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

June 27, 2019

R.C. Bono, VADM, MC, USN, Director
Defense Health Agency
DHHQ / Attn: Vice Admiral Bono
7700 Arlington Boulevard, Ste #5101
Falls Church, VA 22042-5101

SUBJECT: DEFENSE HEALTH AGENCY - NRC INSPECTION NO. 03039046/2018001 AND NOTICE OF VIOLATION

Dear Admiral Bono:

This letter refers to the inspection conducted on November 27-28, 2018, at your Bethesda, Maryland location; and November 29, 2018, at your Fort Belvoir, Virginia location; with continued in-office review until June 5, 2019. This inspection examined activities conducted under your license as they relate to public health and safety, and to confirm compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel. The preliminary results were discussed with your staff on November 30, 2018. A final exit briefing was conducted on June 5, 2019, with Lt. Col. Mike Stewart.

Based on the results of this inspection, the NRC has determined that one Severity Level IV violation of NRC requirements occurred. The violation was evaluated 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 violation is cited in the enclosed Notice of Violation (Notice) because the violation was identified by the NRC.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

Based on the results of this inspection, the NRC has also determined that one additional Severity Level IV violation of NRC requirements occurred. The violation involved the possession and use of licensed material in excess of license possession limits. This violation is being treated as a Non-Cited Violation (NCV), consistent with Section 2.3.2 of the Enforcement Policy, because: the licensee identified the violation; the licensee corrected or committed to correcting the violation within a reasonable period of time by specific corrective action committed to by the end of the inspection, including immediate corrective action and comprehensive action to prevent recurrence; the violation is not repetitive as a result of inadequate corrective action; and the violation is not willful.

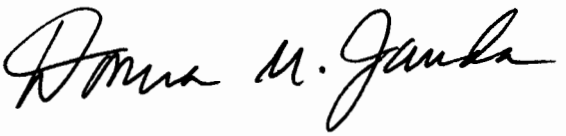
If you contest the NCV you should provide a response within 30 days of the date of this letter, with the basis for your denial, to the Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington DC 20555-0001, with copies to the Regional Administrator, Region I; and the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter 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 document 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 regarding this matter, please contact Shawn Seeley of my staff at 610-337-5102 or via electronic mail at shawn.seeley@nrc.gov.

Thank you for your cooperation.

Sincerely,



Donna M. Janda, Chief
Medical and Licensing Assistance Branch
Division of Nuclear Materials Safety
Region I

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

Enclosure:
Notice of Violation

cc w/ enclosure
H. Mike Stewart, Lt. Col, DHHQ, 7700 Arlington Boulevard, Falls Church, VA 22042-5101

DEFENSE HEALTH AGENCY - NRC INSPECTION NO. 03039046/2018001 AND NOTICE OF VIOLATION DATED June 27, 2019.

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JNick, DNMS

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DATE	6/5/19	6/27/19			

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NOTICE OF VIOLATION

Defense Health Agency
Falls Church, Virginia

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

During an NRC inspection conducted from November 27, 2018, through June 5, 2019, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

> 10 CFR 30.34(b) requires, in part, that the licensee shall not be assigned or transferred another license or permit until the Commission finds that transfer is in accordance with the Act.
>
> 10 CFR 30.34(c) requires, in part, that each licensee shall confine the possession and use of materials to the locations listed on their license.
>
> Contrary to the above, prior to October 1, 2018, the DHA did not receive NRC approval in writing prior to taking control at three medical treatment facilities under the Department of Defense. Subsequently those locations were not added to the license as required. Specifically, on October 1, 2018, DHA was transferred the responsibility for oversight and control of the Jacksonville Naval Hospital, the 81st Medical Group Hospital at Keesler Air Force Base, and the Womack Army Hospital. This transfer of control was not approved by the NRC, prior to October 1, 2018, nor were the locations added to the license as required. Subsequently on December 19, 2019, an amendment request was received in the Region I office to add the three locations on the license.
>
> This is a Severity Level IV violation (Enforcement Policy Section 6.3.d.7)

