UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

May 2, 2016

EN 51796 & 51818
NMED 160127 & 160139 (Closed)

Mr. David J. Gaffney
Vice President, Imaging & Lab Services
Botsford General Hospital
28050 Grand River Ave
Farmington Hills, MI 48336

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03002077/2016002(DNMS)
BOTSFORD GENERAL HOSPITAL

Dear Mr. Gaffney:

On March 31, 2016, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a reactive inspection at your facility in Farmington Hills, Michigan, with continued in-office review through April 11, 2016. The purpose of the inspection was to review the facts and circumstances surrounding two high dose-rate (HDR) remote afterloader brachytherapy treatment medical events reported to the NRC Headquarters Operations Center on March 17, 2016, and March 23, 2016, respectively. The in-office review included review of the written event reports for each event dated March 30, 2016, and April 5, 2016, respectively. The in-office review also included a review of the manufacturer's assessments, dated April 5, 2016 and April 7, 2016. Mr. Zahid Sulaiman of my staff conducted a final exit meeting by telephone with Dr. Timothy McKnight of your staff on April 11, 2016, to discuss the inspection findings. The enclosed inspection report presents the results of the 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, tours of facilities, and interviews with personnel involved in the event.

No violations were identified during this inspection. Therefore, you are not required to respond to this letter unless the description herein does not accurately reflect your understanding of the events or your position. In that case, or if you choose to provide additional information, please submit the information in accordance with the methods described in Title 10 of the *Code of Federal Regulations* (CFR) Section 30.6(a)(1) and (b)(2).

In accordance with 10 CFR 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, your response, if you choose to provide one, 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. Sulaiman of my staff if you have any questions regarding this inspection. Mr. Sulaiman can be reached at 630-829-9752.

Sincerely,

/RA/

Aaron T. McCraw, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-02077
License No. 21-08892-01

Enclosure:
IR 03002077/2016002(DNMS)

cc w/encl: Timothy Allen McKnight, D.O., RSO
State of Michigan

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Please feel free to contact Mr. Sulaiman of my staff if you have any questions regarding this inspection. Mr. Sulaiman can be reached at 630-829-9752.

Sincerely,

/RA/

Aaron T. McCraw, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-02077
License No. 21-08892-01

Enclosure:
IR 03002077/2016002(DNMS)

cc w/encl: Timothy Allen McKnight, D.O., RSO
State of Michigan

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U.S. Nuclear Regulatory Commission
Region III

Docket No.	030-02077
License No.	21-08892-01
Report No.	03002077/2016002(DNMS)
EN No.	51796 & 51818
Licensee:	Botsford General Hospital
Facility:	28050 Grand River Ave Farmington Hills, MI 48336
Inspection Dates:	March 31, 2016, with in-office review through April 11, 2016
Exit Meeting Date:	April 11, 2016
Inspector:	Zahid Sulaiman, Health Physicist
Approved By:	Aaron T. McCraw, Chief Materials Inspection Branch Division of Nuclear Materials Safety

Enclosure

EXECUTIVE SUMMARY

Botsford General Hospital
NRC Inspection Report 03002077/2016002(DNMS)

This was an announced, reactive inspection performed to review the facts and circumstances surrounding two medical events that Botsford General Hospital (licensee) reported to the U.S. Nuclear Regulatory Commission (NRC) on March 17, 2016 (EN 51796) and March 23, 2016 (EN 51818). The medical events occurred at the Botsford Cancer Center at 27900 Grand River Avenue, Farmington Hills, Michigan. Both medical events concerned a high dose-rate (HDR) remote afterloader brachytherapy unit that reported errors during the delivery of HDR administrations.

