



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

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

May 19, 2006

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

**SUBJECT: NRC INSPECTION REPORTS 030-36973/06-008 AND 030-36973/06-009
(FORM 591M PART 1)**

Dear Mr. Coffey:

This letter refers to the routine inspections conducted on April 20, 2006, at your Sioux Falls, South Dakota facility and on April 26, 2006, at your Southfield, Michigan, facility. The inspection results were discussed with Willie Regits of your staff during a final telephonic exit briefing conducted on May 2, 2006.

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 are 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>.

J. Coffey

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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 030-36973/06-008
2. Inspection Report 030-36973/06-009

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

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Cardinal Health Sioux Falls, South Dakota		2. NRC/REGIONAL OFFICE USNRC Region IV 611 Ryan Plaza Drive, Suite 400 Arlington, Texas 76011-4005	
REPORT NUMBER(S) 06-008			
3. DOCKET NUMBER(S) 030-36973	4. LICENSEE NUMBER(S) 34-29200-01MD	5. DATE(S) OF INSPECTION April 20, 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 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	James L. Thompson	/RA/	4/20/2006

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:
Cardinal Health
21681 Melrose Ave
Southfield, MI 48075

2. NRC/REGIONAL OFFICE
REGION III
US NUCLEAR REGULATORY COMMISSION
2443 WARRENVILLE ROAD
LISLE, IL 60532

REPORT 2006-009

3. DOCKET NUMBER(S)
030-36973

4. LICENSEE NUMBER(S)
34-29200-01MD

5. DATE(S) OF INSPECTION
April 26, 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 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.

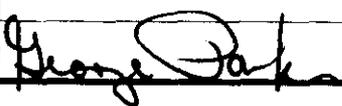
_____ Non-Cited Violation(s) was/were discussed involving the following requirement(s) and Corrective Action(s):

- 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)

STATEMENT OF CORRECTIVE ACTIONS

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			
NRC INSPECTOR	George Parker		4/26/06

Docket File Information
SAFETY INSPECTION REPORT
AND COMPLIANCE INSPECTION



1. LICENSEE Cardinal Health REPORT NUMBER(S) 2006-009		2. NRC/REGIONAL OFFICE Region III	
3. DOCKET NUMBER(S) 030-36973	4. LICENSE NUMBER(S) 34-29200-01MD	5. DATE(S) OF INSPECTION 04/26/2006	
6. INSPECTION PROCEDURES USED 87127	7. INSPECTION FOCUS AREAS 3/01-07		

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 2500	2. PRIORITY 2	3. LICENSEE CONTACT Paul Gottil	4. TELEPHONE NUMBER 614/757-5000
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Main Office Inspection Next Inspection Date: 04/08

Field Office _____

Temporary Job Site _____

PROGRAM SCOPE
Program Scope
87127

The licensee is a regional division of the Cardinal Health chain located in Southfield, MI. This radiopharmacy employs one pharmacist, two pharmacy techs and approximately twenty drivers. Currently the licensee has approximately 800+ customers located in the north eastern Michigan area. The pharmacy serves its customers from approximately 4:00am to 3:00pm daily including Saturdays and Sundays. Licensees first run starts about 4:30am and continues throughout the day. This pharmacy receives Mo99/Tc99m generators each week for the preparation of unit doses to be distributed to clients.

Performance Observations

During the inspection, the inspector toured the facility and observed the preparation of unit doses destined for clients. The inspector observed shipping procedures being performed and interviewed the staff concerning their roles in the process. The inspector determined that they possessed an adequate level of knowledge of shipping requirements. The inspector performed confirmatory surveys of the restricted area and the results were similar to those of the licensee. Conversations between the inspector and licensee staff provided assurances that licensee staff had an adequate knowledge of radiation safety.

Independent surveys performed by the inspector did not detect any unusual or unexpected readings. No abnormal conditions were detected.

Docket File Information
**SAFETY INSPECTION REPORT
AND COMPLIANCE INSPECTION**



1. LICENSEE Cardinal Health REPORT NUMBER(S) 06-008		2. NRC/REGIONAL OFFICE USNRC Region IV	
3. DOCKET NUMBER(S) 030-36973	4. LICENSE NUMBER(S) 34-29200-01MD	5. DATE(S) OF INSPECTION April 20, 2006	
6. INSPECTION PROCEDURES USED 87127	7. INSPECTION FOCUS AREAS all		

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 2500	2. PRIORITY 2	3. LICENSEE CONTACT Tom Wolff, Site RSO	4. TELEPHONE NUMBER (605) 332-3703
Main Office Inspection		Next Inspection Date: April 20, 2008	
<input checked="" type="checkbox"/>	Field Office Sioux Falls, South Dakota		
<input type="checkbox"/>	Temporary Job Site		

PROGRAM SCOPE

This radiopharmacy is staffed with approximately two radiopharmacists, two technicians, and a dozen drivers.

There are approximately 170 unit doses of Tc-99m prepared daily, along with 250 millicuries of I-131 prepared and distributed per week. Other radiopharmaceuticals prepared at this location include I-123 caps, Indium, and MonoClonalAntibody tagged with Tc-99.

The licensee has recently began switching back to the Mallinkrodt generators with depleted uranium shielding, from the Bristol-Myer Squibb generators with lead shielding.

Year-to-date max exposures for 2004 and 2005 were 302 millirem deep/23.9 rem extremity and 340 millirem deep/26.6 rem extremity, respectively. Bioassays are performed weekly.

Internal audits are performed locally monthly, and by the corporate office quarterly.

Radiation levels are checked daily with friskers and area monitors.

Annual refresher training is performed for all personnel including drivers, which includes HAZMAT training on DOT requirements.

There were no violations associated with this inspection.