

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: SSM Regional Health Services d/b/a SSM Health St. Mary's Hospital • Jefferson City 2505 Mission Drive Jefferson City, MO 65109 REPORT NUMBER(S) 2016-001	2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352
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3. DOCKET NUMBER(S) 030-12819	4. LICENSE NUMBER(S) 24-17477-01	5. DATE(S) OF INSPECTION October 19, 2016
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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 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, 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	Dennis P. O'Dowd	<i>Dennis P. O'Dowd</i>	10/19/2016
BRANCH CHIEF	Aaron T. McCraw	<i>[Signature]</i>	11/2/16

Docket File Information

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<p>3. DOCKET NUMBER(S)</p> <p>030-12819</p>	<p>4. LICENSE NUMBER(S)</p> <p>24-17477-01</p>	<p>5. DATE(S) OF INSPECTION</p> <p>October 19, 2016</p>
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<p>6. INSPECTION PROCEDURES USED</p> <p>87131, 87132</p>	<p>7. INSPECTION FOCUS AREAS</p> <p>03.01-03.07</p>
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SUPPLEMENTAL INSPECTION INFORMATION

<p>1. PROGRAM CODE(S)</p> <p>02230, 02120</p>	<p>2. PRIORITY</p> <p>2</p>	<p>3. LICENSEE CONTACT</p> <p>Kenneth Wohlt, M.S., RSO</p>	<p>4. TELEPHONE NUMBER</p> <p>(417) 269-5309</p>
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Main Office Inspection Next Inspection Date: 10/19/2018

Field Office Inspection 1241 W. Stadium Boulevard, Jefferson City, Mo

Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an routine inspection of a 170-bed hospital in Jefferson City, Missouri, authorized to use byproduct material under 10 CFR 35.100, 35.200, 35.300, and in vitro studies using prepackaged kits under 31.11, at its main facility, and 35.600 (HDR) (authorized by Amendment 18, issued in December 2015) at its satellite location at the SSM Health Cancer Center at JCMG. The HDR program had two AUs and several medical physicists. The HDR unit was commissioned in March 2016. As of the inspection date, three patients had undergone HDR treatments (10 fractions each) for breast cancer using a SAVI applicator. The nuclear medicine lab, located in the imaging department at the newly relocated main hospital (as of fall 2014), had one full-time and three part-time nuclear medicine technologists on staff to perform approximately 25 diagnostic administrations per week, Mondays through Fridays. No Xe-133 is used. Nine therapeutic administrations (eight I-131 (capsule only) and one Sm-153 (liquid form)) were performed in 2014; seven (I-131) in 2015, and none to date in 2016. The lab conducts a variety of diagnostic procedures using unit doses of primarily Tc-99m. The lab also maintains a bulk dose of Tc-99m when on-call. The licensee retains the services of a medical physics consultant to perform quarterly audits, instrument calibrations, inventories and leak tests.

PERFORMANCE OBSERVATIONS

The inspector toured the new HDR facility at the Cancer Center, as well as the nuclear medicine lab at the main hospital, to evaluate the licensee's measures for security, hazard communication and exposure control. No HDR treatments took place on the date of the inspection. The licensee's radiation oncology staff demonstrated HDR use and storage. The inspector reviewed all treatment plans and written directives (no issues noted). In nuclear medicine, the inspector observed preparation and administration of one cardiac study using Tc-99m. The inspector conducted independent and confirmatory surveys and found no exposures to members of the public above limits. Technologists on staff demonstrated implementation of procedures for package receipt, area surveys, contamination control, spill response and waste handling. Technologists demonstrated adequate knowledge of radiation protection principles and licensee procedures. The inspector reviewed the licensee's procedures and documentation for the administration of radiopharmaceuticals requiring a written directive, and verified that they provided high confidence that the patient's identity was verified before each administration, and that each administration was in accordance with the written directive. The inspector also reviewed a selection of licensee records for quarterly and annual audits, radiation safety committee meeting minutes, dosimetry, package receipt, area surveys, waste handling and hazmat training. No violations of NRC requirements were identified as a result of this inspection.