

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: SSM Health DePaul Hospital - St. Louis Department of Nuclear Medicine 12303 DePaul Drive Bridgeton, MO 63044 REPORT NUMBER(S) 16-001		2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Rd, Suite 210 Lisle, IL 60532	
3. DOCKET NUMBER(S) 030-02308	4. LICENSE NUMBER(S) 24-02490-03	5. DATE(S) OF INSPECTION January 28, 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 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	Zahid Sulaiman	<i>Zahid Sulaiman</i>	1/28/16
BRANCH CHIEF	Aaron T. McCraw	<i>[Signature]</i>	2/10/16

Docket File Information

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6. INSPECTION PROCEDURES USED 87131 & 87132	7. INSPECTION FOCUS AREAS 03.01-03.07
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SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02240	2. PRIORITY 2	3. LICENSEE CONTACT Joseph Pekala, CNMT, RSO	4. TELEPHONE NUMBER (314) 447-5981
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Main Office Inspection Next Inspection Date: 01/26/2018

Field Office Inspection St. Joseph Hospital West, Lake St Louis, MO

Temporary Job Site Inspection _____

PROGRAM SCOPE

This was a routine inspection of a 420-bed hospital, authorized under NRC license to use byproduct materials for medical uses permitted by 10 CFR 35.100, 35.200, 35.300, 35.400, 35.600, and 35.1000. The nuclear medicine department was staffed with three full-time and one part-time nuclear medicine technologists (NMT) who performed approximately 300 diagnostic nuclear medicine procedures monthly. The licensee received unit doses from a licensed radiopharmacy. Doses were primarily technetium-99m for cardiac, bone scan, lung scan, Hida, renal, gastric emptying and other studies. The nuclear medicine department performed approximately 4 iodine-131 therapy procedures per month. The licensee is also planning to add Xofigo, Ra-223 treatment in near future.

The radiation oncology department at the hospital was staffed with an oncologists, a dosimetrist, and an authorized medical physicist (AMP) who performed approximately 5 iodine-131 cancer therapy treatments and 7 high dose rate brachytherapy (HDR), mostly breast and gynecological cancer treatments per year. The cancer care center located at St. Joseph Hospital West, was staffed with 2 oncologist, 1 dosimetrist and 1 AMP, performed approximately 40 manual brachytherapy, I-125 prostate seed implant procedures annually. The licensee planned to decommission and remove the HDR unit authorization located at 1475 Kisker Road, St Charles, Missouri, from the license, the HDR unit sealed source was removed and returned to the manufacturer on May 23, 2013. The license is authorized for 35.1000 liquid manual brachytherapy using GliaSite, no liquid manual brachytherapy procedure has been performed since last inspection.

Performance Observations:

This inspection consisted of interviews with selected licensee's staff and management; tours of the nuclear medicine, radiation oncology department, and cancer care center. The inspector: (1) observed administration of technetium-99 diagnostic dose to a patient; (2) observed the NMT conduct a physical inventory of sealed sources and all sources were accounted for; (3) had the NMT demonstrated the dose calibrator constancy check, package receiving and check-in procedures, the end of the day daily and weekly area surveys, and proper handling of radioactive waste and disposal procedures.

The inspector had the AMP demonstrate the HDR unit's: (1) security of licensed material; (2) daily spot checks; (3)

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emergency equipment and procedures; (4) safety procedures and instructions; (5) door interlock system; (6) radiation monitoring equipment; and (7) ON-OFF switch to prevent dual operation in the treatment room.

The inspector reviewed selected written directives and treatment plans for manual brachytherapy and HDR unit treatments, with no issues noted. The inspector also reviewed I-131 therapies written directives, quarterly program audits conducted by an outside consultant, leak test results, radiation safety committee minutes, and training documents, with no issues noted.

The inspector reviewed dosimetry records for 2014 and 2015, indicating the maximum annual dose to be 743 mrem - DDE, and 2163 mrem - SDE, and performed independent radiation measurements of the hot lab, imaging, and stress room areas that were consistent with the licensee's survey results and within regulatory limits.

No violations of NRC requirements were identified during this inspection.