

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Cardinal Health Nuclear Pharmacy Services, Dublin, Ohio
Location Inspected: 28 Omega Drive, Building #7
Stamford, Connecticut 06907

REPORT NUMBER(S) 2016006

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 25, 2016

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	Lester Tripp	<i>[Signature]</i> for LT	12/8/16
BRANCH CHIEF	Aaron T. McCraw	<i>[Signature]</i>	12/9/16

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

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3. DOCKET NUMBER(S) 030-36973	4. LICENSE NUMBER(S) 34-29200-01MD	5. DATE(S) OF INSPECTION October 25, 2016	
6. INSPECTION PROCEDURES USED 87127	7. INSPECTION FOCUS AREAS 03.01 - 03.07		

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 2500	2. PRIORITY 2	3. LICENSEE CONTACT Anthony V. Colangelo, Manager	4. TELEPHONE NUMBER (203) 352-1990
<input type="checkbox"/> Main Office Inspection Next Inspection Date: TBD			
<input checked="" type="checkbox"/> Field Office Inspection 28 Omega Drive, Building #7, Stamford, CT			
<input type="checkbox"/> Temporary Job Site Inspection			

PROGRAM SCOPE

This was a routine, unannounced, inspection at a facility authorized under Cardinal Health's multi-site nuclear pharmacy license. The pharmacy prepares 280 to 320 dosages a day, mostly technetium-99m. Some gallium, indium, thallium and iodine-123 is distributed. Six generators are received each week and are used for two weeks before being returned. The licensee averages 4 to 5 iodine-131 doses per month. Iodine-131 capsules are prepared in a glove box and fume hood in a dedicated room. There are three authorized nuclear pharmacists. They usually run two shifts with ~200 dosages prepared for first run, and ~100 for the second run. There are six drivers on average. The radiation safety officer, who is not a nuclear pharmacist, is given ample time to run the Radiation Safety Program.

Performance Observations: Employees were filling prescriptions throughout the facility and were observed performing frequent change-out of disposable gloves, using remote handling tools and syringe shields, and donning lab coats and double gloves. Extremity dosimeters were worn on both hands beneath the glove and the technicians were observed surveying their work stations with a pancake Geiger Mueller probe. There were hand and foot monitors stationed at the work exits and sticky mats at the doors to control the spread of potential contamination. The inspector reviewed personnel dosimetry since the last inspection and found all within regulatory limits and licensee ALARA goals. There is good distribution of exposures among staff. Individuals who handle doses are issued weekly extremity monitors (both hands) and monthly whole body monitors. Radiation areas are well marked and area exposure rates are very low.

Used syringes and unused dosages are returned to the facility and broken down by drivers. There is a very good contamination control program and a waste decay-in-storage program. There is an excellent bioassay program. Air effluent releases to unrestricted areas were in compliance with the regulatory requirements. There is a well-developed training program. The licensee uses good shipping procedures, including blocking and bracing of packages in vehicles. They perform surveys both interior and exterior of shipping containers. Employees have a good knowledge of radiation safety and emergency procedures. Cardinal Health auditors are onsite twice each year.

Within the scope of this inspection, no violations were observed.

Warren, Geoffrey

From: Warren, Geoffrey
Sent: Monday, December 12, 2016 9:08 AM
To: 'Sullivan, Glenn'
Subject: NRC Inspection Report - Stamford CT
Attachments: Cardinal Health - Stamford CT - 591M.pdf

Enclosed is the inspection report for the NRC's October 25 inspection at the Cardinal Health facility in Stamford, Connecticut, as we discussed by telephone on Thursday. No violations were identified as a result of the inspection, and the violation from the previous inspection was closed. No response is required to the report or to this e-mail.

Please contact me if you have any questions.

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Geoffrey Warren
Senior Health Physicist
NRC Region III
630-829-9742