PharmaRx Hawaii LLC

August 24, 2017

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

Re: Reply to a Notice of Violation
NRC INSPECTION REPORT 030-37049/2017-001

Dear Nuclear Regulatory Commission:

This is in response to the inspection conducted at our facility on June 13, 2017. During this inspection, four Severity Level IV violations were identified.

Violation #1: 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.

Reason for Violation: Vendor we used to calibrate velometer stopped calibration of the type of unit we are using. Had difficulty locating another calibration vendor which led to future calibrations being overlooked.

Corrective Actions: Located a company performing calibrations of the type of unit we are using.

Compliance Date: July 10, 2017.

Violation #2: 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.

Reason for Violation: Measurements not taken on a consistent basis (eg. Schedule for leak test, linearity, etc are taken according to a schedule). For ALARA purposes, lead bricks are used as a shield to reduce radiation exposure to Iodine solution.

Corrective Actions: Measurements of fume hood air flow will be placed on schedule with leak testing, thus insuring measurements are taken twice a year on a consistent basis. We will rearrange the shielding used for the Iodine solution so that this is less disruptive to the air flow throughout the fume hood.

Compliance Date: September 30, 2017.

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98-021 Kamehameha Highway, Unit 319 • Aiea, Hawaii 96701 • Cell: (808) 497-9009

Violation #3: 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%.

Reason for Violation: The cause of this violation was the difficulty in accessing the filters and the resulting charcoal residue created when removing these filters. We have been routinely changing these filters whenever our weekly air monitoring showed an increase in air monitoring.

Corrective Actions: Implemented weekly filter checks.

Compliance Date: July 6, 2017.

Violation #4: Licensee failed to ensure that the linear flow measurement 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 portion of the hood system on a daily or prior to use basis.

Reason for Violation: Inadequate training for personnel compounding Iodine capsules.

Corrective Actions: Will review proper procedure for checking glove box linear air flow prior to compounding of Iodine capsules.

Compliance Date: September 30, 2017.

If you have any additional questions or concerns, please give me a call at (808) 347-0761.

Sincerely,

Blaine T. Ikeda, PharmD
Radiation Safety Officer

Cc: U.S. Nuclear Regulatory Commission, Region IV
Regional Administrator
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Arlington, TX 76011-4511