LANTHEUS MEDICAL IMAGING: HIGH DOSIMETRY RESULT

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EVENT REPORT

- Event EN51438 reported on October 1, 2015
- Individual's whole body dosimeter reported 7929 mrem for August 2015
- The individual's exposure of record for 2015 was 8500 mrem.

INSPECTORS AND NRC TALENT

- On-site: John Miller, Celimar Valentin-Rodriguez, and Michael Reichard

- In Office Assistance: Jim Dwyer, Dennis Lawyer, Betsy Ulrich, Jim Cassata, and Scott Wilson

FACILITY OVERVIEW

- The licensee is licensed to produce, possess, handle, and distribute radiochemicals.
- Specifically they produce F-18. They normally run two batches per night, 5 nights per week.
- F-18 has a 1.83 hr. half-life. F-18 is a positron emitter, therefore it also produces two 511 keV gammas per decay.
- The licensee also possesses incidentally activated products and sealed sources for instrument testing.

LICENSEE'S DESCRIPTION

- The individual in question did not work with or perform maintenance on the cyclotron during the month of August.
- According to the use logs, the individual worked one "Hot Job" with a synthesizer. This activity included potential whole body exposures and contamination opportunities.
- Otherwise, the individual performed QA/QC functions with minimal opportunities for a whole body exposure of this magnitude.
- Licensee's investigation looked at QA/QC functions, but focused on the "Hot Job."

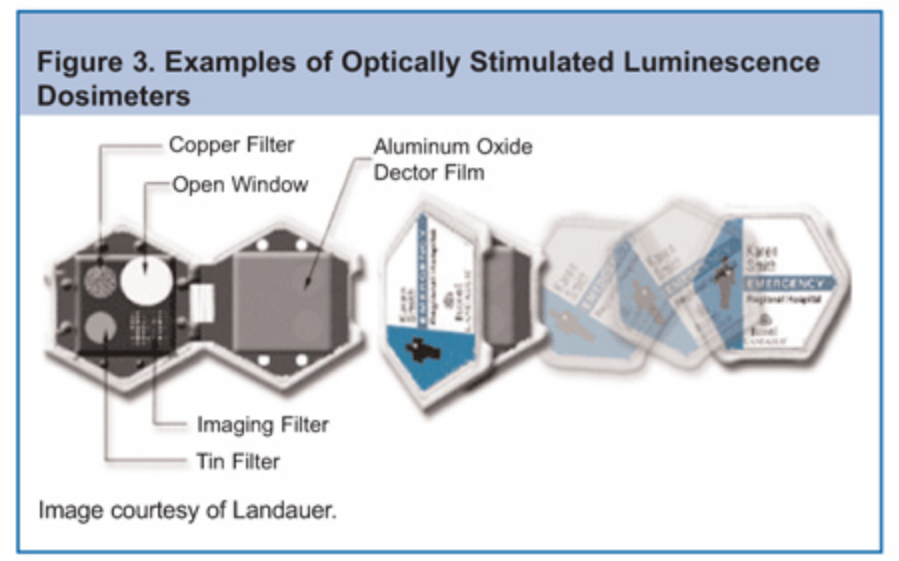
F-18 SYNTHESIZER

DEMONSTRATIONS

- The licensee provided a video of a demonstration of the “Hot Job.”
- The inspectors requested a demonstration, due to some vagueness of the video.
- The licensee also demonstrated/explained the QA/QC checks performed by the licensee.
- Based on the demonstrations, two options appeared reasonable, an external exposure and a contamination event.

IRREGULAR DOSIMETRY RESULT

- There are four active regions in the dosimeter. The exposures were open=6.6 rem, Al filter=12.2 rem, Al/Cu=7.5 rem, and plastic=7.7 rem



INPUT FROM LANDAUER

- Two conference call with licensee and Landauer's Director of Technical Services. One during the on-site inspection, one from office.
- Her perspective was that the exposure was not due to external radiation, or at least not all of it. Because of the irregular results, it was her professional opinion that it was a contamination smudge.
- She provided her assessment to the licensee, and ultimately the NRC, in writing.

