



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

August 28, 2025

EAF-RI-2025-0149
AL-RI-2024-0037

Dr. David J. Smith, Acting Director, DHA
Acting Principal Deputy Assistant
Secretary of Defense for Health Affairs
Defense Health Agency
7700 Arlington Boulevard, Suite #5101
Falls Church, VA 22042-5101

SUBJECT: DEFENSE HEALTH AGENCY - NRC INSPECTION NO. 030-39046/2024-003
AND NOTICE OF VIOLATION AND NRC OFFICE OF INVESTIGATIONS CASE
NO. OI-RI-2024-0022

Dear Dr. David Smith:

This letter refers to the inspection conducted on June 24, 2024, with in-office review through August 12, 2025, at the David Grant U.S. Air Force Medical Center (DGMC), Travis Air Force Base, California. 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, 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, independent radiation measurements, and interviews with personnel. The U.S. Nuclear Regulatory Commission (NRC) conducted a final exit briefing via teleconference on August 21, 2025, with COL Ricardo Reyes, Ph.D., your Radiation Safety Officer, and other representatives of the Defense Health Agency at the DGMC.

Based on the results of this inspection, the NRC has determined that two Severity Level IV violations of NRC requirements occurred. The violations were 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 violations are cited in the enclosed Notice of Violation (Notice) because the violations were identified by the NRC. The violations involved the failures to: (1) provide complete and accurate information to the NRC concerning the qualifications and experience of an Associate Radiation Safety Officer (ARSO); and (2) calibrate the instrumentation required by Title 10 of the *Code of Federal Regulations* (10 CFR) 35.60(a) in accordance with nationally recognized standards or the manufacturer's instructions. These two violations are documented in the publicly available Notice (Enclosure 1).

You are required to respond to this letter and should follow the instructions specified in the enclosed Notices 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 Notices. The NRC review of your response to the Notices will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In addition, based on the results of this inspection, the NRC has also determined that two additional Severity Level IV violations of NRC requirements occurred. These violations involved the failures to: (1) ensure an authorized user dated written directives involving sodium-iodide iodine-131 administrations in accordance with 10 CFR 35.40(a); and (2) create and retain documentation for the basis of the release of individuals administered NRC-licensed byproduct material, as required by 10 CFR 35.2075(a).

These violations are being treated as Non-Cited Violations (NCVs), 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. These non-cited violations are documented in the publicly available Enclosure 2.

If you contest the NCVs 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.

Furthermore, the Region I Field Office, NRC Office of Investigations (OI), initiated an investigation (Case No. OI-RI-2024-0022) on August 2, 2024, to determine whether the Defense Health Agency (DHA) management deliberately provided incomplete or inaccurate information to the NRC regarding the ARSO's qualifications and deliberately permitted an unqualified individual to serve as the ARSO. Based upon documentary and testimonial evidence developed during the OI investigation, the NRC did not substantiate that DHA management deliberately provided incomplete and inaccurate information to the NRC regarding the ARSO's qualifications or deliberately permitted the unqualified ARSO to serve in that capacity.

Please note that final NRC investigation documents, such as the OI report described above, may be made available to the public under the Freedom of Information Act (FOIA) subject to redaction of information appropriate under the FOIA. Requests under the FOIA should be made in accordance with 10 CFR 9.23, "*Requests for Records*." Additional information is available on the NRC website at <http://www.nrc.gov/reading-rm/foia/foia-privacy.html>.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter, the publicly available Notices (Enclosures 1 and 2) and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's ADAMS, accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should segregate your response for health and safety matters from security matters, and further should not include any personal privacy, proprietary, or safeguards information so that as much of your response can be made available to the Public without redaction.

If you have any questions regarding this matter, please contact Jason vonEhr of my staff at (610) 337-5256 or via electronic mail at Jason.vonEhr@nrc.gov.

Notice of Violation
Defense Health Agency

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Thank you for your cooperation.

Sincerely,

Farrah Gaskins, Chief
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security
Region I

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

Enclosures:

1. Notice of Violation
2. Non-Cited Violation

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

SUBJECT: DEFENSE HEALTH AGENCY - NRC INSPECTION NO. 030-39046/2024-003
AND NOTICE OF VIOLATION DATED AUGUST 28, 2025

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NOTICE OF VIOLATION

Defense Health Agency
Falls Church, VA
EAF-RI-2025-0149

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

During an NRC inspection conducted on June 24, 2024, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 30.9(a) requires, in part, that information provided to the Commission by a licensee shall be complete and accurate in all material respects.

