UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINIOIS 60532-4352

August 30, 2010

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

SUBJECT: NRC INSPECTION REPORTS 030-36973/10-07(DNMS) and 030-36973/10-08 (DNMS) (FORM 591M Part 1), SWARTZ CREEK, MICHIGAN AND ST. LOUIS, MISSOURI FACILITIES

Dear Mr. Coffey:

On July 23 and August 3, 2010, the U.S. Nuclear Regulatory Commission (NRC) conducted routine inspections at your Swartz Creek, Michigan and St. Louis, Missouri facilities, respectively. The inspection results were discussed with Willie Regits of your staff during a final telephonic exit briefing conducted on August 12, 2010.

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 Title 10 Code of Federal Regulations 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 Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Should you have any questions concerning these inspections or enclosed reports, please contact Ken Lambert of my staff at (630) 829-9633.

Sincerely,

Tamara E. Bloomer, Chief
Materials Inspection Branch

Docket No.: 030-36973
License No.: 34-29200-01MD

Enclosures:
1. Inspection Report 030-36973/10-07(DNMS)
2. Inspection Report 030-36973/10-08(DNMS)

cc w/encl 1: State of Michigan
cc w/encl 2: State of Missouri
cc w/encls: Willie Regits, Radiation Safety Officer

Should you have any questions concerning these inspections or enclosed reports, please contact Ken Lambert of my staff at (630) 829-9633.

Sincerely,

/RA/

Tamara E. Bloomer, Chief
Materials Inspection Branch

Docket No.: 030-36973
License No.: 34-29200-01MD

Enclosures:
1. Inspection Report 030-36973/10-07(DNMS)
2. Inspection Report 030-36973/10-08(DNMS)

cc w/encl 1: State of Michigan
cc w/encl 2: State of Missouri
cc w/encls: Willie Regits, Radiation Safety Officer

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OFFICE	RIII DNMS	E	RIII DNMS		RIII		RIII	
NAME	KJLambert: jm		TEBloomer					
DATE	08/18/10		08/30/10					

OFFICIAL RECORD COPY

NRC FORM 591M PART 1
(10-2003) 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 Dublin, OH 43017 Swartz Creek, MI pharmacy **REPORT NUMBER(S)** 2010-007	**U.S. Nuclear Regulatory Commission** **Region III** **2443 Warrenville Road** **Suite 210** **Lisle, Illinois 60532-4351**

3. DOCKET NUMBER(S)	4. LICENSEE NUMBER(S)	5. DATE(S) OF INSPECTION
030-36973	34-29200-01MD	July 23, 2010

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:

X 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	Deborah A Piskura	8/12/2010

NRC FORM 591M PART 1 (10-2003)

NRC FORM 591M PART 1
(10-2003) 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 1909 Beltway Drive St. Louis, MO REPORT NUMBER(S) 2010-008	**Region III** **U.S. Nuclear Regulatory Commission** **2443 Warrenville Road, Suite 210** **Lisle, Illinois 60532-4351**

3. DOCKET NUMBER(S)	4. LICENSEE NUMBER(S)	5. DATE(S) OF INSPECTION
030-36973	34-29200-01MD	August 3, 2010

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:

X 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	Ken Lambert	Ken Lambert	8/12/10

NRC FORM 591M PART 3
(10-2003) 10 CFR 2.201

Docket File Information

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE	2. NRC/REGIONAL OFFICE
Cardinal Health REPORT NUMBER(S) 2010-007	**Region III** **2443 Warrenville Road, Suite 210** **Lisle, IL 60532**

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-36973	34-39200-01MD	July 23, 2010

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: *o be determined by project manager

[X] Field Office 70 Miller Road, Swartz Creek, MI

[ ] Temporary Job Site Inspection

PROGRAM SCOPE

The Swartz Creek pharmacy employed four ANPs, two pharmacy technicians, and 25 drivers/couriers. The pharmacy served approximately 30-35 customers located throughout the State of Michigan and distributed approximately 350 doses daily. Due to the shortage of Mo-99, the pharmacy's volume had decreased to only 100 doses daily during the week of this inspection. The licensee typically received four Mo99/Tc99^{m} generators each week; due to the current shortage of Mo-99 only 1-2 generators were received weekly. 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 7/21/2010).

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

	YTD 2010	2009	2008
Whole body	155	328	236
Extremity	9,360	20,470	22,740

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NRC FORM 591M PART 3
(10-2003) 10 CFR 2.201

Docket File Information

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE	2. NRC/REGIONAL OFFICE
Cardinal Health Nuclear Pharmacy Services REPORT NUMBER(S) 2010-008	**NRC Region III** **2443 Warrenville Road, Suite 210** **Lisle, Illinois 60532-4351**

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-36973	34-29200-01MD	August 3, 2010

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
871127	03.01 – 03.08

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
2500	2	Willie Regits, RSO	

[ ] Main Office Inspection — Next Inspection Date: August 2012

[X] Field Office 1909 Beltway Drive, St. Louis, MO

[ ] Temporary Job Site Inspection

PROGRAM SCOPE

The licensee was a busy radiopharmacy serving the St. Louis, MO area. The licensee primarily used Covidian generators and distributed 300-350 technicium-99m doses per day. Due to the shortage of Mo-99 the licensee was milking generators two to three times per day to obtain enough Tc-99m to fulfill its orders. The licensee received generators weekly. The licensee also distributed about 30 flourine-18 PET doses per day and compounded 6-8 iodine-131 capsules per week. The pharmacy also redistributed xenon-133 dosages. The facility's radiation safety officer conducted QA audits monthly of the radiation safety program and the corporate office conducted triennial audits.

Performance Observations

The inspector observed pharmacy operations including a nuclear pharmacy technician drawing doses and verifying doses using a dose calibrator, and conducting exposure rate and removable contamination surveys on outgoing packages of radioactive materials. The inspector observed a driver getting ready for deliveries and verified that the packages were properly secured in the vehicle and that shipping papers were available. The driver appropriately explained how he would respond to a traffic accident involving licensed material. Pharmacy staff discussed/demonstrated dose calibrator daily constancy, quarterly linearity and annual calibration, and waste handling and disposal. The inspector observed that the driver was wearing appropriate dosimetry. The inspector reviewed records involving dose calibrator daily constancy, quarterly linearity and annual calibration activities, area dosimetry, waste storage and disposal, training, effluent releases, and personnel dosimetry. The maximum whole body (WB) and extremity exposures, reported in millirem (mrem) were: 354 mrem WB and 10180 mrem extremity for 2010 to June 30; and 331 mrem WB and 26610 mrem extremity for 2009. Effluent releases to date were 2 – 8 percent of the annual limit, based on the weekly analysis of effluent samples.

No violations were identified during the inspection.

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