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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

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Comment on FR Doc # 2020-19903

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General Comment

November 3, 2020

To Whom it may Concern:

As a patient advocate and patient with thyroid cancer and sarcoma cancer, who has had a nuclear medicine procedure and who has had an extravasation, I believe no additional rulemaking is needed to require reporting of certain nuclear medicine injection extravasations as medical events. The NRCs Advisory Committee on the Medical Uses of Isotopes (ACMUI) Subcommittee on Extravasation in 2019 concluded that extravasations are a practice-of-medicine issue and thus beyond the scope, appropriately, of NRC regulatory oversight. A 2020 report from the ACMUI Subcommittee on Patient Intervention concurred with this conclusion.

In its petition for a rulemaking, Lucerno Dynamics claims that this is a patient safety issue; however, statistics do not bear this out. A systematic review performed by van der Pol, et al., and published in the European Journal of Nuclear Medicine in 2017 concluded that, of more than 3,000 reported cases of extravasation, only three resulted in-patient symptoms where

follow-up was reported.

The value of reporting these events would be minimal compared with the expense and burden placed on the medical community to do so. These reports also may lead to undue anxiety among patients and ultimately to a decrease in the use of nuclear medicine procedures, even in cases where they are the most appropriate procedures for diagnosis or treatment.

In summary, my extravasation was successfully managed internally at the hospital where I had the procedure and I believe extravasations are best managed on an institutional level and do not require additional NRC regulation.

Sincerely,

Theresa Wickerham