

February 15, 2019

U.S. Nuclear Regulatory Commission  
ATTN: Document Control Desk  
Washington, DC 20555-0001

U.S. Nuclear Regulatory Commission  
Regional Administrator, Region IV  
1600 East Lamar Boulevard  
Arlington, TX 76011-4511

RE: Reply to a Notice of Violation  
Avera McKennen: License No.: 40-16571-01  
Docket No.: 030-11252

Dear Sir or Madam:

Please accept this correspondence as Avera McKennen's Reply to a Notice of Violation dated January 24, 2019. Avera McKennen agrees with the inspection report and does not contest that three violations of NRC requirements occurred.

During April through May 2018, Avera McKennen converted from generator use to unit dose supplied by Cardinal Health. The reason for this conversion was based on Avera McKennen's commitment made to the NRC during the predecisional enforcement conference (PEC) on December 1, 2017, to reduce risk in the nuclear medicine department.

REPLY TO NOTICE OF VIOLATIONS "A" & "B"

Regarding the violations identified as "A" and "B", Avera McKennen mistakenly thought that as long as the radioactive shipment delivered by Cardinal Health was not opened, we could take the package in our mobile coach or courier car to the final destination and perform monitoring required by 10 CFR § 20.1906 upon arrival. Avera McKennen was using the Cardinal Health shipping paper for transportation of the package.

As the Radiation Safety Officer (RSO), I became aware of the violations during the NRC inspection conducted on June 14, 2018. All radioactive packages are now monitored per 10 CFR § 20.1906 as soon as practical upon receipt, and if additional transport of the package is needed, a new shipping paper is completed by the Nuclear Medicine Technologist (NMT) prior to transporting the package. For the violations identified as "A" and "B", Avera McKennen achieved full compliance on June 18, 2018.

IED7  
RGNO4  
RGN-TV

## REPLY TO NOTICE OF VIOLATION "C"

Regarding the violation identified as "C", Avera McKennan has updated its Memorandum of Understanding that clearly delineates the authority and responsibilities of the licensee and client. This updated Memorandum of Understanding has been signed by each client. For the violation identified as "C", Avera McKennan achieved full compliance by December 31, 2018.

## SAFETY CULTURE

In addition, the NRC requested that Avera McKennan provide an overview of actions taken to improve safety culture at Avera McKennan, with a focus on safety culture related to NRC licensed activities. Avera McKennan continues to improve safety culture, especially within its Department of Nuclear Medicine (Department). The following information outlines the steps that were taken prior to the PEC held on December 1, 2017. As a reminder, this list was provided to the NRC during the PEC and by email on December 4, 2017.

- September 28, 2015: Shannon Gray was named Manager of the Department. The Manager did not take over day-to-day leadership responsibility until January 1, 2016. The Manager started meeting with staff to get to know them while the former manager was transitioning to his staff role.
- December 31, 2015: Traci Hollingshead, RSO, notified Human Resources (HR) of NRC violations.
- January 2016: Avera McKennan implemented mandatory monthly staff meetings. The following are examples of agenda topics addressed at each monthly meeting: compliance and regulatory items; education; competency of equipment; and review of policies and procedures.
- January 2016: Avera McKennan prohibited NMTs to use personal vehicles to transport Radioactive Material (RAM).
- January 2016: The RSO made more frequent visits to the Department through daily rounding.
- January 2016: Avera McKennan began sending more bulk out to North Central Heart (NCH) in the morning to reduce the need for another run in the afternoon.
- January 2016: Shannon Gray officially begins the role of Manager for the Department.
- January 2016: Avera McKennan instituted a new procedure for wipe testing whereby NMTs would count for a full sixty seconds and equipment was modified accordingly. Avera McKennan updated Policy RS-150 and educated staff.

