

March 16, 2020 – August 31, 2020 RAM NMED Events

5 total events

1 - Radiation level on package exceeds DOT limits

1. On May 11, 2020, a licensee received a 10-gallon drum that was above the DOT dose rate level limitations. The package came from a company in Vancouver, WA. The material inside was a gauge with a Cs-137 sealed source inside with an activity of 100 millicuries. The package was shipped as UN2915, Radioactive Material Type A Package with Yellow-II labeling and a Transport Index of 0.1. Upon survey at receipt, the container exhibited dose rates of 3.4 rem/hr on contact; 240 mrem/hr at 12 inches; and 18 mrem/hr at 3.3 feet. The delivering carrier, FedEx, and the client have been notified.

1 - Equipment failed to function as designed

1. On April 5, 2020, a technician reported to the RSO that when a shutter handle on a Berthold LB8010 with 20 mCi Cs-137 was moved to the closed position, the radiation survey indicated reduced radiation, but not the expected level. The shutter was opened and closed again, and radiation levels were lower but not at normal closed position levels. The gauge was removed from service and secured onsite in Canton, PA, awaiting a shipping container for return to the manufacturer. The gauge will be returned for repair or replacement. No personnel overexposure has occurred.

3 - Medical events

1. On April 3, 2020, a patient was undergoing a Y-90 TheraSphere treatment. The patient was prescribed TheraSphere Y-90 Microsphere at 2.47 GBq total with 2.25 Gbq prescribed to liver because of a 9.1% lung shunt. The licensee reports total dose 1.536 GBq and 1.4 GBq to liver. Ultimately only 62.7% (75.3 Gy) of the planned dose was able to be administered to segment 6 of the liver. While attempting to administer the Y-90 dose to treat a lesion in Segment 6 of the liver, there was significant resistance to the flow. The AU evaluated the microcatheter system to ensure that there were no kinks along the catheter course external to the patient or visualized internally under fluoroscopy. The licensee believes the issue came from blockage at or before the E site on the labeled tubing of the administration set given and when it was disconnected from the microcatheter at that location they were able to successfully flush the catheter. The patient then had a subsequent segment 7 segmentectomy using tubing from a box set from a different lot # without incident. No adverse effects to the patient are anticipated. The patient and referring physician were notified the day of the event.
2. On May 5, 2020, the licensee reported an event involving Varian GammMedplus iX high dose rate remote afterloader (HDR) containing 8.6 curie (Ci) of iridium-192. The patient was set to receive 10 fractions of breast cancer treatment. An error was noted upon the source returning from treating channel 3. It was observed by the Authorized Medical Physicist (AMP) and therapist that the source had retracted to the parked position in the shielded HDR safe. At this time, an error message occurred on the console screen "Afterloader Error (A4:9) – TIMING ERROR, no response from PC." The staff checked all data and power connections and then reset the unit and rebooted. The vault was then surveyed with an ion chamber noting background readings of ~30 uR/hr. This confirmed the source was in shielded safe position. Treatment resumed with channel 4; however, upon returning to safe position the machine experienced another fault. The AMP entered the vault again to take another exposure reading, however this time the source did not fully retract. This was confirmed by the AMP with ion chamber, when he read elevated readings of ~300 uR/hr. Staff then attempted to use two emergency-stop procedures; however, both failed. Staff were finally able to manually retract the source after approximately 2 - 4 minutes total from the second error message occurring. The patient was quickly disconnected from the catheter, everyone was immediately removed, and the room was secured from entry. Patient and all personnel surveyed at background (< 30 uR/hr). The manufacturer has been contacted. The licensee has also requested the log files from the manufacturer for dose reconstruction of those involved.

	<p>On May 6, 2020, the Manufacturer service technicians removed the wire/source from the afterloader. Preliminarily, it appears the source became stuck approximately 4 to 5 inches from the shielded park position (inside the afterloader, but outside the shielded safe). Dosimetry badges have been sent for emergency reading. The dosimetry report indicates three staff members involved in the event. The technologist received 4 mrem whole body dose, the authorized user received 3 mrem whole body dose and the AMP received 3 mrem whole body dose and a 15 mrem dose on their finger dosimeter. No other dose information was received at this time.</p> <p>The licensee believes the root cause of the event was a defective manufacturer part inside the afterloader. More specifically, a small tube at the back of the cable that drives the source out of the safe was found to be flawed. This kept the source from fully retracting to the shielded safe, causing machine errors and higher than expected exposure rates near the afterloader. The patient did eventually receive their full treatment regimen and there are no effects expected for the patient. The patient received an estimated 181.48 cGy of therapeutic dose out of a planned 340 cGy for this fraction. In addition, a conservatively estimated dose of 7.84 cGy was received while the source was stuck. This was 1.04% of the daily dose of the prescribed treatment. The AU decided to discount/ignore the aborted 3rd fraction dose with the new written directive (after repair). The new written directive was for 340 cGy/fraction, twice per day for 4 days using 8 total fractions.</p>
3.	<p>On August 12, 2020, the Department was notified of a medical event involving Yttrium-90 Sir-Spheres. The licensee believes a patient received only 47% of the prescribed dose. The left lobe received 98% of the prescribed dose but the right lobe only received 33% of its planned dose. The prescribed Dose was 1.44 GBq and the delivered dose is believed to be 0.67 GBq. Preliminary cause is believed to be a clotted catheter. In addition, it was later discovered that the delivery box was leaking internally but there was no external contamination. There was no harm to the patient and he and the physician will discuss the possibility of additional treatments. The patient and referring physician were informed following the procedure. As part of updated procedures, a manufacturer representative will assist in refresher training.</p>