

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Cardinal Health Nuclear Pharmacy Services, Dublin, OH
Location Inspected: 1864 Pine Ridge Drive #A
Jenison, MI 49428

REPORT NUMBER(S) 2016-002

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

April 15, 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:


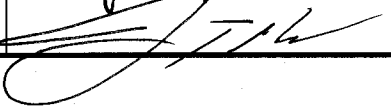
- ☒ 1. Based on the inspection findings, no violations were identified.
- ☐ 2. Previous violation(s) closed.
- ☐ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was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

(07-2012)
10 CFR 2.201**Docket File Information****SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

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34-29200-01MD

5. DATE(S) OF INSPECTION

April 15, 2016

6. INSPECTION PROCEDURES USED

87127

7. INSPECTION FOCUS AREAS

All

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)

02500

2. PRIORITY

2

3. LICENSEE CONTACT

Paul Heim - Site RSO

4. TELEPHONE NUMBER

(616) 662-5013

☐ Main Office Inspection

Next Inspection Date:

TBD

☒ Field Office Inspection 1864 Pine Ridge Drive #A, Jenison, MI☐ Temporary Job Site Inspection**PROGRAM SCOPE**

This was an unannounced routine inspection of a radiopharmacy operating under Cardinal Health's multi-site license. This site, located on the outskirts of Grand Rapids, Michigan, routinely served 15-20 clients across the western half of the state. The pharmacy operated Monday through Friday, with limited hours on weekends. The pharmacy distributed around 130 doses each weekday, primarily on one of two runs. The first run began around 3:00 am, with deliveries out around 4:45 am. The second run began around 8:00 am, with deliveries out around 9:00 am. In addition to compounding doses of Tc-99m and other common isotopes, the pharmacy also routinely redistributed unit doses of F-18 to its clients from Cardinal Health's cyclotron facility in East Lansing, Michigan, and manually compounded a handful of I-131 capsules each week. The licensee had three Authorized Nuclear Pharmacists, two pharmacy technicians and 12-15 drivers on staff at the time of the inspection.

PERFORMANCE OBSERVATIONS: The inspector toured the facility to evaluate the licensee's measures for materials security, hazard communication and exposure control. The inspector conducted independent surveys of restricted and 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 during the licensee's second run, including dose preparation, I-131 capsule preparation, outgoing package preparation, client package return and waste handling, incoming generator and F-18 package receipt, area surveys and delivery vehicle loading. The licensee's staff also demonstrated the implementation of procedures for air effluent monitoring and bioassay for personnel preparing I-131 capsules. Through these observations, demonstrations and other discussions, the inspector found the licensee's staff to be knowledgeable of radiation protection principles and regulatory requirements.

The inspector reviewed a selection of records, including internal and external audits, ALARA and incident reports, dose calibrator quality control records, air effluent monitoring reports, survey meter calibration certificates, hazmat training records, bioassay results and dosimetry reports, which indicated maximum exposures of 150 to 210 millirem whole-body and 15 to 22 rem extremity in 2012 through 2015, and 5 rem extremity in 2016 through March 27 (whole-body monitoring was exchanged quarterly and therefore was not yet available for 2016).

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

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Cardinal Health Nuclear Pharmacy Services, Dublin, OH
Location Inspected: 5370 Miller Road
Swartz Creek, MI 48473

REPORT NUMBER(S) 2016-003

2. NRC/REGIONAL OFFICE

Region III
U. S. Nuclear Regulatory Commission
2443 Warrenton 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

April 26, 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:

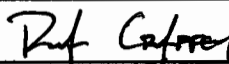
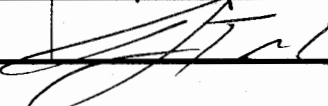
- ☒ 1. Based on the inspection findings, no violations were identified.
- ☐ 2. Previous violation(s) closed.
- ☐ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was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

Docket File Information

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5. DATE(S) OF INSPECTION

April 26, 2016

6. INSPECTION PROCEDURES USED

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7. INSPECTION FOCUS AREAS

All

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)

02500

2. PRIORITY

2

3. LICENSEE CONTACT

Mary Beth Baker - Site RSO

4. TELEPHONE NUMBER

(810) 733-8727

- ☐ Main Office Inspection Next Inspection Date: TBD
- ☒ Field Office Inspection 5370 Miller Road, Swartz Creek, MI
- ☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was an unannounced routine inspection of a radiopharmacy operating under Cardinal Health's multi-site license. This site, located on the outskirts of Flint, Michigan, routinely served around 30 clients across the northeastern portion of the state. The pharmacy operated Monday through Friday, with limited hours on weekends. The pharmacy distributed 150-200 doses each weekday, primarily on one of three runs. The first run began around 1:30 am, with deliveries out around 4:30 am. The second run began around 7:00 am, with deliveries out around 9:00 am. The third run began around 11:00 am, with deliveries out by noon. The pharmacy also routinely prepared unit doses of F-18 for its clients on weekends using bulk quantities obtained from Cardinal Health's cyclotron facility in East Lansing, Michigan. This site no longer compounded I-131 capsules. The licensee had four Authorized Nuclear Pharmacists, four pharmacy technicians and twelve drivers on staff at the time of the inspection.

PERFORMANCE OBSERVATIONS

The inspector toured the facility to evaluate the licensee's measures for materials security, hazard communication and exposure control. The inspector conducted independent surveys of restricted and 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 during the licensee's second run, including generator elution and molybdenum breakthrough checks, unit dose preparation, outgoing package preparation, client package return, waste handling and delivery vehicle loading. The licensee's staff also demonstrated the implementation of procedures F-18 unit dose preparation. Through these observations, demonstrations and other discussions, the inspector found the licensee's staff to be knowledgeable of radiation protection principles and regulatory requirements.

The inspector reviewed a selection of records, including internal and external audits, ALARA reports, dose calibrator quality control records and personnel dosimetry reports, which indicated maximum exposures of 150 to 280 millirem whole-body and 16 to 18 rem extremity in 2012 through 2015, and 4.4 rem extremity in 2016 through March 27 (whole-body monitoring was exchanged quarterly and therefore was not yet available for 2016).

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

Warren, Geoffrey

From: Warren, Geoffrey
Sent: Thursday, May 05, 2016 4:31 PM
To: Claunch, Scott
Subject: NRC Inspection Reports - Jenison and Swartz Creek MI
Attachments: Cardinal Health - Jenison-SwarzCreek - 591M.pdf

Enclosed are the inspection reports for the Cardinal Health facilities in Jenison and Swartz Creek, Michigan, as we discussed by telephone this afternoon. No violations were identified as a result of the inspections. 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