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Reporting Nuclear Medicine Injection Extravasations as Medical Events

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Reporting Nuclear Medicine Injection Extravasations as Medical Events; Notification of Docketing and Request for Comment

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General Comment

See attached file(s)

Attachments

Extravasation

Docket ID NRC-2020-0141

I hold a PhD in Radiological Sciences. I am a Certified Health Physicist and I am licensed to practice Medical Health Physics in Florida and New York. Since 1994, I have been named RSO at three different teaching hospitals on three different broad-scope medical licenses. All three institutions had active nuclear medicine programs.

Bottom line up front: I support the petition for the following reasons:

- Extravasations happen and even though they remain unreported, they can have serious consequences for the patient. They probably can never be eliminated, but the risk can be reduced.
- There is no process in place to track these events or requirements to calculate the dose
- I reject the contention that extravasations are impossible to avoid. The principles of ALARA require this problem to be addressed because the fix is simple – better training for those individuals who inject radiopharmaceuticals, a process for calculating the dose, and surveillance monitoring to assess its effectiveness.

I am responding to the NRC's request for information on questions related to

1. Injection Quality Monitoring
   a. How frequently does radiopharmaceutical extravasation occur?

      Unknown. In my 23 years as a hospital RSO, tens of thousands of nuclear medicine procedures were completed at the three instructions I mentioned above. No extravasations were reported to me. However, during these 23 years, more than 30 spills of a radiopharmaceutical were reported to me; most because of an **inadequately secured or poorly placed IV line**.

   b. Do you know of any extravasations that have resulted in harm to patients? If so and without including information that could lead to the identification of the individual, describe the circumstances, type of effect harm, and the impacts.

      Since none were reported to me, I do not know if any happened and therefore, do not know if any harm was caused to patients.

   c. For medical use licensees, does your facility currently monitor for radiopharmaceutical extravasation? If so, why and how do you monitor? If not, why not?

      No, because extravasation was not on the list of medical events (wrong radiopharmaceutical, wrong patient, wrong dose, wrong route of administration, etc.).

   d. Do you expect that monitoring for extravasation and reviewing the results would improve radiopharmaceutical administration techniques at medical use licensee facilities? If so, how? If not, why not?

Yes. Extravasation of radiopharmaceuticals is well documented as discussed in the Petition. Clearly, extravasations happen. There is nothing special about the process of injecting a radiopharmaceutical that suggests there is no likelihood of an extravasation.

In the spill cases mentioned above, training was given to the Nuclear Medicine personnel (i.e., technologists, nurses, and physicians) involved in the events. The training emphasized the need to assess the patency and security of any IV line that had been previously installed. If there was any question, another IV line should be started. Also, it was emphasized that the patency of any IV should be tested before injection of the radiopharmaceutical by injecting sterile saline. This reduced the occurrence of further spills.

If training can reduce the incidence of leaks and spills, it can reduce the incidence of extravasations.

e. Do you believe an NRC regulatory action requiring monitoring and review of extravasation would improve patient radiological health and safety? If so, how? If not, why not?

Yes. The fundamental basis of all practices in radiological health and safety is ALARA. As mentioned above, extravasations are to be expected and training can probably reduce the incidence of such events. Therefore, reasonable efforts should be made to assess how and why extravasations occur so that appropriate measures can be taken to prevent reoccurrences, but they must be reported first.

2. Medical Event Classification and Reporting Criteria
   a. Are there any benefits, not related to medical techniques, to monitoring and reporting certain extravasations as medical events? What would be the burden associated with monitoring for and reporting certain extravasations as medical events?

As discussed above, the major benefit would be collecting and analyzing data on how often these events occur and why. Best practices for prevention could be solicited from stakeholders and distributed by the NRC via and Information Notice.

Hospitals already have an affirmative requirement to notify regulatory agencies of various events that are never reported to the NRC or agreement state regulators. For example, if a patient receives the wrong radiopharmaceutical and the estimated dose is less than 50 mSv, there is no requirement to report the event. However, for example, such an event would have to be reported in New York State Patient Occurrence Reporting & Tracking System (NYPORTS) (https://www.health.ny.gov/facilities/hospital/nyports/) as “Misadministration of Radiation or Radioactive Materials.”

   b. If the NRC were to require that licensees report certain extravasations as medical events (recorded in NMED), what reporting criteria should be used to provide the NRC data that can be used to identify problems, monitor trends, and ensure that the licensee takes corrective action(s)?

I support the changes to 10 CFR 35.2 and 10 CFR35.3045(a)(1) outlined in the Petition. This would require a licensee to report such an event via the same process for all reportable medical events.

c. If the NRC requires reporting of extravasations that meet medical event reporting criteria, should a distinction be made between reporting extravasations of diagnostic and therapeutic radiopharmaceuticals? If so, why? If not, why not?

Yes. Undoubtedly, there will be many more events reported for diagnostic versus therapeutic radiopharmaceuticals because there are far more administrations for diagnostic purposes. Although the process of injection is similar, more activity may be administered for therapeutic purposes (e.g., 200 mCi in the case of Lu-177 dotatate for therapy vs 10 mCi of F-18 deoxyglucose for diagnosis). Therefore, the potential consequences of an extravasation of a therapy dose could be worse.

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