

**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

1. LICENSEE/LOCATION INSPECTED:  Cardinal Health Nuclear Pharmacy Services 7000 Cardinal Place Dublin, Ohio Indianapolis, Indiana Pharmacy  REPORT NUMBER(S) 2011-010		2. NRC/REGIONAL OFFICE  Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352	
3. DOCKET NUMBER(S)  030-36973	4. LICENSE NUMBER(S)  34-29200-01MD	5. DATE(S) OF INSPECTION  October 20, 2011	

**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.
- 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, to exercise discretion, were satisfied.

Non-cited violation(s) were discussed involving the following requirement(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 in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.  
(Violations and Corrective Actions)

**Statement of Corrective Actions**

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	Michelle Hammond	<i>Ken Lambert</i>	11/3/11
BRANCH CHIEF	Tamara Bloomer	<i>Tamara Bloomer</i>	11/3/11

**Docket File Information**

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6. INSPECTION PROCEDURES USED  87127	7. INSPECTION FOCUS AREAS  03.01-03.08
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**SUPPLEMENTAL INSPECTION INFORMATION**

1. PROGRAM CODE(S)  02500	2. PRIORITY  2	3. LICENSEE CONTACT  Amanda Jehl, Site RSO	4. TELEPHONE NUMBER  (317) 872-3301
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Main Office Inspection                      Next Inspection Date:                      N/A  
 Field Office Inspection    Indianapolis, Indiana Pharmacy  
 Temporary Job Site Inspection

**PROGRAM SCOPE**

This was an unannounced routine assist inspection for Region III. Cardinal Health Nuclear Pharmacy Services is a multi-site license authorized to manufacture and distribute radiopharmaceuticals. This field location has two Authorized NuclearPharmacists (ANP), 6 pharmacy technicians, and 15-20 drivers/couriers. At the time of the inspection, the licensee had 50-60customers located in Indianapolis and surrounding areas distributing approximately 500 doses daily. Cardinal Health receives 4 Mo-99/Tc-99m generators each week. Xe-133 gas vials are received and re-distributed to customers. Cardinal also processes liquid I-131 weekly to compound capsules and oral solution using the Drax Image Smart Fill system to minimize occupational exposure. Licensee receives and prepares F-18 from Cardinal in Cincinnati for PET and redistributes to customers. The facility was located in an industrial park and the ANP typically begins work at 2:00 AM. A driver is usually ready for the first delivery at 4:00 AM and deliveries were observed throughout the week to area hospitals to be between 6:30am - 7:30am. A random selection of delivery vehicles and couriers were assessed and doses were secured inside a tamper proof delivery "ammo box", which was then secured in a metal grid to the bed on the vehicle. The metal grid was equipped with a rack to hold the ammo boxes and a strap to secure the boxes in place to prevent movement while in transport.

**Performance Observations**

The facility is locked 24/7 and requires programmed key-card for entry. The inspector observed the ANP conduct daily QAIQC checks before preparing doses. The ANP was also observed eluting the generator before preparing unit doses for delivery. Through discussion and interviews, inspector confirmed knowledge of thresholds for contamination, radiation safety techniques, ALARA, emergency procedures, and precautions for handling I-131. The licensee wore proper PPE and possessed appropriate survey instruments. Waste manifests, disposal and storage procedures were reviewed, discussed, and found to be adequate. Public dose assessment was adequate for areas around hotlab and facility. Local and corporate radiation safety audits are performed and were reviewed. Annual exposure records were reviewed and occupational dose of personnel was normal for the work performed. The maximum dose in 2010 for Whole Body: 104 mrem and Extremity: 20,240 mrem; The maximum dose in 2011 (YTD) for Whole Body: 144 mrem and Extremity: 17,550 mrem. Licensee performs bioassays at least once per week when working with unsealed Iodine. Confirmatory measurements taken with a Ludlum Model 2401-P radiation survey instrument (NRC sIn 21955G, cal. due date 12/6/2011) showed dose rates were within regulatory limits. (Continued in Part 2)

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(Continued)  
from Part 3

Individuals contacted:  
Dan Burton, ANP  
Melissa George, ANP  
Richard Hawk, Alfred Kamara, Wendy Hill (Pharmacy Technician)  
Roger Crowder, Phyllis Fon, Doyle West (Couriers/Drivers)

Accompanied by: Marv Sticker, State of Indiana