LUCERNO DYNAMICS, LLC
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November 18, 2019

Michael Layton, Director
Division of Materials, Safety, Security, State and Tribal Programs
Office of Nuclear Material Safety and Safeguards
Nuclear Regulatory Commission

Dear Michael,

It has come to my attention that we omitted an important case in our 10/9/2019 request to the NRC to reject the ACMUI recommendations. While we did not include this patient in our initial request, we did include a summary of this case in our response to the NRC request for dosimetry references that we sent you on 11/12/19. In order to provide you more information about this case, we have attached a one-page summary for your review. I apologize for the inconvenience.

In the ***Guide for Diagnostic Nuclear Medicine*** (https://www.nrc.gov/materials/miau/miau-reg-initiatives/guide_2002.pdf) on the NRC website, Dr. Jeff Siegel describes the biological effects of ionizing radiation in two classes: deterministic and stochastic. He defines deterministic effects as side effects that occur after a relatively high dose, or threshold dose, (usually 100 rem or **1 Sv**) is exceeded. Dr. Siegel states that the risk of stochastic effects, potentially cancer-inducing effects, increase as a function of radiation dose. Regarding these effects, Dr. Siegel states: “the risk of deterministic effects attributed to the exposures likely encountered in diagnostic nuclear medicine procedures is insignificant.” In regard to stochastic effects Dr. Siegel explains that “even the most conservative cancer risk estimates at low doses inherent to diagnostic nuclear medicine are extremely low and probably would not be detectable.” Dr. Siegel’s comments are based on the assumption that the diagnostic radiopharmaceutical has been delivered to the patient as prescribed by the physician.

This attached case is important, because it provides another example of how a diagnostic radiopharmaceutical extravasation can expose patient tissue to extremely high doses of radiation. With an estimate by the nuclear medicine physician that over 13 mCi was infiltrated, the dosimetry calculation in this case indicates that the patient received over **31 Sv** to their tissue. This case, along with the other cases provided on 10/9 and 11/12 provide evidence that there is a broad misconception regarding the patient safety issues associated with diagnostic radiopharmaceuticals. When an extravasation occurs, one should consider that patients may be receiving high doses to their tissue.

As you will see in this case, MDP for bone scans is often injected using a straight stick technique. An extravasation of MDP by a straight stick is particularly concerning because technologists are not able to flush after the injection. As a result, an extravasated dose can be contained in a very small initial tissue volume. And due to the properties of MDP, there is very little reabsorption of the radiopharmaceutical into the patient’s vascular system. A combination of high levels of extravasated activity, small tissue volume, and little reabsorption can result in very high doses to the patient tissue.

This case also highlights how by removing the infiltration reporting exemption, the NRC could improve patient safety. When the NRC becomes aware that patients are receiving very high doses of unintentional radiation to their arm tissue through this commonly accepted venous access/injection

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approach employed across centers, the NRC could encourage all centers to modify the venous access approach for use of the MDP radiopharmaceutical.

Finally, we are making progress on the dosimetry calculations for our next set of 10 cases and we will forward these to you and your team for review as soon as we finish this analysis.

Please accept my apologies for our oversight regarding this extravasation case and thank you for your ongoing interest in reviewing the facts about extravasations.

Sincerely,

DocuSigned by:
Ron Lattanze
0C2FCDBE78A7435...

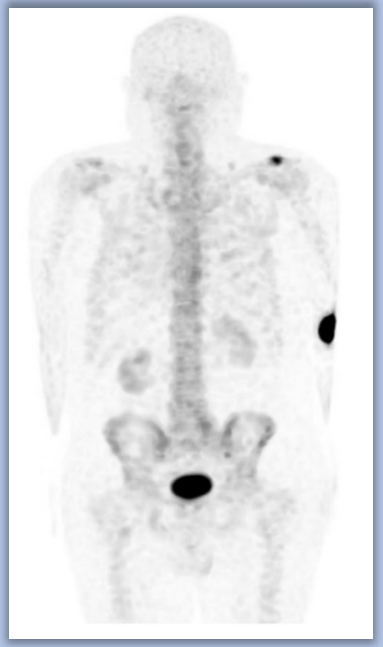
Ron Lattanze
Chief Executive Officer

Enclosure: Infiltrated Patient Case Report

cc:
Andrea Kock
Chris Einberg
Lisa Dimmick
Said Daibes
Kellee Jamerson
Donna-Beth Howe

