August 31, 2021

Kelly Jamerson
Nuclear Regulatory Commission
Submitted electronically to Kellee.Jamerson@nrc.gov

Dear Ms. Jamerson:

On behalf of the Society of Nuclear Medicine and Molecular Imaging (SNMMI),¹ I appreciate the opportunity to comment on both the Advisory Committee for the Medical Uses of Isotopes (ACMUI) Subcommittee on Extravasations’ draft report and the Nuclear Regulatory Commission (NRC) Staff’s Preliminary Evaluation of Radiopharmaceutical Extravasation and Medical Event Reporting. The regulatory treatment of nuclear medicine extravasation is a very important issue in our field with the potential impacts affecting the availability of nuclear medicine services for decades to come.

After the petition for rulemaking (PRM-35-22) was filed, SNMMI responded first with a position statement and with additional comments later in the year. The Petitioner, the manufacturer of a device used to measure extravasation of radiopharmaceuticals, filed a petition seeking NRC rule changes to its benefit and the public’s detriment. There are approximately 20 million nuclear medicine procedures performed annually in the US with no evidence of significant patient harm from extravasation of these radiopharmaceuticals. Additionally, a systematic review of more than 3,000 reported cases of extravasation of diagnostic radiopharmaceuticals (world-wide) revealed that only 3 cases resulted in patient symptoms that required follow-up.² This outstanding level of safety supports the effectiveness of current regulations coupled with qualified medical practitioners.

To summarize our position, the reporting of nuclear medicine extravasations is a practice of medicine issue and not a patient safety issue. Therefore, extravasations are best managed on an institutional level at the discretion of the authorized user and do not require additional NRC regulation. SNMMI recognizes the effect that extravasation of diagnostic radiopharmaceuticals may have on the quality of diagnostic images, particularly on quantitative studies, and is actively addressing this as the quality-control issue that it is, rather than a patient safety issue.

¹ SNMMI’s more than 15,000 members set the standard for molecular imaging and nuclear medicine practice by creating guidelines, sharing information through journals and meetings, and leading advocacy on key issues that affect molecular imaging and therapy, research, and practice.

SNMMI appreciates the NRC putting forth qualitative (non-dose-based) options and focusing medical event reporting on the extremely rare and clinically significant extravasations. Conversely, a quantitative medical event reporting mandate would result in widespread clinical, financial, and professional burdens on healthcare providers and the field of nuclear medicine without benefit to patients. Such a quantitative policy would almost certainly limit access of patients to life-saving nuclear medicine procedures. It is also important to note that the Petitioner’s tool uses non-standard dosimetry to determine if extravasations should be reported to the NRC. In fact, the tool has not been endorsed by physician societies and radiation physics organizations. Hundreds of healthcare organizations opposed the manufacturer’s proposed rule change in their public comments to the NRC.

Therefore, after reviewing both reports, while we feel the current regulations are assuring patient safety, the SNMMI recommends Option 6, a non-dose-based option with a higher and more clearly-defined threshold for medical event reporting than Option 4 (the other non-dose-based option).

Option 6 would require medical event reporting of extravasations determined by a physician to meet the significant harm standard of 10 CFR §35.3045(b). Though the ACMUI Subcommittee on Extravasations recommends Option 4, SNMMI has the following concerns about this option:

A. The phrase “medical attention” is ambiguous. Taken to the extreme, “medical attention” could conceivably include basic IV access care (e.g., compresses, etc.) for temporary injection site bruising, erythema or swelling. If Option 4 is to be seen as a viable option, the manner and intensity of “medical attention” that would trigger medical event reporting requirements must be clearly defined.

B. The injury assessor should be a physician with radiation medicine expertise (i.e. an Authorized User (AU) or AU-eligible physician) who can differentiate normal injection site changes from radiation-caused damage. Option 6 would provide for this physician determination of harm standard whereas Option 4 does not specify the qualifications for the “radiation damage assessors.”

C. Option 4 would require further rulemaking to create a new Medical Event type. Alternatively, Option 6 may likely be implemented through sub-regulatory policy as the language already present in 10 CFR §35.3045(b) does not specifically exclude extravasations.

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3 Option 4 would require reporting if “a patient requires medical attention due to skin damage near the administration site, and the damage is determined to be caused by radiation.”

4 “A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.”
SNMMI appreciates the ACMUI and NRC’s consideration of this statement. Though we hope the ACUMI aligns themselves with Option 6, we are also open to supporting Option 4 if amendments addressing our concerns in A and B (above) are made. As always, we are ready to discuss any of these comments or to meet with the NRC on the above issues. In this regard, please contact Julia Bellinger, Director of Health Policy at jbellinger@snmmi.org or (703) 326-1195.

Respectfully Submitted,

Richard L. Wahl, MD
President, SNMMI