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 Bldg A 6538 Corporate Drive, Indianapolis, Indiana 46278 REPORT NUMBER(S) 2014001	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	March 27 , 2014

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. From 030-37428/2012001

☐ 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	Geoffrey M. Warren / Andrew Brammik	/	3/27/14
BRANCH CHIEF	Aaron T. McCraw		4/7/14

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

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87127	03.01 - 03.07

SUPPLEMENTAL INSPECTION INFORMATION

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

☑ Main Office Inspection Next Inspection Date: 03/27/2016

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was a routine inspection of a nuclear pharmacy in Indianapolis, Indiana. The licensee serviced 20-25 regular clients of hospitals and clinics within an approximate 75-mile radius around Indianapolis. The pharmacy conducted two runs daily: from 2:00 to 5:00 am and from 7:00 to 10:00 am. The licensee drew-up and delivered doses as needed until approximately 4:00 pm. The licensee averaged 180 doses per day, of which approximately 70% were cardiac doses. Three authorized nuclear pharmacists (ANPs) and two technicians prepared and measured doses of liquid technetium-99m and capsules of iodine-131. The licensee did not redistribute brachytherapy sources but occasionally redistributed xenon gas vials, cobalt-57 flood sources, or carbon-14 breath kits. The licensee employed between 12-14 delivery drivers who also assisted with return check-in of packages and shielded containers.

PERFORMANCE OBSERVATIONS

The inspectors observed the licensee prepare for its second run, draw technetium doses, conduct QA/QC checks on its products, measure for loose contamination, label doses, package doses for shipment, complete shipping surveys, and load packages into a transport vehicle. The inspectors also observed the licensee conduct post-run surveys, tests for contamination, and personnel surveys out of the restricted area. Lastly, the inspectors observed delivery drivers conducting package check-in surveys, wipe tests on returned shielded containers, visual inspection of returned items, and cleaning of returned packages and items.

The inspectors interviewed the licensee's RSO, pharmacists, technicians, and selected drivers, all of whom demonstrated adequate levels of understanding of operating and emergency procedures. The inspectors reviewed selected records for area monitor results, ventilation tests, effluent releases, program audits, radiation as well as Department of Transportation hazmat training, bioassays, and personnel dosimetry. The maximum observed whole body and extremity dosimetry results since the previous inspection were 584 millirem and 24,107 millirem, respectively. Independent measurements taken at the licensee's facility did not indicate readings in excess of limits in 10 CFR Part 20 limits in restricted or unrestricted areas.

(Continued on Part 2)

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(Continued)

(Continued from Part 3)

The inspectors also reviewed the licensee's corrective actions to a previously-cited violation in 2012 regarding semi-annual checks of the radioiodine hood that were below the required 200 cubic feet per minute (CFM) exhaust rate. In 2012 and 2013, the licensee hired a contractor to conduct testing and repair work on the roof exhaust fan. As a result of the contract work, the licensee's semi-annual checks of the hood increased to: 203.5 CFM in September 2012; 253.1 CFM in March 2013; 217.1 CFM in October 2013; and 209.8 CFM in January 2014. In addition, the inspectors reviewed the licensee's responses to a safety concern identified by the NRC regarding the average face velocity of the hood reading less than the industry standard of 80-120 feet per minute (FPM). Although the licensee's radioiodine hood was greater than the 50 FPM requirement in their license application, the inspectors observed that semi-annual checks revealed a high value of 76 FPM in March 2013 and the most recent reading of 63 FPM in January 2014. The RSO informed the inspectors that he continued to monitor the situation regarding the exhaust rate and average face velocity of the hood. Based on the licensee's consistent readings of the hood's exhaust rate above the required 200 CFM requirement, the previously-cited violation is closed.

No violations were identified during this inspection.