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

SECRETARY

December 12, 2022

MEMORANDUM TO: Daniel H. Dorman
Executive Director for Operations

FROM: Brooke P. Clark, Secretary Brooke P. Clark Digitally signed by Brooke P. Clark Date: 2022.12.12 11:12:09 -05'00'

SUBJECT: STAFF REQUIREMENTS – SECY-22-0043 – PETITION FOR RULEMAKING AND RULEMAKING PLAN ON REPORTING NUCLEAR MEDICINE INJECTION EXTRAVASATIONS AS MEDICAL EVENTS (PRM-35-22; NRC-2020-0141)

In May 2020, Ronald K. Lattanze, on behalf of Lucerno Dynamics, LLC, submitted a petition for rulemaking (designated PRM-35-22) requesting that the NRC amend Title 10 of the *Code of Federal Regulations* Part 35, "Medical Use of Byproduct Material" to require medical event reporting of certain radiopharmaceutical extravasations. The Commission has approved closure of the docket for PRM-35-22 by considering the petition for rulemaking in the rulemaking process. In particular, the Commission has approved the staff's recommended Option 3, to amend 10 C.F.R. Part 35 to include certain nuclear medicine injection extravasations as reportable medical events. The rulemaking would amend the NRC's regulations to mandate medical event reporting of extravasations that require medical attention for a suspected radiation injury. In addition, the Commission has approved publication of the draft *Federal Register* notice announcing consideration of the issues raised in PRM-35-22 in the rulemaking process, as well as a letter informing the petitioner of this decision, both subject to the enclosed edits.

During the rulemaking process, the staff should continue to explore approaches that would reduce the reliance on patient reporting. Specifically, in the draft proposed rule, the staff should evaluate whether the NRC should require licensees to develop, implement, and maintain written procedures to provide high confidence that radiation-safety-significant extravasations will be detected and reported. The staff should look for opportunities to increase efficiency and accelerate the rulemaking schedule, but the staff should not shorten the public comment periods.

The staff should create guidance that comprehensively explains and illustrates the medical event reporting criteria for evaluating and reporting all medical events, not only extravasation events.

Enclosures:
1. Edits to the *Federal Register* notice
2. Edits to the letter to the petitioner

cc: Chair Hanson
Commissioner Baran
Commissioner Wright
Commissioner Caputo
Commissioner Crowell
OGC
CFO
OCA
OPA
ODs, RAs, ACRS, ASLBP
PDR