(06-2010)
10 CFR 2.201

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
PharmaLogic Michigan, LLC **1144 Boon Street** **Traverse City, Michigan 49686** REPORT NUMBER(S) **2010-01**	**U.S. Nuclear Regulatory Commission** **Region III** **2443 Warrenville Road, Suite 210** **Lisle, Illinois 60532-4351**

3. DOCKET NUMBER(S)	4. LICENSEE NUMBER(S)	5. DATE(S) OF INSPECTION
030-35125	**21-32190-01MD**	October 29, 2010

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) 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. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11

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	Robert P. Hays	Robert P. Hays	10/29/10
Branch Chief	TAMARA BLOOMER	Tamara Bloomer	11/10/10

NRC FORM 591M PART 3 (06-2010)

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U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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6. INSPECTION PROCEDURES	7. INSPECTION FOCUS AREAS
87127 (07/01/08)	03.01-03.07

SUPPLEMENTAL INSPECTION INFORMATION

1.PROGRAM	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
2500	2	Dana Suttle, R.Ph., RSO	231-929-7200

X Main Office Inspection — Next Inspection Date: October 2012

☐ Field Office Inspection _____

☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

This nuclear pharmacy included 2 pharmacists and 5 pharmacy technicians/drivers. Currently the licensee has approximately 15+ customers located in Michigan. The licensee prepares and distributes an average of 160 unit doses/day. The licensee receives two Mo-99/Tc 99m generators each week. In addition to unit doses, the pharmacy distributes Xenon-133 gas vials, occasionally therapeutic beta emitters, iodine-123, and compounded I-131 capsules as ordered. The licensee routinely has two daily "runs" Monday-Friday, at 0200 and 0600. The majority of I-131 compounding is performed on Tuesdays each week.

Volatile isotopes are stored in a hood with a set air flow. The air system within the nuclear pharmacy is not recirculated. The I-131 glove box has a dedicated exhaust system with charcoal filters and is monitored weekly with release concentrations below constraint levels. The licensee's corporate office and pharmacy RSO conduct periodic audits of the pharmacy with follow up of previous items identified needing corrective actions. Independent and confirmatory radiation measurements performed by the inspector indicated results consistent with licensee survey records and postings.

Performance Observations

Interviews with licensee personnel indicated extensive knowledge of radiation safety concepts and procedures. The inspector observed procedures in progress and the licensee's staff demonstrated/discussed: (1) unit dose prep procedures; (2) iodine compounding procedures; (3) package receiving and breakdown procedures; (4) area/contamination surveys; (5) safe use and isotope handling (6) DOT packaging and transportation procedures; (7) unit dose management system; (8) QC procedures; (9) wipe test counting and efficiency procedures; (10) survey instruments and calibrations; (11) postings and labeling; (12) staff training; (13) program audits; (14) weekly bioassays; (15) waste handling; (16) facility security; (17) dose calibrator tests, including a partial linearity test; (18) events (none; two dispensing errors documented) and (19) weekly and monthly dose and dosimetry records indicated for CY 2009: 406mr-WB; 14880mr-rt. finger; and 2010 YTD (July): 358mr-WB; 10686mr-rt.finger.