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

December 21, 2021

EA-21-027

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

SUBJECT: NRC INSPECTION REPORT 030-39216/2021-002 AND INVESTIGATION REPORT 4-2019-007

Dear Dr. Elliott:

This letter refers to the investigation completed on February 26, 2021, by the U.S. Nuclear Regulatory Commission (NRC) Office of Investigations at the Avera McKennan Hospital in Sioux Falls, South Dakota. The investigation was conducted to determine whether nuclear medicine technologists at the Avera McKennan Hospital willfully manipulated dose calibrator instruments to measure and record, before medical use, lower activity levels for dosages than the dosages actually contained. The NRC's investigation results were discussed with you and other members of your staff during a telephone conversation on November 29, 2021. A factual summary of the investigation is provided as Enclosure 1.

Based on the information acquired during the investigation, two apparent violations were identified and are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The apparent violations involved the failure to determine by direct measurement the activity of dosages before medical use; and the failure to maintain information that was complete and accurate in all material respects. The apparent violations are documented in Enclosure 2. To address the apparent violations described in Enclosure 2, the licensee took action to order replacement dippers for the dose calibrators. In addition, the licensee transitioned its nuclear medicine program to a third-party radiopharmacy for individual patient doses, reducing Avera McKennan's dependence on dose calibrators.

Before the NRC makes its enforcement decision, we are providing you an opportunity to either request a predecisional enforcement conference (PEC) or request alternative dispute resolution (ADR) mediation. If a PEC is held, the PEC will be closed to public observation since information related to an Office of Investigations report will be discussed and the report has not been made public. In addition, the NRC may issue a press release to announce the time and date of the conference. If you decide to participate in a PEC or pursue ADR, please contact Dr. Lizette Roldán-Otero at 817-200-1455 or via email at Lizette.Roldan-Otero@nrc.gov within 10 days of the date of this letter. A PEC should be held within 30 days and an ADR mediation within 45 days of the date of this letter.

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 PEC 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. You should also be prepared to discuss management oversight of activities relating to the apparent violations with specific attention to ensuring compliance with regulations applicable to your nuclear medicine program.

In presenting your corrective actions, 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 NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful in preparing your response. You can find the Information Notice on the NRC website at: http://pbadupws.nrc.gov/docs/ML0612/ML061240509.pdf.

In lieu of a PEC, you may request ADR with the NRC in an attempt to resolve this issue. Alternative dispute resolution is a general term encompassing various techniques for resolving conflicts using a neutral third-party. The technique that the NRC has decided to employ is mediation. Mediation is a voluntary, informal process in which a trained neutral 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 ADR program can be obtained at http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html as well as NRC brochure NUREG/BR-0317, "Enforcement Alternative Dispute Resolution Program" Revision 2 (Agencywide Documents Access and Management System (ADAMS) Accession ML18122A101). The Institute on Conflict Resolution at Cornell University has agreed to facilitate the NRC's program as a neutral mediator. Please contact Institute on Conflict Resolution 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 Enclosure 2 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 "Agency 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 Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy or proprietary information so that it can be made available to the public without redaction.

If you have any questions concerning this matter, please contact Dr. Lizette Roldán-Otero of my staff at 817-200-1455.

Sincerely,

Signed by Muessle, Mary
on 12/21/21

Mary C. Muessle, Director
Division of Nuclear Materials Safety

Docket No. 030-39216
License No. 40-16571-02

Enclosures:
1. Factual Summary
2. Apparent Violations

cc w/Enclosures:
John Priest
Sr. Health Facilities Surveyor-radiation
South Dakota Dept. of Health
Licensure & Certification
4101 W. 38th St.
Sioux Falls, SD 57106

SUBJECT: NRC INSPECTION REPORT 030-39216/2021-002 AND INVESTIGATION REPORT 4-2019-007 - DATED DECEMBER 21,2021

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ADAMS ACCESSION NUMBER: **ML21355A366**

☒SUNSI Review: By: JEV | ADAMS: ☒ Yes ☐ No | ☐ Non-Publicly Available ☒ Publicly Available | ☒Non-Sensitive ☐ Sensitive | Keyword: EA-21-027

OFFICE	DNMS:C:MIB	RIV:ACES	RC	OE	NMSS
NAME	LRoldan-Otero	JGroom	DCylkowski	SWoods	RSun
SIGNATURE	/RA/ E	/RA/ E	/RA/ E	/RA/ E	/RA/ E
DATE	11/22/21	11/30/21	11/30/21	12/16/21	12/16/21
OFFICE	OGC	D:DNMS			
NAME	LBaer	MCMuessle			
SIGNATURE	NLO	MCM			
DATE	12/17/21	12/21/21			

OFFICIAL RECORD COPY

FACTUAL SUMMARY

On February 13, 2019, the U.S. Nuclear Regulatory Commission (NRC) Office of Investigations (OI) Region IV initiated an investigation, in part, to determine whether nuclear medicine technologists at the Avera McKennan Hospital in Sioux Falls, South Dakota, willfully manipulated dose calibrator instruments to measure and record, before medical use, lower activity levels for dosages than the dosages actually contained. The investigation was completed on February 26, 2021.

