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 7000 Cardinal Place Dublin, OH 43017 REPORT NUMBER(S) 2019001	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
030-38867	34-32780-04MD	3/20/2019

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	Luis Nieves Folch		3/20/19
BRANCH CHIEF	Aaron T. McCraw	for ATM	3/28/19

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

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-38867	34-32780-04MD	March 20, 2019

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
02511	5	Carra Roberts, RSO	(614) 757-4120

☑ Main Office Inspection Next Inspection Date: March 20, 2024

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was unannounced, routine inspection of a licensed facility that was operated for the production of radium-223 dichloride (Xofigo), a radiopharmaceutical used in treating certain cancers. The licensee started production and distribution on July 6, 2017, after FDA approval. Approximately 50 personnel worked at this facility, most of whom worked with radioactive materials. The source of the radium-223 was elution from actinium-227 generators; at this facility, the material was eluted and prepared in hot cells, then packaged and prepared for distribution from the site as unit vials totaling 600 to 700 per week. Individual doses are prepared at other licensed facilities before distribution to client facilities. At the time of the inspection the licensee had 13 generators.

Performance Observations: The inspector toured all areas of the facility involved in production of materials. Licensee personnel demonstrated and described receipt and elution of generators, chemistry procedures, cleaning and monitoring of hot cells, automated preparation and packaging of dose vials, dosimetry and bioassay procedures, quality assurance testing, air emissions control and monitoring, waste tracking and disposal, equipment calibration and testing, and other procedures. The inspector noted no concerns with these activities. The inspector observed proper use of dosimetry and long-handled tools to handle radioactive materials. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. Review of dosimetry records indicated no exposures of concern. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings. The inspector reviewed spill reports, and documentation of package receipt, area surveys, instrument quality control, waste disposal, and employee training.

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