REVIEW OF RECORDS

- Landauer radiation dosimetry reports, January 2013 through September 2015.
- Daily Cyclotron Running logs, January 2015 through September 2015
- Landauer Report, "Review of Dose Assessment for Participant 16416, Wear Date 08/01/2015," signed by Landauer's Director of Technical Services.
- Various procedures

IN OFFICE CALCULATIONS

- To establish our own independent comfort level, we performed several calculations in-office, prior to getting any reports from the licensee.
- Our calculation used microshield, varskin, and hand calculations.
- The licensee was able to provide precise measures of the activity remaining in the synthesizer and the specific activity after F-18 synthesis. It is an integral part of what they do.

IN OFFICE CALCULATIONS - WHOLE BODY -

- We were initially skeptical of the rejection of a whole body dose.
- However, the activity remaining in the synthesizer was inadequate to produce the reported exposure. We pushed all of the assumptions in the conservative direction and we couldn't get an exposure that high.
- The synthesizer is engineered to be as efficient as possible. i.e. waste as little F-18 as possible.
- Perhaps that's an obvious statement, but we were glad we pushed the assumptions.

IN OFFICE CALCULATIONS - CONTAMINATION -

- The amount of contamination on a dosimeter required to produce a reading of 7929 mrem was calculated to be 0.077 mCi.
- Specific Activity at synthesis = 200 mCi/ml
- Specific Activity after one half life = 100 mCi/ml
- Conservatively assume one half life and you need 0.77 microliters.
- By comparison, one average raindrop is 33 microliters.

LICENSEE'S REPORTS

- The licensee's investigation started with the assumption that the exposure was real.
- The licensee maintained a conservative stance until the facts couldn't support that level of conservativism.
- The licensee took the issue seriously and elected to implement several corrective actions.

LICENSEE'S REPORTS
- MOST LIKELY SCENARIO -

- The technician contaminated the fingertips of his gloves during the "Hot Job."
- At the time, the dosimeters were kept at the technicians' desks.
- The individual's desk was on the way to the doffing area. The individual likely took off his dosimeter before he took off his gloves.
- Following the procedure, there was no requirement for the individual to continue wearing any PPE, a dosimeter, or the lead vest.
- Consistent with his interview, he likely proceeded to doffing immediately after the procedure was over.

LICENSEE'S REPORTS - CALCULATIONS -

- The licensee's reports included calculations for whole body, contamination to the dosimeter, and revised extremity doses.
- Whole body for the month revised from 7.929 rem to 1,000 rem. 862 mrem for the hot job and 138 routine.
- Extremity exposures increased by 16.7 rem.
- Final for the year 1.858 rem whole body, right extremity 23.62 rem, and left extremity 19.85 rem.
- These calculations are actually very conservative.

LICENSEE'S REPORTS
- CORRECTIVE ACTIONS -

- The licensee volunteered to implement enhancements to training, processes, and procedures:
  - Handling, use, and storage of dosimeters
  - Established dosimeter storage locations outside of area
  - Written radiation measurements before non-routine prior to performing non-routine activities.
  - Specific procedures developed for non-routine work with synthesizer.

INSPECTION FINDINGS

- No violations were identified.
- Some consideration was given to violations for inadequate procedures, but the requirements (regulations and tie-downs) were vague, so it was hard to hammer out a solid violation.
- The licensee's corrective actions seemed appropriate.

VARSKIN'S CONTRIBUTION

- Varskin was the primary tool used to assess extremity dose and potential dose that could have occurred in similar situations
- NRC's use of Varskin resulted in the NRC questioning extremity dose estimates originally provided by the licensee. The licensee agreed, performed additional calculations, and ultimately revised their dose calculations to the individual's extremities.
- Potential doses that could occur from similar contaminations were calculated using Varskin and resulted in procedural revisions on the part of the licensee.

DISCUSSION QUESTIONS ??