



January 9, 2023

Dear Chairman Hanson and Commissioners Baran, Wright, Caputo, and Crowell,

Patients for Safer Nuclear Medicine (PSNM) was initially pleased to see the approval of the petition in Docket: NRC-2020-0141 but was deeply disappointed in many of the anti-patient comments in the Commissioners' Policy Issue Notation Vote Response Sheets.

While acknowledging that the reporting exemption for extravasations is no longer supportable, you are initiating a rulemaking that would place responsibility for identifying a radiation safety-significant extravasation on the patient. You are asking patients to detect radiation injury when clinicians themselves often disagree on how injury should be identified. You are asking patients to monitor themselves for months or years while waiting for an injury to present itself, rather than emphasizing the need for providers to identify and mitigate extravasations when they occur. There is only one way to interpret the NRC's staff requirements memo: the patient's voice matters less than the industry that the NRC regulates.

Instead of relying on the subjective assessments of patients, NRC should simply reaffirm the objective criteria that is used to identify any other medical event.

You suggested in your memo to the NRC medical staff that they "should evaluate whether the NRC should require licensees to develop, implement, and maintain written procedures to provide high confidence that radiation safety-significant extravasations will be detected and reported." We agree the NRC should require this. You also tasked the staff to "continue to explore approaches that would reduce the reliance on patient reporting." To help patients now, we ask the NRC to immediately issue **interim guidance**:

1. Patients must be informed when they have experienced a radiation safety- and **procedure**-significant extravasation. This is a basic patient right. They need to know as soon as it happens to mitigate tissue damage. And they need to know how much radiation has entered their tissue, so they better understand the impact to their procedure and care.
2. Patients must be provided with simple, written information to help identify symptoms of extravasation injuries, and they must know when these symptoms might appear. Often there are no visible symptoms of underlying tissue injury.
3. Patients must be given written instructions from their provider explaining where to go and whom to talk to if they experience symptoms. This is necessary to ensure that their suspected radiation injury is, in fact, reported to NRC.

Consider for a moment the additional burden you are placing on patients, who already have so much to worry about. Imagine the struggle a cancer patient would face while determining whether the symptoms they experience are due to an extravasation, chemotherapy, or are



caused by their cancer. Consider the logistical burden. You are asking a patient to contact their provider and make an appointment with a physician to determine whether an extravasation occurred. Patients must travel to and pay for another office visit. The decision also assumes that the patient will be able to make a timely appointment. If the patient's symptoms lessen while they wait for an appointment, then there will be less evidence for the physician to make an informed decision on whether to report. Your concern for provider burden comes at great expense to the patient.

PSNM is also troubled by the NRC's failure to seriously consider the impact of its decision on healthcare inequities. The techniques that most nuclear medicine providers use to gain vascular access are woefully out of date and they fail to consider how skin color impacts the ability to find a vein. As PSNM shared with Chairman Hanson on November 9, patients of color are less likely to self-report suspected injury. An objective dose-based threshold eliminates patient reporting and promotes healthcare equity.

Patients applaud your acknowledgement that the reporting exemption is outdated and that certain radiation safety-significant extravasations will need to be reported. However, we are baffled by the lack of consistency that you apply to the reporting criteria. For extravasations, you suggest patients self-report injury, but NRC's website states that patient harm is not a criterion for medical event reporting.

Patient reporting is subjective; however, an objective dose threshold is used for all other medical event reporting including, for example, an accidental spill on a patient. In such a case, your licensees are required to take immediate steps - including determining the skin dose. Why isn't radiation injected *under* the skin treated with the same degree of concern as a spill *onto* the skin? Your concern seems to be minimizing the number of reports you receive rather than taking steps to quickly ensure that the number of extravasated patients is actually reduced.

By accepting the petition and moving the issue into rulemaking, NRC will eventually drive providers to reduce extravasations. However, your comments, which are inconsistent with existing NRC policies, have created ambiguity. Your preferred reporting criterion will delay the correction of this issue and will surely result in thousands of radiation safety-significant, avoidable extravasations. Your actions have patients across the U.S. asking why the NRC is casting them aside to do the bidding of the industry it regulates.

Sincerely,

Mary Ajango

Mary Ajango, Young Survival Coalition

Patients for Safer Nuclear Medicine Coalition Spokesperson