NRC FORM 591M PART 1
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Guardian Pharmacy of Indianapolis Nuclear, LLC d/b/a Radiopharmacy of Indianapolis Corporate Center North II, Building A 6538 Corporate Drive, Indianapolis, IN 46278 REPORT NUMBER(S) 2016-001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-37428	13-32637-01MD	MAY 18TH, 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 violations(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	Ryan Craffey	5/18/16
BRANCH CHIEF	Aaron McCraw		5/24/16

NRC FORM 591M PART 3
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-37428	13-32637-01MD	May 18, 2016

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87127	All

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02500	2	Brian Hardesty, RPh - RSO	(317) 522-3855

☑ Main Office Inspection Next Inspection Date: 05/18/2018

☐ Field Office Inspection _____

☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an unannounced routine inspection of an independent radiopharmacy in Indianapolis, Indiana, which routinely served up to 26 clients a day across the greater Indianapolis region. The pharmacy operated Monday through Friday, with very limited hours on weekends. The pharmacy distributed about 170 doses each weekday, primary on one of two runs. The first run began around 2:30 am, with deliveries out by 5:00 am. The second run began around 7:30 am, with deliveries out by 8:00 am. The pharmacy remained open until about 4:00 pm to accommodate add-on orders. In addition to unit and bulk doses of diagnostic radiopharmaceuticals, the pharmacy also manually prepared several I-131 capsules per week in a dedicated glove box, and redistributed Xe-133 vials. The pharmacy had three Authorized Nuclear Pharmacists on staff, as well as one technologists and around 13 drivers. The licensee's RSO conducted audits of the pharmacy's operations at quarterly intervals.

PERFORMANCE OBSERVATIONS

The inspector toured the facility in Indianapolis to evaluate the licensee's measures for materials security, hazard communication and exposure control. The inspector conducted independent surveys of unrestricted areas, and found no residual contamination or exposures to members of the public in excess of regulatory limits. The inspector observed a variety of activities on the licensee's second run, including dose preparation, outgoing package preparation, delivery vehicle loading, client package return and waste handling. The licensee's staff also demonstrated the implementation of procedures for I-131 capsule preparation, air handling evaluations, and air effluent monitoring. Through these observations, demonstrations, and additional discussions, the inspector found the licensee's staff to be knowledgeable of radiation protection principles, license conditions, and regulatory requirements. The inspector also reviewed a selection of licensee records for quarterly audits, independent air handling assessments, air effluent monitoring results, dose calibrator quality control, area surveys, sealed source leak tests and inventories, bioassay measurements, and personnel dosimetry, which indicated maximum exposures of 433 millirem (mrem) whole-body / 13,989 mrem extremity in 2015, and 69 mrem whole-body / 2,689 mrem extremity in 2016 through February 29.

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