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Dr. Palestro
Chairman of the Advisory Committee on the Medical
Use of Isotopes
Nuclear Regulatory Commission

Dear Dr. Palestro:

Good day. I am the Medical Director of molecular imaging at the Carilion Clinic in Roanoke, VA. I am aware the ACMUI and the NRC are re-evaluating policy language put forth in 1980 regarding exempting providers from reporting requirements in the event of radioisotope extravasation/infiltration. As you recall, that policy was based on an opinion that these events "happen frequently and are virtually impossible to avoid". I am in agreement that this stance should be reconsidered.

For the past several years, our practice has been using a device that allows us to monitor our injections during PET-CT procedures when administering the intravenous isotope. The device consists of a PET detector crystal that is placed in proximity to the injection site and monitors the delivery of the isotope in real time and can alert the radiologist as to the possible occurrence of an infiltration. For all the years I have been in practice, when I found a patient to have a significant infiltration, I would have the patient return on another day for a repeat scan. Prior to using this new device, I had to rely on visual evaluation of this by placing the injection site, whenever possible, in the imaging field of view. Now with this device, we scan patients with the injection site out of the field of view.

This device has also been instrumental in one of our QA/QC projects where we monitored our technologists for infiltrations over a period of time and found a rate of infiltration of about 13%. When we did an analysis, with statistical review of the data, we had the technologists revise their injection and IV placement techniques. These changes were driven by infiltration associative factors identified by these data. With these modifications, the technologists were able to get their infiltration rate down to about 2%. At the current time,

our infiltration rates are less than 2% and we continue to monitor our technologists going forward.

It has been my stance in practice that when in a test-retest environment, it is critical that all the input parameters for a given test be reproduced at the time of retest to mirror those at the time of the initial test. One of these parameters is knowledge that the radioisotope is delivered systemically. When there is a large infiltration, this can impact the accuracy of the SUV measurement. We have had several cases that exemplify this. Just in the past week, we had a patient returning for follow-up for metastatic cancer. We had a severe infiltration which required that the patient return for repeat scan. The SUVs that were measured on the infiltrated scan suggested a partial response to therapy but the repeated scan without infiltration indicated stable and possibly progressive disease.

I hope that you and the review committee will consider revising the current position on infiltrations. If large infiltrations that exceed NRC reporting limits are required to be reported then providers will begin monitoring their injection quality and implement QA/QC projects like we did to improve our process. This will result in improved imaging, better patient care, less waste, and will also improve patient safety.

Respectfully submitted,

Jackson W. Kiser, MD