Event Number 51796: The first medical event occurred on March 16, 2016, a patient was under spinal anesthesia for a treatment to the prostate to a prescribed dose of 13.5 Gy for the second fraction, during treatment and after completion of the ninth catheter, the treatment console reported an error code 9, indicating that source had moved from the dwell position and that a reset of the treatment console was required. Several attempts were made by the authorized medical physicist (AMP), the authorized user (AU), and with the Elekta field service engineer (FSE) over the phone to troubleshoot the issue, but, the problem persisted. The HDR unit would not resume treatment, and the unit reported another error code 117, indicating an error while driving out the check cable. The licensee terminated the patient treatment due to the malfunction of the HDR unit. The FSE investigated the issue and replaced the suspected parts. The licensee calculated that the patient only received 12.52 percent of the prescribed dose of 13.5 Gray (Gy) to the prostate volume. The licensee identified that the incident constituted a medical event under the requirements of Title 10 of the *Code of Federal Regulations* (CFR), Section 35.3045(a)(1), and reported the event to the NRC on March 17, 2016.

Event Number 51818: The second medical event occurred on March 22, 2016, a patient was under spinal anesthesia for a treatment to the prostate to a prescribed dose of 13.5 Gy for the second fraction, during treatment and after completion of the first catheter, the treatment console reported an error code 4, indicating that friction was detected during source in-drive and that the source was retracted. The AMP reset the unit and made attempts to troubleshoot the issue, but, the problem persisted. The HDR afterloader unit would not resume treatment and reported the similar error code 117, as reported during March 16, 2016 medical event. The licensee contacted an Elekta FSE by phone and made several attempts to troubleshoot the issues, the problem persisted. The FSE determined that several HDR unit parts need replacement. The licensee terminated the patient treatment due to the malfunction of the HDR unit. The FSE investigated the issue and replaced the suspected parts. The licensee calculated that the patient received 0.16 percent of the prescribed dose of 13.5 Gy to the prostate volume. The licensee identified that the incident constituted a medical event under the requirements of 10 CFR 35.3045(a)(1), and reported the event to the NRC on March 23, 2016.

The inspector identified no violations of NRC requirements concerning both medical events. The root cause for both medical events was the failure of electronic components of the HDR remote afterloader unit. As corrective action to prevent recurrence, the licensee had the manufacturer replace the concerned electronic components, service the unit, and test the unit. In addition, the licensee committed that if the HDR unit has any intermittent issues, alarms, or error codes that do not pass the licensee's daily QA or the functionality check, the licensee will postpone all HDR brachytherapy treatments, lock the treatment door, put up a "No Entry" sign, and get the manufacturer clearance certificate for clinical use before resuming treatments.

REPORT DETAILS

1 Program Overview

Botsford General Hospital is authorized to perform a variety of diagnostic, therapeutic, and cancer treatment medical procedures under NRC Materials License No. 21-08892-01. The cancer treatments are performed only at the Botsford Cancer Center at 27900 Grand River Avenue, Farmington Hills, Michigan. The purpose of this announced inspection was to review the facts and circumstances of two medical events involving the licensee's HDR unit (MicroSelectron Model 106.990, Serial No 10322) on March 16, 2016, and March 22, 2016, respectively.

2 Sequence of Events and Licensee Investigation

2.1 Inspection Scope

The inspector interviewed licensee staff and management personnel concerning the facts and circumstances surrounding the medical events that occurred on March 16, 2016 and March 22, 2016, and reviewed documentation concerning the events leading up to and following the medical events.

2.2 Observations and Findings

Medical event #1: EN 51796

On March 16, 2016, licensee staff prepared to perform an HDR administration to a patient to treat prostate cancer. The plan was to treat the prostate to a prescribed dose of 13.5 Gy for the second fraction. A radiation therapist completed the daily QA check in the morning, and the AMP approved the check. The licensee developed a treatment plan for the second fraction based on the ultrasound acquisition that day and the written directive. The treatment plan called for 19 interstitial catheters to treatment volume. The treatment plan was approved by the AU and sent to treatment console in preparation for administration. The HDR unit housed an iridium-192 source with an activity of 10.66 curies as of March 11, 2016, when the source was exchanged by the manufacturer. The AMP conducted a full calibration of the HDR unit on March 14, 2016, following the source exchange.

