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Reporting Nuclear Medicine Injection Extravasations as Medical Events

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General Comment

Comments regarding "Reporting Nuclear Medicine Injection Extravasations as Medical Events" Docket ID NRC-2022-0218

Attachments

Public comment submission

July 18, 2023

Docket ID NRC-2022-0218

Subject: Public Comments regarding “Reporting Nuclear Medicine Injection Extravasations as Medical Events”

The following comments were compiled from various Colorado Associates in Medical Physics staff with over 100 years of professional experience as medical physicists, radiation safety officers, health physicists and subject matter experts for licensees and registrants across the Rocky Mountain region.

1. We want to highlight from the ACMUI Final report dated September 16, 2021 with regards to reported percentage of radiopharmaceutical extravasations:

   “In a review of four studies involving a total of 2613 patients, the reported frequency of radiopharmaceutical extravasation was an average of 17% (range 10.5-21%). However, this data is simply not consistent with the reported extravasation rates for chemotherapy (0.09%) or IV contrast (0.24%) involving 739,812 and 454,497 infusions, respectively. These are similar types of injections to that being performed for radiopharmaceuticals and therefore the extravasation rates should be similar.

   One reason these studies show a higher extravasation rate for radiopharmaceuticals is that the criterion to be counted as an “extravasation” in these studies was any visualized increased uptake of tracer at the injection site. It does not take much activity to be visualized on a gamma camera or PET scanner image, so any leakage of the radiopharmaceutical out of the vein at the injection site would be classified as an extravasation. For non-radiopharmaceuticals, the criterion for extravasation needs to be pain, swelling or redness resulting from a relatively larger volume of injectant, which is a significantly different standard. For the one study that quantified the amount of activity in the extravasation, over 98% of the time the amount of activity was less than 1% of the injected dose.10 So, while visualized increased uptake of the radiotracer at the injection site may occur approximately 10-20% of the time, it will rarely be enough activity to interfere with the study or cause any patient harm, nor will it necessarily indicate poor technique on the part of the individual performing the injection.”

   The percentage of reported of “extravasation” events of radiopharmaceuticals from research appear to overestimate “extravasation” by chemotherapy and IV contrast definition. Care should be used when extrapolating an estimated total number of “extravasated” radiopharmaceuticals across all radiopharmaceutical injections nationwide. Extravasated chemotherapy or IV contrast is only recorded when there is reported pain, swelling or redness while radiopharmaceutical injections extravasations are recorded from any visualized increase of uptake of tracer at the injection site. When an injection of radiopharmaceutical results in pain, swelling or redness then it would be appropriate to classify as an extravasation. Is the pain, swelling or redness caused by the radiation from the radiopharmaceutical or the injectant? The NRC regulates the use radioactive materials to protect public health and safety, but should the NRC be regulating medical practice?

2. The data provided in the original rulemaking petition didn’t provide evidence of radiation injury in their submitted evidence cases. The reported cases did not note documented radiation injury even after the patient returned for repeat imaging, if any. Reviewing the calculated doses, most of the supplied cases could have resulted in transient erythema with a dose threshold of around 3 Gy, but again no note of suspected injury of the injection site. Example: Scan 17967 (pg 38): tissue absorbed dose estimated 1.96 to 6.47 Sv, in the range where transient erythema would be expected. Scan 16380 (pg 35) total absorbed dose 31.3 Gy?? No injury mentioned?? The data

presented has a large dose range for each case (some by more than a factor of 10), very dependent on assumed volumes.

How would it be possible to know when these truly fit the definition of reportable? It is difficult to determine if suspected radiation injury occurred and is attributed to radiation and not from intravenous extravasation. Extravasation without radiopharmaceuticals can cause similar health effects around the injection site as well. Some facilities track extravasation events in their own medical occurrence system and are addressed by medical regulatory compliance.

