UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD, SUITE 102
KING OF PRUSSIA, PA 19406-1415

February 22, 2024

EA-23-090
EA-23-149
NMED 230139 & 230333

LTG Telita Crosland, Director
Defense Health Agency
7700 Arlington Boulevard,
Suite #5101
Falls Church, VA 22042-5101

SUBJECT: DEFENSE HEALTH AGENCY - NRC INSPECTION REPORT 030-39046/2023-002

Dear LTG Telita Crosland:

This letter refers to the announced, reactive inspection conducted on June 22, 2023, at Brooke Army Medical Center (BAMC) in Fort Sam Houston, Texas, in response to your report of a loss of an iodine-125 localization seed (NMED 230139, EN 56443) with an activity between 144 and 209 microcuries at the estimated time of the loss, reported to the Nuclear Regulatory Commission (NRC) on March 31, 2023. Additional inspection activities occurred on August 24, 2023, at the same facility in response to a second report of a loss of a batch of 10 iodine-125 localization seeds (NMED 230333, EN 56647), each between approximately 132 and 192 microcuries at the estimated time of the loss, reported to the NRC on August 11, 2023. The inspection was an examination of activities conducted under your license as they relate to public health and safety, to confirm compliance with the NRC's rules, regulations, and with the conditions of your license. Within these areas, the inspection consisted of a selected examination of procedures and representative records, observations of activities, independent radiation measurements, and interviews with personnel. The preliminary inspection findings were discussed with Defense Health Agency (DHA) representatives following the conclusion of the onsite portions of the inspection activities on June 22, 2023, and August 24, 2023. A final exit briefing was conducted telephonically on January 26, 2024, with COL Ricardo Reyes, Laura Eline, Lt COL Michael Walkingstick, and Shabbir Shivji.

Based on the results of this inspection, the NRC identified two apparent violations, which are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is available on the NRC's Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. These apparent violations involved the apparent failures to secure from unauthorized removal or access and to control and maintain constant surveillance of licensed materials consistent with Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1801 and 20.1802.

During communications with DHA on or around January 2, 2024, DHA identified an additional DHA facility that was considering starting radioactive seed localization (RSL) use, we will note that NRC expects the corrective action procedures described in the enclosed inspection report

to be applied to the entirety of licensed operations wherever RSL is performed and any that may start using RSL in the future.

Since the NRC has not made a final determination in this matter, a Notice of Violation is not being issued for these apparent violations at this time. In addition, please be advised that the number and characterization of the apparent violations described in the enclosed inspection report may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

Since the apparent violations involve the loss of a total of 11 iodine-125 localization seeds, the NRC is considering proposing imposition of a civil monetary penalty. Section 2.3.4, Civil Penalty, of the NRC Enforcement Policy states that for violations where a licensee has lost required control of its regulated licensed material for any period of time, the NRC normally will impose at least a base civil penalty. The NRC may exercise discretion to mitigate or escalate a civil penalty amount based on the merits of the specific case. However, the NRC will not normally decrease the civil penalty to an amount below $9,000 for cases involving lost sources.

Before the NRC makes its enforcement decision, we are providing you an opportunity to (1) respond to the apparent violations addressed in this inspection report within 30 days of the date of this letter, (2) request a Pre-decisional Enforcement Conference (PEC), or (3) request alternative dispute resolution (ADR). If a PEC is held, it will be open for public observation and the NRC will issue a press release to announce the time and date of the conference.

If you decide to participate in a PEC or pursue ADR, please contact Anne DeFrancisco at (610) 337-5078 or via email at Anne.DeFrancisco@nrc.gov within 10 days of the date of this letter. A PEC should be held within 30 days of the date of this letter and an ADR session within 45 days of the date of this letter.