10 CFR 35.50(c)(2) states, in part, that the licensee shall require an individual assigned duties and tasks as an Associate Radiation Safety Officer be an individual who is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on a permit issued by a Commission licensee of broad scope, has experience with the radiation safety aspects of similar types of use of byproduct material for which the licensee seeks the approval of the individual as the Radiation Safety Officer or Associate Radiation Safety Officer, and meets the requirements in 10 CFR 35.50(d).

10 CFR 35.50(d) states, in part, that the individual has training in radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval.

Contrary to the above, on October 2, 2023, the licensee failed to provide information to the Commission that was complete and accurate in all material respects. Specifically, the licensee provided a signed amendment request dated October 2, 2023, that was inaccurate in that it captured and documented training and experience for a proposed Associate Radiation Safety Officer that was determined by the NRC to be inaccurate. This inaccuracy was specifically dealing with the requirements in 10 CFR 35.50(d) for training in radiation safety, regulatory issues, and emergency procedures for the types of uses ought to be authorized.

This is a Severity Level IV violation (Enforcement Policy Section 6.9.d).

- B. 10 CFR 35.60(b) requires that a licensee shall calibrate the instrumentation required by 10 CFR 35.60(a) in accordance with nationally recognized standards or the manufacturer's instructions.

The 60th Medical Group (AMC) Procedure 44-26, "Dose Calibrator Linearity Test" captured a nationally recognized standard and required in Step 4.1.2 that, "If Calicheck procedure fails twice, stop and start Linearity test by Decay method using Excel spreadsheet," and in Step 7.1 that, "If the Decay method Linearity test fails, Dose Calibrator should be removed from service and turned in for repair."

Contrary to the above, on multiple occasions in calendar years 2022, 2023, and 2024, the licensee failed to calibrate the instrumentation required by 10 CFR 35.60(a) in accordance with nationally recognized standards or the manufacturer's instructions, as captured by the 60th Medical Group (AMC) Procedure 44-26, "Dose Calibrator Linearity Test". Specifically, for two dose calibrators, after dose calibrator linearity tests failed the

Calicheck procedure, as described in Step 4.1.2, the linearity test by decay method was not utilized to determine if the dose calibrator should be removed from service and turned in for repair and the calibrator continued to be used for regulatory purposes.

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

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 (EAF-RI-2025-0149)" 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 publicly 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 28th day of August 2025

NON-CITED VIOLATION

Defense Health Agency
Falls Church, VA

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

During an NRC inspection conducted on June 24, 2024, two Severity Level IV, non-cited violations (NCVs) of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the NCVs are listed below:

- A. 10 CFR 35.40(a) requires, in part, that a written directive must be dated by an authorized user before the administration of I-131 sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries (μCi)).

Contrary to the above, during calendar years 2022, 2023, and 2024, the licensee failed to have written directives dated by an authorized user before the administration of I-131 sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries (μCi)). Specifically, during this period, 14 written directives of the administration I-131 sodium iodide greater than 30 μCi were not dated by an authorized user prior to or after the administration.

- B. 10 CFR 35.2075(a) requires, in part, that the licensee shall retain a record of the basis for authorizing the release of an individual in accordance with 10 CFR 35.75.

Contrary to the above, on multiple occasions between 2022 and 2024, the licensee authorized the release of an individual in accordance with 10 CFR 35.75 but failed to retain a record of the basis for the release. Specifically, the licensee released from its control at least 5 patients after the administration of sodium iodide iodine-131 in quantities greater than 33 millicuries without determining that the released patient would not pose an exposure risk to any other individual in excess of 5 mSv total effective dose equivalent.

Both of the above items were identified by the Defense Health Agency (DHA) during a Site Area Visit performed on April 1-3, 2024, as part of DHA's routine oversight of its program, and prior to the NRC's inspection on June 24, 2024. These findings were documented in a letter to the David Grant Air Force Medical Center dated April 15, 2024. In the facility's response to the letter dated April 15, 2024, the facility committed in a letter dated June 21, 2024, to halt all "high energy" radiopharmaceuticals, including yttrium-90 microspheres and iodine-131 ablations until the facility could retain a full time Associated Radiation Safety Officer and restore compliance. As such, the NRC inspection reasonably demonstrated that the two items described above were identified by the licensee, corrected (or in the process of being corrected) by the licensee, non-willful, and non-repetitive.

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 publicly 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.