UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

January 13, 2021

EN 54969
NMED 200440 (closed)

Evan J. Boote, Ph.D.
Radiation Safety Officer
Spectrum Health Hospitals
100 Michigan St. NE
Grand Rapids, MI 49503

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03001989/2020001(DNMS)
SPECTRUM HEALTH HOSPITALS

Dear Dr. Boote:

On November 2, 2020 through December 3, 2020, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a remote reactive inspection and in-office review of activities at Butterworth Hospital in Grand Rapids, Michigan. The purpose of the inspection was to review the events surrounding a report of a potential medical event that you provided to the NRC's Operations Center on October 28, 2020. The potential medical event concerned an iodine-125 seed that had been placed for localization of a lymph node in July 2019 and potentially not removed as scheduled the same day. You contacted the Operations Center again on December 2, 2020, to retract the initial report after determining that the seed had been removed as planned and no medical event occurred. The in-office review included a review of your original and revised written reports and additional documents that you provided to the inspector concerning the potential medical event. The enclosed inspection report presents the results of the NRC inspection.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff examined your compliance with the Commission's rules and regulations as well as the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, and interviews with personnel.

Based on the results of this inspection, no violations were identified concerning the potential medical event. Mr. Geoffrey Warren of my staff discussed these findings with you at the inspection exit meeting on December 16, 2020.

You are not required to respond to this letter or the enclosed report unless you disagree with the information or positions described therein. In this case, or if you choose to respond, clearly mark your response as a "Reply to IR 03001989/2020001(DNMS)" and send it to the NRC's Document Control Desk, Washington, DC 20555-0001, with a copy mailed to the NRC Region III Office, 2443 Warrenville Road, Suite 210, Lisle, Illinois 60532, within 30 days of the date of this letter.

In accordance with Title 10 of the *Code of Federal Regulations* 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, if you choose to provide one, 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 Mr. Warren of my staff if you have any questions regarding this inspection. Mr. Warren can be reached at 630-829-9742.

Sincerely,

David L. Pelton

Digitally signed by David L. Pelton
Date: 2021.01.13 11:53:04 -06'00'

David L. Pelton, Director
Division of Nuclear Materials Safety

Docket No. 030-01989
License No. 21-00243-06

Enclosure:
IR No. 03001989/2020001(DNMS)

cc w/encl: State of Michigan

Letter to Evan Boote from David Pelton, dated January 13, 2021.

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03001989/2020001(DNMS)
SPECTRUM HEALTH HOSPITALS

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U.S. Nuclear Regulatory Commission
Region III

Docket No.	030-01989
License No.	21-00243-06
Report No.	03001989/2020001(DNMS)
EN / NMED No.	54969 / 200440
Licensee:	Spectrum Health Hospitals
Facility:	100 Michigan St. NE Grand Rapids, Michigan
Inspection Dates:	November 2, 2020–December 3, 2020
Exit Meeting Date:	December 16, 2020
Inspector:	Geoffrey Warren, Sr. Health Physicist
Approved By:	Michael Kunowski, Chief Materials Inspection Branch Division of Nuclear Materials Safety

Enclosure

EXECUTIVE SUMMARY

Spectrum Health Hospitals
NRC Inspection Report 03001989/2020001(DNMS)

This was a reactive inspection performed to review the events surrounding the report from Spectrum Health Hospitals (licensee) on October 28, 2020, of a potential medical event. The licensee reported that two iodine-125 seeds had been implanted in a patient on July 5, 2019, for localization of non-palpable lesions and lymph nodes; the seeds were intended to be surgically removed the same day. A routine mammography image taken on October 26, 2020, and a clarifying image taken two days later suggested that one of the two seeds, placed in a lymph node in the patient's left axilla, was not removed as they had believed.

A fifteen-month exposure to the seed would result in a radiation exposure at one centimeter from the seed of 6.72 sievert (672 rem) compared to 0.013 sievert (1.3 rem) for the intended four-hour administration. As such, this would qualify as a medical event under Title 10 of the *Code of Federal Regulations* (CFR) 35.3045(a)(1)(iii).

The licensee's review determined that it was most likely that the item in the mammography image was not a radioactive seed, but rather a surgical clip left behind from the procedure. While they would not remove the item surgically due to risk to the patient, the licensee had sufficient cause to determine that the item in the mammography image was not a seed. In particular, the surgeon recalled verifying using a radiation probe that the item removed from the axilla was a radioactive seed, and the nuclear medicine technologist stated that he visually verified that each seed was a seed rather than a surgical clip before placing it into the waste container. Based on this review, the licensee retracted the report of a medical event on December 2, 2020.

The inspector noted no violations of NRC requirements concerning the events surrounding the potential medical event, the licensee's review of the potential medical event, or the licensee's reporting of the potential medical event.