If you choose to provide a written response, it should be clearly marked as a “Response to Apparent Violations in NRC Inspection Report (030-39046/2023-002); EA-23-090 and EA-23-149,” and should include: (1) the reason for the apparent violations, or, if contested, the basis for disputing the apparent violations; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance was or will be achieved. Your response may reference or include previously docketed correspondence if the correspondence adequately addresses your response. Additionally, your response should be sent to U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy mailed to Paul G. Krohn, Director, Division of Radiological Safety & Security, U.S. Nuclear Regulatory Commission Region I, 475 Allendale Road, Suite 102, King of Prussia, PA, 19406, and emailed to R1Enforcement@nrc.gov within 30 days of the date of this letter. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision.

If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on this matter, including the significance, cause, and corrective actions, as well as any other information that you believe the NRC should take into consideration before making an enforcement decision. The decision to hold a PEC does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference would be conducted to obtain information to assist the NRC in making an enforcement decision. The topics discussed during the conference may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to

the identification of a violation, and information related to any corrective actions taken or planned. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful in preparing your response (Agencywide Documents Access and Management System (ADAMS) Accession No. ML061240509[1]).

In lieu of a PEC, you may request ADR with the NRC in an attempt to resolve this issue. Alternative dispute resolution is a general term encompassing various techniques for resolving conflicts using a neutral third-party mediator. The technique that the NRC has decided to employ is mediation. Mediation is a voluntary, informal process in which a trained neutral mediator works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues. Additional information concerning the NRC's ADR program can be obtained at: http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as a neutral third-party. Please contact ICR at (877) 733-9415 within 10 days of the date of this letter if you are interested in pursuing resolution of this issue through ADR.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter, its enclosure, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room and from the NRC's ADAMS, accessible from the NRC website at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy or proprietary information so that it can be made available to the public without redaction.

If you have any questions related to this matter, please contact Anne DeFrancisco of my staff at (610) 337-5078 or Anne.DeFrancisco@nrc.gov.

Sincerely,

Paul G. Krohn Digitally signed by Paul G. Krohn Date: 2024.02.22 10:42:42 -05'00'

Paul G. Krohn, Director
Division of Radiological Safety and Security

Docket No. 030-39046
License No. 45-35423-01

Enclosure:
NRC Inspection Report 030-39046/2023-002

cc w/ enclosure: COL Ricardo Reyes, Ph.D., Radiation Safety Officer

[1] NRC Agencywide Documents Access and Management System (ADAMS) Accession Numbers listed in this letter may be accessible using the hyperlink below with the associated ADAMS Accession Number inserted in place of the "ML" at the end: https://www.nrc.gov/docs/ML

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ADAMS ACCESSION NUMBER: ML24045A238

☒SUNSI Review: By: JEV | ADAMS: ☒ Yes ☐ No | ☐ Non-Publicly Available ☒ Publicly Available | ☒ Non-Sensitive ☐ Sensitive | Keyword: N/A

OFFICE	RI:DRSS	RIV:DRSS	RI:ORA	NMSS	OGC	OE
NAME	JvonEhr	LWardrobe	CCherie	MBurgess	RAugustus	JPeralta
SIGNATURE	Jason vonEhr	Leo Wardrobe			NLO	
DATE	01/08/2024	01/09/2024	2/1/2024	2/2/2024	2/7/2024	2/6/2024
OFFICE	RI:DRSS	RI:DRSS				
NAME	ADeFrancisco	PKrohn				
SIGNATURE	AED	PGK				
DATE	2/15/24	2/22/24				

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U.S. NUCLEAR REGULATORY COMMISSION
REGION I

Docket:	030-39046
License:	45-35423-01
Report:	2023-002
EA No.:	EA-23-090 and EA-23-149
Licensee:	Defense Health Agency
Location Inspected:	Brooke Army Medical Center, 3551 Roger Brooke Drive, Fort Sam Houston, Texas, 78234-6200
Inspection Dates:	June 22, 2023, and August 24, 2023, with in-office review through January 2, 2024

Inspectors:

Jason vonEhr 01/08/2024
Jason vonEhr, Senior Health Physicist — Date
Medical & Licensing Assistance Branch
Division of Radiological Safety & Security

Robin Elliott 01/19/2024
Robin Elliott, Senior Health Physicist — Date
Medical & Licensing Assistance Branch
Division of Radiological Safety & Security

