

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) 2019002

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 19, 2019

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:

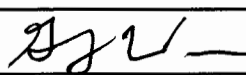

- ☒ 1. Based on the inspection findings, no violations were identified.
- ☐ 2. Previous violation(s) closed.
- ☐ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was 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	Robin Elliott (Geoffrey Warren for RE)		10/3/19
BRANCH CHIEF	Robert Ruiz		10/4/19

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) 2019002		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 19, 2019	
6. INSPECTION PROCEDURES USED 87127	7. INSPECTION FOCUS AREAS 03.01-03.07		

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 04210	2. PRIORITY 2	3. LICENSEE CONTACT John Miller, R. Ph., Site RSO	4. TELEPHONE NUMBER (302) 875-3082
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☐ Main Office Inspection Next Inspection Date: TBD

☒ Field Office Inspection 10250 Stone Creek Drive, Laurel, DE 19956

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was a routine, unannounced inspection of a field office location for the licensee. The pharmacy was relatively small, providing doses for a wide variety of nuclear medicine studies to customers on the Delmarva peninsula. The pharmacy operated Monday through Friday. On weekends, drivers picked-up doses by the Bay Bridge that were prepared in Beltsville, Maryland and delivered them to their customers. One ANP, who typically worked from midnight to 8 am, prepared all the kits and assisted with doses. Two technicians typically prepared doses, and six drivers delivered them. The pharmacy manager and RSO were also ANPs; the site RSO's hours were 8am to 3pm Monday through Friday. The first run included approximately 150 doses and was completed about 4:30am. The drivers left about 5:00am. The second run began about 6:30am and included approximately 70 doses. The farthest distance the drivers had to travel was to Chestertown, MD, about 80 miles away. Doses were typically limited to Tc-99m. Two to three generators were received per week; however, access to the activity they needed was inconsistent. I-123 was received in capsule form and passed along to customers. The pharmacy occasionally prepared doses using In-111, Th-201, and Ga-67. Doses of I-131 and Xe-133 were received from the Beltsville pharmacy and passed along, unopened, to their customers. As a result, no bioassays or air sampling were performed. All doses were prepared in laminar flow hoods that were tested every six months.

Performance Observations: The inspectors toured the facility and observed the following tasks: making kits; drawing doses; performing QA/QC procedures; performing surveys; packaging doses; securing doses; using personal protective equipment and dosimetry; surveying packages; loading of packages into delivery vehicles; preparing transportation paperwork; managing waste; and tracking doses. All personnel were interviewed and found to be knowledgeable of the regulations and using good ALARA practices. The following records were reviewed: dosimetry, audits, leak tests and inventories, surveys, waste, and instrument calibrations. The inspectors confirmed that following the renovation, all dose calibrator tests were performed as required. The inspectors 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.

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

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Cardinal Health Nuclear Pharmacy Services, Dublin, Ohio Location Inspected: 34 New Hope Road, Unit #4 Princeton, West Virginia 24740 REPORT NUMBER(S) 2019003		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 26, 2019

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:

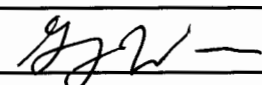

- ☒ 1. Based on the inspection findings, no violations were identified.
- ☐ 2. Previous violation(s) closed.
- ☐ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was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

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TITLE	PRINTED NAME	SIGNATURE	DATE
LICENSEE'S REPRESENTATIVE			
NRC INSPECTOR	Robert Gallagher (Geoffrey Warren for RG)		10/3/19
BRANCH CHIEF	Robert Ruiz		10/7/19

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 Road, Unit #4 Princeton, West Virginia 24740 REPORT NUMBER(S) 2019003		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 26, 2019	
6. INSPECTION PROCEDURES USED 87127	7. INSPECTION FOCUS AREAS 03.01 - 03.07		

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 04210	2. PRIORITY 2	3. LICENSEE CONTACT Justin Goodnite, R.Ph., Site RSO	4. TELEPHONE NUMBER (304) 487-5600
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<input type="checkbox"/> Main Office Inspection	Next Inspection Date: <u>TBD</u>
<input checked="" type="checkbox"/> Field Office Inspection	<u>34 New Hope Road, Unit #4, Princeton, WV</u>
<input type="checkbox"/> Temporary Job Site Inspection	

PROGRAM SCOPE

This was a routine, unannounced inspection of a radiopharmacy. The licensee is staffed with one pharmacist, two technicians and six drivers. The pharmacy prepares 30-50 unit doses daily (all Tc-99m), Monday through Friday from 7 am until 3 pm. The doses for the first runs are prepared in the Huntington, WV pharmacy and transported to the Princeton pharmacy by 4:30 am; 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 at the Princeton pharmacy begins work at 6:30 am.

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

Performance Observations: 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 (which were performed by pharmacy staff once each month and three times per year by the Corporate RSO), dosimetry reports, sealed source inventories/leak tests, inventory, instrument calibrations, package receipts, training (including DOT training), daily/weekly surveys, dose calibrator QA/QC, and waste disposal.

