



For Immediate Release
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House-Passed Appropriations Bills Advance Nuclear Medicine Safety, Transparency

Reports Direct NRC and VA to Prioritize Patient Safety

CARY, NC – Lucerno Dynamics, a North Carolina-based medical technology company, today announced that Fiscal Year 2023 bills passed this week by the U.S. House of Representatives include critical language to improve the safety of nuclear medicine treatments and increase transparency within the American healthcare system.

Extravasations, which occur when a radiopharmaceutical is mistakenly injected into the patient's tissue instead of their vein, can and lead to adverse tissue reactions and negatively affect diagnosis and treatment.

Ron Lattanze, CEO of Lucerno Dynamics, said, "It is essential that patients and physicians know when a patient receives a significant unintentional dose of radiation to their tissue. We are pleased that Congress understands the implications of radiopharmaceutical extravasations on patient care and is asking federal agencies to prioritize patient safety. Extravasations have been exempted from medical event reporting since 1980, based on information that has been proven incorrect. Improved medical event reporting will encourage providers to prevent avoidable extravasations. Reporting will also require providers to communicate with patients when significant extravasations do occur. Our sincere thanks to Members of Congress who advocated for and included these patient safety and healthcare quality provisions."

NRC

The report accompanying the Energy & Water Development Appropriations bill includes the following provision focused on the NRC:

Re-Evaluation of Nuclear Medicine Event Reporting.—The Committee is closely monitoring the Commission's reconsideration of its policy related to significant extravasations and medical event reporting. Evidence shows that nuclear medicine extravasations may be avoidable and that some extravasations may exceed medical event reporting provided in 10 C.F.R. Part 35 Subpart M. These events may harm

patients through unintended radiation exposure, compromised imaging that negatively affects care, additional interventional procedures, and repeated imaging procedures. The Committee continues to encourage the Commission to consider the inclusion of significant extravasations in medical event reporting to improve safety, quality, and transparency for patients, treating physicians, and the Commission itself.

VA

The report accompanying the Military Construction & Veterans Affairs Appropriations bill includes the following provision focused on the Veterans Health Administration (VHA):

Nuclear Medicine Quality Improvements.—The Committee is aware of the consequence of extravasations in nuclear medicine procedures, and understands that the Nuclear Regulatory Commission and Centers for Medicare and Medicaid Services are considering regulatory actions to improve nuclear medicine injection quality. The Committee continues to encourage VA to monitor injection quality, as well as image extravasations, perform dosimetry and notify patients when they occur, and urges the Department to adopt any new regulatory requirements.

Background

NRC requires nuclear medicine providers to report medical events that result in unintended irradiation of patient's tissue of a dose equivalent greater than 0.5 Sieverts. Since 1980, a loophole has allowed extravasations to go unreported, even when patients receive extremely high doses. In creating the exemption 42 years ago, NRC believed that extravasations were inconsequential, occurred frequently, and were "virtually impossible to avoid."

For more than three years, Lucerno Dynamics has presented conclusive scientific and clinical evidence to NRC that extravasations are avoidable and providers can drastically reduce the occurrence of extravasations with dedicated monitoring and feedback to injection technologists, and filed a [petition for rulemaking](#) calling on the Commission to act. Public comment period on the petition resulted in nearly 500 comments from members of the public, including statements from patients, patient advocacy organizations, members of Congress, and experts in nuclear medicine and radiation biology.

Evidence provided to NRC supporting eliminating the exemption includes positive results from the largest quality improvement project ever conducted for nuclear medicine injections; letters of support from leaders in nuclear medicine, imaging technology, and patient advocacy; and dozens of recent case studies where patient tissue was unintentionally irradiated with doses far in excess of NRC's 0.5 Sieverts limit. Patients for Safer Nuclear Medicine, a coalition of 29 patient advocacy groups, filed an [Information Correction Request](#) calling on NRC to correct inaccurate information that formed the basis of the Commission's exemption policy.

In May, NRC's medical staff submitted a final evaluation of the issue and recommendation for action, which the Commission has not made public.

Last week, the Radiation Safety Journal, *Health Physics*, [published ahead of print an article](#) that provides the nuclear medicine community free and simple tools that easily characterize the severity of extravasations in less than five minutes.

Obligation to Act

The appropriations report language is the most recent indication that Congress and the public expect NRC act to protect patients, improve care, and increase transparency. Taken together, the scientific

evidence, expert analysis, and patient perspective make clear that the NRC has an obligation to revise its outdated, inconsistent medical event reporting requirements.

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