

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Cardinal Health Nuclear Pharmacy Services, Dublin, Ohio
Location inspected: 7920 Georgetown Rd.
Indianapolis, Indiana 46268

REPORT NUMBER(S) 2017001

2. NRC/REGIONAL OFFICE

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

3. DOCKET NUMBER(S)

030-36973

4. LICENSE NUMBER(S)

34-29200-01MD

5. DATE(S) OF INSPECTION

January 27, 2017

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:

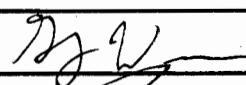

- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is 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	Geoffrey M. Warren		2/9/17
BRANCH CHIEF	Aaron T. McCraw		2/10/17

Docket File Information

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3. DOCKET NUMBER(S) 030-36973	4. LICENSE NUMBER(S) 34-29200-01MD	5. DATE(S) OF INSPECTION January 27, 2017
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6. INSPECTION PROCEDURES USED 87127	7. INSPECTION FOCUS AREAS 03.01 - 03.07
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SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02500	2. PRIORITY 2	3. LICENSEE CONTACT Melissa George, Site RSO	4. TELEPHONE NUMBER (317) 872-3301
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Main Office Inspection Next Inspection Date: TBD

Field Office Inspection 7920 Georgetown Rd, Indianapolis, IN 46268

Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an unannounced routine inspection of this site operating under the Cardinal Health multi-site license. This radiopharmacy was staffed with seven pharmacists, six pharmacy technicians, and 20 drivers. The licensee had approximately 40 regular customers located in central Indiana and east-central Illinois, and distributed approximately 500-600 doses each weekday. The pharmacy was open weekdays from midnight to 3:00 pm, with more limited hours on weekends. The licensee's formal runs began at 1:00 am, 6:30 am, and 8:30 am; later doses were delivered as needed. The licensee received three Mo-99/Tc-99m generators each week for preparation of doses. Pharmacy staff prepared primarily Tc-99m doses, and redistributed Xe-133 vials, I-123 capsules, and F-18 doses prepared at the Cincinnati pharmacy. The pharmacy compounded I-131 therapy capsules for distribution using an automated filling system, and redistributed Ra-223 chloride therapy doses. All I-131 material was manipulated and stored in a glove box with a dedicated exhaust system with dual charcoal filters. The maximum exposure received by site personnel in calendar year 2015 was 98 mrem whole body and 25.1 rem extremity; and in 2016, 183 mrem whole body and 22.9 rem extremity. Higher than normal exposures were investigated by licensee staff. Corporate audits were typically performed two or three times annually, with extended periods after clear audits.

Performance Observations: The inspector observed package receipt surveys, generator elution, molybdenum checks, kit preparation, kit QC testing and retesting, dose drawing, dose packaging and surveys, package assembly and verification, package surveys and wipes, package labeling, shipment paper preparation and placement, package blocking and bracing, package return surveys, waste sorting and handling, and hood surveys and cleaning. Licensee personnel demonstrated I-131 capsule compounding, daily constancy checks, and daily area surveys and wipes, and described emissions monitoring, training, audit procedures, waste handling, and emergency procedures. The inspector noted no concerns with these activities. Licensee personnel used long-handled tools to reduce extremity doses. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings.

No violations were identified during this inspection.

Warren, Geoffrey

From: Warren, Geoffrey
Sent: Friday, February 10, 2017 8:58 AM
To: 'Sullivan, Glenn'
Subject: NRC Inspection Report - Indianapolis IN
Attachments: Cardinal Health 201701 - Indianapolis - 591M.pdf

Enclosed is the inspection report for the NRC's January 27, 2017, inspection at the Cardinal Health facility in Indianapolis, Indiana, as we discussed by telephone this morning. No violations were identified as a result of the inspection. No response is required to the report or to this e-mail.

Please contact me if you have any questions.

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Geoffrey Warren
Senior Health Physicist
NRC Region III
630-829-9742