UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 EAST LAMAR BLVD
ARLINGTON, TEXAS 76011-4511

April 9, 2012

EA-12-031

Department of the Air Force
ATTN: David A. Smith, Lt. Col., USAF, BSC
Chief, Radiation Programs
AF/SGE (AFMSA/SG3PB)
ATTN: Radioisotope Committee
1780 AF Pentagon
Washington, DC 20330-1780

SUBJECT: WRIGHT PATTERSON MEDICAL CENTER - NRC INSPECTION REPORT 030-28641/11-006

Dear Lt. Col. Smith:

This letter refers to the inspection conducted on October 27, 2011, at Wright Patterson Medical Center, Dayton, Ohio, with continued in-office review through March 1, 2012. This inspection was an examination of activities conducted under your license as they relate to safety and compliance with the Commission's rules and regulations and with the conditions of your NRC license. Within these areas, activities authorized under U.S. Air Force Permit OH-04682-03/10AFP were reviewed, with a focus on selected procedures and representative records, security and control of licensed material, observations of activities, and interviews of personnel. At the conclusion of the onsite portion of the inspection, the preliminary inspection findings were discussed with Col. Steven W. Higgins and members of his staff, including Lt. Col. Scott A. Nemmers, Radiation Safety Officer. The inspection results were discussed with you during a final telephonic exit briefing conducted on March 23, 2012. The enclosed report presents the results of this inspection.

Based on the results of this inspection, two apparent violations were identified and are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The violations involved the failure to conduct semiannual physical inventories of an americium-241 sealed source as required by 10 CFR 35.67(g) and the failure to secure the source from unauthorized access or removal as required by 10 CFR 20.1801. The circumstances surrounding these apparent violations, the significance of the issues, and the need for lasting and effective corrective actions were discussed with you during the inspection exit meeting on March 23, 2012. As a result, it may not be necessary to conduct a predecisional enforcement conference in order to enable the NRC to make an enforcement decision.

You should be aware that Section 2.3.4 of the NRC Enforcement Policy states that, for violations involving the loss, abandonment, or improper transfer or disposal of a sealed source

or device, the NRC should normally exercise discretion when proposing the imposition of a civil penalty of at least the base amount. Since the apparent violation involves the loss of a sealed source, the NRC is considering proposing imposition of a civil monetary penalty. The base civil penalty amount is based on approximately three times the expected average cost of authorized disposal; however, the NRC may consider adjusting the civil penalty amount to a more appropriate base amount if you can demonstrate that three times the actual cost of disposal would be significantly less than the base amount. However, NRC will not normally decrease the civil penalty to an amount below the lowest base civil penalty for such cases, i.e., $8,500.

Before the NRC makes its enforcement decision, we are providing you an opportunity to respond to the apparent violations addressed in this inspection report within 30 days of the date of this letter or request a Predecisional Enforcement Conference (PEC). 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. Please contact Jack E. Whitten, Chief, Nuclear Materials Safety Branch B, at 817-200-1197 within 10 days of the date of this letter to inform the NRC of which option you are using. If you decide to participate in a PEC, the PEC should be held within 30 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 030-28641/11-006; EA-12-031” and should include for each apparent violation: (1) the reason for the apparent violation or, if contested, the basis for disputing the apparent violation; (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 will be achieved. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. 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 or schedule a PEC.

If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on the apparent violations and any other information that you believe the NRC should take into consideration before making an enforcement decision. The topics discussed during the conference may include the following: 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 to be taken. 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 the enclosed excerpt from NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful.

In addition, please be advised that the number and characterization of 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.

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

If you have any questions concerning this matter, please contact Mr. Whitten at 817-200-1197.

Sincerely,

/RA/

Roy J. Caniano, Director
Division of Nuclear Materials Safety

Docket: 030-28641
License: 42-23539-01AF

Enclosure:
1. NRC Inspection Report 030-28641/11-006
2. NRC Information Notice 96-28

cc:
Michael Snee
Bureau of Radiation Protection
Ohio Department of Health
246 North High Street
Columbus, Ohio 43215

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ADAMS: □ No ☒ Yes	☒ SUNSI Review Complete	Reviewer Initials: JDC
	☒ Publicly Available	☒ Non-Sensitive
	□ Non-publicly Available	□ Sensitive

RIII	RIV:NMSB-B	C:NMSB-B	
KJLambert;dlf	JDCook	JEWhitten	
E - JDCook	***/RA/***	***/RA/***	
3/27/12	3/27/12	3/28/12	
ACES	RC	C:ACES	D:DNMS
MCMaier	KDFuller	HJGepford	RJCaniano
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4/5 /12	3/29/12	4/5/12	4/9/12

