UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD, SUITE 102
KING OF PRUSSIA, PA 19406-1415

March 6, 2023

Elizabeth Herbert,
VP, Smilow Cancer Network
Yale-New Haven Hospital
20 York Street, NP5-207
New Haven, Connecticut 06510

SUBJECT: YALE-NEW HAVEN HOSPITAL - NRC INSPECTION NO. 03001244/2022002

Dear Elizabeth Herbert:

This letter refers to the announced, reactive, inspection conducted on October 5, 2022 at your New Haven, Connecticut facility in response to your report of a medical event (NMED No. 220484) that occurred on September 28, 2022. 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 a selected examination of procedures and representative records, observations of activities, and interviews with personnel. The findings of the inspection were discussed with you at the conclusion of the inspection on February 14, 2023.

Within the scope of this inspection, no violations were identified.

In accordance with Title 10 of the *Code of Federal Regulation's* (10 CFR) 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

If you have any questions regarding this matter, please contact Robin Elliott of my staff at (610) 337-5076 or via electronic mail at robin.elliott@nrc.gov.

Thank you for your cooperation.

Sincerely,

Anne E. DeFrancisco
Digitally signed by Anne E. DeFrancisco
Date: 2023.03.06 13:29:48 -05'00'

Anne DeFrancisco, Chief
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security
Region I

Docket No. 030-01244
License No.06-00819-03

Enclosure:
Inspection Report 03001244/2022002

cc w/ enclosure
William Hinchcliff, Radiation Safety Officer
State of Connecticut

SUBJECT: YALE-NEW HAVEN HOSPITAL - NRC INSPECTION NO. 03001244/2022002 DATED MARCH 6, 2023

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U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03001244/2022002
NMED No.	220484
Docket No.	03001244
License No.	06-00819-03
Licensee:	Yale-New Haven Hospital
Address:	20 York Street New Haven, CT 06510
Inspection Dates:	October 5, 2022, exit meeting February 14, 2023
Date Follow-up Information Received:	October 14, 2022, December 17, 2022

Inspectors:

Robin L. Elliott Digitally signed by Robin L. Elliott Date: 2023.03.06 13:06:18 -05'00'

Robin L. Elliott — date
Senior Health Physicist
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security

Anne DeFrancisco for — 03/06/2023

Patrick-John Hann — date
Health Physicist
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security

Approved By:

Anne DeFrancisco — 03/06/2023

Anne DeFrancisco — date
Chief
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security

Enclosure

EXECUTIVE SUMMARY

Yale-New Haven Hospital NRC Inspection Report No. 03001244/2022002

An announced, special inspection was conducted to review the circumstances associated with a reported event (NMED 220484) that occurred on September 28, 2022, at Yale-New Haven Hospital (YNHH) in New Haven, Connecticut. The licensee reported the event to the NRC on September 29, 2022. The reported event involved a Gamma Stereotactic Radiosurgery (GSR) treatment to ten lesions in the patient's brain. The patient was prepared and was placed in the unit without incident. The first four lesions were treated as the patient slept. The patient awoke during the fifth shot and started to move. The therapist instructed the patient to limit their movement and noted that the movement was not sufficient to require a pause and check before resuming treatment. The patient requested to use the restroom which was accommodated after the sixth shot. When removing the patient, the therapist noted that the frame had shifted. The patient was removed, the frame was re-attached, and treatment planning revised for the last four shots which were delivered without incident. The patient and the referring physician were informed of the event on September 28, 2022.

YNHH performed treatment plans to recreate the shifted geometry and developed three scenarios that could have occurred which were communicated in the written report submitted October 14, 2022 (ML22299A030). The first was that the shift occurred when removing the patient resulting in no change to the treatment from the intended treatment. The second was that the frame shifted during the fifth treatment resulting in two shots being delivered to the altered geometry. The last scenario was that the shift occurred shortly after the patient was docked into the table resulting in all six shots prior to their removal being altered.

A medical consultant was contracted to evaluate the report provided by YNHH presenting the results of each scenario. The consultant confirmed that a medical event would have occurred if scenario three happened. In this case, two of the shots would have received less than 50% of the intended dose meeting the criteria for 10 CR 35.3045(a)(1)(iii). However, both the licensee and the medical consultant concluded that based on the worst-case scenario dose critical structure dose calculations performed by the Authorized Medical Physicist, no ultrasensitive critical structures (such as optic nerves, optic chiasm, or brainstem) received dose amounts that exceeded acceptable parameters and as such would anticipate no increased toxicity impact of the shift to these ultrasensitive critical structures.

