

**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

1. LICENSEE/LOCATION INSPECTED:  PharmaLogic Michigan, L.L.C. 1501 Cass Street Traverse City, MI 49686  REPORT NUMBER(S) 2017001		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  June 29, 2017	

**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	Edward F. Harvey	<i>Edward Harvey</i>	6/29/17
BRANCH CHIEF	Aaron T. McCraw	<i>AJM - for ATM</i>	7/26/17

**Docket File Information**

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6. INSPECTION PROCEDURES USED  87127	7. INSPECTION FOCUS AREAS  All
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**SUPPLEMENTAL INSPECTION INFORMATION**

1. PROGRAM CODE(S)  02500	2. PRIORITY  2	3. LICENSEE CONTACT  Dana Suttle, RPh - RSO	4. TELEPHONE NUMBER  (231) 929-7200
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Main Office Inspection      Next Inspection Date: June 29, 2019  
 Field Office Inspection \_\_\_\_\_  
 Temporary Job Site Inspection \_\_\_\_\_

**PROGRAM SCOPE**

This was a routine, unannounced inspection of a radiopharmacy in Traverse City, Michigan, which served eight clients in northern Michigan. The pharmacy operated Monday through Friday from 2:00 am to 1:00 pm, and also on Saturdays. The pharmacy distributed 100-150 doses each weekday. The pharmacy's first run began around 3:00 am, but could vary depending on demand. Deliveries for the first run were out around 4:30 am. The second run began around 5:30 am. In addition to unit and bulk doses of technetium-99m, the pharmacy also compounded between two and four iodine-131 capsules per week, typically on Tuesdays.

The inspector toured the facility in Traverse City to evaluate the licensee's measures for materials security, hazard communication and exposure control. The inspector 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 first run, including generator elution, molybdenum breakthrough evaluation, kit preparation, dose drawing, client package preparation, and vehicle loading. The licensee's staff also demonstrated the implementation of procedures for area surveys, package surveys, 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 inspector 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 2016 of 379 mrem whole-body / 21,170 mrem extremity, and 104 mrem whole-body / 5,390 mrem extremity in 2017 through the month of May.

No violations of NRC requirements were identified during this inspection.

*GW for  
ATM  
7/26/17*