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From: Traci Hollingshead [mailto:Traci.Hollingshead@avera .org]
Sent: Wednesday, February 24, 2016 9:30 AM
To: Torres, RobertoJ <RobertoJ.Torres@nrc.gov>
Subject: [External_Sender] Avera McKennan 40-16571-01

Mr. Torres,

I'm writing to you to notify the NRC of some violations that I have discovered in our Nuclear Medicine department. Attached are the details of the findings and our action plan. Please let me know if you need anything else from me.

Thank you,
Traci Hollingshead

Traci Hollingshead
Radiation Safety Officer
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December 30, 2015

Nuclear Medicine Manager was informed by the Nuclear Medicine Supervisor that there are issues of non compliance regarding the Nuclear Regulatory Commission regulations. Nuclear Medicine Manager notified the Radiation Safety Officer and the Assistant Vice President (AVP) of Radiology. A meeting was set up to discuss the issues that have been raised.

December 31, 2015

Radiation Safety Officer contacted Human Resources (HR) to discuss the alleged noncompliance activities that were brought to our attention. Radiation Safety Officer asked HR Partner for a consultation from the HR perspective. A meeting was set up for 1/4/16 to discuss next steps.

January 4, 2015

Meeting was held with AVP of Radiology, Nuclear Medicine Manager, Radiation Safety Officer, and Human Resources Partner to discuss the information of alleged noncompliance that was brought to our attention. During the meeting, it was decided that HR would consult with legal and that we would initiate a full investigation of the Nuclear Medicine staff.

January 5, 2016

Radiation Safety Officer contacted the Chief Medical Officer and the Assistant Vice President of Outpatient Cancer Clinics and informed them of the alleged noncompliance activities and the intent to initiate a full investigation. Radiation Safety Officer also informed the Chief Medical Officer and the Assistant Vice President of Outpatient Cancer Clinics that she would be reaching out to Roberto Torres, with the NRC, for consult. The Chief Medical Officer and the Assistant Vice President of Outpatient Cancer Clinics were supportive of consulting with the NRC and initiating a full investigation.

Radiation Safety Officer contacted Risk Management. Risk Management stated this event was an Avera Human Resources and employee exposure issue; therefore, Risk Management would not be involved in the investigation.

Human Resources Partner contacted the Avera Office of General Counsel and one of its staff attorneys.

Radiation Safety Officer reached out to (Roberto Torres from the NRC and requested a call.

January 6, 2016

The investigation began with employee interviews. Nuclear Medicine Manager, Radiation Safety Officer, and Human Resources Partner were present for the interviews. The investigation included interviewing all of the Nuclear Medicine Technologists regarding the following alleged noncompliance:

> It was brought to Avera McKennan's attention that there may have been some regulatory violations occurring "regularly" in the Nuclear Medicine Department. If so, these actions would

be violations under the Avera Nuclear Regulatory Commission License (NRC) as well as Department of Transportation (DOT) rules and regulations.

Specifically, there has been bulk technetium-99m delivered to North Central Heart, a licensed facility under item 10.D. of Avera McKennan's NRC licnese, without preparing the proper shipping documents, packaging,and following proper transport of a hazardous material. The bulk technetium-99m vial was placed in a lead pig, then in a plastic baggie, and taken over to North Central Heart. No shipping papers, no placarding, markings, labels, no ammo can, no blocking, and no bracing. When the bulk technetium-99m was delivered in this manner, there was no package check-in and surveys performed.

Nuclear Medicine Manager, Radiation Safety Officer, and Human Resources Partner met with nine (9) Nuclear Medicine Technologists. Each Technologist was asked the following questions:

1. How do you transport doses or bulk radioactive material to North Central Heart?
2. Have you observed any nuclear medicine staff not complying with NRC or DOT rules and regulations regarding proper shipping and receiving of radioactive material?
3. What are the details of your observation?
4. How long has this been going on with regards to noncompliance?
5. Did you raised the concern with anyone? What was the outcome?
6. Did you ever engage in noncompliance with NRC or DOT rules and regulations regarding proper shipping and receiving of radioactive material?
7. Are there any other unsafe activities or other noncompliance activities you want to address?

