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Contact: Matt Dennis 202-484-1100

NRC Commences Rulemaking to Close Loophole in Nuclear Medicine Safety

Lucerno Dynamics praises agency for accepting petition for rulemaking to improve patient safety, outcomes, transparency

CARY, NC – Lucerno Dynamics, a North Carolina medical technology company, today praised the U.S. Nuclear Regulatory Commission for accepting its petition for rulemaking submitted in 2020 and directing the commencement of a rulemaking process to close an outdated loophole in nuclear medicine safety regulations. Closing the existing loophole will lead to improved patient safety, higher health care quality, and better transparency for patients, treating physicians, and the public.

"We are pleased that NRC has accepted our petition and commenced a rulemaking process to address a 1980 policy that exempts all radiopharmaceutical extravasations from medical event reporting," said Ron Lattanze, CEO of Lucerno Dynamics. "The scientific and clinical evidence is clear – radiopharmaceutical extravasations happen regularly, and large extravasations can jeopardize patient safety, health care quality, and transparency."

Dr. Darrell Fisher, a nuclear medicine physicist and former member of the NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI) commented, "The Commission's decision highlights the importance of radiation dosimetry for assessing event severity and compliance with regulatory limits for radiation protection of patients."

Lattanze added, "I am extremely satisfied that the NRC agrees that the extravasation topic is important. Today, we know that with improved tools, techniques, and training, most extravasations can be avoided. I look forward to continuing our work during the rulemaking process to determine a risk-informed, objective reporting requirement that prioritizes patients."

At issue is an NRC rule requiring 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. Extravasations, which occur when a radiopharmaceutical is mistakenly injected into the patient's tissue instead of their vein, can lead to adverse tissue effects and negatively affect diagnosis and treatment. Since 1980, a loophole has allowed extravasations to go unreported, even when patients receive extremity doses that are well above the 0.5 Sievert reporting threshold.

Lucerno Dynamics submitted a petition for rulemaking in 2020 presenting conclusive scientific and clinical evidence demonstrating that providers can drastically reduce the occurrence of extravasations with dedicated monitoring and feedback to injection technologists. On the most critical issues raised by the petition for rulemaking, NRC agrees with Lucerno Dynamics:

- NRC **agrees** that requiring medical event reporting of extravasations is within the purview of the Commission's regulatory authority. NRC **rejects** arguments that the issue falls outside NRC's authority and should be considered at the institutional level.
- NRC **agrees** that significant extravasations of some diagnostic radiopharmaceuticals could result in adverse tissue reaction such as skin erythema and even necrosis, and would therefore be considered a safety-significant medical event.
- NRC **agrees** that the current extravasation exemption is outdated, and that the development of higher-energy therapeutic and positron-emitting diagnostic radiopharmaceuticals requires a reconsideration of its policy through the rulemaking process.
- NRC **agrees** that medical event reporting of extravasations would focus licensees on reducing occurrence of extravasations through injection quality improvements, and this would enhance radiation safety for patients.
- NRC **agrees** that medical event reporting of extravasations would increase transparency between patients, physicians and the NRC, and would allow the Commission to identify commonalities and communicate guidance to licensees to reduce occurrence of extravasations and share best practices on mitigation when extravasations occur.

Dr. David Townsend, IEEE Fellow, and co-inventor of the PET/CT scanner, also commented on the statement from the NRC. "This is a significant benefit for patient safety. To their credit, the Commission focused on the scientifically supported evidence and not on the opinions of those who opposed the petition for whatever reason. Statements that no action was necessary; that extravasations were extremely rare; that when they did occur, they could never result in local high radiation doses; or that it was an issue the patient needed to address, were not supported by the extensive published data suggesting the reverse. It is well known that the benefits of low dose nuclear medicine imaging procedures far outweigh any risk from the use of ionizing radiation, but when even a low injected dose is extravasated into a small volume of tissue, the local radiation dose to tissue can be significant. It is encouraging that the NRC are now addressing this issue to ensure reporting requirements include extravasations along with other accidental exposures of the patient to radiation.

"We thank the bi-partisan members of Congress who have supported the petition for several years," Lattanze added. "We also thank patients and patient advocates, and medical and radiation biology experts who have shared their positions with the Commission and who stand ready to ensure rulemaking focuses on patient safety, health care quality, and transparency."

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Matt Dennis
Partner
CRD Associates
600 Maryland Ave. SW Suite 220E
202-484-1100
703-615-1007 (cell)