

## SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

## 1. LICENSEE/LOCATION INSPECTED:

Cardinal Health, Nuclear Pharmacy Services, Dublin, OH  
Location inspected: 846 Service Road  
Room E137  
East Lansing, MI 48824

REPORT NUMBER(S) 2015-004

## 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 24, 2015

## 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		5/5/15
BRANCH CHIEF	Aaron McCraw		5/6/15

**Docket File Information**

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April 24, 2015

6. INSPECTION PROCEDURES USED

87127

7. INSPECTION FOCUS AREAS

All

**SUPPLEMENTAL INSPECTION INFORMATION**

1. PROGRAM CODE(S)

02500

2. PRIORITY

2

3. LICENSEE CONTACT

Jason Foster - Site RSO

4. TELEPHONE NUMBER

(517) 432-8334

- ☐ Main Office Inspection      Next Inspection Date: TBD
- ☒ Field Office Inspection      846 Service Road, E137, East Lansing, MI
- ☐ Temporary Job Site Inspection      \_\_\_\_\_

**PROGRAM SCOPE**

This was an unannounced routine inspection of a PET radiopharmacy in East Lansing, Michigan, which supplied other Cardinal Health radiopharmacies in the Midwest and select clients in Michigan directly with a variety of F-18 (and occasionally N-13) radiopharmaceuticals. The pharmacy, accessible from Woodlot Drive on the south side of the MSU Clinical Center, typically operated Monday through Friday from 2:00 am to 10:30 am. The pharmacy received bulk quantities of PET isotopes from an adjacent cyclotron (34-32840-01 / 030-38511), and distributed 80-100 doses each weekday, primarily on one of three runs. The pharmacy's first run began around 3:00 am, the second around 4:45 am, and the third between 7:30 and 8:00 am. Some radiopharmaceuticals, such as N-13 ammonia and F-18 flutemetamol, were compounded later in the morning, based on the treatment schedule of MSU Hospital's adjacent PET Center.

**PERFORMANCE OBSERVATIONS**

The inspector toured the facility in East Lansing to evaluate the licensee's measures for materials security, hazard communication and exposure control. The inspector conducted independent surveys of restricted and unrestricted areas in the facility, and found no residual contamination or exposures to members of the public in excess of regulatory limits. The inspector observed a variety of activities on the licensee's third run, including dose drawing, client package preparation, personnel surveys and vehicle loading. The licensee's staff demonstrated the implementation of procedures for dose calibrator quality control, waste handling, area surveys, and spill response. The inspector also reviewed a selection of licensee records, including daily surveys, dose calibrator quality control documentation, monthly program assessments and periodic audits by Cardinal Health staff, as well as monthly film badge reports, which indicated maximum exposures of 1,842 mrem whole-body / 14,072 mrem extremity in 2014, and 4,970 mrem extremity in 2015 through February 28th (quarterly whole-body badge results were not yet available).

The inspector also reviewed and discussed with licensee personnel their efforts in reducing the slightly elevated background readings noted in areas where portal monitors were located, and in improving ALARA practices specifically when hand-carrying doses to the MSU Hospital PET Center.

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

**Warren, Geoffrey**

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**From:** Warren, Geoffrey  
**Sent:** Wednesday, May 06, 2015 9:58 AM  
**To:** 'scott.claunch@cardinalhealth.com'  
**Subject:** NRC Inspection Report - Cardinal Health, East Lansing MI  
**Attachments:** Cardinal Health - 591M - ELansing MI.PDF

Enclosed is the inspection report for the Cardinal Health facility in East Lansing, 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 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