Leo Wardrobe 01/09/2024
Leo Wardrobe, Health Physicist — Date
Medical & Licensing Assistance Branch
Division of Radiological Safety & Security

Approved By:

Anne DeFrancisco 02/15/2024
Anne DeFrancisco, Chief — Date
Medical & Licensing Assistance Branch
Division of Radiological Safety & Security

Attachment: Supplementary Information

Enclosure

EXECUTIVE SUMMARY

Defense Health Agency
NRC Inspection Report 030-39046/2023-002

An announced reactive inspection was performed of the Defense Health Agency (DHA) on June 22, 2023, with additional announced inspection effort on August 24, 2023, with in-office review through January 2, 2024, in response to an initial and subsequent independent report of the loss of iodine-125 localization seeds by the DHA. The inspection was an examination of activities conducted under the U.S. Nuclear Regulatory Commission (NRC) license as they relate to public health and safety, to confirm compliance with the NRC's rules, regulations, and with the conditions of the NRC license. The inspection focused on the licensee's report of the loss of radioactive material, its facts and circumstances, and the licensee's immediate response and subsequent corrective actions.

Program Overview

The DHA is a medical broad scope licensee authorized for medical use under Title 10 of the *Code of Federal Regulations* (10 CFR) 35.100, 35.200, 35.300, 35.400, 35.500, 35.600 (high dose rate afterloader), 35.1000 (yttrium-90 microsphere therapies and radioactive seed localization (RSL)), and a wide assortment of isotopes for medical research and other activities not associated with 10 CFR Part 35. The DHA is the federal medical organization directed by Congress to administer and oversee the consolidated medical treatment and associated facilities within the Department of Defense. The license covers more than 30 locations of use, including the Brooke Army Medical Center in Fort Sam Houston, Texas.

Inspection Findings

Two apparent violations of NRC requirements were identified. These apparent violations involved, in two separate instances, the apparent failures to secure from unauthorized removal or access and to control and maintain constant surveillance of licensed materials consistent with NRC requirements.

Corrective Actions

Following the first loss of licensed material, the licensee increased the direct oversight of the Health Physics staff to remove opportunities for other departmental staff to lose control of excised iodine-125 seeds. Other actions included retraining, labeling changes, and increasing existing efforts to pursue non-radioactive alternatives to the iodine-125 seeds.

Following the second loss of licensed materials, the licensee immediately secured the remaining inventory of iodine-125 seeds from their prior storage location and strengthened the controls securing them. The licensee further launched its own internal investigation into the loss of the iodine seeds and revised its protocols and procedures associated with the logistics and storage of the iodine-125 seeds, specifically to reduce the number of involved departments and increase the oversight by the Health Physics staff. As of January 1, 2024, the licensee ceased all use of iodine-125 seeds at BAMC, although some limited, infrequent use still may occur at one other DHA licensed facility.

REPORT DETAILS

1. Program Overview (Inspection Procedure 87134, 87132, & 87103)

1.1. Program Scope

DHA is a medical broad scope licensee authorized for medical use 10 CFR 35.100, 35.200, 35.300, 35.400, 35.500, 35.600 (high dose rate afterloader), 35.1000 (yttrium-90 microsphere therapies and RSL), and a wide assortment of isotopes for medical research and other activities not associated with 10 CFR Part 35. DHA is the federal medical organization directed by Congress to administer and oversee the consolidated medical treatment and associated facilities within the Department of Defense. The license covers more than 30 locations of use, including the Brooke Army Medical Center (BAMC) in Fort Sam Houston, Texas.

BAMC formerly had a specific license of broad scope with the NRC (License No. 42-01368-01) before it was incorporated into the DHA license on November 26, 2019, with the issuance of Amendment No. 4 of the DHA license. BAMC was authorized under the DHA license and before for a wide range of NRC-licensed activities, including the utilization of iodine-125 seeds, typically below 0.5 millicuries each, to perform RSL. This process involved a number of departments and staff who do not ordinarily handle radioactive material and has historically resulted in the loss of radioactive seeds on a number of occasions, including the two incidents described herein.