On September 12, 2017, Manager A was measuring nuclear medicine doses at North Central Heart Hospital. To measure nuclear medicine doses, radioactive material samples (typically contained in a syringe) are placed inside a dose calibrator using a "dipper." The dipper consists of a plastic disk that holds the syringe containing the material in place. The disk is attached to the plastic dipper stem, which lowers the disk and syringe into the dose calibrator for measurement. Manager A noticed that the disk on the dipper at North Central Heart had broken off of the dipper plastic stem and was taped at a higher position than as designed. Manager A correctly identified that the dose measurement would be affected as a result of the disk's placement and shared the observation with Manager B. Because the support disk was placed at a higher position on the dipper stem, the activity levels in the syringe were not measured within the designed measurement range of the dose calibrator. As a result, the measured and recorded activity of the dosage was lower than the dosage the syringe actually contained. (Images comparing a dipper displaying the designed placement of the syringe support disk compared to a modified dipper with the syringe support disk in a newly affixed position are provided below).

Manager B also acknowledged that the modified dippers could not accurately determine and record the activity of the dosage in the syringe before the dosage was administered to the patient. Manager B then visited the main hospital campus and the mobile truck locations and discovered that all dippers at the various Avera McKennan locations – with the exception of the one at the main campus – were physically modified: the syringe support disk had broken off of the dipper stem and was subsequently reaffixed to the stem at a higher level on the stem.

The next day, Managers A and B decided to order new dippers to replace the modified ones. During the time between placing the order and the installation of the new dippers, Managers A and B decided to have the nuclear medicine technologists continue using the modified dippers. The managers stated that they felt that the difference in measurements would not harm patients, and they did not want to prevent potential emergency room patients from getting imaging studies. Instead, the nuclear medicine technologists continued using the modified dippers during that timeframe. As a result, it appears that the activity of each dosage before medical use was not accurately determined and recorded, contrary to the requirements in 10 CFR 35.63.

Based on the evidence developed during the investigation, it appears that Managers A and B engaged in deliberate misconduct in violation of 10 CFR 30.10(a)(1) because, as managers, they permitted the use of modified dippers to determine and record activity levels of dosages before medical use during the period of time between identifying the modified dippers and installing the new dippers, knowing that the practice would cause licensee violations of 10 CFR 35.63.

