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

August 24, 2006

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

SUBJECT: NRC INSPECTION REPORT 030-36973/06-015 (FORM 591M Part 1)

Dear Mr. Coffey:

This letter refers to the routine inspection conducted on August 9, 2006, at your Bethlehem, Pennsylvania facility. The inspection results were discussed with Willie Regits of your staff during a final telephonic exit briefing conducted on August 24, 2006.

This inspection was an examination of activities conducted under your license as they relate to radiation safety, compliance with the Commission's rules and regulations, and 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 this inspection no violations of NRC requirements were identified; therefore, no response to this letter or the enclosed NRC Form 591M is required.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure 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 this inspection or the enclosed report, 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

Enclosure:
Inspection Report 030-36973/06-015

cc w/encl: State of Pennsylvania

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 2444 Brodhead Road, Suite F Bethlehem, Pennsylvania REPORT Nos 2006-015	**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	August 9, 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.

[ ] 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.

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	Stephen Hammann	S. B. Hammann	8/9/06

G:\Docs\Current\Insp Record\R34-29200-01MD.06-015.591P1.wpd

SUNSI Review Completed By: /RA/ STH [X] Public [X] Non-Sensitive

Enclosure

	Initial		Announced	X	Unannounced	X	Routine		Special

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** **7000 Cardinal Place** **Dublin, Ohio** REPORT NOS 2006-015	**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	August 9, 2006

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS	8. INSPECTOR
87127	02.01 - 02.07	S. Hammann

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02500	2	Chris Rock	610-954-9301

☐ Main Office Inspection — Next Inspection Date: 8/2008

☒ Field Office: Bethlehem, Pennsylvania

☐ Temporary Job Site: _____

PROGRAM SCOPE

Licensee is a relatively small radiopharmacy but whose business has increased considerably over the past several years. They currently prepare 250 - 300 unit doses per day, which is almost all Tc-99m and distribute approximately 10 bulk quantities of Tc-99m per day. This is double the amounts from the time of the last inspection. They receive four generators per week: three 15 Curie generators and one 10 Curie generator. The pharmacy distributes 25 doses of Xe-133 per week and 5-10 doses of I-123 per week. These doses just pass through the pharmacy they are not prepared there. There is no compounding of iodine by the licensee. Several times a month the licensee distributes Sm-153 (Quadramet). The licensee redistributes sealed calibration and check sources approximately 2-3 times per month but does not redistribute brachytherapy sources. There are three full time pharmacists, one technician who draws doses, one technician who performs QC duties and fourteen drivers. The highest extremity exposure is less than 20 rem/yr. The facility has a company limit of 800 mr per week for extremity, at which point an investigation must be done and documented. For the past two years the limit of 800 mr per week was exceeded a total of four times (3 times by pharmacist/manager, 1 time by the RSO/pharmacist).

The pharmacy opens at 12:30 AM to prepare the first run and the drivers depart at 4:00 AM. The dose preparation for the second run starts at 7:00 AM and the drivers depart at 8:45 AM.

SUNSI Review Completed By: */RA/* STH ☒ Public ☒ Non-Sensitive