



Materials Inspection Record

1. Licensee Name: Northwest Health - La Porte		2. Docket Number(s): 030-08653		3. License Number(s) 13-15151-01	
4. Report Number(s): 2021-001			5. Date(s) of Inspection: April 23, 2021 / exit meeting on April 27		
6. Inspector(s): Ryan Craffey		7. Program Code(s): 02240		8. Priority: 2	9. Inspection Guidance Used: IP 87131, 87132
10. Licensee Contact Name(s): Jim Hatten - RSO		11. Licensee E-mail Address: jhatten@sahci.com		12. Licensee Telephone Number(s): 815-370-6538	
13. Inspection Type: <input checked="" type="checkbox"/> Routine <input type="checkbox"/> Announced <input type="checkbox"/> Non-Routine <input type="checkbox"/> Unannounced		14. Locations Inspected: <input checked="" type="checkbox"/> Main Office <input type="checkbox"/> Field Office <input type="checkbox"/> Temporary Job Site <input checked="" type="checkbox"/> Remote		15. Next Inspection Date (MM/DD/YYYY): 04/20/2023 <input checked="" type="checkbox"/> Normal <input type="checkbox"/> Extended <input type="checkbox"/> Reduced <input type="checkbox"/> No change	

16. Scope and Observations:

This was a routine inspection of an 84-bed community hospital in La Porte, Indiana, authorized to use byproduct material for diagnostic and therapeutic medical purposes. Since the last inspection, the licensee built and occupied a new hospital on State Street as a replacement for the previous one on Lincolnway. The licensee performed 5-6 diagnostic administrations of radiopharmaceuticals per day, as well as occasional therapeutic administrations of I-131 and Y-90 microspheres. The licensee retained the services of a health physics consultant to fulfill the duties of RSO and perform quarterly audits, and maintained an RSC which met twice a year. In accordance with current agency policy during the Covid-19 PHE, this inspection was announced and conducted remotely by means of video teleconferencing. Relevant records were reviewed via secure file sharing.

Using the video teleconference platform, the licensee's staff provided tours of the nuclear medicine department and interventional radiology suite at the new hospital in La Porte. All areas were properly posted, and all licensed material was adequately secured. Moreover, the facility matched the description provided in the licensee's correspondence, dated June 22, 2020, requesting to add it as an authorized location of use on their license. The inspector observed the preparation of diagnostic radiopharmaceuticals, as well as demonstrations of package receipt, instrument quality control checks, area surveys, and waste handling. Radiation instrumentation was calibrated and operable, and staff utilized appropriate dosimetry and ALARA practices. The inspector also reviewed the conduct of Y-90 microsphere administrations with the AU and nuclear medicine staff, as well as the status and oversight of the program with the RSO and management. All staff were knowledgeable of radiation protection principles, licensee procedures, and regulatory requirements. The inspector also reviewed a selection of licensee records using a secure file sharing platform, including RSC meeting minutes, personnel dosimetry reports, consultant audits, routine nuclear medicine records, written directives and patient release documentation for I-131 cases, and written directives and treatment planning and verification documentation for Y-90 microsphere cases.

During the review of I-131 cases, the inspector noted that a written directive for 150 mCi of I-131 was signed by an individual who was not an authorized user for this quantity of I-131, contrary to 10 CFR 35.40(a). The individual, who was approved to use up to 33 mCi of I-131, was being proctored by an AU approved for all material under 35.300. This AU was present for the administration, but forgot to sign the written directive. The root cause of the violation was an oversight. As corrective action, the licensee had the 35.300 AU review the case again; he identified no concerns and signed the written directive post-administration. The licensee also committed to to revise their procedures to require a second check of I-131 paperwork and to require that the authorized user's name be printed next to their signature. The licensee also stated that it would submit an amendment request seeking approval for the individual in question to use I-131 in quantities greater than 33 mCi.