

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Advanced PET Imaging Network
4000 Wellness Drive
Midland, MI 48670

REPORT NUMBER(S) 2016001

2. NRC/REGIONAL OFFICE

Region III
U. S. Nuclear Regulatory Commission
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

3. DOCKET NUMBER(S)

030-38146

4. LICENSE NUMBER(S)

21-32763-01

5. DATE(S) OF INSPECTION

July 13, 2016

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, Health Physicist	<i>Ryan Craffey</i>	7/26/16
BRANCH CHIEF	Aaron McCraw, Chief, MIB	<i>Robert M. Hutton, Jr. for ATM</i>	8/1/16

Docket File Information

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6. INSPECTION PROCEDURES USED 87130	7. INSPECTION FOCUS AREAS All
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SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02220	2. PRIORITY 3	3. LICENSEE CONTACT James M Botti, MS - RSO	4. TELEPHONE NUMBER (734) 839-1384
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<input checked="" type="checkbox"/> Main Office Inspection	Next Inspection Date: 07/13/2019
<input type="checkbox"/> Field Office Inspection	
<input type="checkbox"/> Temporary Job Site Inspection	

PROGRAM SCOPE

This was an unannounced routine inspection of a mobile PET imaging service owned and operated as a joint venture between two health systems in the mid-Michigan region. The service operated one coach and staffed it with one or two nuclear medicine technologists, depending on the scheduled workload. The technologists performed approximately 140 administrations monthly, using unit doses of F-18 FDG delivered directly to the trailer from a nearby radiopharmacy. On Mondays and some Saturdays, the coach was stationed at one of three small hospitals (in Marlette, Tawas City or Alma, Michigan); on Tuesdays and Wednesdays at the Mid-Michigan Medical Center in Midland; and on Thursdays and Fridays at St. Mary's of Michigan Towne Centre Surgery Center in Saginaw. The licensee's medical physics consultant audited the program quarterly, and served as the RSO.

PERFORMANCE OBSERVATIONS

The inspector toured the imaging coach, located in a parking lot on the southeast corner of the Mid-Michigan Medical Center campus in Midland, Michigan, to evaluate the licensee's measures for materials security, hazard communication, and exposure control. The inspector conducted independent and confirmatory surveys of the coach and adjacent restricted areas of the hospital used for patient holding, and observed three administrations of F-18 FDG. The inspector also observed the receipt of packages containing licensed materials, and demonstrations of the implementation of established procedures for area surveys, spill response, decay-in-storage waste handling, and transportation of licensed material.

The inspector also reviewed a selection of records, including dose calibrator quality control documentation, sealed source inventories and leak test results, dosimetry reports, quarterly consultant audits and hazmat refresher training certificates.

Bb fm ATM