**UNITED STATES**
**NUCLEAR REGULATORY COMMISSION**
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

March 25, 2008

Mr. Jack Coffey
Senior Vice President
Quality and Regulatory
Nuclear Pharmacy Services
Cardinal Health
7000 Cardinal Place
Dublin, OH 43017

SUBJECT: NRC INSPECTION REPORTS 030-36973/08-02 and 030-36973/08-11(DNMS) (FORM 591M Part 1); CARDINAL HEALTH, SOUTH BEND, INDIANA AND SIOUX FALLS, SOUTH DAKOTA

Dear Mr. Coffey:

This letter refers to the routine inspections conducted on February 29, 2008, at your South Bend, Indiana facility, and on March 13, 2008, at your Sioux Falls, South Dakota facility. The inspection results were discussed with Willie Regits of your staff during a final telephonic exit briefing conducted on March 21, 2008.

These inspections were an examination of activities conducted under your license as they relate to radiation safety and to compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of selective examinations of procedures and representative records, interviews with personnel, independent measurements, and observation of activities in progress. Within the scope of these inspections no violations of NRC requirements were identified; therefore, no response to this letter or the enclosed NRC Form 591Ms is required.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Should you have any questions concerning these inspections or enclosed reports, please contact Ken Lambert of my staff at (630) 829-9633.

Sincerely,

John R. Madera, Chief
Materials Inspection Branch

Docket No.: 030-36973
License No.: 34-29200-01MD

Enclosures:
1. Inspection Report 030-36973/08-02
2. Inspection Report 030-36973/08-11

cc w/encl 1: State of Indiana
cc w/encl 2: State of South Dakota

NRC FORM 591M PART 1
(1-2008 edited by RIV)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

# SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

| 1. LICENSEE/LOCATION INSPECTED: | 2. NRC/REGIONAL OFFICE |
|---|---|
| Cardinal Health Nuclear Pharmacy Services<br>Loc: 1603 "C" Avenue, Sioux Falls, South Dakota 57104<br>REPORT NUMBER(S) **2008-011** | **USNRC Region IV**<br>**611 Ryan Plaza Drive**<br>**Arlington, Texas 76011-4005** |

| 3. DOCKET NUMBER(S) | 4. LICENSEE NUMBER(S) | 5. DATE(S) OF INSPECTION |
|---|---|---|
| 030-36973 | 34-29200-01MD | March 13, 2008 |

**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 violations(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) was/were discussed involving the following requirement(s) and Corrective Action(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. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance 10 CFR 19.11.

(Violations and Corrective Actions)

Licensee's Statement of Corrective Actions for Item 4, above.

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 | Lawrence Donovan | Ken Lambert for | 3/25/08 |

NRC FORM 591M PART 3
(1/2008 edited by RIV)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

*Docket File Information*

**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

| 1. LICENSEE | 2. NRC/REGIONAL OFFICE |
|---|---|
| Cardinal Health Nuclear Pharmacy Services<br>REPORT NUMBER(S) 2008-011 | **USNRC Region IV** |

| 3. DOCKET NUMBER(S) | 4. LICENSE NUMBER(S) | 5. DATE(S) OF INSPECTION |
|---|---|---|
| 030-36973 | 34-29200-01MD | March 13, 2008 |

| 6. INSPECTION PROCEDURES USED | 7. INSPECTION FOCUS AREAS |
|---|---|
| 87127 | All |

**SUPPLEMENTAL INSPECTION INFORMATION**

| 1. PROGRAM CODE(S) | 2. PRIORITY | 3. LICENSEE CONTACT | 4. TELEPHONE NUMBER |
|---|---|---|---|
| 2500 | 2 | Tom Wolff | 605-332-3703 |

☐ Main Office Inspection
☒ Field Office Inspection
☐ Temporary Job Site Inspection

1603 "C" Avenue, Sioux Falls, South Dakota 57104

Next Inspection Date: TBD

**PROGRAM SCOPE**

This was an assist inspection of a nuclear pharmacy for Region III. Licensee is authorized for and receives Molybdenum-99/Technicium-99m in 14 and 16 Ci generators each week, 350 mCi/week of Iodine-131, 600 mCi/week of Xenon-133, 20mCi/week of Thallium-201, and 12 mCi / week of Indium-111. This office has 3 Authorized Nuclear Pharmacists (ANPs), 2 technicians, a few rotating student interns, 9 drivers, and a secretarial staff. Deliveries are made to medical facilities all over Sioux Falls and a few other assorted hospitals in the State with primary delivery times of 0600, 1000, and 1300. The pharmacy is operational from 2am to 4pm daily. Inspectors arrived at 3:45 AM. Inspectors observed radiopharmaceutical preparation, calibration, labeling, surveys, swipes, and transportation of 2 separate early deliveries. Examination of set-up of glove box technique and fume hood air sampling monitors were done. Radiation hoods were at negative pressure when using volatile isotopes. Inspectors reviewed dosimetry and records of equipment calibrations, leak tests, surveys, quality control, effluent release, incidents/events, and transportation records. Dose calibrator daily constancy checks were observed and records of geometrical variation, quarterly linearity and semi-annual accuracy records were reviewed and found to be adequate. Dosimtery records were reviewed over the the past 2 years. Maximum annual doses were 1700 mrem Shallow Dose Equivalent (SDE) and 341 mrem Deep Dose Equivalent (DDE) to the staff. All janitorial activities are performed by the AU's or individuals under the supervision of the AU's. Waste is kept for decay in storage until readings are the same as background. Audits are performed internally and by the corporate office to include ALARA and operational practices. The licensee adheres to company-wide dose thresholds as a percentage of NRC limits. Training was up-to-date for radiation safety, hazmat, emergency procedures, and DOT. Annual letters on radioactive material location within the building are sent to the Local Law Enforcement Agency and emergency responders. Bioassays are performed on staff when necessary depending on the isotope. Licensee had appropriate postings and labels on materials and rooms. A public dose assessment was available for review, which the licensee demonstrated by placing a dosimeter in the vicinity of the storage location of the Tc99m generators. DDE for 2006 and 2007 for this location was 234 mrem and 93 mrem respectively. The reduction from 243 to 93 was accounted for because the licensee had moved the area monitor badge to a location just inside an external wall, as opposed to just outside the room where the generators were stored, a difference of about 5.5 feet. Inspectors made a recommendation on TLD placement on adjacent walls which are used as area monitors. Specifically one monitor placed in a hallway wall was attached to a nail at a flat 90 degree orientation from expected radiation beams thus enducing possible angular dependence errors and the reporting of a lower dose. A stack survey was also conducted by inspectors on the licensee's roof using a Ludlum 2401-P survey meter calibrated on 9/21/2007. There are 2 stacks which are connected to the fume hoods below in the laboratory. Readings were indistinguishable from background levels. No potential or apparent violations were identified.