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 Loc: 5630 Silverado Way, #1, Anchorage, Alaska REPORT NO: 2011-002	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	34-29200-01MD	May 16, 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	Jason M. Razo	Ken Lambert for	6/7/11
BRANCH CHIEF	Ken Lambert	Ken Lambert	6/7/11

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

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS	8. INSPECTOR
87127	02.01-02.07	Jason M. Razo

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
2500	2	Douglas Sopp, Site Manager	(907) 562-0229

☐ Main Office Inspection _____ Next Inspection Date: _____

☒ Field Office 5630 Silverado way, #1, Anchorage, Alaska

☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an unannounced routine assist inspection for Region III. Licensee is the only radiopharmacy in Alaska. Inspectors were met by Tara Simonian of Cardinal Health's California office, who was in town for an unannounced audit. Doug Sopp, the site RSO and full-time ANP, was on vacation; ANP Stacy Petot from Cardinal Health's Ohio office was backfilling. In addition, two pharmacy technicians/drivers were present.

Licensee prepares radiopharmaceuticals for distribution to hospitals and clinics in the Anchorage and Wasilla, Alaska, areas, with occasional deliveries to Fairbanks via a courier. Licensee receives a 7.5 Ci Moly generator twice per week. Licensee orders bulk iodine-131 for the preparation of sodium iodide pills, as needed. Licensee prepares about 75 unit doses per day and 6 bulk Tc-99m vials for distribution to its 11 customers. Licensee receives and prepares F-18 from Seattle for PET radiopharmaceutical unit dose preparations on Tuesdays through Fridays.

Performance Observations

Operations begin between 0345-0400 and the first delivery drive leaves at 0600. Entire facility is locked 24/7 and requires a programmed key-card or punch code for entry. Delivery drivers have code access to an anteroom where they drop off generators; however, they do not have code access to the hotlab. Inspectors observed unit dose preparations of Tc-99m and of I-131. There were two prep areas in the main hotlab, one primarily for PET with larger syringe shields, and the other primarily for Tc-99m. I-131 vials were stored in a room attached to the main hotlab. Inspector observed a change-out of the three 10-liter per minute charcoal filters in the iodine use area.

Inspectors observed daily operational checks of radiation survey instruments and egress friskers. Instruments were calibrated at the required intervals. Observed surveys and contamination wipes of outgoing ammo boxes containing unit doses. Reviewed DOT papers, labels, and markings. Interviewed driver departing for 0600 delivery and observed adequate blocking and bracing.

All workers wear a whole-body badge on their torso and ring badges. Reviewed dosimetry results that showed maximum doses in 2009 of 143 mrem DDE and 16320 mrem SDE, and in 2010 of 97 mrem DDE and 11200 mrem SDE. Licensee has implemented a DPW training and monitoring program. Licensee performs thyroid bioassays at least once per week when working with unsealed iodine. Public dose assessment adequate for areas around the hotlab even though occupation by non-radiation workers was minimal.

Local radiation safety and documentation audits are performed locally once per month and at least annually by the corporate office.

Radiation surveys made with RAD EYE G Gamma, serial number 376, NRC asset number 086965, with calibration due date of June 2, 2011. Exposure rates indicated that radioactive materials use and storage areas were properly posted. Background measurements of ~0.01 mR/hr were noted.

Accompanied by Don Stearns and Rachel Browder for training purposes.