



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

REGION IV  
1600 EAST LAMAR BOULEVARD  
ARLINGTON, TEXAS 76011-4511

June 22, 2018

Mark Palazzolo, Executive Director  
Marian Medical Services, LLC  
906 Kingsridge Court  
Wildwood, MO 63021

SUBJECT: NRC INSPECTION 030-37399/2018-001 AND NOTICE OF VIOLATION

Dear Mr. Palazzolo:

This letter refers to the unannounced inspection conducted on May 14, 2018, at your facility in Honolulu, Hawaii. The inspection was an examination of activities conducted under your license as they relate to public health and safety, to confirm compliance with the U.S. Nuclear Regulatory Commission's (NRC) rules, regulations, and with the conditions of your license. Within these areas, the inspection consisted of a selected examination of procedures and representative records, observations of licensed activities, and interviews with personnel. The inspection findings were discussed with you during an exit meeting on June 7, 2018.

Based on the results of this inspection, the NRC has determined that four Severity Level IV violations of NRC requirements occurred. The violations were evaluated in accordance with the NRC Enforcement Policy, which can be found at the NRC's Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The violations are cited in the enclosed Notice of Violation (Notice) because they were identified by the NRC during the inspection. The violations involved a repeat failure to train a newly hired medical assistant who was working in and frequently spending time in the restricted area, failing to survey packages that used to contain unsealed radioactive materials before labeling them as empty, failing to calibrate equipment used to determine each patient's dose before medical use in accordance with the manufacturer's instructions, and failure to survey the areas where unsealed byproduct materials were used at the end of each day of use.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. 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. You can find the Information Notice on the NRC website at: <http://pbadupws.nrc.gov/docs/ML0612/ML061240509.pdf>. Information regarding (1) the reason for the violation, (2) the corrective actions already taken and (3) those planned to correct the violation and prevent recurrence, and (4) the date when full compliance will be (was) achieved needs to be addressed. The NRC review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

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 personal or

proprietary information is necessary to provide an acceptable response, please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such information, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by Title 10 of the *Code of Federal Regulations* (CFR) 2.390(b) to support a request for withholding confidential commercial or financial information).

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter, its enclosure, and your response, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Should you have any questions regarding this letter or the enclosed Notice, please contact Jason C. Dykert at 817-200-1427 or the undersigned at 817-200-1455.

Sincerely,

/RA/

Michael C. Hay, Chief  
Materials Licensing and Inspection Branch  
Division of Nuclear Materials Safety

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

Enclosure:  
Notice of Violation

cc w/enclosure:  
J. Eckerd, Manager  
Hawaii Radiation Control Program

K. Henke, Director  
Missouri Radiation Control Program

NRC INSPECTION 030-37399/2018-001 AND NOTICE OF VIOLATION DATED – DATE  
JUNE 22, 2018

**DISTRIBUTION:**

Kriss.Kennedy@nrc.gov;  
Scott.Morris@nrc.gov;  
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By: JCD                       Yes    No                       Publicly Available                       Sensitive

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**OFFICAL RECORD COPY**

## NOTICE OF VIOLATION

Marian Medical Services, LLC  
Honolulu, Hawaii

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

During an NRC inspection conducted on May 14, 2018, four violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. License Condition 14A. of NRC License 24-29248-01 requires, in part, that the licensee conduct its program in accordance with license application dated February 21, 2017. License application dated February 21, 2017, states that the licensee will implement procedures for safe use of unsealed byproduct material. In the Standard Operating Procedure SOP 11.0, "Training for Individuals Working In or Frequenting Restricted Areas," it states, in part, that individuals who work in or frequent restricted areas will be instructed in the items specified in the NRC and Hawaii State regulations at the time of initial employment, before an employee assumes duties with or in the immediate vicinity of radioactive materials.

Contrary to the above, since January 2018, the licensee failed to ensure that an individual who worked in restricted areas was instructed in the items specified in the NRC and Hawaii State regulations at the time of initial employment, before the employee assumed duties in the immediate vicinity of radioactive materials. Specifically, a medical assistant working in a restricted area was not trained as specified in SOP 11.0.

This is a repeat Severity Level IV violation (Section 6.3.d.3).

- B. License Condition 14A. of NRC License 24-29248-01 requires, in part, that the licensee conduct its program in accordance with license application dated February 21, 2017. License application dated February 21, 2017, states that the licensee will implement procedures for safe use of unsealed byproduct material. In the Standard Operating Procedure SOP 3.0, "Procedures for Safely Opening Packages Containing Radioactive Material," it states that the licensee shall "monitor the packing material and packages for contamination before discarding."

Contrary to the above, since February 21, 2017, the licensee failed to monitor the packing material and packages for contamination before discarding. Specifically, the empty packages were not monitored for contamination prior to discarding them back to the radiopharmacy.

This is a Severity Level IV violation (Section 6.3.d.3).

- C. 10 CFR 35.60(b) requires, in part, that a licensee calibrate the instrumentation that is used to determine and record the activity of each dosage before medical use in accordance with nationally recognized standards or the manufacturer's instructions.

Contrary to the above, since the previous NRC inspection in November 2012, the licensee failed to calibrate the instrumentation that is used to determine and record the activity of each dosage before medical use in accordance with nationally recognized standards or the manufacturer's instructions. Specifically, during quarterly dose

Enclosure

calibrator accuracy tests that measure the equipment's ability to accurately reflect the activity of NIST traceable sources of radioactive material, the licensee only utilized one calibrated reference source instead of using several calibrated sources over a wide range of energies.

This is a Severity Level IV violation (Section 6.3.d).

- D. 10 CFR 35.70(a) requires, in part, a licensee shall survey with a radiation detection survey instrument at the end of each day of use.

Contrary to the above, since 2013, the licensee failed to survey with a radiation detection survey instrument at the end of each day of use. Specifically, the licensee performed surveys at the end of each week of use of licensed materials, instead of at the end of each day of use.

This is a Severity Level IV violation (Section 6.3.d).

Pursuant to the provisions of 10 CFR 2.201, Marian Medical Services, LLC, is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Regional Administrator, Region IV, 1600 E. Lamar Blvd. Arlington, Texas 76011, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for the violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level; (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 previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued requiring information as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Your response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction.

If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., *explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for*

*withholding confidential commercial or financial information*). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21. If Classified Information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR Part 95.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 22<sup>nd</sup> day of June 2018