From:	Shivji, Shabbir CIV (USA)
To:	Elliott, Robin
Cc:	Seeley, Shawn; Reyes, Ricardo A COL USARMY DHA DHSS (USA)
Subject:	[External_Sender] BAMC Corrective Actions RE: 09-12 Dec NRC Inspection (UNCLASSIFIED)
Date:	Wednesday, February 12, 2020 9:57:32 AM
Attachments:	BAMC Corrective Actions 9-12Dec2019 NRC inspection.docx

CLASSIFICATION: UNCLASSIFIED

Good Morning Robin,

Further to the exit meeting, I am attaching the Corrective Actions to the findings with regards to the NRC's BAMC inspection of 09-12 Dec, 2019.

Please let me know if you require any further information.

r/y

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Health Physicist
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*Don't Trust Atoms,
They Make Up Everything!*

CLASSIFICATION: UNCLASSIFIED

Brooke Army Medical Center
Corrective Actions to Findings Identified during 9-12 December 2019 NRC Inspection

#	Cited Regulation/Requirement	Observed Potential Violation	Cause/Contributing Factors	Corrective Action(s)
2	10 CFR 20.2001(a). Improper disposal of radioactive material.	NRC inspectors determined that a corrective action implemented to address the loss of licensed material reported to the NRC Operations Center on 11 April 2019 (Event Notification #53992) was not effective. The on-line radioactive seed tracking log, a reported corrective action, was not updated in a timely fashion, and 17 seeds indicated in log as placed in decay-in-storage (DIS) trailer were instead stored in a staff-member's drawer	While transporting radioactive seeds from Histology to the DIS trailer, staff member stopped in his office update the on-line tracking log since there is no computer access at DIS trailer. Staff member did not immediately transport the seeds to the DIS trailer. Staff member stored the seeds in his locked desk drawer to be transported to the DIS trailer with other waste at a later time. Staff member was not aware the amount of radioactivity of the seeds in question exceeded thresholds requiring posting and other controls. Radioactive waste management, security, and control requirements were published in the BAMC Ionizing Radiation Safety Program (BAMC Memo 40-72), which may have contributed to the lack of awareness. A more specific radioactive waste management procedure might have prevented this action.	Update radioactive seed tracking form to include entry to update on-line tracking log. Publish policy to specify tracking requirements. Transition to technology that does not involve NRC licensed material.
2	10 CFR 20.2001(a). Improper disposal of radioactive material.	17 radioactive I-125 seeds were stored in a staff member's office drawer. The staff member's office is not an approved area of use or storage.		Retrained staff member on 10 CFR 20 Appendix C quantities of radioactive material and associated requirements. Publish separate radioactive waste management procedure.
3	10 CFR 20.1902(e). Did not post an area in which licensed material was used or stored in amounts exceeding 10 times the quantity of such material specified in appendix C to part 20 with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)."	17 radioactive I-125 seeds were stored in a staff member's office drawer. The staff member's office is not an approved area of use. The quantity of radioactive material exceeded amounts above which signage is required.		
4	Contrary to the licensee's approved radiation safety program (BAMC Memo 40-72, Paragraph 7.1.3.6), food and drink were stored in an area where radioactive material was stored.	17 radioactive I-125 seeds were stored in a staff member's office drawer. The staff member's office is not an approved area of use. Food and drinks were stored and consumed in the office.		

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#	Cited Regulation/Requirement	Observed Potential Violation	Cause/Contributing Factors	Corrective Action(s)
5	10 CFR 35.40(b) Written directive signed and dated by AU prior to administration must contain the radioactive drug, dosage, and route of administration	Five (5) written directives for the administration of Xofigo (Ra-223) that did not contain the required dosage information. Instead, the authorized user had written a dose per patient mass (microcurie/kg) value in place of a dosage value (microcurie).	Manufacturer's literature references dosage in terms of dose per kilogram. AU completed written directives prior to the day of treatment. Per the manufacturer, the dosage to be administered is calculated in terms of volume and is based on the patient's mass and the radioactivity concentration of Xofigo on the day and time of treatment. AU considered the 'dosage' as described the Manufacturer's prescribing information to meet the 'dosage' requirement of the written directive. Quality management program reviews did not identify these written directive content errors during post-treatment, quarterly, and annual reviews. Nuclear Medicine written directive is part of the regimen specific treatment form, which contains a significant amount of other patient treatment information. The required written directive information is not easily distinguishable from the other patient procedure information on treatment form.	Retrain Authorized Users on the unique Xofigo written directive dosage documentation requirements, including dose administered, given the manufacturer's prescribing information. Publish BAMC policy for therapeutic radiopharmaceutical administrations standardizing regimen specific written procedures and written directives in order to meet 10 CFR 35 requirements, including review and approval by the BAMC Radiation Safety Committee. Update regimen specific written procedures and written directives.

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#	Cited Regulation/Requirement	Observed Potential Violation	Cause/Contributing Factors	Corrective Action(s)
6	10 CFR 35.41(a). Did not implement written procedures to provide high confidence that administration is in accordance with the written directive.	Inspectors observed a Y-90 SirSphere therapy procedure. There were three Y-90 settings labeled on the dose calibrator used to determine the actual activity of the dosage to be administered. It was not apparent which of the three settings was the correct. The medical staff administering the Y-90 SirSpheres were not observed using any written procedures or checklists to verify that the administration was in accordance with the written directive (e.g. correct activity to be administered).	Written procedures did not adequately address dose calibrator settings. There is no BAMC policy requiring the use of forms or checklists to list minimum actions and verifications necessary to ensure an administration is in accordance with the written directive.	Publish BAMC policy for therapeutic radiopharmaceutical administrations standardizing regimen specific written procedures and written directives in order to meet 10 CFR 35 requirements, including review and approval by the BAMC Radiation Safety Committee. Update regimen specific written procedures, checklists, and written directives. Retrain Authorized Users on the 10 CFR 35 requirements regarding therapeutic procedures, including written directive requirements.
7	10 CFR 35.41(a). Did not implement written procedures to provide high confidence that administration is in accordance with the written directive.	Inspectors observed a Lutathera (Lu-177) therapy procedure. Written procedures for the administration of Lutathera were reviewed and approved by the BAMC RSC. Nuclear medicine technologists had created a separate checklist and drawing to use as aids during the administration of Lutathera. The checklist and drawing were not reviewed and approved by the BAMC RSC. Medical staff administering the Lutathera were not observed referencing the approved written procedure nor the unapproved checklist/drawing to ensure or verify that the administration was in accordance with the written directive.	There is no BAMC policy requiring the use of forms or checklists to list minimum actions and verifications necessary to ensure an administration is in accordance with the written directive.	