

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

PharmaLogic Michigan, LLC
1501 Cass Street
Traverse City, MI 49686

REPORT NUMBER(S) 2015-001

2. NRC/REGIONAL OFFICE

Region III
U. S. Nuclear Regulatory Commission
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

3. DOCKET NUMBER(S)

030-35125

4. LICENSE NUMBER(S)

21-32190-01MD

5. DATE(S) OF INSPECTION

May 1st, 2015

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, to exercise discretion, were satisfied.

Non-cited violation(s) were discussed involving the following requirement(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 in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.
(Violations and Corrective Actions)

Statement of Corrective Actions

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	Ryan Craffey / Ed Harvey	<i>Ryan Craffey / Ed Harvey</i>	5/1/2015
BRANCH CHIEF	Aaron McCraw	<i>Aaron McCraw</i>	5/6/15

Docket File Information

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3. DOCKET NUMBER(S) 030-35125	4. LICENSE NUMBER(S) 21-32190-01MD	5. DATE(S) OF INSPECTION May 1, 2015	
6. INSPECTION PROCEDURES USED 87127	7. INSPECTION FOCUS AREAS All		

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02500	2. PRIORITY 2	3. LICENSEE CONTACT Dana Suttle, RPh - RSO	4. TELEPHONE NUMBER (231) 929-7200
<input checked="" type="checkbox"/> Main Office Inspection Next Inspection Date: 05/01/2015			
<input type="checkbox"/> Field Office Inspection			
<input type="checkbox"/> Temporary Job Site Inspection			

PROGRAM SCOPE

This was an unannounced routine inspection of a radiopharmacy in Traverse City, Michigan, which served nine clients in northern Michigan. The pharmacy operated Monday through Friday from 1:00 am to 1:00 pm, and also on Saturdays. The pharmacy distributed about 150 doses each weekday on one of three runs. The pharmacy's first run began around 1:30 am, with deliveries out between 2:30 am and 4:30 am. The second run began around 6:00 am, and the third around 8:00 am. In addition to unit and bulk doses of technetium-99m, the pharmacy also compounded indium-111 and thallium-201 when needed, as well as 4-5 iodine-131 capsules per week (typically on Tuesdays) using a ventilated glove box. The pharmacy also redistributed xenon-133 gas vials without alteration to its clients.

PERFORMANCE OBSERVATIONS

The inspectors toured the facility in Traverse City to evaluate the licensee's measures for materials security, hazard communication and exposure control. The inspectors conducted independent surveys of unrestricted areas, and found no residual contamination or exposures to members of the public in excess of regulatory limits. The inspectors observed a variety of activities on the licensee's second run, including generator elution, molybdenum breakthrough evaluation, kit preparation, dose drawing, client package preparation and vehicle loading, as well as client package return and waste handling. The licensee's staff also demonstrated the implementation of procedures for area surveys, I-131 capsule preparation, and decay-in-storage waste handling. Through these demonstrations and other discussions, the inspectors found the licensee's staff to be knowledgeable of radiation protection principles and regulatory requirements.

The inspectors also reviewed a selection of licensee records for molybdenum breakthrough checks, dose calibrator quality control, I-131 release evaluations, daily restricted area and weekly unrestricted area surveys, decay-in-storage waste disposals, hazmat training, quarterly program audits and personnel dosimetry, which indicated maximum exposures in 2014 of 364 mrem whole-body / 9,330 mrem extremity, and 121 mrem whole-body / 8,290 mrem extremity in 2015 through April 9th.

No violations of NRC requirements were identified as a result of this inspection.