The root cause of the event was determined to be a loose initial placement of the anterior two pins of the frame; however, YNHH followed its written procedure for patient preparation without incident. The frame was checked at least five times prior to the start of treatment. As a result of the event, YNHH implemented the following corrective actions: (1) The neurosurgery proctoring/credentialing process related to GSR frame placement was reviewed and updated to standardize specific milestones for achieving independence in frame placement (specifically, the decision was made to require the proctoring neurosurgeon to place the frame with any new attending for the first three placements); (2) The GSR treatment Standard Operating Procedure (SOP) was reviewed by the gamma knife team and amended to more explicitly state frame placement and stability checks at each step to enhance current practice; (3) All GSR staff members were refreshed on the frame placement and stability checks as well as the amended SOP; and, (4) The GSR treatment SOP was updated to make patient education more explicit on

advising patients to inform treatment staff in real time during treatment if they feel any frame movement(specifically, language was added to the SOP to advise the patient on the importance of alerting staff during the treatment of frame movement).

No violations were identified from the inspection of the event.

REPORT DETAILS

1. Background

The licensee was a medical institution with a Type A broad scope NRC license authorized for use in medical diagnosis, therapy, and research in humans. Additionally, the licensee was authorized for Ge-68 sealed sources, Y-90 TheraSpheres, Y-90 SIR-Spheres, Sr-90 sealed sources, Mo-99/Tc-99m generators, Pd-103 sealed sources, I-125 sealed sources, Cs-131 sealed sources, Cs-137 sealed sources, I-131 in any form, Gd-153 sealed sources, Am-241 sealed sources, Ra-223 in liquid form, Ir-192 as a High Dose Rate Remote After loader sealed source, and Co-60 as a GSR sealed source. The licensee had seven locations of use at the time of the inspection.

The primary location of use was the Medical Center Campus. This location housed one Nuclear Medicine department with Positron Emission Tomography (PET), one Nuclear Cardiology department with PET, and the Radiation Oncology department where the GSR activities were performed. This inspection was limited to evaluation of the reported event EN56130.

GSR was a multi-disciplinary activity which involved the participation from Neurosurgery, Radiation Oncology, Medical Physics, Therapists, and Nursing staff. YNHH had a written procedure for all steps taken to provide a GSR treatment. The procedures included visual and auditory observations of the patient throughout the treatment, a minimum of five checks on the frame attachment prior to initiation of the treatment, and instructions to the patient regarding the frame attachment and to avoid placing hands near their head or the frame during treatment. All personnel involved with the program received training on the written procedure prior to participation in treatments.

2. Review of the Event

a. Inspection Scope

The inspectors performed a reactive inspection as a result of the report of a potential medical event, EN56130, where YNHH was performing a GSR and determined that 6 of 10 targets may not have been delivered as intended resulting in up to a 50 percent underdose to the intended targets. The inspectors evaluated the GSR program and the circumstances surrounding the reported event. The inspectors reviewed the policies and procedures related to the GSR program, written directive, treatment plan, toured the facility and interviewed all staff involved with the reported event as well as a patient receiving a similar treatment.

b. Chronology of Events

The patient reported on September 28, 2022, to receive treatment to ten lesions in the brain using GSR, according to a written directive approved by the Authorized Users (AU) and consisting of multiple shots to each location ranging in time from approximately 8 minutes to 20 minutes. YNHH followed their procedure for providing this therapy as outlined in the document entitled, “Gammaknife Treatment Standard Operating Procedure” with a review date of 07/2021. No concerns were noted. The patient was docked into the unit and treatment was initiated at 15:11:45. The patient fell asleep for the first four shots. During the fifth shot, the patient awoke at approximately 16:00 and

exhibited some movement which the therapist noted. The therapist spoke to the patient through the intercom informing them not to move their hands up near their head. The therapist noted that the motion was not sufficient to warrant pausing the treatment to check the patient positioning. At the start of the seventh shot the patient requested to use the restroom. The treatment was stopped, and the therapist entered the room to retrieve the patient at 16:27:24. Upon removing the patient, the therapist noted that the patient's head did not look normal in the frame. The radiation oncologist was brought in who determined that the front two screws had shifted approximately 1 cm. The patient was re-fitted with the frame at approximately 17:00 and treatment planning revised for the remainder of the treatments at 17:41 which were performed without incident at 17:47:03. The treatment ended at 19:40:58. The event was disclosed to the patient the same day by the Radiation Oncologist and Neurosurgeon, in accordance with 10 CFR 35.3045(e). A plan was made to follow-up with the patient in six weeks with a Magnetic Resonance Imaging (MRI) to determine efficacy of the treatment.

Following the treatment, on September 29, 2022, the Authorized Medical Physicists (AMPs) reanalyzed the event and created a treatment plan based on the shifted screws to determine the difference from the intended treatment plan. Three scenarios were established and the resulting effects for each were calculated. The first scenario was that the frame shift occurred when the patient was removed from the unit, not affecting any of the shots. The second scenario was that the movement occurred when the patient movement was first observed, effecting shots five and six. The third scenario was that the frame shifted as soon at the patient was placed in the unit resulting in the first six shots being affected. Upon completion of the scenarios, the Radiation Safety Officer was informed. The Radiation Safety Officer (RSO) reported the event to the NRC including all three scenarios, within 24 hours of discovering the event, and the YNHH accreditation and regulatory office. The Radiation Oncology and Safety Coordinator reported the event in the YNHH Quality and Safety Rounds.

