



September 10, 2021

Chairman Christopher T. Hanson  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

Delivered via email

Dear Chairman Hanson:

On behalf of nuclear medicine patients across the United States, we write to urge the Commission to reject the extravasation recommendations of the Advisory Committee on the Medical Uses of Isotopes (ACMUI), grant PRM-35-22 for rulemaking, and adopt “Option 2” of the [NRC Staff Preliminary Evaluation](#) on the reporting of radiopharmaceutical extravasations as medical events. Patients, their physicians, and the NRC have a shared interest in understanding when and how radiopharmaceutical extravasations occur. Option 2 and the changes proposed in PRM-35-22 will provide this insight and encourage safer and more effective use of radiopharmaceuticals for the diagnosis and treatment of cancer and other diseases.

Patients for Safer Nuclear Medicine (PSNM) is dedicated to ensuring the safety of nuclear medicine procedures, which are commonly used to support cardiology, neurology, cancer, and many other types of patients. PSNM believes that patients deserve the safest care available and that federal policies should support safe, transparent, and effective nuclear medicine care. Under current NRC rules, severe radiopharmaceutical extravasations that cause significant unintentional irradiation to patients can – and do – occur unbeknownst to patients. Patients want, and deserve, to know if a potentially dangerous complication occurs during their procedure, and NRC policy should encourage safe nuclear medicine practices and responsible handling of radioactive materials. By granting PRM-35-22 and requiring the reporting of extravasations that exceed the NRC’s existing reporting limits, the agency will encourage the safer handling of radioactive material and address the loophole that has kept patients in the dark for 41 years.

Above all, PSNM urges the NRC to prioritize patient safety in its consideration of medical event reporting requirements and in the regulation of the medical uses of isotopes generally. PSNM was deeply disappointed by the September 2 ACMUI discussion of nuclear medicine extravasations. The ACMUI recommended a course of action – namely a modified version of “Option 4” of the NRC Staff’s Preliminary Evaluation – that prioritizes the parochial interest of nuclear medicine practices at the expense of patient care. As highlighted by the ACMUI Patient Advocate Josh Mailman, Option 4 would put the burden on patients to connect radiation injury symptoms they may experience months or even years later to a bad injection during nuclear medicine procedure, rather than requiring practitioners to take responsibility for the provision and quality of their care. Apart from being a stunning dereliction of the licensee’s responsibilities, it is unreasonable to expect patients to glean the medical knowledge



necessary to understand the signs and symptoms of radiation damage, particularly when radiation damage often takes long periods to manifest. A simpler option that would better protect patients and actually 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 the patient consequences of the poor administration. This option would be simpler to administer, place fewer burdens on patients, and actually improve outcomes for patients. By attempting to avoid accountability for the responsible handling 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.

PSNM urges NRC to immediately grant PRM-35-22 and require the medical event reporting of all extravasations meeting existing medical event criteria reporting. For 41 years, NRC has operated under the erroneous assumption that extravasations are nearly impossible to avoid. Evidence now conclusively demonstrates that extravasations are avoidable, potentially harmful, and represent a failure to minimize radiation exposure to patients. Patients cannot afford to wait another 41 years – or even 41 days – for reasonable protection from unnecessary radiation exposure. NRC must act immediately to grant PRM-35-22 and close the extravasation loophole.

Sincerely,  
Patients for Safer Nuclear Medicine

CC:  
Commissioner Jeff Baran  
Commissioner David A. Wright  
Chris Einberg  
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