



Materials Inspection Report

1. Licensee/Location Inspected: Cardinal Health 414, LLC 7000 Cardinal Place, Dublin, Ohio Location inspected: 1909 Beltway Dr. St. Louis, Missouri 63114 Report Number(s) 2022-004	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 August 5, 2022

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. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements, and were assessed at Severity Level IV, in accordance with the NRC Enforcement Policy.

A. 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, corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy were satisfied.
 (Non-cited violation(s) was/were discussed involving the following requirement(s))

B. The following violation(s) is/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 AND DATE
LICENSEE'S REPRESENTATIVE		
NRC INSPECTOR	Geoffrey M. Warren, Sr. HP	Geoffrey M. Warren <small>Digitally signed by Geoffrey M. Warren Date: 2022.08.31 15:22:42 -0500'</small>
BRANCH CHIEF	Michael A. Kunowski	<i>Michael Kunowski</i> 9/1/2022



Materials Inspection Record

1. Licensee Name: Cardinal Health 414, LLC		2. Docket Number(s): 030-36973		3. License Number(s) 34-29200-01MD	
4. Report Number(s): 2022004			5. Date(s) of Inspection: August 5, 2022		
6. Inspector(s): Geoffrey Warren, Sr. HP		7. Program Code(s): 04210	8. Priority: 2	9. Inspection Guidance Used: IP 87127	
10. Licensee Contact Name(s): Earl Robertson, PharmD, Site RSO		11. Licensee E-mail Address: earl.robertson@cardinalhealth.com		12. Licensee Telephone Number(s): 314-428-4472 tel 314-428-1336 fax	
13. Inspection Type: <input checked="" type="checkbox"/> Routine <input type="checkbox"/> Non-Routine <input type="checkbox"/> Initial <input checked="" type="checkbox"/> Unannounced		14. Locations Inspected: <input type="checkbox"/> Main Office <input checked="" type="checkbox"/> Field Office <input type="checkbox"/> Temporary Job Site <input type="checkbox"/> Remote		15. Next Inspection Date (MM/DD/YYYY): No change <input type="checkbox"/> Normal <input type="checkbox"/> Extended <input type="checkbox"/> Reduced <input checked="" type="checkbox"/> No change	

16. Scope and Observations:

This was an unannounced routine inspection of a nuclear pharmacy operating under the Cardinal Health multi-site license. The radiopharmacy was staffed with five pharmacists, 15 pharmacy technicians, and around 40 drivers. The licensee distributed approximately 500-600 doses to around 60 regular customers in eastern Missouri and southwestern Illinois each weekday. The pharmacy was open weekdays from around midnight through the afternoon with limited hours on weekends. The licensee's formal runs began at 1:00 am (out by 4:30 am), 6:00 am (out by 8:00 am) and 8:30 am; later doses were prepared and delivered as needed. The licensee received four Mo-99/Tc-99m generators and one Ge/Ga-68 each week for preparation of doses. Pharmacy staff prepared primarily Tc-99m diagnostic doses among a variety of other isotopes and redistributed Xe-133 vials and I-123 capsules. The pharmacy compounded I-131 therapy capsules almost daily for distribution and redistributed Ra-223 chloride therapy doses. All I-131 material was manipulated and stored in a glove box with a dedicated exhaust system. The maximum exposure received by site personnel in calendar year 2021 was 244 mrem whole body/26.5 rem extremity; and in January through July 2022, 100 mrem whole body/13.1 rem extremity. Internal audits were performed monthly and corporate audits were typically performed every six months.

Performance Observations: The inspector observed daily contamination surveys, Tc-99m and Ga-68 generator elution, breakthrough tests, kit preparation and QC testing, dose drawing and labeling, dose packaging and wipe tests, package assembly and tracking, package surveys and wipes, shipment paper preparation and placement, package blocking and bracing, package return surveys, and waste sorting and handling. Licensee personnel demonstrated I-131 capsule compounding and described emissions monitoring, audit procedures, waste tracking, and emergency procedures. The inspector noted no concerns with these activities. Licensee personnel used long-handled tools to reduce extremity doses. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings.

No violations were identified during this inspection.

Warren, Geoffrey

From: Warren, Geoffrey
Sent: Thursday, September 1, 2022 1:57 PM
To: Sullivan, Glenn
Subject: NRC Inspection Report - Cardinal Health, St. Louis MO
Attachments: Cardinal Health St. Louis - 591M_sigMK.pdf

Enclosed is the report for the NRC's inspection performed August 5, 2022, at the Cardinal Health facility in St. Louis, Missouri, I notified you by telephone this morning. No violations were identified as a result of this inspection. No response is required to the report or to this message.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this message and its attachment will be available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at <http://www.nrc.gov/reading-rm/adams.html>.

Please feel free to contact me if you have any questions regarding this correspondence.

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