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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

At our facility areas of injection are frequently included in the field of view for imaging. Using intravenous catheters, our instance of extravasation is very low. Occasionally the vein may not hold up even with the IV. This falls under the 1980 rule that it is unavoidable sometimes because it is. There have been no extravasations to date that have resulted in harm that I am aware of. As the use of the radiopharmaceutical is a medical decision, if there is an extravasation of the medication the physician will note it in the patient's report from the study. As I stated, we use intravenous catheters flushed with saline to test that it is working before injecting. There is nothing else you can do to improve that, it is the best technology available. I do not believe that regulatory actions will improve radiological health and safety. On most exams, I do not believe an extravasation has enough potential detrimental harm to necessitate reporting in diagnostic studies. In many cases the exam can still be performed successfully. All it does is place extra burden on Nuclear Medicine Staff, Authorized Users, Radiation Safety Officers and the NRC Staff.

There are no benefits to reporting and monitoring these as medical events. I believe that it places undue burden or stress on the Nuclear Medicine Techs when they are injecting. The equipment has to be set up, cleaned, and the data analyzed for every single injection. Then they would have more follow-up work for it to be reported. This will cause delays in care. It also places an extra burden on the Authorized Users and Radiation Safety Officer to report it and write up all the information and plans of action when it was completely unavoidable. Once a medical event triggers there is a lot of things that have to take place in a facility usually

involving multiple departments. It places additional burden on the NRC staff to field these reports. I would be hard to set a threshold for what an extravasation is. If you are already using best practice than what can you do to correct the issue? Sometimes veins go bad. It would just be reporting for reporting sake.

The final major issue I see with the petitioner. This is being petitioned on behalf of Lucerno who is making a device to test for extravasations. That is a clear conflict of interest. If these rules are put in to place, this company would directly benefit financially and that is the motivation. By adopting rules for extravasations you would be requiring every hospital in the country to purchase one of these devices and, I believe, Lucerno is the sole source for these. That is a huge red flag. Also that places more undue burden on facilities to purchase the equipment as well as refill materials from Lucerno. There is a huge cost to this. There is no way for the NRC to set a threshold or for facilities to monitor without requiring this.

In closing I believe that the NRC rule from 1980 is still valid and that these rules should not be adopted because of the costs, time and extra burden they will cause.