



Materials Inspection Report

1. Licensee/Location Inspected: Cardinal Health 414, LLC 7000 Cardinal Place Dublin, OH 43017 Location Inspected: 3305 Lathrop St., Ste. 100 South Bend, Indiana, 46628 Report Number(s) 2022005	2. NRC/Regional Office Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352
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3. Docket Number(s) 03036973	4. License Number(s) 34-29200-01MD	5. Date(s) of Inspection 11/21/2022
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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	Elizabeth Tindle-Engelmann	Elizabeth D. Tindle-Engelmann <small>Digitally signed by Elizabeth D. Tindle-Engelmann Date: 2022.11.21 10:38:39 -06'00'</small>
BRANCH CHIEF	Rhex Edwards	 <small>Digitally signed by Rhex A. Edwards Date: 2022.11.23 12:08:29 -06'00'</small>



Materials Inspection Record

1. Licensee Name: Cardinal Health 414, LLC		2. Docket Number(s): 03036973		3. License Number(s) 34-29200-01MD	
4. Report Number(s): 2022005			5. Date(s) of Inspection: 11/21/2022		
6. Inspector(s): Elizabeth Tindle-Engelmann		7. Program Code(s): 04210	8. Priority: 2	9. Inspection Guidance Used: 87127	
10. Licensee Contact Name(s): Nathan Johnson, PharmD, RSO		11. Licensee E-mail Address: nathan.johnson02@cardinalhealth.com		12. Licensee Telephone Number(s): 574-233-5970	
13. Inspection Type: <input checked="" type="checkbox"/> Routine <input type="checkbox"/> Announced <input type="checkbox"/> Non-Routine <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 checked="" type="checkbox"/> Normal <input type="checkbox"/> Extended <input type="checkbox"/> Reduced <input type="checkbox"/> No change	
16. Location(s) Inspected List: 3305 Lathrop St., Ste. 100, South Bend, Indiana, 46628					
17. Scope and Observations: This was an announced routine inspection of Cardinal Health’s South Bend, Indiana, location. The pharmacy prepared approximately 200 dosages per day between two runs. The first run began at 2:30 AM and dosages left the facility around 5:00 AM; the second run began around 6:00 AM and dosages left the facility around 8:00 AM. Their primary radionuclide was technetium-99m; however, they also prepared unit doses of with copper-64, gallium-68, indium-111, iodine-131, and thallium-201. Typically, they received three molybdenum-99/technetium-99m generators per week as well as bulk doses of iodine-131 each week and one germanium-68/gallium-68 generator per year. Iodine-131 capsules were prepared in a negative pressure glove box in a dedicated room. The licensee had four authorized nuclear pharmacists that worked at this site; their shifts were staggered so that there was always a pharmacist on duty. The RSO for the license was the corporate RSO; however, the licensee appointed a site RSO who was an authorized nuclear pharmacist that was onsite daily. The site had six pharmacy technicians and 12 drivers. The inspector observed the second run of the day. Observed activities included: generator elution, radiopharmaceutical compounding, dosage preparation, dosage packaging, radiopharmaceutical quality control testing, package preparation/surveys, package transportation, and instrument quality control. During observation engineering controls such as leaded glass, syringe shields, remote handling tools, and leaded contains were regularly utilized. Additionally, administrative controls such as donning/doffing PPE, frequent glove changes, frequent contamination surveys, and rotation of tasks were observed. Staff wore whole body and extremity dosimeters. Employees of various levels of responsibility had sufficient knowledge regarding radiation safety, security, and emergency procedures. The inspector reviewed a sample of the following records: ALARA investigations, ambient radiation level surveys, annual program reviews, bioassays, customer licenses, contamination surveys, decay in storage, dose calibrator quality control, dosimetry, effluents reports, events, instrument calibrations, internal audits, internal exposure evaluations, sealed source leak tests/inventories, and training.					

Materials Inspection Record (Continued)

Independent surveys were performed using a RadEyeG (SN:30652, calibration due date:07/14/2023). Surveys were consistent with the licensee's results and posting.

No violations were identified during the inspection. An onsite exit meeting was held on November 21, 2022.

Signature and Date - Branch Chief



Digitally signed by Rhex A. Edwards
Date: 2022.11.23 12:08:59 -06'00'