

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

<p>1. LICENSEE/LOCATION INSPECTED:</p> <p>Radiopharmacy Incorporated 1409 East Virginia Street Evansville, IN 47711</p> <p>REPORT NUMBER(S) 2018001</p>	<p>2. NRC/REGIONAL OFFICE</p> <p>Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352</p>	
<p>3. DOCKET NUMBER(S)</p> <p>030-31910</p>	<p>4. LICENSE NUMBER(S)</p> <p>13-26246-01MD</p>	<p>5. DATE(S) OF INSPECTION</p> <p>MARCH 29TH 2018</p>

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:

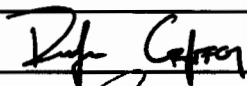
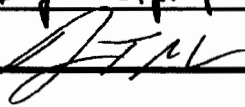
- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is 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		3/29/18
BRANCH CHIEF	Aaron McCraw		05/08/2018

Docket File Information
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6. INSPECTION PROCEDURES USED 87127	7. INSPECTION FOCUS AREAS All
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SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02500	2. PRIORITY 2	3. LICENSEE CONTACT Jason Wilson, RPh - RSO	4. TELEPHONE NUMBER (812) 421-1002
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Main Office Inspection Next Inspection Date: 03/29/2018

Field Office Inspection _____

Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an unannounced routine inspection of a radiopharmacy in Evansville, Indiana. The pharmacy operated Monday through Friday from 12:00 am to 5:00 pm, with some regular hours on weekends. The pharmacy distributed 300-350 doses each weekday, primarily on one of two runs. The pharmacy's first run began around 12:30 am with deliveries out by 5:00 am. The second run began around 6:00 am with deliveries out by 11:00 am. In addition to unit and bulk doses of Tc-99m, the pharmacy also compounded In-111 and Th-201 when necessary, and around six I-131 capsules per week, filled manually. The pharmacy also redistributed Xe-133 gas vials, I-123 capsules, and F-18 FDG unit doses without alteration to its clients. At the time of the inspection, the pharmacy employed four full-time pharmacists, one part-time pharmacist, three pharmacy technicians, and around a dozen drivers.

PERFORMANCE OBSERVATIONS

The inspector toured the facility in Evansville to evaluate the licensee's measures for materials security, hazard communication, and exposure control. The inspector conducted independent surveys of restricted and unrestricted areas, and found no evidence of residual contamination nor exposures to members of the public in excess of regulatory limits. The inspector observed a variety of activities on the pharmacy's second run, including generator elution, dose drawing, dose quality control, client package preparation and vehicle loading, client package return and waste sorting. The licensee's staff also demonstrated the implementation of procedures for I-131 capsule filling, thyroid bioassay, and air effluent monitoring.

The inspector reviewed a selection of records, including daily and weekly area surveys, daily air monitoring evaluations, COMPLY code reports, weekly bioassay results, dose calibrator quality control documentation, radiation safety audits, and dosimetry reports, which indicated maximum exposures in 2016 of 280 mrem whole-body / 15299 mrem extremity, and 256 mrem whole body / 13713 mrem whole body in 2016.

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