YNHH conducted a preliminary root cause analysis of the event and determined it to be loose initial placement of the anterior two screws which allowed frame displacement during patient head movement. While the exact time frame displacement occurred could not be determined, it was best estimated to have happened during table movement of the patient out of the machine for a treatment break since patient motion was directly observed at all times during active treatment and no movement sufficient to cause frame displacement was observed. Corrective actions implemented included: 1) neurosurgery proctoring/credentialing process related to GSR frame placement was reviewed and updated to standardize specific milestones for achieving independence in frame placement; specifically, the decision was made to require the proctoring neurosurgeon to place the frame with any new attending for the first three placements, 2) the GSR treatment SOP was reviewed by the gamma knife team and amended to more explicitly state frame placement and stability checks at each step to enhance current practice, 3) all GSR staff members were refreshed on the frame placement and stability checks as well as the amended SOP; and,4) the GSR treatment SOP was updated to make patient education more explicit on advising patients to inform treatment staff in real time during treatment if they feel any frame movement (specifically, language was added to the SOP to advise the patient on the importance of alerting staff during the treatment of frame movement).

c. Conclusions

The inspectors concluded that YNHH followed their approved written SOP for the treatment, including taking appropriate precautions to prevent a medical event.

3. Notifications and Reports

a. Inspection Scope

The inspectors interviewed the Authorized Users (AU), AMPs, the and other YNHH staff to determine when the licensee possessed sufficient information to estimate the impact of the event on the patient. The inspectors also reviewed YNHH's event notification to the NRC and their 15-day report.

b. Observations and Findings

On September 29, 2022, the AMPs performed the treatment plans showing the effect of the shifted frame for the two scenarios that would have resulted in a shift of the intended target locations of the radiation. Once the plans were overlapped with the intended treatment plans, estimates were made of the effect of the shift. For scenario two it was determined that two targets could have received dose lower than planned; however, they would have received at least 50% of the prescribed dose. For scenario three it was determined that two targets would have been missed. The AUs also determined that no significant dose was administered to critical structures, there would be no impact to normal tissue expected, and the impact on tumor control would vary depending on which scenario occurred and therefore they would closely follow-up with the patient with serial MR imaging.

YNHH made telephonic notification of the event on September 29, 2022, and provided a 15-day report on October 14, 2022.

10 CFR 35.3045(a)(1)(iii) requires, in part, that the licensee to report any event as a medical event, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material results in a dose to the skin or an organ or tissue other than the treatment site that exceeds by (A) 0.5 Sv (50 rem) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and (B) 50 percent or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.

10 CFR 35.3045(c) states that the licensee shall notify by telephone the NRC Operations Center no later than the next calendar day after discovery of the medical event.

10 CFR 35.3045(d) states that by an appropriate method listed in § 30.6(a) of this chapter, the licensee shall submit a written report to the appropriate NRC Regional Office listed in § 30.6 of this chapter within 15 days after discovery of the medical event. The written report must include: (i) The licensee's name; (ii) The name of the prescribing physician; (iii) A brief description of the event; (iv) Why the event occurred;

(v) The effect, if any, on the individual(s) who received the administration; (vi) What actions, if any, have been taken or are planned to prevent recurrence; and (vii) Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not. The report may not contain the individual's name or any other information that could lead to identification of the individual.

A medical consultant was contracted on December 5, 2022, to evaluate the report provided by YNHH. Based on this report (ML23003A785), dated December 17, 2022, for scenario three where two of the targets were missed, it was determined that dose to the tissue not intended to be delivered by the treatment, had it occurred as intended, was in excess of 0.5 Sv resulting in the event meeting the criteria for a medical event.

The inspectors found that the licensee reported the event in a timely manner as it was made the same day the AMPs calculated the effect of the potential shift on the intended plan. Additionally, the licensee submitted the 15-day report within the required timeframe including all the items as spelled out in 10 CFR 35,3045(d).

c. Conclusions

YNHH evaluated the event thoroughly, presenting all possible scenarios. YNHH reported the event as a medical event since the most conservative scenario met the requirements of 10 CFR 35.3045(a)(1)(iii), while recognizing that the most probable scenario did not. YNHH met the immediate and 15-day reporting requirements allowing for the event to be entered into the NMED database for the NRC and other licensees to learn from their experience. No violations of reporting requirements were identified.

