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 7000 Cardinal Place Dublin, Ohio 43017 Location: 2141 Airport Way # 900, Boise, ID 83705 REPORT No 2011-004	U.S. Nuclear Regulatory Commission Region IV, 612 East Lamar Blvd, Suite 400 Arlington, Texas 76011-4125

3. DOCKET NUMBER	4. LICENSE NUMBER	5. DATE OF INSPECTION
030-36973	34-29200-01	April 27, 2011

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.

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	R. Rick Muñoz	R. Rick Muñoz	04/27/2011
BRANCH CHIEF	Vivian H. Campbell	Vivian H. Campbell	5/10/2011

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

	Initial		Announced	X	Unannounced	X	Routine		Increased Controls

NRC FORM 591M PART 3
(10-2003) 10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

SAFETY INSPECTION REPORT & COMPLIANCE INSPECTION

1. LICENSEE	2. NRC/REGIONAL OFFICE
Cardinal Health Nuclear Pharmacy Services REPORT NO: 03036973/2011-004	U.S. Nuclear Regulatory Commission Region IV, 612 East Lamar Blvd, Suite 400 Arlington, Texas 76011-4125

3. DOCKET NUMBER	4. LICENSE NUMBER	5. DATE(S) OF INSPECTION
030-36973	34-29200-01MD	April 27, 2011
6. INSPECTION PROCEDURES USED	**7. INSPECTION FOCUS AREAS**	**8. INSPECTOR**
87127, 86740, 86750	03.03-03.07	Rick Muñoz

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02500	2	Mark Rotman, RPh, & Micah Rydman RPh	(614)757-5000 & (208)336-8422

☐ Main Office Inspection: _____ Next Inspection Date: April 2013

☒ Field Office: 2141 Airport Way, Suite 900, Boise, Idaho 83703

☐ Temporary Job Site Inspection: _____

PROGRAM SCOPE

This was an assist inspection for Region III. "Cardinal Health Nuclear Pharmacy Services" (Cardinal), is a multi-site license authorized to manufacture & distribute radiopharmaceuticals. This inspection was performed at 0200 so that licensed activities could be evaluated during their three batch preparations for the day. The 2nd batch starts at 0730 & the 3rd at 1000. Cardinal receives 2 Mo-99/Tc-99 generators per week (12 Ci on Sunday 5 Ci on Tuesday) from Lanthus. There is 1 weekly shipment of 20 mCi of Xe-133 in a 14-vial package. There is a Standing Order for 2 100-200 µCi caps/day of I-123; 2 caps/day I-131 ranging from 30-200 mCi. Cardinal routinely elutes the generator twice a day or as orders dictate. Cardinal prepares ~130 single unit doses/day; & 4-7/bulk doses of $Tc\text{-}99^{m}$ ranging from 150-300 mCi. The 3-batch preps/day are delivered to 17 customer facilities in Idaho in 5 separate transportation runs. The furthest location driven is to Twin Falls (east) & Ontario, Oregon (west). On average, the 1st batch at 0230 involves the preparation of 100-125 single unit & 4 bulk doses; the 2nd batch at 0730 is 30-40 single unit doses; & the 3rd at 1000 is 2 bulks & 3 Sestamibi plus any emergency doses since open of business for the day. Licensed material is dispensed by two ANPs & handled by 4 drivers & one QA/QC technician/driver. ANPs work every other week with only one ANP on duty/day. At the time of the inspection, the licensee's ANP prepared radiopharmaceuticals & four delivery drivers prepared 12 µCi doses of I-123, single unit doses & bulk $Tc\text{-}99^{m}$ for transport & delivery.

