PATIENTS
FOR SAFER NUCLEAR MEDICINE

February 6, 2024

Dear Chairman Hanson,

In preparation for our meeting with you on February 7, 2024, the PSNM coalition reviewed the notes from our last meeting. On November 9, 2022, members of Patients for Safer Nuclear Medicine (PSNM) met with you. We shared the following key points:

- Nancy Warden from Vascular Wellness shared evidence that the original exemption was wrong. In fact, extravasations are almost entirely preventable.
- Pam Kohl, Hayley Brown, Kimberly Williams, and Gina Spehn shared that large extravasations could result in high doses to our tissue, that patients deserve transparency when this happens, and it is likely that patients of color are disproportionately affected.
- Mary Ajango shared evidence that your medical staff was being deceived by the industry NRC regulates.

The very next day, you documented your decision on the extravasation petition in your Policy Issue Notation Vote Response Sheet. This document and the resulting Commission decision shows us that the patient perspective was not considered. We will address the exact quotes from your notation vote response sheet.

> *"Therefore, it is time for the NRC to revisit this 42-year-old policy and ensure we strike the right balance between patient protection and the continued beneficial use of radiological materials for medical purposes."*

Our conversation with you and evidence presented directly to the Commission clearly show the exemption policy is incorrect. We also believe your qualifying statement is inappropriate for the decision-making process regarding a medical event. We do not believe any other medical events must meet reporting criteria that has to *strike a balance* as a condition of protecting patients. If we are mistaken, please share an example with us.

Your comment that NRC should consider the continued beneficial use of radiological materials for medical purposes indicates a lack of understanding. A large extravasation during the use of radiological materials harms the patient beyond radiation exposure, when the procedure leads to the wrong treatment. Patients do not want to have their imaging or therapy procedures provided by licensees who routinely extravasate patients.

Your comments also suggest that you would prefer to put the burden on patients, even though we are not suited for this role and patients of color are disproportionately burdened. You stated:

> *"The petitioner proposed using the current medical event dose threshold (50-rem) for reporting these events. However, I am skeptical of prescriptive requirements that do not have a clear nexus to safety. The continued use of radiological materials for medical purposes is critical and I agree with the staff's reasoning to develop a risk-informed approach to capture safety significant extravasation events that will be based on qualitative criteria."*

Skepticism about "prescriptive requirements that do not have a clear nexus to safety" is concerning to patients. NRC's own current event 50 rem dose threshold was determined to be risk-informed in 2001 by NRC and the Society of Nuclear Medicine. NRC's medical event reporting system, including this 50 rem threshold, is also designed to identify licensees who may be having difficulty handling medical isotopes as a proactive way to

avoid patient harm. Tracking exposures from large extravasations and driving these licensees to improve how they handle medical isotopes is clearly a nexus to providing adequate radiation protection to patients.

Also concerning to patients is your suggestion of using qualitative reporting criteria. Your predecessors dismissed using qualitative patient injury reporting criteria for the same reasons that still exist today. These are listed in the same 1980 federal register that exempted extravasation reporting based on incorrect information.

Not only is the Commission decision to accept subjective **patient-reported** injury criteria inappropriate, but it also makes this problem worse for patients. Most patients are not even told they are being injected with radiation. We are not told we are extravasated. We are not made aware of symptoms of ionizing radiation damage. We would have no basis to associate pain in our tissue or damage to our nerves with a procedure that happened weeks, months or even a year earlier. And we have since learned that nuclear medicine physicians don't even take patient appointments. Even if they did, who pays for the additional cost of this extra office visit?

We reiterate our concerns about health care inequities. Patient-reported injury criteria disproportionately affects minorities. As a Caucasian male you may not understand how unlikely it is that patients of color would report - much less try to convince a physician - that an injury is related to radiation when there is no documentation that they had been extravasated, and when there may not be visible skin damage.

