

(07-2012)  
10 CFR 2.201

## SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

## 1. LICENSEE/LOCATION INSPECTED:

Cardinal Health Nuclear Pharmacy Services, Dublin, Ohio  
Location Inspected: 10250 Stone Creek Drive  
Laurel, Delaware 19956

## 2. NRC/REGIONAL OFFICE

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

REPORT NUMBER(S) 2015-005

## 3. DOCKET NUMBER(S)

030-36973

## 4. LICENSE NUMBER(S)

34-29200-01MD

## 5. DATE(S) OF INSPECTION

May 20, 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	Farrah C. Gaskins, NRC Region I	<i>FGC</i> for FCG	6/19/15
BRANCH CHIEF	Aaron T. McCraw	<i>ATM</i>	6/22/15

## Docket File Information

## SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

## 1. LICENSEE/LOCATION INSPECTED:

Cardinal Health Nuclear Pharmacy Services, Dublin, Ohio  
Location Inspected: 10250 Stone Creek Drive  
Laurel, Delaware 19956

REPORT NUMBER(S) 2015-005

## 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

May 20, 2015

## 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

John Miller, R.Ph., Site RSO

## 4. TELEPHONE NUMBER

(302) 875-3082

☐ Main Office Inspection

Next Inspection Date:

TBD

☒ Field Office Inspection 10250 Stone Creek Dr., Laurel, DE 19956☐ Temporary Job Site Inspection

## PROGRAM SCOPE

This was a routine, unannounced, inspection. The pharmacy is part of a multi-site license for Cardinal Health. This location is small and serves about 30 customers in the Delaware and Maryland area with the furthest customer being about 80 miles away. There are two Authorized Nuclear Pharmacists (ANP) and two technicians that also draw doses and perform quality control. There are approximately eight drivers. The ANP begins the shift around 12am. The first and second runs have been combined since the last inspection and leave between 4:30am and 5am. The ANP begins drawing doses for the next run at a 7am. This location prepares unit and bulk doses of technetium 99m (Tc-99m) for distribution to licensees authorized to receive it. In addition to Tc-99m, they occasionally prepare unit doses of thallium and indium. Iodine is not compounded at the location. Because of this, no bioassays or air sampling is performed. I-131 is received at this location from from a pharmacy in Beltsville, Maryland, and then sent to customers. On average, 200 doses are drawn on a daily basis. The location receives two generators a week. There is a fume hood dedicated to xenon gas but use is minimal. There are also three hoods that are used as stations to draw doses and there is a fume hood used to label white blood cells.

The RSO performs audits on a monthly basis and the there is a corporate audit conducted two times per year. The licensee now uses computer software that uses a scanner/barcode to manage doses and deliveries. Each client is assigned a barcode and the doses ordered are matched to the barcode to ensure accuracy in delivery. This system is also a repository for some of the records pertaining to radiation safety.

The inspector performed independent surveys and found areas in both the restricted and unrestricted areas and delivery vehicles to be at background radiation levels. The highest reading was on contact with the generator box which was .07mR/hr. The inspector observed the pharmacists and technicians drawing doses and performing quality control on the samples. The inspector also observed the drivers, preparing packages for specific routes. IN addition, personnel were interviewed and were knowledgeable of radiation safety practices and procedures. Records of leak tests, inventory, audits, surveys, waste disposal, and package receipts were reviewed.

There were no violations identified.

(07-2012)  
10 CFR 2.201

## SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

## 1. LICENSEE/LOCATION INSPECTED:

Cardinal Health Nuclear Pharmacy Services, Dublin, Ohio  
Location Inspected: 34 New Hope Street, Unit #4  
Princeton, West Virginia 24740

REPORT NUMBER(S) 2015-006

## 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

May 19, 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	Shawn Seeley, NRC Region I	<i>SS</i> for SS	6/19/15
BRANCH CHIEF	Aaron T. McCraw	<i>ATM</i>	6/22/15

**Docket File Information****SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

## 1. LICENSEE/LOCATION INSPECTED:

Cardinal Health Nuclear Pharmacy Services, Dublin, Ohio  
Location Inspected: 34 New Hope Street, Unit #4  
Princeton, West Virginia 24740

REPORT NUMBER(S) 2015-006

## 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

May 19, 2015

## 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

Justin Goodnite, R.Ph., Site RSO

## 4. TELEPHONE NUMBER

(304) 487-5600

- ☐ Main Office Inspection      Next Inspection Date:      TBD
- ☒ Field Office Inspection      34 New Hope St. Unit #4, Princeton WV 24740
- ☐ Temporary Job Site Inspection

**PROGRAM SCOPE**

This was a routine, unannounced, inspection. The pharmacy in Princeton, West Virginia was staffed by one pharmacist assisted by two technicians and several couriers. The pharmacy prepares about 50 doses daily, using only Tc-99m, for about 15 active customers on the second run of the day only. The doses for the first runs of the day are prepared in the Huntington, WV, pharmacy and transported to Princeton by 4:45 am daily. The Princeton drivers arrive at 4:15 am to prepare the return packages and the vehicles for receiving the doses from the Huntington office. The pharmacist begins work at 6:30 am Monday through Friday. Pharmacy operating hours are from 7:00 am to 3:00 pm Monday through Friday.

Any I-131 capsules and Xe-133 are prepared in Huntington and distributed locally through the Princeton pharmacy. Usual deliveries of Mo-99/Tc-99m generators are two generators weekly. Effluents from the facility are negligible, and fixed dosimeters located to measure maximum exposures on exterior walls of the pharmacy demonstrate compliance with public dose limitations. Personnel exposures were all less than regulatory limits.

The inspection consisted of observations of licensee activities, review of selected records, a tour of pharmacy facilities, interviews of personnel, and independent measurements. All required postings were observed and independent measurements were within regulatory limits. Records reviewed included audits, dosimetry reports, leak tests, inventory, instrument calibrations, package receipts, training, daily/weekly surveys, dose calibrator, and waste disposal.

Within the scope of this inspection, no violations were observed.

**Warren, Geoffrey**

---

**From:** Warren, Geoffrey  
**Sent:** Monday, June 22, 2015 3:30 PM  
**To:** 'Claunch, Scott'; 'glenn.sullivan@cardinalhealth.com'  
**Subject:** NRC Forms 591M - Laurel DE & Princeton WV  
**Attachments:** Cardinal Health - NRC 591M - Princeton & Laurel.PDF

Scott -

Enclosed are the NRC Forms 591M for the two subject inspections, as we discussed this afternoon. Please contact me if you have any questions concerning the inspections, which were performed by NRC Region I personnel.

--

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