PATIENTS
FOR SAFER NUCLEAR MEDICINE

May 24, 2023

To: NRC Rulemaking
Re: Docket ID NRC–2022–0218

On behalf of Patients for Safer Nuclear Medicine, a national coalition advocating for transparency in the administration of radioactive materials in healthcare, we have respectfully urged the Nuclear Regulatory Commission (NRC) to seriously consider the harm caused to patients by extravasation. Unfortunately, recent instructions by the Commissioners to the NRC medical staff will only make matters worse for patients. Patients should not be required to report extravasations. Nuclear medicine providers should be responsible for reporting these misadministrations.

By the NRC's own estimation, some 28,000 major extravasations occur annually in the United States. These extravasations are large enough that they would warrant reporting to the NRC if not for an incorrect reporting exemption that has been in place for 43 years. But because of this blanket reporting exemption, no one knows for sure how many large or small extravasations occur. The Commissioners instructions to the medical staff will not improve visibility to this issue.

Extravasation has a serious economic, physical, and emotional impact on the patient and the healthcare system in general. In these 28,000 cases, no one knows the amount of radioactive material that was injected into the tissue. Consider the diagnostic flaws that result when a precisely measured amount of radioactive material is not properly administered. And what if the radiation dose to the patient's tissue is extremely high? Beyond the expense of a delayed diagnosis of tissue damage and the harm that may cause the patient, the cost of catastrophic later stage treatment can be exorbitantly high.

The Commissioners' decision places additional burdens on patients. The NRC is essentially creating rules that impose upon patients the responsibility of monitoring themselves for an indefinite period, which could range from weeks to months, or even years, to detect radiation injury, despite their inability to discern if they have been extravasated. The agency is initiating rulemaking that would place responsibility for identifying a large extravasation on the patient post-event, rather than emphasizing the need for providers to identify and mitigate extravasations when they occur.

There is another, underreported aspect to the extravasation issue: the erosion of trust in our medical professionals. How can a patient who is just starting their cancer treatment journey maintain trust in their care team when potential harm through extravasation is not disclosed immediately? By keeping critical information from a patient, medical professionals fail to act in the patient's best interest. The medical community's efforts to encourage the Commission's patient injury position actively undermines the patient/clinician relationship. With the NRC admitting that tens of thousands of patients are extravasated annually, why are the medical community and the NRC seemingly so invested in hiding extravasations from patients?

It can be inferred that medical societies endorse this course of action under the assumption that only a small fraction of patients will report, and they are banking on the patients' lack of awareness about the possible gravity of a large extravasation. A charitable reading of this position would suggest that the NRC and its nuclear medicine allies would rather protect the nuclear medicine community rather than patients.

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We have expressed our concerns in letters sent to the NRC in January and March. We believe that, instead of relying on patients who are generally not medical school-trained experts to assess extravasation, the NRC should simply reaffirm that nuclear medicine providers should be responsible for reporting large extravasations.

By using the existing objective dose threshold – as is used for all other medical event reporting, including an accidental spill on a patient - licensees would be required to take immediate steps, including determining the tissue dose. We believe radiation injected under the skin should be treated with the same level of concern as radiation spilled onto the skin, which IS currently considered a reportable medical event.

With all this in mind, we recommend that the NRC rulemaking should be focused on including the word **extravasation** in the current medical event reporting section. By following our recommendation, it would be difficult for anyone to attempt to influence the adoption of a different policy in order to evade reporting. The final regulation will then ensure that large extravasations are reportable, similar to other medical events. In addition, we believe all nuclear medicine licensees should be required to do the following:

- Be certified in gaining venous access if they have responsibility for administering these radioactive drugs.
- Monitor the injection to ensure that if there is an extravasation licensees will know immediately.
- If there is an extravasation, licensees should do everything they can to reduce the radiation dose to the patient tissue.
- If there is an extravasation, licensees should assess the amount of radiation and make sure it is documented in the patient's record.
- Provide patients with information about extravasation, including symptoms to look out for.
- Inform the patient's full care team about the extravasation, to determine next steps in the best interests of the patient.

To make our position abundantly clear: we reject NRC staff's current recommendation to create a unique reporting criterion that forces the patient to 'play doctor' and detect one's own radiation injury rather than asking NRC licensees – the experts – to identify and monitor extravasations. We remain baffled that the NRC plans to make patients directly responsible for their own diagnosis and care for extravasation follow-up, rather than licensees charged with their care.

Please take the opportunity to focus on patients in your deliberations. Consider how the average patient is impacted by your decision: the potential effect to their treatment, the potential radiation damage to their tissue and skin, and the cost (both financial and emotional). Consider the wide-ranging consequence it has on the larger healthcare system: lost productivity, patient harm, higher costs, worse outcomes, and an erosion of trust. There is no better time than now to take patient-positive action.

Sincerely,

Members of the Patients for Safer Nuclear Medicine Coalition