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May 18, 2018

U.S. Nuclear Regulatory Commission
Document Control Desk
Washington, D.C. 20555-0001

Subject: Reply to a Notice of Violation (EA-17-182)

Dear Mr. Morris:

The purpose of this letter is to provide a written response to the notice of violation regarding an inspection conducted June 27-30 2017. For reference, numbers included in the violation are Docket: 3-13426, License: 50-17838-01, EA-17-182. The notice of violation detailed 3 violations summarized below.

A. Written Directives were not being signed and dated by an Authorized User prior to the administration of therapeutic doses of radiation from byproduct material. This occurred from January 1, 2015 to June 27, 2017 with the Y-90 treatments occurring inside of the Radiology Department.

B. Written procedures for the delivery and procedures for use of Y-90 microspheres were not followed. This occurred from January 1, 2015 to June 27, 2017. Specifically the procedure stated that a medical physicist was to review the written directive and calculation prior to ordering. The review failed to be performed.

C. The NRC license guidance on Y-90 Microsphere Brachytherapy requires that all staff involved with the procedure have training commiserate with their duties and responsibilities. Staff did not have the required training. Specifically the nuclear medicine technician that was ordering the sources was not trained in the ordering, measuring, and preparation process for Y-90 microspheres. This occurred from October 28, 2015 to June 27, 2017.

Full details of the specific regulations can be found in the notice of violation, 10CFR35.40(a), 10CFR35.41(a), and Yittrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere and SIR-Sphere License Guidance February 12, 2016 Rev 9.

Specific elements required to be examined by the notice of violation and 10CFR2.201 are summarized below.

1. Reason for violation

   A. Written directives were being signed by the AU after completion of the procedure. The Written Directive spreadsheet provided from the manufacture included items that needed to be filled out after the implant. There was also a section for corrected written directive for stasis or other medical reasons the implanted activity had to be changed. The second signature block for corrected written directive was being signed after the implant and not the

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before implant signature block prior to the implant. Lack of proper training of staff involved in the ordering process created confusion and the need to complete the first portion of the form was not understood. Staff and the Authorized Users did not understand that it was necessary for the AU to sign the directive prior to the implant occurring. The procedure specifying a medical physicist which was also the RSO was not being followed and the forms were not being checked prior to ordering. Lack of oversight contributed to the failure.

B. In Early 2015 the Y-90 implant program was transferred from the Radiation Oncology Department to the Nuclear Medicine group within the Department of Radiology. During this hand off process the procedure was not updated to reflect the new work flow. A failure occurred to evaluate all staff responsibilities and clearly define the new process in Nuclear Medicine. A new workflow was adopted by Nuclear Medicine which deviated from the original procedure. The reason for the transfer between departments was a lack of staff within Radiation Oncology. The former RSO did not have adequate time and believed that it was the responsibility of the Nuclear Medicine Department to conduct the evaluation. Unfortunately, the staff within Nuclear Medicine did not have the relevant specialized expertise in probabilistic risk assessment and developing procedures for delivering therapeutic doses of radiation. Historically there had been an assistant RSO within Radiology that had conducted some oversight of radiation safety in Radiology. That staff member had left PAMC and the radiation safety duties were not properly transferred to another member of the Radiology Department. The position of the ARSO within Nuclear Medicine had been eliminated by administration and the duties transfer to other nuclear medicine technicians without experience or training in the more rigorous process required for therapeutic doses of radiation. The former RSO was not conducting oversight of Nuclear Medicine believing that oversight was the responsibility of the nonexistent Assistant RSO within Nuclear Medicine. The former RSO was over obligated with medical physics duties within Radiation Oncology and could not absorb the responsibilities that had been performed by the ARSO. The former RSO had not communicated this to hospital administration or the Radiation Safety Committee. Lack of staff, lack of oversight, and lack of clear lines of responsibility were the primary reasons for the breakdown of procedures.

C. With the transfer from Radiation Oncology to Nuclear medicine a failure occurred to evaluate all staff involved and train them commiserate with their duties. As detailed in B the program was transferred without adequate oversight by the RSO.