Between 2020 and March 2023, BAMC used 490 iodine-125 seeds across 304 procedures, though with a steadily decreasing trend in favor of non-radioactive alternative technologies.

1.2. Inspection Scope

The first portion of the inspection was an announced, reactive inspection of the licensee at BAMC. The inspection was limited to a review of the event reported to the NRC regarding the loss of a single iodine-125 sealed source with a nominal activity of 0.3 millicuries, used for localization of non-palpable breast lesions.

The second portion of the inspection was also an announced, reactive inspection of the licensee at BAMC. This inspection was similarly limited to a review of the event reported to the NRC regarding the loss of 10 iodine-125 sealed sources, nominal activity 0.3 millicuries each, used for the same purposes.

The inspection efforts were an examination of activities conducted under the NRC license as they relate to public health and safety, to confirm compliance with the NRC's rules, regulations, and with the conditions of the NRC license. The inspection focused on the licensee's report of the loss of radioactive material, its facts and circumstances, and the licensee's immediate response and subsequent corrective actions. Within these areas, the inspection consisted of a selected examination of procedures and representative records, observations of activities, independent radiation measurements, and interviews with personnel.

2. Initial Reactive Inspection of Single Seed Loss

2.1. Observations and Findings

On March 31, 2023, DHA contacted the NRC Headquarters Operations Officer (HOO) to report the loss of one iodine-125 brachytherapy seed used for RSL (NMED 230139, EN 56443), with a nominal activity of 0.3 millicuries. At the time the seed was believed to be lost, the activity was between 144 and 209 microcuries. This was followed up with a written report provided to the NRC on April 28, 2023 (ML24008A117[2]). On June 22, 2023, the NRC performed a reactive inspection onsite at BAMC to review the facts and circumstances surrounding the loss.

The inspector reviewed the actions taken by the licensee before and after the loss of the iodine-125 seed. On March 27, 2023, during a routine inventory, BAMC could not locate an iodine-125 seed (see Figure 1) (Lot 55749-2). The seed had been implanted in a patient on February 22, 2023. It was last accounted for on March 23, 2023, when it was removed from the patient and on March 24, 2023, when it was distributed (with the excised tissue) to histology and pathology staff. The seed was determined to be missing on March 27, 2023, when one of the licensee's Health Physics Technicians went to the pathology lab to take possession of the seeds stored in the pathology lab for placement into the licensee's decay-in-storage storage room. The licensee interviewed the responsible providers and conducted a search of the hospital without success. The search included performance of surveys in pathology, the operating room, and the drawer in which sealed sources were temporarily stored. The surveys included all workstations, sinks, and drains as well as all waste storage areas. The licensee checked the radioactive material waste alarm log and found no alarms having been activated. The licensee also contacted the local landfill and learned they had no radiation alarms from hospital waste during this time period.

