NRC FORM 591M PART 3 (07-2012) 10 CFR 2.201		U.S. NUCLEAR REGULATORY COMMISSION Docket File Information		
SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION				
1. LICENSEE/LOCATION INSPECTED:			2. NRC/REGIONAL OFFICE	
Cardinal Health Nuclear Pharmacy Services 3305 Lathrop Street, Suite 100 South Bend, Indiana			Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352	
REPORT NUMBER(S)	-			
3. DOCKET NUMBER(S)		4. LICENSE NUMBER(S	S)	5. DATE(S) OF INSPECTION
03036973		34-29200-01MD		11/18 & 19/13
6. INSPECTION PROCEDURES USED		7. INSPECTION FOCUS AREAS		
87127		03.01-03.07		
SUPPLEMENTAL INSPECTION INFORMATION				
1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT 4		4. TELEPHONE NUMBER
02500	2	Willie Regits, RSO		(614) 757-5000
Main Office Inspection Next Inspection Date: 11/18/2015				
✓ Field Office Inspection 3305 Lathrop Street, Suite 100, South Bend, IN				
Temporary Job Site Inspection				

PROGRAM SCOPE

The licensee conducts licensed activities Monday through Friday between 2:30 am and 4:00 pm, and on weekends between 4:00 am and 6:00 am. The site has 4 authorized nuclear pharmacists (ANPs) that serve about 20 clients within a 1.5 hour radius from the site. The first two runs happen at 4:00 am. The biggest run happens between 5:00 and 5:30 am. Other runs occur at 6:00 am, 7:30 am, 8:30 am, and 9:30 am. The licensee does not use F-18 or other PET material. The licensee compounds I-131 capsules and does not dispense liquid I-131 dosages. The licensee does not distribute Rb-82 generators. Xofigo is received from the Cardinal Health pharmacy in Denver, Colorado. The South Bend pharmacy staff does not open the dosages before re-distributing the dosages to clients.

Performance Observations

The inspector observed: (1) that licensed material in the authorized location and in an unattended vehicle was secured as required; (2) that the maximum annual whole body and extremity radiation doses received by radiation workers since 2011 were 72 millirem and 22580 millirem, respectively; (3) that sealed source inventories and leak tests were conducted as required; (4) that glove box filter checks and fume hood flow checks were done; (5) that licensee staff donned extremity and whole body dosimeter badges assigned to them; (6) that licensee staff donned personal protection equipment; (7) a pharmacy technician conduct required radiation surveys of packages prior to shipment; (8) a driver demonstrate how he transported licensed material including, in part, blocking and bracing, shipping papers, and security; (9) a driver demonstrate how he would respond to emergency scenarios posed by the inspector; (10) < 0.5 mR/ hr at the surface of selected, labeled packages using a calibrated, NRC-owned survey instrument; (11) that selected fire extinguishers were charged and checked at the frequency indicated on the tag; (12) an ANP demonstrate how I-131 capsules were compounded; (13) an AMP demonstrate how he had checked and exchanged glove box charcoal filters; (14) an AMP demonstrate how he had checked the face velocity of the fume hood; (15) an ANP demonstrate how he would respond to a liquid I-131 spill scenario posed by the inspector; (16) an ANP demonstrate how he conducted thyroid bioassays; (17) an ANP elute a Mo/Tc generator and conduct molybdenum breakthrough tests on each eluate; (18) selected ANPs prepare kits and unit dosages; (19) a pharmacy technician demonstrate how dose calibrator constancy checks were done; and (20) that survey instruments were calibrated as required.