



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

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

April 25, 2006

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

SUBJECT: NRC INSPECTION REPORT 03036973/06-005 (FORM 591M PART 1)

Dear Mr. Coffey:


This letter refers to the routine inspection conducted on April 13, 2006, at your Terre Haute, Indiana facility. The inspection results were discussed with Paul Gotti, Radiation Safety Officer, during a final telephonic exit briefing conducted on April 19, 2006.

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 the enclosed report, 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

Enclosure:
Inspection Report 03036973/06-005

cc w/encl: State of Indiana

Docket File Information
SAFETY INSPECTION REPORT
AND COMPLIANCE INSPECTION



1. LICENSEE Cardinal Health REPORT 2006-005		2. NRC/REGIONAL OFFICE Region III 2334 Warrenville Road Lisle, IL 60532	
3. DOCKET NUMBER(S) 030-36973		4. LICENSE NUMBER(S) 34-29200-01MD	5. DATE(S) OF INSPECTION April 13, 2006
6. INSPECTION PROCEDURES USED 87127		7. INSPECTION FOCUS AREAS 03.01-03.07	
SUPPLEMENTAL INSPECTION INFORMATION			
1. PROGRAM 2500	2. PRIORITY 2	3. LICENSEE CONTACT Matthew Bergen, R.Ph., Pharmacy Mgr.	4. TELEPHONE NUMBER 812-242-9097
<input type="checkbox"/> Main Office Inspection		Next Inspection Date: April 2008	
<input checked="" type="checkbox"/> Field	527 Honey Creek Drive, Terre Haute, IN		
<input type="checkbox"/> Temporary Job Site			

PROGRAM SCOPE

The licensee provides unit and bulk doses of byproduct material to approximately 15 clients in the Terre Haute, IN area as well as central and southern Illinois. The pharmacy is operational Monday-Friday from 2:00am-4:00pm and 4:00am-5:00am Saturday and Sunday. All other times are covered on-call.

The licensee receives three Mo99/Tc99^m generators ranging from 5 to 12.5 curies on varying days each week. This location does not perform Iodine-131 encapsulations. Radiolodine is prepared by Cardinal Health, Indianapolis, IN and shipped to the Terre Haute, IN facility for re-distribution to clients in that area. Xenon-133 is stored in a continually operating glovebox for re-distribution as needed.

This radiopharmacy employs 2 pharmacists, 1 pharmacy technician, approximately 6 drivers and maintains a fleet of dedicated transport vehicles. The licensee's corporate office conducts quarterly program audits.

Performance Observations

The inspector observed a dose preparation during the review which included labeling and packaging the dose for shipment, conducting surveys and wipes for compliance with NRC and DOT requirements and loading in the dedicated transport vehicle. The shipment was observed properly blocked and braced and shipping papers contained all appropriate information and were maintained accessible. Drivers were aware of emergency procedures in the event of an accident. Return package surveys and wipes were also observed.

Proper usage of personal dosimetry for both hands and whole-body was also observed. Badges are exchanged weekly and monthly for extremity and whole-body respectively. Maximum readings for 2005 indicated whole-body exposure of 55 mRem and 19,700 mRem extremity. YTD 2006 maximum whole-body readings were 41 mRem and extremity of 5670 mRem.

Package surveys were performed with an energy compensated GM probe and area contamination surveys were done with a pancake GM. Available survey instrumentation was randomly reviewed and found to be within the required calibration frequency. Side-by-side readings with the NRC instrument revealed similar results.

Independent measurements conducted indicated a maximum of about 1.0 mr/hr over the generator storage area. Vehicle surveys performed did not indicate readings in excess of 0.03 mr/hr. Background levels in the pharmacy measured approximately 0.04 mr/hr.

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Cardinal Health 527 Honey Creek Drive Terre Haute, IN 47802		2. NRC/REGIONAL OFFICE U.S. Nuclear Regulatory Commission Region III 2443 Warrenville Road Lisle, Illinois 60532-4351	
REPORT 2006-005			

3. DOCKET NUMBER(S) 030-36973	4. LICENSEE NUMBER(S) 34-29200-01MD	5. DATE(S) OF INSPECTION April 13, 2006
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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			
IC INSPECTOR	S. J. Mulay		4/19/06