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

April 23, 2020

EA-20-026

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

SUBJECT: DEFENSE HEALTH AGENCY - NRC INSPECTION NO. 03039046/2019001 AND NOTICE OF VIOLATION

Dear LTG Place:

This letter refers to the routine, unannounced inspection conducted December 9 - 12, 2019, at Brooke Army Medical Center (BAMC), with continued in-office review until February 5, 2020. This inspection examined activities conducted under your license as they relate to public health and safety to confirm compliance with the U.S. Nuclear Regulatory Commission's (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 licensed activities, and interviews with personnel. On December 12, 2019, at the conclusion of the onsite portion of the inspection, the inspectors discussed the preliminary inspection findings with GEN BG Harter and other BAMC staff members. A telephonic exit briefing was conducted with COL Reyes, Mr. Shabbir and members of the BAMC staff on February 5, 2020, and a final exit briefing was held with Mr. Shabbir and Dr. Bower on April 21, 2020.

Based on the results of this inspection, the NRC has determined that five Severity Level IV violations of NRC requirements occurred. These violations were evaluated 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. These violations are being cited in the enclosed Notice of Violation (Notice) because the violations were identified by the NRC.

The NRC has concluded that information regarding: (1) the reason for the violation(s); (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was achieved is already adequately addressed on the docket and in your letter dated February 12, 2020 and email dated March 12, 2020. Further you stated on April 21, 2020, that a communication was shared with all DHA permittees regarding the violations noted and that the Radiation Safety Committee, which includes ARSOs from each permittee, discussed the violations and corrective actions. Therefore, you are not required to respond to this letter unless the description herein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

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, 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 or proprietary information so that it can be made available to the Public without redaction.

Should you have any questions regarding this letter or the enclosed Notice, please contact Robin L. Elliott of my staff at 610-337-5076 or via email at Robin.Elliott@nrc.gov.

Sincerely,

Donna M. Janda

Digitally signed by Donna M. Janda
Date: 2020.04.23 15:47:21 -04'00'

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

Docket: 030-39046
License: 45-35423-01

Enclosure:
Notice of Violation (Notice)

cc w/ enclosure
COL Ricardo Reyes, Ph.D., Radiation Safety Director
Commonwealth of Virginia

DEFENSE HEALTH AGENCY - NRC INSPECTION NO. 03039046/2019001 AND NOTICE OF VIOLATION DATED April 23, 2020

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| OFFICE | R1 DNMS | R1 DNMS | R1 DNMS | | |
| NAME | RElliott | MMcLaughlin | DMJanda | | |
| DATE | 4/22/20 | 4/23/20 | 4/23/20 | | |

OFFICIAL RECORD COPY

# NOTICE OF VIOLATION

Defense Health Agency
Falls Church, Virginia

Docket No. 030-39046
License No. 45-35423-01
EA-20-026

During an NRC inspection conducted on December 9 through December 12, 2019, five violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. 10 CFR 20.2001(a) requires, in part, that the licensee shall dispose of licensed material only by transfer to an authorized recipient, decay in storage, or by release in effluents within the limits in 10 CFR Part 20.

Contrary to the above, on or about October 16, 2018, the licensee failed to dispose of licensed material only by transfer to an authorized recipient, decay in storage, or by release in effluents within the limits of 10 CFR Part 20. Specifically, the licensee inadvertently disposed of two iodine-125 localization seeds containing activities of 156 microcuries and 158 microcuries, respectively, to an unauthorized recipient after the seeds had been excised from a patient on October 16, 2018.

This is a Severity Level IV violation (NRC Enforcement Policy Section 6.7.d)

B. 10 CFR 20.1902(e) requires, in part, that the licensee shall post each area or room in which there is used or stored an amount of licensed material exceeding 10 times the quantity of such material specified in appendix C to 10 CFR Part 20 with a conspicuous sign bearing the radiation symbol and the words “CAUTION, RADIOACTIVE MATERIAL(S)” or “DANGER, RADIOACTIVE MATERIAL(S).”

