



Materials Inspection Record

1. Licensee Name: Cardinal Health 414, LLC		2. Docket Number(s): 030-38748		3. License Number(s) 34-31473-03MD	
4. Report Number(s): 2021001			5. Date(s) of Inspection: July 19-21, 2021		
6. Inspector(s): Geoffrey M. Warren, Sr. HP		7. Program Code(s): 02500	8. Priority: 2	9. Inspection Guidance Used: IP 87127	
10. Licensee Contact Name(s): Ben Ellert, R.Ph., RSO		11. Licensee E-mail Address: benjamin.ellert@cardinalhealth.com		12. Licensee Telephone Number(s): Phone: 317-872-3088 Fax: 317-872-3207	
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): July 19, 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 inspection of a radiopharmacy located in Indianapolis, Indiana, that distributed radium-223 dichloride nationwide and to selected other countries. The licensee employed three pharmacists and three technologists in this area, distributing 250 to 300 doses weekly for domestic distribution to other Cardinal Health radiopharmacies for redistribution, or directly to certain clients. In addition, the staff distributed approximately 100 doses internationally each week. The licensee received materials produced at the manufacturing facility in Indianapolis, then prepared doses from these materials or redistributed them without alteration. Staff from the standard radiopharmacy nearby assisted when needed. The pharmacy operated Monday through Friday, with the majority of doses prepared Monday through Wednesday. Their work hours were 6:30am to 4:00pm. In the Innovation Center also operating under this license, the licensee performed research and development into the production of indium-111 and actinium-225 for certain investigational drugs and distributing a small number of doses for evaluation, employing seven staff Monday through Friday. The licensee's corporate office conducted at least semiannual audits of each program and the RSO conducted routine in-house audits.

Performance Observations: The inspector toured the facility via remote tools to evaluate the licensee's measures for materials security, hazard communication and exposure control. Licensee personnel demonstrated or described receipt of licensed materials, handling and preparation of individual doses, packaging for shipment, waste shipments, and preparation of shipping papers and other documentation. The inspector reviewed documentation of corporate and internal audits, monitoring of air emissions and public dose, radiation and contamination survey results, package receipt and shipment surveys, inventory and leak testing of sealed sources, dose calibrator checks, and other records. Interviews with licensee staff indicated knowledge of radiation safety concepts and procedures. Review of dosimetry records indicated exposures well within regulatory limits; the maximum individual exposure for calendar year 2020 was 107 mrem whole body and 4.98 rem extremity, and January through June 2021 was 84 mrem whole body and 2.98 rem extremity.

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

Warren, Geoffrey

From: Warren, Geoffrey
Sent: Thursday, July 29, 2021 8:03 AM
To: Ellert, Benjamin
Cc: Sullivan, Glenn
Subject: NRC Inspection Report
Attachments: Cardinal Health - IN Pharmacy 2021001 - 591M sigMK.pdf

Enclosed is the inspection report for the NRC's recent remote inspection at the Xofigo radiopharmacy and Innovation Center in Indianapolis, Indiana. No violations were identified as the result of this inspection. No response is required to the report or to this email.

Please contact me if you have any questions.

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Geoffrey Warren
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