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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-0424
Comment on FR Doc # 2020-19903

Submitter Information

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General Comment

Nuclear Regulatory Commission
Document Citation: 85 FR 57148
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Docket No. PRM-35-22
NRC-2020-0141
Document Number:
2020-19903

November 24, 2020

I am a Nuclear Technologist practicing in Charlotte, NC. The departments of Nuclear Medicine for which I serve as supervisor performs up to 300 intravenous diagnostic radiopharmaceutical injections per week. This accounts for no more than half of all injections in Mecklenburg County alone.

While diagnostic dose extravasations do occur in a small minority of cases, only rarely do they impact the patient in any way, and never in the form of physical harm at the injection site. The form and quantity of radioactivity in diagnostic injections have never been conclusively shown to cause physical damage or subsequent skin cancer. I have seen no examples of such in my entire career. In addition, "99mTc, 123I, 18F, and 68Ga labelled tracers do not require specific intervention."(Van der Pol, J., V, S., Bucerius, J., & Mottaghy, F. M. (2017). Consequences of radiopharmaceutical extravasation and therapeutic

interventions: a systematic review. European Journal of Nuclear Medicine and Molecular Imaging, 44(7), 1234-1243.)

The concerns raised about image quality are also greatly exaggerated. Diagnostic dose extravasation occurs approximately once per month in my experience, and is easily recognizable by both the technologist and radiologist. Assessing image quality implicitly includes deciding whether sufficient dose was delivered to make a diagnostic image. Therefore monitoring for extravasation is done on every study. Most of the time, the extravasated dose gets absorbed rapidly enough and in sufficient quantity to produce an image of adequate diagnostic quality. In the rare cases where the image is uninterpretable due to insufficient activity, our certified Nuclear Medicine Technologists and Board-Certified Radiologists are trained to recognize the deficiency and arrange for a new IV site with a new dose. This only happens about twice per year at our institution. Our technologists attempt to establish reliable antecubital IV access before resorting to more tenuous distal sites, so our rate of extravasation is already low. Additional real-time monitoring is therefore unlikely to lower the rate further. Therefore, NRC regulatory action requiring monitoring and review of extravasation would not significantly improve patient radiological health and/or safety.

At our facility, the burden of the Proposed Rule would be substantial. At least 12 novel devices would need to be purchased and used on those 300 injections per week. The Lucerno Dynamics Lara product, by the manufacturer's own estimation, would add 90 seconds to each injection. That would be 7.5 additional person-hours per week for data collection, not to mention as-yet unknown time spent maintaining and updating the documentation and reporting. Again, all this effort and cost would go toward a device which will not prevent the problem from occurring in the first place. All you will be doing is finding a very small number of extravasations which would ordinarily be found in routine image review and/or by IV patient assessment.

If the NRC requires reporting of extravasations that meet medical event reporting criteria, it should only be for therapeutic radiopharmaceuticals, where the potential for tissue damage is not as low. That being said, even 223-radium dichloride gets absorbed rapidly enough so as not to pose a substantial stochastic threat in most circumstances.
The petitioner, Mr. Lattanze, is the CEO of Lucerno Dynamics, and is therefore inordinately interested in magnifying an issue for his direct financial gain. Please note that all of the documentation supporting the petition is generated by Mr. Lattanze, Lucerno Dynamics, and their associates in academia and industry. Please do not be persuaded by their motivated reasoning. For decades there has been no outcry from medical professionals or patients because there simply is no pressing problem to solve.

Nuclear Medicine is already a very highly-regulated field, with high levels of efficacy and safety. The proposed rule would add substantial expense in the form of dollars for equipment, patient time, technologist time, and documentation. This extra cost will inevitably be passed on to patients and taxpayers, enriching Lucerno Dynamics, while addressing a problem that does not exist in practice.

Sincerely,

Maday Fernandez
Anthony Carico
Alicia Greene
Richard Eckert
Cassidy Peeler
Jessica Ann
Jeremy Spiby
Karen Perez
Keegan Noble

Attachments

Nuclear Regulatory Commission

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