

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Lakeview Diagnostic 36211 Jefferson Avenue Harrison Township, Michigan 48045 REPORT NUMBER(S) 11-001		2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352	
3. DOCKET NUMBER(S) 030-38442	4. LICENSE NUMBER(S) 21-32817-01MD	5. DATE(S) OF INSPECTION Oct. 19, 2011	

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	Geoffrey M. Warren	<i>G. Warren</i>	10/19/11
BRANCH CHIEF	Tamara E. Bloomer	<i>Tamara Bloomer</i>	11/2/11

Docket File Information
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6. INSPECTION PROCEDURES USED 87127	7. INSPECTION FOCUS AREAS 03.01 - 03.07
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SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02500	2. PRIORITY 2	3. LICENSEE CONTACT David W. Schmitt, R.Ph., RSO	4. TELEPHONE NUMBER (810) 987-3317
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Main Office Inspection Next Inspection Date: Oct. 2013
 Field Office Inspection
 Temporary Job Site Inspection

PROGRAM SCOPE

This was the initial inspection of activities performed under the license. The licensee began operations at this facility in June 2011. The facility is consistent with the map provided to NRC in the application.

This radiopharmacy employed two pharmacists, two technician/drivers, and one additional driver. Licensee personnel delivered approximately 100-130 doses daily to twelve regular customers in southeastern Michigan. The pharmacy was open Monday - Friday from 2:00 am to 3:00 pm, with hours as needed on weekends. The licensee weekday runs were from 2:00 through 4:30 am and 7:30 through 8:45 am, with deliveries made as needed after the second run. The licensee received three Mo-99/Tc-99m generators each week for their own use.

Xenon-133 gas vials and iodine-123 and iodine-131 capsules were received and re-distributed without adjustment to their customers. All iodine-131 material was stored in a glove box. Licensee staff were planning for the first annual audit, to be performed by an outside consultant, in the near future. The maximum dose received by licensee personnel since beginning operations (June through August 2011) was 211 mrem whole body and 15931 mrem extremity dose.

Performance Observations

The inspector observed package return surveys and wipes, disposal of returned syringes, survey of pigs and liners, generator elution, molybdenum checks, dose preparation and packaging, pig surveys and wipes, package preparation and surveys, shipping paper preparation and placement, blocking and bracing, and other procedures. Licensee personnel demonstrated kit preparation and QC, survey meter checks, dose calibrator constancy, and daily surveys and wipes. The inspector noted no concerns with these activities.

The inspector observed proper usage of personal dosimetry for both hands and whole-body, as well as use of long-handled tools to reduce doses. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. Review of dosimetry, survey, and emissions records indicated no concerns with radiation worker or public dose. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings.