



August 8, 2024

Re: Journal Pharmacology Research & Perspectives Case Report

Dear Dr. Jadvar, Dr. Katie Tapp, and Daniel DiMarco,

We reached out to you last month regarding the June 17th ACMUI teleconference materials and the NRC staff's draft rule on reporting nuclear medicine injection extravasations. In that letter, we informed you that well-defined and precise dosimetry criteria should be established to ensure accurate, consistent, and comparable reports of extravasations. We have not yet received a response from you.

I wanted to bring to your attention evidence from unbiased and unconflicted experts that you should not ignore. A published case report in the journal of [Pharmacology Research & Perspectives](#) adds significant weight to the growing body of evidence that extravasations occur frequently and can cause considerable harm. This report, originating from the Netherlands, details a substantial extravasation incident involving Technetium-99 (99m-Tc), the most widely used radioisotope globally. Upon recognizing the extravasation, the clinicians involved took immediate and decisive action.

In contrast, some organizations in the United States argue against the need to monitor or respond to extravasations, suggesting that patients should not be concerned about such incidents with imaging isotopes like 99m-Tc. This stance is deeply flawed and represents poor medical practice. The report reveals that the patient affected by the extravasation not only had to undergo the procedure again, thereby receiving additional radiation exposure but also suffered damage to the skin and underlying tissues despite the physician's efforts to mitigate the harm. Without these mitigation efforts, the damage could have been even more severe.

It is so clear to us that a significant extravasation of any radiopharmaceutical can expose patients to exceedingly high radiation doses, potentially severe enough to require reporting to Congress as Abnormal Occurrences. The experts we talk to, and this case report confirms that when a high amount of radiation is deposited in a small volume of tissue, the patient will experience a high absorbed radiation dose to their tissue. It is also clear to us that the industry NRC is supposed to be regulating opposes this reporting. And we are reaching the conclusion that the industry is actively working to conceal these safety incidents. In that context, the subjectivity in the proposed rule will continue to enable providers to avoid reporting.

Mandating the reporting of large extravasations in a manner consistent with all other medical events would enhance transparency for patients and compel physicians to monitor and improve the administration of radiopharmaceuticals, significantly reducing the occurrence of such events. Furthermore, it would encourage physicians to take necessary mitigation steps when extravasations do occur.

Despite compelling evidence such as this recent case report, it appears to us that NRC continues to rely uncritically on the unfounded and self-serving claims of professional societies that extravasations are rare and inconsequential. This approach is detrimental to patient safety and undermines the integrity of medical practice. We reiterate our concerns about the conflicts of interest within ACMUI and the need for advisers who prioritize patient safety.

We respectfully ask that you look at this mounting evidence we have shared and eliminate any subjectivity from the criteria going forward. Finally, we strongly encourage you to take definitive steps to ensure that ACMUI members provide unbiased advice that prioritizes robust patient radiation protection over industry interests.

Thank you,
Members of the Patients for Safer Nuclear Medicine Coalition

Learn more at www.safernuclearmedicine.org