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SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: PharmaLogic Michigan, L.L.C. 1144 Boon Street Traverse City, Michigan 49686 REPORT NUMBER(S) 2008-001		2. NRC/REGIONAL OFFICE U.S. Nuclear Regulatory Commission Region III 2443 Warrenville Road Suite 210 Lisle, Illinois 60532-4351	
3. DOCKET NUMBER(S) 030-35125	4. LICENSEE NUMBER(S) 21-32190-01MD	5. DATE(S) OF INSPECTION July 22, 2008	

LICENSEE:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, NUREG-1600, to exercise discretion, were satisfied.

_____ Non-Cited Violation(s) was/were discussed involving the following requirement(s) and Corrective Action(s):

- 4. During this inspection certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.
(Violations and Corrective Actions)

Licensee's Statement of Corrective Actions for Item 4, above.

I hereby state that, within 30 days, the actions described by me to the inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

Title	Printed Name	Signature	Date
LICENSEE'S REPRESENTATIVE			
NRC INSPECTOR	Geoffrey M. Warren	<i>G. M. Warren</i>	7/22/08

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6. INSPECTION PROCEDURES USED 87127		7. INSPECTION FOCUS AREAS 03.01 – 03.07	

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02500	2. PRIORITY 2	3. LICENSEE CONTACT Dana Suttle, R.Ph., RSO	4. TELEPHONE NUMBER 231-929-7200
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Main Office Inspection Next Inspection Date: July 2010

Field Office _____

Temporary Job Site Inspection _____

PROGRAM SCOPE

This facility was a nuclear pharmacy located in Traverse City, Michigan. Licensee staff consisted of two pharmacists, two technologists, and five drivers. The pharmacy manufactured and distributed approximately 130-180 unit doses and bulk technetium vials daily Monday through Friday to 11 regular customers in the northern part of the lower peninsula of Michigan, though they expected to be adding clients soon. Most of the unit doses were technetium-99m compounds. Licensee operated from around 12:00 midnight until 12:00 noon on weekdays and occasional hours on weekends. The first run started at 1:00 AM and went out by 3:15 AM; the second run started about 6:00 AM and left starting around 8:00 AM; and other runs were performed as needed throughout the day. The pharmacy received two molybdenum-99/technetium-99m generators weekly. Licensee compounded iodine capsules and received and redistributed xenon-133 vials, iodine-132 capsules, and check sources.

Performance Observations

During this inspection, the inspector observed generator elution, molybdenum assay, kit preparation, kit QC, dose preparation, packaging, dose verification, package surveys and wipes, package placement in vehicles, preparation and placement of shipping papers, package return, dose disposal, area surveys, spot decontamination, and package receipt surveys. Licensee personnel demonstrated dose calibrator constancy checks, iodine-131 dose compounding, waste tracking and disposal, air monitoring, and bioassay procedures, and described response to vehicular accidents. No issues were identified with these practices. Interviews with licensee staff indicated adequate knowledge of radiation safety procedures and policies. Surveys indicated radiation levels consistent with licensee records and postings.

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