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

February 21, 2013

Mr. Jere Palazzolo, President
Marian Medical Services, LLC
906 Kingsridge Court
Wildwood, Missouri 63021

SUBJECT: NRC INSPECTION REPORT 030-37399/2012-001 AND NOTICE OF VIOLATION

Dear Mr. Palazzolo:

This letter refers to the routine unannounced inspection that was conducted on November 27, 2012, at your Lusitana Street and Maluniu Street facilities, Oahu, Hawaii. The inspection continued with in-office reviews until January 17, 2013, and it was an examination of activities conducted under your license as they relate to safety and compliance with the Commission's rules and regulations and with the conditions of the license. Within these areas, the inspection consisted of selected examination of procedures and representative records and interviews with personnel. Inspection findings were discussed with Mr. Blain Ikeda, PharmD/ Radiation Safety Officer, at the conclusion of the on-site inspection. The findings were discussed with you and members of your staff on January 17, 2013, and a final exit briefing was conducted on February 21, 2013.

Based on the results of this inspection, the U.S. Nuclear Regulatory Commission (NRC) has determined that two Severity Level IV violations of NRC requirements occurred. The violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on 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 failure to provide required training and a failure to maintain a record of the occupational exposure received by a medical assistant. Specifically, the licensee failed to train a newly hired medical assistant who was working in and frequenting the restricted area. The licensee provided the medical assistant with a personnel monitoring device with a previous employee's name on the device and the dose was assigned to the previous employee rather than the medical assistant.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. For your consideration and convenience, NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," is enclosed. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with Title 10 of the Code of Federal Regulations (CFR) 2.390 of the NRC's "Rules of Practice," 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

document system (ADAMS), accessible from the 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, 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 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

Should you have any questions regarding this letter or the enclosed Notice, please contact Mr. Rick Muñoz at 817-200-1220 or the undersigned at 817-200-1130.

Sincerely,

/RA/

G. Michael Vasquez, Chief
Nuclear Materials Safety Branch A
Division of Nuclear Materials Safety

Docket: 030-37399
License: 24-29248-01

Enclosures:
1. Notice of Violation
2. Information Notice 96-28

cc w/encl: Director, Hawaii Radiation
Control Program

Blaine Ikeda
PharmaRx Hawaii, LLC
98-021 Kamehameha Highway, Unit 319
Aiea, Hawaii 96701

redaction. If personal privacy 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 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

Should you have any questions regarding this letter or the enclosed Notice, please contact Mr. Rick Muñoz at 817-200-1220 or the undersigned at 817-200-1130.

Sincerely,

/RA/

G. Michael Vasquez, Chief
Nuclear Materials Safety Branch A
Division of Nuclear Materials Safety

Docket: 030-37399
License: 24-29248-01

Enclosures:
1. Notice of Violation
2. Information Notice 96-28

cc w/encls: Director, Hawaii Radiation
Control Program

Blaine Ikeda
PharmaRx Hawaii, LLC
98-021 Kamehameha Highway, Unit 319
Aiea, Hawaii 96701

DISTRIBUTION w/encl:
Elmo.Collins@nrc.gov
Steven.Reynolds@nrc.gov
Anton.Vegel@nrc.gov
Vivian.Campbell@nrc.gov
Jack.Whitten@nrc.gov
Cale.Young@nrc.gov
Marisa.Herrera@nrc.gov
Donna.Austin@nrc.gov
Jenny.Murray@nrc.gov
Lynn.Berger@nrc.gov
NMSB-A
RITS Coordinator

S:\DNMS\!NMIB\Reports in concurrence\MARIAN MEDICAL SERVICES LLC NOV IR 12-001.docx

ADAMS: □ No X Yes	X SUNSI Review Complete	Reviewer Initials: RRM
	X Publicly Available	X Non-Sensitive
	Non-publicly Available	Sensitive
KEYWORD:		

RIV:DNMS/NMSB-A	C:NMSB-A		
RRMuñoz	GMVasquez		
/RA/	***/RA/***		
02/19/13	02/21/13		

OFFICIAL RECORD COPY T=Telephone E=E-mail F=Fax

NOTICE OF VIOLATION

Marian Medical Services LLC
Wildwood, Missouri

Docket: 030-37399
License: 24-29248-01

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted from November 27, 2012, through February 20, 2013, two violations of NRC requirements were identified. In accordance with NRC Enforcement Policy, the violations are listed below:

A. License Condition 15. of byproduct materials license 24-29248-01, requires, in part, that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in license application dated October 16, 2007.

Item 10. of the license application states, in part, that the licensee will develop, implement and maintain procedures for safe use of unsealed byproduct material.

Standard Operating Procedure (SOP) 11.0 titled "Training for Individuals Working In or Frequenting Restricted Areas," Item I, states, in part, that when an individual works in or frequents restricted areas, the individual will be instructed in radiological safety procedures appropriate to their respective duties, safe storage, and potential hazards associated with radioactive material.

Contrary to the above, from 2008 through 2012, individuals that worked in or frequented restricted areas were not instructed in the radiological safety procedures appropriate to their respective duties. Specifically, medical assistants and nurse practitioners working in their respective duties were not trained as specified in SOP 11.0.

This is a Severity Level IV violation (Section 6.3)

B. 10 CFR 20.2106 states, in part, that the licensee shall maintain records of doses received by all individuals for whom monitoring was required pursuant to 10 CFR 20.1502. 10 CFR 20.1502(a) states in part that the licensee shall monitor occupational exposure to radiation and shall supply the individual monitoring device by adults likely to receive in 1 year from sources external to the body, a dose of 10 percent of the limits in 10 CFR 20.1201(a).

Contrary to the above, from July 8 through October 24, 2012, the licensee failed to maintain a record of occupational exposures to radiation for a medical assistant (an adult) who was likely to receive in 1 year a dose of 10 percent of the limit in 10 CFR 20.1201(a). Specifically, the licensee provided a personnel monitoring device to a medical assistant and the device had been assigned to an individual previously employed by the licensee. The licensee maintained no record for the exposure received by the medical assistant; instead the dose had been assigned to the previously employed individual.

This is a Severity Level IV violation (Section 6.3)

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 was, or 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 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, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days. However, you are reminded to review your NRC security orders for superseding requirements that limit the release of information to certain individuals.

Dated this 21st day of February 2013.