



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 EAST LAMAR BOULEVARD
ARLINGTON, TEXAS 76011-4511

October 26, 2021

EA-21-120

Mr. Mark Palazzolo, Executive Director
Marian Medical Services, LLC
906 Kingswood Ct
Wildwood, MO 63021

SUBJECT: NRC INSPECTION REPORT 030-37399/2021-001

Dear Mr. Palazzolo:

This letter and the enclosed inspection report refer to the routine inspection that was conducted remotely between April 27 and October 12, 2021. The inspection was performed to examine activities conducted under your license as they relate to public health and safety and to confirm compliance with the U.S. Nuclear Regulatory Commission's (NRC's) rules and regulations and the conditions of your license. Within these areas, the inspection consisted of an examination of selected procedures and representative records, and interviews with personnel. The enclosed inspection report presents the results of this inspection. The inspector discussed the preliminary inspection findings with you and Mr. Blaine Ikeda, Radiation Safety Officer, via videoconference on June 16, 2021. On October 14, 2021, a final exit briefing was conducted via videoconference with you and Mr. Ikeda.

Based on the results of this inspection, four apparent violations were identified and are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The apparent violations are related to the cessation of NRC licensed activities at your Anchorage, Alaska, facility. The four apparent violations involve the failure to: (1) control and maintain constant surveillance of licensed material or secure the licensed material from unauthorized removal or access; (2) confine your possession and use of licensed material to the locations and purposes authorized in the NRC license; (3) develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with NRC regulations; and (4) conduct a semi-annual physical inventory of all sealed sources in your possession.

The circumstances surrounding these apparent violations, the significance of the issues, and the need for lasting and effective corrective action were discussed with you and Mr. Blaine Ikeda, Radiation Safety Officer, during the videoconference exit meeting on October 14, 2021.

The apparent violations involve the abandonment and loss of control of NRC licensed materials consisting of sealed sources containing approximately 14.2 millicuries of cobalt-57 and approximately 197.0 microcuries of cesium-137. Following your abandonment of these licensed materials, they were subsequently removed by a member of the public and relocated to an

unauthorized location. Accordingly, the NRC is considering proposing imposition of a civil monetary penalty. Section 2.3.4, "Civil Penalty," of the NRC Enforcement Policy states that for violations where a licensee has lost required control of its regulated licensed material for any period of time, the NRC normally will impose at least a base civil penalty. The base civil penalty amount is based on approximately three times the expected average cost of authorized disposal; however, the NRC may exercise its discretion to mitigate or escalate a civil penalty amount based on the merits of a specific case. Therefore, you may provide information regarding the actual expected cost of authorized disposal that you believe the NRC should consider in making a final enforcement decision. However, NRC will not normally decrease the civil penalty to an amount below the lowest base civil penalty for such cases (i.e., \$3,500).

Before the NRC makes its enforcement decision, we are providing you an opportunity to: (1) respond in writing to the apparent violations addressed in the inspection report within 30 days of the date of this letter; (2) request a predecisional enforcement conference (PEC); or (3) request alternative dispute resolution (ADR). If a PEC is held, it will be open for public observation and the NRC may issue a press release to announce the time and date of the conference. Please contact Dr. Lizette Roldán-Otero, Chief, Materials Inspection Branch, at 817-200-1455 or Lizette.Roldan-Otero@nrc.gov within 10 days of the date of this letter to notify the NRC of your intended response to either provide a written response, participate in a PEC, or pursue ADR. A PEC should be held within 30 days and an ADR session within 45 days of the date of this letter.

If you choose to provide a written response, it should be clearly marked as a "Response to Apparent Violations in NRC Inspection Report 030-37399/2021-001; EA-21-120" and should include for each apparent violation: (1) the reason for the apparent violation or, if contested, the basis for disputing the apparent violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance will be achieved. Your response may reference or include previously docketed correspondence if the correspondence adequately addresses the required response. To the extent possible, your response should not include any personal privacy or proprietary information so that it can be made available to the public without redaction. Your written response, should you choose to provide one, should be sent to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with identical copies mailed to Ms. Mary Muessle, Director, Division of Nuclear Materials Safety, Region IV, 1600 East Lamar Boulevard, Arlington, TX 76011, and emailed to R4Enforcement@nrc.gov within 30 days of the date of this letter. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a PEC.

