PATIENTS
FOR SAFER NUCLEAR MEDICINE

August 20, 2025

Attn: Jacob Garcia, Dominic Mancini, Jeffrey Clark

We represent Patients for Safer Nuclear Medicine (PSNM), a 30+ patient advocacy organization-coalition that is focused on ensuring transparency when patients are extravasated with a large amount of the injected radiopharmaceutical. We are volunteers and receive no compensation for our work on behalf of PSNM.

Our coalition is supported by leading corporations in nuclear medicine, the patient safety organization The Leapfrog Group, and distinguished physicians, physicists, technologists, and radiologists affiliated with the Society of Nuclear Medicine and Molecular Imaging, the Health Physics Society, and the American College of Radiology. We are also fortunate to have the expertise of vascular access specialists, all of whom generously contribute their time and knowledge.

We are writing to you today because we are aware that OIRA will soon review a proposed NRC rule, which aims to update an incorrect and outdated internal NRC policy (not even a regulation) that exempts major accidental radiation exposures to patients from ever being reported to NRC and most importantly to the patient. Unfortunately, despite our best efforts and input, NRC's proposed rule is confusing, inconsistent, and scientifically unsound.

We are asking you to resolve this issue quickly and decisively in the best interest of patients, by directing the NRC to issue immediate guidance eliminating its incorrect and outdated policy; and holding both the NRC and its Advisory Committee on Medical use of Isotopes (ACMUI) accountable for their bureaucratic mismanagement and failure to protect patients.

OIRA's direct intervention in this matter is critical to show that patients are a priority and that delivering healthcare properly matters. Taking these steps would be consistent with Executive Orders and President Trump's regulatory agenda.

This issue has also drawn significant media attention, with articles documenting the serious harm caused by extravasations. **Public concern is growing, and there is a clear demand for accountability and meaningful reform.**

There is written evidence from meeting transcripts that the NRC has known that this internal policy negatively affects patients since 2008/2009. When officially petitioned in May 2020 to remove this policy and when provided with over 900 pages of undeniable evidence, the NRC admitted in December 2022 that

the policy needed to be "updated." Rather than addressing the flawed policy, they proposed a new regulation that lacks sound reasoning and appears aligned with the industry responsible for these errors.

Patients want two things from OIRA:

1. We ask the OIRA to **eliminate the incorrect NRC policy.** By telling providers that large exposures will need to be reported like all other medical events, providers will get an 18-month grace period so they can train their staff and provide the tools needed.

2. Hold the NRC accountable for their incompetence. NRC staff has known for almost two decades that there is mistake, and yet they did nothing. We ask you to **eliminate the ACMUI and save taxpayers hundreds of thousands of dollars every year.**

A recent report underscoring the need for better diagnostic results in U.S. healthcare is applicable to this issue: www.healio.com/news/infectious-disease/20250813/how-to-achieve-diagnostic-excellence-according-to-the-cdc.

- Hospital leadership must show commitment and accountability to address diagnostic errors.
- Technologists who extravasate patients are vital to help solving the problem.
- Nuclear medicine centers should strengthen their drug administration processes and learn from extravasation safety events.
- Clinicians should use evidence-based actions (not subjective opinions) to improve patient care and outcomes.
- Clinicians can identify processes (like unmonitored human to human administration of radioactive drugs) that are at risk of problems.
- Clinicians can invest more in education of their staff to improve risky processes.
- Clinicians need to track and monitor problem areas so they can quantify and identify problems and then monitor for improvement.

Nearly 1,000 pages of evidence shows that extravasations are a problem in nuclear medicine and with proper tracking and reporting extravasations could be eliminated. **We need your help, because our efforts with the NRC over the last four years have fallen on deaf ears.**

First, the NRC tried to put the burden of reporting on unqualified patients. When PSNM pushed back on this proposal, the NRC suggested a subjective reporting criterion. They proposed that the clinicians responsible for the accident would decide to report or not based on the clinicians' opinion.

What the NRC is proposing is completely incongruent with all other safety reporting. If a clinician spills a radioactive drug on a patient, the spill needs to be contained, measured, and reported. Ironically, if the patient is extravasated and their tissue receives a dose 100 times the reportable limit, it is **exempted from reporting** as a medical event.

