Warren, Geoffrey

From: Warren, Geoffrey
Sent: Wednesday, September 08, 2021 8:49 AM
To: Sullivan, Glenn
Cc: Tindle-Engelmann, Elizabeth; Nieves Folch, Luis
Subject: NRC Inspection Reports - Stamford CT and Indianapolis IN
Attachments: Cardinal Health 202103 - Stamford CT -sigMK.pdf; Cardinal Health 202104 - Indianapolis IN - 591M -mk.pdf

Enclosed are the inspection reports for the NRC's recent inspections at your radiopharmacies in Stamford, Connecticut, and Indianapolis, Indiana. No violations were identified as the result of these inspections. No response is required to the reports or to this email.

Please contact me if you have any questions.

--
Geoffrey Warren
Senior Health Physicist (Inspector)
NRC Region III, Lisle, IL
630-829-9742

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 7000 Cardinal Place Dublin, OH 43017 REPORT NUMBER(S) 2021004	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	August 19, 2021

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	Luis A. Nieves Folch Digitally signed by Luis A. Nieves Folch Date: 2021.08.31 12:31:21 -05'00'	
BRANCH CHIEF	Michael Kunowski	Michael A. Kunowski Digitally signed by Michael A. Kunowski Date: 2021.08.31 15:39:40 -05'00'	

NRC FORM 591 PART 1
(05-2012)
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: 28 Omega Drive, Building #7 Stamford, Connecticut 06907 REPORT NUMBER(S) 2021003	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
03036973	34-29200-01MD	08/02/2021

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	Glenn Sullivan		
NRC INSPECTOR	Elizabeth Tindle-Engelmann	Elizabeth D. Tindle-Engelmann Digitally signed by Elizabeth D. Tindle-Engelmann Date: 2021.08.19 11:37:27 -04'00'	
BRANCH CHIEF	Michael Kunowski	Michael A. Kunowski Digitally signed by Michael A. Kunowski Date: 2021.09.08 04:19:20 -05'00'	

NRC FORM 592M
(10-2020)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Record

1. Licensee Name:	2. Docket Number(s):	3. License Number(s)
Cardinal Health	030-36973	34-29200-01MD

4. Report Number(s):	5. Date(s) of Inspection:
2021004	August 19, 2021

6. Inspector(s):	7. Program Code(s):	8. Priority:	9. Inspection Guidance Used:
Luis Nieves	04210	2	87127

10. Licensee Contact Name(s):	11. Licensee E-mail Address:	12. Licensee Telephone Number(s):
Adam Timm, RPh, Pharmacy Supervisor	adam.timm@cardinalhealth.com	317-827-3301

13. Inspection Type: ☐ Initial ☑ Routine ☑ Announced ☐ Non-Routine ☐ Unannounced

14. Locations Inspected: ☐ Main Office ☑ Field Office ☐ Temporary Job Site ☐ Remote

15. Next Inspection Date (MM/DD/YYYY): July 6, 2023 ☐ Normal ☐ Extended ☐ Reduced ☑ No change

16. Scope and Observations:

This was an announced, routine inspection of a radiopharmacy operating under Cardinal Health's multi-site license. This site, located in Indianapolis, Indiana, routinely served 35 clients in a one and a half hour range. The pharmacy operated Monday through Friday, with limited hours on weekends. The pharmacy distributed around 450 doses each weekday, primarily in the 1st of three runs. The first run going out around 3:00am, and the second and third runs going out around 8:00am and 10:00am, respectively. In addition to compounding doses of technetium-99m and other common isotopes, the pharmacy also compounded a handful of I-131 and I-123 capsules and doses of Thallium-201 each week. The licensee had nine authorized nuclear pharmacists, five pharmacy technicians, and seventeen drivers on staff at the time of the inspection.

