



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

May 19, 2022

EA-21-027

Dr. Michael Elliott, Chief Medical Officer  
Avera McKennan  
1325 South Cliff Avenue  
Sioux Falls, SD 57117-5045

SUBJECT: CONFIRMATORY ORDER MODIFYING LICENSE - NRC INSPECTION REPORT  
030-39216/2021-002 AND INVESTIGATION REPORT 4-2019-007, AVERA  
MCKENNAN

Dear Dr. Elliott:

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

The settlement agreement relates to apparent violations of NRC requirements as discussed in NRC Inspection Report 030-39216/2021-002 and NRC Investigation Report 4-2019-007 dated December 21, 2021 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML21355A366). The apparent violations involved the failure to determine, by direct measurement, the activity of dosages before medical use as required by Title 10 of the *Code of Federal Regulations* (10 CFR) 35.63(a); and the failure to maintain information that was complete and accurate in all material respects as required by 10 CFR 30.9.


Our December 21, 2021, letter also informed you that the apparent violations were being considered for escalated enforcement action in accordance with the NRC's Enforcement Policy and provided the opportunity to: (1) attend a predecisional enforcement conference or (2) participate in an alternative dispute resolution mediation session in an effort to resolve these concerns. In response to our letter, you requested alternative dispute resolution. An alternative dispute resolution mediation session was held on April 20, 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 Avera McKennan committed to take, as described in the Confirmatory Order, the NRC will not issue a Notice of Violation and will not issue an associated civil penalty for the apparent violations 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 Avera McKennan will implement as documented in the Confirmatory Order. As evidenced by the signed "Consent and Hearing Waiver Form" (Enclosure 2), dated May 17, 2022, Avera McKennan has 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

Docket Nos. 030-11252, 030-39216  
License Nos. 40-16571-01, 40-16571-02

Enclosures:

1. Confirmatory Order
2. Consent and Hearing Waiver Form

SUBJECT: CONFIRMATORY ORDER MODIFYING LICENSE - NRC INSPECTION REPORT  
030-39216/2021-002 AND INVESTIGATION REPORT 4-2019-007, AVERA  
MCKENNAN - DATED MAY 19, 2022

**DISTRIBUTION:**

RidsOeMailCenter Resource;  
RidsSecyMailCenter Resource;  
RidsEdoMailCenter Resource;  
RidsOiMailCenter Resource;  
R4Allegation.resource  
SMorris, RA  
JMonninger, DRA  
MMuessle, DRSS  
GMiller, DRSS  
LRoldan-Otero, DRSS  
VDricks, ORA  
JGroom, ORA  
ARoberts, ORA

RidsNmssOd Resource;  
RidsOcaMailCenter Resource;  
EDO\_Managers;  
RidsRgn1MailCenter Resource;  
R4ACES  
RAlexander, ORA  
MMadison, DRMA  
JKramer, ORA  
CRivera-Diaz, OE  
LBaer, OGC  
AMoreno, CA  
LWilkins, CA  
ROrlikowski, OEDO

RidsOgcMailCenter Resource;  
RidsOigMailCenter Resource;  
RidsOcofoMailCenter Resource;  
RidsRgn3MailCenter Resource;  
R4Enforcement.resource  
MLombard, OE  
TMartinez-Navedo, OE  
JPeralta, OE  
JCook, DRSS  
RErickson, DRSS  
MBurgess, NMSS  
RSun, NMSS  
GWalker, OI

[https://usnrc.sharepoint.com/teams/Region-IV-ACES/ACES S Drive/ENFORCEMENT/ \\_EA CASES - OPEN/Avera  
McKenna EA-21-027/Confirmatory Order/Licensee/ORDER\\_EA-21-027\\_Avera McKenna.docx](https://usnrc.sharepoint.com/teams/Region-IV-ACES/ACES%20S%20Drive/ENFORCEMENT/_EA%20CASES%20-%20OPEN/Avera%20McKenna%20EA-21-027/Confirmatory%20Order/Licensee/ORDER_EA-21-027_Avera%20McKenna.docx)

ADAMS ACCESSION NUMBER: ML22130A588

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	05/10/22
OFFICE	OGC	D:DNMS	RA			
NAME	LBaer	MMuessle	SMorris			
SIGNATURE	/NLO/ E	/RA/ E	/RA/ E			
DATE	05/10/22	05/13/22	05/19/22			

