

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

| | | | |
|---|---|---|--|
| 1. LICENSEE/LOCATION INSPECTED: Cardinal Health 414, LLC 846 Service Road East Lansing, Michigan 48824 REPORT NUMBER(S) 2018001 | | 2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352 | |
| 3. DOCKET NUMBER(S) 030-38511 | 4. LICENSE NUMBER(S) 34-32840-01 | 5. DATE(S) OF INSPECTION 3/1/18 | |

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:

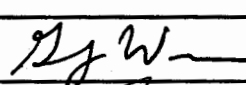
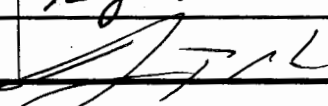
- ☒ 1. Based on the inspection findings, no violations were identified.
- ☐ 2. Previous violation(s) closed.
- ☐ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was 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 | | | 3 |
| NRC INSPECTOR | Geoffrey Warren, Sr. HP |  | 3/1/18 |
| BRANCH CHIEF | Aaron McCraw |  | 3/9/18 |

Docket File Information**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

| | | | |
|---|--|---|--|
| 1. LICENSEE/LOCATION INSPECTED: Cardinal Health 414, LLC 846 Service Road East Lansing, Michigan 48824 REPORT NUMBER(S) 2018001 | | 2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352 | |
| 3. DOCKET NUMBER(S) 030-38511 | 4. LICENSE NUMBER(S) 34-32840-01 | 5. DATE(S) OF INSPECTION March 1, 2018 | |
| 6. INSPECTION PROCEDURES USED 87125 | 7. INSPECTION FOCUS AREAS 03.01 - 03.07 | | |

SUPPLEMENTAL INSPECTION INFORMATION

| | | | |
|---------------------------------|----------------------|--|---|
| 1. PROGRAM CODE(S) 03210 | 2. PRIORITY 2 | 3. LICENSEE CONTACT Jason Foster, RSO | 4. TELEPHONE NUMBER (517) 432-8334 |
|---------------------------------|----------------------|--|---|

☒ Main Office Inspection Next Inspection Date: 3/1/2020

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was an unannounced routine inspection. At this facility, the licensee operated a cyclotron for production of bulk fluorine-18 (F-18) as fluorodeoxyglucose (FDG) for daily distribution on weekdays to a Cardinal Health pharmacy located adjacent to the cyclotron facility and to three other pharmacies in southern Michigan on weekends. In addition, the licensee prepared nitrogen-13 as ammonia on Tuesdays, and occasionally F-18 as sodium fluoride or other chemical forms. At the pharmacies, individual doses were prepared from the bulk materials and distributed for medical and research purposes. The licensee employed one cyclotron engineer, seven cyclotron operators, and two QA personnel. The facility was staffed from 10 pm through 2 pm, with cyclotron runs for F-18 FDG typically completed between 2:15 am and 10 am. The licensee's corporate office performed audits of cyclotron operations at least twice annually. This facility was accessible from Woodlot Drive, on the south side of the MSU Clinical Center.

The maximum exposure among licensee personnel for January 2018 was 275 mrem whole body and 2.6 rem extremity; for 2017 the maximum exposure was 2217 mrem whole body and 18.7 rem extremity; and for 2016, the maximum exposure was 2485 mrem whole body and 31.7 rem extremity. Most of the work with preparation of materials was performed in a hot cell using remote handling tools; outside the hot cell, personnel typically used long-handled tools to transport materials. The cyclotron engineer performed the majority of cyclotron maintenance activities at the facility.

Performance Observations: The inspector observed receipt of materials from the cyclotron, monitoring of chemistry processes, QC sample preparation and evaluation, monitoring and packaging of bulk material, package survey and wipes, preparation of shipping papers, labeling and marking packages, and distribution of a package to the adjacent pharmacy. Licensee personnel demonstrated setup of chemistry and surveys of use areas, and described cyclotron maintenance, monitoring of effluents, spill procedures, and other activities. The inspector noted no concerns with these activities. 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.