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

May 31, 2007

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

SUBJECT: NRC INSPECTION REPORT NO. 030-36973/07-02 (FORM 591M Part 1)
DUNCANSVILLE, PENNSYLVANIA

Dear Mr. Coffey:

This letter refers to the routine inspection conducted on May 2, 2007, at your Duncansville, Pennsylvania facility. The inspection results were discussed with Chris Walters of your staff during a final telephonic exit briefing conducted on May 31, 2007.

The inspection was 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 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 Form 591M, please contact Ken Lambert of my staff at (630) 829-9633.

Sincerely,

Robert G. Gattone, Jr.

Robert G. Gattone, Jr., Acting Chief
Materials Inspection Branch

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

Enclosure:
Inspection Report No. 030-36973/07-02 (NRC Form 591M)

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 Sugar Run Plaza, 3432 Route 764 Duncansville, PA REPORT Nos 2007002	**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	May 2, 2007

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	Todd J. Jackson, CHP	Ken Lambert for	**May 31, 2007**

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

	Initial		Announced	X	Unannounced	X	Routine		Special

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 **7000 Cardinal Place** **Dublin Ohio, 43017** REPORT NOS 2007002	**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	May 2-31, 2007

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS	8. INSPECTOR
87127	All	Todd Jackson

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
2500	2	JoAnn Fitch, R.Ph., Site RSO	814-942-2525

[ ] Main Office Inspection — Next Inspection Date: _____

[X] Field Office Duncansville, PA pharmacy

[ ] Temporary Job Site _____

PROGRAM SCOPE

This pharmacy starts their first run about 1:45 AM, and second run about 6:30 AM, with around 300 doses prepared daily, M-F. Eight Tc-99m generators are maintained as stock, with 4 new generators received weekly to exchange for the older 4 in stock. Most generators now are ordered from Bristol Meyers Squibb, as several months ago they experienced a supply problem from Mallinckrodt. Typically 250 mCi I-131 from Nordion are also received each week. Most I-131 orders are for about 30 mCi, however some therapy orders are for as much as 200 mCi per capsule. Two R.Ph. staff work at the facility, with a third in training. Five drivers deliver to area customers.

During 2005 and 2006 annual average I-131 release concentrations from the facility were at 20-25% of the limit in 10CFR20.1302.b.2(I). Individual monitoring cartridge measurements were as high as 35% of the 10 CFR 20 annual average concentration limit. I-131 handling and processing were performed in a glove box equipped with charcoal filters, however the I-131 shipping container and other storage containers with I-131 not being handled for dose preparations were stored adjacent to the glove box in a fume hood not equipped with charcoal filters.

The inspector reviewed practices and procedures, as well as measurement data, for employee thyroid bioassay measurements. Practices were generally acceptable, however one individual stated their thyroid did not function typically. The inspector noted that licensee dose modeling using thyroid bioassay measurements appeared to be based on the assumption that the subject's thyroid was functioning normally and accumulating iodine at a known rate. This model would not accurately determine thyroid organ exposure for an individual whose thyroid accumulated iodine at a different rate. The licensee had not evaluated the effect on exposure of atypical thyroid function. In the case of the Duncansville facility, exposures calculated assuming typical thyroid function indicated small fractions of the annual dose limit to the thyroid (50 rem), less than the 10% threshold requiring monitoring. However, until the effect of an atypical thyroid function is evaluated it is not clear what is the actual exposure to the affected individual. No violations of regulatory requirements were identified.

SUNSI Review Completed By: */RA/* Kenneth Lambert [X] Public [X] Non-Sensitive