Pursuant to the provisions of 10 CFR 2.201, the Defense Health Agency is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the 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 previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary,

or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated This 27 day of _ 2019 June

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03001303/2018001
Docket No.	03039046
License No.	45-35423-01
Licensee:	Defense Health Agency
Locations:	DHHQ - Arlington, VA; WRNMMC - Bethesda, MD, FBCH - Ft. Belvoir, VA
Inspection Dates:	November 27, 2018, through June 5, 2019

Inspector: _____ June 5, 2019
Shawn Seeley date
Health Physicist
Medical and Licensing Assistance Branch
Division of Nuclear Materials Safety

Approved By: _____ 6/26/2019
Donna Janda, Chief date
Medical and Licensing Assistance Branch
Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

Defense Health Agency
NRC Inspection Report No. 03039046/2018001

An initial routine announced inspection was conducted from November 27 – 30, 2018, at the Defense Health Agency (DHA) in Arlington, VA. This also included facilities located at the Walter Reed National Military Medical Center (WRNMMC) in Bethesda, MD and the Fort Belvoir Community Hospital (FBCH) in Ft. Belvoir, VA. The inspection was to examine activities conducted under License No. 45-35423-01 as they relate to safety and compliance with the Commission's rules and regulations and with the conditions of the license. The inspection was performed in accordance with NRC Inspection Procedure 87134, "Medical Broad Scope Programs."

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.

Two of the licensee's three locations of use were inspected as noted above. The inspection included a review of licensee's facilities, direct observations, and interviews with radiation workers, and review of required records.

Based on the results of this inspection, one violation was identified for the failure to notify the NRC when three new locations of use were transferred to DHA from the Departments of the Army, Navy, and Air Force.

REPORT DETAILS

1. Program Overview

An initial routine announced inspection was conducted from November 27 – 30, 2018, at the Defense Health Agency (DHA) in Arlington, VA. This also included facilities located at the Walter Reed National Military Medical Center (WRNMMC) in Bethesda, MD, and the Fort Belvoir Community Hospital (FBCH) in Ft. Belvoir, VA. The inspection was to examine activities conducted under License No. 45-35423-01 as they relate to safety and compliance with the Commission's rules and regulations and with the conditions of the license. The inspection was performed in accordance with NRC Inspection Procedure 87134, "Medical Broad Scope Programs."

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 the three locations of use at WRNMMC, FBCH, and the Medical Education and Training Center (METC) in San Antonio, TX. WRNMMC and FBCH were inspected during this inspection.

The DHA has established a radiation safety committee (RSC) to assist in the centralized control over its radioactive materials program. The RSC is responsible for providing oversight of the DHA's implementation of the license and associated authorized use activities. The RSC has delegated the authority to manage the day-to-day operations of the DHA's radioactive materials program to the radiation safety officer, currently on staff at Ft. Belvoir Community Hospital. The RSC is comprised of individuals from each location of use as well as the necessary representation required in 10 CFR 35.24(f).

The inspection included a review of licensee's facilities, direct observations, and interviews with radiation workers, and review of required records. During the inspection, it was noted that an additional three medical treatment facilities had been transferred to DHA control on October 1, 2018, through a Congressional mandate. This is an apparent violation of 10 CFR 30.34. This is discussed below in Section 3.

2. Management Oversight

2.1 Inspection Scope

The inspector evaluated the DHA's organization and management oversight activities to determine if the DHA, through the RSC, adequately controlled the use of licensed radioactive material as required by the license and NRC requirements. The evaluation included discussions with licensee representatives, a review of audit reports and program documentation, and an assessment of the licensee's methods and effectiveness of communications with the RSCs at the three locations of use under the license.