If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on these matters and any other information that you believe the NRC should take into consideration before making an enforcement decision. The decision to hold a PEC does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference would be conducted to obtain information to assist the NRC in making an enforcement decision. The topics discussed during the conference may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective

Action,” may be helpful in preparing your response (Agencywide Documents Access and Management System (ADAMS) Accession No. [ML061240509](#)).

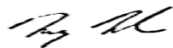
In lieu of a PEC, you may request ADR with the NRC in an attempt to resolve this issue. ADR is a general term encompassing various techniques for resolving conflicts using a neutral third party. The technique that the NRC employs is mediation. Mediation is a voluntary, informal process in which a trained neutral mediator works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues. Additional information concerning the NRC's ADR program can be obtained at <http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html>. The Institute on Conflict Resolution at Cornell University has agreed to facilitate the NRC's program as a neutral third party. Please contact the Institute on Conflict Resolution at 877-733-9415 within 10 days of the date of this letter if you are interested in pursuing resolution of this issue through ADR.

Please be advised that the number and characterization of apparent violations described in the enclosed inspection report may change as a result of further NRC review. You will be advised by separate correspondence of the results on our deliberations in this matter.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter, and its enclosure, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's ADAMS, accessible from the NRC Web website at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy or proprietary information so that it can be made available to the public without redaction.

If you have any questions concerning this matter, please contact Dr. Lizette Roldán-Otero of my staff at 817-200-1455.

Sincerely,



Signed by Muessle, Mary
on 10/26/21

Mary C. Muessle, Director
Division of Nuclear Materials Safety

License No. 24-29248-01
Docket No. 030-37399

Enclosure:
NRC Inspection Report 030-37399/2021-001

cc w/Enclosure:
Irene Casares, Radiological Health Physicist II
Alaska State Public Health Laboratories
Department of Health and Social Services
5455 Dr. Martin Luther King Jr. Avenue
Anchorage, AK 99507

SUBJECT: NRC INSPECTION REPORT 030-37399/2021-001 DATED OCTOBER 26, 2021

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SIGNATURE	/RA/	/RA/	/RA/	DMC	/RA/ E	MCM
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**U.S. NUCLEAR REGULATORY COMMISSION
REGION IV**

Docket No.: 030-37399

License No.: 24-29248-01

Inspection Report No.: 030-37399/2021-001

EA No.: EA-21-120

Licensee: Marian Medical Services, Inc.

Locations Inspected: 4048 Laurel Street, Suite 202 (remote)
Anchorage, Alaska

2421 E. Tudor Road, Suite 103 (remote)
Anchorage, Alaska

Inspection Dates: Remote inspection commenced on April 27, 2021;
continued in-office review conducted through October 12,
2021

Exit Meeting Date: October 14, 2021

Inspector: Janine F. Katanic, PhD, CHP
Senior Health Physicist
Materials Inspection Branch
Division of Nuclear Materials Safety, Region IV

Approved by: Lizette Roldán-Otero, PhD
Chief, Materials Inspection Branch
Division of Nuclear Materials Safety, Region IV

Attachment: Supplemental Inspection Information

Enclosure

EXECUTIVE SUMMARY

Marian Medical Services, LLC (MMS) NRC Inspection Report 030-37399/2021-001

On April 27, 2021, the NRC began a remote routine inspection of MMS. The inspector continued in-office review through October 12, 2021. The scope of the inspection was to examine the activities conducted under the license and to confirm compliance with the NRC's rules and regulations and the conditions of the license. The inspection consisted of a selected examination of procedures and representative records, and interviews with personnel.

Marian Medical Services, LLC, is authorized under NRC Materials License 24-29248-01 to possess and use byproduct material for diagnostic medical use under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35. The licensee provides turn-key nuclear medicine services for private practice physicians by providing nuclear medicine equipment and staff to perform the imaging studies. At the time of the inspection, MMS had two authorized locations of use: Honolulu, Hawaii, and Anchorage, Alaska. The inspection was limited to the NRC licensed activities associated with the MMS location in Anchorage, Alaska.

The inspection determined that the Anchorage facility had ceased licensed activities during 2018. Licensee staff had last observed the licensed materials in January 2019. The licensed facility was permanently closed, which resulted in the abandonment of the licensed materials. In March 2021, the NRC licensed materials, which consisted of approximately 14.2 millicuries of cobalt-57 and approximately 197.0 microcuries of cesium-137, were accessed by a member of the public, removed from the licensed facility, and relocated to an unauthorized location where they were accessible by members of the public. Only as a result of the NRC inspector's inquiry did the licensee become aware that the licensed materials had been accessed, removed, and relocated by a member of the public.

