



Dear Commissioner Baran, Commissioner Wright, and Chairman Hanson,

Patients for Safer Nuclear Medicine (PSNM) is a national coalition of 24 patient organizations representing thousands of patients, and three corporate organizations. 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 reached out to you in June 2021 and felt it necessary to contact you again.

This letter was spurred by the powerful Dec. 27 [opinion piece](#) in STAT by Dr. Dan Fass. He believes the Nuclear Regulatory Commission (NRC) is allowing the industry it regulates to influence whether clear medical events remain concealed from patients. Dr Fass' opinion piece is accompanied by supportive comments from experts on the subject of extravasations. Dr. Jackson (Bill) Kiser, Chief of Molecular Imaging at Carilion Clinic, is among the most experienced in the world at monitoring the administrations of radio-pharmaceuticals. In his comment regarding Dr. Fass' piece, he says, "It is apparent to me that the relationship between the NRC and my community is negatively influencing doing the right thing for patient care." Dr. David Townsend, co-inventor of the PET/CT scanner, cuts right to the chase. He says, when "the regulated are regulating the regulators, it is time for a change."

Other healthcare professionals and patients posted comment after comment demanding the reporting of significant extravasations. Nancy Warden is COO of Vascular Wellness and has been trained in vascular access for more than two decades. "I have been witness to numerous vascular access related failures that resulted in very poor outcomes for the patient. If proper steps are not taken and taken quickly it could very likely result in loss of tissue or limb," Warden says. "I implore the NRC to give this issue the attention that it deserves. When the NRC acts, programs will change and accidents will no longer be swept under the rug."

Unfortunately, it appears your team is not willing to act in a way that protects patients. Dr. Fass, in a comment to his own article, shared a letter from the Organization of Agreement States (OAS) posted on the NRC website after his piece had published. From the OAS letter, we see that your team is proposing three options to address extravasations:

1. Do nothing.
2. Remove the current exemption.
3. Only report extravasations that patients identify.

The OAS letter indicates that your team has chosen to recommend only reporting extravasations that patients identify. This option allows hospitals to abdicate their responsibility for safely administering radioactive drugs. Instead, it assigns the responsibility of the quality check for the proper administration of a radioactive drug to patients. This position is, frankly, baffling. Why shouldn't hospitals be required to take steps to know immediately when they have accidentally injected radiation into patient tissue instead of their veins. It is our understanding that if an extravasation occurs, steps



can be taken to minimize the dose to the patient's tissue; shouldn't the NRC be demanding that hospitals do exactly that to protect patients?

Why does the NRC believe that completely unqualified patients are better suited to this task than trained clinicians and physicists? Why would the NRC advocate for harm to come to a patient before reporting? John Witkowski, CEO of UPPI – a group of independent radio-pharmacies – notes that this policy fails to put the patient's best interests at heart. "The fallacy of the patient finding out skin changes post extravasation and reporting back to the nuclear medicine is impractical," Witkowski notes. "The impracticality seems to be an emphasis on local skin and tissue change and does not consider the eventuality that the infiltrated dose will progress through the lymphatic drainage of the arm."

We are patients, but we know that the reason behind the original reporting exemption is not based on the truth. Extravasations can be prevented. Stephen Harris, a vascular access expert knows that extravasations should not be an expected outcome of an injection. He says that patient safety can be greatly increased, "via policy procedure and competency. This has already been proven in other areas of medicine that inject potentially dangerous intravenous therapies such as chemotherapy and critical care." And we don't have to be physicists, radiologists or radiation safety officers to know that injecting radiation into patient tissue is potentially harmful and a clear misadministration of nuclear material. Leah Binder, President & CEO at Leapfrog Group, notes that extravasation threatens both patient safety and diagnostic integrity. "This can harm the most vulnerable of patients and likely wastes significant money in the process," Binder adds.

Extravasations compromise the images that drive our care as well as improperly exposing us to high doses of potentially harmful radiation. We ask the NRC to carefully reflect on its role in protecting patients from misadministration. Why are some hospitals having problems delivering radiation to patients? How could the NRC help drive them toward root cause, and then share the learning so that other patients do not experience the same harm?

Patients deserve better. We hope you know the option where patients are responsible for identifying significant extravasations and the "no action" option are unacceptable. Rather, it is time the NRC acted immediately on the extravasation issue. We respectfully urge you to review the attached documents for a range of healthcare professionals' comments in support of Dr. Fass' commentary.

We are hopeful that the NRC will recognize the analysis of trained industry experts who are not conflicted in the matter at hand and do the right thing by removing the 1980 reporting exemption. Adopting the recommendations included in the petition in Docket: NRC-2020-0141 can help us protect patients, who have a right to know when our tissue has been inadvertently exposed to high doses of radiation and our images potentially compromised. On behalf of the patients we serve, we thank you for considering our request.



