UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2056 WESTINGS AVENUE, SUITE 400
NAPERVILLE, IL 60563-2657

July 17, 2025

EN 56705
NMED No. 230362 (Closed)

Wallace O. Fuhrman, CNMT
Radiation Safety Officer
SSM Health St. Clare Hospital-Fenton
1015 Bowles Ave.
Fenton, MO 63026

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03002368/2023001(DRSS) AND ROUTINE INSPECTION REPORT NO. 03002368/2024001(DRSS)
SSM HEALTH ST. CLARE HOSPITAL-FENTON

Dear Wallace O. Fuhrman:

This letter refers to the inspections conducted on November 1, 2023, and on October 24, 2024, at your facility in Fenton, Missouri, with continued in-office review through June 23, 2025. The purpose of the first inspection (2023001) was to review the activities surrounding two missing iodine-125 (I-125) seeds identified on August 4, 2023. The second inspection (2024001) was a routine inspection of licensed activities. The purpose of both inspections was to review activities performed under your NRC license to ensure that these activities were being performed in accordance with NRC requirements. The purpose of the in-office review was to evaluate whether the seeds were delivered to your facility. This letter presents the results of the inspection. Geoffrey Warren of my staff conducted a final exit meeting by telephone with you on July 2, 2025, to discuss the inspection findings.

This inspection examined activities conducted under your license as they relate to public health and safety, and to confirm compliance with the Commission's rules and regulations, and with the conditions of your license. Within these areas, the inspection consisted of selected examinations of procedures and representative records, observations of activities, and interviews with personnel. Based on the results of this inspection, the NRC has determined that no violations of NRC requirements occurred.

In accordance with the NRC's "Agency Rules of Practice and Procedure" in 10 CFR 2.390, a copy of this letter, its enclosure, and any response you provide will be made 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. To the extent possible, any response should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction.

Please feel free to contact Geoffrey Warren of my staff if you have any questions regarding this inspection. Geoffrey can be reached at 630-829-9742 or Geoffrey.Warren@nrc.gov.

Sincerely,

Signed by Edwards, Rhex
on 07/17/25

Rhex A. Edwards, Chief
Materials Inspection Branch
Division of Radiological Safety and Security

Docket No. 030-02368
License No. 24-11858-01

Enclosure:
Inspection Report No. 03002368/2023001
03002368/2024001

cc (w/encl):
C. Gifford, Director of Imaging
L. Lehman, Missouri State Liaison Officer

Letter to W. Fuhrman from R. Edwards, dated July 15, 2025.

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03002368/2023001(DRSS) AND ROUTINE INSPECTION REPORT NO. 03002368/2024001(DRSS) SSM HEALTH ST. CLARE HOSPITAL-FENTON

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ADAMS Accession Number: ML25196A131

OFFICE:	RIII-DRSS		RIII-DRSS					
NAME:	GWarren:dc		REdwards					
DATE:	07/15/2025		07/15/2025					

OFFICIAL RECORD COPY

U.S. Nuclear Regulatory Commission
Region III

Docket No.	030-02368
License No.	24-11858-01
Report No.	03002368/2023001(DRSS) 03002368/2024001(DRSS)
NMED No.	230362 (Closed)
Licensee:	SSM Health St. Clare Hospital-Fenton
Facility:	1015 Bowles Ave. Fenton, Missouri
Inspection Dates:	November 1, 2023 - June 23, 2025
Exit Meeting Date:	July 2, 2025
Inspector:	Geoffrey Warren, Sr. Health Physicist
Approved By:	Rhex A. Edwards, Chief Materials Inspection Branch Division of Radiological Safety and Security

Enclosure

EXECUTIVE SUMMARY

SSM Health St. Clare Hospital-Fenton
NRC Inspection Report 03002368/2023001(DRSS) and 03002368/2024001(DRSS)

Inspection Report No. 03002368/2023001(DRSS) was a reactive inspection, performed to review the events surrounding the licensee's report of two missing iodine-125 (I-125) seeds totaling 0.504 mCi on August 4, 2023. After performing a prostate implant procedure, licensee staff identified that two seeds were missing from a needle that had not been removed from a sealed pouch until after the procedure was completed. Surveys showed no evidence of the seeds. The licensee reported the missing seeds and provided the written report within the time frames specified in Title 10 of the *Code of Federal Regulations* (CFR) 20.2201. Based on the information provided during the inspection from the licensee and from the distributor of the seeds, the inspector concurred with the licensee's determination that the seeds had not been included in the shipment by error. As such, the inspector identified no violations concerning the missing seeds.

Inspection Report No. 03002368/2024001(DRSS) was a routine inspection performed in October 2024. The inspector reviewed licensed activities and found no violations of NRC requirements.

REPORT DETAILS

1 Program Overview and Inspection History

SSM Health St. Clare Hospital-Fenton was authorized under NRC Materials License No. 24-11858-01 to use licensed material for medical diagnostic and therapeutic procedures at a 180-bed hospital located in Fenton, Missouri. In particular, the license provided diagnostic and therapeutic nuclear medicine procedures using a variety of isotopes and permanent implant brachytherapy procedures using iodine-125 (I-125) seeds.

