NRC FORM 591M PART 1
(10-2010)
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 10718 Trenton Avenue St. Louis, Missouri REPORT NUMBER(S) 2012001	Region III: 2443 Warrenville Rd., Ste. 210 Lisle, IL 60532-4352	
3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-38222	34-32780-01	Oct. 16 , 2012

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. 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	Geoffrey M. Warren		10/16/12
BRANCH CHIEF	Tamara E. Bloomer		10/25/12

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
Cardinal Health 414, LLC 10718 Trenton Avenue St. Louis, Missouri REPORT NUMBER(S) 2012001	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
030-38222	34-32780-01	October 16, 2012

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87125	03.01 - 03.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
03210	2	Darren Fields, RSO	(314) 423-5103

☑ Main Office Inspection Next Inspection Date: October 2014

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was the initial routine inspection of activities performed under this license. The facility was consistent with maps in the license application provided to NRC.

This licensee operated a cyclotron for production of bulk fluorine-18 (F-18) fludeoxyglucose (FDG) and sodium fluoride (NaF) for distribution to Cardinal Health pharmacies in St. Louis and Springfield, Missouri. This facility employed four cyclotron technologists and one engineer. Pharmacy drivers picked up bulk materials for transport to the pharmacy for preparation of individual unit doses. The cyclotron was staffed from weeknights at 9:30 pm to weekdays at 9:30 am. F-18 FDG runs were completed daily at 1:15, 2:30, and 5:30 am, and F-18 NaF runs were completed Tuesdays and Thursdays at 6:30 am. The maximum dose received by licensee personnel in 2011 was 2.6 rem whole body and 25.6 rem extremity. For January through August 2012, the maximum doses received were 1.0 rem whole body and 14.5 rem extremity; personnel duties were rotated to ensure that no individual exceeded regulatory limits for exposure. The licensee used remote handling tools to manipulate materials inside the hot cell. Site personnel performed monthly audits of the radiation safety program, and corporate personnel provided quarterly program audits.

Performance Observations

The inspector observed hot cell preparation, receipt of F-18 FDG and NaF from the cyclotron, QC analysis, handling of bulk material, NaF chemistry, shielding and packaging of bulk material, surveys and labeling of packages, preparation of shipping papers. blocking and bracing of packages, handling of waste materials, and daily surveys and wipes. Licensee personnel demonstrated FDG chemistry setup and dose calibrator constancy and described sterility testing, cyclotron maintenance and setup, training, and other procedures. The inspector noted no concerns with these activities. Personnel wore appropriate personal protective equipment and dosimetry and stated that there was no tolerance for failure to wear proper dosimetry. Review of dosimetry and survey records indicated no doses of regulatory concern. 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.