American College of Radiology

American College of Radiology (ACR)
FAQ - Nuclear Medicine Clarification Act of 2025 (H.R. 2541)
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Extravasation and Nuclear Medicine

Q: What is *nuclear medicine*?
A: Nuclear medicine is a medical specialty that uses radioactive drugs for imaging exams and for treating cancer and other illnesses. Approximately twenty million nuclear medicine procedures are performed annually in the United States, the overwhelming majority of which are low radiation energy, low radiation dose, and low risk diagnostic imaging procedures.

Q: How is the U.S. Nuclear Regulatory Commission (NRC) related to nuclear medicine?
A: The NRC licenses healthcare facilities for medical use of radioactive materials. The NRC ensures licensed facilities have appropriately licensed and qualified physicians and radiation safety professionals specifically trained to safely handle these materials. The NRC does not regulate healthcare quality, medical decisions, physician-patient communications, or patient care. 39 Agreement States have a formal "agreement" with the NRC to regulate materials to the same or greater stringency as the NRC.

Q: What is *extravasation* and when is it a patient safety concern?
A: Extravasation (or infiltration in tissue) occurs when traces of drugs or fluids injected intravenously partially leak into surrounding tissue. Extravasation can occur with any intravenously administered substance, including saline or nutritional infusions. In rare cases, extravasation can lead to complications; however, injury risk depends on the nature/toxicity and volume of the extravasated fluid.

Extravasation is primarily a patient safety concern when the volume of extravasated fluid is large enough to compress the surrounding anatomy, or when chemically caustic substances, such as certain chemotherapy drugs, damage soft tissue upon contact if extravasated. Neither of these scenarios is relevant to the agents used in diagnostic nuclear medicine procedures.

Q: Why is extravasation generally not a safety concern in diagnostic nuclear medicine?
A: Intravenous diagnostic nuclear medicine agents are small volume injections (often smaller than the seasonal influenza vaccine) of a low dose radioisotope combined with an inert fluid. When extravasated (any vessel leakage), these fluids are spontaneously dispersed and cleared via the body's natural systems without medical intervention or safety concern. Typically, the dose of radioisotope will localize in the patient's body as intended, possibly with a slight delay in timing of the study. As a result, nuclear medicine extravasations are short-lived and typically asymptomatic or only mildly symptomatic and without any meaningful impact on the procedure or patient beyond timing of dose delivery to the imaging site in the body.

Q: Does an extravasation mean a medical error occurred?
A: Typically, no. Extravasations (particularly in the small volumes involved in nuclear medicine procedures) can occur during routine intravenous administrations and do not necessarily indicate an error by the administering physician or technologist. Patient-specific factors such as the patient's age, weight, motion, or underlying medical conditions that impact vascular function and fragility may increase the potential for extravasation.

Additionally, certain vascular access sites, procedures, and devices have an increased potential for extravasation. For example, peripheral (e.g., limb) vascular access has a higher chance of extravasation than surgically administered central access. However, peripheral access is generally safer overall, does not require surgical placement, and is less costly. Further, smaller catheter gauges have a higher extravasation potential than larger gauges, but the risk of tissue tearing and internal bleeding is much lower. Medical decision-making involves weighing all these risks and benefits with the patient, including risks of non-routine complications and side effects.

Q: When can extravasation of nuclear medicine agents be a safety concern?
A: Extravasation can theoretically pose a radiation safety concern with higher dose therapies infused in larger fluid volumes of dilutant. However, serious, long-term complications, have not been observed in the United States, even as the use of therapeutic nuclear medicine procedures has increased. These larger infusions involve different vascular access procedures and monitoring protocols pursuant to the labelling and heightened risk of these agents. The NRC is currently undergoing rulemaking that will address any case involving these therapies that poses a safety concern. If H.R 2451 is passed, this rulemaking would be disrupted and overturned.

