April 1, 2025 – August 26, 2025 RAM NMED Reportable Events	
2 Total Reportable Events	
1.	On April 16, 2025, a patient was receiving an Iridium-192 treatment using an Elekta, Inc. microSelectron HDR 106.990. During the treatment, a software error occurred ("TCS stop working, software problem detected") and the computer shut off. This stopped the treatment and retracted the source into the safe/shielded position. The Elekta service engineer was immediately contacted, and a system reboot was performed to bring the HDR machine and computer back to functional status. The authorized user decided to continue treatment with the service engineer remaining immediately available via telephone. After the treatment was resumed, the source was deployed (verified by room radiation monitor, source indicator at machine console computer, and sound of source movement) but the computer screen did not indicate treatment in progress by visual display and again gave an error message ("software problem detected.") The authorized medical physicist pressed the emergency button and the source was retracted. Per the authorized user physician, the patient's treatment was terminated for the day. It was determined that more computer memory was necessary for the treatments to continue. Elekta arrived on 4/17/25 and created 1 GB space on the local drive for a temporary solution, then permitted the facility's IT personnel to assist. The facility IT came onsite and created 230 GB local drive space, which is confirmed to be enough for the long term. Elekta did note that treatment volumes for this location (which require more memory) are exceptionally high compared to other Elekta brachytherapy clinics.
2.	On June 6, 2025, the licensee was performing the second (of four) Lu-177 Dotatate (Lutathera) treatments. The patient was prescribed 200 mCi of Lu-177 Dotatate. A slow obscured leak in the side-port of the 3-way stopcock was discovered approximately half-way through the 30-minute administration, despite the side-port being properly capped. The remaining dosage (11.4 ml of 25 ml) was slowly pushed by hand after an adjustment was made to the stopcock to stop the leak, and the infusion completed. Subsequent radiological measurements by radiation safety of the absorbent containing the leaked material and of the patient were immediately presumptive for a significant loss of material, which was confirmed by additional measurements and calculations. A medical event was declared upon finding the patient received less than 80% of the intended dose. It is estimated at this time that approximately 88.4 mCi were administered. All leaked material was completely contained to the underlying leakproof absorbent in place for this purpose and articles situated upon it; no other areas of contamination were found. Both the referring physician and the patient were notified the same day. No overexposures were recorded. No harm is expected to the patient. **Causes:** The event occurred due to a combination of equipment failure, human error, and insufficient training: • **Equipment Failure:** The cap provided with the 3-way stopcock apparatus was designed to maintain sterility but not designed to seal the side port, unbeknownst to the administration team. No warning of this feature was found on the packaging. Had the cap properly sealed the side port, the event would not have happened. • **Human Error:** The set-up team had a last minute need to insert extension tubing into the infusion line to maintain the required distance between the stopcock and the syringe pump. Repriming of the additional tubing required turning the system off to the patient, and the line inadvertently remained off as the infusion began. Had the system been correctly turned back on to the patient, the event would not have happened. If a cap was in use that properly sealed the side port, with the system turned off to the patient, the syringe pump would have alarmed, warning the team of an infusion error, and the event would not have happened. • **Training:** As Lutathera was a new treatment as of 4/11/25, the Novartis rep agreed to proctor the first 3 cases to ensure employees were confident in the administration, that all bugs were worked out, and

	that a final checklist could be developed. The Novartis rep did successfully proctor the first case on 4/11/25 but failed to attend the 2nd case on 6/6/25. While sufficient hands-on training was provided prior to the first case, changes were subsequently made with the tubing and administration set-up that warranted additional proctoring. As this was a new procedure and occurring infrequently, insufficient training was a significant contributing factor to the event. **Actions:** The Novartis rep is scheduled to provide retraining to the administration team on 6/12/25 to cover the administration setup options and conduct dry runs to ensure the infusion system method of choice works as intended without leaking or malfunction. The Novartis rep is scheduled to proctor the next 2 Lutathera patient administrations. The licensee will discontinue using caps provided with the Medex stopcock; only use caps known to seal the side-port. The licensee will consider discontinuation of the 3-way stopcock in lieu of alternate methods endorsed by Novartis. An administration checklist will be finalized on 6/12/25 to be used before Lutathera infusion begins, to confirm the proper setup of the administration system and as a quality assurance tool. The RSO will schedule a radiation safety "in-service" with the Lutathera administration team to review the QMP, the Lutathera administration procedure, methods to ensure high confidence that therapeutic radiopharmaceuticals are administered as intended, and prevention of medical events. The licensee issued written counseling memos to the two employees involved in this event.