Contrary to the above, between November 15 and December 12, 2019, the licensee failed to post a room in which there was stored an amount of licensed material exceeding 10 times the quantity of such material specified in appendix C to 10 CFR Part 20 with a conspicuous sign bearing the radiation symbol and he words “CAUTION, RADIOACTIVE MATERIALS” or “DANGER, RADIOACTIVE MATERIAL(S).” Specifically, a room was used to store 17 iodine-125 localization seeds, each containing a nominal activity of 300 microcuries, a quantity exceeding 10 times the one microcurie quantity specified for iodine-125 in appendix C to 10 CFR Part 20, was not posted with a conspicuous sign bearing the radiation symbol and the words “CAUTION, RADIOACTIVE MATERIAL(S)” or “DANGER, RADIOACTIVE MATERIAL(S).”

This is a Severity Level IV violation (NRC Enforcement Policy Section 6.7.d)

C. 10 CFR 20.1101(a) requires, in part, that each licensee develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities.

Brook Army Medical Center (BAMC) Memo 40-72, “Ionizing Radiation Safety Program,” dated May 1, 2018, section 7.1.3.5 states to not eat, drink, smoke, or apply cosmetics in any area where radioactive material is used or stored and section 7.1.3.6, states to not store food, drink, or personal effects in areas where radioactive material is stored or used.

Contrary to the above, between November 15 and December 12, 2019, the licensee failed to implement their radiation protection program in accordance with BAMC Memo 40-72. Specifically, a licensee employee was observed to drink beverages and store food, beverages, cosmetic items (perfume oils), and personal effects in a room where radioactive material was stored.

This is a Severity Level IV violation (NRC Enforcement Policy Section 6.7.d)

D. 10 CFR 35.40(b)(2) requires, in part, that the written directive must contain the patient's name, and for an administration of a therapeutic dosage of unsealed byproduct material other than sodium iodide I-131: the radioactive drug, dosage, and route of administration.

Contrary to the above, between May 17, 2018 and December 4, 2019, the licensee failed to ensure that written directives for administrations of therapeutic dosages of unsealed byproduct material other than sodium iodide iodine-131 contained the dosage. Specifically, five written directives for therapeutic doses of unsealed radium-223 dichloride administered between May 17, 2018 and December 4, 2019, contained the activity to be administered per unit mass and not a specified dosage to be administered to the patient.

This is a Severity Level IV violation (NRC Enforcement Policy Section 6.3.d.1)

E. 10 CFR 35.41(a)(2) requires that for any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.

Contrary to the above, two examples were identified of the licensee's failure to develop, implement, and maintain written procedures to provide high confidence that each administration requiring a written directive is in accordance with the written directive.

i. On December 9, 2019, the licensee failed to develop, implement, and maintain written procedures to provide a high confidence that an administration of yttrium-90 SIR-Spheres® would be administered in accordance with the written directive. Specifically, (1) the licensee's radiopharmacy procedure did not identify the appropriate dose calibrator setting to ensure the measured dosage of yttrium-90 SIR-spheres® was as prescribed on the written directive; (2) during an administration of yttrium-90 SIR-spheres®, individuals relied on prior knowledge and did not closely implement the licensee's Interventional Radiology procedures; and (3) an individual with no defined roles or responsibilities in the licensee's Interventional Radiology procedures was observed to actively participate in the administration of the yttrium-90 SIR-spheres®; and,

ii. On December 11, 2019, the licensee failed to develop, implement, and maintain written procedures to provide a high confidence that an administration of lutetium-177 Lutathera® would be administered in accordance with the written directive. Specifically, the licensee's procedures for the administration of lutetium-177 Lutathera® did not contain adequate guidance to provide high confidence that the administration would be in accordance with the written

directive. Due to the procedural inadequacies, individual members of the nuclear medicine staff developed reference guides for personal use, but these also did not contain adequate guidance to provide high confidence that the administration of lutetium-177 Lutathera® would be in accordance with the written directive. During a Lutathera administration on December 11, 2019, licensee staff did not refer to or closely implement the licensee's procedures or to the individual reference guides during the administration of lutetium-177 Lutathera®.

This is a Severity Level IV violation (NRC Enforcement Policy Section 6.3.d)

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence and the date when full compliance will be achieved is already adequately addressed on the docket. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation," and send it 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).

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.

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

Dated This 23rd day of April 2020