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 7920 Georgetown Road, Suite 300 Indianapolis, Indiana 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
030-38748	34-31473-03MD	May 24 , 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	Geoffrey M. Warren		5/24/16
BRANCH CHIEF	Aaron T. McCraw		6/3/16

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

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Cardinal Health 414, LLC 7920 Georgetown Road, Suite 300 Indianapolis, Indiana 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
030-38748	34-31473-03MD	May 24, 2016

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87127	03.01 - 03.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02500	2	Benjamin Ellert, R.Ph., ANP, RSO	(317) 872-3088

☑ Main Office Inspection Next Inspection Date: May 2018

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was the initial inspection of this license. This radiopharmacy employed two pharmacists, two pharmacy technicians, two dispatchers, and an office administrator in the preparation and nationwide distribution of radium-223 chloride doses. Doses were prepared from dose vials received from overseas, but the licensee planned to use vials from the production facility in Indianapolis when it becomes active. The licensee distributed approximately 80 doses daily from this facility by common carrier directly to some clients but mostly to other Cardinal Health pharmacies, who delivered the doses to clients without alteration or repackaging. The pharmacy was open weekdays from 7:00 a.m. to 5:00 p.m. with limited hours on weekends. The licensee's corporate office conducted at least annual audits of the program and the RSO conducted routine in-house audits. The maximum exposure received by licensee personnel in calendar year 2015 was 72 mrem whole body and 1.2 rem extremity, and from January through April 2016 was 42 mrem whole body and 413 mrem extremity. Production waste was compressed and shipped for disposal. The licensee first distributed doses from this facility in June 2015.

Performance Observations: The inspector toured the facility and determined it was consistent with maps provided by the licensee. The inspector observed cleaning in the dose preparation area, dose preparation, preparation of syringe labels, pig and package wipe surveys, package surveys, preparation of package labels and shipping papers, handling of production waste, and proper use of dosimetry and personal protective equipment. Licensee staff demonstrated survey meter QC, contamination surveys and wipes and air monitoring procedures, and described emergency procedures, receipt surveys on dose vials, dose calibrator constancy and testing, bioassay procedures, and waste disposal. 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.