2.2 Observations and Findings

The RSC had delegated the authority for routine oversight of authorized activities to one radiation safety officer (RSO). The RSO managed the licensee's day-to-day operations under the license and was responsible for maintaining the licensee's radiation safety program. The DHA and RSC responsibilities included, but were not limited to, maintaining an adequate level of staff to execute the radioactive materials program; training and qualifying the oversight staff; implementing the authorization and approval for uses and users; maintaining the audit program; responding to events, incidents, and allegations; and maintaining effective communications with authorized users under the license.

The RSC met quarterly and was comprised of senior Navy headquarters and field representatives. An annual audit had been conducted in accordance with 10 CFR Part 20, and provided the licensee management with an opportunity to evaluate the RSC's effectiveness in the implementation of the radiation safety program.

2.3 Conclusion

The inspector concluded that the RSC met and conducted business as required and provided adequate oversight of the radiation safety and regulatory compliance programs in a manner that protected the health and safety of licensee staff and the public. The inspector noted that although the RSO had ensured the program was operating smoothly, with the additional sites being transferred by Congress, there was a concern about the amount of time one person would have to ensure the success of the expanded program without the hiring of additional staff. The inspector discussed the concern with management at the exit briefing. Management agreed and outlined their plan to add additional staff over the next two years in the budget.

3. Radioactive Materials Program

3.1 Inspection Scope

The inspector evaluated the DHA's use of radioactive materials at locations authorized by the license to determine if the DHA controlled the use of licensed radioactive material as required by the license and NRC requirements. The evaluation included direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, to determine if the licensee's performance has: controlled access to and prevented loss of licensed material so as to limit radiation exposure to workers and members of the public to values below NRC regulatory limits; maintained shielding of licensed materials in a manner consistent with operating procedures and design and performance criteria for devices and equipment; implemented comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material; implemented a radiation dosimetry program to accurately measure and record radiation doses received by workers or members of the public as a result of licensed operations; implemented the use of radiation instrumentation in sufficient number, condition, and location to accurately monitor radiation levels in areas where licensed material is used and stored; ensured that workers are knowledgeable of radiation uses and safety practices, skilled in radiation safety practices under normal and accident conditions, and are empowered to

implement the radiation safety program. The inspector also examined licensed activities performed by contracted personnel such as radiation safety staff.

3.2 Observations and Findings

DHA is a large broad scope medical organization that currently has three locations of use authorized on their license: WRNMMC in Bethesda, Maryland; FBCH in Fort Belvoir, Virginia; and METC in San Antonio, Texas. DHA was created by Congress to consolidate all medical treatment facilities across the Department of Defense. License No. 45-35423-01 authorizes DHA for use of materials in accordance with 10 CFR Part 35 for use in medical diagnosis, therapy, and research in humans. The licensee has a Radiation Safety Committee (RSC) that meets on a quarterly basis to discuss radiation safety issues, including approvals of locations of use and users.

WRNMMC is the largest of the facilities on the license. They are authorized to use materials covered under 35.100, 35.200, 35.300, 35.400, 35.600, and 35.1000. They are also authorized for research activities, although they have conducted no research studies to date. Nuclear medicine employs 10 certified nuclear medicine technologists (CNMT) and has eight cameras. They conduct studies on 20-50 patients per day. The quarterly average number of procedures is around 1,100. Since license issuance, they have conducted 11 prostate implants, 17 HDR procedures, and 8 therapies, mostly Iodine-131 (I-131) on an out-patient basis.

WRNMMC has a health physics (HP) staff, including an associate RSO (ARSO), which operates the radiation safety program for the facility. The HP staff reports locally to their RSC and the ARSO has a direct line of communication with the RSO at DHA headquarters (DHHQ). The HP staff conducts routine audits, monitoring, and training of personnel. Currently they have 450 personnel wearing dosimeters and train over 1,000 hospital personnel annually.

