

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Lakeview Diagnostic
36211 Jefferson Avenue
Harrison Township, MI 48045

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)

030-38442

4. LICENSE NUMBER(S)

21-32817-01MD

5. DATE(S) OF INSPECTION

OCTOBER 20TH, 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.

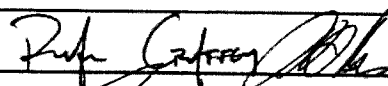
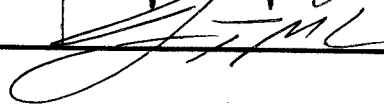
Non-cited violation(s) were discussed involving the following requirement(s):

- ☐ 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 / Luis Nieves		10/20/15
BRANCH CHIEF	Aaron McCraw		11/5/15

Docket File Information

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3. DOCKET NUMBER(S) 030-38442	4. LICENSE NUMBER(S) 21-32817-01MD	5. DATE(S) OF INSPECTION October 20, 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 David W. Schmitt, RPh - RSO	4. TELEPHONE NUMBER (586) 466-6260
<input checked="" type="checkbox"/> Main Office Inspection Next Inspection Date: 10/20/2017 <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 Harrison Township, Michigan, which served approximately 15 clients in an area stretching from the Detroit Metropolitan area north to Flint and Port Huron. The pharmacy operated Monday through Friday from 2:00 am until 4:00 pm, with limited hours on weekends. The pharmacy distributed around 90 doses each weekday, most of which went out on its first run. This run typically began shortly after opening, with deliveries out around 4:30 am. The pharmacy compounded additional doses after the first run on an as-needed basis. The licensee almost exclusively compounded unit doses of technetium-99m, and redistributed I-123 capsules and xenon-133 gas vials without alteration to its clients. The licensee did not compound any I-131 capsules. The licensee relied primarily on one pharmacist, the owner and RSO, to prepare doses, with two other pharmacists available on contingency and three drivers on staff. The licensee also retained the services of a medical physics consultant to review the content and implementation of the radiation safety program annually.

PERFORMANCE OBSERVATIONS: The inspectors toured the licensee's facility in Harrison Township to evaluate the licensee's measures for materials security, hazard communication and exposure control. The inspectors conducted independent surveys of restricted 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 following the licensee's first run, including dose preparation, outgoing package preparation, incoming package receipt, client package return and waste handling, and delivery vehicle loading. Through these observations and additional 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 instrument quality control, area surveys, sealed source inventories, hazmat training, annual radiation program audits, and personnel dosimetry, which indicated maximum exposures in 2014 of 146 millirem (mrem) whole-body / 14,324 mrem extremity, and 72 mrem whole-body / 22,592 mrem extremity in 2015 through August 31st. The inspectors noted the marked increase in extremity dose, which was due primarily to the licensee's increased reliance on a single pharmacist, and discussed with the licensee its measures to ensure that occupational limits would not be exceeded, as well as potential measures to improve ALARA practices.

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