

INSPECTION RECORD

Inspection Report Nos. 12-001 & 12-003

License No. 34-29200-01MD

Docket No. 030-36973

Licensee (Name and Address):

Cardinal Health Nuclear Pharmacy Services
7000 Cardinal Place
Dublin, OH 43017

Locations (Authorized Site) Being Inspected:

2715 West Main Street, Highland, Indiana

1100 Airport North Office Park, Suite D, Fort Wayne, Indiana

Licensee Contact: Willie Rejits, Ph.D., Radiation Safety Officer

Telephone No. 614-757-5000

Priority: 2 Program Code: 02500

Date of Last Inspections: February 16, 2010 (Highland), January 7, 2010 (Fort Wayne)

Date of This Inspection: The Highland, Indiana facility was inspected on May 14 through 15, 2012, with continued review through May 30, 2012. The Fort Wayne, Indiana facility was inspected on May 16, 2012, with continued in-office review through May 30, 2012. The in-office review included receipt and review of information that was unavailable during the onsite inspections, including information about how dose calibrators were used to measure the radioactivity of beta emitters.

Type of Inspection: ☐ Initial ☐ Announced ☒ Unannounced
 ☒ Routine ☐ Special

Next Inspection Dates: May 14, 2014 for Highland, and May 16, 2014 for Fort Wayne
(X) Normal () Reduced

Justification for reducing the routine inspection interval: N/A

Summary of Findings and Actions:

- ☐ No violations cited, clear letter issued
- ☐ Non-cited violations (NCVs)
- ☐ Violation(s), Form 591 issued
- ☒ Violation(s), regional letter issued
- ☐ Followup on previous violations

Inspectors

Robert G. Gattone, Jr.

Date

6/11/12

Robert G. Gattone, Jr., Senior Health Physicist

Robert G. Gattone, Jr. for

Date

6/11/12

Michael G. Herr, CHP, Health Physicist

Approved

Hironori Peterson

Date

6/15/12

Hironori Peterson, Chief
Materials Inspection Branch

PART I-LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES:

<u>AMENDMENT #</u>	<u>DATE</u>	<u>SUBJECT</u>
30	2/8/10	Changed the Radiation Safety Officer (RSO)
31	5/17/10	Update fume hood/glove box filter change process
32	5/27/10	Added Radium-223 distribution
33	7/1/10	Removed Griffith, IN facility
34	3/22/11	Added/deleted users, relocate hood in Jenison, MI
35	6/24/11	Added new location of use in Lansing, MI
36	1/23/12	Renewal
37	2/29/12	Changed address for East Lansing, MI location
38	4/23/12	Added Honolulu, Hawaii location

2. INSPECTION AND ENFORCEMENT HISTORY:

No violations were identified during the last inspection that was conducted on May 4, 2012, at the East Lansing, Michigan facility.

No violations were identified during the previous inspection that was conducted on May 12, 2012, at the Sioux Falls, South Dakota facility.

No violations were identified during the last inspection at the Highland, Indiana facility on February 16, 2010.

No violations were identified during the last inspection at the Fort Wayne, Indiana facility on January 7, 2010.

3. INCIDENT/EVENT HISTORY:

None

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

Highland, Indiana Facility

The organization included:

John McElfresh, Authorized Nuclear Pharmacist (ANP) In Charge
Rosalyn Jamison, Pharmacy Manager
Steven Ray, ANP
Jessie Rickelman, ANP
Carl Czarnecki, ANP
Christie Holland, Pharmacy Technician
Derek Richardson, Pharmacy Technician
Jessica Mikesell, Pharmacy Technician
Ron Grochkowski, Pharmacy Technician
Alison Kemp, Pharmacy Technician

The licensee employed 16 drivers.

The hours of operation were 1:00 am to 3:00 pm Monday through Friday and 2:30 am to 9:00 am on Saturday. The pharmacy served about 30 clients in the south suburbs of Chicago and an area of Indiana bounded by Portage, Hoopston, and Rennselier.

The pharmacy received 3 Tc-99m generators per week, including 19 Ci Mallinckrodt generators and 14 Ci Lantheus generators. No generators were distributed from the pharmacy. Spent generators were returned to the manufacturer.

The pharmacy prepared about 325 unit dosages per day, most of which included Tc-99m unit dosages. Other products included Xe-133 unit dosages, In-111 labeled material, Tl-201, I-123 capsules, I-131 liquid and capsules, Ga-67, Sm-153, and Y-90.

The following summarizes the maximum doses received since the last inspection based on Landauer dosimetry badge records:

	<u>2010</u>	<u>2011</u>	<u>2012 (through 5/17/12)</u>
WB max (mrem)	83	96	18
Extremity max (mrem)	16,400	19,900	5,750

Based on records of bioassays that were conducted since the last inspection, all results were less than 1 microcurie.

Fort Wayne, Indiana Facility

The organization included:

Mark Peters, ANP
Todd Holliday, ANP
Tina Hickman, ANP

Stan Miller, ANP

The pharmacy employed 4 Pharmacy Technicians and 6 Drivers.

The hours of operation were 1:15 am to 4:30 pm Monday through Friday, and 2:00 am to 5:00 am Saturday and Sunday. The pharmacy served about 30 clients bounded by Oaklawn, Michigan; Elwood, Indiana; Lima, Ohio; and Kosciusko, Indiana.

