



Materials Inspection Report

1. Licensee/Location Inspected: Warsaw Health System, LLC d/b/a Lutheran Kosciusko Hospital 2101 E Dubois Dr. Warsaw, IN 46580-3288 Report Number(s) 2023001	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) 030-34848	4. License Number(s) 13-32129-01	5. Date(s) of Inspection 10/26/2023
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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. 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	Luis Nieves	Luis A. Nieves Folch <small>Digitally signed by Luis A. Nieves Folch Date: 2023.11.02 14:19:56 -05'00'</small>
BRANCH CHIEF	Rhex Edwards	 <small>Digitally signed by Rhex A. Edwards Date: 2023.11.16 06:52:45 -06'00'</small>



Materials Inspection Record

1. Licensee Name: Warsaw Health System, LLC		2. Docket Number(s): 030-34848		3. License Number(s) 13-32129-01	
4. Report Number(s): 2023001			5. Date(s) of Inspection: 10/26/2023		
6. Inspector(s): Luis Nieves Folch		7. Program Code(s): 02121	8. Priority: 5	9. Inspection Guidance Used: 87130	
10. Licensee Contact Name(s): Elizabeth Wise, CNMT		11. Licensee E-mail Address: estump@kch.com		12. Licensee Telephone Number(s): 574-371-1230	

13. Inspection Type: <input type="checkbox"/> Initial		14. Locations Inspected: <input type="checkbox"/> Hybrid		15. Next Inspection Date (MM/DD/YYYY):	
<input checked="" type="checkbox"/> Routine	<input type="checkbox"/> Announced	<input checked="" type="checkbox"/> Main Office	<input type="checkbox"/> Field Office	10/26/2028	
<input type="checkbox"/> Non-Routine	<input checked="" type="checkbox"/> Unannounced	<input type="checkbox"/> Temporary Job Site	<input type="checkbox"/> Remote	<input checked="" type="checkbox"/> Normal	<input type="checkbox"/> Extended
				<input type="checkbox"/> Reduced	<input type="checkbox"/> No change

16. Location(s) Inspected List:
2101 E. Dubois Dr. Warsaw, IN 46580-3288

17. Scope and Observations:

This was an unannounced, routine inspection of a hospital authorized by its NRC license to use unsealed byproduct material for diagnostic procedures under 10 CFR 35.100, and 35.200. The nuclear medicine department was staffed with three full-time nuclear medicine technologists (NMTs) who performed approximately three cardiac stress tests and four PET's per day on Mondays, Wednesdays, and Fridays. The licensee utilized an Intego PET infusion system. The licensee retained a medical consultant to perform calibrations, trainings, and quarterly audits.

The inspectors toured the nuclear medicine department and discussed with the NMT package receipt, surveys, and instrument quality control checks. The inspectors observed the preparation and administration of a heart stress study. Through interviews, the NMT demonstrated adequate knowledge of radiation safety principles and practices. The inspectors performed independent surveys of the hot lab and other areas of the nuclear medicine department and found no contamination or exposure to members of the public distinguishable from the background. The inspector reviewed quarterly audit reports, instrument quality control, inventory, dose calibrator linearity and accuracy, and training. The inspector also reviewed monthly dosimetry reports, which indicated annual whole-body and extremity doses were below regulatory limits.

During the last inspection, a violation was identified for failure to secure material from unauthorized removal or access regarding their Intego machine. The inspector asked the NMT to demonstrate how they keep the bulk dose inside the Intego machine secure and also the inspector observed the licensee added a padlock that prevents access to the bulk dose inside the machine. This violation is closed.

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

Signature and Date - Branch Chief



Digitally signed by Rhex A. Edwards
Date: 2023.11.16 06:52:03 -06'00'

From: [Luis Nieves Folch](#)
To: estump@kch.com
Subject: NRC 591 Warsaw Health System, LLC
Date: Monday, November 20, 2023 9:33:00 AM
Attachments: [591M- Warsaw Health sign_RAE.pdf](#)

Dear Elizabeth

Attach is the clear 591 report for the inspection conducted on 10/26/2023. 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
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