Four apparent violations were identified regarding the licensee's failure to: (1) secure from unauthorized removal or access licensed materials that were stored in controlled or unrestricted areas, and to control and maintain constant surveillance of licensed material that was in a controlled or unrestricted area and that was not in storage; (2) confine the possession and use of licensed materials to the locations and purposes authorized in the license; (3) develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of 10 CFR Part 20; and (4) conduct a semi-annual physical inventory of all sealed sources that were possessed and authorized under 10 CFR Part 35.

As corrective actions, the licensee located the NRC licensed materials at a sleep study center in Anchorage, Alaska, where the materials had been relocated by a member of the public. The RSO accounted for all five sealed sources possessed by the licensee and collected leak test samples, which were later analyzed with no evidence of leakage. The RSO subsequently packaged the five sources and shipped them for proper disposal to an authorized entity.

REPORT DETAILS

1 Program Overview (Inspection Procedures (IPs) 87130)

1.1 Program Scope

Marian Medical Services, LLC (MMS or licensee) is authorized under NRC Materials License 24-29248-01 to possess and use byproduct material for diagnostic medical use under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35 at its facilities in Alaska and Hawaii.

1.2 Observations and Findings

On April 27, 2021, the NRC began a remote routine inspection of MMS. The purpose of the inspection was to examine the activities conducted under the NRC license and to confirm compliance with the NRC's rules and regulations and with the conditions of the license. Within these areas, the inspection consisted of a selected examination of procedures and representative records and interviews with personnel.

Marian Medical Services, LLC, provides turn-key nuclear medicine services for private practice physicians. They build relationships with physicians and offer them the ability to perform nuclear medicine diagnostic imaging services in-house at their private practice facility rather than having to refer their patients to other facilities for nuclear medicine diagnostic imaging. As part of the turn-key service, MMS acquires all of the necessary equipment to run a small nuclear medicine department, including the gamma camera, hot lab equipment, and stress-test equipment for cardiology practices. Staff, consisting of a nuclear medicine technologist and medical assistant are also provided by MMS. As part of the overall service, MMS provides the applicable accreditations and licenses, including the NRC license, to operate the nuclear medicine service. The physician client provides physical space within their medical office facility and provides medical supervision for their patients undergoing nuclear medicine imaging.

The MMS NRC license authorizes imaging and localization studies under 10 CFR 35.200. As physician clients are brought on board, MMS adds the physician client facility to the MMS NRC license as a location of use. The Radiation Safety Officer (RSO) listed on the MMS license, who is a consultant to MMS and not a direct employee, is responsible for oversight and licensee compliance at the locations of use listed on the MMS license. At the time of the inspection, there were two authorized locations of use on the MMS license: (1) Honolulu, Hawaii, and (2) Anchorage, Alaska. The inspection was limited to the licensed activities associated with the MMS location in Anchorage, Alaska.

2 MMS Anchorage, Alaska, Licensed Activities (IP 87130)

2.1 Inspection Scope

On April 27, 2021, the NRC began a remote routine inspection of MMS. The inspection was limited to licensed activities associated with the licensee's facility in Anchorage, Alaska. The inspection consisted of a selected examination of procedures and representative records, and interviews with personnel.

2.2 Background

The licensee was authorized to perform licensed activities under the provisions of 10 CFR 35.200 at its facility in Anchorage, Alaska. The MMS facility in Anchorage, Alaska, was added to the MMS license with Amendment No. 11, issued on April 1, 2016.

The NRC performed an inspection on June 21, 2016, shortly after NRC licensed activities commenced at the Anchorage, Alaska, facility. The inspection was documented in NRC Inspection Report 030-37399/2016-001 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML16225A609). The inspectors observed that there were two MMS staff employed at the location: a nuclear medicine technologist and a medical assistant. A fully functional nuclear cardiology imaging department was observed, including a gamma camera, fully equipped hot lab, and cardiac stress area. At the time of the NRC inspection, diagnostic nuclear medicine imaging had only been performed for three patients, but the licensee anticipated that the practice would grow based on the projected demand in the geographic area.

On April 27, 2021, the NRC began a remote routine inspection of the MMS Anchorage, Alaska, facility. The RSO related that the Anchorage facility was not successful in growing its business and that very few nuclear medicine imaging studies had been performed. The RSO further related that the Anchorage facility had ceased licensed activities during 2018. The RSO had last visited the Anchorage facility in December 2018, and the MMS nuclear medicine technologist was terminated in January 2019. At the time of the nuclear medicine technologist's termination, the licensed materials, including sealed sources, stated to have been secured in the hot lab within the Anchorage facility. During the remote inspection, the RSO stated that he was unaware of the current status of the facility or the NRC licensed materials.