**OFFICIAL RECORD COPY**

**Avera McKennan**

**CONFIRMATORY ORDER  
MODIFYING LICENSE**

UNITED STATES OF AMERICA  
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	Docket No. 030-11252
AVERA MCKENNAN	)	
	)	License No. 40-16571-01
	)	
	)	Docket No. 030-39216
AVERA MCKENNAN/NUCLEAR MEDICINE	)	
	)	License No. 40-16571-02
	)	
	)	EA-21-027

CONFIRMATORY ORDER MODIFYING LICENSE  
(EFFECTIVE UPON ISSUANCE)

I

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). The licenses authorize the operation of facilities in accordance with conditions specified therein. The facilities are located on the licensee's sites in South Dakota.

This Confirmatory Order (CO) is the result of an agreement reached during an Alternative Dispute Resolution (ADR) mediation session conducted on April 20, 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 two apparent violations involving the failure to determine, by direct measurement, the activity of dosages before medical use as required by 10 CFR 35.63(a); and the failure to maintain information that was complete and accurate in all material respects as required by 10 CFR 30.9. It is Avera McKennan's view that no violation of requirements occurred.<sup>1</sup> The parties agree to disagree on whether violations occurred. By letter dated December 21, 2021 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML21355A366), the NRC notified Avera McKennan of the results of the investigation and provided Avera McKennan with an opportunity to: (1) attend a predecisional enforcement conference or (2) participate in an ADR mediation session in an effort to resolve these concerns.

In response to the NRC's offer, Avera McKennan requested the use of the NRC ADR process. On April 20, 2022, the NRC and Avera McKennan 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 20, 2022 ADR session.

### III

During the ADR session, Avera McKennan and the NRC reached a preliminary settlement agreement.

---

<sup>1</sup> Avera McKennan's view on the apparent violations is available at ML22117A183.

“Avera McKennan” refers to the licensees of Avera McKennan (License 40-16571-01) and Avera McKennan/Nuclear Medicine (License 40-16571-02). “Contractors” refers to individuals performing NRC licensed activities under either the Avera McKennan license (License 40-16571-01) or the Avera McKennan/Nuclear Medicine license (License 40-16571-02).

The NRC recognizes the corrective actions that Avera McKennan has already implemented associated with the apparent violations:

- A. Avera McKennan ordered new dippers for use in all dose calibrators and replaced the modified dippers for all dose calibrators.
- B. Avera McKennan communicated that the new dippers were ordered and that modified dippers should not be used after new dippers arrived.
- C. Avera McKennan transitioned from the use of molybdenum generators to create individual dosages to the use of unit doses supplied by a third-party radiopharmacy.
- D. Avera McKennan implemented a field observation program that includes an annual one-on-one observation of each nuclear medicine technologist focused on ensuring radiation safety. Each annual observation includes formal documentation of any improvement, if needed.
- E. Avera McKennan has retained the use of an outside entity to provide an independent assessment of Avera McKennan performance.

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

Communications

- A. Avera McKennan will develop a communication that will: include a summary of the events that resulted in the Confirmatory Order, stress the importance of complying with NRC regulations and the conditions of the license, and emphasize the importance of ensuring documents are complete and accurate, and the consequences for engaging in willful violations. Avera McKennan will submit the communication to the NRC for review and approval within 2 months of the issuance date of the Confirmatory Order.
  
- B. Within 2 months of NRC approval of the communication, Avera McKennan will issue the Condition A communication as a stand-alone communication from a senior hospital official to all authorized users, nuclear medicine technologists, all other employees performing in NRC licensed activities and Contractors. Avera McKennan will retain a copy of the communication presented and a record of the personnel receiving the communication.
  
- C. Beginning on the date Avera McKennan has issued the Condition A communication and until December 31, 2026, Avera McKennan will provide the Condition A communication to all new employees performing NRC licensed activities or Contractors prior to those individuals performing NRC licensed activities. Avera McKennan will also provide the Condition A communication to current employees or Contractors with new duties performing NRC licensed activities prior to those individuals performing the new duties. Avera McKennan will retain a record of the personnel receiving the communication.



