



## Materials Inspection Report

<b>1. Licensee/Location Inspected:</b>  Cardinal Health 414, LLC, Dublin Ohio Location Inspected: 10250 Stone Creek Drive Laurel, Delaware 19956  Report Number(s) 2024001	<b>2. NRC/Regional Office</b>  Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352
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<b>3. Docket Number(s)</b> 030-36973	<b>4. License Number(s)</b> 34-29200-01MD	<b>5. Date(s) of Inspection</b> 1/25/24 (exit held 3/6/24)
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**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	Hiba Ahmed	Hiba Ahmed <small>Digitally signed by Hiba Ahmed Date: 2024.02.16 14:20:31 -05'00'</small>
BRANCH CHIEF	Rhex Edwards	 <small>Digitally signed by RHEX EDWARDS Date: 2024.03.06 12:54:02 -06'00'</small>



### Materials Inspection Record

<b>1. Licensee Name:</b> Cardinal Health 414, LLC		<b>2. Docket Number(s):</b> 030-36973		<b>3. License Number(s)</b> 34-29200-01MD	
<b>4. Report Number(s):</b> 2024001			<b>5. Date(s) of Inspection:</b> 1/25/2024 (Exit meeting held 3/6/2024)		
<b>6. Inspector(s):</b> Hiba Ahmed; Robin Elliott		<b>7. Program Code(s):</b> 04210	<b>8. Priority:</b> 2	<b>9. Inspection Guidance Used:</b> 87127	
<b>10. Licensee Contact Name(s):</b> John Miller, R. PH., Site RSO		<b>11. Licensee E-mail Address:</b> john.a.miller@cardinalhealth.com		<b>12. Licensee Telephone Number(s):</b> (302) 875-3082	
<b>13. Inspection Type:</b> <input type="checkbox"/> Initial <input checked="" type="checkbox"/> Routine <input checked="" type="checkbox"/> Announced <input type="checkbox"/> Non-Routine <input type="checkbox"/> Unannounced		<b>14. Locations Inspected:</b> <input type="checkbox"/> Hybrid <input type="checkbox"/> Main Office <input checked="" type="checkbox"/> Field Office <input type="checkbox"/> Temporary Job Site <input type="checkbox"/> Remote		<b>15. Next Inspection Date (MM/DD/YYYY):</b> <input type="checkbox"/> Normal <input type="checkbox"/> Extended <input type="checkbox"/> Reduced <input checked="" type="checkbox"/> No change	
<b>16. Location(s) Inspected List:</b> 10250 Stone Creek Drive, Laurel DE 19956					
<b>17. Scope and Observations:</b> This was a routine inspection at the Laurel, Delaware, field office location of the Cardinal Health 414, LLC's multi-site radiopharmacy license. This was a small facility that served 20 to 25 customers with the furthest customer being approximately 80 miles away. They received two generators each week, and four generators were kept on site. Approximately 220-250 doses were prepared and distributed on a daily basis, and approximately 30 doses on Saturday and Sunday. There were two Authorized Nuclear Pharmacists (ANP) and three technicians that assisted with quality control as well as dose preparation, handling, and packaging. One of the ANPs was also the site RSO. There were nine drivers, two of which deliver on Saturdays and Sundays. The pharmacy hours were 1:00 a.m. to 3:00 p.m. There were four runs total; the third and fourth runs were for emergent doses. Preparation for the first run began at 2:00 a.m. and the deliveries for that run left by 5:30 a.m. Preparation for the second run began at 7:30 a.m. The deliveries for that run left at 9:00 a.m. The pharmacy did not provide on-call service. The pharmacy prepared unit and bulk doses of technetium-99m for licensees authorized to receive the radiopharmaceuticals for patient-specific use. The pharmacy was not compounding any iodine, gallium or thallium. Iodine-131 was received at this location from the pharmacy in Beltsville, Maryland, and was then distributed directly to customers. They occasionally received xenon-133 and iodine-123 capsules as packaged unit doses which were then sent to the customer. Due to this, no bioassay or air sampling was performed. Two biological safety cabinets were designated for white blood labeling in accordance with USP-825 standards. All ventilation units were certified twice per year by an outside contractor. Radiation Safety audits were performed two times per year by the corporate RSO.  The inspectors observed the pharmacists and technicians wearing dosimetry, eluting the generator, preparing and assaying doses, and performing quality control on prepared radiopharmaceuticals for detection of radiochemical impurities. The inspectors also observed the drivers wearing dosimetry, surveying and preparing packages for deliveries as well as loading and unloading vehicles before and after runs. Personnel were interviewed and were knowledgeable of radiation safety practices and procedures and wore appropriate personal protective equipment. Records reviewed included: audits, program reviews, sealed source leak tests and inventories, training, instrument calibrations, waste records, dosimetry, surveys and wipes tests. No concerns were noted. Independent and					

**Materials Inspection Record (Continued)**

confirmatory radiation measurements were made and found to be consistent with licensee posting and within regulatory limits.

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

Signature and Date - Branch Chief



Digitally signed by RHEX EDWARDS  
Date: 2024.03.06 12:51:59 -06'00'

**From:** [Geoffrey Warren](#)  
**To:** [Still, Cami](#)  
**Cc:** [Hiba Ahmed \(She/Her\)](#); [Robin Elliott \(She/Her\)](#)  
**Subject:** NRC Inspection Report - Laurel DE  
**Date:** Wednesday, March 6, 2024 1:10:00 PM  
**Attachments:** [Cardinal Health 2401 Laurel DE - 591M RAE".pdf](#)

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Enclosed is the inspection report for the NRC's inspection at the Cardinal Health nuclear pharmacy in Laurel, Delaware, as we discussed at the inspection exit meeting this morning. The inspection was performed on April 19, 2023. You attended the onsite exit meeting for this inspection by telephone. No violations were identified as a result of this inspection. No response is required to the report or to this email.

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)  
Division of Radiological Safety & Security  
NRC Region III, Lisle, IL  
630-829-9742