

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Cardinal Health Nuclear Pharmacy Services
5630 Silverado Way
Anchorage, Alaska 99518

2. NRC/REGIONAL OFFICE

USNRC Region IV
612 East Lamar Blvd., Suite 400
Arlington, Texas 76011-4125

REPORT NUMBER(S) **2009-009**

3. DOCKET NUMBER(S)

030-36973

4. LICENSEE NUMBER(S)

34-29200-01MD

5. DATE(S) OF INSPECTION

April 23, 2009

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 violation(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 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	James L. Thompson	<i>Ken Lambert for</i>	4/23/2009

(1/2008 edited by RIV)

10 CFR 2.201

Docket File Information
SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE Cardinal Health Nuclear Pharmacy REPORT NUMBER(S) 2009-009		2. NRC/REGIONAL OFFICE USNRC Region IV	
3. DOCKET NUMBER(S) 030-36973		4. LICENSE NUMBER(S) 34-29200-01MD	5. DATE(S) OF INSPECTION April 23, 2009
6. INSPECTION PROCEDURES USED 87127		7. INSPECTION FOCUS AREAS 02.01-02.07	

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02500	2. PRIORITY 2	3. LICENSEE CONTACT Douglas G. Sopp, Site Mgr.	4. TELEPHONE NUMBER 907-301-3177
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<input type="checkbox"/> Main Office Inspection	Next Inspection Date: April 2011
<input checked="" type="checkbox"/> Field Office Inspection	5630 Silverado Wy, #1, Anchorage, AK 99518
<input type="checkbox"/> Temporary Job Site Inspection	

PROGRAM SCOPE

This was a Region III assist, unannounced health and safety inspection of the new radiopharmacy location in Anchorage, Alaska, previously licensed under Scela, Inc., which was added to the Cardinal Health Master License Amendment No. 14, dated December 12, 2007.

Persons contacted: Douglas G. Sopp, Pharm.D., R.Ph., Pharmacy Manager/Site RSO; Amy Nighswonger, Pharmacy Tech; and Linda Cossaut, Pharmacy Tech and delivery driver. The corporate RSO, Jack Coffey, and five other corporate regulatory QA/QC managers conduct audits 3-4 times per year at this location. The Site RSO reported and documentation supported that all audits were satisfactory or above.

This is a small nuclear pharmacy located at a new location added to the license of Cardinal Health Nuclear Pharmacy Service. The inspectors arrived at the facility before the licensee employees and verified that the facility was secure. The outside of the facility was surveyed by the inspectors with a Ludlum model 2401- EC2 survey meter, serial #159789, calibrated 10/30/09, with background levels noted ~0.05 mR/hr. The inspectors noted that the operating time commenced at 0400 and began the inspection with the first two employees to arrive, the pharmacy manager and a pharmacy tech, who confirmed that daily operation commences at ~0400 each day. The third routine employee to arrive was the driver/pharmacy tech. The current staff has been with the licensee since the addition of this location approximately 1-1/2 years ago and has a staff of rotating pharmacists and techs to cover as needed.

The facility has approximately 8 routine customers. They receive radioisotopes from Mallinckrodt and dispense 50-80 doses per day; each dose is shrink-wrapped within the transport container prior to shipment. They employ the use of a step off pads at the prep station and at the fume hood. The licensee receives F-18 doses for PET studies in doses of 15 mCi from Mallinckrodt and tailors them to the customer's specifications. They use a dedicated fume hood for F-18 processing. The licensees fume hoods are calibrated by the Board of Pharmacy, with documented calibration dates of June 2009 and March 2009. The licensee uses Friskers and GM counters upon entry/egress and shipment surveying, with documented calibration dates February 2009.

All access doors have card-key access and were properly posted. The licensee has 5 sealed sources they use for QA/QC purposes, with only one of them requiring a leak test, which was documented as being performed on 04/01/09. The licensee has not had any reportable incidents, which was concurred by this inspection staff after review of applicable records. Personnel dosimetry records and qualification/training documents were reviewed. A random review of required records, logs and radiation survey documentation demonstrated compliance with the regulations by the licensee. No violations were noted during this inspection.