

## SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE	
Methodist Hospital of Gary, Inc. 8701 Broadway Merrillville, IN 46410	Region III U. S. Nuclear Regulatory Commission 2443 Warrendale Road, Suite 210 Lisle, IL 60532-4352	
REPORT NUMBER(S) 2019001		
3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-11234	13-16558-01	June 3-6 & 14, 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 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.

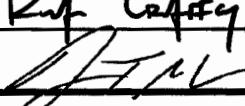
Non-cited violation(s) were discussed involving the following requirement(s):

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- 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	Ryan Craffey		6/14/19
BRANCH CHIEF	Aaron McCraw		06/18/2019

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2443 Warrendale Road, Suite 210  
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(Continued)

The inspector reviewed written directives as well as planning and verification documentation for a selection of GSR, HDR, and I-131 treatments performed since the last inspection. The inspector found that the licensee's procedures provided high confidence that such treatments were performed in accordance with these written directives. The inspector also reviewed a selection of other records, including RSC meeting minutes, consultant audits, HDR, GSR and nuclear medicine dose calibrator quality assurance documentation, personnel dosimetry reports, sealed source inventories and leak tests, and routine nuclear medicine survey records.

The licensee was previously cited in IR 03011234/2017001(DNMS) for failure to maintain a record of the basis for authorizing the release of patients in accordance with 10 CFR 35.75, as required by 10 CFR 35.2075(a). The inspector noted that of the dozen or so I-131 administrations the licensee performed since the previous inspection, none were of sufficient quantity (i.e., greater than 33 mCi per Table U.1 in NUREG-1556 Vol. 9, Rev. 2) to have required calculations of TEDE using any of the items specified by 35.2075(a)(1) through (4). The licensee's staff still appeared to be knowledgeable of licensee procedures as they related to I-131 patient release criteria; however, in the absence of any instances requiring such calculations, this violation remains open pending future evaluation.

No violations of NRC requirements were identified as a result of this inspection.

**Docket File Information**  
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6. INSPECTION PROCEDURES USED 87131, 87132, 87133	7. INSPECTION FOCUS AREAS All		
<b>SUPPLEMENTAL INSPECTION INFORMATION</b>			
1. PROGRAM CODE(S) 02230	2. PRIORITY 2	3. LICENSEE CONTACT Carmen Kmety-Stevenson, PhD - RSO	4. TELEPHONE NUMBER (219) 757-7363
<input checked="" type="checkbox"/> Main Office Inspection		Next Inspection Date: 06/03/2021	
<input checked="" type="checkbox"/> Field Office Inspection 200 E 86th Pl, Merrillville; 600 Grant St, Gary			
<input type="checkbox"/> Temporary Job Site Inspection _____			

**PROGRAM SCOPE**

This was an unannounced routine inspection of a regional medical center authorized to use byproduct material for diagnostic and therapeutic medical purposes at its campus in Merrillville, Indiana, and at satellite facilities in Merrillville and Gary. At the main hospital's nuclear medicine department, the licensee performed a dozen diagnostic administrations per day, half a dozen therapeutic administrations of I-131 capsules per year, and possessed two Cs-137 attenuation correction sources in storage pending disposal. At the main hospital's radiation oncology center, the licensee had performed 11 treatments with its Lexsell Perfexion GSR unit since installing and commissioning the unit in late 2018, performed one treatment per month using its Varian VariSource iX HDR unit, and possessed a Sr-90 eye applicator in storage pending disposal. The licensee had not performed any manual brachytherapy or GliaSite treatments since the last inspection. At the nuclear medicine department in Gary, the licensee performed up to a dozen diagnostic administrations per day, and around one therapeutic administration of I-131 capsules per year. At the clinic on 86th Place in Merrillville, the licensee performed 2-7 cardiac stress tests per day, two to three days per week. During the week of the inspection, the clinic performed these tests Monday through Wednesday, however this schedule does vary.

**PERFORMANCE OBSERVATIONS**

The inspector toured all three facilities to evaluate the licensee's measures for materials security, hazard communication, and exposure control. The inspector conducted independent and confirmatory radiation surveys, as well as quantitative airflow measurements of rooms where Xe-133 was being used for lung ventilation studies. The inspector observed multiple diagnostic administrations, including cardiac stress tests using Tc-99m at all three facilities, lung ventilation studies using Xe-133 at both hospitals, and a lumbar cisternogram using In-111 at the main hospital. The staff also provided demonstrations of package receipt, waste handling, and area surveys including spill response. At the radiation oncology center, the inspector observed one GSR treatment for brain cancer and one fraction of an HDR treatment for gynecological cancer, including spot checks and treatment planning for both. The inspector also interviewed members of the licensee's staff and management to discuss procedures for the safe use of license material and oversight of the radiation safety program.

[continued on Part 2]