NRC FORM 591M PART 1
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Cardinal Health 414, LLC 846 Service Road East Lansing, MI 48824 REPORT NUMBER(S) 2016-001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-38511	34-~~21~~-32840-01	JANUARY 22ND, 2016

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 violations(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	Ryan Craffey	01/22/16
BRANCH CHIEF	Aaron McCraw		2/3/16

NRC FORM 591M PART 3
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
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3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-38511	34-32840-01	January 22, 2016

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87125	All

SUPPLEMENTAL INSPECTION INFORMATION

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

☑ Main Office Inspection Next Inspection Date: 01/22/2018

☐ Field Office Inspection _____

☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an unannounced routine inspection of a cyclotron facility authorized for the production of radiopharmaceuticals using an accelerator at its facility in East Lansing, Michigan. The facility, accessible from Woodlot Drive on the south side of the MSU Clinical Center, produced fluorine-18 on a daily basis in the form of fluoride, FDG and flutametamol, as well as nitrogen-13 as ammonia on Tuesdays. This material was then transferred to an adjacent radiopharmacy for dose preparation and distribution either to the adjacent PET Center at the hospital or to other Cardinal Health pharmacies. The facility operated Monday through Friday from 10:00 pm through 2:30 pm the next day, with limited hours on weekends. The facility typically performed three runs for FDG which ended around 2:15 am, 4:00 am, and 7:00 am. When needed, the licensee also produced flouride in a run ending at 5:00 am, flutametamol in a run ending around 10:00 am and ammonia in a run ending anywhere between 9:00 am and 12:00 pm, depending on the schedule at the adjacent PET Center. The licensee operated the facility with two shifts of cyclotron operators, including one cyclotron engineer who performed the majority of required maintenance of the unit.

PERFORMANCE OBSERVATIONS: The inspector toured the facility to evaluate the licensee's measures for materials security, hazard communication, exposure control, and to confirm that the facility matched the description provided in an amendment request dated January 14, 2014, which described renovations (since completed) to accommodate an aseptic environment for material preparation. The inspector conducted independent surveys of the facility and evaluated the licensee's ALARA practices during the first run of the day for FDG. The inspector also observed short-lived waste handling from the previous evening's run, as well as synthesis kit preparations, and product quality control evaluations. The licensee's staff also demonstrated and discussed cyclotron maintenance procedures, long-lived waste handling and airborne effluent monitoring. Through these demonstrations and discussions, the inspector found the licensee's staff to be knowledgeable of licensee procedures, regulatory requirements, and ALARA practices. The inspector also reviewed a selection of licensee records including internal and external audits, air effluent monitoring results, dose calibrator quality control documentation, sealed source leak tests and inventories, area survey results, and dosimetry reports, which recorded maximum annual exposures of 2,217 mrem whole-body and 12,340 mrem extremity in 2014, and 1,602 mrem whole-body and 23,486 mrem extremity in 2015.

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