

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Cardinal Health Nuclear Pharmacy Services 7000 Cardinal Place, Dublin, OH 43017 Location Inspected: 5370 Miller Road Swartz Creek, Michigan REPORT NUMBER(S) 2022-001		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 March 25, 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. 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	Ryan Craffey		Digitally signed by Ryan J. Craffey Date: 2022.04.26 14:38:11 -04'00'
BRANCH CHIEF	Michael Kunowski GW for MK	Geoffrey M. Warren	Digitally signed by Geoffrey M. Warren Date: 2022.04.26 13:42:31 -05'00'



Materials Inspection Record

1. Licensee Name: Cardinal Health		2. Docket Number(s): 030-36973		3. License Number(s) 34-29200-01MD	
4. Report Number(s): 2022-001			5. Date(s) of Inspection: March 25, 2022		
6. Inspector(s): Ryan Craffey		7. Program Code(s): 04210		8. Priority: 2	9. Inspection Guidance Used: IP 87127
10. Licensee Contact Name(s): William Balogh - Area Manager		11. Licensee E-mail Address: william.balogh@cardinalhealth.com		12. Licensee Telephone Number(s): 810-733-8720	
13. Inspection Type: <input type="checkbox"/> Routine <input type="checkbox"/> Announced <input checked="" 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 type="checkbox"/> Normal <input type="checkbox"/> Extended <input type="checkbox"/> Reduced <input checked="" type="checkbox"/> No change	

16. Scope and Observations:

This commercial radiopharmacy in Swartz Creek, Michigan, prepared and distributed 200-250 unit doses of Tc-99m radiopharmaceuticals and 30-50 unit doses of F-18 PET radiopharmaceuticals per day to clients north of Detroit. On weekdays, the PET doses were prepared by the company's cyclotron radiopharmacy in East Lansing, Michigan. On weekends, they were prepared by pharmacists in Swartz Creek using bulk quantities of F-18 from East Lansing. The pharmacy had four authorized nuclear pharmacists, three pharmacy technicians, and fifteen drivers. The pharmacy's first run began around 1:30 am with doses out by 4:00 am, and the second run began around 7:00 am (sometimes earlier) with doses out by 8:30 am. Additional doses were prepared on an as-needed basis after that until the pharmacy closed at 3:30 pm. The pharmacy did not prepare I-131 capsules, but was planning to begin receiving Ge/Ga-68 generators for the preparation of Ga-68 dotatate within the month, and to offer preparation of unit doses of Y-90 microspheres from bulk quantities as a service to clients. The pharmacy also prepared In-111 radiopharmaceuticals and redistributed unit doses of Ra-223 dichloride to its clients.

The inspector toured the facility in Swartz Creek and observed a variety of activities on the pharmacy's second run, including dose drawing, radiopharmaceutical quality control, outgoing package preparation, area surveys, loading of packages prepared in-house and those prepared in East Lansing for transport, and return waste handling. The inspector conducted independent surveys of restricted and unrestricted areas, and found no residual contamination nor exposures to members of the public in excess of regulatory limits. The inspector interviewed the licensee's pharmacists, technologists, drivers and management. All personnel were familiar with radiation protection principles, implemented adequate ALARA practices, wore appropriate dosimetry, and used calibrated and operable survey instruments effectively.

The inspector reviewed the pharmacy's process for verifying customer radioactive materials authorizations and reviewed a selection of records. These included facility and corporate audits, spill reports since the last inspection (both minor), ALARA investigations (mostly due to backfilling at the East Lansing pharmacy or preparing PET doses in Swartz Creek on weekends), dose calibrator quality control records, area survey results, hazmat training documentation, and personnel dosimetry reports. These reports indicated maximum occupational doses of 664 millirem whole-body / 32,894 millirem extremity in 2020 and 416 millirem whole-body / 23,727 millirem extremity in 2021.

No violations of NRC requirements were identified as a result of this inspection. Exit meeting with site personnel was held March 30, 2022.

Warren, Geoffrey

From: Warren, Geoffrey
Sent: Wednesday, April 27, 2022 1:40 PM
To: Sullivan, Glenn
Subject: NRC Inspection Report - Swartz Creek, MI
Attachments: Cardinal Health 2022001 - Swartz Creek MI - 591M.pdf

Enclosed is the inspection report for the NRC's inspection at the Cardinal Health facility in Swartz Creek, Michigan, as we discussed 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