NRC FORM 592M
(10-2020)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Record

1. Licensee Name:	2. Docket Number(s):	3. License Number(s)
NorthStar Medical Technologies, LLC	150-00048	WI-025-2038-02

4. Report Number(s):	5. Date(s) of Inspection:
2022-001	January 24, 2022; exit on January 31, 2022

6. Inspector(s):	7. Program Code(s):	8. Priority:	9. Inspection Guidance Used:
Ryan Craffey	03226	2	IP 87126

10. Licensee Contact Name(s):	11. Licensee E-mail Address:	12. Licensee Telephone Number(s):
Richard Granberg - RSO	rgrandberg@northstarnm.com	269-998-2712

13. Inspection Type:	14. Locations Inspected:	15. Next Inspection Date (MM/DD/YYYY):
☐ Initial ☐ Routine ☑ Announced ☑ Non-Routine ☐ Unannounced	☐ Main Office ☐ Field Office ☑ Temporary Job Site ☐ Remote	TBD ☐ Normal ☐ Extended ☐ Reduced ☑ No change

16. Scope and Observations:

NorthStar Medical Technologies was authorized by the State of Wisconsin to perform a variety of licensed activities incident to the manufacture of radiochemicals with the RadioGenix system at its facility in Beloit, Wisconsin, and to perform service activities at temporary job sites in State jurisdiction. The company performed service activities at temporary job sites in NRC jurisdiction under the terms of a reciprocity request filed in December 2021 for calendar year 2022. The scope of this inspection was limited to an evaluation of service activities (investigating a report of elevated dose rates and restoring a RadioGenix system to normal operations) at the Purdue University's College of Pharmacy in West Lafayette, Indiana.

The inspector accompanied the licensee's service personnel to the University and observe troubleshooting and restoration activities. The personnel were knowledgeable of the RadioGenix system and associated radiation hazards, wore adequate dosimetry and PPE and used calibrated and operable survey instruments throughout. The personnel confirmed that elevated dose rates measured by a pharmacy student the week prior were due to the student leaving a cap on the needle used to fill the product vial. Rather than piercing the vial's septum, the capped needle forced the entire septum into the vial, plugging it and forcing the 700-800 mCi of Tc-99m expected in 5 mL of product solution into the space between the vial and its tungsten shield. A small amount of dried product was also found on the plastic tray on which the shield stood upon disassembly by service personnel.

After determining this spilled product to be the cause of the elevated dose rates and restoring the system to normal operation, the inspector interviewed the service personnel to discuss the scope of their work, extremity monitoring results (the inspector reviewed a selection of them in-office following the visit), as well as other instances of this and other abnormal conditions caused by user error (such as attempting to remove product early) and the licensee's ongoing initiatives to address the potential for their recurrence.

No violations of NRC requirements were identified as a result of this inspection. The inspector held an exit meeting with the licensee's RSO by telephone on January 31, 2022.