov/document/NRC-2020-0141-0001>.

<sup>2</sup> 45 Fed. Reg. 31701 (1980).

<sup>3</sup> See Association for Vascular Access comments in response to PRM-35-22, at: <https://www.nrc.gov/docs/ML2101/ML21019A332.pdf>.

<sup>4</sup> T. Z. Wong, et al., Quality Improvement Initiatives to Assess and Improve PET/CT Injection Infiltration Rates at Multiple Centers, 47 J. Nuclear Med. Tech. 326–331 (2019).

<sup>5</sup> S. Shigematsu, et al. Practical Preventive Strategies for Extravasation of Contrast Media During CT: What the Radiology Team Should Do. Academic Radiology, in press, at: <https://www.sciencedirect.com/science/article/abs/pii/S1076633222000563#!>; T. M. Dykes, M. Bhargavan-Chatfield M & R.B. Dyer. Intravenous contrast extravasation during CT: a national data registry and practice quality improvement initiative. 12 J. Am. Coll. Radiology 183- 191 (2015); C.L.Wang, et al. Frequency, Management, and Outcome of Extravasation of Nonionic Iodinated Contrast Medium in 69,657 Intravenous Injections, 243 Radiology 80-87 (2007).

<sup>6</sup> T. Z. Wong, et al., Quality Improvement Initiatives to Assess and Improve PET/CT Injection Infiltration Rates at Multiple Centers, 47 J. Nuclear Med. Tech. 326–331 (2019).



## Recommended Correction to Incorrect Information

NRC should immediately issue a notice of interpretation in the *Federal Register* stating: 1) the statement that extravasations are “virtually impossible to avoid” is factually inaccurate; 2) as a result, the underlying rationale for exempting extravasations from reporting criteria is unjustified; and 3) the NRC should immediately modify 10 C.F.R. § 35.2 and 10 C.F.R. § 35.3045 to require reporting of extravasations resulting in a localized dose equivalent exceeding 0.5 Sv. These steps will eliminate the effect of the incorrect information published in 1980 and put NRC on the path to issuing evidence-based policies that protect patients.

## Effect of the Incorrect Information

The incorrect information contained at 45 *Fed. Reg.* 31701 (1980) affects hundreds of thousands of patients like me every year. Extravasations harm patients in several ways. First, extravasations expose patients to unnecessary ionizing radiation when a radiopharmaceutical is injected into a patient’s healthy tissue. The higher the dose, the more likely it is that a patient will suffer some kind of physical harm; however, under current NRC rules, there is no obligation for providers to characterize or report the type of exposure that has occurred, even when these exposures grossly exceed existing dose thresholds for the reporting of other medical events. Patients are also negatively affected in other ways. As the NRC itself noted in 1980, “[t]he significance of a diagnostic misadministration goes beyond the unnecessary radiation exposure if it results in misdiagnosis.”<sup>7</sup> Patients that are extravasated do not get the full benefit of the radiopharmaceutical that is injected, which can lead to misdiagnosis, inaccurate cancer staging, or choosing the wrong treatment.<sup>8</sup> During therapeutic treatments, extravasations can negatively affect the lymphatic system and unprotected organs and result in delayed delivery of therapeutic doses to intended targets.

Because extravasations are exempt from reporting requirements based on incorrect information in the *Federal Register*, patients are kept in the dark about their care and the NRC doesn’t have the information it needs to keep future patients safe. Without a requirement to report significant extravasations to the NRC, nuclear medicine providers have little incentive to lower their extravasation rates even though nuclear medicine extravasations are avoidable. Correcting this inaccurate information will eliminate a falsehood that has left patients vulnerable to unnecessary radiation exposure for more than 40 years.

Thank you for your consideration.

Sincerely,

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Young Survival Coalition on behalf of the Patients for Safer Nuclear Medicine Coalition

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<sup>7</sup> 45 Fed. Reg. 31702 (1980).

<sup>8</sup> D. Osborne, et al. The Scientific and Clinical Case for Reviewing Diagnostic Radiopharmaceutical Extravasation Long-Standing Assumptions. *Front. Med.* (2021), at: <https://www.frontiersin.org/articles/10.3389/fmed.2021.684157/full>.