3. From the Journal of Nuclear Medicine, published on December 15, 2022, “Diagnostic RPE Is Not Dangerous” by van der Pol and Mottaghy:

   “A dose estimation assuming the worst case of no clearance of the extravasated radiopharmaceutical in tissue would result in doses that have shown local deleterious effects in external-beam irradiation. However, the real world looks different since there is usually rapid and effective clearance via the lymphatic system. That is the reason that reports on serious adverse events are scarce. Only one recent study has found some cases. The investigators summarize several cases with multiple registered clinically relevant symptoms; however, the cases are not presented with enough detail to find a causal relation to the tracer extravasation [Osborne D, Lattanze R, Knowland J, et al. The scientific and clinical case for reviewing diagnostic radiopharmaceutical extravasation long-standing assumptions. Front Med (Lausanne). 2021;8:684157.].

   Biological clearance should be a factor to consider for dose delivered to the extravasation site. The dosimetry calculation for the extravasation site would quickly be complicated from the contribution from the radiopharmaceutical that is “correctly” administered and flowing throughout the patient. The exercise of dosimetry calculation can be done, but without observable deterministic effects it is difficult to definitively determine that the observed affects are from the radiopharmaceutical.

4. In other areas of medical imaging modalities, like CT, repeated studies can happen due to patient intervention. Therefore, it might be appropriate follow-up for repeat study. Are repeat studies significant radiation harm to patient? It is already as low as reasonably achievable. Radiopharmaceutical studies are used by Authorized Users to aid in a patient’s overall medical treatment. Radiation risk is minimal in comparison to overall patient treatment and has already been considered when the AU orders the study.

5. A patient’s physical condition can be considered as a “passive” intervention because no matter how well the injection technique a technologist has, they cannot overcome the venous condition that the patient possess. There is so much variability in patients who receive radiopharmaceutical administrations that this cannot be consistently regulated.

6. “What criteria should the NRC use to define “suspected radiation injury?”

   The criteria to define suspected radiation injury should be ”Suspected radiation injury means an observable deterministic health effect to the area around an injection site that is attributed to radiation.”

   It is best to define what is observable health effect to define an actual radiation injury because there are various and inconsistent assumptions that can be made to determine the “potential” for radiation injury. The radiation injury should be observable to be reportable. Non-radiopharmaceutical extravasation events can also present with similar symptoms to a

radiopharmaceutical extravasation. The deterministic health effects attributed to radiation will need to be determined separately to differentiate radiation damage vs injectant extravasation.

7. “Who should be able to identify an extravasation that could result in a “suspected radiation injury?”

   The medical use staff (Authorized User, nuclear medicine staff, other supervised staff) associated with the medical facility should be able to identify an extravasation at the time of injection. The authorized user should be able to identify an extravasation that could result in a suspected radiation injury because the training and experience requirements include ‘radiation biology’ for them to be an Authorized User. Nuclear Medicine Technologists or other supervised individuals should have the appropriate level of radiation biology education to accurately identify radiation effects/damage. Primary care physicians may not have the level training and education to accurately identify radiation effects/damage on tissue.

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

   With new regulatory requirements, it is best if the NRC provides guidance that will standardize the dosimetry determination of the event. Extravasations are variable and are event specific, but consider limiting parameters such as: dose to minimum of 10 cc volume of tissue, dose to minimum of 10 cm2 of skin etc. In addition, detail an acceptable dosimetry method to determine whether an extravasation event is reportable.

   Acknowledging that there are commercial systems available that possess, some facilities may not have the financial means to obtain such systems. It will be beneficial to also provide alternative/acceptable radiation detection equipment/methods to characterize the dose from an extravasation with typical Nuclear Medicine equipment (e.g., gamma counter, solid-state detector, portable or stationary count-rate meter, portable or stationary dose-rate or exposure-rate meter, single or multichannel analyzer, liquid scintillation counter, proportional counter).

   Recommend external/surface dose levels that will require a dosimetry evaluation, procedural guidance for a level where evaluation by RSO/AMP/HP is needed to evaluate the potential extravasation.

   Identify a table of common radionuclides where extravasations cannot potentially be a reportable extravasation event. Similar to the tables from Reg Guide 8.39.

Thank you for the opportunity to provide the above comments.