Two employees were placed on paid leave while the investigation took place. The first employee was the former Nuclear Medicine Department Manager and the second was a Lead Technologist in the Department. In addition to the Manager and the Lead, two other staff members were identified several times throughout the investigation as individuals who inappropriately transported the isotope.

January 7, 2016

The employee interviews continued. Nuclear Medicine Manager, Radiation Safety Officer, and Human Resources Partner were present for the interviews. The remaining 9 Nuclear Medicine Technologists were interviewed. Each technologist was asked the same questions as listed above.

Radiation Safety Officer spoke with Robert Torres, Senior Health Physicist, Region IV-Division of Nuclear Materials Safety, United States Nuclear Regulatory Commission. Radiation Safety Officer informed Mr. Torres that there were events identified that are not in compliance with Avera McKennan's license conditions. The noncompliance was not reportable under a medical event in 10 CFR part 35. Mr. Torres advised the Radiation Safety Officer to continue with the investigation and when complete, submit the documentation to the Nuclear Regulatory Commission to self-identify and report the noncompliance.

January 8, 2016

Nuclear Medicine Manager, Radiation Safety Officer, and Human Resources Partner discussed the findings.

The findings were as follows:

On the second isotope run out to North Central Heart, which is about 5 miles from the Avera McKennan main campus hot lab, it was a consistent practice that the bulk technetium-99m was taken out of the department not properly packaged, placarded, and without shipping papers. When the package was delivered in this manner, the package receipt was not performed at North Central Heart. Although it was fairly consistent practice for the package to be delivered in violation, there were times that it was done appropriately.

Through the investigation, Avera McKennan learned that this practice had occurred fairly consistently for at least two (2) years. The majority of the Nuclear Medicine staff identified the former Nuclear Medicine Manager as the person who primarily was responsible for transporting the second run of isotope out to North Central Heart, although it is likely that all staff at one point were responsible for transporting the isotope to North Central Heart.

Based on their job duties as the hot lab technologists, certain personnel were more likely than others to prepare and transport this second run.

It was identified that the majority of the Nuclear Medicine Technologists observed the dose being transported inappropriately and/or not received according to Avera policy and Nuclear Regulatory Commission regulations at North Central Heart. When the dose was shipped in this manner, no package receipt was performed or documented.

During the investigation, the question was asked to all the Nuclear Medicine Technologists whether or not they understood that transporting the isotope in this manner was not in compliance with NRC and DOT regulations. All the Nuclear Medicine Technologists stated that they understood these practices were not compliant with the Department of Transportation and Nuclear Regulatory Commission regulations.

The Nuclear Medicine Technologists were also asked if they brought up these concerns or questioned the practice. None of the technologists raised concerns or brought the issue forward. The question was then asked why they had not brought this issue or concerns forward. Comments were as follows:

"Who do you tell when your supervisor is the one doing this?"

"People who are supposed to be setting the example are the worst offenders."

"Questioned it at first but was told this is how we do it."

"Who would you question?"

"It's not harming anyone."

"I trusted my manager; he was doing it so I thought it was ok."

"If the manager is doing it that way why ask?"

"The leader of the department is doing it. Doesn't make it right, but what are you going to do?

January 11, 2016

A meeting was held to discuss the investigation findings and next steps. The following people were present at the meeting:

Radiation Safety Officer;
Human Resources Officer;
Human Resources Partner;
Attorney, Avera Office of General Counsel;
Manager, Nuclear Medicine & PETCT;
Assistant Vice President of Imaging; and
Chief Medical Officer.

In review of the Nuclear Regulatory regulations, it appears that:

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

Please see Avera McKennan's Action Plan, which is attached, to address the issues identified in this investigation.