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Reporting Nuclear Medicine Injection Extravasations as Medical Events

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Reporting Nuclear Medicine Injection Extravasations as Medical Events

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Submitter Information

Name: Josh Knowland
Address: United States,

General Comment

Thank you for requesting input from the public on this topic. I have feedback regarding the proposed change to § 35.3045, "(3) The administration of byproduct material results in an extravasation that requires medical attention for a suspected radiation injury." If I am interpreting the rule correctly, medical event reporting would only be required for suspected radiation injuries if medical attention ("any techniques used to reduce the chance, severity, or symptoms of a suspected radiation injury.") is provided.

During the NRC's public meeting on May 24, 2023, a commenter supposed that nuclear medicine practitioners may forego injecting higher risk patients out of fear they would tarnish their track record of having no reported medical events. While admittedly sardonic, if that sort of fear mongering is to be believed, then one must assume practitioners would also choose to withhold medical attention following extravasation to similarly protect their reputations. Personally, I believe both courses of action would be unthinkable; clinicians take patient care very seriously.

Notwithstanding the proposed “medical attention” requirement, the proposal to base medical event reporting on suspicion of injury is by itself an unjustifiable deviation from established dose-based thresholds. The drastic change in regulatory stance would create a precedent in conflict with all other medical event reporting requirements. Will instances of the wrong radionuclide being administered now be subjected to the same injury threshold? What about administration to the wrong individual or to a fetus?

The logical solution is to treat extravasations the same as any other event—if unintended dose to tissue or skin exceeds 50 rem, then it is reportable. NRC has been correct in establishing quantitative dose thresholds, and requirements based on subjective or qualitative metrics will only cause confusion.