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Reporting Nuclear Medicine Injection Extravasations as Medical Events

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General Comment

See attached file(s)

Attachments

CORAR Extravasation Comments (7-18-23)

CORAR

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July 18, 2023

U.S. Nuclear Regulatory Commission
One White Flint North
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RE: DOCKET ID NRC-2022-0218, REPORTING NUCLEAR MEDICINE INJECTION EXTRAVASATIONS AS MEDICAL EVENTS; FEDERAL REGISTER VOL. 88, NO. 75; APRIL 19, 2023.

I am writing today on behalf of the Council on Radionuclides and Radiopharmaceuticals, Inc. (CORAR) to provide comments regarding the preliminary proposed rule language for a rulemaking on the reporting of nuclear medicine injection extravasations as medical events published in the Federal Register, Vol. 88, No. 75, published on April 19, 2023 for Docket ID NRC-2022-0218. CORAR is an industry association of firms that manufacture diagnostic and therapeutic radiopharmaceuticals, radionuclides, and other radioactive products primarily used in medicine, research, and industry. Also, CORAR members include firms that operate nuclear pharmacies that prepare and dispense radiopharmaceuticals in patient-ready doses for administration to patients in health care facilities.

In 1980 the U.S. NRC issued a rule excluding extravasations from misadministration reporting. The Commission stated that "Extravasation frequently occurs in otherwise normal intravenous or intra-arterial injections. It is virtually impossible to avoid. Therefore, the Commission does not consider extravasation to be a misadministration.[1]"

Several recent studies demonstrate the low frequency and lack of adverse events of radiopharmaceutical extravasations (RPEs). In a retrospective review of the records of 31,679 ^{99m}Tc-MDP whole body bone scintigraphy studies showed RPEs documented in 118 studies (0.37%)[2]. The authors concluded that reported RPEs were rare and short-term local symptoms were observed in three patients (0.009%), all of which were likely related to the prior higher volume intravenous contrast extravasations. The smaller volume diagnostic radiopharmaceutical injections for whole body bone scintigraphy are highly unlikely to cause local symptoms on their own. In a second recent study, the authors reviewed data on the frequency and significance of

[1] Public Meeting: U.S. Nuclear Regulatory Commission Staff Evaluation of Extravasation December 8, 2020 Lisa Dimmick Medical Radiation Safety Team Leader NMSS/MSST/MSEB, ML20338A283.pdf (nrc.gov)

[2] https://jnm.snmjournals.org/content/early/2022/10/13/jnumed.122.264994.abstract?papetoc

injection infiltration events in clinical PET/CT practice through quantitative analysis of 1,000 subjects from 10 US imaging sites[3]. In the results section, the authors reported that in these 1,000 patient multi-center investigations, no infiltrations of >1% injected dose were found.

CORAR believes that reporting of radiopharmaceutical extravasations as medical events will not necessarily resolve the perceived issue. It will require a great deal more investigation and documentation by the licensed facility to perform, and use more time and resources of both medical and administrative staff. Much of this investigation burden will fall on the medical physicist to perform dose calculations, not only for more obvious radiopharmaceutical extravasations, but for suspected ones as well. Please note that the use of the medical physicist's time in making these dose determinations would be in addition to other existing duties and could result in a dilution of resources. For larger institutions this may require the need for additional staffing. Also, there will be additional resources used by the NRC and Agreement States to evaluate these reported events and determine if additional corrective actions are required.

Please consider that a radiopharmaceutical extravasation leading to a high dose (i.e. 50 rem (0.5 Sievert)) to the tissue in proximity to the injection site could lead to an underdose to the treatment area. If this were to cause a potential underdose, this would be reported as a medical event. In addition, on May 17, 2022 the Chairperson of the Conference of Radiation Control Program Directors (CRCPD) H-47 Committee on Nuclear Medicine urged regulators not to require the reporting of extravasations, which he stated would cause a lot of administrative burden and little perceived benefit[4]. CORAR concurs with the CRCPD Committee and does not believe it is necessary to amend 10 CFR 35 to require the reporting of radiopharmaceutical extravasations as medical events. CORAR supports the NRC's 1980 assessment to not require the reporting of radiopharmaceutical extravasations as a misadministration[5]. Nevertheless, we have included our comments on this rule change below.

Comments Regarding Proposed Changes to 10 CFR 35:

There are three new proposed definitions in the regulations:

§ 35.2 Definitions.

Extravasation means the leakage of a radiopharmaceutical from the blood vessel into the surrounding tissue.

We propose the following alternative definition: "Extravasation means the mis-injection of a blood vessel, resulting in the leakage of a radiopharmaceutical from the blood vessel into the surrounding tissue. Extravasations may be partial, in which a portion of the radiopharmaceutical has been injected into the blood vessel, or complete, where the injection has completely missed the blood vessel."

Medical attention means any techniques used to reduce the chance, severity, or symptoms of a suspected radiation injury.