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U.S. NUCLEAR REGULATORY COMMISSION REGION IV

Docket:	030-28641
License:	42-23539-01AF
Report:	030-28641/11-006
EA:	12-031
Licensee:	Department of the Air Force USAF Radioisotope Committee
Permit Holder: Permit: Location:	Wright Patterson Medical Center OH-04682-03/10AFP Dayton, Ohio
Date:	October 27, 2011
Inspector:	Kenneth J. Lambert, Senior Health Physicist Region III
Approved By:	Jack E. Whitten, Chief Nuclear Materials Safety Branch B
Attachment:	Supplemental Inspection Information

Enclosure

EXECUTIVE SUMMARY

Department of the Air Force
NRC Inspection Report 030-28641/11-006

This inspection was a routine, unannounced inspection at Wright Patterson Medical Center, Dayton, Ohio, Permit No. OH-04682-03/01AFP, authorized by U.S. Air Force Master Materials License 42-23539-01AF. The inspection was performed using Inspection Procedures 87131, "Nuclear Medicine Programs, Written Directive Required" and 87132, "Brachytherapy Programs." The inspection focused on security and control of radioactive materials, radiation instrumentation and surveys, shielding of radioactive materials, comprehensive safety measures, handling of radioactive materials, and management oversight. The inspection also reviewed the circumstances surrounding the loss of an americium-241 sealed source that was reported to the NRC on September 30, 2011 (EN 47309). The licensee provided the NRC with a written report, dated October 25, 2011, regarding the lost source.

Inspection Findings

The inspector identified two apparent violations of NRC requirements regarding the lost americium-241 sealed source. The apparent violations are:

1. Failure to conduct a semiannual physical inventory of the americium-241 sealed source as required by 10 CFR 35.67(g). (Section 6.3)

2. Failure to secure from unauthorized access or removal licensed materials in storage as required by 10 CFR 20.1801. (Section 6.7)

The root cause of the apparent violations was the failure of the Air Force staff to understand that a physical inventory meant that the source is viewed during the inventory to confirm that the source is present and that simply confirming that a lock is on a cabinet where a source is expected to be located does not satisfy the requirement for a physical inventory.

Corrective Actions

Immediate Corrective Actions:

- The permittee performed a search of where the source was believed to be stored and three separate searches of all source storage locations.

- A photographic inventory of all radioactive sources was conducted.

- A review of electronic records and hard copy records was conducted by both the licensee and permittee, which did not locate any potential transfer or disposition records for the missing source.

Long-Term Corrective Actions:

- The permittee has started to restructure the records/database to streamline the process and generate a more user-friendly record database which will aid in source tracking.

- The permittee is reviewing the training requirements for medical center radiation safety staff members. Annual training for the primary areas with sealed sources (Nuclear Medicine and Radiation Therapy) was modified to reflect heightened awareness on control and security of sources. Annual training for Radiation Therapy was completed on February 10, 2012, and Nuclear Medicine annual training was completed March 16, 2012.

- The fourth quarter physical inventory for Calendar Year 2011 was conducted on October 5, 2011, and the first quarter physical inventory for Calendar Year 2012 was conducted March 8-9, 2012. All sealed sources, with the exception of the americium-241, were accounted for during the inventory. The next physical inventory will be scheduled for sometime between April 16-27, 2012.

REPORT DETAILS

Summary of Facility

Radioactive Materials Permit OH-04682-03/01AFP for Wright Patterson Medical Center (permittee) authorized 10 CFR 35.100, 35.200, 35.300, 35.400, and 35.600 modalities. The Nuclear Medicine Department operated with 5 technologists and performed approximately 12 procedures per day. The department performed approximately six studies per week utilizing fluorine-18. The permittee performed approximately 11 hyperthyroid treatments per year and 11 thyroid carcinoma treatments per year utilizing iodine-131 in capsule form. The medical center was authorized to perform high dose rate (HDR) afterloader therapeutic procedures. The medical center was also authorized to perform prostate manual brachytherapy procedures using iodine-125 and palladium-103 seeds.

1 Nuclear Medicine Programs (87131)

1.1 Inspection Scope

The security and control of radioactive materials, shielding of licensed materials, labeling and posting requirements, radiation surveys, physical security of radioactive materials, and management oversight were reviewed by the inspector to verify that licensed activities were conducted in accordance with NRC regulations. The NRC assessment was performed based on observation of ongoing activities, interviews with personnel, and review of associated records.

