

NUCLEAR REGULATORY COMMISSION

[Docket No. 030-34325; License No. 03-23853-01VA; EA-21-059; NRC-2022-0101]

In the Matter of Department of Veterans Affairs

AGENCY: Nuclear Regulatory Commission.

ACTION: Confirmatory order; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing a Confirmatory Order to the Department of Veterans Affairs to memorialize the agreement reached during an alternative dispute resolution mediation session held on March 2, 2022. The order will resolve all issues related to apparent violations that occurred when a nuclear medicine technologist willfully failed to conduct a measurement of the concentration of strontium-82 and strontium-85 prior to use of a strontium-82/rubidium-82 generator and willfully falsified records relating to the same failure to conduct the required measurement. The Confirmatory Order includes a number of significant commitments undertaken by the Department of Veterans Affairs to enhance the safety culture among its employees involved in nuclear medicine. The Confirmatory Order is effective upon issuance.

DATES: The confirmatory order was issued on April 21, 2022.

ADDRESSES: Please refer to Docket ID **NRC-2022-0101** when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- **Federal Rulemaking Website:** Go to <https://www.regulations.gov> and search for Docket ID **NRC-2022-0101**. Address questions about Docket IDs in Regulations.gov to Stacy Schumann; telephone: 301-415-0624; email:

Stacy.Schumann@nrc.gov. For technical questions, contact the individual listed in the "For Further Information Contact" section of this document.

- **NRC's Agencywide Documents Access and Management System**

(ADAMS): You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to PDR.Resource@nrc.gov. The Confirmatory Order to the Department of Veterans Affairs is available in ADAMS under Accession No. ML22062B353.

- **NRC's PDR:** You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1-800-397-4209 or 301-415-4737, between 8:00 a.m. and 4:00 p.m. (ET), Monday through Friday, except Federal holidays

FOR FURTHER INFORMATION CONTACT: Shelbie Lewman, Region III, U.S. Nuclear Regulatory Commission, telephone: 630-810-4373, email: Shelbie.Lewman@nrc.gov.

SUPPLEMENTARY INFORMATION: The text of the Order is attached.

Dated: April 25, 2022.

For the Nuclear Regulatory Commission.

John B. Giessner,
Regional Administrator,
NRC Region III.

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

)	
)	030-34325
In the Matter of)	
)	03-23853-01VA
)	
Department of Veterans Affairs,)	EA-21-059
Greater Los Angeles Healthcare System)	
)	

CONFIRMATORY ORDER MODIFYING LICENSE
(EFFECTIVE UPON ISSUANCE)

I

The Department of Veterans Affairs (VA) holds Master Materials License No. 03-23853-01VA, issued to the U.S. Department of Veterans Affairs on March 17, 2003, by the U.S. Nuclear Regulatory Commission (NRC or Commission) pursuant to Part 35 of Title 10 of the *Code of Federal Regulations* (CFR). The license authorizes the use of any byproduct material for purposes authorized by the National Radiation Safety Committee and the use of depleted uranium for shielding, as described in its application dated September 21, 1998, in accordance with conditions specified therein.

This Confirmatory Order is the result of an agreement reached during an Alternative Dispute Resolution (ADR) mediation session conducted on March 2, 2022, in Lisle, Illinois.

II

On April 22, 2021, the NRC completed Investigation Report 03-2020-010, which documented the identification of apparent violations at the facility of VA's permittee, VA Greater Los Angeles Healthcare System. The apparent violations were being considered for escalated enforcement action in accordance with the NRC Enforcement

Policy. The apparent violations involved the willful failure of a nuclear medicine technologist (NMT) to conduct a measurement of the concentration of strontium-82 and strontium-85 prior to use of a strontium-82/rubidium-82 generator, as required by 10 CFR 35.204(c), and falsification of records by the same NMT relating to the same failure to conduct the required measurement, in violation of 10 CFR 30.9, 10 CFR 35.204(d) and 10 CFR 35.2204. VA formally requested a copy of the NRC report on December 13, 2021. In accordance with established Commission policy (see SRM-SECY-05-0213, ML060060088), NRC denied this request on December 14, 2021.

By letter, dated December 2, 2021, the NRC provided VA with a factual summary of the results of the investigation with an opportunity to: (1) provide a response in writing, (2) attend a predecisional enforcement conference or (3) participate in an ADR mediation session in an effort to resolve these concerns.

In response to the NRC's offer, VA requested the use of the NRC's ADR process to resolve differences it had with the NRC. On March 2, 2022, the NRC and VA met in an ADR session mediated by a professional mediator, arranged through Cornell University's Institute on Conflict Resolution. The ADR process is one in which a neutral mediator, with no decision-making authority, assists the parties in reaching an agreement on resolving any differences regarding the dispute. This Confirmatory Order is issued pursuant to the agreement reached during the ADR process.