D. Within 6 months of the date Avera McKennan has issued the Condition A communication, Avera McKennan will issue an additional communication to all authorized users, nuclear medicine technologists, all other employees involved in NRC licensed activities, and Contractors reemphasizing its intolerance of willful misconduct and update such workforce on the status of compliance with this Confirmatory Order. Avera McKennan will continue to issue this communication at intervals not to exceed 12 months until December 31, 2026. Avera McKennan will retain a copy of the communication presented and a record of the personnel receiving the communication. Avera McKennan will document the reason for any person not obtaining the communication and the additional efforts used to provide the communication.

#### Training

E. Avera McKennan will develop a training program to provide to all authorized users, nuclear medicine technologists, all other employees involved in NRC licensed activities, and Contractors. The training will address what is meant by willfulness and the potential enforcement actions that the NRC may take against employees who engage in deliberate misconduct and the associated NRC enforcement actions that may be taken against a licensee. The training will request that the recipients provide feedback on the training. Avera McKennan will submit this training program to the NRC for review and approval within 6 months of the issuance date of the Confirmatory Order.

F. Within 6 months of NRC approval of the training program, Avera McKennan will provide this training to all authorized users, nuclear medicine technologists, all other employees involved in NRC licensed activities, and Contractors. Avera McKennan will continue to provide this training at least once every calendar year until December 31, 2026. Avera

McKennon will maintain a record of the individuals receiving the training, a summary of the feedback on the training, the instructor providing the training (if applicable), and the date of the training.

G. Beginning on the date Avera McKennon has first provided the Condition E training and until December 31, 2026, Avera McKennon will provide the Condition E training to all new employees or Contractors within 3 months of starting work in NRC licensed activities. Avera McKennon will also provide the Condition E training to current employees or Contractors with new duties performing NRC licensed activities. Avera McKennon will retain a record of the individuals receiving the training, a summary of the feedback on the training, the instructor providing the training (if applicable), and the date of the training.

H. Until December 31, 2024, while Ms. Shannon Gray remains employed by Avera McKennon, Avera McKennon will support and allow Ms. Gray to provide a total of eight live training sessions to personnel involved in NRC licensed activities at Avera McKennon, Avera St. Mary's Hospital (40-07328-03), Avera St. Luke's (40-18000-01), and Avera Sacred Heart Hospital (40-01683-01). Until December 31, 2024, while Ms. Traci Hollingshead remains employed by Avera McKennon, Avera McKennon will support and allow Ms. Hollingshead to provide a total of eight live training sessions to personnel involved in NRC licensed activities at Avera McKennon, Avera St. Mary's Hospital (40-07328-03), Avera St. Luke's (40-18000-01), and Avera Sacred Heart Hospital (40-01683-01). These eight live training sessions may be co-presented by Ms. Gray and Ms. Hollingshead.

Field Observation Program, applicable to License 40-16571-02 only

- I. Avera McKennan will develop or maintain a field observation program for Avera McKennan/Nuclear Medicine license (License 40-16571-02). Avera McKennan will observe NRC licensed activities performed by each nuclear medicine technologist. The observations shall include, at a minimum, mobile medical operations, dosage measurements, and dosimetry practices. Avera McKennan will submit the field observation program to the NRC for review and approval within 2 months of the issuance date of the Confirmatory Order.
  
- J. Within 2 months of NRC approval of the field observation program, Avera McKennan will conduct a field observation developed in Condition I and will document the results of the field observation. Avera McKennan will then perform an annual field observation for each nuclear medicine technologist until December 31, 2026, and will document the results of each field observation.

Assessment, applicable to License 40-16571-02 only

- K. Avera McKennan will engage an outside entity to perform a comprehensive assessment of Avera McKennan/Nuclear Medicine's radiation safety program. The outside entity should have familiarity and experience with 10 CFR 35.80 mobile nuclear medicine authorizations. The assessment will include an evaluation of the corrective actions associated with NRC Inspection Report 030-39216/2021-002 and Investigation Report 4-2019-007 dated December 21, 2021, and the corrective actions associated with the

Notice of Violation, NRC Inspection Report 030-11252/2017-001 and Investigation Report 4-2016-021 dated December 21, 2017. This will include the following actions:

1. Within 3 months of the issuance date of the Confirmatory Order, Avera McKennan will submit the qualifications of the outside entity to the NRC for review and approval.
2. Within 6 months of the NRC approval of the outside entity, Avera McKennan will submit a copy of the assessment report and Avera McKennan's written response to the assessment report to the NRC. Avera McKennan's written response will either address how it will implement the recommendations and corrective actions of the assessment report, including a proposed timeline; or provide an explanation and justification for why the recommendation(s) and corrective action(s) will not be implemented.

