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July 8, 2019

Maryann Ayoade
Health Physicist, Office of Nuclear Material Safety and Safeguards

Re: Estimated Equivalent Dose to Tissue from Radiotracer Infiltration

Dear Maryann,

As promised in our letter to Dr. Palestro dated 4/29/2019, we have estimated the equivalent dose resulting from the previously reported radiotracer infiltration. We ask that you share this new information with Dr. Palestro and the subcommittee investigating the 1980 policy that exempts infiltrations from being reported to the NRC.

Figure 1. Maximum intensity projection view from PET images.

The hospital's nuclear medicine trained radiologist analyzed the PET image data and found that when using a threshold of 10% of SUV_{max}, the infiltrated activity was 3.51 mCi within 86 cm^3 in the left forearm. The radiotracer injection consisted of 10.22 mCi in 1.5 mL. Through analysis of dynamic activity measurements recorded near the injection site throughout the uptake time, as well as the static measurements from PET data, we estimate that initially the entire injection was paravenous. We estimate that the equivalent dose to the arm tissue for this patient was 4.9 Sv.

Our estimation considered the ways in which the infiltrated activity would change throughout the 62-minute uptake time. Initially, the infiltration would comprise a relatively small volume of concentrated radiotracer. Over time, this volume would expand through the interstitial space, undergoing changes in both overall volume as well as heterogeneity of activity concentration within that volume. This process of expansion is complex and dependent on both the patient as well as the location and nature of the infiltration. We modeled the expansion process for this infiltration in order to estimate the dose.

Our model used an exponential function to represent the way in which radiotracer diffused within the interstitial fluid. Additionally, we modeled concentration within the infiltrated volume as an exponential with maximal concentration located at the SUV_{max} voxel at imaging time. We assumed an initial infiltrated volume of 3 cm^3, expanding to 86 cm^3 as measured at imaging time.

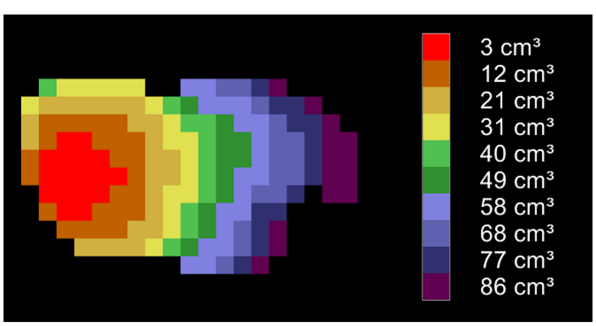

Figure 2. An X-Y view of the infiltrated tissue segmented by volume.

Since the tissue nearest to the initial infiltration site would be exposed to the highest concentrations of radiotracer over time, we chose to focus our analysis on this area.

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Based on the dynamic activity measurements taken throughout the uptake time, we estimated the entire activity (10.22 mCi) was initially infiltrated within the 3 cm^3 volume. From PET data, we know the activity present within the same volume at imaging time (0.35 mCi). Using our radiotracer diffusion model, we calculated activity over time within the 3 cm^3 volume. We used Monte Carlo simulation to estimate the equivalent dose from 1 mCi of ^{18}F to the 3 cm^3 volume (Fig. 3) for 1 minute (32.7 mSv/min/mCi). By applying this dose rate to the activity over time, we calculated equivalent dose over time, which was then integrated to find total equivalent dose (4.9 Sv) (Fig. 4)

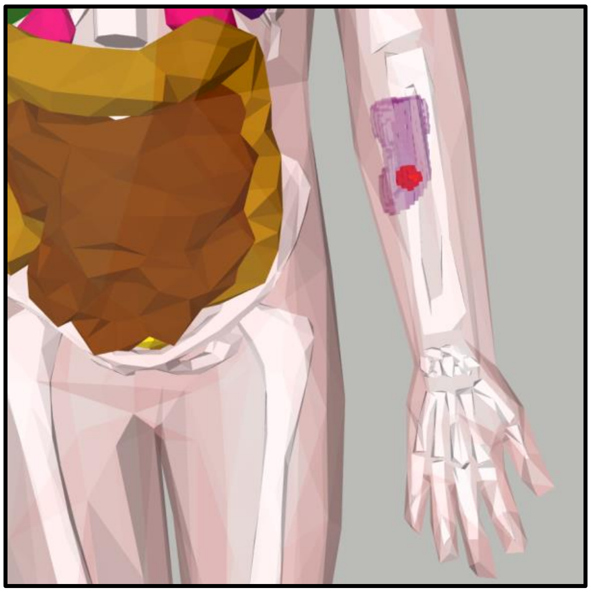

Figure 3. 3D model showing the total infiltrated volume geometry (86 cm^3, purple) and the 3 cm^3 volume used for analysis (red).

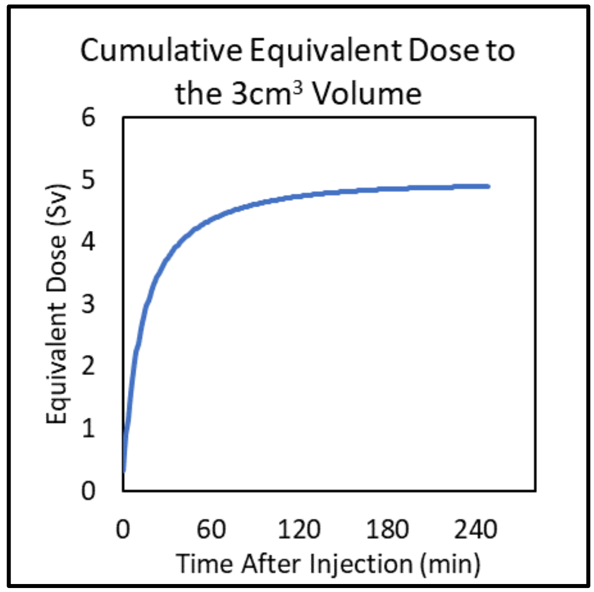

Figure 4. Cumulative equivalent dose to the 3 cm^3 volume over time.

This analysis demonstrates that a diagnostic radiotracer infiltration can result in high equivalent dose to the patient's tissue—exceeding the Subpart M reporting limits in this example by nearly 10 times. This result is conservative because it does not consider the effects of the infiltrated activity outside of the 3 cm^3.

Based on our experience in monitoring diagnostic nuclear medicine injections, we believe that patients are frequently experiencing infiltrations that exceed the reporting limit.

Josh Knowland
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