



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 EAST LAMAR BOULEVARD
ARLINGTON, TEXAS 76011-4511

May 19, 2022

IA-21-060

Ms. Shannon Gray
[NOTE: HOME ADDRESS DELETED
UNDER 10 CFR 2.390]

SUBJECT: CONFIRMATORY ORDER AND NRC INVESTIGATION REPORT 4-2019-007

Dear Ms. Gray:

A Confirmatory Order (Enclosure 1) is being issued to you as a result of a successful alternative dispute resolution mediation session. The Confirmatory Order commitments were made as part of a settlement agreement between you and the U.S. Nuclear Regulatory Commission (NRC).

The settlement agreement relates to your apparent violation of an NRC requirement as discussed in NRC Investigation Report 4-2019-007 dated December 21, 2021 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML21354A776). The apparent violation involved your failure to comply with Title 10 of the *Code of Federal Regulations* (10 CFR) 30.10(a)(1), which requires, in part, that an employee of a licensee may not engage in deliberate misconduct that causes a licensee to be in violation of any rule or regulation issued by the Commission.

Our December 21, 2021, letter also informed you that the apparent violation was being considered for escalated enforcement action in accordance with the NRC's Enforcement Policy and provided you the opportunity to: (1) provide a response in writing, (2) attend a predecisional enforcement conference, or (3) participate in an alternative dispute resolution mediation session in an effort to resolve this concern. In response to our letter, you requested alternative dispute resolution. An alternative dispute resolution mediation session was held on April 19, 2022, and a preliminary settlement agreement was reached. The elements of that agreement, formulated and agreed to at the mediation session, are incorporated in the Confirmatory Order.

Based on the actions you committed to take, as described in the Confirmatory Order, the NRC will not issue a Notice of Violation for the apparent violation discussed in our letter dated December 21, 2021. The NRC is satisfied that its concerns will be adequately addressed based on the legally binding commitments that you will implement as documented in the Confirmatory Order. As evidenced by the signed "Consent and Hearing Waiver Form" (Enclosure 2), dated May 16, 2022, you have agreed to the issuance of this Confirmatory Order.

Pursuant to Section 223 of the Atomic Energy Act of 1954, as amended, any person who willfully violates, attempts to violate, or conspires to violate, any provision of the Confirmatory Order shall be subject to criminal prosecution, as set forth in that section. Violation of the Confirmatory Order may also subject the person to civil monetary penalties.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice and Procedure," a copy of this letter and its enclosures will be made available electronically for public inspection in the NRC Public Document Room and from the NRC's ADAMS, accessible from the NRC website at <http://www.nrc.gov/reading-rm/adams.html>. The Confirmatory Order will be published in the *Federal Register*. The NRC also includes Confirmatory Orders on its website at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions>.

Sincerely,



Signed by Morris, Scott
on 05/19/22

Scott A. Morris
Regional Administrator

Enclosures:

1. Confirmatory Order
2. Consent and Hearing Waiver Form

SUBJECT: CONFIRMATORY ORDER AND NRC INVESTIGATION REPORT 4-2019-007 -
DATED MAY 19, 2022

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ADAMS ACCESSION NUMBER: ML22130A037

SUNSI Review: ADAMS: Non-Publicly Available Non-Sensitive Keyword:
By: JGK Yes No Publicly Available Sensitive

OFFICE	SES:ACES	C:MIB	TL:ACES	RC	NMSS	OE
NAME	JKramer	LRoldan-Otero	JGroom	DCylkowski	RSun	JPeralta
SIGNATURE	/RA/ E	/RA/ E	/RA/ E	/RA/ E	/RA/ E	/RA/ E
DATE	04/22/22	04/26/22	04/25/22	04/27/22	05/04/22	05/09/22
OFFICE	OGC	D:DNMS	RA			
NAME	LBaer	MMuessle	SMorris			
SIGNATURE	/NLO/ E	/RA/ E	/RA/ E			
DATE	05/09/22	05/13/22	05/19/22			