2. Corrective Steps that have been taken and the results achieved:

I. After an evaluation of the root cause, our corrective actions included:

a. Performance of a series of audits to identify deficiencies.
b. Process change for the preparation and review of written directive, the ordering of Y-90 doses, and the verification of Y-90 microsphere vial activities against the written directive.
c. To reflect the process change we revised the written procedures for performing Y-90 microspheres administrations
d. Staffing changes.
e. Retraining staff involved with Y-90 microsphere procedures.
f. Providing additional Radiation Safety oversight of the Y-90 microsphere program.

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g. Engaging the Y-90 microspheres vendor to incorporate feedback on the ordering process.

II. The results we have achieved from the above corrective actions.

a. The audit was conducted by several members of the staff and an external consultant. The audit provided a thorough evaluation of the process from several different perspectives and allowed us to identify several areas of failure and develop changes necessary to improve safety.
b. We evaluated the entire process and developed a process flow diagram detailing each step of the work. Each step was evaluated to ensure that work was double checked to ensure if there was a mistake by one person a second person would catch the error. Having a clear process flow diagram with defined responsibilities has increased reliability.
c. Utilizing the process flow diagram we developed an updated procedure to reflect the new process. We discontinued the use of the treatment window illustrator in favor of the more straightforward online iDoc application as well as a second calculation performed by the Radiation Oncology medical physicist using an independent spreadsheet. Updating the procedure has increased the reliability of the system.
d. An additional medical physicist was added and the RSO was replaced with a medical physicist that possessed more experience in radiation safety and probabilistic risk assessment. We have also engaged a consulting to assist with radiation safety oversight within Radiology. The new RSO has also been taking a more proactive approach hospital wide. Tangible progress has been made on several projects throughout the hospital.
e. All staff have completed training in areas commensurate with their duties as defined by the process flow diagram. The duties of the nuclear medicine technician have been reduced to reflect their training and experience. The initial calculation of ordered activity have be given to the authorized user with a second calculation and order check done by a medical physicist.
f. Additional radiation safety oversight is in place with the medical physicist reviewing each order prior to placing the order. This review has also included verifying the signature and dating of the written directive. The senior medical physicist is also the new RSO.
g. We worked with the vendor to provide feedback on some of the spreadsheet used for the written directive. We were able to add two checks where significant differences between ordered activity, desired activity, and measured activity displayed a caution to the users.

Implementation of all of this activities have increased the reliability and safety of the Y-90 system.

3. Corrective steps that will be taken

   All corrective actions have been taken.

4. Date when full compliance will be achieved

   Completion of the above mentioned changes was achieved in April 2018.

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Under the guidance of NRC Information Notice 96-28 a review of our corrective action plan is detailed below:

1. Conduct a complete and thorough review of the circumstances that led to the violation.

   In the early 2010s several staff members associated with health and medical physics support within the hospital moved on to other positions. These positions were eliminated or not fully replaced. This included the nuclear medicine technician that also acted as ARSO in Radiology and the second medical physicist in radiation oncology. The Radiation Safety Officer for the hospital was assigned as the sole medical physicist for Radiation Oncology. The lack of staff resulted in several Radiation Safety duties being neglected.

2. Identify the root cause of the violation.

   In early 2015 the Y-90 microsphere implant program was transferred from Radiation Oncology to Nuclear Medicine. This hand off was necessary because of a lack of staff within Radiation Oncology. Nuclear medicine staff did not have the necessary expertise to appreciate the rigorous requirements necessary for delivering therapeutic doses of radioactive material. The RSO did not have enough time to supervise the transfer. A mistake was made with ordering the incorrect radioactive material that was not discovered. Because of the lack of oversight and not updating or following procedures the patient was administered the incorrect activity.

3. Take prompt and comprehensive corrective action that will address the immediate concerns and prevent recurrence of the violation.

   As specified above several actions have been taken to address the immediate concerns including: audits, process changes, staffing changes, retraining, oversight, engaging the manufacturer, updating procedures.

   1. Has management been informed of the violation(s)?

      Management was informed of the violations.

   2. Have the programmatic implications of the cited violation(s) and the potential presence of similar weaknesses in other program areas been considered in formulating corrective actions so that both areas are adequately addressed?

      The process of signing written directives in radiation oncology was reviewed. It was confirmed that the written directive form is signed by the AU and confirmed by the AMP prior to using the HDR Ir-192 after loader. Prostate seed Brachytherapy has been discontinued. The signature of the AU is confirmed prior to ordering for I-131 for thyroid therapy as well as Xofigo Ra-223 therapy.