1.2 Observations and Findings

The Nuclear Medicine Department did not possess a radiopharmaceutical generator. The department ordered and received only unit dosages of radioactive materials prepared by a nuclear pharmacy. The inspector conducted a tour of the Nuclear Medicine Department and observed members of the nuclear medicine staff performing injections of radiopharmaceuticals. Radioactive materials were secured in the locked hot lab during the inspection. Permittee staff demonstrated radiopharmaceutical package receipt procedures, daily dose calibrator checks, daily and weekly surveys, radioactive materials spill procedures, and radiological waste handling practices for short half-life radioactive waste.

The annual audit of the radiation protection program content and implementation was performed and the results of the audit were reviewed by management.

Techniques employed by the staff demonstrated good handling practices as well as an adequate knowledge of radiation safety.

1.3 Conclusions

The inspector did not identify any violations of regulatory requirements.

2. Lost Americium-241 Sealed Source (87131)

2.1 Inspection Scope

The inspector reviewed the circumstances surrounding the report of a lost americium-241 (Am-241) sealed source that was reported to the NRC on September 30, 2011. The inspector reviewed the permittee's written report on the lost source and interviewed selected staff.

2.2 Observations and Findings

On September 30, 2011, the Air Force Radioisotope Committee (licensee) reported that a nominal 12 millicurie Am-241 sealed source was lost sometime between September 2009 and September 2011 at the permittee's facility. The source was part of an anatomical marker device that was designed to be used with a portable nuclear medicine gamma camera, but had not been used since at least 1994. The sealed source was originally stored in the Nuclear Medicine Department hot lab. Inventory and leak tests were performed quarterly through July 2, 2002. The Am-241 sealed source was placed in inactive storage sometime between the July 2, 2002, and January 17, 2003, inventories. The sealed source was not leak tested after that. The Am-241 sealed source was moved to the medical center's designated low-level radioactive waste storage room between the October 16, 2003, and January 9, 2004, inventories. The sealed source was placed into a drawer in the new storage location and the drawer was secured with a padlock.

Permittee staff indicated that the device was visually (physically) inspected in September 2009 during an inventory in preparation for a change in the medical center's radiation safety officer. The staff further indicated that the September 2009 inventory was not documented on the inventory record.

Permittee staff indicated that, during an inventory on September 27, 2011, for transition from one radiation safety officer to another, the device was again physically inspected. During this inventory, the permittee staff performed surveys of the device, using both an alpha detector and a sodium iodide detector, with measurements indistinguishable from background. On September 30, 2011, the base alternate radiation safety officer, being concerned over the background readings, surveyed the device a second time. The measurements from this survey were also indistinguishable from background. As a result, the alternate radiation safety officer determined that the sealed source was not attached to the device. As a result, the permittee staff began a search of all medical center storage and use locations and a search of records that could have indicated the Am-241 sealed source was transferred to another location on or off the base. The storage locations and the Nuclear Medicine Department were searched on three separate occasions between September 27 and 30, 2011. Based on not locating the sealed source and being unable to find a record of the sealed source being transferred, on September 30, 2011, the permittee notified the Air Force Radioisotope Committee (licensee) of the lost source. On September 30, 2011, the licensee reported the lost sealed source to the NRC Headquarters Operation Center.

Based on a review of inventory records, the permittee had been performing inventories of its sealed sources quarterly. However, for inventories of the Am-241 sealed source between November 2, 2004, and September 2009, the permittee did not conduct a physical inventory of the sealed source; it only confirmed that the drawer was locked.

Title 10 Code of Federal Regulations (CFR), Part 35.67(g), requires, in part, that a licensee in possession of sealed sources or brachytherapy sources conduct a semiannual physical inventory of all such sources in its possession. The permittee's failure to conduct semiannual physical inventories of the Am-241 sealed source after November 2, 2004, is an apparent violation of 10 CFR 35.67(g). (030-28641/11-001)

Title 10 CFR, Part 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas. The permittee's failure to secure from unauthorized removal or limit access to a 12 millicurie Am-241 sealed source located in the low-level radioactive waste storage room, which is a controlled area, is an apparent violation of 10 CFR 20.1801. (030-28641/11-002)

The inspector determined that the root cause of the violation was the permittee's failure to understand that a physical inventory requires that the source is viewed during the inventory to confirm that the sealed source is present, rather than simply verifying that the storage location (drawer) is locked to indicate that the sealed source had not been accessed. As an alternative to a physical inventory, other methods may be used to confirm the presence of the source and to maintain uses ALARA (as low as reasonably achieveable); for example, use of a radiation survey meter to confirm the presence of a source.

