



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

December 2, 2021

EA-21-059

David L. Bushnell, M.D., Chair
National Radiation Safety Committee
Department of Veterans Affairs
National Health Physics Program (115 HP/NLR)
Veterans Health Administration
2200 Fort Roots Drive
North Little Rock, AR 72114

SUBJECT: NRC INVESTIGATION REPORT 3-2020-010 – DEPARTMENT OF VETERANS
AFFAIRS

Dear Dr. Bushnell:

On April 28, 2020, the U.S. Nuclear Regulatory Commission (NRC) Office of Investigations (OI), Region III Field Office, initiated an investigation to determine whether a Nuclear Medicine Technician (NMT) at the Department of Veterans Affairs (VA), Greater Los Angeles Healthcare System (GLAHS) failed to complete a required test and falsified records related to that test. The OI completed its investigation on April 22, 2021. A factual summary of the NRC investigation is included in Enclosure 1.

Prior to the initiation of the NRC OI investigation, the National Health Physics Program (NHPP), which oversees the inspection and permitting of licensed activities under your Master Materials License (MML), conducted a special inspection at the GLAHS facility on April 23–25, 2019, with continued in-office review through July 9, 2019. The details of the onsite inspection have been documented in NHPP Special Inspection Report No. 691-19-I01 for VA Permit No. 04-00181-04 dated July 18, 2019. The purpose of the report was to resolve all open items associated with the inspection and to document additional findings. The in-office review included a review of the facts and circumstances surrounding the findings identified during the inspection. The NHPP provided those inspection findings for NRC's information and review on July 18, 2019. Copies of these documents are located in the NRC Agencywide Documents Access and Management System (ADAMS) at accession numbers ML21314A006 and ML21314A025. Dr. Ed Leidholdt, NHPP Director, of your staff, was notified by Bryan Parker and Robert Orlikowski of my staff by telephone on November 2, 2021, regarding the preliminary results of the NRC's review of this matter.

As a result of this NHPP inspection, the NRC staff examined activities conducted under your MML related to public health and safety. Additionally, the staff examined your compliance with the Commission's rules and regulations as well as the conditions of your license.

Based on the results of the NHPP inspection, the NRC OI investigation, and further NRC review, two apparent violations were identified and are being considered for escalated

enforcement 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 first apparent violation involved the NMT's failure to perform the required "breakthrough" test on the eluant from a strontium-82/rubidium-82 (Sr-82/Rb-82) generator contrary to Title 10 of the *Code of Federal Regulations* (CFR) 35.204(c). The second apparent violation involved the NMTs' falsification of records required to be created and maintained by 10 CFR 35.204(d) and 10 CFR 35.2204(b), which resulted in a failure to maintain complete and accurate information contrary to 10 CFR 30.9.

Before the NRC makes its enforcement decision, we are providing you an opportunity to (1) respond to the apparent violations within 30 days of the date of this letter, (2) request a Pre-decisional Enforcement Conference (PEC), or (3) request Alternative Dispute Resolution (ADR) mediation. If a PEC is held, the NRC will issue a press release to announce the time and date of the conference; however, the PEC will be closed to public observation since information related to an OI report will be discussed, and the report has not been made public. **If you decide to participate in a PEC or pursue ADR, please contact Shelbie Lewman, Acting Enforcement/Investigations Officer at 630-829-9653 within 10 days of the date of this letter.** A PEC should be held within 30 days and an ADR session within 45 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, EA-21-059" 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; 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. Your response should include corrective actions involving the identification and initial response to potential deliberate violations. Specifically, a master material licensee (MML) may address the corrective actions to prevent recurrence of violations that include actions by the involved permittee and other permittees, as well as the MML oversight program to identify and respond to violations consistent with NRC policy. Additionally, your response should be sent to the NRC's Document Control Desk, with a copy mailed to David Pelton, Director, Division of Nuclear Material Safety, 2443 Warrenville Road, Suite 210, Lisle, IL 60532-4352 within 30 days of the date of this letter. 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 these matters and any other information that you believe the NRC should take into consideration before making an enforcement decision. The decision to hold a predecisional enforcement conference does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference would be conducted to obtain information to assist the NRC in making an enforcement decision. The topics discussed during the conference 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. In presenting your corrective action, 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. Further, the description of MML corrective action considerations provided in the paragraph above also serves as a helpful reference.

In lieu of a PEC, you may also request Alternative Dispute Resolution (ADR) mediation with the NRC in an attempt to resolve this issue. ADR is a general term encompassing various techniques for resolving conflicts using a third party neutral. The technique that the NRC has decided to employ is mediation. Mediation is a voluntary, informal process in which a trained neutral (the "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's 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's 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.**

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 enclosure(s), 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 Bryan Parker of my staff at 678-828-7050.

Sincerely,



Signed by Pelton, David
on 12/02/21

David L. Pelton, Director
Division of Nuclear Material Safety

Docket No. 030-34325
License No. 03-23853-01VA

Enclosures: OI Factual Summary

Letter to David L. Bushnell from David Pelton, dated December 2, 2021.

SUBJECT: NRC INVESTIGATION REPORT 3-2020-010 – DEPARTMENT OF VETERANS AFFAIRS

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OFFICIAL RECORD COPY

FACTUAL SUMMARY OF OFFICE OF INVESTIGATIONS REPORT 3-2020-010

On April 28, 2020, the U.S. Nuclear Regulatory Commission (NRC), Office of Investigations (OI), Region III Field Office initiated an investigation to determine whether a Nuclear Medicine Technician (NMT) at the Department of Veterans Affairs (VA) Greater Los Angeles Healthcare System (GLAHS) failed to perform a measurement of the concentration of strontium-82 and strontium-85 in a strontium-82/rubidium-82 generator before the first patient use of the day and falsified the associated test records. OI completed its investigation (OI Report No. 3-2020-010) on April 22, 2021.

The investigation identified that, on April 11, 2019, the NMT did not measure the radionuclide concentration as required by 10 CFR 35.204(c) when they failed to perform the required "breakthrough" test before the first patient use of the day. Specifically, the NMT stated in an interview that on the day in question, they understood the requirement to perform this measurement but decided not to do so to meet schedule pressures. Additionally, the RSO observed the NMT's work on that day and that the NMT did not perform the required test. The investigation also identified that the NMT had completed recertification training on the proper procedure for using the equipment and conducting the test approximately four months prior to the event. During the investigation, the NMT admitted that they created a false record of the test in the GLAHS computer system based on what would be acceptable results. Rather, the results of actual measurements must be recorded and maintained in accordance with the requirements by 10 CFR 35.204(d) and 10 CFR 35.2204.

Based on a review of the OI report and available records, it appears that on April 11, 2019, the NMT at GLAHS deliberately failed to perform the "breakthrough" test on a Sr-82/Rb-82 generator required by 10 CFR 35.204(c), contrary to 10 CFR 30.10(a)(1). In addition, it appears, that in violation of 10 CFR 30.10(a)(2), the NMT deliberately falsified the break-through test record required by 10 CFR 35.204(d) and 10 CFR 35.2204(b). As a result, there appears to be a failure to maintain complete and accurate information contrary to the requirements of 10 CFR 30.9.

Enclosure