REPORT DETAILS

1 Program Overview

Spectrum Health Hospitals (licensee) is authorized under NRC Materials License No. 21-00243-06 to use licensed material for a variety of medical and research purposes at several facilities in Grand Rapids, Michigan, and the surrounding area. Among these medical purposes is the use of iodine-125 (I-125) seeds for localization of non-palpable lesions and lymph nodes.

2 Potential Medical Event Occurrence and Follow-up

2.1 Inspection Scope

The inspector evaluated the events surrounding the potential medical event through interviewing licensee staff, including the radiation safety officer (RSO), surgeon, and technologists involved in the procedure; and reviewing written procedures and records of the seed placement and removal.

2.2 Observations and Findings

The licensee uses around 350 to 400 I-125 seeds annually for localization of non-palpable lesions and lymph nodes. Seeds are initially placed at the licensee's heart center, part of the cancer center in Grand Rapids. While most procedures use a single seed, some procedures involve placing two or more seeds. Within a few days, the seed or seeds are surgically removed with the surrounding tissue at Spectrum Health's Butterworth Hospital or Blodgett Hospital in Grand Rapids. The seeds are tracked to ensure that all seeds are accounted for. Any seeds not reported as removed and stored for disposal by the end of the day when they are scheduled to be removed are investigated to ensure that none are lost.

On July 5, 2019, licensee staff prepared to perform a routine procedure to implant two Best Medical Model 2301 seeds, each containing 250 microcuries (μCi) of I-125 into a patient. The authorized user physician prepared and signed a written directive/tracking form for the procedure and the radioactive seeds were checked out from the oncology service for implantation. The seeds were implanted as planned into the patient, one into a lymph node in the left axilla and the other into a lesion in the left breast. Two wrist bands were placed on the patient's left wrist to indicate the presence of the two seeds. The written directive/tracking form was updated to indicate that the seeds had been implanted, then scanned and emailed to the nuclear medicine service at Butterworth Hospital. The patient was then transported to Butterworth Hospital for surgery to remove the two seeds and the surrounding tissues.

The patient went through surgery and both seeds were removed. When the surgeon cut into the tissue, the seed placed into the lymph node was freed from its site in the tissue, fell out, and was captured by the surgeon. The surgeon verified with the radiation probe that this was a radioactive see and placed it into a seed waste vial that was in the operating room for that purpose. The breast tissue (lesion) specimen was surgically removed, still containing the seed placed there. Both specimens were x-rayed in the operating room in accordance with the licensee's procedure. The radiologist who reviewed the radiographs noted that, contrary to usual practice, there was no seed in the lymph node specimen; the surgeon subsequently confirmed that the seed had been freed and accounted for. The wrist bands were removed from the patient.

Both tissue specimens, the free seed in the waste vial, and the wrist bands were transported to the pathology laboratory, where the pathology staff removed the seed from the breast tissue specimen and placed it into a second waste vial. Both seeds with the wrist bands attached to the vials were placed into a locked cabinet and the hospital's nuclear medicine staff was notified that the seeds were ready to pick up. Pathology staff began their evaluation of the two tissue specimens.

That same day, nuclear medicine staff picked up the seeds from the locked cabinet in the pathology lab and transported them to the nuclear medicine waste area for decay in storage. The nuclear medicine technologist picked up each seed with tweezers briefly to verify its identity, then placed each seed into the waste seed vial for calendar year 2019 that was maintained there for decay in storage. The technologist reviewed the written directive/tracking form that had been emailed from the oncology service, printed and initialed it to document that the seeds were removed and placed into waste at Butterworth Hospital, and provided it back to the oncology service. The licensee considered the procedure complete.

Approximately fifteen months later, on October 26, 2020, the patient returned to the hospital for a routine mammogram. The radiologist who reviewed the image noted an object in the patient's left axilla and suspected that it was a radioactive seed that had not been removed. The patient returned on October 28 for follow-up imaging. Based on this imaging, licensee staff made a preliminary determination that the seed might not have been removed as previously believed, considering that the item removed might have been a surgical clamp instead. They began an investigation to evaluate their concern. They noted that the seed, which was 250 μCi at the time of placement, would have decayed to 0.9 μCi by this time. As such, it would not be detectable from outside the patient's body with their instrumentation. Licensee staff did not note any signs of radiation exposure such as erythema in the patient.

Dose estimates performed by licensee physics staff determined that the seed would have exposed tissue at 1 centimeter (cm) from the seed at 6.72 sievert (Sv). This compares to a dose of approximately 0.013 Sv at 1 cm for a seed removed as originally scheduled, four hours after implantation. Based on this exposure, the licensee identified that leaving the seed in place for this period would constitute a medical event, and the RSO reported it to the NRC Operations Center on October 28.

During this time, licensee staff began to consider whether the object that they had seen in the mammography images might be a surgical clip that had been left behind. Interviews by the inspector of the surgeon and other personnel indicated that enough checks had been performed during the original implant and removal procedure to believe that the seed had been removed as originally believed. In particular, the surgeon stated that she had verified the seed with the probe when removing it from the patient. The nuclear medicine technologist stated that, while he did not remember this specific case, he visually verified that each item he placed into the waste vial was a seed rather than a clip. The licensee also provided documentation from a professional journal that surgical clips and radioactive seeds can appear similar in mammography images.