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

(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: 131 Hartland Street
East Hartford, Connecticut 06108

REPORT NUMBER(S) 2019006

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 25, 2019

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:

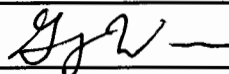
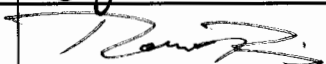
- ☒ 1. Based on the inspection findings, no violations were identified.
- ☐ 2. Previous violation(s) closed.
- ☐ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, to exercise discretion, were satisfied.

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(Violations and Corrective Actions)

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TITLE	PRINTED NAME	SIGNATURE	DATE
LICENSEE'S REPRESENTATIVE			
NRC INSPECTOR	Farrah Gaskins (Geoffrey Warren for FG)		10/3/19
BRANCH CHIEF	Robert Ruiz		10/4/19

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

1. LICENSEE/LOCATION INSPECTED:

Cardinal Health Nuclear Pharmacy Services, Dublin, Ohio
Location Inspected: 131 Hartland Street
East Hartford, Connecticut 06108

REPORT NUMBER(S) 2019006

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 25, 2019

6. INSPECTION PROCEDURES USED

87127

7. INSPECTION FOCUS AREAS

03.01 - 03.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)

04210

2. PRIORITY

2

3. LICENSEE CONTACT

Joshua Pruitt, Site RSO

4. TELEPHONE NUMBER

(860) 291-9027

☐ Main Office Inspection

Next Inspection Date: TBD

☒ Field Office Inspection 131 Hartland St., East Hartford CT 06108☐ Temporary Job Site Inspection**PROGRAM SCOPE**

The inspection was a routine, unannounced inspection for this licensee, which holds a multi-site license to manufacture and distribute radiopharmaceuticals. Since the last on-site inspection, the pharmacy had designated a new site RSO; the former site RSO still worked as an ANP at the site. Five pharmacists prepared doses at this site. The pharmacy manager was also an ANP, but only drew doses as necessary. Five technicians assisted the pharmacists in drawing doses, and approximately 25 couriers packaged doses, delivered the doses, and segregated waste upon return.

The licensee used a variety of radionuclides including Tc-99m, I-123, I-131, In-111, F-18, Tl-201, Ga-67, Sm-153, and occasionally Xe-133. The majority of the doses prepared were Tc-99m. Preparation of the unit doses and the kits were done in a clean room where protective clothing was worn. The clean room had four dedicated hoods for drawing doses. Molybdenum generators were stored in the clean room. Since the last inspection, this site started using a Ge/Ga generator. The inspector ensured that the licensee was adhering to commitments made in accordance with guidance and the manufacturer's instructions. F-18 was provided by the cyclotron that was adjacent to the pharmacy. The F-18 was transferred to the pharmacy within a tungsten pig and placed in a hot cell that was dedicated to preparing F-18 radiopharmaceuticals. Each of the glove boxes used for preparing the pharmaceuticals was serviced annually to ensure proper airflow. Preparation of iodine capsules was performed in a separate iodination room, using an automated smart fill system to inject the specified doses into the capsule. Charcoal filters were used for effluent monitoring.

Performance Observations: The inspection included a walk-around of the perimeter of the facility, a tour of the facilities, observations of activities, and interviews with a variety of pharmacy staff. The inspector observed the pharmacists and technicians drawing doses and preparing kits. The pharmacist on duty also demonstrated how the smart fill system worked for making iodine capsules. The couriers demonstrated performing surveys and loading vehicles. The staff were knowledgeable of regulations and practiced safe use of materials. In addition, records of dosimetry, audits, equipment calibrations, sealed source inventory and leak tests, incident reports, effluent releases, required surveys, waste, and dose calibrator checks were reviewed and determined to be in compliance.

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

Warren, Geoffrey

From: Warren, Geoffrey
Sent: Thursday, October 10, 2019 6:53 AM
To: Sullivan, Glenn
Cc: Elliott, Robin; Gallagher, Robert; Gaskins, Farrah
Subject: NRC Inspection Reports - Laurel DE, Princeton WV, and East Hartford CT
Attachments: Cardinal Health 2019002 (Laurel DE) 2019003 (Princeton WV) and 2019006 (E Hartford CT) - 591Ms.pdf

Enclosed are the inspection reports for the NRC's inspections at the Cardinal Health facilities in Laurel, Delaware; Princeton, West Virginia; and East Hartford, Connecticut, as we discussed by telephone this afternoon. No violations were identified as a result of these inspections. No response is required to the reports or to this message.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this message and its attachment will be available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at <http://www.nrc.gov/reading-rm/adams.html>.

Please feel free to contact me if you have any questions regarding this correspondence.

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Geoffrey Warren
Senior Health Physicist (Inspector)
NRC Region III, Lisle, IL
630-829-9742