Sincerely,

The Patients for Safer Nuclear Medicine Coalition

2 for 2 Boobs
ACE Collaborative
AltusLearn
Cactus Cancer Society
Cancer in the Know
Cancer is an Asshole
Carrie's Touch
Cervivor
Chicago Hispanic Health Coalition
Dia de la Mujer Latina Inc
Elephants & Tea
Inflammatory Breast Cancer Research Foundation
International Cancer Advocacy Network
New Day Foundation for Families
Patients Rising Now
Peer Plus Advocates
Research Advocacy Network
Steven G Cancer Foundation
Stupid Cancer
Teen Cancer America
The Pink Fund
Tigerlily Foundation
Touch, The Black Breast Cancer Alliance
UPPI
Vascular Wellness
Young Adult Survivors United
Young Survival Coalition



John Witkowski, Chief Executive Officer at UPPI, LLC (group of independent radio-pharmacies)

I appreciate the article by Dr. Fass on radioisotope extravasation in nuclear medicine as an issue of patient care. My time in nuclear medicine goes back to the establishment of the mis-administration reporting for radiopharmaceuticals which included extravasation at that time. Then, forty years ago, the reporting of extravasation literally disappeared from requirement eliminating the evaluating the problem, amount of occurrences and potentially providing guidance to lessen re-occurrence. This discussion needs a context as well to the importance of monitoring/reporting significant dose extravasation. It has been reported by many sources that 50,000 nuclear medicine studies are performed each working day across the U.S. healthcare community. If a patient undergoes a rest and stress nuclear cardiac procedure, then that is two injections on the same day of imaging. It's safe to assume there are greater than 50,000 injections of radioactive medicines each day. It has been stated even in NRC reviews that extravasations, or dose infiltration into the tissues of the injection site, does occur. An infiltration of a radioactive dose either in its entirety, or a partial extravasation is an unintended consequence, but it does happen.

The concern going forward regarding patient safety is in the advancement of nuclear imaging products and radiotherapeutic injections in "new and emerging" radiopharmaceuticals as classified by the NRC in 10 CFR Part 35, subpart K 35.1000 "other medical uses of byproduct material". The emerging products will include imaging radionuclides and radiotherapeutics. New theranostic products (imaging and therapy with related radionuclides such as Ga68 for imaging and Lu177 for the therapy) brings forward radioisotopes that emit beta and alpha decays which have greater dose absorption within the body, the tumor tissue. The future holds for the combination of particle emitters (beta and alpha) potentially labeled to the chemotherapy drug. So to hold extravasation exempt from medical event reporting with the advancements to come does not seem prudent. Likewise the fallacy of the patient finding out skin changes post extravasation and reporting back to the nuclear medicine is impractical. The impracticality seems to be an emphasis on local skin and tissue change and does not consider the eventuality that the infiltrated dose will progress through the lymphatic drainage of the arm. Such imaging of the lymphatic drainage of extravasation of F18 doses was shown in Lucerno submitted documents to the NRC. Alpha and beta radiopharmaceuticals, possibly nano-particle radionuclides, will cause high exposure to the lymph and lymph nodes of the axillary area for an infiltration in the antecubital vein. How would the patient know what type of unwarranted exposure has occurred beyond the injection site? That determination requires the expertise of nuclear medicine professionals and medical physicists to assess and determine if a medical event should be reported. It is time to move to a well defined process for extravasation reporting, despite the reporting hassle.

Nancy Warden, Chief Operating Officer at Vascular Wellness

I am a vascular access professional that has been trained in vascular access for over 20 years. In short I have been witness to numerous vascular access related failures that resulted in very poor outcomes for the patient. I am sad to say that nothing has changed in regard to nuclear medicine vascular access device failures as far as reporting. Vascular access is the fulcrum to treatment for most diagnoses. Vascular access skills have atrophied across the board in the hospital setting. Nurses no longer know



how to properly select the correct site much less cannulate the vessel. Delivering nuclear medicine therapies through a peripheral line that was never in a safe position is problematic. What happens after the IV site infiltrates, even worse. If proper steps are not taken and taken quickly it could very likely result in loss of tissue or limb. I implore the NRC to give this issue the attention that it deserves.

The solution is simple as the problem has already been identified. The only way this changes is for the NRC to get behind the safety issues. When the NRC acts programs will change and accidents will no longer be swept under the rug. Nuclear Medicine departments need to implement strong training programs with yearly competency assessments. When key safety metrics are in place staff will understand that vascular access is not a benign procedure where see one, do one, teach one serves as legitimate training.

