

From: [Warren, Geoffrey](#)
To: ["Sullivan, Glenn"](#)
Cc: [Draper, Jason](#)
Subject: NRC Inspection Reports - Fort Wayne IN and Corporate
Date: Tuesday, July 13, 2021 1:02:00 PM
Attachments: [Cardinal Health 202102 - Corporate - 591M-sigMK \(002\).pdf](#)
[NRC 591M - Cardinal Health Fort Wayne 202101 jdMK.pdf](#)

Enclosed are the inspection reports for the NRC's recent inspections at your radiopharmacy in Fort Wayne, Indiana, and at your corporate office. No violations were identified as the result of these inspections. No response is required to the reports or to this email.

Please contact me if you have any questions.

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Geoffrey Warren
Senior Health Physicist (Inspector)
NRC Region III, Lisle, IL
630-829-9742

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Cardinal Health Nuclear Pharmacy Services 7000 Cardinal Place Dublin, OH 43017 REPORT NUMBER(S) 2021001	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 June 25, 2021, with in-office review through July 8, 2021

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	Jason D. Draper, Health Physicist	Jason D. Draper	Digitally signed by Jason D. Draper Date: 2021.07.09 08:47:37 -05'00'
BRANCH CHIEF	Michael A. Kunowski	Michael A. Kunowski	Digitally signed by Michael A. Kunowski Date: 2021.07.12 11:43:27 -05'00'



Materials Inspection Record

1. Licensee Name: Cardinal Health Nuclear Pharmacy Svc.		2. Docket Number(s): 030-36973		3. License Number(s) 34-29200-01MD	
4. Report Number(s): 2021002			5. Date(s) of Inspection: July 6-7, 2021		
6. Inspector(s): Geoffrey M. Warren, Sr. HP		7. Program Code(s): 04210	8. Priority: 2	9. Inspection Guidance Used: IR 87127	
10. Licensee Contact Name(s): Glenn Sullivan, Director, Health Physics, Corporate RSO		11. Licensee E-mail Address: glenn.sullivan@cardinalhealth.com		12. Licensee Telephone Number(s): 614-757-9586 (office)	
13. Inspection Type: <input type="checkbox"/> Initial <input checked="" type="checkbox"/> Routine <input checked="" type="checkbox"/> Announced <input type="checkbox"/> Non-Routine <input type="checkbox"/> Unannounced		14. Locations Inspected: <input checked="" type="checkbox"/> Main Office <input type="checkbox"/> Field Office <input type="checkbox"/> Temporary Job Site <input checked="" type="checkbox"/> Remote		15. Next Inspection Date (MM/DD/YYYY): 07/06/2023 <input checked="" type="checkbox"/> Normal <input type="checkbox"/> Extended <input type="checkbox"/> Reduced <input type="checkbox"/> No change	

16. Scope and Observations:

This was a routine announced inspection of corporate-level activities for the Cardinal Health multi-site license. Cardinal Health is a company that operated 126 facilities under its nuclear pharmacy division in the United States. Twenty of these facilities operated under the NRC's multi-site license; the remainder operated under Agreement State licenses. Each pharmacy prepared and distributed radioactive drugs to clients primarily for medical use. Nationally, the pharmacies distributed around one million individual doses monthly. In addition, each facility was authorized to redistribute sealed sources as calibration sources and brachytherapy sources.

Cardinal Health employed 3000 personnel at the corporate office in Dublin, Ohio. Five personnel at the corporate office, including the radiation safety officer, had primary duties concerning the radiation safety program, and five auditors based around the country performed semiannual audits at the individual pharmacies. This inspection was focused on the activities performed by corporate staff in support of radiation safety at the radiopharmacy facilities.

Performance Observations: The inspector has attended some of the licensee's radiation safety committee meetings since the previous corporate inspection. Licensee personnel described (1) training and qualification of nuclear pharmacists, radiation safety officers, and technologists; (2) the corporate audit program (both on-site and remote) for radiopharmacy facilities, including rating results and actions taken to correct deficiencies and strengthen programs; (3) initial and annual radiation safety training for pharmacy and corporate staff; (4) dosimetry and bioassay programs, including follow-up and tracking of doses exceeding ALARA levels; (5) effluent monitoring and public dose calculations; and (6) follow-up to issues identified through the employee concerns program. The inspector noted no concerns with these activities. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. Review of dosimetry records indicated no exposures exceeding regulatory limits.

Licensee personnel also described plans to start using gallium/germanium generators at pharmacy sites and preparation of yttrium-90 microspheres doses for distribution to client facilities.



Materials Inspection Record

1. Licensee Name: Cardinal Health - Fort Wayne		2. Docket Number(s): 030-36973		3. License Number(s) 34-29200-01MD	
4. Report Number(s): 2021001			5. Date(s) of Inspection: June 25, 2021, with in-office review through July 8, 2021		
6. Inspector(s): Jason Draper		7. Program Code(s): 04210	8. Priority: 2	9. Inspection Guidance Used: IP 87127	
10. Licensee Contact Name(s): Nicholas Underwood, Site RSO		11. Licensee E-mail Address: nicholas.underwood@cardinalhealth.com		12. Licensee Telephone Number(s): 260-489-1173	
13. Inspection Type: <input type="checkbox"/> Initial		14. Locations Inspected:		15. Next Inspection Date (MM/DD/YYYY):	
<input checked="" type="checkbox"/> Routine <input checked="" type="checkbox"/> Announced <input type="checkbox"/> Non-Routine <input type="checkbox"/> Unannounced		<input type="checkbox"/> Main Office <input checked="" type="checkbox"/> Field Office <input type="checkbox"/> Temporary Job Site <input type="checkbox"/> Remote		<input type="checkbox"/> Normal <input type="checkbox"/> Extended <input type="checkbox"/> Reduced <input checked="" type="checkbox"/> No change	

16. Scope and Observations:

This was a routine, announced inspection of a radiopharmacy in Fort Wayne, Indiana, operating under Cardinal Health's multi-site license. This radiopharmacy was staffed with four pharmacists, six pharmacy technicians and twenty delivery associates. The licensee distributed approximately 250 doses each weekday. The pharmacy was open weekdays from 1:30am to 4:00pm, with more limited hours on the weekend. Pharmacy staff prepared primarily Tc-99m, I-123, I-131, In-111, Tl-201, Ga-67, and Cu-64, and rarely dispensed F-18 unit doses. The pharmacy compounded I-131 therapy capsules in a glove box with a dedicated exhaust system and charcoal filters.

Due to the Covid-19 public health emergency, the inspector contacted the licensee prior to the inspection to ensure an on-site inspection could be performed safely. During the inspection, the inspector observed generator elution, molybdenum checks, QC sampling and evaluation, kit preparation, dose preparation, dose surveys and wipes, package assembly and verification, package wipes and surveys, shipment preparation, blocking and bracing of packages, and preparation and placement of shipping papers. The inspector interviewed the licensee personnel regarding compounding of I-131 capsules, waste disposal, package receipt surveys and wipes, tracking of customer licenses, stack and effluent monitoring, bioassays, and other procedures. These observations and interviews indicated that licensee personnel possessed adequate knowledge of radiation safety concepts and procedures. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with the licensee's survey records and postings. The inspector also reviewed licensee records pertaining to dosimetry, instrument calibrations, incident evaluations, air monitoring, waste disposal, and licensee audits.

No violation of NRC requirements were identified as a result of this inspection.