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Reporting Nuclear Medicine Injection Extravasations as Medical Events

Comment On: NRC-2020-0141-0004
Reporting Nuclear Medicine Injection Extravasations as Medical Events; Notification of Docketing and Request for Comment

Document: NRC-2020-0141-DRAFT-0443
Comment on FR Doc # 2020-19903

Submitter Information

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General Comment

Re: Docket ID NRC-2020-0141

Dear Madame/Sir,
On May 18, 2020, Lucerno Dynamics, LLC ("Lucerno") filed a petition for rulemaking with the Nuclear Regulatory Commission (NRC) to amend 10 C.F.R. § 35.2 and 10 C.F.R. § 35.3045 to require the reporting of extravasations that exceed the 0.5 Sv dose equivalent to tissue as medical events. In their petition Lucerno cites the NRC's final ruling in May, 1980, which exempted extravasations from medical event reporting with the understanding that extravasations are virtually impossible to avoid. Lucerno further states that "ample evidence has been published that nuclear medicine extravasations are, in fact, avoidable and are capable of causing considerable harm to the patients," and conclude by requesting that the NRC revisit the policy established in 1980 and require the reporting of certain extravasations as medical events.
The University of California, Los Angeles (UCLA) Radiation Safety Committee has reviewed Lucerno's petition and the relevant literature, and finds that the current NRC policy regarding extravasations established in May 1980 (and reviewed several times during the ensuing years, most recently in 2020) remains sufficient as is stands and does not require additional rulemaking as petitioned by Lucerno.

The petitioner claims that diagnostic extravasations may be causing patient harm, despite more than half a century of clinical experience with no evidence of harm from diagnostic infiltrations.

Furthermore the adoption of the proposed petition would have a significant negative impact on the practice of Nuclear Medicine, because enormous time, effort and resources would have to be spent on reporting medically insignificant extravasations.

Lastly, Lucerno fails to mention that it is in the business of selling devices to track extravasations. It

would therefore seem that the prime motivation of the petition is to benefit financially and not as Lucerno claims, “to ensure that diagnostic and therapeutic nuclear medicine patients are protected from avoidable irradiation and given access to vital information to understand when and how medical events impact their care”.

In summary, we believe that part 35, title 10 of the Code of Federal Regulations is sufficient and that regulations requiring the reporting of certain Nuclear Medicine injection extravasations as medical events are not required.

Respectfully,

Martin Allen-Auerbach, MD
Chair, UCLA Radiation Safety Committee
University of California, Los Angeles