

INSPECTION RECORD

Region: III Inspection Report No. 2018001

License No. 34-29200-01MD
Docket No. 030-36973

Licensee: Cardinal Health
 Nuclear Pharmacy Services
 7000 Cardinal Place
 Dublin, OH 43017

Location Inspected: 525 Kokea Street, Suite B-2
 Honolulu, Hawaii 96817

Licensee Contact: Glenn Sullivan, Corp. RSO Telephone No: 614-757-9586

Program Code: 2500 Priority: 2

Date of Last Inspection of Honolulu, Hawaii location: September 18, 2014

Date of This Inspection: February 23, 2018

Type of Inspection: () Initial () Announced (X) Unannounced
 () Routine () Special (X) Field Office (X) Assist

Next Inspection Date: TBD () Normal () Reduced

Summary of Findings and Actions:

- () No violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued
- () Non-cited violations (NCVs)
- () Violation(s), Form 591 issued
- (X) Violation(s), regional letter issued
- () Followup on previous violations

Inspector(s): Janine F. Katanic, PhD, CHP, Senior Health Physicist, MLIB, DNMS, Region IV

/RA via email/
Signature

Date: 5/17/2018

Approved: Aaron T. McCraw, Chief, MIB, DNMS, Region III

/RA John Giessner Acting for/
Signature

Date: 5/18/2018

PART I – LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES:

<u>AMENDMENT #</u>	<u>DATE</u>	<u>SUBJECT</u>
49 cc	10/25/2016	Corrected errors, change RSO
50	10/25/2016	Remodel radiopharmacies
51	2/15/2017	Remove radiopharmacy
52	8/2/2017	Update radiopharmacy drawings
53	10/5/2017	Add Ge-68/Ga-68 generators
54	1/19/2018	Increase possession limits
55	1/31/2018	Remodel radiopharmacies

2. INSPECTION AND ENFORCEMENT HISTORY:

No violations were identified as a result of the initial inspection of the Honolulu, Hawaii facility performed on September 18, 2014.

3. INCIDENT/EVENT HISTORY:

None related to the Honolulu, Hawaii facility

PART II – INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

This was an unannounced routine inspection of the Cardinal Health facility at 525 Kokea Street, Honolulu, Hawaii. The inspection was conducted by an NRC Region IV inspector as an assist request for NRC Region III. There is one pharmacist and one lead pharmacy technician on duty per shift. Other individuals serve as delivery drivers; one pharmacy supervisor and technician also serve as drivers. There are three dedicated transport vehicles. Additionally, the facility uses the services of a contracted courier to make some deliveries. There are two shifts, which means that there are two pharmacists. Pharmacy operations start around 3:00 am on weekdays. The facility receives molybdenum-99 (Mo-99)/technetium-99m (Tc-99m) generators twice weekly. On Saturdays, the facility is open for 3 hours. All other times the pharmacists are on call. Customers include NRC licensees on Oahu and the other Hawaiian islands and an NRC licensee on Guam. Iodine-131 capsules are compounded in a dedicated glove box.

The facility had been audited by Cardinal Health most recently on November 15, 2016, and on August 15, 2017, with only a few deficiencies noted. A separate radiation safety compliance audit is performed monthly by the facility staff. Every Thursday, the staff perform routine radiation safety tasks such as waste disposal, weekly surveys, etc.

The pharmacist noted that the licensee plans on remodeling the pharmacy in 2018. The inspector reminded the pharmacist that any changes to facilities that are significant and differ from the description and drawing tied down to the license will require a license amendment.

2. SCOPE OF INSPECTION:

Inspection Procedure Used: IP 87127; Focus Areas Evaluated: 03.01-.07

The inspector found the facility to be constructed as indicated in the drawing submitted by the licensee in letter dated January 30, 2012. The inspector observed: dose calibrator daily checks, survey and measurement instrument checks, Mo-99/Tc-99m generator elution, Mo-99 breakthrough checks, radiopharmaceutical kit preparation, dose drawing, radiopharmaceutical QC testing, dose packaging, transportation preparation and surveys, shipping paper generation, and blocking and bracing in transport vehicles. The inspector observed licensee personnel using appropriate radiation safety techniques, such as long-handled tools, shielding, and personal protective equipment. The licensee possessed a sufficient number and type of calibrated survey instruments and other radiation measurement instrumentation.

The inspector reviewed records for incoming and outgoing package survey results, effluent release determinations/air sampling, area radiation surveys, waste disposal logs, training records, dosimetry records, bioassay results, leak tests, instrument calibration records, and records maintained by the pharmacy regarding customer licenses.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

The inspector performed independent radiation surveys with the following NRC-owned survey equipment:

- Ludlum 2401-P, NRC tag 21953G, serial 232484, calibration due 4/6/2018
- Thermo RadEyeG, NRC tag 086964, serial 371, calibration due 4/18/2018

The inspector noted no areas of concern.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

The inspector identified a violation of 10 CFR 20.1802, which requires that the licensee control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

Upon arrival at the facility, the inspector knocked on the front door and rang the doorbell more than once. The inspector observed a licensee employee through the window blinds. After receiving no response, the inspector walked to the side entrance (the vestibule door), knocked on the door, rang the doorbell, then pulled the door handle and observed that the door opened. The inspector observed that two Radioactive White I labeled Class 7 Radioactive Material packages that were prepared for shipping were on the floor of the unsecured vestibule. The inspector recognized that the boxes contained spent Mo-99/Tc-99m generators that were prepared by the licensee for shipment back to the manufacturer.

The two shipper's declaration for dangerous goods forms that were on top of the boxes stated that one box contained 1.2 gigabecquerels (GBq) (32 millicuries (mCi)) of Mo-99 and the other box contained 0.52 GBq (14 mCi) of Mo-99. The boxes contained a total of 46 mCi of Mo-99. The inspector took photos of the boxes and wrote down the information from the two forms. A licensee employee then greeted the inspector.

The licensee explained that the week prior to the inspection, one of the drivers had reported to the pharmacy supervisor that the side door was not latching fully. As a

corrective action, the pharmacy supervisor sprayed lubricant on the locking mechanism. The day of the inspection, the licensee employee said that he thought the inspector's first doorbell ring came from the vestibule door, so he went to the vestibule door and opened it. Noticing no one present, he let the door close behind him, not observing that the door did not latch properly. The licensee employee stated that when the doorbell rang again, he went to the front door and observed no one present, because by this time the inspector had walked around to the vestibule door.

The inspector discussed the unsecured material with the licensee employee. Later, when the pharmacy supervisor and pharmacist showed up for work, the inspector further discussed the matter. The pharmacy supervisor stated that the week earlier, he had only lubricated the locking mechanism, and not the hinges. As an immediate corrective action, he lubricated the hinges and tested the door latching mechanism. At this time, the door latched properly. The pharmacist planned to discuss the matter with the Cardinal Health corporate office to see if there were any additional physical controls, such as different door closure mechanisms, that could be implemented. Additionally, the pharmacist planned on briefing the staff and reminding them of the importance of ensuring that the door latches firmly and is locked.

5. PERSONNEL CONTACTED:

- # Seung Yoon Yeo, Pharm.D., Pharmacy Manager, Pharmacist
- # Cynthia Martin, Pharmacist
- # Robert Phan, Pharmacy Supervisor
- Eric Laride, Pharmacy Technician
- Glenn Sullivan, Corporate RSO

Individuals present at onsite preliminary exit meeting

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