PATIENTS
FOR SAFER NUCLEAR MEDICINE

October 3, 2023

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

Earlier this year, the U.S. Nuclear Regulatory Commission (NRC), in response to a simple request to eliminate an incorrect medical event reporting exemption of radiopharmaceutical extravasations, initiated rulemaking. The NRC rulemaking proposed that only extravasations that result in patient injury should be reported. It is of note that all other medical events use an objective dose-based threshold as part of the reporting criteria.

In this harm-based proposed rulemaking, NRC has eschewed over 40 years of using objective dose-based threshold criteria for medical event reporting and the previous Commissions' decisions to avoid subjective-based clinician assessment of potential injury as a criterion. Instead, the NRC has chosen to follow the recommendation of the industry they regulate. NRC has put the burden on patients, rather than asking the providers to use technology to monitor the administration of a radioactive drug and to report when they misadminister these drugs and accidentally expose patients to radiation doses that exceed the existing reporting threshold. In effect, this approach maintains the original reporting exemption and continues to hide medical errors that are affecting thousands of patients every year.

In the NRC's proposed rulemaking, patients will be responsible for initiating reports. While we all recognize that this idea already sounds crazy, there is more. In the proposed rulemaking, NRC would require patients who do not understand ionizing radiation and have not been told they were extravasated to identify symptoms of radiation exposure that could appear weeks, months, or years later, then schedule and pay for an appointment with a physician they have never met at the nuclear medicine facility center where the patient was extravasated, and finally convince this physician that the injury is related to an extravasation. This approach asks a physician to subjectively review symptoms that may have resolved in between patient identification and the appointment time or by the nature of the extravasated isotope may never even cause visible symptoms on the patient's skin. Our coalition members think this idea is utterly ridiculous. Here is an analogy:

> The nuclear power industry and the US Navy propose to scrap the historical monitoring of radiation safety. From now on, nuclear power plant workers or Navy personnel handling nuclear weapons or power plants no longer need to wear a dosimeter. Nor do they need to be trained on radiation injury symptoms or be even told that they are dealing with radiation. By chance if any of these workers are exposed to radiation, develop symptoms, and believe that these symptoms could be related to radiation, they should schedule a meeting with the power plant CEO or the commanding officer of their ship and share their symptoms. If the CEO or commanding officer believes that these symptoms suggest some previous exposure, then and only then, would these exposures be reported.

PSNM is not only disappointed in the NRC for their process and proposed rule, but it is especially discouraging that the Commission has failed to look critically at the unscientific advice they have received from trade groups whose mission is to protect the providers – not the patients.

These nuclear medicine industry comments state that diagnostic extravasations should be ignored. Patients should not be told. Extravasations should not be assessed. These statements have been made, even though the community knows that a large extravasations can affect the imaging and therapy procedures and thus patient

care, even though there is evidence that diagnostic extravasations can result in high absorbed doses of radiation, and even though EVERYONE knows that high absorbed radiation doses to healthy tissue are not good for patients.

One society went so far as to state that technology should not be used to identify extravasations when they occur. It is unfathomable to us that physicians would specifically rule out tools that may improve patient safety and the effectiveness of procedures.

The leaders of the Veterans Health Administration (VHA) National Health Physics Program and National Nuclear Medicine Program want to avoid assessing the severity of the extravasation and dose to tissue. They minimize the harm that diagnostic extravasations can cause for patients, despite knowing that diagnostic extravasations can affect images and patient care. These suggestions conflict with the VHA policy, Disclosure of Adverse Events to Patients. This adverse event policy covers ionizing radiation exposures and close calls and acknowledges the VHA belief in "an unwavering ethical obligation to disclose to patients harmful adverse events that have been sustained in the course of their Department of Veterans Affairs (VA) care, including cases where the harm may not be obvious, or where there is a potential for harm to occur in the future."

Patients want to understand if their extravasation impacts their procedure. Patients want to understand how much unnecessary radiation they have received. And patients want the NRC to treat radiopharmaceutical extravasations no differently than any other reportable medical event.

We also want the NRC to understand the information they are receiving from the medical members of the community does not represent the opinion of all clinicians. We have recently become aware of two published papers that support our position and that NRC should read.

