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AveraMcKennen.org

February 16, 2016

Nuclear Regulatory Commission
Nuclear Materials Safety Branch B
Region IV
1600 East Lamar Boulevard
Arlington Texas 76011

RE: NRC license #40-16571-01

To Whom It May Concern:

The intent of this letter is to provide notification to the NRC that Avera McKennan has identified violations that have occurred in our program.


It was brought to my attention on December 30, 2015, that there was noncompliance occurring in the Nuclear Medicine Department regarding NRC regulations as well as Avera McKennan's NRC license conditions.

A full investigation was performed and documented. Attached to this letter is a summary of the findings as well as Avera McKennan's short and long term plans to prevent any future noncompliance. To the best of my knowledge, I believe the following to be true:

1. 10 CFR 35.3045 does not apply to this event. This event did not involve a patient.
2. This is a violation of Avera McKennan's NRC license condition number 15.
3. This is a violation of NRC Regulations 10 CFR 71.5 Transportation of licensed material which includes:
 - (i) Packaging -49 CFR part 173;
 - (ii) Marking and labeling-49 CFR part 172
 - (iii) Placarding-49 CFR part 172;
 - (v) Shipping papers; and
4. 10 CFR 71.8 Deliberate misconduct.

If you have any questions or need additional information, please contact me at (605) 310-0916 or by email at traci.hollingshead@avera.org.

Sincerely,


Traci Hollingshead
Radiation Safety Officer
Avera McKennan



Action Plan

Short term

1. After reviewing the findings of the investigation, Aver McKennan determined that the former manager of the Nuclear Medicine Department would be terminated immediately. The Lead Nuclear Medicine Technologist was placed on a ten (10) day unpaid suspension and the "Lead" title and duties have been removed from his responsibilities. The two Nuclear Medicine Technologists who were identified through the investigation were placed on corrective action.
2. A meeting was held on January 13, 2016, to discuss the investigation findings and next steps. The nuclear medicine staff was informed that Avera McKennan would self report the violations to the NRC.
3. John Wood, consultant with Associates in Medical Physics, provided Hazmat training on January 26, 2016. Attendees included Department Manager, RSO, Medical Director and all Nuclear Medicine Technologists. Previous training occurred in July and August of 2015.

Long term

1. The Nuclear Medicine Manager and Nuclear Medicine Supervisor will coordinate educational monthly staff meetings. Education will be ongoing and will include topics specific to nuclear medicine operations. Education will focus on regulatory issues, compliance, competency of equipment, and review of policies and procedures. The first meeting will be held in March, 2016.
2. Avera McKennan will be adding a new position in the Nuclear Medicine Department. This new position will be a Compliance Coordinator (exact position title may be subject to change). The Compliance Coordinator will report 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 their 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.