#### Organizational Health Survey

- L. Avera McKennan will engage an outside entity to develop and conduct an organizational health survey to identify safety culture concerns that could contribute to willful misconduct. The outside entity will also develop recommendations and corrective actions based on the results of the survey.
  1. Within 6 months of the issuance date of the Confirmatory Order, Avera McKennan will submit the qualifications of the outside entity to the NRC for review and approval.

2. Within 6 months of the NRC approval of the outside entity, the outside entity will conduct the organizational health survey and will develop recommendations and corrective actions based on the results organizational health survey.
3. Within 6 months of the conducting the Condition L.2 organization health survey, Avera McKennan will submit the survey results and a written response to the NRC. Avera McKennan's written response will either address how it will implement the recommendations and corrective actions of the survey, including a proposed timeline, or provide an explanation and justification for why the recommendation(s) and corrective action(s) will not be implemented.

M. Between 24 to 36 months after the completion of the survey in Condition L, the outside entity will conduct a second organizational health survey and will develop recommendations and corrective actions based on the results of the survey.

#### Effectiveness Reviews

N. By December 31 of calendar years 2022, 2024, and 2026 or 6 months after the last organizational health survey is conducted, whichever is later, Avera McKennan will perform an effectiveness review of the corrective actions implemented as a result of this Confirmatory Order. The effectiveness review will include: the lessons learned from feedback from the communications and training, if any is received; and the results of the radiation safety program assessment, field observations, and the organizational health surveys. Avera McKennan will modify its corrective actions, as needed and consistent with this Confirmatory Order, based on the results of the effectiveness review. Avera McKennan will send a copy of the effectiveness review and provide, as applicable, a

copy of any additional corrective actions and modifications made to previously developed corrective actions as a result of the effectiveness review to the NRC.

#### Administrative Items

- O. By March 31 of each calendar year 2023 through 2028, Avera McKennan will provide in writing to the NRC a summary of the actions implemented the previous calendar year as a result of the Confirmatory Order.
  
- P. Until December 31, 2028, Avera McKennan will retain a copy of all documentation created to demonstrate compliance with the conditions of the Confirmatory Order.
  
- Q. Documents that are required to be sent to the NRC as a result of the Confirmatory Order conditions will be sent the Director, Division of Radiological Safety and Security, U.S. Nuclear Regulatory Commission, Region IV, by email to [R4Enforcement@nrc.gov](mailto: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 and not impose a civil penalty for the apparent violations discussed in NRC Inspection Report 030-39216/2021-002 and Investigation Report 4-2019-007 (EA-21-027) to Avera McKennan dated December 21, 2021.

On May 17, 2022, Avera McKennan consented to issuing this Confirmatory Order with the commitments, as described in Section V below. Avera McKennan 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 the corrective actions that Avera McKennan 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 Avera McKennan's commitments be confirmed by this Confirmatory Order. Based on the above and Avera McKennan'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 LICENSE NOS. 40-16571-01 AND 40-16571-02 ARE MODIFIED AS FOLLOWS:

For the purposes of this Confirmatory Order, "Avera McKennan" refers to the licensees of Avera McKennan (License 40-16571-01) and Avera McKennan/Nuclear Medicine (License 40-16571-02). "Contractors" refers to individuals performing NRC licensed

activities under either the Avera McKennan license (License 4016571-01) or the Avera McKennan/Nuclear Medicine license (License 401657102).

### Communications

- A. Avera McKennan will develop a communication that will: include a summary of the events that resulted in the Confirmatory Order, stress the importance of complying with NRC regulations and the conditions of the license, emphasize the importance of ensuring documents are complete and accurate, and discuss the consequences for engaging in willful violations. Avera McKennan will submit the communication to the NRC for review and approval within 2 months of the issuance date of the Confirmatory Order.
  
- B. Within 2 months of NRC approval of the communication, Avera McKennan will issue the Condition A communication as a stand-alone communication from a senior hospital official to all authorized users, nuclear medicine technologists, all other employees and Contractors performing in NRC licensed activities. Avera McKennan will retain a copy of the communication presented and a record of the personnel receiving the communication.
  
