



October 20, 2021

Attn: Members of the Organization of Agreement States (OAS)

Dear Chairman Ong, OAS Board Members, and Member States:

I am writing to you on behalf of Patients for Safer Nuclear Medicine (PSNM), a national coalition of 19 patient advocacy organizations across several therapeutic areas, representing hundreds of thousands of patients in the US. The coalition is growing every week and is proud to have two corporate partners - UPPI, a radiopharmacy organization representing 80 nuclear pharmacies and Vascular Wellness, an organization focused on improving quality and safety in healthcare. Together, we are dedicated to the development of federal policies that support safe, transparent, and effective nuclear medicine care on behalf of patients throughout the U.S.

We are reaching out about an issue of urgent concern for the patients we represent - radiopharmaceutical extravasations. *PSNM is following this issue closely and requests a meeting with the OAS Board to share the patient perspective on this important matter.*

We commend the OAS and fully agree with your written position that the petition before the Nuclear Regulatory Commission (NRC) be immediately accepted. We contend that requiring the reporting of extravasations is medically necessary and will encourage providers to take the necessary steps to ensure nuclear medicine is as safe and effective as possible.

The patients we serve have voiced their legitimate concerns about high doses of ionizing radiation from an extravasation as well as the negative impact to diagnostic images which can lead to misdiagnosis and inaccurate treatment. Patients have a right to know when an extravasation occurs, as do their physicians. When clinicians have the information they need, they can act immediately and minimize damage to the tissue.

Pam, an extravasated patient, recently spoke with our coalition members about her experience. You can view her compelling testimony [here](#) which highlights the need for monitoring and mitigation. Not shown in the video is Pam's testimony that her technetium extravasation caused her pain in the underlying tissue but did not result in reddening of her skin near the injection site.

PSNM was deeply disappointed with the September 2 ACMUI/NRC discussion of nuclear medicine extravasations. Nearly all of the recommendations provided by the NRC medical staff do not support radiation protection of patients. Additionally, PSNM and many of our members submitted written comments to the NRC prior to the meeting, yet none of these comments were shared. To ensure you understand the patient perspective, we are providing a link [here](#) to the transcripts and written comments from this meeting. We have also attached a brief synopsis of all the comments for your review.

The ACMUI recommended a course of action—a modified version of “Option 4” of the NRC Staff’s Preliminary Evaluation prioritizing the parochial interest of nuclear medicine practices at the expense of patient care. This recommendation was also very disappointing. As highlighted by the ACMUI Patient Advocate, Josh Mailman, Option 4 would put the burden on patients to identify delayed symptoms of radiation injury rather than requiring practitioners to take responsibility at the time of the procedure. As Pam so clearly articulated in her video, patients who are facing a life-changing diagnosis do not want the added responsibility of identifying when their clinicians have accidentally extravasated them and are in no condition to accept this responsibility. Furthermore, patients do not have the medical knowledge necessary to understand the signs and symptoms of radiation damage, especially when this damage can take weeks to months to appear.

A better option to protect patients and help reduce the rate of extravasation would be to simply monitor for extravasations at the time of the nuclear medicine procedure. Patients who are not extravasated could feel confident that the procedure was performed correctly. When the monitoring suggests an extravasation, clinicians should be trained on how to mitigate possible consequences of the poor administration. This option would be simple to implement, place fewer burdens on patients, and improve outcomes. By attempting to avoid accountability for the responsible use of radiopharmaceuticals and ignoring the input of its designated patient advocate, the ACMUI demonstrated a concerning inability to provide unbiased counsel to the NRC on this important policy issue.

The ACMUI continued to disappoint us during the October 5 meeting with the NRC Commissioners. The ACMUI showed a lack of attention to the extravasation issue in their prepared comments and then made contradictory statements in response to the Commissioners’ questions. While unhappy with many of the NRC medical staff’s proposals, PSNM was pleased with the Commissioner’s focus on and obvious knowledge of the extravasation issue. It appears the Commissioners understand the negative effects of extravasations for patients and how the ACMUI’s recommendations do not fit with the traditional NRC approach to radiation protection.

Since OAS is the NRC’s regulatory partner, we understand that member states can take a more conservative approach to radiation protection than the NRC. On behalf of the hundreds of thousands of patients we collectively serve, we ask the OAS to keep the patient perspective in mind as you work with the NRC. Please continue to support the immediate approval of the petition and work with member states to notify their hospitals as soon as possible to start monitoring and reporting.

