INSPECTION RECORD

Region I Inspection Report No. 2008-008 License(s) No. 34-29200-01MD

Docket(s) No. 03036973

Licensee (Name and Address): Cardinal Health Nuclear Pharmacy Serv., 7000 Cardinal Place, Dublin, OH 43017

Location (Authorized Site) Being Inspected: 30 Murray Hill Parkway, East Rutherford, NJ 07073

Licensee Contact: Jack L. Coffey, Radiation Safety Officer Telephone No. 614-757-5000

Priority: 2 Program Code: 02500

Date of Last Inspection: March 22, 2006 Date of This Inspection: May 1, 2008

Type of Inspection: ( ) Initial ( ) Announced (X) Unannounced
( ) Increased Controls (X) Routine ( ) Special

Next Inspection Date: May 2010 (X) Normal ( ) Reduced

Justification for reducing the routine inspection interval:

Summary of Findings and Actions:

( ) No Violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued
( ) Non-cited violations (NCVs)
( ) Violation(s), Form 591 issued
(X) Violation(s), regional letter issued
( ) Followup on previous violations

Inspector: Steven R. Courtemanche Date: May 28, 2008

Name(s)

Ken Lambert for

Signature(s)

Approved: PATRICK LOUDEN Date: 5/28/08

Name

Signature

SUNSI Review Completed By: Ken Lambert X Public X Non-Sensitive

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

1. AMENDMENTS AND PROGRAM CHANGES:
(License amendments issued since last inspection, or program changes noted in the license)

AMENDMENT No. DATE SUBJECT

6 – 16 issued since last inspection none dealing directly with site inspected except procedural changes.

2. INSPECTION AND ENFORCEMENT HISTORY:
(Unresolved issues; previous and repeat violations; Confirmatory Action Letters; and orders)

None

3. INCIDENT/EVENT HISTORY:
(List any incidents, or events reported to NRC since the last inspection. Citing "None" indicates that regional event logs, event files, and the licensing file have no evidence of any incidents or events since the last inspection.)

None

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:
(Management organizational structure; authorized locations of use, including field offices and temporary job sites; type, quantity, and frequency of material use; staff size; delegation of authority)

The licensee is a multi-state pharmacy license. Corporate offices are in Dublin, Ohio. The facility in East Rutherford consists of an iodine prep area, waste storage area, and generator storage room off of the main prep/shipping/QC room. There are four drawing stations with fume hoods. Operations are conducted on Monday thru Saturday from 12 midnight until 12 noon (First run: Midnight to 5:00 a.m. and second run: 7:00 a.m. to noon). 450 radiopharmaceutical doses are drawn each day. Whole body and extremity exposures were within regulatory limits. It was noted that personnel drawing FDG doses had exposures 3 times higher than others not drawing FDG doses. Licensee attributed this to a "learning curve" with new equipment and higher dose rates from the material. Thyroid bioassay measurements were within regulatory limits. Variability of calibration factor from previous inspection (i.e., 39 percent min/max) decreased due to greater precision of licensee.

There are four pharmacists on staff with one manning the night shift. Five technicians (one in training) draw doses. There are 10 drivers who also package doses prior to shipment. The inspector observed preparation of doses, handling of licensed material, radiation and contamination surveys (See Part II, Section 4), preparation and loading of radioactive material shipments, handling of radwaste and other routine operations.

2. SCOPE OF INSPECTION:
(Identify the inspection procedure(s) used and focus areas evaluated. If records were reviewed, indicate the type of record and time periods reviewed)

Inspection Procedure(s) Used: 87127

Focus Areas Evaluated: 03.01 – 03.07

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:
(Areas surveyed, both restricted and unrestricted, and measurements made; comparison of data with licensee's results and regulations; and instrument type and calibration date)

Performed confirmatory survey after licensee completed pharmacy run and surveys for contamination. Areas surveyed included the preparation hoods, QC/QA area, generator room, waste storage area, and shipping area. Radiation dose rate level measurements were made with a Ludlum 14c end-window GM survey instrument (SN NRC09663) calibrated on February 26, 2008. The inspector's measurements were in agreement with the licensee's and did not exceed any regulatory limits.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:
(State the requirement, how and when the licensee violated the requirement, and the licensee's proposed corrective action plan. For NCVs, indicate why the violation was not cited. Attach copies of all licensee documents needed to support violations.)

License Condition 24 requires, in part, that the licensee conduct its program in accordance with the application, dated March 29, 2001, including any enclosures. Item 10.4.C of the application

requires that personnel monitor their hands and clothing for contamination before exiting the restricted area.

Contrary to the above, on January 28, March 27, and May 1, 2008, personnel failed to monitor their hands and clothing for contamination before leaving the restricted area. Specifically, during audits on January 28 and March 27, 2008, the licensee identified personnel leaving the restricted area without monitoring. In addition, on May 1, 2008, an individual performed the required monitoring, but rather than exiting the door by the frisking station, walked through the restricted area exiting through a different door without again monitoring himself.

5. PERSONNEL CONTACTED:
(Identify licensee personnel contacted during the inspection, including those individuals contacted by telephone.)

Use the following identification symbols:
Individual(s) present at entrance meeting
* Individual(s) present at exit meeting

Mary Ndumale, Pharmacist#
Abdul Kamara, Pharmacy Manager
Jose Cruz, Driver
Willie Regits, Corporate Safety Office *
Et al.

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