From: drwpeddoc@aol.com
To: RulemakingComments Resource
Subject: [External_Sender] Re: Public comment: Docket ID NRC–2022–0218
Date: Monday, August 21, 2023 12:13:59 PM

Re: Public comment: Docket ID NRC–2022–0218

I am writing this comment in response to a public comment (125) from Mary Spilker. Risk management officers in every hospital should have the hairs standing up on the back of their necks. The NRC should have alarms bells going off in their headquarters. And members of Congress should be taking note of what is going on in nuclear medicine. This is a group that is so excited that highly expensive therapies are getting approval and coming to boost their salaries, yet they don't even understand the basics of the delivery of the lower energy products they administer nearly 30 million times each year. Nor do they understand the intent of the regulations that govern medical event reporting. Case in point. Comment 125 from Ms. Mary Spilker: "a board certified nuclear medicine professional of more than 21 years as well as a Radiation Safety Officer, I have an educated opinion concerning the proposed regulation regarding extravasation."
Here is her statement:
"Extravasation is the "unintentional" leakage of vesicant fluids or medications from the vein into surrounding tissue. Being that it is unintentional and thus out of the control of the person administering the radionuclide, this should not be considered a medical event. The extravasated dosage would not meet medical event criteria set forth in 10 CFR 35. Also, the presence of a monitoring device will not stop an extravasation in nuclear medicine due to the small volume of the radiopharmaceuticals being administered. The first clue should be swelling, burning, or stinging at the injection site. In addition, imaging will always show an extravasation, so immediate knowledge of this is not helpful. Requiring a monitoring device will only incur additional costs to the facility and/or patient and will not stop extravasations from occurring. Requiring the use of indwelling catheters and testing the line with an inert substance such as normal saline is a more useful approach to reducing the risk of extravasations. The American College of Radiology (ACR) reports that less than .001% of diagnostic nuclear medicine extravasations result in temporary symptoms. This could just be tissue irritation and most likely not tissue damage. As previously stated, the volume of these administrations is small and not likely to cause any inherent danger to tissue."

I am including every statement from Ms. Spilker's "educated opinion" to make my points.

1. "Extravasation is the 'unintentional' leakage of vesicant fluids or medications from the vein into surrounding tissue. Being that it is unintentional and thus out of the control of the person administering the radionuclide, this should not be considered a medical event."
So, should we take it that just because a clinician did not intentionally make a mistake, that they shouldn't consider an event that meets medical event reporting criteria an actual medical event? How is it possible that a Radiation Safety Officer could make such a statement? If a clinician unintentionally spills a

radiopharmaceutical on a patient and exposes their skin and underlying tissue to 10 Gy, this is a reportable event. And one would expect a root cause analysis to help the center understand how this event happened and what needs to be done in order to ensure it does not happen again. But Ms. Spilker is arguing that if a clinician unintentionally extravasates a patient and irradiates their tissue and parts of their skin with 10 Gy, this should be ignored. This makes absolutely no sense whatsoever. An extravasation is almost entirely preventable and is likely caused by a clinician who has not received the latest training in vascular access or is not using the latest technology to ensure they have accessed the patient's vein properly. As a physician, I know that none of us intentionally makes a mistake. Regulatory reporting is agnostic to intent.

2. "The extravasated dosage would not meet medical event criteria set forth in 10 CFR 35."
How would Ms. Spilker even know that the radiation in the tissue does not meet medical event criteria? If clinicians are not monitoring when they extravasate and then not assessing the severity of the extravasation by performing dosimetry using the latest published techniques, they cannot know the absorbed dose to tissue.

3. "Also, the presence of a monitoring device will not stop an extravasation in nuclear medicine due to the small volume of the radiopharmaceuticals being administered."
Again, Ms. Spilker appears uneducated. While a monitoring device will not stop an extravasation when it happens, they can alert the clinician to the fact there is an issue. Monitoring can lead to more immediate steps to minimize the dose to tissue (e.g., flushing with saline, massaging, adding warm compresses, etc.). Monitoring can also provide patient-specific biological clearance, information which helps clinicians perform more accurate dosimetry and provides more accurate assessment of how much of the delivered dose was not available during the uptake period prior to imaging. This is important information that helps quantitatively determine whether the procedure should be repeated or not.

4. "The first clue should be swelling, burning, or stinging at the injection site."
Ms. Spilker's lack of understanding of the issue of radiopharmaceutical extravasations is alarming. Especially since she is a Radiation Safety Officer. The vast majority of the 30 million administrations of radiopharmaceuticals used in the 20 million nuclear medicine procedures each year involve small volumes (Ms. Spilker makes the mistake of associating small volumes with small amounts of radioactivity later in her comment) that will not result in swelling at the injection site. Even if 1.5 cc of a dose of 18 mCi of 18F FDG is deposited through the antecubital vein into the underlying tissue of a man who weighs 200lbs+, I challenge Ms. Spilker to see this "first clue." And glucose does not cause stinging. Nor does MDP. So, the patient will not feel a thing. No burning. No stinging.

