



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

[Date]

Ronald K. Lattanze
Chief Executive Officer
Lucerno Dynamics, LLC
140 Towerview Court
Cary, NC 27513

Dear Ronald K. Lattanze:

This letter is in response to the petition for rulemaking (PRM) that you submitted to the U.S. Nuclear Regulatory Commission (NRC) on behalf of Lucerno Dynamics, LLC, on May 18, 2020 (Agencywide Documents Access and Management System Accession No. ML20157A266). In the PRM, Lucerno Dynamics, LCC, requests the NRC to amend its regulations in Part 35, "Medical Use of Byproduct Material," of Title 10 of the *Code of Federal Regulations* (10 CFR) to require reporting of certain nuclear medicine injection extravasations as medical events. The NRC docketed the PRM on June 5, 2020, under Docket ID No. PRM-35-22.

The NRC published a notice of docketing and request for comment in the *Federal Register* on September 15, 2020 (85 FR 57148). The comment period closed on November 30, 2020, and the NRC received 486 public comment submissions on the petition.

The NRC has reviewed the PRM and the public comments. For the reasons provided in the enclosed notice, the NRC will evaluate within the rulemaking process medical event reporting of extravasations that require medical attention for suspected radiation injury.

Public comments and supporting materials related to this petition can be found at <https://www.regulations.gov> by searching on the petition Docket ID NRC-2020-0141. The NRC tracks the status of all PRMs on its websites at <https://www.nrc.gov/reading-rm/doc-collections/rulemaking-ruleforum/petitions-by-year.html> and <https://www.nrc.gov/about-nrc/regulatory/rulemaking/rules-petitions.html>.

The docket for this petition is closed. You may direct any questions regarding this matter to Pamela Noto at 301-415-6795 or by e-mail to Pamela.Noto@nrc.gov.

Sincerely,

Brooke P. Clark
Secretary of the Commission

Enclosure:
Federal Register notice

SUBJECT: LETTER TO PETITIONER FOR REPORTING NUCLEAR MEDICINE
INJECTION EXTRAVASATIONS AS MEDICAL EVENTS (PRM-35-22;
NRC-2020-0141)

DATE: APRIL XX, 2022

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