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 Nuclear Pharmacy Services, Dublin, Ohio Location inspected: Marion Ridge Business Park 9668 Marion Ridge Kansas City, Missouri 64137 REPORT NUMBER(S) 2015-001	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
030-36973	34-29200-01MO	March 27, 2015

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 / Dennis O'Dowd	GMW / Dennis O'Dowd	4/7/15
BRANCH CHIEF	Aaron T. McCraw		4/8/15

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 Nuclear Pharmacy Services, Dublin, Ohio Location inspected: Marion Ridge Business Park 9668 Marion Ridge Kansas City, Missouri 64137 REPORT NUMBER(S) 2015-001	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
030-36973	34-29200-01MO	March 27, 2015

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	Asma Abbasi, ANPT, Site RSO	(816) 966-2020

☐ Main Office Inspection Next Inspection Date: _____

☑ Field Office Inspection 9668 Marion Ridge, Kansas City MO

☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

This was a routine, unannounced, inspection of this site operating under the Cardinal Health multi-site license. This radiopharmacy was staffed with three pharmacists, four pharmacy technicians, and 15 drivers. The licensee had approximately 45 regular customers located in Missouri and Kansas, and distributed approximately 200 doses each weekday. The pharmacy was open weekdays from midnight to 4:00 pm, with more limited hours on weekends. The licensee's scheduled runs were from 2-5 am, 6-8 am, and 9-11 am, with additional doses delivered as needed. The licensee received two Mo-99/Tc-99m generators each week for preparation of doses. Pharmacy staff prepared primarily Tc-99m, F-18, I-123, and In-111 diagnostic doses, with occasional Tl-201 doses, and redistributed Xe-133 vials. F-18 doses were prepared from bulk material received from a Cardinal Health cyclotron in Omaha. The pharmacy compounded I-131 therapy capsules. All I-131 material was manipulated and stored in a glove box with a dedicated exhaust system with dual charcoal filters.

The maximum exposure received by licensee personnel in calendar year 2014 was 381 mrem whole body and 28.2 rem extremity; and in January through February 2014, 8 mrem whole body and around 3 rem extremity. Corporate audits were typically performed every four months, with extended periods after clear audits. The Cs-137 calibration source previously maintained at this site has been shipped to another facility.

Performance Observations: The inspectors observed generator elution, molybdenum checks, QC sampling and evaluation, kit preparation, dose preparation, dose surveys and wipes, package assembly and verification, package wipes and surveys, shipment preparation, blocking and bracing of packages, preparation and placement of shipping papers, package return surveys, waste tracking, and daily surveys and wipes. Licensee personnel demonstrated In-111 blood labeling, and compounding of I-131 capsules, and described waste disposal, package receipt surveys and wipes, tracking of customer licenses, stack and effluent monitoring, training, and other procedures. The inspectors noted no concerns with these activities. Licensee personnel used long-handled tools to reduce extremity doses. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. The inspectors performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings.

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 Nuclear Pharmacy Services, Dublin, Ohio Location Inspected: 1602 "C" Avenue Sioux Falls, South Dakota 57104 REPORT NUMBER(S) 2015-003	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
030-36973	34-29200-01MD	March 18, 2015

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	Don Stearns	for DS	4/8/15
BRANCH CHIEF	Aaron T. McCraw		4/8/15

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 Nuclear Pharmacy Services, Dublin, Ohio Location Inspected: 1602 "C" Avenue Sioux Falls, South Dakota 57104 REPORT NUMBER(S) 2015-003	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
030-36973	34-29200-01MD	March 18, 2015

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	Bruce Jorgensen, Site RSO	(605) 332-3703

☐ Main Office Inspection Next Inspection Date: TBD

☑ Field Office Inspection 1603 "C" Avenue, Sioux Falls, SD

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was a routine, unannounced, inspection. This field office primarily services customers in South Dakota, southwestern Minnesota, and northwestern Iowa. The radiopharmacy currently has 3 pharmacists, one pharmacy technician, and 8 drivers. Periodically, the pharmacists may deliver to local customers. The pharmacy begins operation at approximately 2:00 AM and operates until about 4:00 PM Monday through Friday. The pharmacy has limited operation on weekends, primarily on a case by case situation. The first run of the day usually leaves the pharmacy at approximately 3:45 AM. Five more runs are completed by 8:00 AM. Appropriate training was documented for all drivers. The licensee receives two generators each week; one on Monday, and one on Thursday. The licensee also receives iodine capsules on a daily frequency from Mallinckrodt in Omaha, Nebraska.

The pharmacy compounds I-131 capsules (therapy) for distribution. All work with the I-131 capsules is performed in a separate room with work performed in a glove box. Negative ventilation is verified and the box is tested on a periodic basis. On Wednesdays of each week the pharmacist replaces filter cartridges in the air sample lines and analyzes those for activity. Activity results are entered in to a computer program to determine release activity and calculated dose.

The corporate office performs audits at least semi-annually, and the site RSO performs internal audits of the radiation safety program. The maximum dose received by any individual in 2014 was 808 mrem whole body, and 1410 mrem extremity. The licensee has administrative action levels of 125 mrem per quarter whole body, and 800 mrem per month extremity.

The inspector observed package receipt for the incoming iodine and F-18 FDG shipments. All surveys and records were completed as required. The inspector observed generator elution, molybdenum tests, unit dose preparation, package preparation and labeling, and other activities associated with daily operation of the facility. No concerns were noted by the inspector. All pharmacists wore the appropriate whole body and extremity dosimetry. Interviews with personnel indicated adequate knowledge of radiation safety. The inspector performed independent and confirmatory surveys. The site RSO explained the sites bioassay program due to the use of iodine.

No violations were identified during the inspection.

NRC FORM 591M PART 1
(4-2008)
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 Nuclear Pharmacy Services 5630 Silverado Way#1 Anchorage, AK 99518 REPORT NO: 2015-002	U.S. Nuclear Regulatory Commission Region IV, 1600 East Lamar Blvd Arlington, Texas 76011-4511

3. DOCKET NUMBER	4. LICENSE NUMBER	5. DATE OF INSPECTION
030-36973	34-29200-01MD	9 March 2015

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:

[X] 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) was/were discussed involving the following requirement(s) and Corrective Action(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)

Licensee's Statement of Corrective Actions for Item 4, above.

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	Marti Poston	Marti Poston	3/9/15
BRANCH CHIEF	G. Michael Vasquez	G M Vasq	3/9/2015

[ ] Non-Public [ ] Sensitive – Security-Related [X] Public [X] Non-Sensitive

Warren, Geoffrey

From: Warren, Geoffrey
Sent: Wednesday, April 08, 2015 3:09 PM
To: 'scott.claunch@cardinalhealth.com'
Subject: NRC Inspection Reports - Cardinal Health
Attachments: Cardi001.PDF

Enclosed are the inspection reports for Cardinal Health facilities in Kansas City, Anchorage, and Sioux Falls. No issues were identified as a result of these inspections. No response is required to these reports or this e-mail.

Please contact me if you have any questions.

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Geoffrey Warren
Senior Health Physicist
NRC Region III
630-829-9742