Cardinal's 2009 &2010 internal audits ("excellent" rating) & the monthly manager audits of the radiation safety program were reviewed. The licensee's I-131 continuous air monitoring program including the weekly glove-box filter change-out program was maintained. All instrumentation, survey, assay & RP equipment was properly calibrated. Instruments included; a Ludlum-177, 2200-Scaler, radiation detection equipment used for transportation, & surface surveys. The laminar flow hoods & fume hood used mainly for Iodine were properly calibrated & maintained by ASEPSIS. BHP Enterprises provides calibration services. An independent stack exiting out the top of the roof is maintained. There is one stack connecting the fume hoods below in the iodine laboratory. The Inspector reviewed the radiopharmacy driver's & ANP's initial & re-current training, as well as personnel monitoring results for whole body, extremity & bioassay program. The licensee exchanges WB dosimetry monthly & extremity badges weekly. Proper usage of personal dosimetry was observed. All personnel exposure doses were well within regulatory limits although Cardinal maintains administrative limits of 800 mRem/wk (extremity) & 125 mRem per month (WB). The highest exposures for 2010 were 5600 mRem (extremity) & 155 mRem (WB). NRC form-5 is mailed to each employee's home address. Security appeared adequate. The facility is electronically alarmed & monitored by an offsite third party monitoring service. The dose preparation area/hot lab is secured with mechanical locks & proxy card access. All short-lived waste generated is disposed of by decay-in-storage, secured & maintained in the I-131 fume hood room & storage area. Cardinal uses long-term decay in storage to final disposition of all radioactive waste. Other waste is shipped to Stericycle Inc. located in N. Salt Lake, UT. There are no other RAM or waste storage areas at this location. The licensee properly maintains inventories of exempt material in sealed form used as reference & calibration sources. Cardinal-Boise uses five area monitors, 6 survey instruments, 2 dose calibrators, & 1 deep well counter. Cardinal maintains a bioassay program to monitor any thyroid uptakes. Bioassays are performed as prescribed by procedure for routine handlers of Iodine. Bi-weekly (I-131) 6-24 hours (I-123) A random review of weekly bioassays performed did not indicate results approaching the established action II or I levels for I-131 (.04 µCi) & I-123 (5.4 µCi). The bioassay procedure was last revised 6/26/2009.

SUNSI Review By: R. Rick Muñoz

Supervisory Review By: Ke Lambert

☐	Non-Public	☐	Sensitive – Security-Related
☒	Public	☒	Non-Sensitive

NRC FORM 591M PART 3 (continuation)
(10-2003) 10 CFR 2.201

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SUPPLEMENTAL INSPECTION INFORMATION

CONTINUED FROM PART 3

Performance Observations:

The inspector observed the ANP perform the daily checks & QC on the dose calibrator as well as the single channel analyzer & the MCA. The ANP was observed eluting two generators (2.6 & 4.8 Ci), preparing kits & dispensing single unit & bulk doses. The technician/drivers were observed preparing syringe labels, performance of required radiation surveys including swipes, transportation, area & egress surveys. The inspector interviewed three delivery drivers & inspected two delivery vehicles prior to departure from the Cardinal facility. Drivers performed surveys & wipes prior to shipment, proper loading of packages, block & brace technique & shipping documentation accessibility in dedicated transport vehicles, package receipt surveys & wipes, personal egress survey meter "frisk" upon leaving the restricted area. One technician performed all the QA/QC tests & recorded all results. No I-131 encapsulation was performed during this inspection. The licensee's staff demonstrated or discussed: (1) the licensee's internal audit program which included, frequencies, non-compliance items, corrective actions, & management follow-up & review; (2) radiation dosimetry program including bioassays, notifications to individuals, & investigations of doses that exceed administrative limits for whole body & extremities; (3) environmental monitoring including the monthly evaluations of doses to members of the public using Z-badge (5-area monitors) evaluations, & air effluents & monitoring reports; (4) the training program; & (5) reportable events & incidents (none). Licensee driver personnel demonstrated the processes used to document & protocols for the shipment & receipt of licensed material on public highways. The licensee demonstrated security of licensed material & wipe test procedures for both work surfaces & transport containers. The licensee also demonstrated & discussed the use of radiation detection & survey instrumentation, material accountability & routine security of radioactive material. A physical verification of all sealed source inventory (13 sealed sources 4 Ba-133, 1 Cd-109, 3 Co-57, 1 Co-60, 2 Cs-137, 1 Mn-54, 1 Na-22) & records did not identify inconsistencies & had been adequately maintained. The inspector walked down the licensee's material use, storage, transportation shipping containers & security of the licensed material. Shipping containers were properly labeled meeting the requirements. The inspector performed independent radiological surveys*** of the generator storage, hood areas, draw station floors, benches, & unrestricted areas were consistent with expected levels & verified that the public dose was below the regulatory limit. No possession or use discrepancies, or reportable events or issues were identified. No inventory differences or reporting issues were identified.

The last inspection of the Boise, Idaho field office conducted on April 16, 2009, was clear. No violations of safety significance were noted under the performance & document review guidance prescribed in NRC Manual Chapter 2800 "Inspection Program". A clear inspection NRC form 591-M will be mailed by the NRC's R-III field office to Cardinal Health's corporate office located in Dublin, Ohio.

Persons Contacted:

Mark Rotman, R.Ph.
Dennis O'Neil, NPT Driver/Driver
Melanie Rotman, Driver
Hy Myrick, NPT Technician/Driver
Carol Turlay, Driver

***NRC survey instrument used: Ludlum 2401-P, #216052, calibration due 10/25/2011