NRC FORM 591M PART 1
(1-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Cardinal Health Nuclear Pharmacy Services 7000 Cardinal Place Dublin, Ohio Kansas City, Missouri Pharmacy REPORT NUMBER(S) 2012-06	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-36973	34-29200-01MD	March 2, 2012

LICENSEE:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

☑ 1. Based on the inspection findings, no violations were identified.

☐ 2. Previous violation(s) closed.

☐ 3. The violations(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, to exercise discretion, were satisfied.

Non-cited violation(s) were discussed involving the following requirement(s):

☐ 4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.
(Violations and Corrective Actions)

Statement of Corrective Actions

I hereby state that, within 30 days, the actions described by me to the Inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE	DATE
LICENSEE'S REPRESENTATIVE			
NRC INSPECTOR	Ken Lambert / Bill Lin	Ken Lambert / Bill	3/19/12
BRANCH CHIEF	Tamara Bloomer	Robert D. Hatten, Jr. for	3/20/12

NRC FORM 591M PART 3
(1-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87127	03.01- 03.08

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
2500	2	Willie Regits, RSO	(614) 757-3147

☐ Main Office Inspection Next Inspection Date: N/A

☑ Field Office Inspection Kansas City, Missouri Pharmacy

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This radiopharmacy employed four pharmacists, seven pharmacy technicians, and approximately 20 drivers. The licensee served the Kansas City, Missouri and surrounding areas and distributed approximately 300 doses each day, primarily technetium-99m unit doses and bulk technetium. The licensee operated Monday through Friday, and started operations at approximately 2:00 am, with the first run leaving around 4:00 am; the second run started around 6:00 am with doses leaving around 8:30 am; and further runs were performed as needed. The pharmacy received three generators weekly. The Licensee received and redistributed xenon-133 gas vials and iodine-123 capsules. The pharmacy compounded I-131 therapy capsules. All I-131 material was manipulated in a glove box and either stored in the glove box or a fume hood. Since the last inspection the licensee has added preparation and distribution of PET radiopharmaceuticals to its customers. The licensee possesses a nominal 100 mCi Cs-137 sealed source for customer instrument calibration, but the RSO indicated that the pharmacy no longer provides this service to its customers. The source is currently in storage. The licensee's audit group performed audits three times/year with the facility RSO performing additional audits.

Performance Observations

The inspectors observed, compounding of I-131 therapy doses, dose preparation and verification, lead pig sealing and surveys, package sealing, package surveys and wipes, shipping paper preparation, label verification, blocking and bracing of packages, shipping paper storage in transport vehicles, returned package surveys and wipes, processing of returned unit dose pigs. The licensee staff demonstrated or discussed daily surveys, dose calibrator constancy tests, iodine filter surveys, package receipt surveys, and decay in storage and waste handling processes. The inspectors reviewed select records including waste disposal, instrument calibrations, dose calibrator constancy and linearity, and area surveys and wipe results. The inspectors observed licensee staff using long handled tools for handling doses. Interviews with licensee staff indicated an adequate knowledge of procedures and radiation safety concepts.

The inspectors reviewed personnel monitoring with the maximum exposures of 2880 mrem SDE and 64 mrem DDE for 2012; 26101 mrem SDE and 631 mrem DDE for 2011; and 19300 mrem SDE and 737 mrem DDE for 2010.

No Violations were identified.