4. Licensees Corrective Actions

a. Inspection Scope

The inspectors interviewed the AUs, the AMPs, the RSO and other members of YNHH's staff and reviewed documentation of the corrective actions submitted in the 15-day report of this event.

b. Observations and Findings

YNHH conducted a preliminary root cause analysis of the event and determined it to be loose initial placement of the anterior two screws which allowed frame displacement during patient head movement. The neurosurgeon that placed this frame was a junior neurosurgeon who had done their residency (which included more than 20 frame placements) with YNHH and was still being proctored by an established neurosurgeon. This placement was either 3 or 4 of a required ten cases that needed to be proctored. The neurosurgeon who was overseeing the junior did not double check the frame placement; although others did, i.e., nurses and therapists. Factors that can affect the frame placement include patient anatomy and tightness.

The inspectors interviewed a patient undergoing a treatment about the placement of the frame. The patient stated that they did not think that they would be able to feel slight movement of the frame due to the local anesthetic used to address any pain resulting from the frame placement.

YNHH implemented a number of corrective actions intended to address the possible cause of inadequate frame placement:

1) The neurosurgery proctoring/credentialing process related to GSR frame placement was reviewed and updated to standardize specific milestones for achieving independence in frame placement. Specifically, the decision was made to require the proctoring neurosurgeon to place the frame with any new attending for the first three placements.

2) The GSR treatment SOP was reviewed by the gamma knife team and amended to more explicitly state frame placement and stability checks at each step to enhance current practice.

3) All GSR staff members were refreshed on the frame placement and stability checks as well as the amended SOP.

4) The GSR treatment SOP was updated to make patient education more explicit on advising patients to inform treatment staff in real time during treatment if they feel any frame movement. Specifically, language was added to the SOP to advise the patient on the importance of alerting staff during the treatment of frame movement.

c. Conclusions

The inspectors determined that the corrective actions taken by YNHH after the event were appropriately timely and comprehensive.

5. Medical Consultant Report

A medical consultant was contracted by the NRC in accordance with MC1360, on December 5, 2022, to evaluate the 15-day report provided by YNHH presenting the results of each scenario. The consultant provided a report on December 17, 2022 (ML23003A785). The consultant reviewed the documentation provided by the NRC and YNHH and interviewed the AU and AMP. The consultant provided information to support that a medical event would have occurred in scenario three. In this case, two of the shots were missed and thus would have received less than 50% of the intended dose, meeting the criteria for 10 CR 35.3045(a)(1)(iii). However, both the licensee and the medical consultant concluded that based on this worst-case scenario dose critical structure dose calculations performed by the AMP, no ultrasensitive critical structures (such as optic nerves, optic chiasm, or brainstem) received dose amounts that exceeded acceptable parameters and as such would anticipate no increased toxicity impact of the shift to these ultrasensitive critical structures.

6. Exit Meeting

An inspection debrief was conducted at the conclusion of the on-site inspection on October 5, 2022, and a final exit meeting was held with the YNHH RSO and management representatives on February 14, 2023.

ATTACHMENT

PARTIAL LIST OF PERSONS CONTACTED

Individual(s) present at virtual entrance meeting
+ Individual(s) present for on-site inspection debrief on October 5, 2022
^ Individual(s) present for virtual exit meeting on February 14, 2023

#+ Dave Carlson, PhD, DABR, Director of Therapeutic Medical Physics, RSC chair
#+^ Dr. Veronica Chiang, Professor of Neurosurgery, Director of Gamma Stereotactic Radiosurgery
#+ Frank Claudio, Director of Radiation Oncology
^ Dave Depukat, YNHH Director of Regulatory Affairs
^ Emily Draeger, PhD, Authorized Medical Physicist,
#+^ James Hansen, Authorized User, Chief Gamma Knife Program
^ Sharlene Hench, Radiation Oncology Quality and Safety Coordinator
#+^ Bill Hinchcliffe, Radiation Safety Officer
^ Ngoc (Bic) Nguyen, Authorized Medical Physicist
Violet Ratchford, Radiation Therapist
^ Donna Wysocki, Senior Regulatory Specialist
Jacky Yeung, Neurosurgeon

INSPECTION PROCEDURES USED

IP 87103 Inspection of Materials Licensees Involved in an Incident or Bankruptcy
IP 87133 Medical Gamma Stereotactic Radiosurgery and Teletherapy Programs
IP 87134 Medical Broad Scope Programs

LIST OF ACRONYMS USED

AMP	Authorized Medical Physicist
AU	Authorized User
CFR	*Code of Federal Regulations*
EN	Event Notice
GSR	Gamma Stereotactic Radiosurgery
MRI	Magnetic Resonance Imaging
NMED	Nuclear Materials Events Database
NRC	Nuclear Regulatory Commission
PET	Positron Emission Tomography
RSO	Radiation Safety Officer
SOP	Standard Operating Procedure
YNHH	Yale-New Haven Hospital