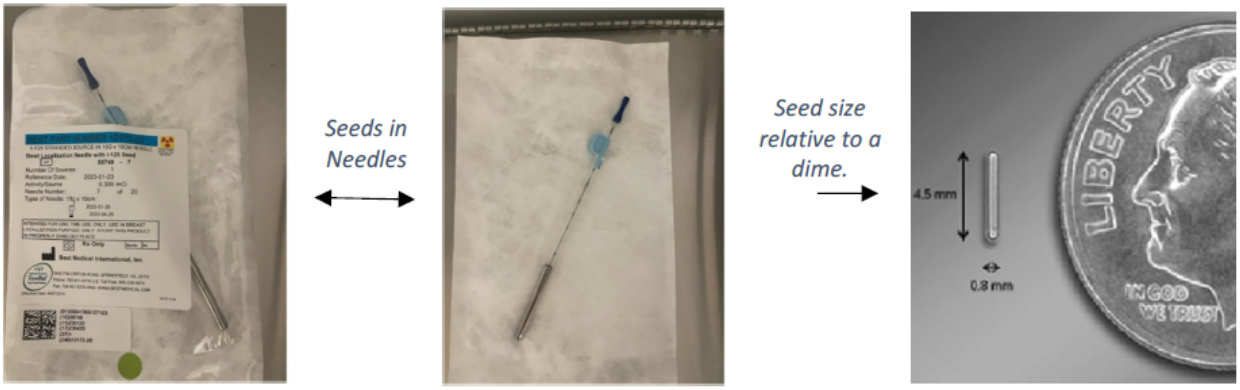

Figure 1 - Relative size and form of the Iodine-125 seeds involved in both the initial and follow-up losses. Image credit: DHA.

The inspector reviewed the updated procedures, updated checklists, and walked through the new procedure with the Associate Radiation Safety Officer. The corrective action anticipated to be the most effective was having the Health Physics staff waiting in the pathology lab for the pathologist to excise the iodine-125 seed and immediately

[2] NRC Agencywide Documents Access and Management System (ADAMS) Accession Numbers listed in this letter may be accessible using the hyperlink below with the associated ADAMS Accession Number inserted in place of the "ML" at the end: https://www.nrc.gov/docs/ML

taking possession of the seed and placing it into secure storage. In the period of time following the incident, the licensee performed an additional 14 procedures at BAMC without incident.

As a result of the above, an apparent violation of 10 CFR 20.1802 was identified (030-39046/2023-002-01). This apparent violation is described below:

> 10 CFR 20.1802 requires that licensees shall control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.
>
> Contrary to the above, as of March 27, 2023, the DHA's BAMC failed to control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage. Specifically, during a routine inventory and transfer of seeds between departments, the licensee could not locate an iodine-125 localization seed. The seed had last been positively accounted for on February 24, 2023, when it was temporarily implanted in a patient.

2.2. Corrective Actions

BAMC increased its efforts to accelerate an existing trend away from radioactive seeds to alternative, non-radioactive technologies. In effect, physicians are restricted from using iodine-125 seeds out of preference unless the use of the radioactive seed is deemed medically necessary. Radiation Safety staff will be present during the seed removal from the tissue post-implantation to immediately take possession of seeds for transfer to secure storage. Additional retraining was provided to involved staff and physicians on the proper handling of radioactive seeds and associated tools/logistics. BAMC improved the labeling of the seeds and related equipment and forms to increase awareness of the radioactive iodine-125 seed as opposed to a lesser-controlled non-radioactive equivalent seeds.

2.3. Conclusions

One apparent violation of 10 CFR 20.1802 was identified associated with the loss of control of a single iodine-125 seed following its excision from a patient.

3. Additional Reactive Inspection over Subsequent Seed Loss

3.1. Observations and Findings

On August 11, 2023, DHA contacted the NRC HOO to report the loss of 10 iodine-125 brachytherapy seed used for RSL (NMED 230333, EN 56677), nominal activity 0.3 millicuries each. The lost seeds were individually packaged, individually shielded, and were all the same lot number, Lot # 56406. At the time the seeds were believed to be lost, the activity was between 132 and 192 microcuries, each. This was followed up with a written report provided to the NRC on September 10, 2023 (ML24008A134). On August 24, 2023, the NRC performed a reactive inspection onsite at BAMC to review the facts and circumstances surrounding the loss.

The licensee stored the iodine-125 seeds in a Pyxis unit located in the Mammography Suite. A Pyxis is a fingerprint-controlled station that consists of a series of locked

cabinets and drawers. The radioactive seeds were placed in a drawer within this system, along with other non-radioactive medical drugs and supplies, for control and accountability while stored in the Mammography department. Access into the unit required personnel to enter an individual code (access requests/control was overseen by the Supply Department) into the unit. The Pyxis unit recorded and documented each accession by a user as well as the specific door or drawer that they accessed. The supply technicians re-supplied the unit when needed and recorded into the system the amount entered, lot number if required, and expiration date of the supplies. Personnel accessing the unit and removing supplies were trained to enter the amount withdrawn from the unit for each individual item.