Devastating Effects of H.R. 2541 on Cancer Care

Q: What would the mandate in H.R. 2541 cost?
A: The Nuclear Regulatory Commission (NRC) estimates that the "dose estimation" methodology mandated by H.R. 2541 would cost healthcare providers, the NRC, and the 39 Agreement States[1] **over $6.4 billion**.[2]

For the 5,933 licensed healthcare facilities across the country performing nuclear medicine procedures, including small/rural facilities and critical access hospitals, the NRC estimates the dosimetry product and personnel costs would exceed **$2.5 billion**. This devastating, unrecoverable, and untenable expense would lead to patient access shortfalls and cancer care delays as community hospitals and local imaging centers become unable to offer nuclear medicine imaging and therapy. In remaining medical institutions, these unreimbursed, but federally mandated compliance expenses would lead to reduced scheduling availability and increased out-of-pocket costs for cancer patients and families.

In addition, the NRC would incur the cost of reviewing and processing medically insignificant "Medical Event" reports, of which there would be a significant increase from approximately 8 per year involving nuclear medicine to several thousand per year, costing the NRC approximately **$355 million**. Finally, the 39 Agreement States would need to adopt new state laws and regulations, which the NRC estimates would cost state governments nearly **$3.5 billion**.

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[1] Agreement States are states that have agreements in place with the NRC to regulate the medical use of nuclear materials.
[2] U.S. Nuclear Regulatory Commission, *Regulatory Analysis for the Proposed Rule: Reporting Nuclear Medicine Injection Extravasation as Medical Events*. Available at: https://www.nrc.gov/docs/ML2401/ML24016A293.pdf

Q: Why is the "dose estimate" mandate in H.R. 2541 impractical and counterproductive?
A: Extravasation cases are currently tracked based on observation (e.g., imaging the injection site in specific situations) and/or symptomatic presentation pursuant to risk. In nuclear medicine, this is typically for quality assurance and evaluation, and not due to safety concerns.

Small volume extravasations in nuclear medicine rapidly self-resolve (often in minutes), making these instances challenging and of minimal value to quantify. There are no medical or radiation safety standards defining the appropriate timing, tools, or methodology for "measuring" radiation dose to small areas of tissue from extravasation. Moreover, all nuclear medicine injection sites will invariably show measurable radioactivity during and immediately following injections simply from the presence of the isotope injections regardless of whether the measured dose is within or outside the vein, rendering measurement data imprecise and inaccurate.

Q: Would patients benefit from the additional Medical Event reporting requirements mandated in H.R. 2541?
A: No. Under current regulations, if a medical event occurs, licensed facilities are required to send a "Medical Event Report" to the NRC. Each time a licensed facility sends a medical event report to the NRC, they must also inform the patient that their data was shared with the government. The notification sent to the patient is a regulatory reporting requirement and does not contain any healthcare information. This notification of the NRC Medical Event report often causes unnecessary confusion as most patients are unfamiliar with NRC's mission and rules.

Q: Would H.R. 2541 close a "loophole" in existing NRC regulations?
A: No. NRC's policy, which is currently in the process of revision via rulemaking, broadly excludes extravasation. However, even without the prior policy, extravasations would not be included as a "dose-based" Medical Event for two specific reason: 1) it occurs following routine administrations of the correct dose of the correct agent given to the correct patient via the correct mode of treatment; and, 2) extravasation does not change the total radiation dose administered to the patient from that prescribed by the physician.[3] Nothing in HR 2541 would result in the prevention of the already rare occurrence of extravasations or provide better patient care.

Instead, H.R. 2541 would create a new type of "***low safety-significance***" Medical Event that indicates neither error nor harm to patients. It would force NRC and Agreement States to collect patient data the agency itself sees no value in collecting, as it "***would impose significant regulatory and financial burden*** *on the NRC, the National Materials Program, and licensees to monitor all radiopharmaceutical administrations and perform dosimetry for each detected or suspected extravasation* ***without safety benefit***." [4]

[3] 10 CFR 35.3045(a). https://www.ecfr.gov/current/title-10/chapter-I/part-35/subpart-M/section-35.3045
[4] U.S. Nuclear Regulatory Commission, *Regulatory Analysis for the Proposed Rule.* available at https://www.nrc.gov/docs/ML2401/ML24016A293.pdf