September 27, 2021

Dear SNMMI leadership team,

I am a certified nuclear medicine technologist with 30 years of nuclear medicine experience. I have had the good fortune in my career to work in nuclear medicine centers, nuclear pharmacies, authorized user training, and currently in a health physics/regulatory role. I have also had the pleasure of working with Dr. Richard Wahl and I know he is passionate about accurate PET data and quantification.

I have closely followed the discussions on radiopharmaceutical extravasations over the last couple of years. I engaged many colleagues on this topic and have learned that my perspective is shared by many other concerned SNMMI members. Therefore, I am writing this letter to you share the perspective of this group.

As a community, we invest heavily in quality control and assurance, but the quality of the administration (arguably one of the most important steps in a nuclear medicine study) is not routinely monitored in a meaningful way. Furthermore, we know significant extravasations can and do happen, are not characterized, and patients are not followed. When centers are aware of a significant extravasation, there are no established mitigation techniques and there are no clear criteria on whether to repeat these studies. However, what is clear to us is that the society is on the wrong side of this issue. Many of us have read the ACMUI, SNMMI, and other societies' positions, including the SNMMI's latest letter to the NRC, dated August 31. These positions are contrary to our experiences and frankly not supported by evidence. We have also read and agree with NRC public comment 485. This comment was sent by experts (including some of the most senior leaders in the SNMMI and the radiology community), and, like us, these leaders have no conflict of interest in this matter.

Not only is the SNMMI on the wrong side of the extravasation issue, but the society is not taking appropriate actions to address the issue. We have seen SNMMI suggest that centers are best left to address this issue individually. But we have also seen hundreds of our colleagues send form letters to the NRC, indicating extravasations are harmless. It is improbable that any of these centers will voluntarily fix their extravasation issue. Additionally, in the midst of the recent Alzheimer's drug approval, we watched in disbelief as the Mayo Clinic presented their findings on extravasations at the recent SNMMI annual meeting. Two technologists presented that they extravasated 8% of the 185 patients who had their injection site imaged, but the injection site could not be imaged in another 7.5% of their patients. The technologists also shared that some extravasations negatively affected the quality of the images, yet they concluded that it was ok to switch to a new camera that did not allow easy imaging of the injection site. How did they reach this conclusion that it was ok to stop monitoring for extravasations? They reached this conclusion because they believed that the number of patients potentially affected by extravasations would be low. Not only is it shocking that this presentation was submitted and accepted for presentation, but it is hard to believe that the moderators did not address this matter. No one would want their family member to be in the group of the 4-5% of patients with poor quality images being used to help guide their care.

We have also seen an SNMMI patient leaflet that suggests ice as possible mitigation for a radiopharmaceutical extravasation. How could a mitigation technique that retains radioactivity at the site rather than disperse it make it into a SNMMI sponsored patient leaflet? We have seen more and more information about expanding radiotherapies promulgated by the SNMMI – therapies where an extravasation will result in dramatically high absorbed doses (see the recent Fox Chase Cancer center Lutathera case where the staff believe they injected all 200+ mCi into the patient tissue). Many therapy administrations are not imaged immediately after delivery. If some of the Lutathera dose in the Fox Chase extravasation was delayed in delivery and reached the kidneys beyond the window of protection provided by the delivered amino acids, what was the impact to the patient's

kidneys? Why is the SNMMI not demanding that any therapy administration use some sort of monitoring technology so extravasations might be identified as soon as possible?

The recent NRC and ACMUI meeting on September 2 and their submitted meeting material suggests that these organizations have begun to learn more about extravasations, but they are still not where they need to be. Yet, it is obvious to many of us that extravasations should be, and soon will be, regulated just like any other medical event.

I participated in the recent Organization of Agreement States annual meeting. I attended the Fox Chase extravasation case that was presented by the RSO. I also attended an educational information session on extravasations by a company that is petitioning the NRC on extravasations. It is evident that many member states are not willing to accept the current NRC position and want to be informed when patients in their states are extravasated and experience an absorbed dose to their tissue greater than 0.5 Gy. This is what I want in my state, as well. Additionally, the OAS Board has come out in writing asking the NRC to retract the reporting exemption. I support this position whole heartedly and so do many of my colleagues. We also know, from our friends in the insurance industry, that CMS is looking into the matter, and now patients are getting involved as well.