The AMP ran the treatment checklist, verifying that the source activity was correct for that day, that the treatment plan time matched, that catheter position was correct using catheter 12 as a reference, and that the HDR unit was ready for treatment. The AMP and AU were present when the treatment was initiated. After completion of 9 of 19 catheters, the treatment console reported an error code 9 on the tenth catheter. The error code message indicated that the source had moved from the dwell position and a reset of the treatment console was required. The licensee pressed the emergency stop button, and the treatment console then provided an error code 4, indicating that friction was detected during source in-drive at 1,193 millimeters in catheter 10. The AMP and AU noticed the error on the console and determined that the system was indicating that the source had retracted back to the HDR unit safely. The AMP went inside the treatment room with the survey meter, ensured the source was retracted, checked the transfer tube and the applicator, and noted that they were connected appropriately. The

AMP then cleared the error code at the treatment console and tried to resume the treatment; however, the HDR unit would not resume treatment and reported an error code 117, indicating an error during check cable out-drive in catheter 10.

The licensee attempted to troubleshoot the issue with the manufacturer over the phone. The licensee made several attempts to resolve the issue, but the problem persisted. The FSE determined that the HDR unit need to have certain electronic parts replaced. The licensee terminated the administration due to the malfunction of the HDR unit and sent the patient to the recovery room. The AU notified the family and referring physician about the treatment termination due to the HDR unit malfunction.

Using information from the post-treatment report, the licensee calculated that the target volume received 12.52 percent of the prescribed dose of 13.5 Gy. The licensee recognized that this constituted an underdose to the planned treatment volume and met the criteria for reporting to the NRC under 10 CFR 35.3045(a)(1). The licensee reported the medical event to the NRC Headquarters Operations Center on March 17, 2016.

The FSE repaired the HDR on March 17, 2016. The FSE replaced two parts (v-block and opto-pair). The licensee and the FSE tested the HDR unit several times without failure. The licensee conducted the daily QA on March 18, 2016 with no issue noted. Furthermore, on March 18, 2016, the licensee conducted a gynecological cancer treatment using ring and tandem to a patient with the HDR unit. The treatment was completed successfully without any issues.

Medical event #2: EN 51818

On March 22, 2016, licensee staff prepared to perform an HDR administration to a patient to treat prostate cancer. The plan was to treat the prostate to a prescribed dose of 13.5 Gy for the second fraction. A radiation therapist completed the daily QA in the morning and noted an error code 20, indicating that the source could not be driven out in channel 12. The radiation therapist repeated the daily QA several times and passed without issue. The AMP verified and approved the daily QA. The licensee developed a treatment plan for the second fraction based on the ultrasound acquisition that day and the written directive. The treatment plan called for 18 interstitial catheters to treatment volume. The treatment plan was approved by the AU and sent to treatment console in preparation for administration.

The AMP ran the treatment checklist, verifying that the source activity was correct for that day, that the treatment plan time matched, that catheter position was correct using catheter 12 as a reference, and that the HDR unit was ready for treatment. The AMP and AU was present when the treatment was initiated. After completion of the first catheter, the treatment console reported error code 4, indicating that friction was detected during source in-drive at 1,205 mm in catheter 1. The AMP and AU noticed the error on the console and determined that the system was indicating that the source had retracted back to the HDR unit safely. The AMP went inside the treatment room with the survey meter, ensured the source was retracted, checked the transfer tube and the applicator, and noted that they were connected appropriately. The AMP then cleared the error code at the treatment console and tried to resume the treatment; however, the HDR unit would not resume treatment and the treatment console reported an error code 117, indicating an error during check cable out-drive in catheter 2. This was the

same error code that occurred during the first medical event on March 16, 2016 (EN 51796).

The licensee attempted to troubleshoot the issue with the manufacturer over the phone. The licensee made several attempts to resolve the issue, but the problem persisted. The FSE determined that the HDR unit need to have certain electronic parts replaced. The licensee terminated the administration due to the malfunction of the HDR unit and sent the patient to the recovery room. The AU notified the family and referring physician about the treatment termination due to the HDR unit malfunction.

Using information from the post-treatment report, the licensee calculated that the target volume received 0.16 percent of the prescribed dose of 13.5 Gy. The licensee recognized that this constituted an underdose to the planned treatment volume and met the criteria for reporting to the NRC under 10 CFR 35.3045(a)(1). The licensee reported the medical event to the NRC Headquarters Operations Center on March 23, 2016.