2.3 Observations and Findings

Four apparent violations were identified regarding the licensee's failure to: (1) secure from unauthorized removal or access licensed materials that were stored in controlled or unrestricted areas, and to control and maintain constant surveillance of licensed material that was in a controlled or unrestricted area and that was not in storage; (2) confine the possession and use of licensed materials to the locations and purposes authorized in the license; (3) develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of 10 CFR Part 20; and (4) conduct a semi-annual physical inventory of all sealed sources that were possessed and authorized under 10 CFR Part 35.

Based on interviews with the RSO, the Anchorage facility had only performed about 20 nuclear medicine studies from when it commenced licensed activities on April 1, 2016, to when it ceased licensed activities during 2018. The anticipated patient workload at the Anchorage facility never materialized, and the nuclear medicine activities could not be sustained. The RSO visited the Anchorage facility on December 19, 2018, to inventory the licensed materials and to perform an audit. On January 15, 2019, the decision was made to cease NRC licensed activities, and the MMS nuclear medicine technologist was terminated. At the time, the nuclear medicine technologist informed MMS executive management that the licensed materials were secured in the hot lab inside of the licensed Anchorage facility.

The inspector expressed concern that the licensee was unaware of the status of the licensed materials, since it appeared that they had been abandoned and last accounted for in January 2019.

In response to the inspector's concerns, the RSO called the telephone number for the Anchorage facility to inquire about the status of the facility and NRC licensed materials. The RSO spoke with an individual member of the public, hereafter referred to as "Individual A," who was previously affiliated with the Anchorage nuclear cardiology private practice as an investor. The RSO made plans to visit the Anchorage facility to ascertain the status of the NRC licensed materials.

The RSO traveled to Anchorage on June 7, 2021, went to the licensed facility, and found that it was locked and vacant. The RSO contacted Individual A and was informed that all of the nuclear medicine equipment, including the hot lab contents, had been removed from the licensed facility and relocated to a storage room at a nearby sleep study center in Anchorage owned by Individual A. Although Individual A was previously affiliated with the Anchorage nuclear cardiology private practice as an investor, Individual A was not authorized to access the NRC licensed materials. The inspector was unable to establish the specific date that the NRC licensed materials were accessed, removed, and relocated, but it appears to have occurred in March 2021.

On June 7, 2021, after finding out that the licensed materials had been relocated, the RSO visited the sleep study center in an effort to locate and account for the NRC licensed materials. The RSO located the five sealed sources that were possessed by the licensee under 10 CFR 35.65, which consisted of: (1) one 10 millicurie cobalt-57 flood source with a manufacture date of December 27, 2018; (2) one 5.7 millicurie cobalt-57 vial source with a manufacture date of October 30, 2018; (3) one 0.1 microcurie cobalt-57 rod source with a manufacture date of April 28, 2016; (4) one 211.0 microcurie cesium-137 vial source with a manufacture date of January 21, 2016; and (5) one 0.1 microcurie cesium-137 rod source with a manufacture date of January 26, 2016. At the time the sources were accessed, removed, and relocated, by Individual A, the sources had decayed to approximately 14.2 millicuries of cobalt-57 and approximately 197.0 microcuries of cesium-137.

After the RSO located and inventoried the licensed materials at the sleep study center, leak test samples were obtained for analysis. The RSO placed the five sealed sources into a locked plastic toolbox, and left the toolbox in the sleep study center storage room. The leak test samples were analyzed on June 12, 2021, with no evidence of leakage.

On June 14, 2021, the RSO ordered proper shipping containers and had them sent to the Anchorage sleep study facility so that the sources could be properly shipped for disposal.

On June 15, 2021, the inspector spoke with Individual A, who related that he had moved some of the facility contents himself and that a moving company helped move the rest of the materials to the sleep study center. Individual A was not fully aware that some of the items that were relocated contained licensed radioactive material, nor was Individual A aware of NRC regulations regarding the possession and use of the licensed materials. Individual A stated that he had accessed, removed, relocated the materials after the lease on the licensed facility expired. Individual A thought that some of his expenses could be recouped through the sale of the abandoned nuclear medicine, stress-test, and

hot lab equipment. The inspector informed Individual A that the five sealed sources that were abandoned by MMS could not be sold, and requested that Individual A not access these sources. The inspector explained that the MMS RSO was planning on returning to the facility to properly package, ship, and dispose of the five sealed sources.

