Initial		Announced	X	Unannounced	X	Routine		Special	Increased Controls

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

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE	2. NRC/REGIONAL OFFICE
Cardinal Health REPORT NO: 2010-005	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	February 25, 2010
6. INSPECTION PROCEDURES USED	**7. INSPECTION FOCUS AREAS**	**8. INSPECTOR**
87127	O3.01-03.07	Donovan

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
2500	2	Jesse Rickleman Facility RSO	(605) 332-3703

- [ ] Main Office Inspection _____ Next Inspection Date: _____
- [X] Field Office 1603 North C Street, Sioux Falls South Dakota
- [ ] Temporary Job Site Inspection _____

PROGRAM SCOPE

Medium size nuclear pharmacy licensee located in Sioux Falls South Dakota operated under Cardinal Health's multisite license. Operations commence at 0200 hours daily, Monday through Friday, first with a radio pharmacist arriving and then a technician showing up at 0230, and drivers arriving at 0300. The first shipment occurs at 0345 hours. Staff consists of three radio pharmacists, a technician and 8 drivers. The facility prepares 200 doses of Technicium-99m per day, usually between 10 and 30 millicuries per unit dose, 2 doses of Indium-111 per week at 15 to 20 millicuries per dose, and Iodine-131 therapy capsules, 5 to 6 times a week, varying from 15 to 150 millicuries per dose. Other isotopes such as Thallium 201, Iodine 123 and Samarium 153 are prepared infrequently. Since the last inspection in 2008, Flourine-18 in Fludeoxyglucose (FDG) had been added to the output inventory, usually 10 to 15 doses per week at 15 millicuries per dose. FDG is received from the Pet Net cyclotron in Omaha Nebraska. Radiopharmaceuticals prepared at the Cardinal Health Sioux Falls location are distributed to hospitals in the Sioux Falls area as well as hospital to the north (Brookings and Watertown), west (Mitchell and Rapid City), south (Yankton) as well as DMS mobile vans. Corporate conducts field audits on a trimester bases. Such reports were reviewed from January 2007 to November 2009 and appeared to be adequate. This facility includes a hot area, several radioactive hoods , radioactive sinks and radioactive refrigerators used for storage. Survey instrumentation are calibrated annually; dose calibrator quality control tests to include, geometrical variation, daily constancy, quarterly linearity and yearly accuracy were performed as required and results within manufacture's suggested tolerances. Staff conducts weekly thyroid bioassays, results within limits. Staff conducts package level and swipe test surveys before shipping. Staff was observed monitoring hands and feet before leaving controlled areas. Quarterly inventory and semi-annual leak tests of sealed sources are performed as required. Public Dose assessments using Landauer TLDs were done demonstrating compliance with 10 CFR 20.1301. Daily level and weekly contamination swipe surveys are conducted as required and documented in appropriate units as specified in the license. Radioactive hood air flow checks are done annually and effluent checks are performed weekly to demonstrate compliance. Staff were interviewed and observed wearing lab coats, latex gloves, whole body and extremity dosimetry. Staff, including drivers, receive yearly radiation safety and hazmat training. Dosimetry results are within regulatory limits with the whole body and extremity readings at 245/15040 millirem for 2009 and 163/17270 millirem for 2008. Area monitor TLD showed results less than 100 millirem per year limit. Radioactive waste is segregated by half life, decayed to 10 half lives and monitored prior to disposing as normal trash. Caution radioactive material, radiation area, and NRC form 3s were posted as required. Independent confirmatory measurements were taken using a Thermo Fisher Rad Eye G, NRC number 086961, calibrated March 2, 2009, showed levels within regulatory limits, from background to 1 mr/hour (FDG) at contact of doses being prepared. No violations identified. Clear 591 issued.