The inspection consisted of a tour of the facilities, a review of sampling of records, and interviews with authorized users (AU), authorized medical physicists (AMP), and other licensee staff. The inspector observed staff performing routine nuclear medicine administration, required surveys, and instrumentation quality control. Written directives were reviewed of patient procedures which required them and were found to be in accordance with regulations and licensee procedures. There are two separate waste storage areas. One area is located in nuclear medicine and one is located in the basement of the parking garage adjacent to the hospital. Both areas are secured. Before being disposed, waste is properly surveyed and results are recorded.

FBCH is a small community hospital located on the Army Post at Ft. Belvoir. They are authorized to use materials covered under 35.100, 35.200, 35.300, and 35.1000. They are also authorized for research activities, although they have conducted no research studies to date. Nuclear medicine employs six CNMTs and has six cameras. They conduct studies on 8-10 patients per day. Since license issuance, they have conducted 17 therapies, mostly I-131 on an out-patient basis, and 3 Yttrium-90 (Y-90) microspheres treatments.

FBCH has an HP staff, including an ARSO, which operates the radiation safety program for the facility. They report locally to their RSC and the ARSO has a direct line of

communication with the RSO at DHHQ. The radiation safety staff conducts routine audits, monitoring, and training of personnel.

METC is the training center located in San Antonio, Texas and was not inspected as part of this inspection. They are authorized for a few sealed sources and 35.100, 35.200, and 35.300 materials for training purposes. They also have an HP staff, including an ARSO, which operates the radiation safety program for the facility. They report locally to their RSC and the ARSO has a direct line of communication with the RSO at DHHQ. The HP staff conducts routine audits, monitoring, and training of personnel.

During the inspection, it was determined that DHA had been transferred the control of three additional facilities to their program on October 1, 2018. These were the Jacksonville Naval Hospital, the 81st Medical Group Hospital at Keesler Air Force Base, and the Womack Army Hospital. Subsequently these facilities had not been added to the license as required by 10 CFR 30.34(b). The inspector also determined that 13 additional facilities are slated to come under DHA control on October 1, 2019; 11 facilities on October 1, 2020; and 3 facilities on October 1, 2021. The inspector discussed with the RSO and DHA management the importance of filing for an amendment to add these facilities before they were transferred to DHA. By letter dated December 19, 2018, DHA requested to add the Jacksonville, Keesler, and Womack locations to their license. The amendment is currently being reviewed by RI staff.

Additionally, the RI office received two letters dated June 15, 2018, and November 15, 2018, notifying the NRC of the possession of amounts of radioactive material in excess of the amounts listed on the license. Specifically, FBCH and WRNMMC had received Flourine-18 (F-18), a PET isotope, in excess of the quantities authorized. This was primarily due to the transition from a master materials license permit or an NRC license to the DHA license. Under the permits and NRC license, each facility was authorized a possession limit for F-18 "as needed." The DHA license capped the amount at 200 mCi per facility. This was not detected by the radiopharmacy or the nuclear medicine staff until a program review was conducted at each facility. At no time did this pose a safety hazard for any staff, patient, or member of the public. Whereas this was self-identified and prompt corrective action was taken, and in accordance with the enforcement policy, this will be a non-cited violation. By letter dated July 31, 2018, DHA requested to increase the F-18 possession limits for each facility. The amendment was approved on September 5, 2018. This non-repetitive, licensee-identified and corrected violation is being treated as a Non-Cited Violation (NCV) in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG 1600.

3.3 Conclusions

The inspector determined that each facility has adequate staff to conduct studies and ensure that public health and safety is maintained. There is adequate communication between the DHHQ RSO and each facility.

The inspector determined that three facilities had not been added to the license as required by 10 CFR 30.34. This is an apparent violation of NRC requirements. The violation is described in Section 4.

4. Independent and Confirmatory Measurements

Areas surveyed, both restricted and unrestricted, and measurements made; comparison of data with licensee's results and regulations; and instrument type and calibration date.