The FSE replaced the opto-pair interface board, power supply control board, and stepper motor control board and adjusted the source side wire-in switch to return it back to normal. The FSE tested the HDR unit several times without failure and cleared the unit for treatment. The licensee conducted their own daily QA with no issue noted and the unit was cleared for further treatment.

The root cause for both medical events was the failure of electronic components of the HDR remote afterloader unit. As corrective action to prevent recurrence, the licensee had the manufacturer replace the concerned electronic components, service the unit, and test the unit. In addition, the licensee committed that if the HDR unit has any intermittent issues, alarms, or error codes that do not pass the licensee's daily QA or the functionality check, the licensee will postpone all HDR brachytherapy treatments, lock the treatment door, put up a "No Entry" sign, and get the manufacturer clearance certificate for clinical use before resuming treatments.

The licensee did not anticipate any negative effects to the patients as a result of the medical events. Both patients were rescheduled to receive the remainder of the prescribed dose in order to complete the treatments.

The inspector determined that the licensee followed its established protocols, including emergency procedures, for each of the administrations. The inspector determined that the licensee appropriately responded to the situations. The inspector did not identify any violations with respect to both medical events.

2.3 Conclusions

The inspector did not identify any violations concerning the events surrounding the medical events on March 16, 2016 and March 22, 2016 at Botsford General Hospital.

3 Licensee Notifications to the NRC

3.1 Inspection Scope

The inspector interviewed licensee staff and management personnel concerning the initial telephonic notification to the NRC for both medical events and the subsequent

written reports. The inspector reviewed the documentation of the notifications for completeness of required information.

3.2 Observations and Findings

EN 51796:

On March 16, 2016, the licensee identified that the fractionated dose delivered differed from prescribed dose, for a single fraction, by 50 percent or more due to the malfunction of the HDR unit. Licensee staff notified the NRC's Headquarters Operations Office about the medical event by telephone on March 17, 2016, meeting the requirement in 10 CFR 35.3045(c) to notify the NRC no later than the next calendar day after discovery.

The inspector verified that the licensee notified the referring physician and the patient's family about the medical event and that the referring physician notified the patient on March 16, 2016; updates were provided as appropriate. This met the requirement in 10 CFR 35.3045(e).

On March 30, 2016, the NRC received the licensee's written report by mail. This was within the 15 days, as required by 10 CFR 35.3045(d). The written report contained all required information.

EN 51818:

On March 22, 2016, the licensee identified that the fractionated dose delivered differed from prescribed dose, for a single fraction, by 50 percent or more due to the malfunction of the HDR unit. Licensee staff notified the NRC's Headquarters Operations Office about the medical event by telephone on March 23, 2016, meeting the requirement in 10 CFR 35.3045(c) to notify the NRC no later than the next calendar day after discovery.

The inspector verified that the licensee notified the referring physician and the patient's family about the medical event and that the referring physician notified the patient on March 22, 2016; updates were provided as appropriate. This met the requirement in 10 CFR 35.3045(e).

On April 5, 2016, the NRC received the licensee's written report by mail. This was within the 15 days, as required by 10 CFR 35.3045(d). The written report contained all required information.

3.3 Conclusions

The inspector did not identify any violations concerning the licensee's reporting of both the medical events to the NRC.

4 Exit Meeting Summary

The inspector presented the preliminary inspection findings immediately following the onsite inspection on March 31, 2016. The licensee did not identify any documents or processes reviewed by the inspectors as proprietary, and acknowledged the findings presented. A final exit meeting was held by telephone on April 11, 2016, to discuss the inspection findings.

LIST OF PERSONNEL CONTACTED

Timothy Allen McKnight, D.O., Radiation Safety Officer
David J. Gaffney, Vice President, Imaging & Lab Services
Bethany Parish, Radiation Therapy Manager
Laurel Jackson, Director, Cancer Center
Meghan Sharpe, Corporate Accreditation Coordinator
Misbah Gulam, Authorized Medical Physicist
Sandra J. Adkins, Supervisor Nuclear Medicine
Teamour (Tim) Nurushev, Regional Director, Physics, 21st Century Oncology

Attended exit meeting on April 11, 2016.

INSPECTION PROCEDURES (IP) USED

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