NRC FORM 591M PART 1
(07-2012)
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 43017 REPORT NUMBER(S) 2016007	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	August 3-4, 2016

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)

Contrary to 10 CFR 30.41(a) and (b)(5), on or about June 19, 2013, the licensee transferred from its facility in Joplin, Missouri, a source containing approximately 5.4 millicuries of iodine-131 to Mercy Hospital Joplin, a person who was not authorized to receive such byproduct material under the terms of a specific or general license issued by the NRC or Agreement State. The root cause of the violation was that Mercy Hospital Joplin had only recently amended their license, ~~and the licensee had not updated their~~ (sic) As corrective action, the licensee now requires new updates of licenses every six months and, in the letter requesting the updates, requests that their clients send updates any time there is a change in the authorizations on the client's license.

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	David W. Pellicciarini Vice President, Pharmacy Safety, Proc. + Tech Ops.	David W. Pellicciarini	8/4/16
NRC INSPECTOR	Geoffrey M. Warren	Geoffrey M. Warren	8/4/16
BRANCH CHIEF	Aaron T. McCraw	Robert D. Gattone, Jr. for ATM	8/15/16

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

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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	Glenn Sullivan, Acting Corp. RSO	(614) 757-9586

☑ Main Office Inspection Next Inspection Date: August 3, 2018

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was a routine inspection at the corporate office of Cardinal Health, a company that operated 140 facilities under its nuclear pharmacy division in the United States. Twenty of these facilities were radiopharmacies under this NRC multi-site license. Each pharmacy prepared and distributed radioactive drugs to clients at hospitals, medical clinics, and other facilities. In addition, each facility was authorized to redistribute sealed sources as calibration sources, brachytherapy sources, and sources for diagnosis.

Cardinal Health employed 3000 personnel at the corporate office in Dublin, Ohio. Six personnel at the corporate office had primary duties concerning the radiation safety program, and five auditors based around the country performed audits at the individual pharmacies. This inspection was focused on the activities performed by corporate staff in support of radiation safety at the radiopharmacy facilities.

Performance Observations: The inspector attended the licensee's radiation safety committee meeting on August 3, 2016. Licensee personnel described (1) the corporate audit program for radiopharmacy facilities, including rating results, actions taken to correct deficiencies and strengthen programs, and oversight of auditors; (2) dosimetry and bioassay programs, including follow-up to doses exceeding ALARA levels; (3) effluent monitoring and public dose calculations; (4) training and qualification of authorized users, nuclear pharmacists, and radiation safety officers; (5) initial and annual radiation safety training for pharmacy and corporate staff; (6) tracking of client licenses and authorizations; and (7) the employee concerns program. The inspector noted no concerns with these activities except as noted below. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. Review of dosimetry records indicated no exposures of concern.

The inspector identified one violation of NRC requirements. In June 2013, the Cardinal Health radiopharmacy in Joplin, Missouri, provided an iodine-131 dose to Mercy Hospital Joplin, a client who was no longer authorized to possess such materials. The hospital had recently amended their license to remove this authorization. This is a violation of 10 CFR 30.41(a) and (b)(5). Since then, Cardinal Health has taken action to reduce the likelihood of recurrence. This would normally have been cited at the pharmacy inspection, but the Joplin pharmacy was closed soon after this occurred.

BB for ATM