

PUBLIC SUBMISSION

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Docket: NRC-2020-0141

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-0460

Comment on FR Doc # 2020-19903

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General Comment

Dear NRC Representative,

I am writing in regard to Docket ID NRC-2020-0141.

I support the petition and strongly urge the NRC to change the outdated policy and remove the extravasation reporting exemption. While I expected that nuclear medicine centers should be focusing on patient safety by using best practices to ensure the proper use of radiopharmaceutical drugs, I was very surprised to learn that this is not the case. While educating myself on the extravasation topic, a few discrepancies attract my attention that I want to focus on in my comment.

The nuclear medicine community claims that extravasations of radiotracers are rarely associated with serious complications. At the same time, the community states that a dose of 1.0 Sv could lead to deterministic effects, including reddening of the skin, sterility, cataracts, radiation sickness, and even death if the dose is high enough. I have a question for those experts who told that they have almost 10, 20, 30 years of experience in nuclear medicine and have never observed or do not know of any serious side effects of extravasations. Do they perform dosimetry? Do they know that the effects of such events may not be visible for weeks, months, or years? Do they follow those patients who were extravasated? Those no harm claims look like ignorance, but what is even more disappointing it looks like a choice to be ignorant on the topic.

Also, many experts in the nuclear medicine community state that the extravasation of radiotracer is an uncommon event. It would be helpful to know how do they monitor extravasations so that they conclude that this is an uncommon event? Is it possible that those who think extravasations do not happen frequently use compromised images unknowingly? How is it possible to make that statement without monitoring extravasations?

By claiming that extravasations are unavoidable nuclear medicine community simply ignores the latest evidence, which are peer-reviewed studies that illustrate how centers were able to improve their extravasation rate significantly. Nowadays, extravasations are detectable and avoidable. By choosing to

ignore this latest evidence, the nuclear medicine community chooses to ignore best practices and choose to put patients under the risk that can be avoided.

The NRC is aware that diagnostic extravasations can harm patients, that that they are not impossible to avoid, but didnt take any actions. The NRC followed ACMUIs recommendations twice, while the biggest concern of those advisors was related to the administrative burden. Extravasations could not be ignored anymore. NRC should fix the extravasation issue and remove the extravasation reporting exemption.

Thank you for the opportunity to add a public comment and I hope my voice will be considered.