- C. Beginning on the date Avera McKennan has issued the Condition A communication and until December 31, 2026, Avera McKennan will provide the Condition A communication to all new employees and Contractors performing NRC licensed activities prior to those individuals performing NRC licensed activities. Avera McKennan will also provide the Condition A communication to current employees and Contractors with new duties



performing NRC licensed activities prior to those individuals performing the new duties. Avera McKennan will retain a record of the personnel receiving the communication.

- D. Within 6 months of the date Avera McKennan has issued the Condition A communication, Avera McKennan will issue an additional communication to all authorized users, nuclear medicine technologists, all other employees and Contractors involved in NRC licensed activities reemphasizing its intolerance of willful misconduct and update such workforce on the status of compliance with this Confirmatory Order. Avera McKennan will continue to issue this communication at intervals not to exceed 12 months until December 31, 2026. Avera McKennan will retain a copy of the communication presented and a record of the personnel receiving the communication. Avera McKennan will document the reason for any person not obtaining the communication and the additional efforts used to provide the communication.

### Training

- E. Avera McKennan will develop a training program to provide to all authorized users, nuclear medicine technologists, all other employees and Contractors involved in NRC licensed activities. The training will address what is meant by willfulness and the potential enforcement actions that the NRC may take against employees who engage in deliberate misconduct and the associated NRC enforcement actions that may be taken against a licensee. The training will request that the recipients provide feedback on the training. Avera McKennan will submit this training program to the NRC for review and approval within 6 months of the issuance date of the Confirmatory Order.
- F. Within 6 months of NRC approval of the training program, Avera McKennan will provide

this training to all authorized users, nuclear medicine technologists, all other employees and Contractors involved in NRC licensed activities. Avera McKennan will continue to provide this training at least once every calendar year until December 31, 2026. Avera McKennan will maintain a record of the individuals receiving the training, a summary of the feedback on the training, the instructor providing the training (if applicable), and the date of the training.

G. Beginning on the date Avera McKennan has first provided the Condition E training and until December 31, 2026, Avera McKennan will provide the Condition E training to all new employees and Contractors within 3 months of starting work in NRC licensed activities. Avera McKennan will also provide the Condition E training to current employees and Contractors with new duties performing NRC licensed activities. Avera McKennan will retain a record of the individuals receiving the training, a summary of the feedback on the training, the instructor providing the training (if applicable), and the date of the training.

H. Until December 31, 2024, while Ms. Shannon Gray remains employed by Avera McKennan, Avera McKennan will support and allow Ms. Gray to provide a total of eight live (e.g., in person or virtual) training sessions to personnel involved in NRC licensed activities at Avera McKennan, 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). Until December 31, 2024, while Ms. Traci Hollingshead remains employed by Avera McKennan, Avera McKennan will support and allow Ms. Hollingshead to provide a total of eight live training sessions to personnel involved in NRC licensed activities at Avera McKennan, 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). These eight live training sessions may be co-presented by Ms. Gray and Ms. Hollingshead.

Field Observation Program, applicable to License 40-16571-02 only

- I. Avera McKennan will develop or maintain a field observation program for Avera McKennan/Nuclear Medicine license (License 40-16571-02). Avera McKennan will observe NRC licensed activities performed by each nuclear medicine technologist. The observations shall include, at a minimum, mobile medical operations, dosage measurements, and dosimetry practices. Avera McKennan will submit the field observation program to the NRC for review and approval within 2 months of the issuance date of the Confirmatory Order.
- J. Beginning December 31, 2022, or within 2 months of NRC approval, whichever date is later, Avera McKennan will implement the field observation program developed under Condition I. Upon the program's implementation, and until December 31, 2026, Avera McKennan will perform annual field observations of each nuclear medicine technologist and will maintain documentation of the observations.

Assessment, applicable to License 40-16571-02 only

- K. Avera McKennan will engage an outside entity to perform a comprehensive assessment of Avera McKennan/Nuclear Medicine's radiation safety program. The outside entity should have familiarity and experience with 10 CFR 35.80 mobile nuclear medicine authorizations. The assessment will include an evaluation of the corrective actions associated with NRC Inspection Report 030-39216/2021-002 and Investigation Report

4-2019-007 dated December 21, 2021, and the corrective actions associated with the Notice of Violation, NRC Inspection Report 030-11252/2017-001 and Investigation Report 4-2016-021 dated December 21, 2017. This will include the following actions:

1. Within 3 months of the issuance date of the Confirmatory Order, Avera McKennan will submit the qualifications of the outside entity to the NRC for review and approval.
2. Within 6 months of the NRC approval of the outside entity, Avera McKennan will submit a copy of the assessment report and Avera McKennan's written response to the assessment report to the NRC. Avera McKennan's written response will either address how it will implement the recommendations and corrective actions of the assessment report, including a proposed timeline; or provide an explanation and justification for why the recommendation(s) and corrective action(s) will not be implemented.

