



Materials Inspection Report

1. Licensee/Location Inspected:

St. Catherine Hospital, Inc.
4321 Fir St.
East Chicago, IN 46312

Report Number(s) 2022001

2. NRC/Regional Office

Region IV
U. S. Nuclear Regulatory Commission
1600 E. Lamar Boulevard
Arlington, TX 76011-4511

3. Docket Number(s)

030-01590

4. License Number(s)

13-01148-01

5. Date(s) of Inspection

10/20/2022 - 11/10/2022

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. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements, and were assessed at Severity Level IV, in accordance with the NRC Enforcement Policy.

A. 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, corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy were satisfied.

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

B. The following violation(s) is/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 AND DATE
LICENSEE'S REPRESENTATIVE	Roberto Gonzales	
NRC INSPECTOR	Elizabeth Tindle-Engelmann	Elizabeth D. Tindle-Engelmann <small>Digitally signed by Elizabeth D. Tindle-Engelmann Date: 2022.11.20 07:16:23 -06'00'</small>
BRANCH CHIEF	Rhex Edwards	 <small>Digitally signed by Rhex A. Edwards Date: 2022.11.23 12:22:27 -06'00'</small>



Materials Inspection Record


1. Licensee Name: St. Catherine Hospital, Inc.		2. Docket Number(s): 030-01590		3. License Number(s) 13-01148-01	
4. Report Number(s): 2022001			5. Date(s) of Inspection: 10/20/2022 - 11/10/2022		
6. Inspector(s): Elizabeth Tindle-Engelmann		7. Program Code(s): 02240		8. Priority: 2	9. Inspection Guidance Used: 87130
10. Licensee Contact Name(s): Roberto Gonzales		11. Licensee E-mail Address: roberto.e.gonzalez@comhs.org		12. Licensee Telephone Number(s): (219) 392-1700	
13. Inspection Type: <input checked="" type="checkbox"/> Routine <input type="checkbox"/> Non-Routine <input type="checkbox"/> Initial <input type="checkbox"/> Unannounced		14. Locations Inspected: <input checked="" type="checkbox"/> Main Office <input type="checkbox"/> Temporary Job Site <input type="checkbox"/> Hybrid <input type="checkbox"/> Field Office <input type="checkbox"/> Remote		15. Next Inspection Date (MM/DD/YYYY): 10/20/2024 <input checked="" type="checkbox"/> Normal <input type="checkbox"/> Extended <input type="checkbox"/> Reduced <input type="checkbox"/> No change	
16. Location(s) Inspected List: 4321 Fir St., East Chicago, IN 46312					
17. Scope and Observations: <p>This was an announced routine inspection. The licensee was a medical facility located in East Chicago, IN, with authorization for diagnostic and therapeutic uses of byproduct material pursuant to 10 CFR 35.100-300 and yttrium-90 microspheres pursuant to 10 CFR 35.1000. The licensee's radiation safety officer (RSO) was employed by the hospital system (Community HealthCare System) and was onsite frequently and available by phone as needed. The licensee used an external consultant to perform program reviews and equipment calibrations. The licensee maintained a radiation safety committee that met quarterly. The nuclear medicine department was staffed with two full-time and one part-time nuclear medicine technologists. The licensee's nuclear medicine staff administered approximately 10 SPECT doses per day, 1 dose of unsealed byproduct material requiring a written directive per year, and 5 microsphere doses per year. The department received unit doses of primarily technetium-99m from a licensed radiopharmacy; other radionuclides were used less frequently.</p> <p>The inspector observed ambient radiation level surveys, dose calibrator quality control, dose preparation and administration, and a sealed source inventory. The licensee's staff demonstrated decay in storage procedures and package receipt surveys. The licensee's staff described a microsphere dose preparation. Interviews with licensee personnel indicated adequate knowledge of radiation safety and security concepts and procedures. The inspector reviewed the following records: area surveys, dose calibrator calibrations, dosimetry, package receipt, package return, program reviews, radiation safety committee meeting minutes, sealed source leak tests and inventories, select policies and procedures, spill reports, training, waste logs, and written directives.</p> <p>The inspector's survey instrument malfunctioned during the inspection. In lieu of independent and confirmatory radiation measurements, the inspector observed the licensee perform radiation measurements and reviewed the calibration of the instrument used by the licensee. During the survey, the licensee identified a small amount of contamination in an injection area. It was determined that the contamination was isolated. The inspector observed the licensee clean the area and reduce the levels to background. Response to the contamination was consistent with the licensee's procedures and survey results were consistent postings.</p>					

Materials Inspection Record (Continued)

No violations were identified as a result of this inspection.

Signature and Date - Branch Chief



 Digitally signed by Rhex A. Edwards
Date: 2022.11.23 12:21:58 -06'00'