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 5370 Miller Road Swartz Creek, Michigan 48473 REPORT NUMBER(S) 2012-08	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	July 13, 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	Geoffrey M. Warren	GMW	7/24/12
BRANCH CHIEF	Tamara E. Bloomer	TE Bloomer	7/26/12

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 - 03.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02500	2	Sharon Jackson, site RSO	(810) 733-8727

☐ Main Office Inspection Next Inspection Date: TBD

☑ Field Office Inspection Swartz Creek, MI

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This radiopharmacy employed four pharmacists, three pharmacy technicians, four laboratory technicians, and 15 drivers. The licensee had approximately 30-40 regular customers located in eastern Michigan, and distributed approximately 230 doses on weekdays. The pharmacy was open Monday - Friday from 1:30 a.m. to 5:00 p.m., with limited hours on weekends. The licensee's weekday runs were out by 4:30 a.m., 9:00 a.m., and noon, with runs as needed in the afternoon. The licensee received Mo-99/Tc-99m generators each week for preparation of doses for distribution to clients. Xenon-133 gas vials were received and re-distributed. The pharmacy compounded I-131 therapy capsules for distribution. All iodine-131 material was manipulated and stored in a glove box. The glove box had a dedicated exhaust system with charcoal filters. The pharmacy occasionally prepared and distributed doses from bulk material containing additional isotopes such as fluorine-18.

The licensee's corporate office conducted audits of the program three times yearly and the RSO conducted additional in-house audits. The maximum dose received by licensee personnel in calendar year 2011 was 450 mrem whole body and 21.6 rem extremity, and from January through May 2012, the maximum was 250 mrem whole body and 12.7 rem extremity.

Performance Observations

The inspector observed generator elution, molybdenum assay, kit preparation and QC, dose drawing and wipes, package surveys and wipes, dose tracking, hood survey and cleaning, shipping paper preparation and placement, package placement, package return, and waste disposal and tracking. Licensee personnel demonstrated daily surveys and wipes, survey meter QC, dose calibrator constancy, iodine capsule preparation, and package receipt surveys. The inspector noted no concerns with these activities. The inspector observed proper usage of extremity and whole-body personal dosimetry, as well as use of long-handled tools to reduce 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.