Stephen Harris C.R.N.I, VA-BC, Vascular Access Expert at Vascular Wellness

As a health care professional who has seen the impact of extravasation on patients, I was astounded to first learn that other healthcare professionals are actually arguing AGAINST reporting of these events. Extravasation risk can be mitigated, and patient safety greatly increased, via policy procedure and competency. This has already been proven in other areas of medicine that inject potentially dangerous intravenous therapies such as chemotherapy and critical care. While some healthcare institutions have formalized protocols around the injection of radioactive materials from the time the intravenous device is placed to the completion of the study, many do not. The impetus for ensuring that all institutions engaging in radioisotope studies have these protocols in place, and that these procedures can be as safe as possible, starts with reporting.

Alan Etkin, President and General Counsel at Vascular Wellness

As President of Vascular Wellness, a nursing organization providing vascular access services at the bedside for hospitals and others, we have seen firsthand the damage that nuclear extravasations cause. We strongly support reporting to the patient, the doctor, the NRC, and others when this occurs not just for analysis and because the patient has the right to know, but so that proper observation will be done and treatment obtained, as clinically appropriate. In addition, a review of how compromised the diagnostic images may have become needs to occur to ensure proper treatment of the underlying problem. The idea that ignoring an extravasation is consistent with the practice of medicine is irresponsible and out of touch with the foundation of all healthcare - transparency and trust between the provider and patient.

Dr. Jackson (Bill) Kiser, Chief of Molecular Imaging at Carilion Clinic

I am a nuclear medicine physician with likely the most experience in the world at monitoring the administrations of radio-pharmaceuticals. It is apparent to me that the relationship between the NRC and my community is negatively influencing doing the right thing for patient care. Dr Fass is entirely correct with his description of the issue and how it should be resolved. Every patient should know that they received a high quality administration of a radioactive drug. If they did not then they should also



know that information and their provider should perform dosimetry to assess the impact to the patient and their procedure.

Dr. David Townsend, Co-inventor of the PET/CT Scanner

As the co-inventor of the PET/CT scanner and author of a STAT article (Hospitals shouldn't be exempt from reporting faulty radioisotope injections) that was linked to this article, I would like to support the assessment by Dr Fass of "regulatory capture". It really makes no scientific sense that a certain level of radioactivity spilled on a patient is reportable, whereas a similar amount of radiation spilled (extravasated) internal to the patient is not reportable. In the almost four decades I have worked in nuclear medicine departments I have observed radioactivity accidentally spilled onto a patient on only three occasions, whereas published extravasation rates can be as high as 15% representing thousands of patients per year. The contradictory arguments in opposition to changing the reporting requirement for extravasations include: 'extravasation occurs so rarely that a reporting requirement is unnecessary' or 'mandating reporting of significant extravasations will place an additional financial and regulatory burden on the economics of nuclear medicine imaging departments'. You can't have it both ways, although those opposing the regulatory change would appear to want to do so! Extravasated radioactivity can result in a significant local radiation dose to tissue and compromise both the quality and quantitation of the resulting imaging study. Nuclear medicine imaging contributes enormously to patient care and is overall a well-regulated procedure that includes the production of the nuclide and radiopharmaceutical labeling, the operation and calibration of the imaging equipment, the computer software to reconstruct and display the images, and the process for reading and reporting the images. However, there is no such obligation to quality control and monitor the administration of the radiopharmaceutical to the patient to ensure that the entire dose is injected cleanly into the vein. This would indeed seem to be a loophole that needs to be closed such that the injection process is properly monitored, and significant extravasations reported. As convincingly argued by Dr Fass in his article, when the regulated regulate the regulators, it really is time for a change. Finally, for the record, while I have provided scientific advice to the company petitioning the NRC, I have absolutely no financial relationship with that company to report, and I never have had one.

Maria del Paso, Nuclear Medicine Technologist and State Regulator

I have been a CNMT for more than 30 years and I have also been a state regulator. What Dr. Fass is saying makes perfect sense and I completely agree with his statements. I have witnessed full doses of NMT and PET radiopharmaceuticals being extravasated and there is no feedback to the patient or the referring doctor, which is unethical and unacceptable; patients deserve better. The amount of paperwork and/or reporting should have no weight in this decision to provide a higher standard of patient care in NM and PET. Patients have the right to make decisions about their care and they should also get honest, reliable, and full disclosure reporting from every procedure performed. The NRC exemption has to stop. I wonder if the ACMUI members would be comfortable having a full F-18 dose extravasated into their family member's arm?



I also attended an ACMUI meeting when I-131 patient release was discussed and I positively know they don't want to deal with that either, which is a risk to the public, but no one wants to confront the problem. Extravasations and I-131 release should both get the loopholes closed so patients and referring physicians get all the pertinent information to proceed with the best treatment plan possible.

Leah Binder, President & CEO at Leapfrog Group (employer-driven nonprofit rating patient safety)

Thank you for this important perspective. On behalf of employers and other payors, The Leapfrog Group has been studying this issue, which threatens patient safety and diagnostic integrity. At the very least regulators should demand transparency. We are puzzled why radiation oncologists aren't voluntarily transparent; this can harm the most vulnerable of patients and likely wastes significant money in the process.