UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BLVD.
KING OF PRUSSIA, PA 19406-2713

December 9, 2021

EA-21-132

LTG Ronald J. Place, MC, USA, Director
Defense Health Agency
DHHQ
7700 Arlington Boulevard, Suite 5101
Falls Church, VA 22042-5101

SUBJECT: DEFENSE HEALTH AGENCY (DHA) - NRC INSPECTION REPORT 03039046/2021002

Dear LTG Place:

On May 17, 2021, with continued in-office review through October 7, 2021, Shawn Seeley of this office conducted a special remote inspection of your activities performed under your NRC License No. 45-35423-01. The inspector discussed the inspection findings with COL Ricardo Reyes, telephonically, on November 18, 2021.

Based on the results of this inspection, the NRC determined that two apparent violations of NRC requirements occurred 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 https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The first apparent violation is related to the failure to secure licensed material as required by 10 CFR 20.1802. Specifically, on May 13, 2021, staff at the Defense Health Agency's (DHA) permittee facility located at Naval Medical Center San Diego lost four brachytherapy seeds, each containing 0.26 mCi of iodine-125, as described in Event Notification #55262. The second apparent violation involved the failure to immediately report any lost, stolen, or missing licensed material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in appendix C to part 20 under such circumstances that it appears to the licensee that an exposure could result to persons in unrestricted areas, by contacting the NRC Headquarters Operations Officer (HOO), as required by 10 CFR 20.2201(a). Namely, DHA informed the NRC HOO about the May 13 incident on May 17, 2021. The circumstances surrounding these apparent violations, the significance of the issues, and the need for lasting and effective corrective actions were discussed with members of your staff at the inspection exit meeting on November 18, 2021.

Since the NRC has not made a final determination in this matter, a Notice of Violation is not being issued at this time. 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 review. You will be advised by separate correspondence of the results of our deliberations on this matter. The circumstances surrounding the apparent violation, the

significance of the issue, and the need for lasting and effective corrective actions were discussed with you during the November 18, 2021, telephone call.

Since one of the apparent violations involves the loss of regulated material, 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 base civil penalty amount is based on approximately three times the expected average cost of authorized disposal; however, the NRC may exercise its discretion to mitigate or escalate a civil penalty amount based on the merits of a specific case. Therefore, you may provide information regarding the actual expected cost of authorized disposal that you believe the NRC should consider in making a final enforcement decision. However, NRC will not normally decrease the civil penalty to an amount below the lowest base civil penalty for such cases (i.e., $3,500).

Before the NRC makes its enforcement decision regarding the apparent violations, we request that you provide additional information regarding DHA's corrective and preventative actions for this event. Although we noted that your immediate corrective actions to cancel all permanent brachytherapy procedures until a root cause analysis was conducted appeared to be effective, it is not clear if adequate actions to prevent recurrence have been developed and/or implemented. Therefore, please provide to us the additional measures you have implemented as a result of the analysis and any recommendations for future brachytherapy procedures. You should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violation. 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.

The written response should be sent to the NRC within 30 days of the date of this letter. The NRC recognizes that many licensees have been impacted by the public health emergency caused by the Coronavirus Disease 2019 (COVID-19). Consequently, you may request an extension of time to submit the response by contacting Anne DeFrancisco, Chief, Medical and Licensing Assistance Branch, via electronic mail at anne.defrancisco@nrc.gov. Such an extension request should explain the basis for the request and should specify the amount of additional time being requested. This extension request must be submitted to the NRC no later than 20 days from the date of this letter (i.e., at least 10 days before the initial 30-day deadline to submit the written response).

Your response 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; 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. You should clearly mark the response as a "Response to Apparent Violation in NRC Inspection Report No. 03039046/2021002; EA-21-132," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, NRC Region I, 2100 Renaissance Boulevard, Suite 100, King of Prussia, PA 19406. 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 pre-decisional enforcement conference (PEC).

In lieu of providing this written response, you may choose 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 by: (1) requesting a PEC to meet with the NRC and provide your views in person; or (2) requesting Alternative Dispute Resolution (ADR).

If you choose to request a PEC, the meeting should be held within 30 days of the date of this letter, although this timeframe may be extended due to impacts from COVID-19. The conference will include an opportunity for you to provide your perspective on these matters and any other information that you believe the NRC should take into consideration before making an enforcement decision. The topics discussed during the PEC 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. Please note that if a PEC is held, the NRC would issue a press release to announce the conference time and date.

In lieu of a PEC or written response, you may request ADR with the NRC in an attempt to resolve this issue. ADR is a general term encompassing various techniques for resolving conflicts using a neutral third party. The technique that the NRC has decided to employ is mediation; 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 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 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. The ADR mediation session should be held within 45 days of the date of this letter, although this timeframe may be extended due to impacts from COVID-19. The mediation session would be closed to public observation, but the time and date would be publicly announced.

Please contact Ms. DeFrancisco at anne.defrancisco@nrc.gov within **10 days** of the date of this letter to notify the NRC which of the above options you choose. If you do not contact the NRC within the time specified, and an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision.