Once the permittee identified that the sealed source was missing, immediate corrective actions included three separate searches of all source storage locations in the medical center. In addition, the Nuclear Medicine Department was searched. The permittee and the licensee also reviewed source transfer documentation, permits, and Radiation Safety Committee meeting minutes in an attempt to determine if the sealed source was transferred or disposed.

Based on the licensee's written report, corrective actions to prevent recurrence included photographing all sources in its inventory to help in positively identifying sources. The permittee also performed a review of all records and determined that a more streamlined and organized method for storing records was needed. The permittee has begun reorganizing records. Finally, the medical center staff is reviewing its training program and plans to make any necessary changes in the program to ensure that its staff is appropriately trained on NRC requirements, including the physical inventory of sealed sources. Annual training for radiation therapy and nuclear medicine was completed on February 10 and March 16, 2012, respectively.

2.3 Conclusions

The inspector identified two apparent violations involving the failure to conduct a semiannual physical inventory of the Am-241 sealed source and the failure to secure licensed material in a controlled area from unauthorized removal or access.

3 Brachytherapy Programs (87132)

3.1 Inspection Scope

The inspector reviewed the permittee's radiation safety program, training of personnel, physical security of radioactive materials, and management oversight to verify that licensed activities were conducted in accordance with NRC regulations. The NRC assessment was performed based on interviews with personnel and review of associated records.

3.2 Observations and Findings

The permittee was authorized to possess an HDR afterloader. The facility had treated one patient in 2010 and two patients in 2011. All three procedures were for vaginal treatments using a cylinder. The inspector reviewed treatment plans and records of the daily checks of the HDR unit. Treatments were performed in accordance with the written directive and treatment plan. At the time of the inspection, the medical physicists were not present to demonstrate the daily checks or operation of the HDR unit.

The permittee was authorized to perform manual brachytherapy prostrate seed implants using iodine-125 and palladium-103. The licensee had performed 17 implants since the inception of the program in 2009. The permittee performed a Computerized Tomography scan at approximately 30 days post treatment to verify the treatment was in accordance with the written directive and treatment plan. The inspector reviewed five of the cases that had been performed and no discrepancies were noted in the review.

3.3 Conclusions

The inspector did not identify any violations of regulatory requirements.

4 Exit Meeting Summary

On October 27, 2011, the inspector presented the preliminary inspection results to Col. Steven W. Higgins and other members of the Wright Patterson medical center staff, including Lt. Col. Scott A. Nemmers, Radiation Safety Officer. A final exit briefing was held telephonically with Lt. Col. David Smith and Lt. Col. Alden Hilton of the USAF Radioisotope Committee on March 23, 2012, to discuss the findings of this inspection. The licensee acknowledged the inspector's findings. No proprietary information was identified.

ATTACHMENT

PARTIAL LIST OF PERSONS CONTACTED

Col. Steven W. Higgins, 88th Medical Group (88 MDG) Commander
Mr. Gerald M. Laughner, Director, Organizational Improvement Office
Lt. Col. Scott A. Nemmers, Diagnostic Imaging Flight Commander & 88 MDG RSO
Maj. Steven B. Graves, Officer-in-Charge (OIC), Medical Physics Element
Lt. Col. Stanley M. Searcy, OIC, Health Physics Element
MSgt. Jeffrey R. Eller, Section Chief, Molecular Imaging
TSgt. Edward C. Parker, Noncommissioned Officer-in-Charge (NCOIC), Nuclear Medicine

INSPECTION PROCEDURE USED

IP 87131, Nuclear Medicine Programs, Written Directive Required
IP 87132, Brachytherapy Programs

ITEMS OPENED, CLOSED, OR DISCUSSED

Opened

030-28641/11-001	APV	Apparent violation involving the failure to conduct a semiannual physical inventory of sealed sources in accordance with 10 CFR 35.67(g).
030-28641/11-002	APV	Apparent violation involving the failure of an Am-241 sealed source from unauthorized access or removal in accordance with 10 CFR 20.1801.

Closed

None

Discussed

None

LIST OF ACRONYMS USED

ALARA	as low as reasonably achievable
Am-241	americium-241
CFR	*Code of Federal Regulations*
HDR	high dose rate
Notice	Notice of Violation
NRC	U.S. Nuclear Regulatory Commission
RSO	radiation safety officer
USAF	United States Air Force