2 Loss of I-125 Seeds – IR 03002368/2023001(DRSS)

2.1 Inspection Scope

From November 1, 2023, through June 23, 2025, the inspector interviewed licensee staff and manufacturer/distributor staff and reviewed relevant procedures and records concerning the loss of two I-125 seeds.

2.2 Observations and Findings

On August 4, 2023, the licensee performed a permanent prostate implant procedure using I-125 seeds to treat prostate cancer in a patient. The licensee had ordered 28 needles with seeds for the planned procedure as well as 7 extra needles in case the authorized user wanted to use them in the procedure. These 35 needles were placed into 3 sealed pouches by the distributor before mailing. During the implant procedure, the authorized user placed the 28 planned needles and decided not to use any of the extra needles.

Following the procedure, the physicist returned to the hot lab to extract the seeds from the extra needles into a lead pig in order to return them to the manufacturer. The first 6 needles were emptied into the lead pig without issue, but the final needle only had 1 seed instead of the expected 3. The final needle had been ordered with 3 seeds, and the radiograph of the seeds taken by the distributor showed 3 seeds. Licensee staff had not opened the pouch that contained the final needle until it had been returned to the hot lab. The pouch and package were surveyed showing no additional seeds. Because the pouch had been sealed until this point, licensee staff determined that it could not have fallen out any time earlier, but additional surveys were performed of the operating room and other areas to be certain. Based on the surveys and observations, the licensee determined that 2 seeds, totaling 0.504 mCi I-125, were missing. The Licensee's staff also contacted the distributor for further assistance in following up on the missing seeds.

During further review, the licensee identified that the number hand printed on the last needle did not visually match the image of the needles provided by the distributor. As such, the licensee determined that most likely the needle was switched out prior to the shipment and was thus likely never received by the licensee.

Title 10 of the *Code of Federal Regulations* (CFR) 20.2201(a)(1)(ii) requires, in part, that the licensee report missing material by telephone to the NRC no later than 30 days after the occurrence of this quantity of material being or missing becomes known to the licensee. The licensee reported the missing material to the NRC Operations Center on September 1, 2023, within 30 days of identifying the missing material on August 4. Title 10 CFR 20.2201(b) requires, in part, that the licensee provide to the NRC a written report within 30 days after making the telephone report; the licensee provided this written report on September 19, 2023. The report contains all required information.

Further communications between the inspector and the distributor suggested that sometimes needles are switched out prior to shipment. Based on this and other factors, the distributor could not definitively state that the material had been shipped properly. As such, the inspector concurred with the licensee's determination that the material was not received.

Following this procedure, the licensee revised their procedures such that all extra seeds would be ordered in needles to be provided in a separate pouch from the seeds and needles included in the treatment plan. In addition, the licensee stated that if these extra needles were not used, this pouch would be returned to the distributor without opening.

2.3 Conclusions

The inspector reviewed the events surrounding the identification of missing seeds, including follow-up and communications with the NRC and had no findings in these areas.

3 Routine Inspection – IR 03002368/2024001(DRSS)

3.1 Inspection Scope

On October 24, 2024, the inspector observed licensed activities, interviewed staff, and reviewed relevant procedures and records concerning licensed activities performed at SSM Health St. Clare Hospital-Fenton. The inspector observed two diagnostic administrations of licensed material and demonstrations of a variety of activities.

3.2 Observations and Findings

The licensee was a 180-bed hospital in Fenton, Missouri, with authorization to perform diagnostic and therapeutic nuclear medicine procedures as well as brachytherapy procedures.

The nuclear medicine department was staffed with 2 full-time nuclear medicine technologists who administered around 300 diagnostic procedures monthly, including a wide variety of imaging procedures. Diagnostic doses were received as unit doses or occasionally prepared from bulk technetium received from a licensed radiopharmacy. In addition, the nuclear medicine staff performed around 5 to 10 iodine-131 therapeutic procedures annually. All waste was either held for decay-in-storage (DIS) or returned to the radiopharmacy.

The radiation oncology department was staffed with 2 authorized users and 1 medical physicist involved with prostate seed implants; around 10-12 procedures were performed annually using I-125 seeds.

The inspector reviewed written directives for radiopharmaceutical therapies and prostate implant procedures and identified no concerns. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. A review of radiation dosimetry records indicated no exposures of concern. The review of the Radiation Safety Committee minutes indicated good attendance and discussion of appropriate topics. The inspector performed independent and confirmatory radiation measurements with results that were consistent with licensee survey records and postings.

3.3 Conclusions

The inspector performed a routine inspection of licensed operations at this location and identified no violations of NRC requirements.

4 Exit Meeting Summary

The NRC inspector presented preliminary inspection findings following each onsite inspection on November 1, 2023, and on October 24, 2024, as well as a final exit meeting by telephone on July 2, 2025. The licensee did not identify any documents or processes reviewed by the inspector as proprietary. The licensee acknowledged the findings presented.

PARTIAL LIST OF PERSONNEL CONTACTED

Cricket Gifford, Director of Imaging
John Kostelac, Medical Physicist
Wallace Fuhrman, CNMT, RSO

Attended exit meeting on July 2, 2025.

INSPECTION PROCEDURES USED

IP 87103 – Inspection of Materials Licensees Involved in an Incident or Bankruptcy Filing
IP 87130 – Nuclear Medicine Procedures
IP 87132 – Brachytherapy Programs