OFFICIAL RECORD COPY

Shannon Gray

CONFIRMATORY ORDER

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

In the Matter of)
)
SHANNON GRAY) IA-21-060

CONFIRMATORY ORDER
(EFFECTIVE UPON ISSUANCE)

I

Shannon Gray is employed by Avera McKennan in Sioux Falls, South Dakota. Avera McKennan and Avera McKennan/Nuclear Medicine (collectively known as Avera McKennan or the licensee) are the holders of Materials License Nos. 40-16571-01 and 40-16571-02 respectively, issued by the U.S. Nuclear Regulatory Commission (NRC or Commission) pursuant to Part 30 of Title 10 of the *Code of Federal Regulations* (10 CFR).

This Confirmatory Order (CO) is the result of an agreement reached during an Alternative Dispute Resolution (ADR) mediation session conducted on April 19, 2022.

II

On February 13, 2019, the NRC's Office of Investigations (OI) opened an investigation (OI case No. 4-2019-007) at Avera McKennan. Based on the evidence developed during its investigation, the NRC identified an apparent violation of 10 CFR 30.10(a)(1), which requires, in part, that an employee of a licensee may not engage in deliberate misconduct that causes a licensee to be in violation of any rule or regulation issued by the Commission i.e., 10 CFR 35.63(a). Shannon Gray disagrees that a violation of 10 CFR 35.63(a) occurred and

disagrees that deliberate misconduct was associated with the apparent violation.¹ The parties agree to disagree on whether the violation occurred. By letter dated December 21, 2021 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML21354A776), the NRC notified Shannon Gray of the results of the investigation and provided Shannon Gray with the 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 this concern.

In response to the NRC's offer, Shannon Gray requested the use of the NRC ADR process. On April 19, 2022, the NRC and Shannon Gray 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 to resolve any differences regarding the dispute. This Confirmatory Order is issued pursuant to the agreement reached during the April 19, 2022 ADR session.

III

During the ADR session, Shannon Gray and the NRC reached a preliminary settlement agreement.

The NRC recognizes the corrective actions that Shannon Gray has already implemented associated with the apparent violations:

¹ Shannon Gray's view on the apparent violation is available at ML22117A183.

- A. Discovered the problem with the modified dippers and reported to Avera McKennan management.
- B. Agreed with another manager that an informal evaluation of the consequences of the modified dippers would be performed.
- C. Initiated the ordering new dippers and replacement of the modified dippers when received.
- D. With another manager, communicated to technicians that the new dippers were ordered and that modified dippers should not be used after new dippers arrived.

Additional commitments made in the preliminary settlement agreement, as signed by both parties, consist of the following:

- A. Shannon Gray will develop live training for Avera McKennan staff involved in NRC-regulated material. The training will include at least the following: (1) a summary of the events that led to the discovery of physically modified dose calibrators at Avera McKennan, (2) the importance of compliance with NRC regulations, (3) the consequences of engaging in willful violations, (4) what to do if there is a perceived or actual medical issue that conflicts with NRC regulations, and (5) any personal lessons-learned associated with this issue. The other manager involved with Avera McKennan case EA-21-027 may co-present the training with Shannon Gray. This will include the following actions:

1. Within 3 months of the issuance date of the Confirmatory Order, Shannon Gray will submit the training to the NRC for approval.
 2. Within 18 months of the NRC approval of the training and if supported by Avera McKennan, Shannon Gray will provide a total of five live training sessions split between the personnel of Avera McKennan (License 40-16571-01) and Avera McKennan/Nuclear Medicine (License 40-16571-02) involved with NRC regulated activities.
 3. Within 1 month of the completion of each training session, Shannon Gray will submit to the NRC the date of the training, a list of the personnel receiving the training, a summary of the feedback received on the training, and any lessons learned from providing the training.
 4. In the event that Avera McKennan does not agree to support Shannon Gray providing any of the five training sessions to personnel involved with NRC regulated activities, Shannon Gray will provide a written notice to the NRC within 1 month of the unwillingness of Avera McKennan to support any particular training session. The written notice will include the date of the notification and any details that Avera McKennan provided for not supporting the training sessions.
- B. Shannon Gray will develop three live training sessions, one for each of the following: Avera St. Mary's Hospital (40-07328-03), Avera St. Luke's (40-18000-01), and Avera Sacred Heart Hospital (40-01683-01) that includes at least the following: (1) a summary of the events that led to the discovery of physically modified dose calibrators at Avera McKennan, (2) the importance of compliance with NRC regulations, (3) the