The following represents a timeline of events associated with the second seed loss incident:

- May 9, 2023, the licensee received the lot of 10 iodine-125 seeds (Lot #56406), each with a nominal activity of 0.3 millicuries. The incoming package was surveyed and stored in the Nuclear Medicine Suite.
- May 11, 2023, the seeds were transferred to the Pyxis system located in the Mammography Suite and entered into the Pyxis inventory (Note: the supply technician entered the wrong expiration date in the system of June 25, 2023. The correct expiration date was August 23, 2023).
- May 23, 2023, a Health Physics staff member along with the Mammography supervisor conducted a quarterly inventory of the iodine-125 seeds located in the Pyxis system. This accounted for 12 seeds total: 10 seeds from Lot #56406 and 2 seeds from a previous Lot.
- May 31, 2023, and June 12, 2023, one seed each used in performing two localization procedures, and inventory reduced accordingly: 10 seeds remaining in the Pyxis system after June 12, 2023, procedure.
- June 15, 2023, a new lot of 10 iodine-125 seeds (Lot # 56668) arrived and was entered into the Pyxis system. Pyxis now contains 20 seeds total.
- No seed procedures were performed from June 15, 2023, through July 16, 2023. Pyxis logs indicated two personnel accessed the Pyxis unit during this time frame: a supply technician and Mammography technician. However, no seeds were recorded as removed or used.
- July 17, 2023, a supply technician updated the Pyxis system's inventory from 20 seeds to 10 seeds.
- No seed procedures performed during July 17, 2023, through August 2, 2023. Pyxis logs indicated three personnel accessed the Pyxis unit during this timeframe (supply technician, Mammography technician, and nursing staff) and no seeds were recorded as removed or used.
- On August 3, 2023, a seed procedure was performed, and a single seed (Lot #56668-1) was removed from the Pyxis unit.
- No seed procedures were performed between August 4 through 9, 2023.
- On August 10, 2023, a seed procedure was performed, and a single seed (Lot #56668-2) was removed from the Pyxis unit. The staff withdrawing the seed noted that 10 seeds were missing from the Pyxis unit (all the seeds from Lot #56406). Health Physics staff was notified, and multiple searches were performed of the Pyxis unit located in Mammography, in addition to all Pyxis units located on the first floor of the hospital, the Mammography Ward, the Health Physics

lab, the supply office, the Nuclear Medicine Department, the Supply Warehouse, and the Health Physics storage area.
- On August 11, 2023, the seeds were declared lost, and the NRC was informed of the event.

Starting on September 6, 2023, a formal DHA-internal investigation was launched to determine the facts and circumstances surrounding the loss of the 10 iodine-125 seeds. This investigation concluded on September 29, 2023, but did not definitively identify how or when the seeds were removed from the Pyxis unit. Nonetheless, DHA offered its best conclusion that the most probable scenario was the newly hired and no-longer-employed logistics technician disposing of the "expired" radioactive seed lot (having the expiration date mis-recorded) without following proper protocol. Between the NRC's reactive inspection efforts and the DHA-internal investigation, several additional observations and findings were identified.

- The Health Physics staff identified that there were approximately 300 personnel that could access the Pyxis unit located in the Mammography Ward.
- On August 1, 2023, the Mammography supervisor checked into the Pyxis unit and observed that there were only 10 iodine-125 seeds in the Pyxis unit and sent an email to logistics to order another lot of seeds.
- Even if a user did not access a drawer or withdraw supplies or materials, the Pyxis would nonetheless record the log-in of the user.
- The inventory system associated with the Pyxis unit required that personnel entering the unit must subtract the amount of supplies/medicine, et cetera that is withdrawn from the unit into the software for the inventory to be updated.
- The Pyxis unit does not lock immediately upon closure, although the few seconds between closure and locking did not provide a realistic opportunity for theft by an individual not otherwise logged into the Pyxis.
- In the database of the Pyxis unit, there were line items for all materials stored in the unit with a corresponding flag if the material exceeded its expiration date.

