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

March 2, 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 030-36973/06-001, 030-36973/06-004 and 030-36973/06-010 (FORM 591M Part 1)

Dear Mr. Coffey:

This letter refers to the routine inspections conducted February 9 through March 2, 2006, at your Kansas City, Missouri facility; February 13 and 14, 2006, at your Sharon Hill, Pennsylvania facility; and February 21, 2006, at your St. Louis, Missouri facility. The inspection results were discussed with Willie Regits of your staff during final telephonic exit briefings conducted on February 17 and March 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 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.

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 030-36973/06-001
2. Inspection Report 030-36973/06-004
3. Inspection Report 030-36973/06-010

cc w/encl 1: State of Pennsylvania
cc w/encls 2 and 3: State of Missouri

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 Kansas City, MO pharmacy REPORT NUMBER(S) 2006-004	**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	Feb. 9-Mar. 2, 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

[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**		**03/02/2006**

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

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE	2. NRC/REGIONAL OFFICE
Cardinal Health ***Nuclear Pharmacy Services*** **7000 Cardinal Place** **Dublin, Ohio 43017** REPORT NOS 030-36973/2006-001	**U.S. Nuclear Regulatory Commission** **Region I, 475 Allendale Road** **King of Prussia, Pennsylvania 19406-1415**

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-36973	34-29200-01MD	February 13&14, 2006

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS	8. INSPECTOR
IP 87127	03.01-03.07	James Dwyer/D. Lawyer

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
2500	2	Terry Klar	610-461-7070

☐ Main Office Inspection — Next Inspection Date: February 2008

☒ Field Office Sharon Hill, Pennsylvania

☐ Temporary Job Site _____

PROGRAM SCOPE

Radiopharmacy dispenses 600 dosages in an average day (including ~50 [F-18] fluorodeoxyglucose (FDG) dosages manufactured in the facility cyclotron). Approximately two-thirds of dosages dispensed during the first run which begins at 11:00 PM. Three daily runs. Shipments are at 4:00 AM, 8:30 AM and 11:30 AM. The facility receives eight Mo/Tc generators each week with generators ranging in size between 12 and 18 curies at time of receipt. Receive bulk I-131 for preparation of liquid and capsule dosages. Prepare approximately six I-131 therapy dosages each week. Do not dispense beta-emitters on a daily basis but one to two a quarter. Iodine-125 seeds are not distributed. Four dispensing hoods. One radiopharmacist per shift assisted by three pharmacy technologists and up to 12 customer service assistants/drivers. Iodine 123 compounding is performed in the morning. Iodine 131 compounding is performed in the afternoon. The pharmacist and the technicians are responsible for all of the dosage prep and dispensing. The drivers assist by packing shipping containers, preparing shipping documentation, performing package removable contamination and exposure rate surveys, breaking down shipments returning from client facilities and delivering shipments to client facilities.

All staff are issued whole body exposure monitors which are processed monthly. Individuals who dispense dosages are issued rings to monitor the extremity exposures to both hands. These rings are processed weekly. Customer Service Assistants/drivers and other staff are issued a single extremity monitor which is worn on the dominant hand. These rings are processed monthly. Highest extremity dose is under 39 Rem. Weekly bioassay is performed when compounding iodine.

Corporate audits are performed three times each year. Internal audits are performed monthly. The audits cover a broad range of regulatory requirements (NRC, DOT, FDA, OSHA, EPA), Pharmacy Board requirements and Corporate procedures. Facility corrective and preventive actions are tracked to completion.

NRC FORM 591M PART 1 U.S. NUCLEAR REGULATORY COMMISSION
(10-2003)
10 CFR 2.201

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Cardinal Health **1909 Beltway Drive** **St. Louis, MO 63114** REPORT **2006-010**	**U.S. Nuclear Regulatory Commission** **Region III** **2443 Warrenville Road** **Lisle, Illinois 60532-4351**

3. DOCKET NUMBER(S)	4. LICENSEE NUMBER(S)	5. DATE(S) OF INSPECTION
030-36973	**34-29200-01MD**	**February 8-17, 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:

[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.

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(Violations and Corrective Actions)

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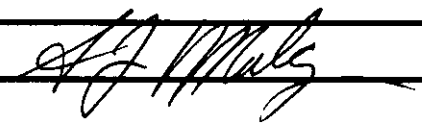
Title	Printed Name	Signature	Date
LICENSEE'S REPRESENTATIVE			
NRC INSPECTOR	**S. J. Mulay**		**2/21/06**

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

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE	2. NRC/REGIONAL OFFICE
Cardinal Health (Kansas City, MO pharmacy) REPORT NUMBER(S) **2006-004**	**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	34-29200-01MD	Feb. 9-Mar. 2, 2006

6. INSPECTION PROCEDURES	7. INSPECTION FOCUS AREAS
87127	03.01, 03.02, 03.03, 03.04, 03.05, 03.06, 03.07, and 03.08

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02500	G 2	Doug Hall, R.Ph.	816.966.2020

