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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-0458
Comment on FR Doc # 2020-19903

Submitter Information

Name: Karl Fischer
Address:
1239 Kipke Dr.
Ann Arbor, MI, 48109
Email: kfisch@umich.edu

General Comment

These comments are my own and may not reflect those of my employer.

I oppose the proposed rulemaking and urge the NRC to reject it. Available peer-reviewed works on radiopharmaceutical extravasations indicate that extravasations are not uncommon in the practice of medicine but very rarely result in serious adverse health effects. A peer-reviewed systematic review (van der Pol et al, 2017) of 37 publications cited by the petitioner reported 3,016 cases of diagnostic radiopharmaceutical extravasation, of which only three (<0.1%) reported symptoms after extravasation. The total number of diagnostic administrations was not reported, but it is likely in the hundreds of thousands, making diagnostic extravasations with symptoms exceedingly rare. My institution performs over 11,000 diagnostic radiopharmaceutical administrations per year, and I'm not aware of any extravasation events that have resulted in harm to patients. Similarly, eight publications reported just 10 cases of therapeutic radiopharmaceutical extravasation; again, the total number of administrations was not reported but is assumed to be high in comparison to the reported number of extravasations.

Extravasations are a practice of medicine issue, which is beyond the scope of NRC oversight and regulation. The ACMUI has reviewed the subject of extravasations on more than one occasion, recommending they not be considered a misadministration or medical event. In 2019, the ACMUI received the petitioners presentation, reviewed available data and information on extravasations, and again concluded that extravasations should not be considered a medical event (in the absence of unintended permanent function damage). The petitioner has not demonstrated that extravasations are a patient safety issue or a public health risk. The proposed rulemaking does not serve the public interest, and it would create a negative and unnecessary burden on medical licensees for little or no patient safety benefit. I urge the NRC to listen to clinical and nuclear medicine experts including the respected experts

on the ACMUI and reject the proposed rulemaking.

Karl W. Fischer, CHP