

(07-2012)
10 CFR 2.201

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

SSM Health St. Joseph Hospital - St. Charles
300 First Capitol Dr.
St. Charles, MO 63301

REPORT NUMBER(S) 2019001

2. NRC/REGIONAL OFFICE

Region III
U. S. Nuclear Regulatory Commission
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

3. DOCKET NUMBER(S)

030-08664

4. LICENSE NUMBER(S)

24-¹/₅159-01

5. DATE(S) OF INSPECTION

February 5, 2019

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>	02/05/19
BRANCH CHIEF	Aaron T. McCraw	<i>ATM for ATM</i>	2/25/19

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6. INSPECTION PROCEDURES USED

87130, 87131, & 87132

7. INSPECTION FOCUS AREAS

03.01-03.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)

02240, 02120

2. PRIORITY

2

3. LICENSEE CONTACT

Kelsey McClure, RSO

4. TELEPHONE NUMBER

(636) 498-7949

☒ Main Office Inspection Next Inspection Date: 02/05/2021

☒ Field Office Inspection St. Charles, Mo., Lake St. Louis, Mo., &

☐ Temporary Job Site Inspection St. Peters, Mo. locations

PROGRAM SCOPE

This was a routine, unannounced inspection of a 200-bed hospital, authorized under its license to use byproduct materials for medical uses permitted by 10 CFR 35.100, 35.200, 35.300, 35.400, and 35.1000 (Sr-90 in a Beta-Cath Intravascular Brachytherapy (IVB) system).

The nuclear medicine department at SSM St. Joseph Hospital-St. Charles location was staffed with two full-time nuclear medicine technologists (NMT) who performed approximately 150 diagnostic nuclear medicine procedures monthly. The licensee received unit and bulk doses from a licensed radiopharmacy. Doses were primarily technetium-99m for cardiac, bone scan, lung, HIDA, renal, gastric emptying and other studies. The nuclear medicine department performed 20 iodine-131 therapy procedures per year. Licensee had not conducted any manual brachytherapy since 2012, and had transferred its 35.400 permanent implant sealed sources to the SSM DePaul Health Center, Bridgeton, Mo. license in 2012. The license was amended in November 2018 to authorize use of IVB at the St. Charles location. The licensee had two Authorized Users (AUs) and one Authorized Medical Physicist (AMP) for IVB use.

At the St Joseph Hospital West, a 200-bed hospital, the nuclear medicine department was staffed with two full-time NMT who performed approximately 180 diagnostic nuclear medicine procedure monthly and 5 iodine-131 therapy procedure per year. The last manual brachytherapy was performed in 2012. The licensee had a separate cardiac clinic at the St. Joseph West location, with one full-time NMT performing approximately 90 nuclear cardiology procedures a month.

The licensee's facility located at 5401 Veterans Memorial Parkway, St. Peters, MO, was authorized for 35.200 uses only, and was staffed with one full-time NMT who performed approximately 120 diagnostic nuclear cardiology procedures monthly.

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PROGRAM SCOPE

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Performance Observations

At each of the four locations of use inspected, (i.e., St. Joseph Hospital-St. Charles, Mo., St. Joseph Hospital West's (Lake St. Louis, Mo.) nuclear medicine department, and its nuclear cardiology clinic, and the cardiology clinic in St. Peters, Mo.), the inspector toured the licensee's facility to evaluate the licensee's measures for materials security, hazard communication and exposure control. At each of the locations, licensee staff successfully demonstrated/discussed (1) radioactive material package receiving, check-in and opening procedures; (2) instrument quality control, including dose calibrator constancy checks, (3) security of licensed materials; (4) daily and weekly area surveys; (5) sealed sources inventory and leak tests; (7) proper handling of radioactive waste for decay-in-storage, (7) training of staff, including DOT HazMat training, and ancillary staff training, (8) spill response, and (9) contamination incidents (none). During the inspection, the inspector observed several administrations of Tc-99m to patients at all of the facilities with the exception of the cardiac clinic in St. Peters, Mo. No therapeutic procedures were conducted at the time of the inspection.

At the St. Joseph Hospital-St. Charles, and the St. Joseph Hospital West locations, the inspector reviewed written directives (WD) and related documents for iodine-131 procedures, with no issues noted. At the St. Joseph Hospital-St. Charles location, the new IVB use was reviewed in detail with the licensee's AMP. As of the inspection date, three IVB procedures had been performed in January 2019. The licensee's IVB plans and procedures, along with all WDs were reviewed, with no issues noted. The inspector also reviewed the quarterly program audits conducted by the licensee's consultant physicist, as well as radiation safety committee minutes.

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At each location of use, the inspector reviewed a selection of relevant records, including those for survey instrument calibration, leak tests, periodic dose calibrator tests; and dosimetry records. The review of dosimetry records indicated no exposures of regulatory concern. The inspector performed independent and confirmatory radiation measurements at each of the locations inspected, which indicated results consistent with licensee survey records and postings.

The inspector reviewed a violation (SLIV) cited during an inspection on November 12, 2015. The violation involved the licensee's failure to document the disposal of each decay-in-storage waste. The inspector determined that the licensee's corrective actions were completed as described in the NRC Form 591M inspection report, and that the violation had not recurred. Based on this review, this violation is considered closed.

No violations of NRC requirements were identified during this inspection.