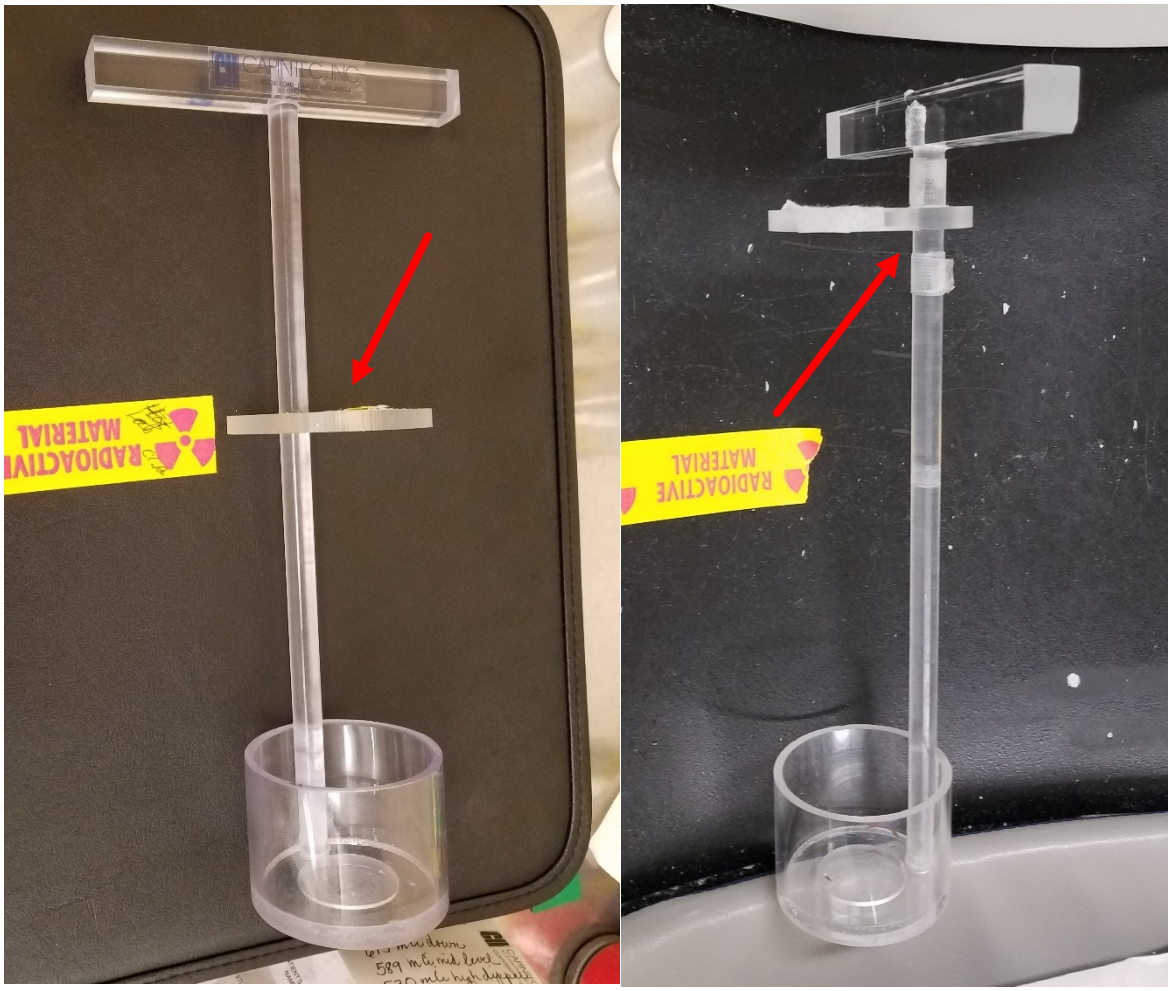

Figure 1 – On the left is an unmodified dipper reportedly used by Avera McKennan in the main hospital hot lab. On the right is an example of a physically modified dipper used by Avera McKennan to measure activity for the dosages of radioactive material intended for administration to patients. The red arrow shows the location where the syringe containing the radioactive material was supported inside the dose calibrator during the measurement. Images provided by Avera McKennan.

SUPPLEMENTAL INFORMATION

Docket:	030-39216
License:	40-16571-02
Report:	030-39216/2021-002
EA No:	EA-21-027
Licensee:	Avera McKennan/Nuclear Medicine
Exit Meeting Date:	November 29, 2021
Regional Contact:	Jason vonEhr, Health Physicist Commercial, Industrial, R&D and Academic Branch Division of Radiological Safety and Security, Region I
Approved By:	Lizette Roldán-Otero, PhD, Chief Materials Inspection Branch Division of Nuclear Materials Safety, Region IV
Attachment:	Additional Information

APPARENT VIOLATIONS

Based on the results of an NRC investigation completed on February 26, 2021, two apparent violations of NRC requirements were identified. The apparent violations are listed below:

A. 10 CFR 35.63(a) requires that a licensee shall determine and record the activity of each dosage before medical use.

10 CFR 35.63(b) requires, in part, that for unit dosages, this determination must be made by direct measurement of radioactivity or a decay correction.

10 CFR 35.63(c) requires, in part, that for other than unit dosages, this determination must be made by direct measurement of radioactivity, a combination of measurement of radioactivity and mathematical calculations, or a combination of volumetric measurements and mathematical calculations.

10 CFR 35.2 defines *unit dosage* as: a dosage prepared for medical use for administration as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

Contrary to the above, from September 12 to approximately 22, 2017, the licensee failed to accurately determine and record the activity of each dosage before medical use. Specifically, the licensee made the determination by directly measuring the activity of dosages before medical use with dose calibrators. The dose calibrators used were physically modified, resulting in inaccurate determinations and records. (030-39216/2021-002-01)

B. 10 CFR 30.9(a) requires, in part, that information required by the Commission's regulations to be maintained by the licensee shall be complete and accurate in all material respects.

10 CFR 35.63(e) requires, in part, that a licensee shall retain a record of the dosage determination required by 10 CFR 35.63 in accordance with 10 CFR 35.2063.

10 CFR 35.2063 requires, in part, that a licensee shall maintain a record of dosage determinations required by 10 CFR 35.63 for 3 years. The record must contain: (1) the radiopharmaceutical; (2) the patient's name or identification number if one has been assigned; (3) the prescribed dosage, the determined dosage, or a notation that the total activity is less than 30 microcuries; (4) the date and time of the dosage determination; and (5) the name of the individual who determined the dosage.

Contrary to the above, from September 12 to approximately 22, 2017, the licensee failed to maintain information required by the Commission's regulations that was complete and accurate in all material respects. Specifically, the licensee created and maintained records of dosage determinations required by 10 CFR 35.63 that contained inaccurate dosage information as a result of physical modification of the licensee's dose calibrators. This was material to the NRC because it demonstrates the licensee's compliance with NRC regulations related to the administration of unsealed byproduct material and the NRC would routinely review this information as part of its inspection oversight. (030-39216/2021-002-02)

Additional Information

INSPECTION PROCEDURES USED

N/A – NRC Investigation Only

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened		
030-39216/2021-002-01	AV	Failure to determine and record the activity of each dosage via direct measurement of radioactivity. (10 CFR 35.63(a))
030-39216/2021-002-02	AV	Failure to create and retain information that was complete and accurate in all material respects. (10 CFR 30.9(a))
Closed		None.
Discussed		None.