Hundreds of thousands of patients are experiencing large mistakes every year, yet these extravasations are preventable with proper training and tools. These mistakes affect treatment plans and assessments, they expose patients to accidental radiation exposure that exceeds appropriate levels, and they create unnecessary healthcare costs. The NRC's proposed regulation does not resolve the fundamental problem.

To substantiate our position, below is an overview of PSNM efforts demonstrating the NRC staff have not fully met their obligations. You can find all the letters referenced in the timeline at: www.safernuclearmedicine.org/position-statements-recommendations.html.

January 2022: PSNM becomes aware of an opinion piece from a radiation oncologist in STAT (12/27/2021) claiming NRC suffers from regulatory capture. PSNM wrote the NRC expressing their concern.
Spring - Fall 2022: PSNM worked with the NRC OIG to provide evidence that the NRC is captured by the industry. PSNM requested the NRC correct the policy that exempts the reporting of extravasations.
December 2022: NRC approved a petition regarding the reporting of extravasations and then endorsed the position of the Society of Nuclear Medicine and Molecular Imaging (SNMMI), American College of Radiology, and the NRC medical staff to allow only patient-reported extravasations reportable to the NRC.
January 2023: PSNM wrote the NRC opposing their decision to put the reporting burden on patients. Patient reporting was the solution SNMMI suggested, proving that the NRC is being led by the industry they are supposed to be regulating.
March 2023: PSNM wrote the NRC supporting an Information Correction Request (ICR) that clearly showed how the NRC received incomplete, incorrect, and biased information to make their regulatory decision.
Summer 2023: Throughout this period PSNM checked with the NRC OIG on the findings of their investigation, provided evidence to the NRC that supported the need for the NRC to report large extravasations no differently than any other medical event, and provided critiques of the NRC's proposed rule based on the SNMMI recommendation to put the reporting burden on patients.
October 2023: After seeing more evidence that the NRC had failed to protect patients, PSNM submitted an official request that the NRC OIG investigate five specific allegations of the NRC failing to protect patients, providing evidence that proved the validity of each of the allegations made.
February 2024: PSNM met with Chairman Hanson, shared findings that the NRC was failing in their responsibilities to protect the public and expressed concern that the NRC was being improperly influenced.
March 2024: NRC OIG issued their report, *"Special Inquiry into the Appearance of a Conflict of Interest Involving Members of the Advisory Committee on the Medical Uses of Isotopes."* The report made it clear that the NRC used biased information from conflicted advisers to develop the proposed rule. Yet, the NRC has not corrected their decision.
Summer 2024: PSNM made another request of the NRC OIG to investigate the five allegations. PSNM provided the NRC and Congress with evidence that extravasations matter, that medical societies continued to provide misinformation about extravasations, and the NRC continued to inappropriately address the extravasation issue.
October 2024: PSNM reached out to members of Congress to point out that the NRC OIG had not

appropriately responded to our officially submitted five allegations.
Winter 2024 - Spring 2025: PSNM reached out to members of Congress, NIH, and the FDA urging these organizations to protect patients, since the NRC is failing to meet their responsibilities.
July 2025: PSNM sent a letter to the new president of the SNMMI, Dr. Jean-Luc Urbain, providing evidence that he misled the NRC in a public written comment.

It is now August 2025, and the NRC has yet to correct a critical error or take steps to protect the thousands of patients regularly exposed to high radiation levels. This ongoing failure—driven by undue influence from the nuclear medicine community and ineffective NRC management—cannot continue. **Action is urgently required.**

One day you or a loved one may need an injection of a radioactive drug. Right now, no one can tell which one in six patients suffers extravasation, leaving incorrect scans to guide life-and-death decisions about cancer, dementia, or heart disease.

Every day over a thousand patients in the U.S. are extravasated with large amounts of radiation that compromise their care. These patients, your friends and family members, are being affected. Please act quickly to stop this injustice.

Sincerely,

Simon Davies, Executive Advisor
Teen Cancer America

Mary Ajango, Director of Advocacy & Partnerships
Young Survival Coalition (YSC)

CC: Commissioners Caputo, Marzano, and Crowell
Representative Cline
Representative Davis
Representative Griffith
Representative Guthrie
Representative Pallone
Russell Vought, Director of the Office of Management and Budget
Vince Haley, Director of the Domestic Policy Council
Marty Makary, MD, Commissioner of Food and Drugs
Robert F. Kennedy Jr., Secretary of Health and Human Services
Grace Graham, Deputy Commissioner for Policy & Legislation