   3. Have precursor events been considered and factored into the corrective actions?

      There was a second order that had the wrong delivery date that was caught by the RSO. This occurred between audits and redefining the procedure. Checking the ordered date and verifying that it matched the patient's appointment in the Cath Lab was added into the check process. The person scheduling the patient's treatment was also tasked with completing the

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initial order form with the AU. This removed a possible source of error with coping the information and removed a hand of.

4. In the event of loss of radioactive material, should security of radioactive material be enhanced?

   N/A, No radioactive material was lost.

5. Has your staff been adequately trained on the applicable requirements?

   All staff have been retrained to match their responsibilities as defined by the process map.

6. Should personnel be re-tested to determine whether re-training should be emphasized for a given area? Is testing adequate to ensure understanding of requirements and procedures?

   A dry run was performed with a fictitious patient to verify the process.

7. Has your staff been notified of the violation and of the applicable corrective action?

   All staff involved with the ordering process have been informed of the violation and new ordering procedure.

8. Are audits sufficiently detailed and frequently performed? Should the frequency of periodic audits be increased?

   At the end of each patient treatment paperwork is sent to the RSO/medical physicist for final review.

9. Is there a need for retaining an independent technical consultant to audit the area of concern or revise your procedures?

   An independent consultant was contracted to audit the process. The new RSO attended the Health Physics Society midyear meeting with a special session on Y-90 microsphere delivery and attended training by the manufacture. This allowed us to compare our process to others in the industry.

10. Are the procedures consistent with current NRC requirements, should they be clarified, or should new procedures be developed?

    New procedures were developed and submitted to the NRC.

11. Is a system in place for keeping abreast of new or modified NRC requirements?

    I reviewed the draft Y-90 Rev 10 guidance. The consultant contracted to provide extra radiation services regularly keeps abreast of any updates. I review any notices sent by the NRC.

12. Does your staff appreciate the need to consider safety in approaching daily assignments?

    Staff understands the necessity to follow safe work practices.

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13. Are resources adequate to perform, and maintain control over, the licensed activities? Has the radiation safety officer been provided sufficient time and resources to perform his or her oversight duties?

    The RSO has been provided enough resources. An external consultant has been contracted to provide specialized expertise and assistance with various projects. An effort was undertaken to streamline the RSO duties. All survey instruments are no longer calibrated by the RSO, but sent to an outside vendor. We are in the process of disposing of approximately 50 legacy sources. This will reduce the inventory and swipe testing burden on the RSO. Some of the duties formerly assigned to the assistant RSO were incorporated into the manager of nuclear medicine. Through training provided by the RSO, It has been emphasized to staff that monitoring of personnel for daily safe work practices is everyone's responsibility. Syntrac is used to track radioactive material. The software has been installed on the RSO's computer allowing him to electronically monitor all radioactive material in the hospital from his desk.

14. Have work hours affected the employees' ability to safely perform the job?

    Fatigue from overwork has not impacted staff's ability to safely perform their jobs.

15. Should organizational changes be made (e.g., changing the reporting relationship of the radiation safety officer to provide increased independence)?

    The RSO reports to a quarterly environment of care meeting with senior level management.

16. Are management and the RSO adequately involved in oversight and implementation of the licensed activities? Do supervisors adequately observe new employees and difficult, unique, or new operations?

    The RSO acting as the AMP has direct involvement with the use of radioactive materials in Radiation Oncology and regular meetings with staff in Radiology. Supervisors adequately observe new staff and verify credentials prior to work.

17. Has management established a work environment that encourages employees to raise safety and compliance concerns?

    The hospital has a web based program through with staff can anonymously submit concerns.

18. Has management placed a premium on production over compliance and safety? Does management demonstrate a commitment to compliance and safety?

    With this incident more resources have been allocated to radiation safety. Management had not been made aware of the problems that had been created by cutting staff.

19. Has management communicated its expectations for safety and compliance?

    Safety compliance has been included in required annual training for all staff. A short portion of this includes radiation safety for non-radiation workers. For radiation workers, a more detailed online training class is required annually. The COO is a member of the RSC.

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20. Is there a published discipline policy for safety violations, and are employees aware of it? Is it being followed?

    There is no safety policy specifically, each violation is handled on a case by case basis. The annual complain training class states that violations can result in discipline up to and including termination.

Sincerely,

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