Based upon the timeline of the events, the seeds likely went missing between June 15 and July 17, 2023. These dates represent the arrival of the new 10-seed lot on June 15, and the inventory update by a supply technician on July 17 which reduced the seed inventory from 20 seeds to 10 seeds. None of the personnel interviewed by the NRC during the reactive inspection (supply technician, Mammography technician, Mammography nurse and Mammography supervisor) nor by the DHA investigator knew or observed any unusual events that could explain the missing seeds. The personnel that entered the Pyxis unit during that timeframe stated that they did not enter the drawer containing the seeds nor did they remove any seeds when entering the drawer.

As of the date of this report there is still no evidence to indicate where the seeds are. The NRC noted that the error in the recording of the expiration date (June 25, 2023), which fell between the June 15 and July 17 dates noted above, is the most likely trigger for the missing lot of seeds as these now-expired seeds would be flagged in the Pyxis inventory display and may have led to the inexperienced logistics technician to dispose of the seeds in a manner inconsistent with the proper disposal pathway for expired radioactive seeds.

As a result of the above, an apparent violation of 10 CFR 20.1801 was identified (030-39046/2023-002-02). This apparent violation is described below:

> 10 CFR 20.1801 requires that the licensee shall secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.
>
> Contrary to the above, between June 15 through July 17, 2023, the DHA failed to secure from unauthorized removal or access licensed materials that were stored in controlled or unrestricted areas. Specifically, at an unknown point in time between June 15 and July 17, 2023, 10 iodine-125 seeds used for RSL, each with a nominal activity of 300 microcuries as of May 10, 2023, went missing and were not recovered by the licensee during the subsequent searches and investigation.

3.2. Corrective Actions

In response to the loss of the 10 iodine-125 seeds, DHA immediately removed the remaining seeds from the Pyxis storage unit and placed them in the Health Physics staff long-term storage unit where the seeds would remain under stricter security and controls than was the case with the Pyxis. Approximately one month after discovery, DHA launched its own internal investigation on September 6, 2023, to perform a comprehensive review of the facts and circumstances behind the loss of the 10 iodine-125 seeds, as well as to provide recommendations to the command regarding present and future corrective actions.

DHA revised its protocol/procedure within a week to reduce the responsibilities of the Mammography staff in favor of increased involvement, oversight, and control by the Health Physics staff. The procedure change, specifically, required the Mammography staff inform the Health Physics staff at least 24 hours prior to implantation in order to coordinate the delivery of the seed(s) to the Mammography staff immediately prior to performing a procedure with the seeds, eliminating the need to store seeds within the Mammography department and increasing the direct control and oversight by the Health Physics staff over the seeds.

Additionally, when the seeds are received from the vendor, the pharmacy staff will perform a receipt survey and notify the Health Physics staff to pick up seeds for storage in its long-term storage unit rather than the Pyxis system.

Finally, DHA has discontinued the use of iodine-125 seeds at BAMC for localization of non-palpable breast lesions in favor of an alternative technology utilizing non-radioactive seeds, either Radio Frequency Identification (commonly known as RFID) or magnetic seeds. This transition for BAMC was confirmed as of January 1, 2024. Any sources remaining in BAMC's inventory were transferred to decay-in-storage for eventual disposal. One other licensed facility within DHA (Dwight D. Eisenhower Army Medical Center) continued to use iodine-125 seeds for localization purposes on a limited, infrequent basis, and has incorporated the lessons learned from BAMC into its operating procedures.

3.3. Conclusion

An apparent violation of 10 CFR 20.1801 was identified associated with the loss of control of the 10 iodine-125 seeds from the Pyxis unit.

4. NRC Reporting Requirements

The reportability of the theft or loss of radioactive material is addressed in 10 CFR 20.2201. Specifically, the loss of radioactive material equal to or greater than 1,000 times the quantity specified in 10 CFR Part 20, Appendix C, is reportable immediately after its occurrence becomes known (and that it appears to the licensee that an exposure could result to persons in unrestricted areas) and within 30 days if the quantity is greater than 10 times the Appendix C quantity. Iodine-125 has an Appendix C value of 1 microcurie and is therefore reportable to the NRC within 30-days in quantities of greater than 10 microcuries and immediately in quantities greater than 1 millicurie.