- January 2016: Avera McKennan terminated the former manager; the former lead technologist was demoted to a NMT role and suspended (unpaid) for 10 days; and issued Final Written Warnings to NMTs.
- January 2016: A Department staff meeting was held to discuss the investigation findings and next steps. The Department staff was informed that Avera McKennan would self-report violations to the NRC.
- January 2016: Avera McKennan audited the daily area surveys and weekly wipe entries on a daily basis and sent out reminders to staff who missed information from the day prior.
- January 2016: Avera McKennan provided HAZMAT training to Department staff by John Wood, consultant with Associates in Medical Physics. Avera McKennan previously provided HAZMAT training in July and August 2015.
- March 2016: Avera McKennan initiated discussions to convert from generator to unit dose.
- March 2016: Avera McKennan initiated discussions on using Nucltrac/NMIS.
- April 2016: The RSO implemented a new process for "car checks" prior to NMTs using personal vehicles. A NMT must demonstrate knowledge of RAM and how it is blocked and braced in the vehicle.
- May 2016: Avera McKennan hired a Mobile Compliance Coordinator (MCC) for the Department. The MCC reports directly to the Manager to ensure the MCC has the appropriate authority and support to do the job. The MCC assists the Manager, the Nuclear Medicine Supervisor (the Supervisor), and the RSO to ensure that a department quality assurance program is established that meets or exceeds state and national nuclear regulatory standards. The MCC works closely with the RSO to reinforce radiation safety in the Department and to address quickly and satisfactorily any variances that may arise. The MCC also assists with performing employee competency evaluations and provides education as needed.
- May 2016: Avera McKennan changed the structure of the Radiation Safety Committee (RSC). The former RSC addressed issues involving both radiology and RAM. The RSC was split so that issues regarding RAM are addressed by its own RSC.
- May 2016: The MCC began to review all aspects of the program to promote best practices including compliance with regulations and manufactures' guidelines.
- May 2016: The MCC began working with the Department focusing on compliance with regulations for mobile coaches.
- May 2016: The Department conducts an annual Authorized User Technologist Supervision review performed by the Authorized User/Medical Director.

- May 2016: The Department staff received education on the role and responsibilities of the Authorized User and the RSO. This education continues by having interactions with the Authorized User and the RSO at monthly staff meetings and is discussed during individual Radiation Safety Reviews. NRC's Nine Safety Culture Traits are also discussed.
- May 2016: The MCC performed a review of records that included surveys and wipe tests and she developed an accountability form if a daily survey is missed by a NMT.
- May 2016: The Department purchased two Ludlum 2241-2 Digital Survey Meters to assess dose-only packages check-ins and to comply with regulations.
- May 2016: The MCC conducted a review of transportation of sealed sources on mobile coaches. As a result of a few deficiencies, changes were instituted to the packaging of RAM to ensure proper labeling.
- May 2016: Avera McKennan eliminated the "continuous" Bill of Lading.
- June 2016: The Manager set expectations for a respectful work environment during the Department staff meeting and employees signed the "Commitment to Coworkers". The Manager reinforces the expectation of a respectful work environment during staff meetings, one-on-one meetings with staff, and employee evaluations.
- July 2016: The RSC implemented a Stop Work Policy. The Stop Work Policy empowers the staff to halt Department activities in certain circumstances. Situations that may warrant a "stop work" include, but are not limited to, conditions that may place a patient, an employee, or the environment at risk of harm. The Stop Work Policy also encompasses situations when Department employees need to pause and ask leaders for clarification.
- August 2016: The Manager and the RSO incorporated the NRC's Nine Safety Culture Traits during staff radiation safety audits.
- August 2016: The MCC began conducting annual radiation safety audits in the field. This allows each staff member to ask questions and develop open communication between the staff, the MCC, and the RSO.
- September 2016: The RSO implemented mandatory one-on-one meetings with newly hired Department staff. The purpose of these meetings is to provide direct education on best practices as well as setting expectations to bring forward safety concerns.
- September 2016: The RSO and the MCC held individual staff education sessions to demonstrate appropriate packaging and labeling of UN2910, White I, and Yellow II packages.
- October 2016: The Department staff received education regarding transportation, shipment and receipt policies; Department of Transportation requirements for shipments and monitoring empty packages; and received a survey meter demonstration.

