



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

November 12, 2008

Mr. Jack Coffey
Senior Vice President
Quality and Regulatory
Nuclear Pharmacy Services
Cardinal Health
7000 Cardinal Place
Dublin, OH 43017

SUBJECT: NRC INSPECTION REPORT 030-36973/08-17 (FORM 591M PART 1)
CARDINAL HEALTH – JENISON, MICHIGAN FACILITY

Dear Mr. Coffey:

This letter refers to the routine inspection conducted on October 29, 2008, at your Jenison, Michigan facility. The inspection results were discussed with Willie Regits and Chris Walters of your staff during a final telephonic exit briefing conducted on November 6, 2008.

This inspection was an examination of activities conducted under your license as they relate to radiation safety and to compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of selective examinations of procedures and representative records, interviews with personnel, independent measurements, and observation of activities in progress. Within the scope of this inspection no violations of NRC requirements were identified; therefore, no response to this letter or the enclosed NRC Form 591M is required.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Should you have any questions concerning this inspection or enclosed report, please contact Ken Lambert of my staff at (630) 829-9633.

Sincerely,

A handwritten signature in black ink, appearing to read "John R. Madera", written over a large, loopy circular flourish.

John R. Madera, Chief
Materials Inspection Branch

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

Enclosures:
Inspection Report 030-36973/08-17

cc w/encl: State of Michigan



SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE Cardinal Health, Jenison, MI		2. NRC/REGIONAL OFFICE NRC Region III 2443 Warrenville Road, Suite 210 Lisle, Illinois 60532-4351	
REPORT NUMBER(S) 2008-017			
3. DOCKET NUMBER(S) 030-36973	4. LICENSE NUMBER(S) 34-29200-01MD	5. DATE(S) OF INSPECTION Oct. 29, 2008	
6. INSPECTION PROCEDURES USED 87127		7. INSPECTION FOCUS AREAS 03.01 – 03.07	

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02500	2. PRIORITY 2	3. LICENSEE CONTACT Barbara M. Atunrase, Site RSO	4. TELEPHONE NUMBER 616-662-5013
<input checked="" type="checkbox"/> Main Office Inspection		Next Inspection Date: <u>As scheduled by Project Lead</u>	
<input type="checkbox"/> Field Office		_____	
<input type="checkbox"/> Temporary Job Site Inspection		_____	

PROGRAM SCOPE

This facility was a nuclear pharmacy located in Jenison, Michigan. Licensee staff consisted of three pharmacists and one in training, three technologists, and fifteen drivers. The pharmacy manufactured and distributed approximately 250-260 unit doses and bulk technetium vials daily Monday through Friday to 15-20 customers in western Michigan. Most of the unit doses were technetium-99m compounds, but licensee personnel also prepared doses of fluorine-18 from bulk fluorine. Licensee operated from around 2:00 AM until 4:00 PM on weekdays and occasional hours on weekends. The first run started at 2:30 AM and went out by 5:00 AM; the second run started about 8:30 AM and left by around 10:00 AM; and other runs were performed as needed throughout the day. The pharmacy received three molybdenum-99/technetium-99m generators weekly. Licensee compounded iodine capsules and received and redistributed xenon-133 vials. Corporate office personnel performed audits twice annually to review performance at this facility.

Performance Observations

During this inspection, the inspector observed lab area surveys, generator elution, molybdenum assay, kit preparation, kit QC, technetium-99m and fluorine-18 dose preparation, packaging, dose verification, outgoing package surveys and wipes, package placement in vehicles, preparation and placement of shipping papers, package return, dose disposal, spot decontamination, package receipt surveys, iodine filter monitoring, and testing of licensee meter usage. Licensee personnel demonstrated dose calibrator constancy checks, and iodine-131 dose compounding, and described waste tracking and disposal, air monitoring, bioassay procedures, and response to vehicular accidents. No issues were identified with these practices. The inspector reviewed licensee audit reports and documentation. Interviews with licensee staff indicated adequate knowledge of radiation safety procedures and policies. Surveys indicated radiation levels appropriate for restricted and unrestricted areas.