III

During the ADR session, VA and the NRC reached a preliminary settlement in an Agreement in Principle.

The NRC recognizes that VA has already taken corrective actions including:

1. Removing the NMT who committed the willful violations as soon as the misconduct was witnessed by the Radiation Safety Officer (RSO); and

2. Retraining the NMT staff concerning proper quality control procedures.

Therefore, the parties agree to the following terms and conditions:

1. VA commits to conduct an anonymous safety culture survey of VA employees nationwide working in nuclear medicine or related activities as identified below:
 - a. Individuals handling permitted, unsealed, radioactive material in a patient care setting (e.g., nuclear medicine technologists);
 - b. Authorized User physicians;
 - c. Radiation Safety Officers (RSOs) and their staffs;
 - d. National Health Physics Program staff and National Radiation Safety Committee (NRSC) members; and,
 - e. Other personnel required by 10 CFR Part 20 to be monitored due to occupational exposure to permitted, unsealed, radioactive material in a patient care setting.

The survey will be conducted by VA's National Center for Patient Safety (NCPS), an organization independent of the VHA National Health Physics Program, or another independent entity contracted by VA.

The NRSC will review the results of the survey in consultation with the survey designer and the NRSC will determine corrective actions. Corrective actions identified and taken or a justification for no corrective actions will be available for NRC inspection upon request.

The survey will be completed and analyzed no later than 18 months from the date of the Confirmatory Order and the results will be available for NRC inspection upon request.

2. VA commits to conduct safety culture training. This training will consist of two

National Health Physics Program (NHPP) webinars related to safety culture with announcement to VHA Email Groups for RSOs, Nuclear Medicine Supervisors, and Chief/Lead Nuclear Medicine Technologists (VA-wide). The NRSC Chair will lead at least one of the webinars. The webinars will be recorded for future reference to allow RSOs, Nuclear Medicine Supervisors, and Chief/Lead Nuclear Medicine Technologists to complete later. Ninety (90) percent of the combined group of RSOs and Nuclear Medicine Supervisors, and Chief/Lead Nuclear Medicine Technologists must complete one webinar or view one recording.

Documentation of the webinars and their attendance will be available for NRC inspection upon request. The NRC will be invited to attend one of the webinars. This commitment will be met no later than nine months from the date of the Confirmatory Order.

3. VA commits to “re-energize” its employee concerns program related to reporting of radioactive program allegations or adverse events. Specifically, VA will:
 - a. Add safety culture content to the “Reporting Radiation Safety Concerns” posters and programs;
 - b. Re-emphasize 24/7/365 availability of the hotline in webinars discussed above; and,
 - c. Issue one or two “Scatterings” newsletters discussing its employees concerns program, with poster attached.

This commitment will be met no later than nine months from the date of the Confirmatory Order. Documentation of this commitment will be available for NRC inspection upon request.

4. In consideration of the completed actions and commitments delineated above and the license modifications described below, the NRC agrees to refrain from issuing a Notice of Violation or proposing a civil penalty in connection with the NRC's December 2, 2021, letter. The NRC agrees that the Confirmatory Order documenting the above items will not be considered an escalated enforcement action by the NRC for future assessment of violations occurring at VA if VA does not violate the terms of this Confirmatory Order.

The terms and conditions set forth herein shall continue to apply for the duration of the Master Material License issued to VA.

On March 2, 2022, VA consented to issuing this Confirmatory Order with the commitments, as described in Section V below. VA further agreed that this Confirmatory Order is to be effective upon issuance, the agreement memorialized in this Confirmatory Order settles the matter between the parties, and that it has waived its right to a hearing.

IV

I find that VA's completed actions, as described in Section III above, combined with the commitments as set forth in Section V are acceptable and necessary, and conclude that with these commitments the public health and safety are reasonably assured. In view of the foregoing, I have determined that public health and safety require that VA's commitments be confirmed by this Confirmatory Order. Based on the above and VA's consent, this Confirmatory Order is effective upon issuance.

By no later than thirty (30) days after the completion of the commitments specified in Section V, VA is required to notify the NRC in writing and summarize its actions.

V

Accordingly, pursuant to Sections 81, 161b, 161i, 161o, 182, and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and 10 CFR Parts 30 and 35, IT IS HEREBY ORDERED, EFFECTIVE UPON ISSUANCE, THAT LICENSE NO. 03-23853-01VA IS MODIFIED AS FOLLOWS:

1. VA will conduct an anonymous safety culture survey of VA employees nationwide working in nuclear medicine or related activities as identified below:
 - a. Individuals handling permitted, unsealed, radioactive material in a patient care setting (e.g., nuclear medicine technologists);
 - b. Authorized User physicians;
 - c. Radiation Safety Officers (RSOs) and their staffs;
 - d. National Health Physics Program staff and National Radiation Safety Committee (NRSC) members; and,
 - e. Other personnel required by 10 CFR Part 20 to be monitored due to occupational exposure to permitted, unsealed, radioactive material in a patient care setting.