- October/November 2016: the RSO and the MCC updated the Department's radiation safety policies.
- November 2016: The Manager and the RSO began rounding at NCH, the facility where RAM was shipped that prompted the NRC self-report.
- January 2017: The Department introduced a variance log to track and trend data and report to the RSC on a quarterly basis. Department leadership uses this information to identify areas for improvement.
- February 2017: The Department purchased a Caprac T well counter so that all sites are stand alone.
- April 2017: The Department updated and enhanced its incident reporting form to provide more detail regarding the identified issue.
- April 2017: The Department leadership began meeting with each staff member to ask if employees had any concerns or questions regarding rules, regulations or the culture of safety, and reminded staff they can raise concerns at any time.
- April 2017: The MCC initiated dose reconciliation with results reported to the RSC.
- May 2017: Technologist Supervision review was performed by the Authorized User/Medical Director.
- May 2017: The MCC provided education to the Diagnostic Physicist and the Biomed personnel on transporting RAM.
- June 2017: The Department leadership reviewed the conditions required to maintain Avera McKennan's NRC license at a Department staff meeting.
- July 2017: Department leadership, with staff input, developed a patient information sheet for dose accountability.
- August 2017: The RSO met with David Flicek, Avera McKennan's newly appointed President and CEO, to discuss the nuclear medicine investigation and reviewed the conditions required to maintain Avera McKennan's NRC license.
- August 2017: The Department conducted a survey regarding the culture of safety. Out of the nine categories surveyed, low scores were noted for the categories of Environment for Raising Concerns, Respectful Work Environment, and Questioning Attitude. The results were provided to Department leadership and the RSC. The Department leadership met with staff at a later date to ask for their suggestions regarding communication.
- September 2017: The RSO provided education on the NRC's Nine Safety Culture Traits during a staff meeting. A copy of the NRC's Nine Safety Culture Traits is posted in the

control room and the mobile coaches, and each employee provided with a copy. A standing agenda item at both staff and RSC meetings relates to the culture of safety.

- September 2017: The Department purchased new dose calibrator dippers for all-dose calibrators to ensure uniformity.
- September 2017: The Assistant Vice President of Imaging, the Manager, and HR met with the then current Supervisor to discuss concerns raised by staff in the culture of safety survey. The discussions involved his lack of leadership with the group. Examples discussed included:
  - Not holding staff accountable to their day-to-day functions;
  - Failure to be present to the staff at off-site locations; thus, not recognizing or bringing forward concerns about NMT practice; and
  - Failure to attend leadership development courses.
- September 2017: The supervisor met with the Manager and HR about his decision to step down from his supervisor role and work as a NMT.
- October 2017: The RSO conducted one-on-one meetings with staff.
- October 2017: The Department conducted radiation safety training presented by the Consulting Group of Associates of Medical Physics.

The following is a list of actions taken by Avera McKennan after December 1, 2017. Due to confidential information, this is not an exhaustive list, but provides multiple examples demonstrating Avera McKennan's commitment to improve safety culture. In an attempt to be more responsive, Avera McKennan specifically identifies the applicable safety culture trait(s).

- Safety culture continues to be a standing agenda item at the Department's monthly meetings. [Environment for Raising Concerns; Questioning Attitude; Effective Safety Communications]
- The Department posted the NRC's Nine Safety Culture Traits in the breakroom and in all mobile coaches. [All Safety Culture Traits]
- The Department placed a "Table Tent" of safety culture traits on the work counter in the Department. [All Safety Culture Traits]
- The Manager, RSO, and Supervisor conduct one-on-one meetings with staff. The goal of the meeting is to provide staff with an opportunity to discuss any concern with Department leadership. The RSO asks the staff member if any safety traits are not being met. The RSO tries to conduct these one-on-one meetings with each employee twice a year. [Environment for Raising Concerns; Leadership Safety Values and Actions]

