

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: St. Mary Medical Center - Hobart 1500 S. Lake Park Ave. Hobart, IN 46342 REPORT NUMBER(S) 202101	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) 030-31379	4. LICENSE NUMBER(S) 13-03459-03	5. DATE(S) OF INSPECTION August 18, 2021
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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	Luis Nieves Folch	Luis A. Nieves Folch <small>Digitally signed by Luis A. Nieves Folch Date: 2021.08.26 14:56:51 -05'00'</small>	
BRANCH CHIEF	Michael Kunowski	Michael A. Kunowski <small>Digitally signed by Michael A. Kunowski Date: 2021.08.27 06:43:56 -05'00'</small>	

From: [Nieves Folch, Luis](#)
To: ["Skkar@comhs.org"](mailto:Skkar@comhs.org)
Subject: St Mary Medical Center Hobart 591 report
Date: Friday, August 27, 2021 8:58:00 AM
Attachments: [St Marys 591M\(2\)mk.pdf](#)

Dear Mr. Kar

Attach is the clear 591 report for the inspection conducted on August 18, 2021. At this point there is no further actions on your part.

In accordance with Title 10 of the Code of Federal Regulations 2.390 of the NRC's "Rules of Practice," a copy of this message will be available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at <http://www.nrc.gov/reading-rm/adams.html>. Please feel free to contact me if you have any questions regarding this correspondence.

Thank you,

Luis Nieves
Health Physicist
U.S. Nuclear Regulatory Commission
Division of Nuclear Materials Safety
Office: (630) 829-9571
Fax: (630) 515-1259



Materials Inspection Record

1. Licensee Name: St. Mary Medical Center - Hobart		2. Docket Number(s): 030-31379		3. License Number(s) 13-03459-03	
4. Report Number(s): 2021001			5. Date(s) of Inspection: August 18, 2021		
6. Inspector(s): Luis Nieves		7. Program Code(s): 02240	8. Priority: 2	9. Inspection Guidance Used: 87132	
10. Licensee Contact Name(s): Santosh Kar, M.S., RSO		11. Licensee E-mail Address: skkar@comhs.org		12. Licensee Telephone Number(s): 219-836-1600 ext. 31725	
13. Inspection Type: <input type="checkbox"/> Initial		14. Locations Inspected:		15. Next Inspection Date (MM/DD/YYYY):	
<input checked="" type="checkbox"/> Routine <input checked="" type="checkbox"/> Announced		<input checked="" type="checkbox"/> Main Office <input checked="" type="checkbox"/> Field Office		August 18, 2023 <input checked="" type="checkbox"/> Normal <input type="checkbox"/> Extended	
<input type="checkbox"/> Non-Routine <input type="checkbox"/> Unannounced		<input type="checkbox"/> Temporary Job Site <input type="checkbox"/> Remote			

16. Scope and Observations:

This was an announced, routine inspection of a hospital authorized by its NRC license to use unsealed byproduct material for diagnostic and therapeutic procedures under 10 CFR 35.100, 200, 300, and 1000(Y-90). At the time of the inspection, the licensee performed a comprehensive spectrum of diagnostic procedures. The nuclear medicine department was staffed with five full-time and two part-time nuclear medicine technologists (NMTs) who performed approximately 12 diagnostic nuclear medicine procedures daily including their PET location on 61st Ave. which is walking distance from the main hospital. The licensee has one hot lab at their main hospital that works from Mondays to Fridays. The licensee performed thirteen I-131(all under 30 mCi), and three Y-90 treatments in the last year. The licensee retains a consultant health physicist to perform quarterly audits of the radiation safety program and calibrations.

Their PET location on 61st Ave. also works Mondays to Fridays. Their Valparaiso location works Monday, Tuesdays, Thursdays, and Fridays and performs a comprehensive spectrum of diagnostic procedures. Their Portage location only does heart test and is open Mondays to Fridays.

PERFORMANCE OBSERVATIONS

The inspector conducted a tour of the nuclear medicine hot labs at the main hospital and their PET location and discussed with the NMT package receipt, surveys, and instrument quality control checks. The inspector observed the preparation and administration of one heart rest test. The NMTs demonstrated adequate knowledge of radiation safety principles and practices through interviews. The inspector reviewed audit reports, instrument quality control, safety committee minutes, written directives, inventory, dose calibrator linearity and accuracy, leak tests, and training. The inspector also reviewed monthly dosimetry reports which indicated annual whole-body and extremity doses were below regulatory limits.

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