NRC FORM 591M
(04-2022)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Report

1. Licensee/Location Inspected:	2. NRC/Regional Office
PharmaLogic Michigan, L.L.C. 1501 Cass St. Traverse City, MI 49684 Report Number(s) 2022001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. Docket Number(s)	4. License Number(s)	5. Date(s) of Inspection
030-35125	21-32190-01MD	March 23, 2022

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. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements, and were assessed at Severity Level IV, in accordance with the NRC Enforcement Policy.

A. 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, corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy were satisfied.
(Non-cited violation(s) was/were discussed involving the following requirement(s)

B. The following violation(s) is/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 AND DATE
LICENSEE'S REPRESENTATIVE		
NRC INSPECTOR	Jason Draper, Health Physicist	Jason D. Draper Digitally signed by Jason D. Draper Date: 2022.04.11 15:06:41 -05'00'
BRANCH CHIEF		Michael A. Kunowski Digitally signed by Michael A. Kunowski Date: 2022.04.13 14:37:39 -05'00'

Add Continuation Page

NRC FORM 592M
(10-2020)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Record

1. Licensee Name:	2. Docket Number(s):	3. License Number(s)
PharmaLogic Michigan, L.L.C.	030-35125	21-32190-01MD

4. Report Number(s):	5. Date(s) of Inspection:
2022001	March 23, 2022

6. Inspector(s):	7. Program Code(s):	8. Priority:	9. Inspection Guidance Used:
Jason Draper	02500	2	IP 87127

10. Licensee Contact Name(s):	11. Licensee E-mail Address:	12. Licensee Telephone Number(s):
Dana Suttle, R.Ph, RSO	dsuttle@radiopharmacy.com	(231) 929-7200

13. Inspection Type:	14. Locations Inspected:	15. Next Inspection Date (MM/DD/YYYY):
☐ Initial	☑ Main Office	☑ Normal
☑ Routine	☐ Field Office	☐ Extended
☐ Announced	☐ Temporary Job Site	☐ Reduced
☐ Non-Routine	☐ Remote	☐ No change
☑ Unannounced		03/23/2024

16. Scope and Observations:

This was an unannounced routine inspection of a radiopharmacy in Traverse City, Michigan, which served approximately 9 clients in northwest Michigan. The pharmacy employed two Authorized Nuclear Pharmacists, one nuclear pharmacy technician, and six drivers. The pharmacy operated Monday through Friday from 2:30am to approximately 2:30pm with limited hours on weekends. The pharmacy distributed approximately 100 dosages each weekday on two runs (occasional third runs) with first run deliveries out by 4:00am and second run deliveries out by 7:00am. In addition to unit and bulk dosages of technetium-99m, the pharmacy also performed indium-111 white blood cell tagging and prepared occasional iodine-131 capsules using a ventilated glove box. While the licensee is authorized to use germanium-68/gallium-68 generators, they have not started that operation yet. Quarterly audits were performed by the pharmacy, and annual audits were performed by corporate representatives.

The inspector toured the facility in Traverse City to evaluate the licensee's measures for materials security, hazard communication, and exposure control. The inspector observed a variety of activities, including kit preparation, dose drawing, client package preparation, vehicle loading, and waste handling. The licensee's staff demonstrated the implementation of procedures for instrument check and calibrations, area surveys, iodine-131 capsule preparation, decay-in-storage waste handling, generator elution, and molybdenum breakthrough evaluation.

The inspector reviewed a selection of licensee records for molybdenum breakthrough checks, dose calibrator quality control, effluent release evaluations, area radiation and contamination surveys, waste disposal, training, dosimetry, and radiation safety program reviews.

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