The pharmacy prepared about 300 unit dosages per day, and most contained Tc-99m. Additional products included I-123 capsules, TI-201, I-131 capsules, Xe-133 unit dosages, Sm-153, and Y-90.

The following summarizes the maximum doses received since the last inspection based on Landauer dosimetry badge records:

	<u>2010</u>	<u>2011</u>	<u>2012</u>
WB max (mrem)	82	79	20 (through 3/31)
Extremity max (mrem)	10,410	10,930	3,140 (through 4/1)

Based on records of bioassays that were conducted since the last inspection, all results were less than 1 microcurie.

2. SCOPE OF INSPECTION:

Inspection Procedure Used: 87127

Focus Areas Evaluated: 02.01-02.07

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

Highland, Indiana Facility

The inspectors conducted independent and confirmatory radiation surveys with an NRC Ludlum Model No. 2403, Serial No.161606, that was calibrated on 12/23/11 with a Ludlum Model 44-38 probe (Serial No. PRIO9308). The inspectors conducted confirmatory ambient dose rate surveys of selected packages and determined that the licensee's ambient dose rate surveys of the packages were adequate. The inspectors conducted independent ambient dose rate surveys of selected areas in the restricted area and the maximum result was 1 mR/hr at the surface of the Tc-99m generator storage cabinet. In addition, the inspectors conducted independent ambient exposure rate surveys of selected areas of unrestricted areas and the result were indistinguishable from background in a low background area.

Fort Wayne, Indiana Facility

The inspectors conducted independent and confirmatory radiation surveys with an NRC Ludlum Model No. 2403, Serial No.161606, that was calibrated on 12/23/11 with a Ludlum Model 44-38 probe (Serial No. PRIO9308). The inspectors conducted independent and confirmatory ambient dose rate surveys of selected packages and determined that the licensee's ambient dose rate surveys of the packages were

adequate. The inspectors conducted independent and confirmatory ambient dose rate surveys of selected areas of the restricted area and the maximum result was 1.7 mR/hr at 1 foot from Quality Control samples on a countertop.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

The licensee failed to stow shipping papers as required by Title 10 of the Code of Federal Regulations (CFR) Part 71.5 and 49 CFR 177.817(e)(2)(ii). On several occasions as of May 14, 2012, including May 14, 2012, drivers from the Highland, Indiana facility failed to ensure that, when they were not at the vehicle's controls, the shipping paper was in a holder which is mounted to the inside of the door on the driver's side of the vehicle or on the driver's seat in the vehicle. In addition, on several occasions as of May 16, 2012, including May 14 and 15, 2012, a driver from the Fort Wayne, Indiana facility failed to ensure that, when he was not at the vehicle's controls, the shipping paper was in a holder which is mounted to the inside of the door on the driver's side of the vehicle or on the driver's seat in the vehicle. Specifically, when the drivers were not at the vehicle's controls, the shipping papers were left on the front passenger seat of the vehicle while licensed material was in the vehicle.

The root cause of the shipping paper violation was ineffective training on the regulatory requirement. As corrective action, the licensee committed to promptly train applicable staff on the requirement. In addition, the licensee planned to revise its training program to emphasize the regulatory requirement during future training sessions.

The licensee failed to secure licensed material as required by 10 CFR 20.1801. Specifically, on August 25, 2011, a driver from the Highland, Indiana facility stored approximately 73 millicuries of technetium-99m in an unlocked, unattended vehicle that was in an unrestricted area. The licensee identified the violation during an audit conducted by a member of its corporate staff. Based on the inspections at both facilities, the licensee's corrective actions to prevent a similar violation were adequate. The security violation was treated as a Non-Cited Violation (NCV), consistent with Section 2.3.2 of the Enforcement Policy.

5. PERSONNEL CONTACTED:

Highland, Indiana Facility

Kellie Fanning, Driver
Ron Grochkowski, Pharmacy Technician
Bill Haizlip, Driver
#*Christie Holland, Pharmacy Technician, Site RSO
Mike Mefford, Driver
Patricia Mitchell, Driver
Dante Nelson, Driver
^Vai Paye, Health Physicist
^*Willie Regits, RSO (via telephone)
Derek Richardson, Pharmacy Technician
Jessie Rickelman, ANP
Tom Sawochka, Driver

Use the following identification symbols:

- # Individual(s) present at entrance meeting
- * Individual(s) present at on-site, preliminary exit meeting
- ^ Individual(s) participating in telephonic, final exit meeting on May 30, 2012

Fort Wayne, Indiana Facility

Jared Gutierrez, Pharmacy Technician

*Todd Holliday, ANP

Karilee Johnson, Pharmacy Technician

Dan Kruge, Pharmacy Technician

*Stan Miller, ANP

^Vai Paye, Health Physicist

#*Mark Peters, ANP

^Willie Regits, RSO (via telephone)

Mike Thomas, Pharmacy Technician

Jennifer Zvers, Pharmacy Technician

Use the following identification symbols:

- # Individual(s) present at entrance meeting
- * Individual(s) present at on-site, preliminary exit meeting
- ^ Individual(s) participating in telephonic, final exit meeting on May 30, 2012

-END-