NRC FORM 591M PART 1 U.S. NUCLEAR REGULATORY COMMISSION
(10-2003)
10 CFR 2.201

# SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

| 1. LICENSEE/LOCATION INSPECTED: | 2. NRC/REGIONAL OFFICE |
|---|---|
| Cardinal Health<br>Nuclear Pharmacy Services<br>Dublin, OH 43017<br>Jenison, MI pharmacy<br><br>REPORT NUMBER(S) 2006-018 | **U.S. Nuclear Regulatory Commission**<br>**Region III**<br>**2443 Warrenville Road, Suite 210**<br>**Lisle, Illinois 60532-4351** |

| 3. DOCKET NUMBER(S) | 4. LICENSEE NUMBER(S) | 5. DATE(S) OF INSPECTION |
|---|---|---|
| 030-36973 | 34-29200-01MD | Aug. 25, 2006 |

**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

[X] 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)

NMED No. 060123

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 | **Deborah A. Piskura** |  | **09/06/2006** |

**NRC FORM 591M PART 3** (10-2003) 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 (Jenison, MI pharmacy)**<br>REPORT NUMBER(S) **2006-018** | **Region III**<br>**2443 Warrenville Road, Suite 210**<br>**Lisle, IL 60532** |

| 3. DOCKET NUMBER(S) | 4. LICENSE NUMBER(S) | 5. DATE(S) OF INSPECTION |
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| 6. INSPECTION PROCEDURES | 7. INSPECTION FOCUS AREAS |
|---|---|
| 87127 | 03.01, 03.02, 03.03, 03.04, 03.05, 03.06, 03.07, and 03.08 |

**SUPPLEMENTAL INSPECTION INFORMATION**

| 1. PROGRAM CODE(S) | 2. PRIORITY | 3. LICENSEE CONTACT | 4. TELEPHONE NUMBER |
|---|---|---|---|
| 02500 | G 2 | Cindy Gaudreau, R.Ph., Pharmacy RSO | |

☐ Main Office Inspection — Next Inspection Date: 9/2006* Corporate

☒ Field — Jenison, MI pharmacy

☐ Temporary Job Site

**PROGRAM SCOPE**

The Jenison, Michigan pharmacy employed 3 ANPs, 3 pharmacy technicians, and 12 drivers/couriers. The pharmacy served approximately 15 customers located in the Southeastern Michigan area and distributed approximately 300 doses daily. The licensee received 3 Mo99/Tc99$^{m}$ generators each week. Xenon-133 gas vials were received and re-distributed to their customers, however, the inner containers were not opened in the pharmacy. The pharmacy processed liquid I-131 for compounding therapy capsules and I-131 labeled Cholortoxin (TM 601). Occasionally, the pharmacy prepared and distributed beta-emitting radiopharmaceuticals. These beta doses were measured, using a correction factor, in the licensee's dose calibrator prior to transfer to the customer.

This inspection consisted of interviews with licensee personnel, a review of selected records, tour of the radiopharmacy, and independent measurements. During this inspection, the inspector observed morning runs. These observations included observing licensee personnel performing dose calibrator QC/QA tests, eluting generators, drawing doses, receiving packages, packaging doses for shipment and conducting surveys for compliance with NRC and DOT requirements.

The inspector noted that as of June 7, 2006, all weekly air monitoring results of the I-131 glove box failed the licensee's internal investigational level II limits; however the year-to-date effluents were 30% of Part 20 limits. Weekly bioassay results were less than the licensee's in-house limit of 0.04 microcuries. These monitoring failures may be attributed to the significant increase of I-131 usage for capsule compounding (using pharmaceutical grade I-131) and TM 601 (using chemical grade I-131). The inspector also noted that the pharmacy filters were secured within the stack using duct tape. The last corporate audit also identified these issues. During the telephonic exit, the corporate health physics group committed to evaluate the issue regarding the elevated effluent releases and to correct the manner in which the filters were secured within the stack.

This inspection also reviewed a matter concerning the pharmacy's shipment of two packages with apparent contamination in excess of regulatory limits. On February 17, 2006, St. Mary's Health Care (Lic. No. 21-01078-01) reported excessive Tc-99m contamination levels on two packages containing I-131 dosages received from the Cardinal Health Jenison pharmacy. Discussions with St. Mary's indicated that hospital personnel surveyed the exterior of the packages and found high contamination prior to opening the packages. The licensee initially believed the packages were originally contaminated at the pharmacy. Additional conversations with the RSO of St. Mary's revealed that the contamination may have resulted from migration of a Tc-99m spill in the hot lab dose prep area. A review of the pharmacy's survey records and an incident report on this matter indicated that survey results on both packages were well below the regulatory limits prior to shipment to the customer. Vehicle and personnel survey results indicated background levels. Therefore, the source of the excess Tc-99m contamination on the two packages was most likely from the hospital and not the pharmacy.

The maximum whole body and extremity exposures (in millirem) were reported as follows:

| | 2005 | YTD 2006 |
|---|---|---|
| whole body | 259 | 138 |
| extremity | 27,170 | 16,390 |