

MARIAN MEDICAL SERVICES

906 Kingsridge Ct. | Wildwood, MO 63021 | 636.220.8228

November 23, 2021

U.S. Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, DC 20555-0001

Subject: Response to Apparent Violations in
NRC Inspection Report 030-37399/2021-001; EA-21-120

Dear Nuclear Regulatory Commission,

This is in response to four apparent violations identified during an inspection of our facility conducted from April 27, 2021 through October 12, 2021. The first violation involves securing and maintaining constant surveillance of licensed material from unauthorized removal or access to the materials that are stored in controlled or unrestricted areas. The violation states "contrary to the above, from January 15, 2019 to June 23, 2021, the licensee failed to: (1) secure from unauthorized removal or access licensed materials that were stored in controlled or unrestricted areas, and (2) control and maintain constant surveillance of licensed material that was in a controlled or unrestricted area and that was not in storage." It also notes that, "The licensed materials were relocated to an unrestricted area and the licensee failed to maintain constant surveillance of these licensed materials." We agree with these violations.

Root Cause: As noted in the inspection report, MMS was contracted to provide nuclear cardiology services to a medical practice in Anchorage, AK. There was a business/management agreement that MMS entered into with a couple individuals that operated the medical practice. After they failed to produce an adequate amount of patients for the service, they unilaterally decided to terminate our nuclear technologist, and to close our bank accounts. We engaged legal council, and were working towards filing a complaint. During that time, we were instructed not to make any direct contact with the other parties. We acknowledge that this was not responsible to leave the Anchorage facility unattended, and that the pending legal action should not have taken precedence to securing and properly disposing of the materials.

Corrective Actions: The RSO called Individual A notifying him of the issue, and made travel arrangement to ascertain the status of the licensed materials. On June 7, 2021, the RSO located and inventoried the licensed materials and performed leak test samples. The RSO analyzed the leak test samples on June 12, 2021, and they showed no evidence of leakage. On June 14, 2021, The RSO ordered and shipped the proper containers to Anchorage for disposal of the licensed materials. On June 23, 2021, the RSO travelled back to Anchorage and shipped the five sources to an NRC licensed entity for disposal. On June, 28, 2021, the NRC licensed entity acknowledged receipt and transfer of possession of the five sealed sources.

Compliance Date: June 28, 2021

The second violation involves the failure to confine the possession and use of licensed materials to the location and purposes authorized in the license. Violation states: "Contrary to the above, from March 2021 to June 23, 2021, the licensee failed to confine his possession and use of the byproduct material to the locations and purposes authorized in the license. Specifically, the licensee failed to confine its possession and use of byproduct material to the location authorized in the license, 4048 Laurel Street, Suite 202, Anchorage, Alaska. The byproduct material was possessed and stored at 2421. E. Tudor Road, Suite 103, Anchorage, Alaska, a location not authorized in the license". We agree with this violation.

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Root Cause: Similar to the above violation, communication with Individual A had been discontinued from the direction of our legal council. Although Individual A was previously aware that no unauthorized persons were to possess or access the "hotlab", I was unaware that they decided to vacate the office at 4048 Laurel Street, and ultimately remove the byproduct and relocate it to a storage room of a different office they occupy.

Corrective Actions: The RSO called Individual A and explained to him that the byproduct material should not have been relocated, and that RSO needed to travel to Alaska to assess the situation. On June 7, 2021, the RSO located and inventoried the licensed materials and performed leak test samples. RSO placed the five sealed sources into a locked plastic toolbox within the storage room. On June 14, 2021, The RSO ordered and shipped the proper containers to Anchorage for disposal of the licensed materials. On June 23, 2021, the RSO travelled back to Anchorage and shipped the five sources to an NRC licensed entity for disposal. On June 28, 2021, the NRC licensed entity acknowledged receipt and transfer of possession of the five sealed sources.

Compliance Date: June 28, 2021 after receiving acknowledgement of receipt and transfer of the sources by the licensed NRC entity.

The third violation involves the requirement that each licensee shall develop, document and implement a radiation protection program commensurate with the scope of licensed activities and sufficient to ensure compliance with the provisions of 10 CFR Part 20. Violation states "contrary to the above, from January 15, 2019 to June 23, 2021, the licensee failed to develop, document and implement a radiation protection program commensurate with the scope of licensed activities and sufficient to ensure compliance with the provisions of 10 CFR Part 20. Specifically the licensee ceased licensed activities at its facility in Anchorage, Alaska, and its radiation protection program was not sufficient to ensure compliance with the provisions for the storage and control of licensed materials in 10 CFR 20.1801 and 10 CFR 20.1802." We agree with this violation.

Root Cause: As stated above, Individual A terminated our nuclear technologist without consulting with me. Subsequently, Individual A closed our mutual bank accounts, and refused to comply with the terms of our contract. We engaged legal council and were instructed to stop all communications with Individual A. We acknowledge that this was not appropriate, and should have immediately prioritized disposing of the sources.

Corrective Actions: In addition to the actions taken to remedy the above violations, on August 13th, 2021 we submitted an amendment request to the NRC to remove the Anchorage, Alaska facility from our Radioactive Materials License. On October 27, 2021 we received an Acknowledgement of Receipt of Amendment Request.

Compliance Date: June 28, 2021 after receiving acknowledgement of receipt and transfer of the sources by the licensed NRC entity. We have not received an Amended License, that includes the removal of the facility in Alaska.

The fourth violation involves the requirement that licensees in possession of sealed sources shall conduct a semi-annual physical inventory of all such sources in its possession. Violation states "contrary to the above, from December 19, 2018 to June 7, 2021 the licensee possessed sealed sources authorized under 10CFR Part 35 and failed to conduct a semi-annual physical inventory of all such sources in its possession. Specifically, the licensee possessed calibration and reference sources authorized to be possessed under 10 CFR 35.65, containing approximately 14.2 millicuries of cobalt-57 and approximately 197.0 microcuries of cesium-137, and the licensee failed to conduct a semi-annual physical inventory." We agree with this violation.

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Root Cause: MMS should have made arrangements for an RSO located in Anchorage, Alaska, as it did not anticipate the challenges of travelling to do regular on-site visits. MMS also did not know if a second RSO could be added to an existing RML. I should have gotten better clarification of this prior to submitting the amendment to add the Anchorage location. The COVID pandemic also make travelling a challenge during this time.

Corrective Actions: During the RSO audit and refresher training conducted in December 2018, RSO and technologist developed a regulatory schedule for 2019. Included with this training was the sealed source inventory and leak test instructions, as well as premade leak test kits to be performed in 2019. For future locations Marian Medical Services will consult with RSO to assure that site visitations and regulatory functions can be performed adequately by the RSO. For Marian Medical Services in Honolulu, Hawaii this is not an issue because RSO is there to perform the duties, and isotopes are delivered to this location frequently.

Compliance Date: November 15, 2021.

We acknowledge the severity of these violations and do not take them lightly. We responded poorly to a bad situation, with business partners that breached our contract, and effectively shut down operations. These are violations that we have never had issues with in our facilities in Hawaii for over 15 years, and they will never happen again.

If you have any additional questions or concerns please give me a call at (808) 487-0814.

Sincerely,

Mark Palazzolo, Executive Director
Marian Medical Services, LLC

cc: Ms. Mary Muessle, Director
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