☐ Main Office Inspection — Next Inspection Date: March 2008

☒ Field — 9668 Marion Ridge, Kansas City, MO pharmacy

☐ Temporary Job Site

PROGRAM SCOPE

The Kansas City, Missouri pharmacy employed 5 ANPs, 6 pharmacy technicians, and 15 drivers/couriers. The pharmacy served approximately 60 customers located in the Northeastern Missouri area and distributed approximately 450+ doses daily. The licensee received 6 $Mo99/Tc99^{m}$ generators each week. Xenon-133 gas vials were received and re-distributed to their customers, however, the inner containers were not opened in the pharmacy. The pharmacy processed liquid I-131 weekly to compound therapy capsules and oral solution. Occasionally, the pharmacy prepared and distributed Sr-89 and Y-90/In-111 (Zevalin) dosages. These beta doses were measured, using a correction factor, in the licensee's dose calibrator prior to transfer to the customer. The licensee's corporate office audited the radiation safety program 3 times annually (last 12/20/05).

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 morning 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 inspection also included in-office review of the licensee's public dose assessment for the generator storage area. The licensee identified high environmental badge readings in areas adjacent to the generator storage room. Further review identified that the vendor used a lower Z shielding thickness for its generators. This change in shielding thickness resulted in higher than expected exposure rates between Nov-Dec. 2005. Additional calculations (considering occupancy factors, etc.) confirmed the pharmacy's compliance with the public dose limits.

The maximum whole body and extremity exposures were reported as follows:

	2004	2005	YTD 1/8/2006
whole body	307	309	*
extremity	22,580	21,290	590

*data unprocessed by vendor at time of inspection

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 650 Elmwood Avenue Sharon Hill, Pennsylvania 19079 REPORT Nos 030-36973/2006-001	**U.S. Nuclear Regulatory Commission** **Region I, 475 Allendale Road** **King of Prussia, Pennsylvania 19406-1415**

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-36973	04-29200-01MD	February 13 & 14, 2005

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.

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Title	Printed Name	Signature	Date
LICENSEE'S REPRESENTATIVE			
NRC INSPECTOR	**Jim Dwyer/ Dennis Lawyer**	Ken Lambert for	**02/16/2006**

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

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE	2. NRC/REGIONAL OFFICE
Cardinal Health REPORT **2006-010**	**Region III** **2334 Warrenville Road** **Lisle, IL 60532**

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-36973	**34-29200-01MD**	**February 8-17, 2006**

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87127	**03.01-03.07**

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
2500	**2**	**Steve Horvath, R.Ph., Pharmacy Mgr.**	**314-428-2906**

☐ Main Office Inspection — Next Inspection Date: **February 2008**

☒ Field — **1909 Beltway Drive, St. Louis, MO (Overland, MO)**

☐ Temporary Job Site

PROGRAM SCOPE

The licensee provides unit and bulk doses of byproduct material to approximately 80 clients in the St. Louis, MO area as well as southern Missouri and central Illinois. The pharmacy is operational Monday-Friday from 12:00am-4:15pm and 4:00am-11:00am Saturday and 5:00am - 7:00am Sunday. All other times are covered on-call. The facility prepares and distributes approximately 500 doses daily.

The licensee receives five Mo^{99}/Tc^{99m} generators (Bristol Myers) ranging from 12 to 18 curies on varying days each week. On average, an authorized pharmacist will perform about 12 iodine-131 encapsulations per week ranging from 4.0 to 400 millicuries. Encapsulations were not being performed at time of inspection. The licensee re-distributes xenon-133, samarium-153 as well as occasional Y-90-Zevlin. Fluorine-18 is also dispensed from this location and is prepared at a dedicated draw station.

This radiopharmacy employs 5 pharmacists, 3 pharmacy technicians, approximately 20 drivers and maintains a fleet of about 16 dedicated transport vehicles. The licensee's corporate office conducts quarterly program audits. According to licensee representatives, the previous site RSO, Jerrod Brown, left the employ of Cardinal Health approximately two weeks prior to the inspection. Mr. Brown was replaced by the former site RSO, Janet Frigo.

Performance Observations

The inspector observed the second morning run which included drawing doses, labeling and packaging doses for shipment, conducting surveys and wipes for compliance with NRC and DOT requirements and loading in dedicated transport vehicles. Return package surveys and wipes were also observed.

Corporate program audit documentation was randomly reviewed and contained an adequate evaluation of program activities. Adequate block/brace procedures were also observed as well as proper shipping paper documentation and accessibility. Drivers were aware of emergency procedures in the event of an accident.

Proper usage of personal dosimetry for both hands and whole-body was also observed. Maximum readings for 2004 indicated whole-body exposure of 229 mRem and 29,200 mRem extremity. 2005 maximum readings were whole-body 210 mRem and extremity of 31,100 mRem. Bioassays are also performed for those performing iodine-131 encapsulations and indicated no readings approaching the licensee's established trigger level of 0.04 microcuries.

Independent measurements conducted indicated a maximum of about 12.0 mr/hr over the generator storage compartment. Background levels at various times during the inspection ranged from 0.02-0.5 mr/hr.