Many patient advocacy organizations have formed a new coalition to specifically address this issue. They are on Facebook, Twitter, and are writing to members of Congress and meeting with them. This coalition had a guest speaker who had been extravasated with Tc-99m MDP at a top US institution speak at their September meeting. I saw a video of part of her talk on YouTube. It is a classic case of an extravasation that should have been reported. However, it wasn't reported due to the exemption and would not be reported if the NRC chooses Option 4 as the ACMUI suggested. The patient's tissue was harmed by an inadvertent misadministration, but that licensee is learning nothing from this experience, and these extravasations will continue to happen.

It will not be long before patients realize that the societies representing nuclear medicine are not focusing on patient safety and are also not ensuring that their images or therapy administrations are of the highest quality. In a recent *Health Imaging* article, the American College of Radiology implied that the reporting of significant extravasations was "inconsequential," and Dr. Packard said, "On those rare occasions when a significant extravasation occurs, it is managed under existing procedures under the direction of the authorized user." How could the SNMMI suggest significant extravasations are rare, when we don't track or characterize them and when more than half the time, we don't even know they happened? And exactly how do centers manage extravasations? Do they follow the leaflet? They didn't for that patient in the video! Her technologist had NO IDEA what to do. No mitigation. No dosimetry. This patient experienced pain in her arm below her skin at the injection site that woke her up at night. Cases like this are not good for patients, nor our community.

In the August 31 letter, the SNMMI states there are approximately 20 million nuclear medicine procedures and no evidence of significant patient harm. I agree that no one is identifying or characterizing when large extravasations happen, and no one is following these patients. But that does not mean patients are not being harmed by an almost completely preventable medical error. Furthermore, the SNMMI's recommendations for Options 6, and possibly Option 4, to avoid quantification of extravasations is counter to our own practice guidelines to characterize the amount of activity that has been extravasated. Performing dosimetry for the tissue can follow a number of published methods; it is required now for skin that has been affected. Tissue dosimetry is not significantly different. Surely our MIRD Committee is aware of a recently published method that suggests using reasonably larger tissue volume than the volume we use today for skin doses. This reference tissue volume will result in the reporting of truly significant extravasations. Extravasations that need to be reported.

We suggest that the SNMMI take a different approach. The SNMMI should address extravasations head on by focusing on what is best for our patients. We think the SNMMI should state the following:

- SNMMI realizes the importance that every nuclear medicine patient experiences a proper radiopharmaceutical administration.
- SNMMI will establish a new quality initiative and an aggressive goal. SNMMI will partner with the Association for Vascular Access to encourage all centers to improve training, tools, and techniques so that the community can make this preventable condition as close to non-existent as possible.
- SNMMI will encourage, support, and promote incentivizing technologists to improve their vascular access skills.
- SNMMI understands the importance of accurately characterizing significant extravasations and reporting those that exceed medical event reporting limits.
- Patients, their referring physicians, and the interpreting physician have a right to know the absorbed dose to the patient's tissue.
- Patients who experience significant extravasations need to be followed periodically for 2-3 years.

We believe addressing extravasations will not only benefit patients but will improve the repeatability and quantification of nuclear medicine studies. This is good for nuclear medicine, not bad. The approach will build trust between patients and the nuclear medicine community and will minimize the chance of complete extravasations like the recent event at Fox Chase Cancer Center. An impactful patient-oriented initiative is a perfect fit for the future of nuclear medicine.

I am a regulator, and the NRC has made it clear in some recent petition denials that licensees must make "every reasonable effort" to reduce patient exposure to as low as reasonably achievable and in these cases, licensees must incorporate measures to track and, if necessary, reduce exposures. The NRC also states that expense is not an excuse licensees can use to avoid radiation protection efforts. In their preliminary findings on extravasations, the NRC is also clear that by exempting extravasations from reporting they are not meeting their obligation to Congress in the reporting of Abnormal Occurrence. Addressing these issues requires the characterization of extravasations.

We know our community is up for this challenge. We are confident that if licensees actively address the issue, extravasation rates will plummet and centers that embrace these changes will rarely extravasate. Combining thoughtful rulemaking with licensees that identify significant extravasations, characterize them, and actively follow patients, will all be important to ensure that the reporting burden is minimal for licensees actively reducing extravasations.

Thank you for your time and considering our request. We strongly encourage the SNMMI to do what is best for patients and to fulfill regulatory obligations. Many of us have remained silent on this issue, but we cannot stand idly by anymore and are copying members of the NRC and OAS on this communication.

Cc: Christopher Hanson, Chairman, Nuclear Regulatory Commission
David Crowley, Past-Chairman, Organization of Agreement States
Auggie Ong, Chairman, Organization of Agreement States