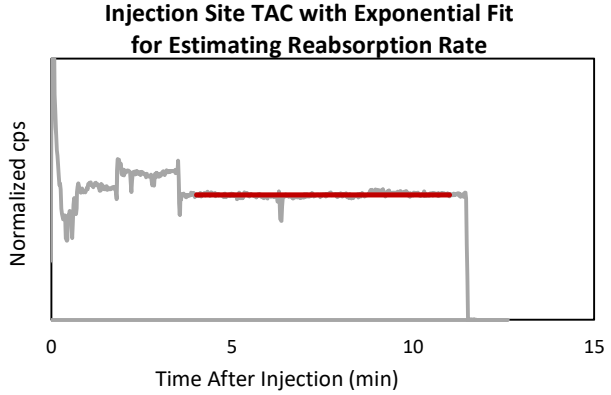
Scan #16380

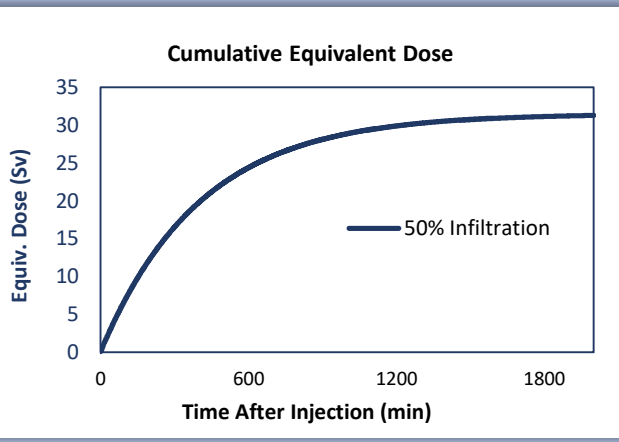
Equivalent Dose: 31.3 Sv



Radioisotope:	Tc-99m	
Physical Half-life	360.4	min
Injection Method	Manual	
Injection Location:	Left AC	
Injected Activity:	26.2	mCi
Radiotracer Volume	0.5	mL
Saline Flush Volume	0.0	mL
Imaging Time:	201	min
% Infiltration:	50	%
Initial Activity	13.1	mCi
Imaging Time Activity	8.9	mCi
Reabsorption Rate (half-life):	n/a	

Dose Calculation Volume	1.0	cm^3
Dose Rate	5.9	mSv/mCi-min
Total Equivalent Dose	31.3	Sv





For a bone scan, the patient was injected in the left antecubital with 26.2 mCi of Tc-99m. Lucerno's Lara® System identified the presence of excess radiotracer near the injection site.

The resulting SPECT images were found to be of "no diagnostic value" by the nuclear medicine physician. A repeat imaging study was performed 2 days later.

No activity quantification could be made from the SPECT images and the infiltrated tissue was partially outside of the imaging view. The visible portion of the infiltration at imaging time was measured to be 9.17 cm^3, but we conservatively estimated its true volume to be 30 cm^3. Time-activity curve data indicated that reabsorption was essentially nonexistent.

This injection was a "straight stick" procedure with no saline flush after the radiotracer injection. When no flush is performed, initial infiltration volumes are very small. We used 1cm^3 as the minimum initial volume.

Based on image quality, the infiltration was estimated to be at least 50% by the nuclear medicine physician. Thus, we calculated equivalent dose to the arm tissue for a 50% initial infiltration: 31.3 Sv.

- Dose Calculation Volume is twice the infiltrated radiotracer volume or the total flush volume plus the infiltrated radiotracer volume. Volume is not allowed to be less than 1 cm^3.
- Reabsorption rate estimates are based on injection site monitoring data from Lara® sensors.
- Dose rates are based on nuclear decay data from ICRP Publication 107 using the IDAC-dose 2.1 software's sphere module.