The discovery on March 27, 2023, involved a missing iodine-125 seed with a nominal activity of 300 microcuries and therefore fell within the lesser of the reporting requirements. DHA's contact with the NRC via the HOO on March 31, 2023, was well within the 30-day requirement specified in 10 CFR 20.2201(a)(ii) and deemed compliant.

The discovery on August 10, 2023, of the missing batch of 10 iodine-125 seeds involved a nominal activity of 300 microcuries each. The licensee's efforts to identify the sources, how many and under what circumstances they were missing, occurred throughout the remainder of August 10 and into August 11 before these efforts were exhausted and the sources were declared missing, and contact was made with the NRC HOO. At the time of discovery, the activity was approximately 97 microcuries each, and a cumulative activity of 0.97 millicuries. As a result, the licensee's report technically fell under the lesser reporting requirement of 30-days (i.e. a cumulative activity of greater than 10 microcuries but less than 1.0 millicuries), which was met by its report to the NRC HOO on August 11, and was therefore deemed compliant. When the sources were believed to have been removed from the Pyxis, the seeds had a decayed activity of between 132 and 192 microcuries each, and a cumulative activity of 1.32 and 1.92 millicuries.

In addition to the above initial reporting requirement, a follow-up written report is required under 10 CFR 20.2201(b) within 30 days after making a report described by 10 CFR 20.2201(a). The licensee's initial report on March 31, 2023, to the NRC's HOO of the single seed loss, was followed by a written report provided to the NRC on April 28, 2023. For the subsequent ten-seed loss, the initial report was made to the NRC's HOO on August 11, 2023, with a follow-up written report provided to the NRC on September 10, 2023. In both of these instances, the licensee met the requirement for a 30-day follow-up written report.

5. Exit Meeting Summary

The NRC inspectors presented preliminary inspection findings following the onsite inspections on June 22, 2023, and August 24, 2023, at BAMC. The NRC conducted a final exit briefing via teleconference on January 26, 2024, with DHA representatives including: COL Ricardo Reyes, Laura Eline, Lt COL Michael Walkingstick, and Shabbir Shivji. The licensee acknowledged the findings and did not dispute any of the facts presented.

SUPPLEMENTARY INFORMATION

LIST OF PERSONS CONTACTED

COL Ricardo Reyes, Radiation Safety Officer (RSO)
Lt COL Michael Walkingstick, Facility RSO/Chief of Health Physics
LT Mark Daily, Health Physics staff
Laura Eline, Health Physics staff/Assistant RSO
SGT Jacob Riggle, Health Physics staff
COL Michael Wirt, Chief of Radiology
Christopher Upshaw, Supply Technician
Gayle Goldsmith, Mammography Nurse
Leslie Eckenrode, Mammography Supervisor

INSPECTION PROCEDURES USED

87134	Medical Broad-Scope Programs
87132	Brachytherapy Programs
87103	Inspection of Materials Licensees Involved in an Incident or Bankruptcy Filing

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-39046/2023-002-01	AV	10 CFR 20.1802 – apparent failure to control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.
030-39046/2023-002-02	AV	10 CFR 20.1802 – apparent failure to secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

Closed

None

Discussed

None

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LIST OF ACRONYMS AND ABBREVIATIONS USED

ADAMS	Agencywide Documents Access and Management System
ADR	Alternative Dispute Resolution
AV	Apparent Violations
BAMC	Brooke Army Medical Center
CFR	*Code of Federal Regulations*
DHA	Defense Health Agency
EN	Event Number
HOO	NRC Headquarters Operations Officer
ICR	Institute on Conflict Resolution (Cornell University)
NMED	Nuclear Materials Event Database
NRC	Nuclear Regulatory Commission
PEC	Pre-decisional Enforcement Conference
RFID	Radio Frequency Identification
RSL	Radioactive Seed Localization