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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

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Comment on FR Doc # 2020-19903

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General Comment

On behalf of The Leapfrog Group, a national nonprofit organization representing employers and other purchasers advancing the quality and safety of American health care, I am writing regarding the NRCs reevaluation of NRCs 1980 determination related to infiltration and medical event reporting [Docket ID NRC-2020-0141].

The Leapfrog Group was founded in 2000 by large employers and other purchasers of health care, and our flagship Leapfrog Hospital Survey collects and transparently reports hospital performance, empowering purchasers to find the safest, highest quality care and giving consumers the lifesaving information they need to make informed decisions. We also assign letter grades to hospitals based on their record of patient safety, helping consumers protect themselves and their families from errors, injuries, accidents, and infections. The Leapfrog

Group reports data on over 2,000 hospitals nationwide.

Diagnostic errors, such as those caused by infiltrations, are a significant concern for purchasers as well as many other stakeholders nationally. Unfortunately, data on diagnostic errors is virtually nonexistent. That is why we are interested in new data demonstrating the prevalence and consequence of infiltrations in nuclear medicine procedures. We are aware that infiltrations can have a serious impact on the quantification of a PET/CT scan, potentially affecting the care that a physician provides a patient, and can result in unnecessary radiation exposure.

We were concerned to learn that NRC's Advisory Committee on the Medical Use of Isotopes (ACMUI) recently recommended NRC maintain its 39 year-old policy exempting infiltrations of radiopharmaceutical injections from NRC reporting requirements, even if that infiltration results in radiation exposure in excess of NRC limits. We are also unaware of literature supporting the ACMUI recommendation to classify infiltrations as a patient intervention.

In our judgment, monitoring of nuclear medicine injection quality and reporting of infiltrations to the Nuclear Regulatory Commission would improve the quality, safety, and value of health care, and would increase transparency in our health care system. Rather than accepting ACMUI's recommendations, we urge NRC to protect patients from unintended radiation and misdiagnosis by requiring reporting of infiltrations that exceed NRC reporting limits.

Thank you for your attention to this matter.