

**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

1. LICENSEE/LOCATION INSPECTED:  
Cardinal Health  
Nuclear Pharmacy Services  
Dublin, OH 43017  
Southfield, MI pharmacy  
REPORT NUMBER(S) 2011-009

2. NRC/REGIONAL OFFICE  
U.S. Nuclear Regulatory Commission  
Region III  
2443 Warrenville Road, Suite 210  
Lisle, IL 60532-4351

3. DOCKET NUMBER(S)  
030-36973

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

5. DATE(S) OF INSPECTION  
August 12, 2011

**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, to exercise discretion, were satisfied.
- ☐ 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

**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'S REPRESENTATIVE			
NRC INSPECTOR	Deborah A. Piskura	<i>Deborah A. Piskura</i>	8/29/2011
Branch Chief	Tamara E. Bloomer	<i>Tamara E. Bloomer</i>	8/29/11

*Docket File Information*  
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6. INSPECTION PROCEDURES

7. INSPECTION FOCUS AREAS

03.01-03.08

**SUPPLEMENTAL INSPECTION INFORMATION**

1. PROGRAM

02500

2. PRIORITY

2

3. LICENSEE CONTACT

Willie Regits, Ph.D., RSO

4. TELEPHONE NUMBER

614.757.5000

☒ Main Office Inspection

Next Inspection Date: \_\_\_\_\_ N/A \_\_\_\_\_

☐ Field Office Inspection

☐ Temporary Job Site Inspection \_\_\_\_\_

**PROGRAM SCOPE**

The Southfield pharmacy employed four ANPs, three pharmacy technicians, and 15 drivers/couriers. The pharmacy served approximately 50 customers located throughout the Metropolitan Detroit area and distributed approximately 300-350 doses daily. The licensee typically received three Mo99/Tc99<sup>m</sup> generators each week. Xenon-133 gas vials were received and re-distributed to their customers, 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 Y-90/In-111 (Zevalin) and Sm-153 (Quadramet) 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.

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 mid-morning runs. These observations included dose calibrator QC/QA tests, drawing doses (including PET doses), receiving packages (including bulk F-18), 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 2011</u>	<u>2010</u>	<u>2009</u>
Whole body	119	175	288
Extremity	7,770	14,350	16,250

*KGP*