

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Cardinal Health Nuclear Pharmacy Services, Dublin, Ohio
Location inspected: 2715 West Main Street
Highland, Indiana 46332

REPORT NUMBER(S) 2016008

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

September 29, 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:

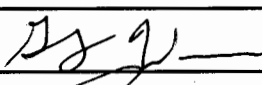
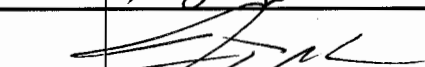
- ☒ 1. Based on the inspection findings, no violations were identified.
- ☒ 2. Previous violation(s) closed.
- ☐ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was 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	Geoffrey M. Warren		10/5/16
BRANCH CHIEF	Aaron T. McCraw		10/6/16

Docket File Information

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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

Christie Holland, AU, NPT, Site RSO

4. TELEPHONE NUMBER

(219) 924-3795

☐ Main Office Inspection

Next Inspection Date: TBD

☒ Field Office Inspection 2715 West Main Street, Highland, IN 46332☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was a routine, unannounced, inspection of this site operating under the Cardinal Health multi-site license. This radiopharmacy was staffed with three pharmacists, five pharmacy technicians, and 20 drivers. The licensee had approximately 20 regular customers located in northwest Indiana and northeast Illinois, and distributed approximately 400 doses each weekday. The pharmacy was open weekdays from 1:30 am to 3:00 pm, with more limited hours on weekends. The licensee's formal runs began at 2:00 am, 6:00 am, and 9:00 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 and In-111 diagnostic doses, and redistributed Xe-133 vials and I-123 capsules. The pharmacy compounded I-131 therapy capsules for distribution 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 60 mrem whole body and 16.1 rem extremity; and in January through July 2016, 39 mrem whole body and 10.2 rem extremity. Corporate audits were typically performed every four months, with extended periods after clear audits.

Performance Observations: The inspector observed package receipt surveys, generator elution, molybdenum checks, kit preparation, kit QC testing, dose drawing, bulk Tc-99m vial preparation, I-131 capsule compounding, dose packaging and surveys, package surveys and wipes, shipment paper preparation and placement, package blocking and bracing, package return surveys, and waste sorting and handling. Licensee personnel demonstrated 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.

The licensee was previously cited for the failure to properly place shipping papers when the vehicle was parked, as required by 10 CFR 71.5(a) and 49 CFR 172.602(c). Corrective actions were completed as described and the violation has not recurred. Interviews with licensee staff indicated knowledge of the proper placement of shipping papers. Based on this, the violation is closed. No violations were identified as a result of this inspection.

Warren, Geoffrey

From: Warren, Geoffrey
Sent: Thursday, October 06, 2016 8:41 AM
To: 'Sullivan, Glenn'
Subject: NRC Inspection Report - Highland IN
Attachments: Cardinal Health - Highland IN - IR 2016008.pdf

Enclosed is the inspection report for the NRC's September 29 inspection at the Cardinal Health facility in Highland, Indiana, as we discussed by telephone this morning. No violations were identified as a result of the inspection, and the violation from the previous inspection was closed. 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