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Reporting Nuclear Medicine Injection Extravasations as Medical Events

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Reporting Nuclear Medicine Injection Extravasations as Medical Events; Notification of Docketing and Request for Comment

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General Comment

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To Whom it may Concern:

As a patient advocate and patient with a neuroendocrine tumor, who has had over a dozen nuclear imaging procedures and five nuclear medicine therapies. I also work with a community of patients who routinely receive nuclear diagnostic imaging and therapy.

No patient or patient advocate is for extravasations it is something as a patient we all fear. We do want everything to go correctly when we are imaged and/or have therapy and want safeguards and procedures in place when things don't go smoothly.

While I believe we should do all we can to train to avoid and recognize when extravasations occur I do not believe that any additional rulemaking is required at this time.

I applauded Lucerno's technology to quantify and track when extravasation occurs and to turn that into learning opportunities. I encourage those in the nuclear medicine community to use their tool or other methods to determine when extravasation has occurred and take appropriate action for patient care. My hope is that a method/procedure can be done that would allow test dose that would not cause a medical event to take place to be done prior to therapy so that this can be remedy PRIOR to therapeutic agents being administered rather than reporting after a therapeutic has been given.

In its petition for rulemaking, Lucerno Dynamics provides articles that this is a patient safety issue; however, other articles do not show the concern. 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 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 given the small number of patients that will ultimately require any follow-up care. This may ultimately lead to a decrease in the use of nuclear medicine procedures, even in cases where they are the most appropriate procedures for diagnosis or treatment.

The NRC's 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.

I concur with the SNMMI, ACNM, ASNC statement "that extravasation of chemotherapeutic agents is an on-going safety concern in medical oncology and that there are well-established procedures for the management of extravasated chemotherapeutic agents, similar to those in place for extravasated radiotherapeutic agents."

I believe that there are methods in place to manage extravasated agents whether they are chemotherapy or radiotherapy agents. Extravasations are best managed on an institutional level and do not require additional NRC regulation.