



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION IV
1600 E. LAMAR BLVD
ARLINGTON, TX 76011-4511

July 26, 2017

Mr. Blaine Ikeda
Radiation Safety Officer
PharmaRx Hawaii, LLC
98-021 Kamehameha Highway, Unit 319
Aiea, HI 96701

SUBJECT: NRC INSPECTION REPORT 030-37049/2017-001; AND NOTICE OF VIOLATION

Dear Mr. Ikeda:

This letter refers to the unannounced inspection conducted on June 13, 2017 with continued in-office review of air flow calculations through July 7, 2017, at your facility in Aiea, 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 activities, and interviews with personnel. The preliminary inspection findings were discussed with your staff on June 13, 2017, at the conclusion of the onsite portion of the inspection at your Aiea, Hawaii, facility. A final exit briefing was conducted with you and your staff on July 7, 2017.

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 the failure to conduct your program in accordance with commitments made in the license application.

The violations cited in the Notice involved the volatile substance handling system, or fume hood, where volatile radioisotopes are prepared or stored prior to distribution. The first violation involved a failure to annually calibrate the air flow measuring equipment, an Alnor velometer, that can be used to validate whether the fume hood is working as required. The second violation involved the failure to semi-annually measure and validate a base line linear air flow, using the velometer, to demonstrate consistency with the assumed amount of air flow through the fume hood. The third violation involved a failure to perform weekly checks on the efficiency of the charcoal filters used in the liquid radioiodine trapping system. The fourth violation involved a failure to use the velometer to validate the linear air flow through the liquid radioiodine handling portion of that system on a daily basis or prior to its 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 the reason for the violation, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance will be (was) achieved should 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.

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 in the NRC's Agencywide Document Access and Management System (ADAMS), accessible from the NRC's Web site 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.

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/ by RJTorres Acting For/

Vivian H. Campbell, Chief
Materials Licensing and Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-37049
License No. 53-29217-01MD

Enclosure:
Notice of Violation

cc w/enclosure:
Hawaii Radiation Control Program Director

NOTICE OF VIOLATION

PharmaRx Hawaii, LLC
Aiea, Hawaii

Docket No.: 030-37049
License No.: 53-29217-01MD

During an NRC inspection conducted on June 13, 2017, four violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

1. License Condition 22 of NRC License 53-29217-01MD, Amendment No. 7, dated May 18, 2016, requires, in part, that the licensee conduct its program in accordance with the license application. The license application, dated November 18, 2015, Item 8.9, Facilities and Equipment, states that the air flow measuring equipment will be calibrated annually using a mass flow calibrator which is calibrated annually for NIST traceability.

Contrary to the above, from 2007 until June 2017, the licensee failed to ensure that the air flow measuring equipment was calibrated annually using a mass flow calibrator which is calibrated annually for NIST traceability. Specifically, the Alnor velometer air flow measuring equipment was not calibrated annually using a gas mass flow rate meter that was calibrated annually for NIST traceability.

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

2. License Condition 22 of NRC License 53-29217-01MD, Amendment No. 7, dated May 18, 2016, requires, in part, that the licensee conduct its program in accordance with the license application. The license application, dated November 18, 2015, Item 8.9, Facilities and Equipment, states that a base line linear flow will be measured, which shall be consistent with the value used to calculate standard cubic feet per minute semi-annually.

Contrary to the above, from 2015 until June 2017, the licensee failed to ensure that a base line linear flow was measured, which shall be consistent with the value used to calculate standard cubic feet per minute semi-annually. Specifically, a base line linear air flow on the fume hood was measured only once in 2015 and 2016, and the measurement was inconsistent with the value used to calculate standard cubic feet per minute through the fume hood because it did not account for a lead brick shield blocking part of the sash opening.

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

3. License Condition 22 of NRC License 53-29217-01MD, Amendment No. 7, dated May 18, 2016, requires, in part, that the licensee conduct its program in accordance with the license application. The license application, dated November 18, 2015, Item 8.9, Facilities and Equipment, states, regarding the special system for handling millicurie quantities of liquid radioiodine, that the efficiency of this trapping system is checked weekly.

Contrary to the above, from February 10, 2015, until June 28, 2017, the licensee failed to ensure that the efficiency of this trapping system was checked weekly. Specifically, the two charcoal filters used to trap volatile iodine were not measured with a survey meter on a weekly basis to ensure a trapping efficiency of at least 90%.

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

Enclosure

4. License Condition 22 of NRC License 53-29217-01MD, Amendment No. 7, dated May 18, 2016, requires, in part, that the licensee conduct its program in accordance with the license application. The license application, dated November 18, 2015, Item 8.9, Facilities and Equipment, states that the linear flow measurement will be obtained at the same position to ensure consistency, and will be obtained daily or prior to use of the hood system for handling iodine-131.

Contrary to the above, from February 10, 2015, until June 28, 2017, the licensee failed to ensure that the linear flow measurement will be obtained at the same position to ensure consistency, and will be obtained daily or prior to use of the hood system for handling iodine-131. Specifically, an airflow measurement was not obtained on the liquid radioiodine handling portion of the hood system on a daily or prior to use basis.

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

Pursuant to the provisions of 10 CFR 2.201, PharmaRx Hawaii, 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, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

The reply should be clearly marked as a "Reply to a Notice of Violation; and should include for each 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. 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.

If you request withholding of such material from public inspection in the NRC Public Document Room or in the NRC's Agencywide Document Access and Management System (ADAMS), 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).

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

Dated this 26th day of July 2017

NRC INSPECTION REPORT 030-37049/2017-001; AND NOTICE OF VIOLATION DATED JULY 26, 2017.

DISTRIBUTION:

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ADAMS ACCESSION NUMBER: ML17192A475

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