On June 16, 2021, the inspector spoke with the MMS Executive Director, in order to discuss the abandonment of the licensed materials and to obtain assurances regarding the proper disposal of the licensed materials. On June 17, 2021, the MMS Executive Director provided a letter to the NRC, describing its completed corrective actions along with the anticipated timeline to complete its planned corrective actions. The letter contains sensitive security-related information and is not publicly available.

On June 23, 2021, the RSO traveled back to Anchorage sleep study center. The five sources were packaged into the proper shipping containers and shipped to an NRC licensed entity for disposal. The RSO stated that the total cost for disposal of the five sources was \$2360 plus two proper shipping containers at \$75 each, plus the cost of shipping.

On June 28, 2021, the NRC licensed entity acknowledged the receipt and transfer of possession of the five sealed sources.

Apparent violation of 10 CFR 20.1801 and 10 CFR 20.1802

Title 10 CFR 20.1801 requires that the licensee shall secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

Title 10 CFR 20.1802 requires that the licensee shall control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

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. Specifically, the licensee failed to secure from unauthorized removal, licensed materials consisting of approximately 14.2 millicuries of cobalt-57 and approximately 197.0 microcuries of cesium-137. Unauthorized individuals had access to the licensed materials and the licensed materials were removed from their licensed storage area without the licensee's knowledge or awareness. The licensed materials were relocated to an unrestricted area and the licensee failed to maintain constant surveillance of these licensed materials.

The licensee's failure to secure from unauthorized removal or access licensed materials that were stored in controlled or unrestricted areas, and to control and maintain constant surveillance of licensed material that was in a controlled or unrestricted area and that was not in storage was identified as an apparent violation of 10 CFR 20.1801 and 10 CFR 20.1802. (030-37399/2021-001-01)

Apparent violation of 10 CFR 30.34(c)

Title 10 CFR 30.34(c) requires, in part, that each person licensed by the Commission pursuant to the regulations in 10 CFR Part 30 and Parts 31 through 36 and 39 shall confine his possession and use of the byproduct material to the locations and purposes authorized in the license.

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.

The licensee's failure to confine the possession and use of the byproduct material to the locations and purposes authorized in the license was identified as an apparent violation of 10 CFR 10 CFR 30.34(c). (030-37399/2021-001-02)

Apparent violation of 10 CFR 20.1101(a)

Title 10 CFR 20.1101(a) requires, in part, that each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of 10 CFR Part 20.

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 and extent 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.

The licensee's failure to develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of 10 CFR Part 20 was identified as an apparent violation of 10 CFR 20.1101(a). (030-37399/2021-001-03)

Apparent violation of 10 CFR 35.67(g)

Title 10 CFR 35.67(g) requires, in part, that a licensee in possession of sealed sources shall conduct a semi-annual physical inventory of all such sources in its possession.

Contrary to the above, from December 19, 2018, to June 7, 2021, the licensee possessed sealed sources authorized under 10 CFR 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.

The licensee's failure to conduct a semi-annual physical inventory of all sources in its possession was identified as an apparent violation of 10 CFR 35.67(g).
(030-37399/2021-001-04)

2.4 Causal Evaluation

A formal root cause analysis was not performed as it was beyond the scope of the inspection. The MMS business model appeared to be focused on developing relationships with physicians with the goal of setting up new nuclear medicine imaging facilities. Once the relationships were built and the new nuclear medicine imaging facility was set up, MMS would add the new location to the existing MMS NRC license as a location of use. As new locations were developed and added to the MMS license, commensurate effort was not placed on ensuring compliance with NRC requirements and the terms and conditions of the NRC license. Although extensive "front end" work was performed by MMS to set up new facilities with staff and equipment, MMS did not focus on the "back end" work of appropriate oversight of the licensed activities. The lack of appropriate oversight contributed to the conditions that allowed the licensed materials to be abandoned by the licensee.

Furthermore, when adding the Anchorage facility to the MMS NRC license, MMS executive management did not consult with the RSO. The RSO stated that he found out about the Anchorage facility after it was added to the MMS NRC license in April 2016. At the time, the RSO was based in Hawaii, and therefore could easily provide oversight of the MMS facility in Hawaii. When the Anchorage facility was added to the MMS NRC license, it was much more challenging for the RSO to maintain awareness of licensed activities and to provide direct oversight.

