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

September 11, 2007

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

SUBJECT: NRC INSPECTION REPORT 030-36973/07-05 (FORM 591M Part 1)
CARDINAL HEALTH - GLASTONBURY, CONNECTICUT FACILITY

Dear Mr. Coffey:

This letter refers to the routine inspection conducted on June 21, 2007, at your Glastonbury, Connecticut facility with continued in office review thru August 15, 2007. The in office review included a review of your staff's written report, dated July 3, 2007, regarding the mislabeling of vials containing iodine-131 dose with their respective and transport shields, and discussions with Glastonbury pharmacy staff. The inspection results were discussed with Willie Regits of your staff during a final telephonic exit briefing conducted on September 7, 2007.

This 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.

Based on the results of this inspection, the NRC has determined that a Severity Level IV violation of NRC requirements occurred. This violation is being treated as a Non-Cited Violation (NCV), consistent with Section VI.A of the Enforcement Policy. The NCV involves the failure to ensure that the label on two vials, containing 4.0 and 5.5 millicuries of iodine-131 each, were correlated with the information on their respective transport radiation shield labels. The NCV is described in the subject inspection report (NRC Form 591M Part 1). Please sign the attached NRC Form 591M Part 1 and return a copy to Ken Lambert, United States Nuclear Regulatory Commission, Region III, 2443 Warrenville Road, Lisle, IL 60532.

If you contest the violation or significance of the NCV, you should provide a response within 30 days of the date of this inspection report, with the basis for your denial, to the Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington DC 20555-0001, with copies to: (1) the Regional Administrator, Region III; and (2) the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system

(ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

Should you have any questions concerning this inspection or enclosed Form 591M, 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 030-36973/07-05

cc w/encl: State of Connecticut

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 628 Hebron Avenue, Building 4 Glastonbury, Connecticut 06033 REPORT Nos 2007005	**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	June 21, 2007 - August 15, 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:

1. Based on the inspection findings, no violations were identified.

2. Previous violation(s) closed.

X 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.

X Non-Cited Violation(s) was/were discussed involving the following requirement(s) and Corrective Action(s):

The NCV involves the failure, in accordance with 10 CFR 32.72(a)(4), to ensure that the label on two vials, containing 4.0 and 5.5 millicuries of iodine-131 each, were correlated with the information on their respective transport radiation shield labels. Specifically, the pharmacy staff placed the first vial in the second vial's transport radiation shield and visa versa. The root cause of the NCV was the switching of the two transport shields with their respective labels by the individual who wrapped the package preparation for shipping. The corrective action included having the individual compounding the iodine-131 capsule apply the transport shield label and wrap the transport shield.

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	Ken Lambert for	9/11/07

SUNSI Review Completed By: /RA/ STH [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 2007-005	**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	June 21, 2007

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

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
2500	2	Matt Svejk - site RSO	860-657-2520

Main Office Inspection — Next Inspection Date: _____

X Field Office 628 Hebron Avenue, Glastonbury, Connecticut

Temporary Job Site _____

PROGRAM SCOPE

This facility is a radiopharmacy with a fairly large volume of business. The facility ships out approximately 750 unit doses and 30 bulk doses per day of which most are Tc-99m. The facility also dispenses between 5-15 capsules of I-131 and 10 doses of Xe-133 per day. The I-131 is compounded at the facility. Other radioisotopes dispensed less frequently include Tl -201, I-123, Y-90 and Ga-67. The facility employs four pharmacists, five technicians and 18 drivers/general employees. All technicians draw doses under the supervision of the pharmacists. The facility receives eight generators per week. The facility redistributes two 5 curie generators to Yale University per week and also occasionally redistributes sealed sources to authorized recipients. The highest extremity reading for the past year was 15 rem, which is consistent with the volume of work per number of individuals drawing doses.

The facility has three runs per day. The first run starts at midnight with the drivers leaving at about 4:00 AM. The second run starts at 6:30 AM with the drivers leaving at 8:30 AM. The time of the third run varies depending on the number and locations of orders to be filled.

The inspector also reviewed the circumstances surrounding the mislabeling of vials containing iodine-131 dose with their respective and transport shields. The inspector reviewed the licensee's report and discussed the incident with Glastonbury pharmacy staff. A non-cited violation was identified involving the failure, in accordance with 10 CFR 32.72(a)(4), to ensure that the label on two vials, containing 4.0 and 5.5 millicuries of iodine-131 each, were correlated with the information on their respective transport radiation shield labels. Specifically, the pharmacy staff placed the first vial in the second vial's transport radiation shield and visa versa. The root cause of the NCV was the switching of the two transport shields with their respective labels by the individual who wrapped the package preparation for shipping. The corrective action included having the individual compounding the iodine-131 capsule apply the transport shield label and wrap the transport shield.

SUNSI Review Completed By: */RA/* S. Hammann [X] Public [X] Non-Sensitive