In accordance with 10 CFR 2.390 of the NRC's Rules of Practice," 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 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 Shawn Seeley of my staff at shawn.seeley@nrc.gov.

Sincerely,

Blake D. Welling

Digitally signed by Blake D. Welling
Date: 2021.12.09 13:24:26 -05'00'

Blake Welling, Director
Division of Radiological Safety and Security
Region I

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

Enclosures:
1. Inspection Report No. 03039046/2021002
2. NRC Information Notice 96-28

cc w/Encl: COL Ricardo A. Reyes, Ph.D., RSO

DEFENSE HEALTH AGENCY (DHA) - NRC INSPECTION REPORT 03039046/2021002, FALLS CHURCH, VIRGINIA DATED DECEMBER 9, 2021

ADAMS (PARS)
J Peralta, OE
L Sreenivas, OE
N Hasan, OE
S Rodriguez, OE
M Burgess, NMSS
R Sun, NMSS
B Welling, DRSS
A DeFrancisco, DRSS
B Klukan, RI
R1Enforcement
D Garvin, ORA
S Villar, RI
Region I OE Files (with concurrences)

DOCUMENT NAME: https://usnrc.sharepoint.com/teams/Region-I-MLA/Inspection%20Reports/Inspection%20Documentation%20-%20Draft/L45-35423-01.03039046.2021007.docx
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DATE	11/9/21		11/18/21		11/18/21		12/09/21	

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U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03039046/2021002
Docket No.	030-39046
License No.	45-35423-01
EA No.	EA-21-132

Defense Health Agency (DHA)
DHHQ
7700 Arlington Boulevard, Suite 5101
Falls Church, VA 22042-5101

Naval Medical Center San Diego – Balboa
34800 Bob Wilson Drive
San Diego, CA 92134-5000

Inspection Dates: May 17, 2021, through October 7, 2021

Exit Meeting: November 18, 2021

Inspector: Shawn W. Seeley
Digitally signed by Shawn W. Seeley
Date: 2021.12.09 11:57:11 -05'00'

Shawn Seeley date
Health Physicist
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security

Approved By: Anne E. DeFrancisco
Digitally signed by Anne E. DeFrancisco
Date: 2021.12.09 12:01:13 -05'00'

Anne DeFrancisco, Chief date
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security

Enclosure

EXECUTIVE SUMMARY

Defense Health Agency (DHA)
NRC Inspection Report No. 03039046/2021002

On May 17, 2021, the NRC initiated an announced reactive inspection to review the organization and scope of activities performed under the Defense Health Agency's NRC License No. 45-35423-01 after they reported the loss of four brachytherapy seeds after a routine procedure on May 13, 2021 (EN #55262). The DHA is the Federal medical organization directed by Congress to administer and oversee the consolidated medical treatment facilities within the Department of Defense (DOD). They are authorized for a wide range of materials under their broad scope medical license and issue authorizations to 31 locations of use throughout the DOD. One permittee, the Naval Medical Center in San Diego, reported to the radiation safety officer (RSO) that on May 14, 2021, while performing a final reconciliation of the seeds for return to the manufacturer, that four seeds could not be located. Subsequently, the licensee notified the Headquarters Operations Office on Monday May 17, 2021.

Two apparent violations of NRC requirements were identified and are being considered for escalated enforcement. The violations included the failures to meet: (1) 10 CFR 20.1802, which requires that the licensee shall control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage; and, (2) 10 CFR 20.2201(a) which requires, in part, that licensees shall report by telephone to the NRC Headquarters Operations Center immediately after its occurrence becomes known to the licensee, any lost, licensed material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix C to Part 20, under such circumstances that it appears to the licensee that an exposure could result to persons in unrestricted areas. Specifically, the licensee inadvertently disposed of four Iodine-125 prostate brachytherapy seeds in the medical trash and did not report the lost sources to the NRC HQ Operations Center as required.

DHA's immediate corrective action included not performing brachytherapy procedures until measures were implemented to ensure that proper seed accountability was in place. Furthermore, DHA conducted a reactive on-site inspection to perform a root cause analysis of the incident and recommend corrective actions to prevent reccurrence.

REPORT DETAILS

1. Organization and Scope of the Program

a. Inspection Scope

The inspector reviewed the organization and scope of activities performed under Defense Health Agency's NRC License No. 45-35423-01. Information was gathered through interviews with licensee staff, including the Radiation Safety Officer (RSO), and through reviews of selected records.

b. Observations and Findings

The DHA is a broad scope medical licensee headquartered in Falls Church, Virginia. The DHA is the Federal medical organization directed by Congress to administer and oversee the consolidated medical treatment facilities within the Department of Defense (DOD). They are authorized for a wide range of materials under their broad scope medical license and issue authorizations to 31 locations of use throughout the DOD.

The RSO for DHA's license is a career uniformed officer who is available by telephone daily and onsite at the various commands as necessary. The RSO oversees the daily operation of the licensed activities and chairs the Radiation Safety Committee. He also ensures that DHA policy is implemented consistently throughout the 31 Commands.

c. Conclusions

No violations of NRC requirements were identified.