2.5 Corrective Actions

In response to the inspector's concerns about the location and security of the abandoned NRC licensed materials, on June 7, 2021, the RSO went to Anchorage and observed that the licensed facility was locked and vacant. The RSO located the NRC licensed materials at a nearby sleep study center in Anchorage, where the licensed materials were accessible by members of the public. The RSO accounted for all five sealed sources and collected leak test samples. The RSO placed the licensed materials into a plastic toolbox, which was subsequently locked by the RSO. The toolbox remained at the unlicensed location until the leak test results could be analyzed and the RSO could return to Anchorage to package the sources for transfer and disposal. On June 12, 2021, the leak test samples were analyzed and did not identify any evidence of leakage or contamination.

On June 23, 2021, the RSO returned to the sleep study center, packaged the sources into proper shipping containers, and shipped the sources for transfer and disposal to an authorized NRC licensee. The RSO performed surveys of ambient radiation levels at the sleep study center and obtained samples for the detection of removable radioactive contamination. Ambient radiation surveys and removable contamination results did not indicate any areas of concern. The RSO also obtained access to the abandoned and vacant NRC licensed facility. The RSO performed surveys of ambient radiation levels at the abandoned facility and obtained samples for the detection of removable radioactive contamination. Ambient radiation surveys and removable contamination results did not indicate any areas of concern.

On August 13, 2021, the licensee submitted an amendment request to the NRC to remove the Anchorage location from its NRC license.

The MMS Executive Director discussed with the inspector that it was in negotiations with other physicians to add additional nuclear medicine imaging facilities to the MMS NRC license. The licensee has not provided the NRC with information regarding measures that it plans to put in place to assure compliance with 10 CFR Part 20, and that there will not be a recurrence of the abandonment and loss of control of licensed materials.

2.6 Conclusions

Four apparent violations were identified. The four apparent violations are associated with the licensee's activities at its Anchorage, Alaska, facility regarding the licensee's failure to: (1) secure from unauthorized removal or access licensed materials that were stored in controlled or unrestricted areas, and to control and maintain constant surveillance of licensed material that was in a controlled or unrestricted area and that was not in storage; (2) confine the possession and use of licensed materials to the locations and purposes authorized in the license; (3) develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of 10 CFR Part 20; and (4) conduct a semi-annual physical inventory of all sealed sources that were possessed and authorized under 10 CFR Part 35.

3 **Exit Meeting Summary**

On October 14, 2021, a final videoconference exit meeting was conducted with Mr. Mark Palazzolo, MMS Executive Director, and Mr. Blaine Ikeda, Radiation Safety Officer, to discuss the inspection findings. The NRC representatives discussed the content of the inspection report, described the NRC's enforcement process, and described the options for the licensee to: (1) respond in writing to the apparent violations described in the inspection report; (2) request a predecisional enforcement conference, or (3) request alternative dispute resolution. The licensee did not identify any proprietary information.

Supplemental Inspection Information

PARTIAL LIST OF PERSONS CONTACTED

Mark Palazzolo, Executive Director
Blaine Ikeda, Radiation Safety Officer

INSPECTION PROCEDURES USED

IP 87130 Nuclear Medicine Programs, Written Directive Not Required

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-37399/2021-001-01	AV	Failure to secure from unauthorized removal or access licensed materials that were stored in controlled or unrestricted areas, and to control and maintain constant surveillance of licensed material that was in a controlled or unrestricted area and that was not in storage. (10 CFR 20.1801, 10 CFR 20.1802)
030-37399/2021-001-02	AV	Failure to confine the possession and use of licensed material to the locations and purposes authorized in the license. (10 CFR 10 CFR 30.34(c))
030-37399/2021-001-03	AV	Failure to develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of 10 CFR Part 20. (10 CFR 20.1101(a))
030-37399/2021-001-04	AV	Failure to conduct a semi-annual physical inventory of all sources possessed. (10 CFR 35.67(g))

Closed

None

Discussed

None

LIST OF ACRONYMS AND ABBREVIATIONS USED

10 CFR	Title 10 of the <i>Code of Federal Regulations</i>
ADAMS	Agencywide Documents Access and Management System
ADR	Alternative Dispute Resolution
AV	Apparent Violation
IP	Inspection Procedure
MMS	Marian Medical Services
NRC	Nuclear Regulatory Commission
PEC	Predecisional Enforcement Conference
RSO	Radiation Safety Officer