The survey will be conducted by VA's National Center for Patient Safety (NCPS), an organization independent of the VHA National Health Physics Program, or another independent entity contracted by VA.

The NRSC will review the results of the survey in consultation with the survey designer and the NRSC will determine corrective actions. Corrective actions identified and taken or a justification for no corrective actions will be available for NRC inspection upon request.

The survey will be completed and analyzed no later than 18 months from the date of the Confirmatory Order and the results will be available for NRC

inspection upon request.

2. VA will conduct safety culture training. This training will consist of two National Health Physics Program (NHPP) webinars related to safety culture with announcement to VHA Email Groups for RSOs, Nuclear Medicine Supervisors, and Chief/Lead Nuclear Medicine Technologists (VA-wide). The NRSC Chair will lead at least one of the webinars. The webinars will be recorded for future reference to allow RSOs, Nuclear Medicine Supervisors, and Chief/Lead Nuclear Medicine Technologists to complete later. Ninety (90) percent of the combined group of RSOs and Nuclear Medicine Supervisors, and Chief/Lead Nuclear Medicine Technologists must complete one webinar or view one recording.

Documentation of the webinars and their attendance will be available for NRC inspection upon request. The NRC will be invited to attend one of the webinars. VA will complete this safety culture training, including the 90% participation requirement, no later than nine months from the date of this Confirmatory Order.

3. VA will "re-energize" its employee concerns program related to reporting radioactive program allegations or adverse events. Specifically, VA will:
 - a. Add safety culture content to the "Reporting Radiation Safety Concerns" posters and programs;
 - b. Re-emphasize 24/7/365 availability of the hotline in webinars discussed above; and,
 - c. Issue at least one "Scatterings" newsletters discussing the employee concerns program, with poster attached.

This commitment will be met no later than nine months from the date of the Confirmatory Order. Documentation relating to the fulfillment of this commitment

will be available for NRC inspection upon request.

The Regional Administrator, Region III may, in writing, relax or rescind any of the above conditions upon demonstration of good cause by VA or its successors.

VI

In accordance with 10 CFR 2.202 and 10 CFR 2.309, any person adversely affected by this Confirmatory Order, other than VA, may request a hearing within thirty (30) calendar days of the date of issuance of this Confirmatory Order. Where good cause is shown, consideration will be given to extending the time to request a hearing. A request for extension of time must be made in writing to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and include a statement of good cause for the extension.

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene (hereinafter "petition"), and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007, as amended at 77 FR 46562, August 3, 2012). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by e-mail at hearing.docket@nrc.gov, or by telephone at 301-415-1677, to (1) request a digital

identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals/getting-started.html>. Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit adjudicatory documents. Submissions must be in Portable Document Format (PDF). Additional guidance on PDF submissions is available on the NRC's public Web site at <http://www.nrc.gov/site-help/electronic-sub-ref-mat.html>. A filing is considered complete at the time the document is submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an e-mail notice confirming receipt of the document. The E-Filing system also distributes an e-mail notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed so that they can obtain access to the documents via

the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the "Contact Us" link located on the NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals.html>, by e-mail to MSHD.Resource@nrc.gov, or by a toll-free call at 1-866-672-7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) first class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland, 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in NRC's electronic hearing docket, which is available to the public at <https://adams.nrc.gov/ehd>, unless

excluded pursuant to an order of the Commission or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

The Commission will issue a notice or order granting or denying a hearing request or intervention petition, designating the issues for any hearing that will be held and designating the Presiding Officer. A notice granting a hearing will be published in the Federal Register and served on the parties to the hearing.

If a person (other than VA) requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Confirmatory Order and shall address the criteria set forth in 10 CFR 2.309(d) and (f).

If a hearing is requested by a person whose interest is adversely affected, the Commission will issue an order designating the time and place of any hearings. If a hearing is held, the issue to be considered at such hearing shall be whether this Confirmatory Order should be sustained.

In the absence of any request for hearing, or written approval of an extension of time in which to request a hearing, the provisions specified in Section V above shall be final 30 days from the date of this Confirmatory Order without further order or proceedings. If an extension of time for requesting a hearing has been approved, the provisions specified in Section V shall be final when the extension expires if a hearing request has not been received.

For the Nuclear Regulatory Commission

/RA/

John B. Giessner
Regional Administrator
NRC Region III

Dated this 21st day of April 2022