2. Review of Licensed Activities

a. Inspection Scope

The inspector performed a remote announced reactive inspection utilizing NRC Inspection Procedure 87134, "Medical Broad Scope Programs." Information was gathered through interviews with cognizant personnel and a review of records.

b. Observations and Apparent violations

On May 17, 2021, the DHA contacted the NRC Headquarters Operations Officer (HOO) to report the loss of four I-125 prostate brachytherapy seeds under one of their authorizations (EN #55262). Specifically, DHA Authorization, 124-NH, located at Naval Medical Center San Diego, ordered 111 I-125 prostate brachytherapy seeds for a procedure to be conducted on May 13, 2021. On the day of the procedure, they implanted 88 seeds into the patient and had 23 remaining. As noted in the EN, the oncology medical physicist mistakenly thought that she had placed the 23 unused seeds in two lead containers, but she did not perform a physical inventory to confirm it and failed to identify that 4 of the seeds had been left in a shielded box. That box was placed in a medical waste bag and was discarded as such. The following day, while preparing to return the unused seeds to the vendor, a physical count was conducted and only 19 seeds were observed. The permittee searched the procedure room, waste receptacles and dumpster bins and also contacted the waste disposal company, but the seeds were not located. The permittee notified the DHA RSO of the missing seeds in the evening of May 14, and the RSO sent an

email message about the occurrence to two Region I NRC inspectors at approximately 1:00 AM May 15. The RSO made the HOO notification the following Monday (May 17).

Due to the Covid-19 public health emergency, an inspection was initiated remotely. During the inspection, the inspector determined that the DHA performed their own reactive inspection from June 14-18, 2021, at the San Diego Naval Hospital. During the DHA inspection, they conducted a re-enactment of the prostate procedure and reviewed all associated procedures to determine areas for improvement.

The licensee submitted a description of their corrective actions on June 18, 2021. The actions included: 1) the hospital discontinued the prostate brachytherapy program until proper corrective measures were implemented to ensure with absolute certainty that proper accounting of seeds is in place; 2) a root cause analysis of the incident was performed with recommended corrective measures to prevent reoccurrence; 3) the procedure was changed to require two individuals, both a member of the radiation oncology and radiation safety groups, to physically inventory seeds immediately post-surgery. After which, the associate RSO, or his/her alternate will perform a secondary physical inventory of the seeds; and 4) training for new staff and re-training of current staff in radiation oncology and radiation safety, would be developed and implemented to ensure all involved are properly trained and to prevent recurrence.

Apparent Violations

1. 10 CFR 20.1802 requires that the licensee 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 May 13, 2021, the Defense Health Agency 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, the licensee lost control of four sealed brachytherapy sources, each containing approximately 0.26 mCi of iodine-125, that had been in a brachytherapy procedure room at the Naval Medical Center, San Diego.

2. 10 CFR 20.2201(a) requires, in part, that licensees shall report by telephone to the NRC Headquarters Operations Center immediately after its occurrence becomes known to the licensee, any lost, stolen, or missing licensed material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix C to Part 20 under such circumstances that it appears to the licensee that an exposure could result to persons in unrestricted areas.

   Contrary to the above, on May 14, 2021, the Defense Health Agency did not report by telephone to the NRC Headquarters Operations Center immediately after its occurrence became known to the licensee that licensed material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix C to part 20 was missing under such circumstances that it appeared to the licensee that an exposure could result to persons in unrestricted areas. Specifically, the licensee identified that four sealed brachytherapy sources, each containing approximately 0.26 mCi of iodine-125, could not be located and were presumed to have been improperly disposed. The aggregate quantity of the missing material was 1.04 mCi, which is greater than 1 mCi (1,000 times the quantity specified in Appendix C to Part 20). The licensee reported the occurrence to the NRC Headquarters Operations Center on May 17, 2021.

Summary of Corrective Actions

DHA's immediate corrective action included not performing brachytherapy procedures until measures were implemented to ensure that proper seed accountability was in place. Furthermore, DHA conducted a reactive on-site inspection to perform a root cause analysis of the incident and recommend corrective actions to prevent reccurrence.

c. Conclusions

Two apparent violations of NRC requirements were identified and are being considered for escalated enforcement as noted above.

3. Exit Meeting

On November 18, 2021, the inspector presented the results of the inspection by telephone. The licensee acknowledged the apparent violations.

ATTACHMENT: SUPPLEMENTAL INFORMATION

PARTIAL LIST OF PERSONS CONTACTED

Licensee
* COL Reyes, Radiation Safety Officer

*Present at telephone exit meeting on November 18, 2021

INSPECTION PROCEDURES USED

1) Manual Chapter 2800, “Materials Inspection Program”
2) Inspection Procedure 87134, “Medical Broad Scope Programs”

LIST OF NRC SURVEY INSTRUMENTS USED

None used – remote inspection only

LIST OF ACRONYMS USED

CFR	Code of Federal Regulations
CNMT	Certified Nuclear Medicine Technologist
DHA	Defense Health Agency
DOD	Department of Defense
HOO	Headquarters Operations Officer
NRC	Nuclear Regulatory Commission
RSO	Radiation Safety Officer