The licensee considered performing additional scans to verify whether the object was a seed or a clip, but the patient declined to return to the hospital. The licensee determined that they would not consider surgery to remove the object to provide certainty because it was not in the patient's interest.

The licensee identified one area of uncertainty concerning their review. As part of the review, the RSO opened and inventoried the contents of the 2019 seed waste vial in the

Butterworth Hospital nuclear medicine waste area. He was willing to do this because the seeds had decayed for a minimum of approximately ten months prior to reopening the vial. In the waste container, he identified several seeds more than he had anticipated based on the number of procedures performed, as well as a surgical clip. While this indicated possible irregularities in their process, it did not indicate that any seeds were missing. He stated that it was possible that a patient who had intended to have the seeds removed at Blodgett Hospital had them removed at Butterworth Hospital, or that the 2019 vial had not been open strictly for the 2019 calendar year – it could have been opened early or closed late.

Based on their review, the licensee determined that it was most likely that the item identified on the mammography image was a surgical clip rather than a radioactive seed. As such, they determined that this did not constitute a medical event. The RSO contacted the NRC Operations Center on December 2 to retract the previous report of a medical event. In the written report, the licensee stated that they will put a process in place as soon as practicable for nuclear medicine staff to verify using a survey meter that seeds recovered from pathology are radioactive. and define steps to be taken if no activity is identified or if the seed is determined to be a clip. This survey will be documented on the written directive/tracking form.

2.3 Conclusions

The inspector identified no violations concerning the events surrounding the identification and review of a potential medical event. While no violations were found, the licensee is taking action to improve the tracking of seeds used in such procedures. The inspector further supports the licensee's determination that no medical event occurred.

3 Notifications and Written Report

3.1 Inspection Scope

The inspector reviewed notifications to the NRC, the referring physician, and the patient though interviewing the licensee's RSO and reviewing records and other documentation of the potential medical event.

3.2 Observations and Findings

On October 28, 2020, licensee staff determined that this case appeared to meet the requirements in Title 10 of the *Code of Federal Regulations* (CFR) 35.3045(a)(1)(iii), for a dose to an organ or tissue exceeding 0.5 Sv (50 rem) and 50 percent or more of the dose expected from the administration defined in the written directive. The tissue at 1 cm from a seed would have received 6.72 Sv (672 rem) as compared to 0.013 Sv (1.3 rem) if the seed had been removed, exceeding both 0.5 Sv and 50 percent over the expected dose. Title 10 CFR 35.3045(c) requires that the licensee report a medical event no later than the next calendar day after discovery of the medical event. The licensee provided this report telephonically to the NRC Operations Center on October 28, the same day that the licensee determined that it appeared to be a medical event.

Title 10 CFR 35.3045(e) requires that the licensee contact the referring physician and the individual who is the subject of the medical event no later than 24 hours after its discovery. The licensee notified both the referring physician and the patient on October 28, 2020, the same day as the discovery.

Title 10 CFR 35.3045(d) requires the licensee to submit a written report to the NRC Region III Office within 15 days after discovery of the event and specifies what information the report must include. The licensee provided the written report via email to the inspector on November 12, 2020, within 15 days of the determination of a possible medical event. The inspector determined that the written report contained all required information.

Title 10 CFR 35.3045(g) requires the licensee to provide a copy of this written report annotated with the name and identification number of the individual who is the subject of the medical event to the referring physician no later than 15 days after discovery of the event. The licensee provided this annotated report to the referring physician on November 12, 2020, within 15 days of discovery of the potential medical event.

On December 1, 2020, the licensee RSO contacted the NRC Operations Center to retract this report upon determining that no medical event occurred. The licensee provided an updated written report via email to the inspector on December 2, 2020, to document the basis for this determination.

3.3 Conclusions

The inspector identified no violations concerning notifications to the NRC, the referring physician, or the patient concerning this potential medical event.

4 Exit Meeting Summary

The NRC inspector presented inspection findings following the inspection on December 16, 2020. The licensee did not identify any documents or processes reviewed by the inspector as proprietary. The licensee acknowledged the findings presented.

LIST OF PERSONNEL CONTACTED

\# Evan Boote, Ph.D., Radiation Safety Officer
Kristi Koenig, Pathology Assistant
Thomas Kumpuris, Medical Physicist
Melinda Miller, M.D., Surgery
Jon-Eric Notarnicola, M.D, Radiology
Tyler Schrader, Nuclear Medicine Technologist

\# Attended exit meeting on December 16, 2020.

INSPECTION PROCEDURES USED

IP 87103	Inspection of Materials Licensees Involved in an Incident or Bankruptcy Filing
IP 87132	Brachytherapy Programs