



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

September 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 REPORT 030-36973/08-06 (FORM 591M Part 1)
CARDINAL HEALTH – KANSAS CITY, MISSOURI FACILITY

Dear Mr. Coffey:

This letter refers to the routine inspection conducted on August 28, 2008, at your Kansas City, Missouri facility. The inspection results were discussed with Chris Walters of your staff during a final telephonic exit briefing conducted on September 19, 2008.

This inspection was 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 this inspection no violations of NRC requirements were identified; therefore, no response to this letter or the enclosed NRC Form 591M is required.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure 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 this inspection or enclosed report, please contact Ken Lambert of my staff at (630) 829-9633.

Sincerely,

A handwritten signature in black ink, appearing to read "P. L. Loudon", with a stylized flourish at the end.

Patrick L. Loudon, Chief
Materials Inspection Branch

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

Enclosures: Inspection Report 030-36973/08-06

cc w/encl: State of Missouri

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

| | | | |
|--|---|---|--|
| 1. LICENSEE/LOCATION INSPECTED: Cardinal Health Nuclear Pharmacy Services Dublin, OH 43017 Kansas City, MO pharmacy REPORT NUMBER(S) 2008-06 | | 2. NRC/REGIONAL OFFICE U.S. Nuclear Regulatory Commission Region III 2443 Warrenville Road Suite 210 Lisle, Illinois 60532-4351 | |
| 3. DOCKET NUMBER(S) 030-36973 | 4. LICENSEE NUMBER(S) 34-29200-01MD | 5. DATE(S) OF INSPECTION August 28, 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 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, NUREG-1600, 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 with 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 | Sam Mulay |  | 9/3/08 |

SAFETY INSPECTION REPORT
AND COMPLIANCE INSPECTION

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|--|--|--|--|
| 1. LICENSEE Cardinal Health (Kansas City, MO . REPORT NUMBER(S) 2008-06 | | 2. NRC/REGIONAL OFFICE Region III 2443 Warrenville Road, Suite 210 Lisle, IL 60532 | |
| 3. DOCKET NUMBER(S) 030-36973 | | 4. LICENSE NUMBER(S) 34-29200-01MD | 5. DATE(S) OF INSPECTION August 28, 2008 |
| 6. INSPECTION PROCEDURES USED 87127 | | 7. INSPECTION FOCUS AREAS 03.01-03.07 | |

SUPPLEMENTAL INSPECTION INFORMATION

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|--|-------------------------|---|--|
| 1. PROGRAM CODE(S) 2500 | 2. PRIORITY 2 | 3. LICENSEE CONTACT Asma Abbasi, ANPT., RSO | 4. TELEPHONE NUMBER 816-966-2024 |
| <input checked="" type="checkbox"/> Main Office Inspection | | Next Inspection Date: 08/2010 | |
| <input type="checkbox"/> Field Office | | | |
| <input type="checkbox"/> Temporary Job Site Inspection | | | |

PROGRAM SCOPE

The licensee provides unit and bulk doses of byproduct material to approximately 50 clients within the States of Missouri and Kansas. The pharmacy is operational Monday-Friday from 12:00am-5:00pm Monday-Friday and 5:00am-10:00am Saturday and Sunday. All other times are covered on-call.

The licensee receives three Mo99/Tc99^m generators weekly in various quantities as authorized. On average, an Authorized Nuclear Pharmacist (ANP) will perform about 3 iodine-131 encapsulations per day. Encapsulations were not being performed at time of inspection.

This radiopharmacy employs 5 ANP's, 10 pharmacy technicians, approximately 15 drivers and maintains a fleet of seven delivery vehicles. In addition, the licensee possesses four dose calibrators and three draw stations. One dose calibrator is used exclusively for approximate measurements prior to obtaining final reading at one of the other draw stations. Corporate audits are performed at approximately three month intervals which appear to adequately maintain program compliance.

Performance Observations

The inspector observed a generator elution procedure, unit dose preparation and drawing, unit dose quality control, performance of surveys and wipes prior to shipment, loading in dedicated transport vehicles, package receipt surveys and wipe tests and personal survey meter "frisk" upon leaving the restricted area during the third run with no problems or issues identified. Adequate block/brace procedures were also observed as well as proper shipping paper documentation and accessibility. Vehicle surveys and wipe tests were demonstrated during the review with no problems or concerns identified.

Proper usage of personal dosimetry was also observed. The licensee exchanges whole-body dosimetry monthly and extremity badges weekly for ANP's, and technicians. Driver dosimetry is exchanged monthly. Maximum annual readings for 2007 indicated whole-body exposure of 381 mRem and 17,390 mRem extremity. YTD 2008 maximum readings were whole-body 370 mRem and extremity of 15,410 mRem.

Independent measurements conducted indicated maximum readings of 0.6 mr/hr over the generator storage cabinet. Draw station floors, benches etc., revealed approximately 0.05 mr/hr. Unrestricted area levels did not exceed background levels (0.03mr/hr). Side by-side comparison of licensee's survey instruments did not indicate significant variances. The licensee's security monitoring system was verified operational during the review and appeared to function as designed.