5. "In addition, imaging will always show an extravasation, so immediate knowledge of this is not helpful."
Please have Ms. Spilker tell the NRC how many injection sites are imaged in neurology patients and cardiology patients. And please ask Ms. Spilker how many oncology patients beyond bone scan patients, have their injection site in the imaging

field of view. Ms. Spilker is in a nuclear medicine fantasy world. The vast, vast, vast majority of the 30 million radiopharmaceutical administrations injection sites are not imaged. And, by the way, there are recent studies from UT Knoxville and Portugal that show that even when an extravasation is visible in the image, they are NOT reported in the radiology report. How is that possible? That goes completely against the ACR requirements for documenting such events.

6. “Requiring a monitoring device will only incur additional costs to the facility and/or patient and will not stop extravasations from occurring.”
Ms. Spilker continues to show her ignorance of this issue with this statement. When processes are monitored, they improve. PERIOD. The nuclear medicine community has never effectively monitored the administration of radioactive drugs into patients’ veins. They have no clue how many times they have gotten this procedure wrong. If centers were required to monitor these administrations and report large extravasations that exceed dose to tissue or skin of 0.5 Gy, I can assure you that they would get better at this process. I can also assure you that patients who count on the NRC to protect them from these accidental exposures, find Ms. Spilker’s comments extremely offensive. She is basically saying, we don’t want to spend the time or a few dollars to ensure that we are doing our job properly. I bet this is the same argument that was used when doctors were first asked to wash their hands before delivering babies or the first argument used when doctors were told to employ “time outs” before starting a surgical procedure.

7. “Requiring the use of indwelling catheters and testing the line with an inert substance such as normal saline is a more useful approach to reducing the risk of extravasations.”
I suspect that Ms. Spilker’s suggestion to do a test injection is not a bad idea, but it does not mean that an extravasation will not happen during the actual injection of a small amount of radiation through a very small needle gauge into a low pressure vein or in the subsequent flushing of the dose. And in such a case, this process still needs monitoring.

8. “The American College of Radiology (ACR) reports that less than .001% of diagnostic nuclear medicine extravasations result in temporary symptoms.”
This is yet another statement that makes no sense. The ACR has absolutely NO IDEA of the number of nuclear medicine extravasations, much less how many result in harm. And frankly, what difference does that make? The NRC medical event reporting system is using a dose threshold criteria that the SNMMI lobbied for in 2001-2002. SNMMI wanted a more risk-informed dose threshold. They got it. Now that they know they extravasations easily exceed this dose, they want to still avoid reporting. And while 0.5 Gy may not necessarily mean patient harm, that is not the point of the regulation. The point is to report misadministrations that indicate a possible chance that a facility is not handling isotopes appropriately. I can guarantee you, Ms. Spilker, if your center has a clinician that extravasates every other patient, then your center is not handling isotopes appropriately. The NRC should know. Patients should know. And you as the Radiation Safety Officer should resign because you are not doing your job.

9. “This could just be tissue irritation and most likely not tissue damage. As previously stated, the volume of these administrations is small and not likely to cause any inherent danger to tissue.”
Ms. Spilker saved her most ignorant line for last. It is obvious that this Radiation Safety Officer does not understand the latent effects of ionizing radiation. Does not understand that if you don’t follow patients, then you will have no insight into the longer term effects. Does not understand that the volume of the radiopharmaceutical has NOTHING to do with the amount of radiation being injected. And worst of all, DOES NOT UNDERSTAND, that ionizing radiation accidentally injected into tissue is, in fact, inherently dangerous to tissue!
EVERY SINGLE STATEMENT Ms. Spilker made shows that she does not understand this issue. Patients, her organization, the NRC, and Congress should be alarmed. What is very scary is that Ms. Spilker is extremely representative of the several dozen other public comments made by nuclear medicine “professionals.” If I were a Commissioner at the NRC and I saw this comment, I would realize just how uneducated the nuclear medicine community on this topic. I would task my team to fix it. NRC is supposed to be providing regulations that protect the public.

I have nothing against Ms. Spilker, but I do have something against her comments. Every statement she made was wrong. It cannot stand. NRC must put an end to this nonsense and make large extravasations that exceed existing medical event reporting criteria reportable. And if they don’t do this immediately, then Congress needs to step in. This issue in essence is absolutely no different than the issue that faced patients and mammography centers in the 1990s. Perhaps it requires the same solution: the introduction of the Nuclear Medicine Quality Standards Act. As a family member of patients who have experienced nuclear medicine procedures and as a future nuclear medicine patient, I am calling on the NRC to ACT NOW and if they don’t, Congress NEEDS to act for them.

Rob Williams, MD