Your comments regarding medical event criteria suggest the existing criteria do not apply. Your attempt to build a case of why extravasations are not being reported is inaccurate. You stated:

> *"Currently, the 50-rem dose threshold is not the sole criterion for a medical event. The NRC's medical event reporting regulation in 10 CFR 35.3045 lists administration errors that qualify for this designation, such as, wrong drug, wrong dosage, wrong patient, or wrong route. With some exceptions, for an event to be considered a medical event, there must be an administration error covered by the regulation that in turn causes the dose threshold to be exceeded. The NRC has not considered an extravasation to be an administration error for the purposes of this regulation because it can be caused by unintentional leakage that is not the result of misadministration."*

We have read ACMUI transcripts and prior NRC documentation. The only reason that extravasations are not being reported today is because of your internal exemption policy. Your comments rely on past attempts to continue to justify the exemption. Please read the ACMUI transcripts from December 2008 and May 2009. This topic is extensively covered. The only reason that extravasations are not reported today is that the ACMUI and the industry lobbied NRC to retain the exemption, so they don't have to report when patients receive large radiation doses. If the exemption were gone, then many extravasations would meet the reporting criteria.

The nuclear medicine community intentionally prescribes that radiopharmaceuticals be administered intravenously. For these drugs to provide **a beneficial medical purpose**, they **must be delivered completely into the venous system**. When radiopharmaceuticals are accidentally delivered into tissue, they are not delivered into the vein, as prescribed by clinicians. When extravasated, radiation has been delivered using the **wrong route**. An incorrect route can invalidate the procedure and is clearly an administration error. To your point, leakage of a radiopharmaceutical through the venous wall is not a misadministration and would not likely pass the dose threshold, and therefore would not be reportable. However, a radiopharmaceutical extravasation that exceeds an objective dose-based threshold is a concerning misadministration.

We were also disappointed that you chose to rely on the misleading and incomplete statements from certain medical societies. You stated:

> *"On top of that, if the NRC were to promulgate a 50-rem dose threshold for reporting extravasations, physicians would need to monitor, characterize, and calculate extravasation doses for millions of nuclear medicine injections each year. This would impose a regulatory burden without a nexus to safety, and as the medical community has warned, may hinder the use of these diagnostics and therapeutics."*

Chairman Hanson, have you considered the similarities of this situation to Boeing and their relationship with the Federal Aviation Administration? Your comments suggest the only advice you heeded was that of the industry NRC regulates. If licensees are required to report extravasations just as they would any other medical event, then this effort will not hinder the use of medical isotopes. However, it will ensure that these providers take the steps necessary to reduce extravasations. If they do not, and if their incorrect practices continue to result in large extravasations, then these centers should not be administering radiopharmaceuticals. A misadministered radiopharmaceutical can not only cause tissue damage, but it can also lead to the wrong treatment.

And by eschewing NRC's existing objective-based dose threshold to avoid "regulatory burden," you proposed a rule that creates "patient-burden." This is indefensible. It ensures that centers will neither assess nor reduce extravasations. As a result, no mitigation of the tissue dose will take place. This policy harms patients. You have the power to change that. If you close the loophole and treat extravasations like the medical events they are, then centers will monitor and characterize extravasations. It will drive these centers to put mitigation steps in place to lessen the tissue dose to patients. It will drive transparency for patients and your organization.

In our opinion, your staff is being misled. We voiced our concerns to you when we met in 2022. Yet, you stated:

> *"I thank the staff for their thorough consideration of radiopharmaceutical extravasation. There has been significant input from several stakeholders, including the ACMUI, Agreement States, the medical community, the petitioner, and members of the public, and the staff has done a tremendous job evaluating and incorporating that input into its recommendation. The staff will continue to solicit input throughout the rulemaking process. I am confident that patient safety will be improved as result of this effort."*

Our experts read the SECY document that informed your decision. This document regurgitates the incorrect positions of the industry you regulate.

Patients are not nuclear medicine physicians; however, we understand that a process that is measured will improve over time. Administering radiopharmaceuticals is no different. Fixing the error in the exemption policy and treating large extravasations like any other medical event will strongly encourage providers to finally address their extravasation issues. If licensees are forced to report, they will reduce their extravasation rates to the rate of other similar IV procedures. We would expect 3,000 potential reportable events in the first year after a reporting grace period. Therefore, licensees would not be characterizing or performing dosimetry on millions of extravasated radiopharmaceutical administrations.

We believe that the NRC is failing in their responsibilities to protect patients. So, we will continue to work with the Office of Inspector General to ensure that there is an investigation into the influence of the licensees. We are also working with key members of Congress to get us the protection we deserve to treat these events no differently than any other event. We will do everything we can to educate the public directly and through the media. We are passionate and tireless on this issue because our lives depend on it.