From:	Ralph Johnson
To:	RulemakingComments Resource
Subject:	[External_Sender] NRC-2022-0218
Date:	Monday, July 17, 2023 8:31:29 AM
Attachments:	image001.png image002.png 2023 NRC Rulemaking.docx

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Please find attached our comments for the above mentioned rule making docket.

Thank you,
Ralph

Ralph Johnson, MS, CPHQ, FHIMSS
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July 17, 2023

To NRC Rulemaking

RE: Docket ID NRC-2022-0218

The Leapfrog Group, Our Board of Directors, and members collectively comprise hundreds of the leading purchaser and employer organizations across the country. We are committed to improving the safety, quality, and affordability of health care with meaningful metrics that inform consumer choice, payment, and quality improvement. Above all Leapfrog is a strong advocate for transparency in health care. We are writing today to urge the NRC to require Nuclear medicine providers to report extravasations. We find it unacceptable that the burden of reporting and monitoring is on the patient and not the provider that injected the nuclear material.

By the NRC's own estimation, some 28,000 major extravasations occur annually in the United States. These extravasations are large enough that they would warrant reporting to the NRC if not for an incorrect reporting exemption that has been in place for 43 years. But because of this blanket reporting exemption, no one knows for sure how many large or small extravasations occur. The Commissioners instructions to the medical staff will not improve visibility to this issue.

Extravasation has a serious economic, physical, and emotional impact on the patient and the healthcare system in general. In these 28,000 cases, no one knows the amount of radioactive material that was injected into the tissue. Consider the diagnostic flaws that result when a precisely measured amount of radioactive material is not properly administered. And what if the radiation dose to the patient's tissue is extremely high? Beyond the expense of a delayed diagnosis of tissue damage and the harm that may cause the patient, the cost of catastrophic later stage treatment can be exorbitantly high.

By using the existing objective dose threshold – as is used for all other medical event reporting, including an accidental spill on a patient - licensees would be required to take immediate steps, including determining the tissue dose. We believe radiation injected under the skin should be treated with the same level of concern as radiation spilled onto the skin, which IS currently considered a reportable medical event.

To make our position abundantly clear: we reject NRC staff's current recommendation to create a unique reporting criterion that forces the patient to 'play doctor' and detect one's own radiation injury rather than asking NRC licensees – the experts – to identify and monitor extravasations. We remain baffled that the NRC plans to make patients directly responsible for their own diagnosis and care for extravasation follow-up, rather than licensees charged with their care.

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Please take the opportunity to focus on patients in your deliberations. Consider how the average patient is impacted by your decision: the potential effect to their treatment, the potential radiation damage to their tissue and skin, and the cost (both financial and emotional). Consider the wide-ranging consequence it has on the larger healthcare system: lost productivity, patient harm, higher costs, worse outcomes, and an erosion of trust. There is no better time than now to take patient-positive action.

Sincerely,

Leah Binder, M.A., M.G.A.

President & Chief Executive Officer

The Leapfrog Group