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Lucerno Dynamics Submits 'Information Correction Request' to Address NRC Extravasation Reporting Decision

Highlights flawed information in NRC analysis that undercuts patient benefit from approval of extravasation petition

CARY, NC – Lucerno Dynamics, a North Carolina medical technology company, again applauded the Nuclear Regulatory Commission's (NRC) acceptance of its petition for rulemaking regarding an outdated loophole in nuclear medicine safety regulations, and the Commission's concession of nearly the entire evidentiary basis of the petition.

However, the petitioner also announced official submission of an Information Correction Request to highlight information that failed to meet NRC's information standards. Commission Paper SECY-22-0043 was used as the basis for the Commission's decision to create a unique extravasation reporting criterion. In at least 35 instances, SECY-22-0043 failed to meet Information Quality Guidelines standards published in OMB Federal Register Notice Vol. 67, Num. 190. The unique criterion places the burden for quality control of a radioactive drug administration on patients, rather than on trained clinicians.

"We are pleased NRC conceded that nuclear medicine extravasations can harm patients and that closing its outdated reporting exemption would improve transparency and quality of care. But it is disturbing that the Commission was provided with wrong information regarding the need for a unique reporting criterion for extravasations," said Ron Lattanze, CEO of Lucerno Dynamics. "Our Information Correction Request clearly details how influential information that formed the basis of the Commission's decision was inaccurate, incomplete, unreliable, and biased. Had the Commission been provided with the proper information, we believe they would have come to the logical conclusion that the existing dose-based threshold is appropriate for extravasation reporting."

Background

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 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. In its decision, NRC agreed that the Commission has the authority to act, that large extravasations of diagnostic and therapeutic extravasations can cause patient injury, that the current rule is outdated, and that medical event reporting of extravasations would improve transparency and radiation safety.

But rather than requiring reporting of large extravasations that exceed the current risk-informed dose-based threshold used for all other medical event reports, the Commission created a new and unique reporting criterion requiring patients to prove they were injured and that they get an NRC authorized user's confirmation of injury for an event to be reportable. This unprecedented criterion places the entire safety burden on the back of the patient and contravenes NRC's policies and statements in every other aspect of radiation protection.

The Commission's decision relied heavily on SECY-22-0043, which failed to adhere to Information Quality Guidelines, published in OMB Federal Register Notice Vol. 67, Num. 190. These requirements set standards for utility and objectivity that SECY-22-0043 failed to meet. Rather than ensuring information presented was "accurate, complete, reliable, and unbiased," SECY-22-0043 parroted errors of omission and commission that had been promulgated by industry groups with a direct conflict of interest in the outcome. In its Information Correction Request, Lucerno provided NRC with specific recommendations with supporting information to correct the 35 errors.

Lucerno Dynamics further called on NRC to issue immediate Interim Staff Guidance to ensure extravasations are reported using the existing dose-based threshold, standardize a dosimetry model for tissue using latest published methods, and require licensees begin immediate efforts to improve injection quality.

"Patients deserve for the Commission to enforce existing risk-informed, objective reporting requirements that prioritize safety," said Lattanze. "We thank the bipartisan members of Congress, 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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