consequences of engaging in willful violations, (4) what to do if there is a perceived or actual medical issue that conflicts with NRC regulations, and (5) any personal lessons-learned associated with this issue. The other manager involved with Avera McKennan case EA-21-027 may co-present the training with Shannon Gray.

1. Within 3 months of the issuance date of the Confirmatory Order, Shannon Gray will submit the training to the NRC for approval.
2. Within 18 months of NRC approval of the training, Shannon Gray will provide the three training sessions to the licensees identified in Condition B.
3. Within 1 month of the completion of each training session, Shannon Gray will submit to the NRC the date of the training, a list of the personnel receiving the training, a summary of the feedback received on the training, and any lessons learned from providing the training.
4. In the event that Avera McKennan or the recipient licensee does not agree to support Shannon Gray providing any of the three training sessions to personnel involved with NRC regulated activities, Shannon Gray will provide a written notice to the NRC within 1 month of the unwillingness of Avera McKennan or the recipient licensee to support any particular training session. The written notice will include the date of the notification and any details that Avera McKennan or the recipient licensee provided for not supporting the training sessions.

C. Documents that are required to be sent to the NRC as a result of the Confirmatory Order Conditions will be sent to the Director, Division of Radiological Safety and Security, U.S. Nuclear Regulatory Commission, Region IV, by email to R4Enforcement@nrc.gov.

Based on the completed actions described above, and the commitments described in Section V below, the NRC agrees not to issue a Notice of Violation for the apparent violation discussed in the NRC Investigation Report 4-2019-007 issued to Shannon Gray dated December 21, 2021.

On May 16, 2022, Shannon Gray consented to issuing this Confirmatory Order with the commitments, as described in Section V below. Shannon Gray 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 Shannon Gray has waived her right to a hearing.

IV

I find that the corrective actions that Shannon Gray has already implemented, as described in Section III above, combined with the commitments as set forth in Section V below, are acceptable and necessary, and I 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 Shannon Gray's commitments be confirmed by this Confirmatory Order. Based on the above and Shannon Gray's consent, this Confirmatory Order is effective upon issuance.

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 Part 30, IT IS HEREBY ORDERED, EFFECTIVE UPON ISSUANCE, THAT:

- A. Shannon Gray will develop live (e.g., in person or virtual) training for Avera McKennan staff involved in NRC-regulated material. The training will include at least the following: (1) a summary of the events that led to the discovery of physically modified dose calibrators at Avera McKennan, (2) the importance of compliance with NRC regulations, (3) the consequences of engaging in willful violations, (4) what to do if there is a perceived or actual medical issue that conflicts with NRC regulations, and (5) any personal lessons-learned associated with this issue. Traci Hollingshead may co-present the training with Shannon Gray. This will include the following actions:
1. Within 3 months of the issuance date of the Confirmatory Order, Shannon Gray will submit the training to the NRC for approval.
 2. Within 18 months of the NRC approval of the training and if supported by Avera McKennan, Shannon Gray will provide a total of five live training sessions split between the personnel of Avera McKennan (License 40-16571-01) and Avera McKennan/Nuclear Medicine (License 40-16571-02) involved with NRC regulated activities.
 3. Within 1 month of the completion of each training session, Shannon Gray will submit to the NRC the date of the training, a list of the personnel receiving the training, a

summary of the feedback received on the training, and any lessons learned from providing the training.

4. In the event that Avera McKennan does not agree to support Shannon Gray providing any of the five training sessions to personnel involved with NRC regulated activities, Shannon Gray will provide a written notice to the NRC within 1 month of being informed of Avera McKennan's unwillingness to support any particular training session. The written notice will include the date of the notification and any details that Avera McKennan provided for not supporting the training sessions.

