NRC FORM 591M PART 1 (05-2012) 10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Cardinal Health Nuclear Pharmacy Services 7000 Cardinal Place Dublin, OH 43017 REPORT NUMBER(S) 2012-009	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-36973	34-29200-01MD	May 25, 2012

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 violations(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.

Non-cited violation(s) were discussed involving the following requirement(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 in accordance with NRC Enforcement Policy. 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'S REPRESENTATIVE			
NRC INSPECTOR	Deborah A. Piskura, Health Physicist	/RA/	6/8/2012
BRANCH CHIEF	Hironori Peterson, Chief, MIB	/RA Lambert for/	6/8/12

NRC FORM 591M PART 3
(05-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87127	03.01-03.08

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02500	2	Willie Regits, Ph.D., RSO	(614) 757-5000

☐ Main Office Inspection Next Inspection Date: TBD by PM

☑ Field Office Inspection 1909 Beltway Drive, St. Louis, MO

☐ Temporary Job Site Inspection

PROGRAM SCOPE

The St. Louis pharmacy employed six ANPs, six pharmacy technicians, and 20 drivers/couriers. The pharmacy served approximately 30-35 customers located in the St. Louis Metropolitan area and distributed approximately 400 doses daily. The licensee received three Mo99/Tc99m 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 (last 3/21/2012, with 0 points).

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, receiving packages, packaging doses for shipment, and conducting surveys for compliance with NRC and DOT requirements. The inspector noted that the pharmacy personnel followed the following radiation safety practices during this inspection:
-All pharmacy personnel wore their assigned dosimetry
-Staff performed personal surveys prior to leaving the restricted area
-Pharmacists wore gloves/protective clothing and used tongs while handing RAM
-No evidence of eating or drinking in the restricted area

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

	YTD 2012	2011	2010
Whole body	370	841	801
Extremity	14,500	27,030	21,170