POLICY ISSUE
NOTATION VOTE

RESPONSE SHEET

TO: Brooke P. Clark, Secretary

FROM: Chair Hanson

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

Approved X **Disapproved** ____ **Abstain** ____ **Not Participating** ____

COMMENTS: **Below** ____ **Attached** X **None** ____

Christopher T. Hanson

Digitally signed by Christopher T. Hanson
Date: 2022.11.10 12:39:38 -05'00'

Signature
Christopher T. Hanson

Date **11/10/2022**

Entered in STARS
Yes X
No ____

Chair Hanson comments on
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, Lucerno Dynamics, LLC submitted a petition for rulemaking (PRM-35-22) concerning extravasations. An extravasation is the unintentional leakage of some or all of an intravenously infused drug of any type around the injection site into the tissue surrounding a vein or artery. The Nuclear Regulatory Commission (NRC) currently does not require the reporting of extravasations. In its petition, Lucerno asked the NRC to amend its medical use regulations to require reporting of certain nuclear medicine injection extravasations as medical events. Specifically, the petitioner requested that an extravasation that leads to an irradiation resulting in a localized dose equivalent exceeding 50-rem, the current medical event dose threshold, be reported.

The Commission's decision not to require licensees to report extravasations to the NRC dates to 1980. At the time, the Commission stated, "[e]xtravasation frequently occurs in otherwise normal intravenous or intraarterial injections. It is virtually impossible to avoid, and therefore, the Commission does not consider extravasation to be a misadministration." Since then, nuclear medicine has evolved to use higher energy radiopharmaceuticals. While few, there have been past reports of radiation injury from extravasation published in literature. We have also learned that although extravasations might not be entirely preventable, there are factors that the licensee can control to reduce the likelihood of extravasations. Therefore, it is time for the NRC to revisit this 42-year-old policy and ensure we strike the right balance between patient protection and the continued beneficial use of radiological materials for medical purposes.

The staff recommends that any extravasation that requires medical attention for suspected radiation injury be reported to the NRC. This approach has multiple benefits, including (1) increased transparency, communication, and knowledge transfer between patients, physicians, and the NRC; (2) identification of trends and generic issues; and (3) encouragement of medical licensees to identify and implement best practices to reduce extravasation rates and mitigate their consequences. All these benefits have a direct positive impact on patient safety, while avoiding an undue regulatory burden.

The petitioner proposed using the current medical event dose threshold (50-rem) for reporting these events. However, I am skeptical of prescriptive requirements that do not have a clear nexus to safety. The continued use of radiological materials for medical purposes is critical and I agree with the staff's reasoning to develop a risk-informed approach to capture safety significant extravasation events that will be based on qualitative criteria.

Currently, the 50-rem dose threshold is not the sole criterion for a medical event. The NRC's medical event reporting regulation in 10 CFR 35.3045 lists administration errors that qualify for this designation, such as, wrong drug, wrong dosage, wrong patient, or wrong route. With some exceptions, for an event to be considered a medical event, there must be an administration error covered by the regulation that in turn causes the dose threshold to be exceeded. The NRC has not considered an extravasation to be an administration error for the purposes of this regulation because it can be caused by unintentional leakage that is not the result of misadministration.

Further, the 50-rem threshold was not intended to be applied to very small volumes of tissue, such as that surrounding an extravasation. The Advisory Committee on the Medical Uses of Isotopes (ACMUI), in their July 2021 report, stated that "Extravasation of diagnostic radiopharmaceuticals will rarely, if ever, result in any patient harm, even if the tissue dose exceeds 0.5 Sv [50 rem]…" ACMUI also explained in their report that using simplistic and conservative models to calculate the dose from an extravasation could result in even a very small amount of a radiopharmaceutical quickly exceeding the 50-rem threshold. This could result in tens of thousands of low safety-significant

extravasation events being reported to the NRC each year. On top of that, if the NRC were to promulgate a 50-rem dose threshold for reporting extravasations, physicians would need to monitor, characterize, and calculate extravasation doses for millions of nuclear medicine injections each year. This would impose a regulatory burden without a nexus to safety, and as the medical community has warned, may hinder the use of these diagnostics and therapeutics.

I support the additional activities the staff will conduct for this rulemaking as part of their recommended approach, including guidance development, establishment of a dosimetry model to characterize safety significant extravasations, and publication of a solicitation for information to obtain early feedback from the medical community on qualitative criteria for determining radiation injury and defining "medical attention." These are valuable tools and activities that will assist with rule implementation.

In addition to these efforts, the staff should also take this opportunity to create guidance that can be used for evaluating and reporting all medical events, not only extravasation events. I find the medical event criteria in § 35.3045 to be unnecessarily complex. Licensees and regulators would benefit from a guidance document that comprehensively explains and illustrates the medical event reporting criteria.

For the reasons indicated above, I approve the staff's recommended rulemaking option (Option 3)—reporting requirements for extravasation events that require medical attention for suspected radiation injury. I also approve closing the docket for PRM-35-22 by considering the PRM in the rulemaking process, publishing the draft notice in the *Federal Register,* and informing the petitioner.

I thank the staff for their thorough consideration of radiopharmaceutical extravasation. There has been significant input from several stakeholders, including the ACMUI, Agreement States, the medical community, the petitioner, and members of the public, and the staff has done a tremendous job evaluating and incorporating that input into its recommendation. The staff will continue to solicit input throughout the rulemaking process. I am confident that patient safety will be improved as result of this effort.