Instrument type: Model # 2401-P NRC S/N: 231352 calibration date 6/8/2018

Survey/measurement results:

All areas surveyed at WRNMMC and FBCH were within regulatory limits.

5. Violations, NCVs, and Other Safety Issues:

State the requirement, how and when the licensee violated the requirement, and the licensee's proposed corrective action plan. For NCVs, indicate why the violation was not cited. Attach copies of all licensee documents needed to support violations.

A. Based on the results of this inspection, one violation was identified for the failure to notify the NRC when three new locations of use were transferred to DHA from the Departments of the Army, Navy, and Air Force.

10 CFR 30.34(b) requires, in part, that the licensee shall not be assigned or transferred another license or permit until the Commission finds that transfer is in accordance with the Act.

10 CFR 30.34(c) requires, in part, that each licensee shall confine the possession and use of materials to the locations listed on their license.

Contrary to the above, on October 1, 2018, DHA was transferred the responsibility for oversight of three facilities by Congress. This transfer had not been approved in writing by the NRC nor had the locations been added to the license as required. Specifically, the DHA took control of Jacksonville Naval Hospital, 81st Medical Group Hospital at Keesler Air Force base, and Womack Army Hospital on October 1, 2018. This transfer was not approved by the NRC nor were the locations added to the license as required.

This is a Severity Level IV violation. (Section 6.3.d.7)

B. Based on the results of this inspection, the NRC has also determined that one additional Severity Level IV violation of NRC requirements occurred and involved the possession and use of licensed material in excess of license possession limits.

This violation is being treated as a Non-Cited Violation (NCV), consistent with Section 2.3.2 of the Enforcement Policy, because: the licensee identified the violation; the licensee corrected or committed to correcting the violation within a reasonable period of time by specific corrective action committed to by the end of the inspection, including immediate corrective action and comprehensive action to prevent recurrence; the violation is not repetitive as a result of inadequate corrective action; and the violation is not willful.

I. Exit Meeting

A preliminary exit meeting was conducted on November 30, 2018, to discuss the scope of the inspection and the inspector's initial observations. On June 5, 2019, an exit meeting was held with Lt. Col. Mike Stewart, the Radiation Safety Officer, to discuss the results of this inspection.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

*+# LT COL H. Michael Stewart., Radiation Safety Officer
*+ Paul Cordts, MD, Chief Medical Officer, RSC Chair
+ Guy Kiyokawa, DHA Deputy Director
*+ Kevin Allen, WRNMMC RSO
*+ Marie Parry, Chief, WRNMMC Rad Safety
*+ Jason Schroeder, DCS, WRNMMC
*+ Michael DeVon, Deputy DCS, WRNMMC
*+ Marie Parry, Chief, Rad Safety WRNMMC
*+ Marie Parry, Chief, Rad Safety WRNMMC
+ Kari McRae, WRNMMC Public Health Dept.
*+ Daniel Hamilton, Interim Asst. RSO, WRNMMC
*+ COL Melinda Cavicchia, DHA, Deputy Chief, Public Health
*+ Frank Fota, FBCH RSO
*+ MAJ Jose Rodriguez, Chief Health Physics, FBCH
*+ CDR Emily Sprague, Director DCSS, FBCH
*+ LT COL Susan Carbognin, Deputy Director DCSS, FBCH
*+ Mike Forcier, METC RSO
* CAPT Robert Fri, Director, FBCH
* COL Clinton Schreckhise, Deputy Director, FBCH
* MAJ Grant Evans, Chief, Preventive Medicine, FBCH
+ Donald Hall, Ph.D., PE, Assistant Director CBT SPT, DHA
+ COL Mark Ireland, Chief PHD, DHA

Various CNMTS, Authorized Users, Nuclear Pharmacists, and Medical Physicists

* Present at entrance briefing on November 27, 2018
+ Present at preliminary exit meeting on November 30, 2018
# Present at telephone exit briefing on June 5, 2019