

January 8, 2018

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

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Dear Sir or Madam:

Subject: Avera McKenna's Reply to a Notice of Violation; EA-17-104

This letter is in response to the U.S. Nuclear Regulatory Commission Notice of Violation, NRC Inspection Report 030-11252/2017-001 and Investigation report 4-2016-021.

Avera McKenna agrees with the inspection report and does not contest any of the violations. On several occasions Avera McKenna Nuclear Medicine Technologists failed to properly package shipments of radioactive material that were transported on public highways, describe the hazardous material on shipping papers, mark each package containing hazardous material for shipment, label packages for shipment, secure packages containing radioactive material to prevent shifting during normal transportation conditions, and monitor the external surfaces of labeled packages for radioactive contamination upon receipt.

Avera McKenna has determined that the cause of the violations was a poor safety culture and a failure by the former manager and former lead technologist to demonstrate a commitment to safety and adhere to U.S. Nuclear Regulatory rules and regulations as well as Avera McKenna license conditions, policies and procedures.

The corrective action steps taken by Avera McKenna specifically related to the violations are:

- The former manager and former lead nuclear medicine technologist were terminated.
- A third party consultant provided Hazmat training to staff. Previous training occurred in July and August of 2015.
- Temporarily discontinued allowing nuclear medicine technologists to use own personal vehicle to transport RAM.
- Implemented new process of "car checks" prior to nuclear medicine technologist using personal vehicle. Nuclear Medicine Technologist must demonstrate knowledge of radioactive material transportation and demonstrate how they will block and brace radioactive material in their vehicle.

- Began sending more bulk 99mTC out to North Central Heart in the morning to reduce the need for 2nd runs.
- Converting to unit dose instead of generators to reduce shipping from the hot lab.
- Manager and Radiation Safety Officer more frequent visits to the department-daily rounding.
- Hired Mobile Compliance Coordinator. This is a new position in the Nuclear Medicine Department. The Compliance Coordinator reports directly to the Nuclear Medicine Manager. The intent of this direct reporting structure is to ensure the individual has the appropriate authority and support to do his/her job. This individual will assist the Nuclear Medicine Manager, Nuclear Medicine Supervisor, and Radiation Safety Officer to ensure that a department quality assurance program is established that meets or exceeds state and national nuclear regulatory standards. This individual will work closely with the Radiation Safety Officer and help the Radiation Safety Officer reinforce radiation safety throughout the program, implement and monitor the quality assurance program, and work with Nuclear Medicine Manager, Nuclear Medicine Supervisor and Radiation Safety Officer to address any variances that may arise for a quick and satisfactory resolution. This individual may also assist with performing employee competency evaluations and provide education as needed.
- Compliance Coordinator was assigned to look at all program aspects to ensure best practices, regulations and manufacture guidelines are followed.
- Performed an audit of transportation of sealed sources on mobile coaches. Checked for appropriate containers and ensured proper labeling.
- Initiated Bill of Lading for Sealed Sources that did not meet UN2910 criteria. Eliminated the "continuous" Bill of Lading.
- Radiation Safety Officer and Compliance Coordinator held individual staff demonstrations of the packaging and labeling of UN2910, White I, and Yellow II packages. This was a blind box activity.
- Reviewed transportation, shipment and receipt policies with staff at staff meeting.
- Compliance Coordinator provided education on DOT shipments. Also introduced monitoring empty packages.
- Avera McKennan Nuclear Regulatory Commission license condition review education at staff meeting.

Other program enhancements by Avera McKennan that have been made to improve safety culture include:

- Implemented monthly staff meetings where mandatory attendance is required. Compliance, regulatory items, education, competency of equipment, and review of policies and procedures are discussed.
- Auditing the daily area surveys and weekly wipe entries on a daily basis.
- Changed the structure of the Radiation Safety Committee meetings. Split into two different meetings one for materials and the other for radiology allowing more focus on materials division.

- Annual Authorized User Technologist Supervision review performed by the Authorized User/Medical Director.
- Began education with Nuclear Medicine Staff on the role and responsibility of the Authorized User and Radiation Safety Officer pertaining to the importance within the Nuclear Medicine Program. This education continues currently by having staff interactions with the Authorized User and Radiation Safety Officer at monthly meetings. This topic is discussed during individual Radiation Safety Reviews. NRC Safety Culture traits are also discussed.
- Nuclear Medicine Manager set expectations for a respectful work environment.
- Radiation Safety Committee implemented stop work policy.
- Incorporated discussion items about the Nuclear Safety Culture 9 Traits during staff radiation safety audits.
- Safety Culture Survey completed by staff.
- Compliance Coordinator began doing annual radiation safety audits in the field. This allows one on one time to ask questions and develop open pathways for communication between the staff, coordinator, and Radiation Safety Officer.
- Implemented new process where all new staff must meet with the Radiation Safety Officer.
- Updated the Nuclear Medicine Radiation Safety Policies.
- More frequent visits to North Central Heart by Manager and Radiation Safety Officer.
- Variance log implementation.
- Updated and enhanced incident reporting form.
- Management began holding one on one meeting with staff. Manager asks employees if they have any concerns or questions regarding rules, regulations or safety culture. Remind staff they can raise concerns at any time.
- Compliance Coordinator initiated dose reconciliation. Authorized User reviews report quarterly. Compliance Coordinator reports results to Radiation Safety Committee.
- Provided education to Diagnostic Physicist and Biomed on transporting radioactive material.
- Radiation Safety Officer began one on one meeting with staff.

Full compliance was achieved in January 2016.

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

Sincerely,

Traci Hollingshead

Traci Hollingshead
Radiation Safety Officer