



August 29, 2019

Dr. Christopher Palestro:  
Chairman of the Advisory Committee on the Medical Use of Isotopes  
U.S. Nuclear Regulatory Commission

Dear Dr. Palestro:

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 in support of the NRC and ACMUI's reevaluation of NRC's 1980 determination related to infiltrations and medical event reporting [45 FR 31703].

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.

In addition, we urge NRC, through this reevaluation, to ensure that patients are informed of radiological injections that result in infiltrations and that there is full public reporting of this information.

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.

Thank you for your attention to this matter, and please do not hesitate to contact me if you have any questions.

Sincerely

Leah Binder  
President and CEO  
The Leapfrog Group