On September 5, 2023, Dr. Tim Bartholow published a paper stating that physicians are ethically obligated to report large extravasations and that patients need to be told when these extravasations occur. This viewpoint is clearly supported by another paper published a dozen years earlier by Chamberlain, Koniaris, Wu, and Pawlik.

While the Chamberlain et al. paper is focused on surgeons, the messages are transferable to nuclear medicine clinicians. Here are two important paragraphs:

> "In Western societies, individual autonomy and self-determination are seen to have an inherent self-worth and intrinsic value. Self-determination and the ability of the individual to make autonomous decisions about his or her health care have particularly critical roles in medical decision making.[17] When deciding whether to disclose a nonharmful medical event or error, patient autonomy must be considered. If a physician chooses not to disclose certain events or errors because of their perceived nonharmful nature, the physician first must presuppose what a patient may or may not want to know. However, research shows that most patients want to be made aware of virtually all events and potential mistakes and believe that full disclosure may in fact improve the patient-physician relationship.[5,7,13,18-21] Patients understand that medical events and mistakes can occur, but they want to be informed and involved when an error takes place.[5] Instead of being passive recipients of care from a physician who paternalistically decides it is in their best interest not to be informed, most patients want to participate in decision making.[22-24] However, full disclosure of events to patients can create more questions and uncertainty for patients, especially those less versed in health care. As such, patient education has a critical role in the disclosure process."

> "The patient-surgeon relationship has an intrinsic fiduciary nature that is based on confidence and trust.[25] In a fiduciary relationship, one party (the patient) is in part dependent on the other party's (the physician's) privileged position in the relationship. The essence of the relationship is based on mutual respect and honesty; surgeons have an ethical responsibility to uphold the principles of nonmaleficence (doing no harm) and beneficence (acting in the welfare of the patient) (Figure).[5,17,22] Surgeons are charged with disclosing all information that can facilitate patient participation in the fiduciary relationship. In this manner, the physician acknowledges patient autonomy, allowing the patient to partner in his or her own care.[5] This can only be accomplished when physicians are forthright about all medical issues, including when an error occurs. When a physician fails to disclose a potential medical error, even a minimal or no-harm error, the foundation of the fiduciary relationship is undermined. Physicians may inappropriately withhold information based on well-intentioned, but misplaced, assumptions about what a patient may or may not want to know. By not disclosing, the surgeon shifts the focus of the relationship away from being patient centered. The decision to not disclose a harmless event places emphasis on physician decision making rather than inviting patient-surgeon conversation and deliberation. Other pillars of the patient-physician fiduciary relationship are the principles of nonmaleficence and beneficence. A decision not to disclose an error because of self-interest is at odds with these principles.[25] Rather, when an error occurs, the physician must work to abrogate the harm induced by such a mistake. By disclosing and discussing near-miss or nonharmful errors, the surgeon can take ownership of the incident and work constructively to minimize any resulting subjective harm. Perhaps as important, the surgeon can use the experience to inform systematic processes and institutional policies so that similar potential harmful errors do not occur in the future."

We remain extremely discouraged by the lack of transparency that the medical community and the NRC demonstrate when discussing the injection of radiation into a patient's healthy tissue. These extravasations are medical errors and depending on the severity, obvious medical events for reporting to the NRC. It seems this entire medical specialty is more concerned about their own convenience and reputation than patient safety and transparency. Furthermore, the NRC seems to be either unable to understand the issue and to follow their own policies or unduly influenced by the industry they are regulating. Either or both of these situations are unacceptable and need to be rooted out. Patients want and deserve transparency in their care. They want these errors to be analyzed for a true root cause and then the findings shared with others who administer radiopharmaceuticals so these errors can be prevented in the future.

The PSNM coalition wants the NRC to stop delaying. We want NRC to issue immediate interim guidance that the reporting exemption will be eliminated. Give the providers some time (12-18 months) to address extravasations and then demand that large extravasations be reported using existing event criteria as of January 1, 2025. If NRC doesn't act now, then Congress needs to act for them.

Sincerely,

Mary Ajango, Young Survival Coalition
Spokesperson, Patients for Safer Nuclear Medicine Coalition