PERFOMANCE OBSERVATIONS

The inspector toured the facility to evaluate the licensee's measures for materials security, hazard communication, and exposure control. The inspector conducted independent surveys of restricted and unrestricted areas, and found no residual contamination or exposures to members of the public in excess of regulatory limits. The inspector observed a variety of activities, including dose preparation, outgoing package preparation, client package return and waste handling, incoming generator and area surveys, and delivery vehicle loading. The licensee's staff also demonstrated the implementation of procedures for air effluent monitoring and bioassay for personnel preparing I-131 capsules. Through these observations, demonstrations, and discussions, the inspector found the licensee's staff to be knowledgeable of radiation protection principles and regulatory requirements. The inspector reviewed a selection of records, including internal and external audits, ALARA and incident reports, dose calibrator quality control records, air effluent monitoring reports, survey meter calibration certificates, hazmat training records, and dosimetry reports.

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

NRC FORM 592M
(10-2020)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Record

1. Licensee Name:	2. Docket Number(s):	3. License Number(s)
Cardinal Health Nuclear Pharmacy Service	03036973	34-29200-01MD

4. Report Number(s):	5. Date(s) of Inspection:
2021003	08/02/2021

6. Inspector(s):	7. Program Code(s):	8. Priority:	9. Inspection Guidance Used:
Elizabeth Tindle-Engelmann, Valerie Gray	04210	2	87127

10. Licensee Contact Name(s):	11. Licensee E-mail Address:	12. Licensee Telephone Number(s):
Jay Simmons, Site RSO, RPh	Jay.Simmons@cardinalhealth.com	203-352-1990

13. Inspection Type:	14. Locations Inspected:	15. Next Inspection Date (MM/DD/YYYY):
☐ Initial	☐ Main Office	No change
☑ Routine	☑ Field Office	☑ Normal
☑ Announced	☐ Temporary Job Site	☐ Extended
☐ Non-Routine	☑ Remote	☐ Reduced
☐ Unannounced		☐ No change

16. Scope and Observations:

Due to COVID-19 this inspection was announced; Box was used to perform a partial record review prior to the onsite inspection. This was an inspection of Cardinal Health's Stamford location. The pharmacy prepares approximately 300 dosages per day between two runs. The first run begins at 1:30 AM and dosages leave the facility around 5:00 AM; the second run begins around 6:00 AM and leaves the facility around 9:30 AM. Their primary radionuclide is technetium-99m; however, they also prepare gallium-67, indium-111, iodine-123, iodine-131, thallium-201, and xenon-131. They receive three molybdenum-99/technetium-99m generators per week as well as bulk doses of iodine-131 and xenon-133. Iodine-131 capsules are prepared in a negative pressure glove box in a dedicated room. The licensee has three authorized nuclear pharmacists that work at this site; their shifts are staggered so that there is always a pharmacist on duty. The RSO for the license is the corporate RSO; however, the licensee appointed a site RSO who is an authorized nuclear pharmacist that is onsite daily. The site has four pharmacy technicians and eight drivers. In 2018 the licensee remodeled this facility; the updated facilities were found to match descriptions provided in the license commitments.

Performance Observations: The inspectors observed the first run of the day. Observed activities included generator elution, radiopharmaceutical compounding, dosage preparation, dosage packaging, radiopharmaceutical quality control testing, package preparation/surveys, package transportation, and instrument quality control. During observation engineering controls such as leaded glass, syringe shields, glove boxes, remote handling tools, and leaded contains were regularly utilized. Additionally, administrative controls such as donning/doffing PPE, frequent glove changes, frequent contamination surveys, and rotation of tasks were observed. Staff wore whole body and extremity dosimeters. Employees of various levels of responsibility had sufficient knowledge regarding radiation safety, security, and emergency procedures.

The inspectors reviewed a sample of the following records: ambient radiation level surveys, annual program reviews, customer licenses, contamination surveys, decay in storage, dose calibrator quality control, dosimetry, effluents measurements, events, instrument calibrations, internal audits, package receipts, RSC meeting minutes, sealed source leak tests/inventories, and training. During a review of events the inspectors determined that a contract carrier delivered four radioactive packages to the facility but failed to close the vestibule garage door prior to leaving the facility. The licensee and contract carrier both investigated the event and implemented corrective actions.

Independent surveys were performed using a RadEyeG (SN:30839, calibration due date:10/12/2021). Surveys were consistent with the licensee's results and posting.

Materials Inspection Record (Continued)

During the inspection no violations were identified. An onsite exit briefing was held on August 2, 2021 and an exit meeting with held with the site RSO on August 11, 2021.