

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Cardinal Health Nuclear Pharmacy Services, Dublin, Ohio
Location Inspected: 1100 Airport North Office Park
Fort Wayne, IN 46825

2. NRC/REGIONAL OFFICE

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

REPORT NUMBER(S) 2016-001

3. DOCKET NUMBER(S)

030-36973

4. LICENSE NUMBER(S)

34-29200-01

5. DATE(S) OF INSPECTION

January 27, 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:

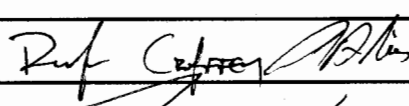

- ☒ 1. Based on the inspection findings, no violations were identified.
- ☒ 2. Previous violation(s) closed.
- ☐ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was 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 / Luis Nieves Folch		2/10/16
BRANCH CHIEF	Aaron T. McCraw		2/10/16

Docket File Information

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Location Inspected: 1100 Airport North Office Park
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REPORT NUMBER(S) 2016-001

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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)

34-29200-01

5. DATE(S) OF INSPECTION

January 27, 2016

6. INSPECTION PROCEDURES USED

87127

7. INSPECTION FOCUS AREAS

03.01-03.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)

02500

2. PRIORITY

2

3. LICENSEE CONTACT

Mark R. Peters, R. Ph., Site RSO

4. TELEPHONE NUMBER

(260) 489-1173

☐ Main Office Inspection

Next Inspection Date: January 27, 2018

☒ Field Office Inspection Fort Wayne, IN☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was a routine, unannounced inspection of this site operating under Cardinal Health's multi-site license. This radiopharmacy was staffed with four pharmacists, four pharmacy technicians, and 20 drivers. The licensee distributed approximately 250 doses each weekday. The pharmacy was open weekdays from 1:30am to 4:00pm, with more limited hours on the weekend. The licensee's schedule runs were completed around 5am, 9am, and in the afternoon. Pharmacy staff prepared primarily Tc-99, I-123, I-131, In-111, Tl-201, and Xe-133. On rare occasion they redistributed F-18 unit doses. The pharmacy compounded I-131 therapy capsules. All I-131 material was manipulated and stored in a glove box with a dedicated exhaust system with dual charcoal filters.

Performance Observations: The inspectors observed generator elution, molybdenum checks, QC sampling and evaluation, kit preparation, dose preparation, dose survey and wipes, package assembly and verification, package wipes and surveys, shipment preparation, blocking and bracing of packages, preparation and placement of shipping papers, package return surveys, waste tracking, and daily surveys and wipes. Licensee personnel demonstrated compounding of I-131 capsules, and described waste disposal, package receipt surveys and wipes, tracking of customer licenses, stack and effluent monitoring, training, and other procedures. The inspectors 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 inspectors performed independent and confirmatory radiation measurements with a calibrated NRC survey instrument which indicated results consistent with licensee survey records and postings. Review of licensee documents audits, training, surveys, dosimetry, and calibrations were satisfactory.

The licensee was previously cited in NRC Inspection Report 12-001 and 12-003 for the violation of 10 CFR 71.5 and 49 CFR 177.817(e)(2)(ii) concerning the failure for drivers to ensure that when they were not at the vehicle's controls, the shipping paper was in a holder mounted on the inside of the door of the driver's side or on the driver's seat in the vehicle. The inspectors found that the licensee had taken effective corrective actions as described in the inspection report, and that the violation had not reoccurred. Therefore, the NRC considers this violation closed.

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

Warren, Geoffrey

From: Warren, Geoffrey
Sent: Wednesday, February 10, 2016 1:31 PM
To: Claunch, Scott
Subject: NRC Inspection Report - Cardinal Health, Fort Wayne MI
Attachments: Cardinal Health - Ft Wayne - 591M.pdf

Enclosed is the inspection report for the Cardinal Health facility in Fort Wayne, Indiana, as we discussed by telephone yesterday. No violations were identified as a result of the inspection, and the previous violation cited at this site is closed. No response is required to the report or 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