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Reporting Nuclear Medicine Injection Extravasations as Medical Events

Comment On: NRC-2022-0218-0004
Reporting Nuclear Medicine Injection Extravasations as Medical Events

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General Comment

I am responding to the NRC regarding the proposed language for a rulemaking decision on the reporting of nuclear medicine injection extravasations as medical events (Document ID NRC—2022—0218: Reporting Nuclear Medicine Injection Extravasations as Medical Events).

Attachments

John W UPPI Public Comment to NRC_07172023

Email to: rulemaking.comments@nrc.gov
Subject: **Public comment: Docket ID NRC–2022–0218**

I am responding to the NRC regarding the proposed language for a rulemaking decision on the reporting of nuclear medicine injection extravasations as medical events (Document ID NRC—2022—0218: Reporting Nuclear Medicine Injection Extravasations as Medical Events).

The removal of the exemption to reporting extravasations, in the injection of radiopharmaceuticals, as a medical event is an important decision. The removal should bring attention to improving patient care for the millions of radioactive product injections that occur annually for diagnostic imaging and radiotherapeutic treatment regimes.

The proposal to have a patient who received a radioactive drug injection identify an injury at some point post injection and to return to the institution to consult with the Authorized User physician on care has inherent problems that need to be addressed before the final rulemaking.

Authorized User is the term used for the physician allowed on the institution or facility's Radioactive Materials License as the named individual(s) with the prerequisite training and experience to safety handle the use of the radiopharmaceutical or the radiotherapy drug, including supervising the patient awareness and injection.

I have concerns related to the Authorized User which is the patient's essential "referral" physician for imaging or therapeutic procedure. After a procedure, the patient returns to the primary care giver whether it be the cardiologist, oncologist, endocrinologist, etc. for their continued care. A patient typically does not seek contact from the Authorized User after a procedure and may not even have that physician's name. It would prove hard to locate the Authorized User as is demonstrated in two examples below:

For instance, mobile nuclear imaging is performed throughout the United States at temporary job sites where the imaging is performed by a licensed service. NRC Web-based ADAMS document ML23131A356 is a public document of an inspection at a temporary job site by a licensed mobile imaging service. On the document's inspection date, ten (10) patients received radiopharmaceuticals for imaging. The administration was performed by the nuclear medicine technologist and no violations were observed. The potential rulemaking proposal puts the responsibility on the patient, with an injection related issue, to find the Authorized User, who will be very difficult to locate. The mobile imaging service Radioactive Materials License amendment document ML2234A172 lists 12 pages of Authorized Users -over 130 Authorized Users that are located in many institutions across the country. Who would be the person to contact that would know of the procedure performed, the dose injected, etc.?

Also, NRC Web-based ADAMS document ML19044A655 reports a Notice of Violation at a university system involving a contamination from a radiotheranostic product infusion. Within the Executive Summary (page 8) it was pointed out that the system has over 190 Authorized Users and 1,000 others working as supervised users. The point to be made here is how does a patient at some period post injection of a radioactive drug, who thinks they are experiencing an issue, find the Authorized User?

This author made a FOIA inquiry to the Agency in 2018 about the number of Authorized Users, education, and other queries and it was evident that there is not one source for Authorized Users information, like a registry, between the NRC and the Agreement States that regulate byproduct materials and who uses the products. So, there are great limitations or obstacles to a patient inquiring about a radioactive drug injection and extravasation, after the fact, when seeking the best care response.

There are means to find a solution to handling extravasations as a medical event. Springer publication: Clinical Translational Imaging (2022) 10 (Suppl 1):S1–S111 for the 15th National Congress of the Italian Association of Nuclear Medicine and Molecular Imaging March 12-15, 2022 Poster Exhibit 179 page S111 entitled: Guidelines on Prevention of Errors Related to Radiopharmaceuticals whose Background – Aim as stated "To lay the groundwork for implementation of guidelines on prevention of errors due to incorrect management of radiopharmaceuticals in hospital care, with the purposes of improve patient safety." Including *administration of radiopharmaceuticals* (emphasis mine) provides the following:

> Results: To minimize the likelihood of unintended and accidental medical exposure due to radiopharmaceuticals, the Panel proposed:
> (a) The introduction of safety measures at identified critical points in the process, with specific quality control checks at these points.
> (b) To actively encourage a culture of always working with awareness and alertness.
> (c) To set up detailed protocols and procedures for each process.
> (d) To adapt the staff to the needs and provide them with good education and training support to appropriate level and an effective organization, ensuring reasonable patient throughput.
> (e) To develop continuous professional improvement and practical professional courses, and training in applications for all staff involved in providing NM services.
> (f) Clear define roles, responsibilities and functions of staff in the NM facility that are understood by whole staff. Preventive measures should include checking the robustness of the safety system of the facility against reported incidents (retrospective risk analysis), as well as applying a prospective risk management strategy.

The current proposal is problematic, at best, and has flaws in patient care, or post care, should there be the untoward event of an extravasation and something must be done, including reporting the medical event. My concern is the advancement of radiopharmaceuticals to imaging which could at some point include nanoparticles and other compounds and, in the radiotherapeutics, using alpha and beta emitters and combinations potentially with chemotherapeutic drug can pose extravasation issues. Images I have seen indicate an extravasated dose can migrate through the lymphatic ducts and exposure could happen to the lymph nodes along the pathway. More investigation needs to be made to true internal exposure and human response and care should be taken to any rulemaking related to extravasations.

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