#### Organizational Health Survey

- L. Avera McKennan will engage an outside entity to develop and conduct an organizational health survey to identify safety culture concerns that could contribute to willful misconduct. The outside entity will also develop recommendations and corrective actions based on the results of the survey.
  1. Within 6 months of the issuance date of the Confirmatory Order, Avera McKennan will submit the qualifications of the outside entity to the NRC for review and approval.

2. Within 6 months of the NRC approval of the outside entity, the outside entity will conduct the organizational health survey and will develop recommendations and corrective actions based on the results organizational health survey.
3. Within 6 months of the conducting the Condition L.2 organization health survey, Avera McKennan will submit the survey results and a written response to the NRC. Avera McKennan's written response will either address how it will implement the recommendations and corrective actions of the survey, including a proposed timeline, or provide an explanation and justification for why the recommendation(s) and corrective action(s) will not be implemented.

M. Between 24 to 36 months after the completion of the survey in Condition L, the outside entity will conduct a second organizational health survey and will develop recommendations and corrective actions based on the results of the survey.

#### Effectiveness Reviews

N. By December 31, 2022; December 31, 2024; and December 31, 2026 or 6 months after the second organizational health survey described in Condition M is conducted, whichever is later, Avera McKennan will perform an effectiveness review of the corrective actions implemented as a result of this Confirmatory Order. The effectiveness review will include: the lessons learned from feedback from the communications and training, if any is received; and the results of the radiation safety program assessment, field observations, and the organizational health surveys. Avera McKennan will modify its corrective actions, as needed and consistent with this Confirmatory Order, based on the results of the effectiveness review. Avera McKennan will send a copy of the

effectiveness review and provide, as applicable, a copy of any additional corrective actions and modifications made to previously developed corrective actions as a result of the effectiveness review to the NRC.

#### Administrative Items

- O. By March 31 of each calendar year 2023 through 2028, Avera McKennan will provide in writing to the NRC a summary of the actions implemented the previous calendar year as a result of the Confirmatory Order.
  
- P. Until December 31, 2028, Avera McKennan will retain a copy of all documentation created to demonstrate compliance with the conditions of the Confirmatory Order.
  
- Q. Documents that are required to be sent to the NRC as a result of the Confirmatory Order conditions will be sent the Director, Division of Radiological Safety and Security, U.S. Nuclear Regulatory Commission, Region IV, by email to [R4Enforcement@nrc.gov](mailto:R4Enforcement@nrc.gov).

In the event of the transfer of the license(s) of Avera McKennan to another entity, the terms and conditions set forth hereunder shall continue to apply to the new entity and accordingly survive any transfer of ownership or license. The Regional Administrator, Region IV, may, in writing, relax, rescind, or withdraw any of the above conditions upon demonstration by Avera McKennan or its successors 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 Avera McKennan, 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](mailto: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](mailto: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 Avera McKennan) 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

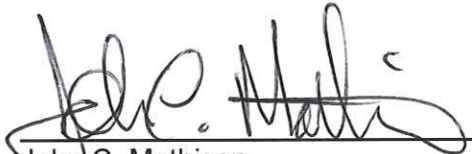
Scott A. Morris  
Regional Administrator  
NRC Region IV

Dated this 19th day of May 2022

# **CONSENT AND HEARING WAIVER FORM**

**CONSENT AND HEARING WAIVER FORM**

Avera McKennan hereby agrees to comply with the terms and conditions of this Confirmatory Order arising out of an alternative dispute resolution mediation session on April 20, 2022, to be issued relating to Enforcement Action EA-21-027. This Confirmatory Order will be effective upon its issuance. By signing below, Avera McKennan 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.

  
\_\_\_\_\_  
John C. Mathison  
Vice President of Specialty Clinics  
Avera McKennan

05-17-22  
Date