

## UNITED STATES NUCLEAR REGULATORY COMMISSION

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

November 14, 2007

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

SUBJECT: NRC INSPECTION REPORT 030-36973/07-04 (FORM 591M Part 1)

SPRINGFIELD, MISSOURI FACILITY

Dear Mr. Coffey:

This letter refers to the routine inspection conducted on October 17, 2007, at your Springfield, Missouri, facility. The inspection results were discussed with Willie Regits of your staff during a final telephonic exit briefing conducted on November 13, 2007.

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 <a href="http://www.nrc.gov/reading-rm/adams.html">http://www.nrc.gov/reading-rm/adams.html</a>.

Should you have any questions concerning this inspection or the enclosed Form 591M, please contact Ken Lambert of my staff at (630) 829-9633.

Sincerely,

John R. Madera, Chief Materials Inspection Branch

Docket No.: 030-36973

License No.: 34-29200-01MD

Enclosure:

Inspection Report 030-36973/07-04

cc w/encl: State of Missouri

NRC FORM 591M PAR (10-2003)	IT 1			U.S. NUCLEAR REGULATO	RY COMMISSION	
10 CFR 2.201	SAFETY INSPE	ECTION REPORT	AND COMPLIA	ANCE INSPECTION		
1. LICENSEE/LOCATION INSPECTED: Cardinal Health, Dublin, Ohio 43017 Location inspected: 3040 East Elm Street, Springfield, Missouri 65802			2. NRC/REGIONAL OFFICE  REGION III  US NUCLEAR REGULATORY COMMISSION  2443 WARRENVILLE ROAD, SUITE 210  LISLE, ILLINOIS 60532			
REPORT	2007-004		LISEE, ILLINOIS 60			
		4. LICENSEE NUMBER(S)			5. DATE(S) OF INSPECTION	
030-36973 LICENSEE:		34-29200-01MD		October 17, 2007		
The inspection was an e Nuclear Regulatory Com	mission (NRC) rules an	d regulations and the conditi	ons of your license. T	radiation safety and to complian The inspection consisted of select ector. The inspection findings at	tive examinations	
X 1. Based on the		violations were identified.				
non-repetitive, a				not being cited because they wer NRC Enforcement Policy, NUREG		
	Non-Cited Violation(s) v	vas/were discussed involving	the following requirem	ent(s) and Corrective Action(s):		
cited. This form	is a NOTICE OF VIOLAT	TION, which may be subject t	o posting in accordanc		and are being	
		Statement of Correct				
corrective actions is mad date when full compliance Title	e in accordance with the e will be achieved). I und	requirements of 10 CFR 2.20	11 (corrective steps alre	at the violations identified. This st eady taken, corrective steps whic be required, unless specifically re Signature	h will be taken,	
LICENSEE'S REPRESENTATIVE						
NRC INSPECTOR	Geoffre	v M. Warren	2/1 2	Jam	10/24/07	

NRC FORM 591M PAR (10-2003) 10 CFR 2.201		SAFETY INSPE	Information CTION REPORT ICE INSPECTION	S. NUCLEAR REGULATORY COMMISSION				
1. LICENSEE	· <u></u>		2. NRC/REGIONAL OFFICE					
Cardinal Health, Springfield, MO REPORT NUMBER(S) 2007-004			Region III					
3. DOCKET NUMBER(S)		4. LICENSE NUMBER(S)		5. DATE(S) OF INSPECTION				
030-36973		34-29200-01MD		October 17, 2007				
6. INSPECTION PROCEDURES USED		7. INSPECTION FOCUS AREAS						
87127		03.01 - 03.07						
SUPPLEMENTAL INSPECTION INFORMATION								
PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT		4. TELEPHONE NUMBER				
02500	2	Sam Leveritt, S	ite RSO	417-831-5190				
X Main Office Inspection		Next Inspection Date:	TBD					
Field Office			,	_				
Temporary Jo	b Site							

## PROGRAM SCOPE

This facility was a nuclear pharmacy located in Springfield, Missouri. Licensee staff consisted of two pharmacists, four technologists, and eleven drivers. The pharmacy manufactured and distributed approximately 230-250 unit doses and bulk technetium vials daily Monday through Friday to 22 regular customers in southwestern Missouri and northern Arkansas. Most of the unit doses were technetium-99m compounds. Licensee operated from around 12:30 AM until 4:30 PM on weekdays, with limited hours on weekends. The first run left at 5:30 AM and the second ran from 7:00 am through around 10:00 am, with additional runs as needed throughout the day. The pharmacy received two molybdenum-99/technetium-99m generators weekly. Licensee compounded iodine capsules and received and redistributed xenon-133 vials. The licensee's corporate office performed independent safety audits on the radiation safety program quarterly, and the licensee had addressed concerns raised by these audits.

## **Performance Observations**

During this inspection, the inspector observed generator elution and molybdenum testing, kit preparation and quality assurance, dose preparations, iodine-131 compounding, dose packaging, package surveys, survey meter checks, package transport, shipping paper preparation, package transport, and returned package receipt surveys. Licensee personnel demonstrated dose calibrator constancy checks, waste tracking and disposal, and daily contamination surveys. No issues were identified with these practices. Interviews with licensee staff indicated adequate knowledge of radiation safety procedures and policies. Surveys indicated radiation levels consistent with licensee records and postings.

In addition, the inspector observed a delivery of licensed material from the pharmacy received at St. John's Physicians and Clinics in Springfield, Missouri. The inspector observed the placement of packages and shipping papers in the delivery vehicle and the package labels and markings and noted no concerns.