We thank you for your attention to this matter and look forward to meeting with the OAS Board soon.



Sincerely,

Patients for Safer Nuclear Medicine Coalition

Patient Advocacy Members:

ACE, Advocates for Collaborative Education
Cactus Cancer Society
Cancer in the Know
Cancer is an Asshole
Cervivor
Chicago Hispanic Health Coalition
Día de la Mujer Latina
Inflammatory Breast Cancer Research Foundation
ICAN, International Cancer Advocacy Network
New Day Foundation for Families
Patients Rising
Peer Plus Advocates
Research Advocacy Network
Stupid Cancer, Inc.
Survivingbreastcancer.org
The Pink Fund
Tigerlily Foundation
Touch, The Black Breast Cancer Alliance
YSC, Young Survival Coalition

Corporate Members:

UPPI
Vascular Wellness

Comments in Response to NRC Staff Policy Options & September 2 ACMUI Meeting

Category	Name	Comment Synopsis
Patient Advocacy Organizations	Patients for Safer Nuclear Medicine	Urges NRC to adopt the recommendations made in the petition in Docket: NRC-2020-0141 and explains the health risks of extravasations.
	Amanda R. Ferraro, Cancer Is an Asshole	Addresses ACMUI's statement on Medical Event reporting and psychological harm, noting that this concern puts optics and public relations above a patient's safety and right to information.
	Venus Ginés, MA, P/CHWI, Día de la Mujer Latina	Addresses the danger of extravasations interfering with accurate imaging, which can affect a patient's cancer diagnosis and treatment plan.
	Marcia K. Horn, JD, ICAN, International Cancer Advocacy Network	Addresses the ACMUI statement: "All nuclear medicine facilities <u>should</u> have comprehensive quality control measures in place to monitor and track extravasations to improve the quality and safety of patients undergoing medical procedures involving the use of radiopharmaceuticals." Suggests that centers do NOT have comprehensive quality control measures in place and that centers are NOT following the honor system for reporting.
	Gina Kell Spehn, New Day Foundation	Shares support for petition and addresses the problems that result from a lack of reporting of extravasations, including cancer patients and their doctors not having information they need.
	Molly MacDonald, The Pink Fund	Urges support for the petition and highlights the danger of inaccurate imaging leading to improper staging for cancer patients.
	Mary Farrell Ajango, Young Survival Coalition	Highlights the importance of patients having as much information as possible about their own health so they receive the best possible treatment and have the information they need to advocate for themselves.
Patient Advocates	Pam Kohl	Details personal extravasation experience and lack of information provided to patients on what to expect when an extravasation occurs. Suggests that medical societies do not understand the patient consequences of extravasations, that there is a lack of monitoring for extravasations, and then suggest questions NRC should ask centers.
	Drew Garner	Raises concerns about the failure to consider patient perspectives, notes that extravasations are preventable, and highlights inconsistencies and the lack of evidence to support certain assertions by ACMUI members.
Clinician Experts & Trusted Patient Partners	Nancy Williams & Alan Etkin Vascular Wellness	Notes that extravasations are preventable, do not result from patient intervention, result in patient harm that may not be immediately obvious, and represent an irresponsible handling of nuclear material.
	Daniel Guerra Jr., AltusLearn & Dr. David Townsend	Summarizes findings from a CE-accredited webinar on radiopharmaceutical extravasations: extravasations negatively affect image quality, quantification, and interpretation of images; radiation effects are not readily visible immediately; and vascular experts expect a first time access success rate of 98%, indicating that extravasations are avoidable.

PATIENTS

FOR SAFER NUCLEAR MEDICINE

Category	Name	Comment Synopsis
Medical Societies	American College of Radiology	No regulators should be alerted about an extravasation unless a patient <i>sustains permanent functional damage.</i>
	American Society for Radiation Oncology	No regulators should be alerted about an extravasation unless a patient <i>sustains permanent functional damage or requires medical attention, narrowly defined.</i>
	Society of Nuclear Medicine & Molecular Imaging	No regulators should be alerted about an extravasation unless a patient <i>sustains permanent functional damage or requires medical attention, narrowly defined.</i>