



Materials Inspection Report

1. Licensee/Location Inspected: Ascension Genesys Hospital One Genesys Parkway Grand Blanc, MI 48439 Report Number(s) 2023-001	2. NRC/Regional Office Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352	
3. Docket Number(s) 030-34188	4. License Number(s) 21-26740-01	5. Date(s) of Inspection June 1, 2023

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		
NRC INSPECTOR	Ryan Craffey	<i>R. Craffey</i> <small>Digitally signed by Ryan J. Craffey Date: 2023.06.09 17:25:47 -04'00'</small>
BRANCH CHIEF	Geoffrey Warren, Acting	Geoffrey M. Warren <small>Digitally signed by Geoffrey M. Warren Date: 2023.06.12 15:19:20 -05'00'</small>



Materials Inspection Record

1. Licensee Name: Ascension Genesys Hospital		2. Docket Number(s): 030-34188		3. License Number(s) 21-26740-01	
4. Report Number(s): 2023-001			5. Date(s) of Inspection: June 1, 2023		
6. Inspector(s): Ryan Craffey		7. Program Code(s): 02240	8. Priority: 2	9. Inspection Guidance Used: IP 87130, 87132	
10. Licensee Contact Name(s): Laura Luna, Consultant		11. Licensee E-mail Address: lluna@mpcphysics.com		12. Licensee Telephone Number(s): 734-662-3197	

13. Inspection Type: <input checked="" type="checkbox"/> Routine <input type="checkbox"/> Announced <input type="checkbox"/> Non-Routine <input checked="" type="checkbox"/> Unannounced		14. Locations Inspected: <input checked="" type="checkbox"/> Main Office <input type="checkbox"/> Field Office <input type="checkbox"/> Temporary Job Site <input type="checkbox"/> Remote		15. Next Inspection Date (MM/DD/YYYY): 06/01/2025		<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Extended <input type="checkbox"/> Reduced <input type="checkbox"/> No change	
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16. Location(s) Inspected List:
One Genesys Parkway, Grand Blanc, MI

17. Scope and Observations:
Ascension Genesys Hospital is a 309-bed community hospital and level III trauma center in Grand Blanc, Michigan, authorized for diagnostic and therapeutic administrations of radiopharmaceuticals and for therapeutic administration of Y-90 microspheres. At the time of the inspection, two full time nuclear medicine technologists performed 150-200 diagnostic administrations per month at one of two hot labs (general and cardiology) using unit doses from a radiopharmacy in the Flint area, as well as occasional therapeutic administrations of I-131. The licensee has also performed three Y-90 microspheres administrations since receiving authorization to do so in February 2023. The licensee maintained an RSC, which met quarterly, and retained the services of a consultant to audit the radiation protection program. A mobile imaging service provider (Alliance HealthCare Services, docket no. 030-35774) performed PET scans on-site every Wednesday and Friday.

The inspector toured the hospital in Grand Blanc. All areas were properly posted and all licensed material was adequately secured. The inspector performed independent and confirmatory radiation surveys in and around restricted areas and found no evidence of residual contamination or exposures in unrestricted areas in excess of limits to members of the public. The inspector observed the administration of Tc-99m doses for cardiac stress tests, as well as demonstrations of instrument checks, receipt of packages containing licensed material, and decay-in-storage waste handling including microsphere waste. The inspector found that staff were knowledgeable of radiation protection principles, wore personnel dosimetry as assigned, and used calibrated and operable radiation detection instruments and adequate ALARA measures.

The inspector reviewed the licensee's procedures for microsphere administrations, as well as written directives and treatment documentation of all three administrations performed to date. The procedures provided high confidence that each treatment had been performed in accordance with the written directive. Moreover, each treatment had been performed in accordance with the manufacturer's instructions with a representative present for guidance. The inspector also discussed with staff and management the licensee's commitments per NRC's microsphere licensing guidance, notably those regarding medical event reporting.

Materials Inspection Record (Continued)

The inspector also reviewed written directives and release evaluations for I-131 therapies since the last routine inspection, as well as RSC meeting minutes, consultant audits, personnel dosimetry reports, a selection of routine survey records, instrument quality control records, and sealed source return documentation.

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

Signature and Date - Branch Chief

Geoffrey M. Warren



Digitally signed by Geoffrey M. Warren

Date: 2023.06.12 15:18:37 -05'00'