



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

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

July 17, 2007

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

**SUBJECT: NRC INSPECTION REPORT 030-36973/07-09 (FORM 591M Part 1)
FORT WAYNE, INDIANA**

Dear Mr. Coffey:

This letter refers to the routine inspection conducted on June 25, 2007, at your Fort Wayne, Indiana facility. The inspection results were discussed with Willie Regits of your staff during a final telephonic exit briefing conducted on July 13, 2007.

The 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>.

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Cardinal Health 1100 Airport North Office Park Fort Wayne, IN 46925		2. NRC/REGIONAL OFFICE U.S. Nuclear Regulatory Commission Region III 2443 Warrenville Road Suite 210 Lisle, Illinois 60532-4351	
REPORT 2007-09			
3. DOCKET NUMBER(S) 030-36973	4. LICENSEE NUMBER(S) 34-29200-01MD	5. DATE(S) OF INSPECTION 6/25/2007	

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	Darrel G. Wiedeman	<i>Ben Lambert for</i>	7/13/07

(10-2003)
10 CFR 2.201

Docket File Information
SAFETY INSPECTION REPORT
AND COMPLIANCE INSPECTION

1. LICENSEE Cardinal Health REPORT NUMBER(S) 2007-09		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 6/25/2007
6. INSPECTION PROCEDURES USED 87127		7. INSPECTION FOCUS AREAS 02.03 thru 02.11;02.2e,0213 thru 02.14;9216 thru 02.19; and 02.21	

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02500	2. PRIORITY 2	3. LICENSEE CONTACT Stan Miller, R.Ph, RSO	4. TELEPHONE NUMBER (260) 489-1173
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Main Office Inspection
 Field Office _____
 Temporary Job Site Inspection _____

Next Inspection Date: _____

PROGRAM SCOPE

This radiopharmacy employs four (4) full-time pharmacists, two (2) pharmacy technicians, and sixteen (16) drivers. Currently the licensee has approximately 30 customers located in the Fort Wayne and Battle Creek, MI areas, and distributes approximately 300-350 doses/day. The pharmacy is open Monday - Friday from 12:30 am to 4:30 pm and Saturday from 2:00 pm to 5:00 pm. The licensee's first weekday run starts @ 1:30 a.m. with deliveries continuing throughout the day. The licensee receives three Mo99/Tc99^m generators each week for redistribution of the elution to clients. Xenon-133 gas vials were received and re-distributed to their customers; however, the inner containers were not opened in the pharmacy. The pharmacy reconstituted and redistributed approximately 350 millicuries of iodine-131 therapy solution weekly; however, most of the iodine-131 is used to compound therapy capsules. All I-131 material was manipulated and stored in a specific glove box with charcoal filters in the exhaust system. The air system within the facility is not recirculated. The iodine glove box has a dedicated exhaust system with dual charcoal filters.

Occasionally, the pharmacy re-distributed unit doses of samarium-153 and yttrium-90. These doses were measured, using an appropriate correction factor, in the licensee's dose calibrator prior to transfer to the customer. The licensee's corporate office conducts three regulatory audits/year of the program and the RSO conducts a monthly in-house audit. The last corporate audit was conducted on 3/8/2007 and showed one minor deficiency which was subsequently corrected.

Performance Observations

The inspector arrived at the site at 7:00 a.m. to observe the second run. During this inspection, the inspector observed the late morning runs. This included performing dose calibrator QC/QA tests, drawing doses, packaging doses for shipment, and conducting surveys for compliance with NRC and DOT requirements.

Proper usage of personal dosimetry for both hands and whole-body was observed. The highest wholebody exposure for 2007 (YTD) was <20 mrem and the highest extremity exposure was 5.8 rem. The drivers that were interviewed indicated that boxes containing licensed material would not be left in unsecured areas and shipping papers are always carried in the passenger compartment of the vehicle. Proper vehicle surveys were also demonstrated with no problems noted. The inspector performed independent and confirmatory radiation measurements which indicated similar results as noted in the licensee's survey records, < 2 mR/hour in the unrestricted area of the pharmacy. A side-by-side comparison of both instruments using a 1.0 microcurie cesium-137 button source showed both instrument readings were within ±20%.

No violations of NRC requirements were identified within the scope of this inspection.