[3] https://jnm.snmjournals.org/content/64/7/1095

[4] Emerging Medical Technology in Nuclear Medicine, Radiation Protection, and Regulatory Issues, May 17, 2022,Augustinus Ong, the Administrator of the New Hampshire Radiological Health Section, Dept. of Health and Human Services and Chairperson of the Conference of Radiation Control Program Directors (CRCPD) H-47 Committee on Nuclear Medicine, Proceedings_2022 (flippingbook.com)

[5] In 2002, the term and criteria for "misadministration" were replaced with "medical event" and several changes were made to § 35.3045, "Report and notification of a medical event." Referenced in Federal Register Vol. 88, No. 75; April 19, 2023

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No comment.

Suspected radiation injury means a potential or observable deterministic health effect to the area around an injection site that can be attributed to radiation.

No comment.

<u>New Proposed Sections of the Regulations:</u>

§ 35.42 Procedures for evaluating and reporting extravasations.

(a) For any administration in which an extravasation can occur, the licensee must develop, implement, and maintain written procedures to provide high confidence that an extravasation that requires medical attention for a suspected radiation injury will be detected and reported in a timely manner and in accordance with § 35.3045.
(b) The written procedures required by paragraph (a) of this section must address how the licensee determines that an extravasation meets the criteria in § 35.3045(a)(3) for a medical event.
(c) A licensee must retain a copy of the procedures required under paragraph (a) in accordance with § 35.2042.

No comment.

§ 35.3045 Report and notification of a medical event.
(a) A licensee shall report any event as a medical event, except for an event that results from patient intervention, in which –
(1) * * *
(2) * * *
(3) The administration of byproduct material results in an extravasation that requires medical attention for a suspected radiation injury.

No comment.

<u>Below are comments to the specific questions listed in the Federal Register dated April 19, 2023:</u>

1. What term should the NRC use (e.g., extravasation, infiltration) when describing the leakage of radiopharmaceuticals from a blood vessel or artery into the surrounding tissue?

Extravasation.

2. What criteria should the NRC use to define ''suspected radiation injury''?

No comment: defer to authorized user physicians to determine.

3. What techniques or methods should be included in the definition of ''medical attention''?

No comment: defer to authorized user physicians to determine.

4. What steps could the licensee take to minimize the chance of a radiopharmaceutical extravasation occurring?

Steps could include the use of written procedures and appropriate training.

5. What steps should the licensee take when an extravasation is suspected or discovered?

No comment: defer to authorized user physicians to determine.

6. What techniques, technologies, or procedures (e.g., post-treatment imaging, visual observation, patient feedback) should be used to help identify an extravasation during or immediately after a radiopharmaceutical injection?

No comment.

7. What techniques, technologies, or procedures (e.g., post-treatment imaging, survey measurement) should be used to better characterize an extravasation after radiopharmaceutical treatment?

No comment.

8. What information should licensees provide to nuclear medicine patients on how to identify an extravasation and how to follow up with their physician if they suspect a radiation injury?

Regarding what information should be provided to patients, this question should be answered by authorized user physicians. There should be some guidelines established regarding whether this information should be provided to all patients upon discharge or only those with a suspected incident.

9. When should a reportable extravasation be counted as ''discovered'' for the purposes of notification (e.g., when medical attention is administered, when the physician identifies that the injury is from radiation)?

When the authorized user physician determines that there is a radiation injury from an extravasation.

10. The NRC requires that licensees notify the referring physician and the individual who is the subject of a medical event no later than 24 hours after discovery of the medical event. When should licensees be required to provide notification of an extravasation medical event to the referring physician and the individual?

Same time interval.

11. Who (e.g., patient's primary physician, authorized user, nuclear medicine technician) should be able to identify an extravasation that could result in a ''suspected radiation injury'?"

CORAR recommends the authorized user physician.

12. What topics should the NRC include in guidance to assist licensees to accurately identify, characterize, and report extravasation events in a timely manner?

NRC should clearly outline the following guidance topics to ensure licensees remain compliant to any new rule:

- Any required patient education, procedure risk review, and patient instructions prior to treatment including a sample template with required signatures and suggested language.
- If any dedicated Nuclear Medicine Department Standard Operating Procedure (SOP) is required, examples of content and worker training expectations (e.g. time/frequency) should be included.
- The training and qualification of the person involved to identify and evaluate a suspected extravasation (e.g. Medical Physicist, Dermatologist, Authorized User Physician, Radiation Oncologist, etc.). As mentioned above, CORAR recommends the Authorized User Physician.
- Example of manual absorbed dose calculations the licensee may follow to show compliance with an identified extravasated radiopharmaceutical dose.
- Example of preferred method of monitoring post-injection patients for deterministic skin injury (e.g. patient follow up appointment, telemedicine, etc.).
- Multiple examples of patient/event scenarios in the guidance document, helping educate licensees on NRC expectations of handling these patient events.

13. What regulatory actions could help ensure that extravasations in patients affected by healthcare inequities are accurately assessed and reported?

All reporting should be computer based and signed by the participating investigators.

14. Are vascular access tools and other technologies (e.g., ultrasound guided vein finders) likely to reduce the potential for an extravasation in all patients, particularly in patients of color?

No comment.

Please do not hesitate to contact me at (202) 547-6582 if you have questions or need additional information regarding our comments.

Sincerely,

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