- B. Shannon Gray will develop three live (e.g., in person or virtual) training sessions, one for each of the following hospitals: Avera St. Mary's Hospital (License 40-07328-03), Avera St. Luke's (License 40-18000-01), and Avera Sacred Heart Hospital (License 40-01683-01) that includes at least the following: (1) a summary of the events that led to the discovery of physically modified dose calibrators at Avera McKennan, (2) the importance of compliance with NRC regulations, (3) the consequences of engaging in willful violations, (4) what to do if there is a perceived or actual medical issue that conflicts with NRC regulations, and (5) any personal lessons-learned associated with this issue. Traci Hollingshead may co-present the training with Shannon Gray.

1. Within 3 months of the issuance date of the Confirmatory Order, Shannon Gray will submit the training to the NRC for approval.
2. Within 18 months of NRC approval of the training, Shannon Gray will provide the three training sessions to the licensees identified in Condition B.

3. Within 1 month of the completion of each training session, Shannon Gray will submit to the NRC the date of the training, a list of the personnel receiving the training, a summary of the feedback received on the training, and any lessons learned from providing the training.
 4. In the event that Avera McKennan or any of the three involved hospitals do not agree to support Shannon Gray providing any of the three training sessions to personnel involved with NRC regulated activities, Shannon Gray will provide a written notice to the NRC within 1 month of being informed of Avera McKennan's or any of the involved hospitals' unwillingness to support any particular training session. The written notice will include the date of the notification and any details that Avera McKennan or the recipient licensee provided for not supporting the training sessions.
- C. Documents that are required to be sent to the NRC as a result of the Confirmatory Order Conditions will be sent to the Director, Division of Radiological Safety and Security, U.S. Nuclear Regulatory Commission, Region IV, by email to R4Enforcement@nrc.gov.

The Regional Administrator, Region IV, may, in writing, relax, rescind, or withdraw any of the above conditions upon demonstration by Shannon Gray of good cause.

VI

In accordance with 10 CFR 2.202 and 10 CFR 2.309, any person adversely affected by this Confirmatory Order, other than Shannon Gray, 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 and petition for leave to intervene (petition), any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities that request to participate 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. Detailed guidance on making electronic submissions may be found in the Guidance for Electronic Submissions to the NRC and on the NRC website at <https://www.nrc.gov/site-help/e-submittals.html>. 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 email 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 <https://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 website at <https://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 email notice confirming receipt of the document. The E-Filing system also distributes an email 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 <https://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 stating why there is good cause for not filing electronically and 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, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing adjudicatory documents 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 the 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. If you do not have an NRC-issued digital ID certificate as described above, click "cancel" when the link requests certificates and you will be automatically directed to the NRC's electronic hearing dockets where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or personal phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. For example, in some instances, individuals provide home addresses in order to demonstrate proximity to a facility or site. 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 Shannon Gray) 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



Signed by Morris, Scott
on 05/19/22

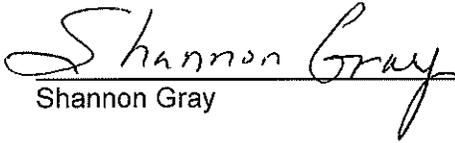
Scott A. Morris
Regional Administrator
NRC Region IV

Dated this 19th day of May 2022

CONSENT AND HEARING WAIVER FORM

CONSENT AND HEARING WAIVER FORM

Shannon Gray hereby agrees to comply with the terms and conditions of this Confirmatory Order arising out of an alternative dispute resolution mediation session on April 19, 2022, to be issued relating to Individual Action IA-21-060. This Confirmatory Order will be effective upon its issuance. By signing below, Shannon Gray consents to the issuance of the referenced Confirmatory Order, and, by doing so, agrees to waive the right to request a hearing on all or any part of this Confirmatory Order.


Shannon Gray

5-16-2022
Date