March 3, 2023

Dear Chairman Hanson and Commissioners Baran, Caputo, Crowell, and Wright,

On February 17, 2023, we received a copy from Lucerno Dynamics of an Information Correction Request they submitted to the NRC. On behalf of the Patients for Safer Nuclear Medicine Coalition (PSNM), we are writing to express our support for this Information Correction Request in response to Commission Paper SECY-22-0043, which was used in the drafting of the Nuclear Regulatory Commission's (NRC) response to Petition for Rulemaking regarding extravasation reporting.

On January 9, 2023, we wrote you to express our displeasure regarding your decision to endorse your staff's recommendation to create a unique reporting criterion asking patients to detect radiation injury rather than asking your licensees to identify and monitor extravasations. In that letter we asked you to reconsider your decision and to reaffirm the objective criteria that is used to identify other medical events. Now that we have reviewed the findings of the Information Correction Request, we are asking you again to ensure nuclear medicine centers report extravasations based on NRC's existing reporting threshold.

Based upon our own assessment, as well as the reviews of experts closest to the issue, we believe SECY-22-0043 contains several dozen errors and fails to adhere to Information Quality Guidelines, published in OMB Federal Register Notice Vol. 67, Num. 190. Now that we are aware of the quality of the information presented to you, we understand how you may have reached the conclusion you reached.

SECY-22-0043 was based on inaccurate, incomplete, and biased information. Your resulting decision to use a unique reporting criterion places an inappropriate onus on the patient to not only self-diagnose, but also seek an appointment with a physician to "independently" verify that an extravasation has occurred, essentially having to prove they suffered an injury before any action is taken.

We ask you to make the necessary changes to ensure the record is rooted in fact.

Had SECY-22-0043 not been littered with factual errors and biased reporting, the NRC would have likely recognized that there is no need for a unique criterion. The current 0.5 Sievert threshold that covers all other types of unintended patient irradiation as medical events is sufficient for extravasation reporting as well, and we ask the NRC to issue interim staff guidance that reflects this.

We fail to understand how radiopharmaceuticals spilled on the skin is a reportable medical event, but having that same radiopharmaceutical injected into the body is not. We fail to understand why the NRC would wait for patients to be injured when measures exist today that can allow nuclear medicine practitioners to mitigate the effects of these accidents if they are monitoring administrations. NRC fails to understand how large extravasations can also affect our treatments. That is why we support the Information Correction Request and urge the NRC to recognize the continued harm that patients face because of an outdated extravasation policy.

At the time of drafting this request, we became aware of a peer-reviewed paper that was published in Frontiers in Nuclear Medicine on February 27. This paper provides the patient perspective on radiopharmaceutical extravasations. This patient was extravasated and she experienced tissue pain that did not result in skin damage. Are you aware that many radiopharmaceutical extravasations will likely only cause subdermal tissue damage?

This peer-reviewed paper provides insight into how patients view the matter, the NRC decision, and asks many important questions that cannot be answered now, including the propriety of the relationship between your staff and the nuclear medicine community NRC regulates. You can find the paper at: www.frontiersin.org/articles/10.3389/fnume.2023.1127692/full.

We thank you for considering our request and would be happy to answer any questions you may have about our position.

Sincerely,

The Patients for Safer Nuclear Medicine Coalition