PRM-35-22
85 FR 57148

PUBLIC SUBMISSION

As of: 12/16/20 3:39 PM
Received: November 20, 2020
Status: Pending_Post
Tracking No. 1k4-9k7a-2feq
Comments Due: November 30, 2020
Submission Type: API

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-0412
Comment on FR Doc # 2020-19903

Submitter Information

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General Comment

I am a certified nuclear medicine technologist with 30 years of experience in nuclear medicine, nuclear pharmacy, health physics, and Authorized User training. I hold a BS, MS and PhD. I am writing anonymously because my position is in direct conflict to the position of many of my peers and the nuclear medicine community.

This is a simple issue. Extravasations of diagnostic and therapeutic radiopharmaceuticals can exceed the medical event reporting limit of 0.5 Sv. These events have been exempted from reporting because there was a belief in the past that extravasations are virtually impossible to avoid. I have read the petition and the cited references. There is clear evidence that extravasations are avoidable. There is clear evidence in the literature that therapeutic extravasations can exceed medical event reporting limits. There is clear evidence in the petition that significant diagnostic extravasations can also exceed medical event reporting limits. Even though patient harm is NOT a prerequisite for reporting of medical events, there is also clear evidence that extravasations harm patients either through compromised imaging (the nuclear medicine societies have affirmed this in their public statement) or through absorbed dose to the tissue or both. Based on the NRCs role in ensuring the accurate delivery of radiopharmaceuticals and protecting patients from unintentional irradiation, the reporting of significant extravasations is a must.

I would also like to make some observations regarding the comments that have been presented to the NRC in opposition to the petition. These comments reveal the expected and natural reluctance of an industry to be regulated. More importantly, the NRC should take note that

these comments also reflect a substantial lack of awareness in the energy spectrum of diagnostic radiopharmaceuticals, as well as a lack of awareness in the biological radiation injury. These observations are alarming to me and should also be alarming to the NRC, patients, and their physicians. Many posted comments state that diagnostic radiopharmaceuticals cannot harm patients. Certainly, these radiopharmaceuticals, when administered properly, are very safe and the benefits of their use far exceed the risks associated with radiation. However, for nuclear medicine physicians, health physicists, and technologists to not understand how these same radiopharmaceuticals, when misadministered, can lead to radiation injury is disturbing. These comments show an ignorance regarding the conversion electron, auger electron, fluorescent x-ray energy and very low energy gamma radiation that will be deposited in the tissue when the most commonly used radioisotope, Tc-99m, is extravasated. There is a similar ignorance when positron energy from extravasations of commonly used F-18 radiopharmaceuticals are deposited in tissue. Furthermore, comments suggesting that therapeutic extravasations may be an issue if they exceed reporting limits, but not diagnostic extravasations that exceed reporting limits, reinforces this lack of basic nuclear medicine awareness from the clinical community responsible for the safe administration of medical isotopes.

Finally, with the exception of just a few public comments, there seems to be a lack of awareness from the community regarding how patient harm will manifest. Radiation injuries to the tissue and possibly to the adjacent skin will not appear the same day or even the same week (unless perhaps it is a catastrophic extravasation), but rather these injuries can take many weeks and more usually months or years to occur. The form letter comments from many members of the community are misquoting the 2017 literature review regarding radiation harm and should be ignored. I hope the NRC has read the entire article and noted that the authors observed that NONE of the other diagnostic extravasation patients had dosimetry performed or were followed.

Working in healthcare, one must always ask, Is this best practice for the patient? Also, Would I accept this for my child, my family member, and myself? Witnessing full doses of F-18 getting extravasated, I highly doubt anyone would agree that this is acceptable.

I would encourage the NRC to quickly approve this petition. The petitioner suggests a reporting grace period (but still suggests patients are informed) to allow licensees who routinely extravasate to start improving their injection processes. The sooner the centers focus on this issue, the better for patients. Thank you for considering my comments.