

NATIONAL INSTITUTES OF HEALTH OPPOSES NRC RULE; SUPPORTS OBJECTIVE DOSE-BASED EXTRAVASATION REPORTING

NIH: “It would be preferable for the NRC to adopt the medical event reporting criteria already established” in the Code of Federal Regulations

WASHINGTON, DC – Patients for Safer Nuclear Medicine (PSNM) coalition, which is comprised of more than 30 non-profit patient organizations, commended the National Institutes of Health (NIH) for publicly supporting objective, dose-based criterion and transparency in the reporting of radiopharmaceutical extravasations.

“PSNM adamantly opposes U.S. Nuclear Regulatory Commission’s proposed rule, which fails to protect patients and provide the transparency they deserve, and we are pleased to see that NIH also opposes it,” said PSNM spokesperson Mary Ajango. “NIH is absolutely correct in stating that ‘...*medical event reporting requirement should cover extravasations no differently than other events...*’ PSNM has reviewed the scientific evidence and the NIH position in opposition to NRC’s draft proposed rule is completely aligned with our goal for safety and transparency of radiopharmaceutical administrations.”

An extravasation occurs when radiopharmaceuticals used for nuclear medicine scans or therapies is injected into a patient’s tissue instead of their vein. The result can cause pain and damage to underlying tissue and sometimes cause visible skin damage. Large extravasations also compromise the images used to determine the recommended course of treatment. Currently, clinicians are not required to report any extravasation to the U.S. Nuclear Regulatory Commission (NRC) or even the patient in question.

In December 2022, NRC accepted a petition for rulemaking to close the regulatory loophole that exempted extravasations from reporting even if the extravasation exposed the patient to very high doses of radiation. In May 2023, NRC published a draft proposed rule. But instead of using existing reporting criterion, the NRC proposed patients should report extravasations to the nuclear medicine physician. NRC proposed that this physician, ultimately responsible for the extravasation, use subjective criteria to decide whether to report or not.

As part of the NRC’s recent public request period to address proposed revisions to “Reporting Nuclear Medicine Injection Extravasations as Medical Events” (Docket ID: NRC-2022-0218), [NIH comments were submitted on August 15, 2023, by the NIH Radiation Safety Officer, Catherine Ribaud.](#)

Ajango also highlighted that the current rule change under consideration by NRC requires patients to understand the nuances of nuclear medicine, self-diagnose an extravasation that they were never told happened, then seek – and pay for – a medical professional to concur before further action occurs. “The NRC proposal harms those already coping with a life-changing diagnosis by delaying a response and placing additional burdens directly on patients. We urge the medical community and other federal agencies to embrace the NIH position. We must ensure that if an extravasation happens, the clinician identifies it quickly, mitigates the radiation dose to the patient, assesses the severity, and reports large doses.”