



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

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

March 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 REPORTS 030-36973/08-02 and 030-36973/08-11(DNMS)
(FORM 591M Part 1); CARDINAL HEALTH, SOUTH BEND, INDIANA
AND SIOUX FALLS, SOUTH DAKOTA**

Dear Mr. Coffey:

This letter refers to the routine inspections conducted on February 29, 2008, at your South Bend, Indiana facility, and on March 13, 2008, at your Sioux Falls, South Dakota facility. The inspection results were discussed with Willie Regits of your staff during a final telephonic exit briefing conducted on March 21, 2008.

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 is 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 030-36973/08-02
2. Inspection Report 030-36973/08-11

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

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Cardinal Health Nuclear Pharmacy Services Dublin, OH 43017 South Bend, IN pharmacy REPORT NUMBER(S) 2008-002	2. NRC/REGIONAL OFFICE U.S. Nuclear Regulatory Commission Region III 2443 Warrenville Road Suite 210 Lisle, Illinois 60532-4351
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3. DOCKET NUMBER(S) 030-36973	4. LICENSEE NUMBER(S) 34-29200-01MD	5. DATE(S) OF INSPECTION Feb. 29, 2008
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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			
NRC INSPECTOR	Deborah A. Piskura		3/07/2008

**SAFETY INSPECTION REPORT
AND COMPLIANCE INSPECTION**

1. LICENSEE Cardinal Health REPORT NUMBER(S) 2008-002		2. NRC/REGIONAL OFFICE Region III 2443 Warrenville Road, Suite 210 Lisle, IL 60532	
3. DOCKET NUMBER(S) 030-36973	4. LICENSE NUMBER(S) 34-39200-01MD	5. DATE(S) OF INSPECTION Feb. 29, 2008	
6. INSPECTION PROCEDURES USED 87127		7. INSPECTION FOCUS AREAS 03.01 – 03.08	

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02500	2. PRIORITY 2	3. LICENSEE CONTACT Jack Coffey	4. TELEPHONE NUMBER 614.757.5000
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Main Office Inspection Next Inspection Date: _____

Field Office South Bend Pharmacy, 3305 Lathrop Street, South Bend, IN

Temporary Job Site Inspection

PROGRAM SCOPE

The South Bend, Indiana pharmacy employed 4 ANPs, 6 pharmacy technicians, and 18 drivers/couriers. The pharmacy served approximately 40 customers located in the Michiana area and distributed approximately 400 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 by the pharmacy. The pharmacy processed liquid I-131 weekly to compound therapy capsules and oral solution. Occasionally, the pharmacy prepared and distributed Sm-153, Y-90/In-111 (Zevalin), I-131 (Bexxar) and Y-90 (investigational monoclonal antibody) dosages. These beta doses were measured, using a correction factor, in the licensee's dose calibrator prior to transfer to the customer. The corporate office conducted triennial audits of the pharmacy (last 1/23/2008).

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 early and midmorning runs. These observations included observing licensee personnel performing dose calibrator QC/QA tests, drawing doses, receiving packages, packaging doses for shipment and conducting surveys for compliance with NRC and DOT requirements.

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

	<u>YTD 2/10/2008</u>	<u>2007</u>	<u>2006</u>
Whole body	7	149	100
Extremity	2,100	19,330	20,020