

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Cardinal Health 414, LLC
10718 Trenton Avenue
St. Louis, MO

REPORT NUMBER(S) 12-001

2. NRC/REGIONAL OFFICE

Region III
U. S. Nuclear Regulatory Commission
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

3. DOCKET NUMBER(S)

030-38222

4. LICENSE NUMBER(S)

34-32780-01

5. DATE(S) OF INSPECTION

1/27/12

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	Ken Lambert	<i>Ken Lambert</i>	1/27/12
BRANCH CHIEF	Tamara Bloomer	<i>Tamara Bloomer</i>	2/16/12

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

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5. DATE(S) OF INSPECTION

January 27, 2012

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

Darren Fields, RSO

4. TELEPHONE NUMBER

(314) 423-5103



Main Office Inspection

Next Inspection Date:

No Change



Field Office Inspection



Temporary Job Site Inspection

PROGRAM SCOPE

This facility has an NRC license to operate a General Electric 16 million electron volt (MeV) PETtrace cyclotron to produce fluorine-18 (F-18) for synthesis into fludeoxyglucose (FDG). The FDG will be transported to Cardinal Health's nuclear pharmacy in St. Louis, Missouri, for drawing into unit doses for distribution to medical facilities. The license application is currently under NRC review.

PERFORMANCE OBSERVATIONS

This inspection was a follow up to an escalated enforcement action involving an individual who deliberately removed his extremity dosimetry prior to handling curie quantities of fluorine-18. The inspectors reviewed the implementation of the licensee's corrective actions described in a letter dated September 29, 2011. Inspectors verified that the licensee added a no tolerance clause to its Corrective Action policy regarding the use of dosimetry. The licensee committed to provide training to all Cardinal Health nuclear pharmacy and PET facilities personnel through an online training program and through an in-service training. St. Louis PET personnel completed an in-service training on the Dosimetry zero tolerance and the High Radiation Task Log on November 20, 2010. St. Louis PET staff completed online training regarding The company's Dosimetry Policy between May and June 2011.

The inspectors noted a new employee at the facility and asked her if she was aware of the incident. The individual indicated that she was aware of the incident and the zero tolerance for not wearing dosimetry and the proper use of the High Radiation Task Log.

This violation is considered closed.