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Docket: NRC-2020-0141
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-0450
Comment on FR Doc # 2020-19903

Submitter Information

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General Comment

The American Pharmacists Association (APhA) is pleased to submit these comments on behalf of the American Pharmacists Association-Academy of Pharmacy Practice and Management (APhA-APPM) Nuclear Pharmacy Practice Special Interest Group (SIG) in response to the Petition for rulemaking; notification of docketing and request for comment [Docket ID NRC-2020-0141].

Please, see, attached .PDF for full comments.

APhA is the largest association of pharmacists in the United States and the only organization advancing the entire pharmacy profession. APhA represents pharmacists in all practice settings, including community pharmacies, hospitals, long-term care facilities, physician offices, clinics, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health. Within APhA, the Nuclear Pharmacy Practice SIG represents over 3,100 APhA members involved in the specialty practice of nuclear pharmacy.

In summary, we do not support the need of additional rulemaking for reporting nuclear medicine injection extravasations as medical events. Such matters are best managed locally at an institutional/hospital level of the facility practice as a quality improvement process.

Thank you for the opportunity to comment. The APhA-APPM Nuclear Pharmacy Practice SIG looks forward to working with the NRC. If you have any questions or require additional information, please

contact Michael Baxter, Senior Director of Regulatory Policy, at mbaxter@aphanet.org.

Attachments

APhA Comments to NRC November 30



November 30, 2020

[Submitted electronically via www.regulations.gov and Rulemaking.Comments@nrc.gov]

Annette Vietti-Cook
Secretary
U.S. Nuclear Regulatory Commission (NRC)
Washington, DC 20555-0001

ATTN: Rulemakings and Adjudications Staff

Re: Petition for rulemaking; notification of docketing and request for comment [Docket ID NRC-2020-0141]

Dear Secretary Vietti-Cook:

The American Pharmacists Association (APhA) is pleased to submit these comments on behalf of the American Pharmacists Association-Academy of Pharmacy Practice and Management (APhA-APPM) Nuclear Pharmacy Practice Special Interest Group (SIG) in response to the Petition for rulemaking; notification of docketing and request for comment [Docket ID NRC-2020-0141].

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To assist the NRC's efforts to respond to the petitioner request that the NRC revise its regulations to require reporting of certain nuclear medicine injection extravasations as medical events, the APhA-APPM Nuclear Pharmacy Practice SIG offers the following comments:

Since the injection sites are typically anatomically distant from the organs being imaged, testing for extravasation would require either an additional scan be performed on every patient, increasing the scan time and reducing patient throughput, or the acquisition of specialized detection equipment commensurate with the patient population. Additionally, the discovery of an extravasation event would require a dose calculation to verify it was below the proposed limit of 50 rem to affected tissues, an arbitrary dose threshold not related to any known complications. The doses expected to result from extravasations from diagnostic radiopharmaceutical administrations are not known to cause any measurable patient harm. Extravasations from

therapeutic quantities of radiopharmaceuticals can deliver doses that are hazardous, but such an event is already considered a misadministration reportable per the current rules in 10 CFR 35.3045.¹

Therefore, we do not support the need of additional rulemaking for reporting nuclear medicine injection extravasations as medical events. Accordingly, we do not see value in additional NRC rulemaking for reporting nuclear medicine injection extravasations as medical events. Such matters are best managed locally at an institutional/hospital level of the facility practice as a quality improvement process.

Conclusion

Thank you for the opportunity to comment. The APhA-APPM Nuclear Pharmacy Practice SIG looks forward to working with the NRC. If you have any questions or require additional information, please contact Michael Baxter, Senior Director of Regulatory Policy, at mbaxter@aphanet.org.

CC:

Pamela Noto, Office of Nuclear Material Safety and Safeguards, NRC
The Honorable Commissioner Kristine L. Svinicki, Chairman, NRC
The Honorable Commissioner Jeff Baran, NRC
The Honorable Commissioner Annie Caputo, NRC
The Honorable Commissioner David A. Wright, NRC
The Honorable Commissioner Christopher T. Hanson, NRC

¹ <https://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-3045.html>