NRC FORM 591M PART 1
(06-2010)
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 3305 Lathrop Street South Bend, Indiana 46628 REPORT NUMBER(S): 2011-005	U.S. Nuclear Regulatory Commission, Region III 2443 Warrenville Road, Suite 210 Lisle, Illinois 60532

3. DOCKET NUMBER(S)	4. LICENSEE NUMBER(S)	5. DATE(S) OF INSPECTION
030-36973	34-29200-01MD	September 2, 2011

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:

[X] 1. Based on the inspection findings, no violations were identified.

[ ] 2. Previous violation(s) closed.

[ ] 3. The violation(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, NUREG-1600, 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. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11

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	Geoffrey M. Warren	GM Warren	9/16/11
Branch Chief	Tamara E. Bloomer	TE Bloomer	9/16/11

NRC FORM 591 M PART 3 (06-2010) 10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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1. LICENSEE	2. NRC/REGIONAL OFFICE
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6. INSPECTION PROCEDURES	7. INSPECTION FOCUS AREAS
87127	03.01 – 03.07

SUPPLEMENTAL INSPECTION INFORMATION

1.PROGRAM	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02500	2	Nathan Johnson, Site RSO	574-233-5970

☒ Main Office Inspection — Next Inspection Date: TBD

☐ Field Office Inspection _____

☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

This radiopharmacy employed four pharmacists, eight pharmacy technicians, and 10 to 15 drivers. The licensee had approximately 30 regular customers located in northern Indiana and southwest Michigan, and distributed approximately 250 to 300 doses each day, primarily technetium-99m unit doses and bulk technetium. The pharmacy was open weekdays from 2:00 a.m. to 4:30 p.m. and limited hours on weekends. The licensee's first weekday run started at 2:45 am, with doses leaving around 4:00 am; the second run started at 6:00 am, with doses leaving around 8:00 am; and further runs were performed as needed throughout the day. The pharmacy received three technetium-99m generators weekly. The licensee received and redistributed xenon-133 gas vials, iodine-123 capsules, and occasional calibration sources. The pharmacy compounded I-131 therapy capsules and provided iodine-131 liquid for distribution. All iodine-131 material was manipulated and stored in a glove box.

The licensee's corporate office conducted audits of the program three times annually, and pharmacy staff performed monthly in-house audits. The maximum dose received by licensee personnel in calendar year 2010 was 40 mrem whole body and 17990 mrem extremity, and from January through August 2011, the maximum was 30 mrem whole body and 12320 mrem extremity.

Performance Observations

The inspector observed generator elution, kit preparation and QC testing, dose preparation and verification, molybdenum testing, pig sealing and surveys, package sealing, package surveys and wipes, shipping paper preparation and placement, label verification, blocking and bracing of packages, returned package surveys and wipes, cleaning of returned pigs, daily surveys, and cleaning of hoods. Licensee personnel demonstrated daily surveys, dose calibrator constancy tests, iodine filter surveys, package receipt surveys, weekly iodine bioassays, preparation of beta-emitting therapy doses, and iodine-131 dose preparation. The inspector noted no concerns with these activities. The inspector noted that licensee personnel used long-handled tools for handling doses. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings.