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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-0306

Comment on FR Doc # 2020-19903

Submitter Information

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General Comment

"On May 18, 2020, Lucerno Dynamics, LLC ("Lucerno") filed a petition for rulemaking with the Nuclear Regulatory Commission (NRC) to amend 10 C.F.R. 35.2 and 10 C.F.R. 35.3045 to require the reporting of extravasations that exceed the 0.5 Sv dose equivalent to tissue as medical events. In their petition Lucerno cites the NRC's final ruling in May, 1980, which exempted extravasations from medical event reporting with the understanding that extravasations are virtually impossible to avoid. Lucerno further states that "ample evidence has been published that nuclear medicine extravasations are, in fact, avoidable and are capable of causing considerable harm to the patients," and conclude by requesting that the NRC revisit the policy established in 1980 and require the reporting of certain extravasations as medical events."

As a Board Certified Nuclear Medicine Physician that has been practicing for over 30 years in Academic Institution I disagree with the above paragraph that considers revisiting or amending 10 C.F.R. 35.2 and 10 C.F.R. 35.3045. I have never seen extravasation of Radiopharmaceutical particularly from Diagnostic stand point that has cause considerable harm to patients. In fact there will be: Not necessarily resources utilizations and consequently

increased in health care cost without improving patients care. Therefore no additional revisiting or amending 10 C.F.R. 35.2 and 10 C.F.R. 35.3045 the policy is needed.