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 NUMBER(S) **2005-001**	**US Nuclear Regulatory Commission Region IV**

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-33224	**04-26507-01MD**	**Nov. 16 - Dec. 29, 2004**

6. INSPECTION PROCEDURES	7. INSPECTION FOCUS AREAS
IP 87127	**03.01-.07**

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
2500	**2**	**Kathy Benson**	**616-662-5013**

[ ] Main Office Inspection — Next Inspection Date: **Normal: 11/16/2006**

[X] Field Office **1864 Pine Ridge Drive, #A, Jenison, Michigan**

[ ] Temporary Job Site

PROGRAM SCOPE

The licensee is a medium to large pharmacy which can ship 100-200 doses per day to 15-20 clients. Pharmacy hours are between 2:00 am to 4:00 pm with Saturday and Sunday hours On-call only. There are three pharmacists and 10-12 drivers. Most doses are diagnostic, but some are Sm-153, Y-90, I-131 and Sr-89. The licensee receives three Mo-99 - Tc-99m generators per week but none are distributed. No brachytherapy authorized for 35.400 activities or sealed sources authorized under 10 CFR 35.500 are distributed at this facility.

Performance Observations

The site inspection was conducted on November 16, 2004. The inspection was extended through December 7, 2004 as a result of the continuing review of the licensee's corrective actions taken as a result of a previous inspection. The inspector interviewed the licensee's management and authorized users and found that personnel were knowledgeable regarding their responsibilities under the license. The licensee generated and possessed the required shipping documentation that contained all appropriate information and was accessible during transport. The licensee blocks and braces all licensed material for transport. The licensee's security either during transport or at the facility was found to be in compliance with NRC regulations. The inspector noted that the licensee staff handled licensed material as required under NRC regulations. The inspector performed independent radiation measurements and found no abnormal radiation levels throughout the facility. The inspector reviewed the licensee's effluent monitoring program and found that the program was in compliance with NRC regulations. The inspector reviewed the licensee's dosimetry records from 2002 to present and found no abnormal exposures were noted during the review period.

The inspector reviewed the corrective actions implemented by the licensee as a result an incident (documented in NRC Inspection Report 030-33224/2003-019) where the licensee failed to adequately measure, by combination of measurements and calculations, the amount of samarium-153 (Sm-153) prior to transfer to a medical facility in St. Joseph, Michigan. The inspector found all corrective actions as stated by the licensee were implemented. However, the inspector noted that the licensee's "Pharmacy Practice Policy and Procedures Manual" (which references the dose calibrator corrective factors and usage procedures) located on its Intranet (one of the corrective actions) was difficult for the licensee staff to find during the inspection.