- The MCC conducts an annual Radiation Safety Review with NMTs regarding work-related procedures. [Personal Accountability; Work Processes] The following is specifically evaluated as it relates to the NRC's Nine Safety Culture Traits.
  - NMT is knowledgeable on the NRC's Nine Safety Culture Traits. The MCC conducts an internal inspection and discusses safety culture at the end of the meeting with staff. This is a one-on-one activity. [All Safety Culture Traits]
  - NMT is able to choose one trait and express why he or she believes it is important. [All Safety Culture Traits]
  - NRC Safety Culture Brochure is handed out to the NMT. [All Safety Culture Traits]
- The Department continues to use the variance log. [Problem Identification and Resolution; Effective Safety Communications; Work Processes]
- May 2018: All employees are required to complete annual mandatory education modules as assigned. [Continuous Learning; Respectful Work Environment; Effective Safety Communications].
- July 2018: The Department reviewed the results of the 2018 Employee Engagement Survey with staff. [Respectful Work Environment; Leadership Safety Values and Actions]
- August 2018: The Department conducted a safety culture survey for 2018. [All Safety Culture Traits; Questioning Attitude]. Below are three of the comments received from staff as well as an attempt by Department leadership to address them.
  - "Nuclrac with Cardinal Health." Department leadership began the process of training and implementation of the Nuclrac software system this month, February 2019.
  - "I know it has been tried before to have group get together and not many people came but I'd like to see after meeting gathering attempts. If we grow to trust each other outside of work, then we can begin to trust each other at work and vice versa". The Department arranged for an after-hours, off-site gathering in December where a cookie exchange occurred on December 13, 2017.
  - "More communication from RSO would be great". As noted above, the RSO initiated one-on-one meetings with Department staff.
- November 2018: The Avera Mission, Vision and Values were reviewed at the staff meeting. The Manager thanked the Department for living out Avera's Mission. [Leadership Safety Values and Actions]

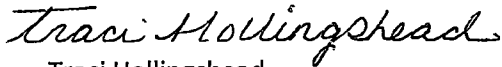
- November 2018: A concern was raised during the monthly staff meeting regarding soiled linen. The concern was that the same people are emptying the soiled linen when the expectation is that everyone has that responsibility. Department leadership emphasized that it is everyone's responsibility to empty soiled linen. [Personal Accountability; Respectful Work Environment; Environment for Raising Concerns]
- November 2018: The MCC discussed an inconsistency regarding dose entering on the thyroid probe. The MCC directed that the actual assay amount and time will be used to maintain consistency. [Work Processes; Problem Identification and Resolution]
- December 2018: Dr. Michael Elliott, Avera McKennan Senior Vice President of Medical Affairs and Chief Medical Officer, addressed the staff to thank them for their efforts since the self-reported RAM issue, changes in the Department, and their commitment to improve the culture of safety. Dr. Elliott reminded the staff that he is available to listen to their questions or concerns. [Leadership Safety Values and Actions; Environment for Raising Concerns]
- December 2018: During the staff meeting, the RSO discussed a new process explaining the flow of therapy administration. At the request of the NRC, a simpler form was developed with a check box and a place for signature. The RSO also discussed the appropriate time out procedure. [Work Processes; Environment for Raising Concerns; Problem Identification and Resolution]
- December 2018: The Department conducted a team-building exercise at its staff meeting. The RSO conducted a paper chain exercise where groups are given instructions on how to make a paper chain as well as a time limit for completion. The goal of this exercise is to build teamwork and improve communication skills among the staff. [Effective Safety Communication; Respectful Work Environment]
- At Present: Avera McKennan is in the process of hiring for the newly-created position of Assistant Radiation Safety Officer (the ARSO). The ARSO will assist the RSO, Manager, and Supervisor to ensure that a Department quality assurance program is established that meets or exceeds state and national radiation equipment or nuclear regulatory standards. The ARSO will ensure radiation safety throughout the practice, implement and monitor the quality assurance program, and work with the Manager, Supervisor, and the RSO to address any variances that may arise for a quick and satisfactory resolution. The ARSO will be assigned the following tasks directly related to the Department. [Leadership Safety Values and Actions; Problem Identification and Resolution; Work Processes; Environment for Raising Concerns]
  - Take the lead in maintaining and monitoring the Nuclear Medicine variance log. Track and trend information and report on the same at the RSC. [Problem Identification and Resolution; Effective Safety Communications; Work Processes]



- Ensure licensed material is properly secured. Ensure licensed material is transported in accordance with all applicable DOT requirements. Ensure licensed material is disposed of properly. [Work Processes]
- Audit Department personnel annually and document any program weaknesses that are identified. [Personal Accountability; Problem Identification and Resolution]

If you have any questions concerning this reply, please contact me at (605) 310-0916.

Sincerely,



Traci Hollingshead  
Radiation Safety Officer

cc: David Flicek, President & CEO  
Dr. Michael Elliott, SVP of Medical Affairs and Chief Medical Officer  
Richard Korman, EVP and General Counsel