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

October 12, 2016

EA-16-066
EN 50369
NMED No. 140443 (closed)

Mr. David Gaffney
Vice President, Imaging Services
Botsford General Hospital
28050 Grand River Avenue
Farmington Hills, MI 48336-5933

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03002077/2014001(DNMS) AND INVESTIGATION REPORT 3-2015-011 – BOTSFORD GENERAL HOSPITAL

Dear Mr. Gaffney:

On August 28 and 29, 2014, inspectors from the U.S. Nuclear Regulatory Commission (NRC) conducted an announced, reactive inspection at your facility in Farmington Hills, Michigan, with continued in-office review through May 12, 2016. The purpose of the inspection was to review the facts and circumstances surrounding a medical event that was reported to the NRC on August 14, 2014. The NRC Office of Investigations (OI) began an investigation on April 30, 2015, and the investigation report was issued on March 18, 2016. The in-office review included a review of the OI investigation report and related issues. The enclosed inspection report (Enclosure 1) presents the results of the inspection. A factual summary of the investigation is also enclosed (Enclosure 2). Mr. Geoffrey Warren and Mr. Ryan Craffey of my staff conducted a final exit meeting by telephone with you and members of your staff on May 16, 2016, to discuss the inspection findings.

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, observations of activities, and interviews with personnel.

Based on the results of this inspection, one apparent violation of NRC requirements was identified and is being considered for escalated enforcement action in accordance with the NRC's Enforcement Policy. The current Enforcement Policy is included on the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The apparent violation concerned the failure to develop a written procedure for high dose rate remote afterloader administrations that provided high confidence that each administration is in accordance with the written directive, as required by Title 10 of the *Code of Federal Regulations* (CFR) Section 35.41(a)(2). Specifically, the procedure did not provide sufficient assurance that the proper plan is imported into the treatment system.

Because the NRC has not made a final determination in this matter, the NRC is not issuing a Notice of Violation for this inspection finding at this time. The circumstances surrounding this apparent violation, the significance of the issue, and the need for lasting and effective corrective action were discussed with you during the inspection exit meeting on May 16, 2016.

Before the NRC makes its enforcement decision, we are providing you an opportunity to either: (1) respond in writing to the apparent violation addressed in this inspection report within 30 days of the date of this letter; (2) request a Predecisional Enforcement Conference (PEC); or (3) request Alternative Dispute Resolution (ADR). **Please contact Aaron McCraw at 630-829-9650 within ten days of the date of this letter to notify the NRC of your intended response.**

If you choose to provide a written response, it should be clearly marked as "Response to the Apparent Violation in Inspection Report No. 03002077/2014001(DNMS); EA-16-066," and should include, for the apparent violation: (1) the reason for the apparent violation, or, if contested, the basis for disputing the apparent violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance was or will be achieved. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violation. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be useful in preparing your response. You can find the information notice on the NRC's website at: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a PEC.

If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on the apparent violation and any other information that you believe the NRC should take into consideration before making an enforcement decision. The topics discussed during the conference may include the following: information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned to be taken. If a PEC is held, the NRC will issue a press release to announce the time and date of the conference; however, the conference will be closed to public observation because OI Investigation related information will be discussed. In addition, the NRC will record and transcribe the meeting. The NRC normally tries to schedule a PEC within 30 days of the date of the letter.

In lieu of a PEC, you may also request ADR with the NRC in an attempt to resolve this issue. ADR is a general term encompassing various techniques for resolving conflicts using a third party neutral. The technique that the NRC has decided to employ is mediation. Mediation is a voluntary, informal process in which a trained neutral (the "mediator") works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of

agreement, and reach a final resolution of the issues. Additional information concerning the NRC's program can be obtained at http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as a neutral third party. Please contact ICR at 877-733-9415 within 10 days of the date of this letter if you are interested in pursuing resolution of this issue through ADR.

Because your facility has not been the subject of escalated enforcement action within the last two years or two inspections, a civil penalty may not be warranted in accordance with Section 2.3.4 of the Enforcement Policy. In addition, based upon NRC's understanding of the surrounding circumstances and your corrective actions, it may not be necessary to conduct a PEC in order to enable the NRC to make an enforcement decision.

In addition, please be advised that the number and characterization of the apparent violations described in the enclosed inspection report may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

The NRC has also determined that a Severity Level IV violation of NRC requirements occurred. This violation was evaluated in accordance with the NRC Enforcement Policy. The violation concerned the failure to calibrate two survey instruments at the cancer center annually as required by 10 CFR 35.61(a). This non-repetitive, non-willful, licensee-identified, and corrected violation is being treated as a Non-Cited Violation, consistent with Section 2.3.2.b of the Enforcement Policy. Detailed information concerning the violation is in Enclosure 1.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, 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 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,

/RA/

John B. Giessner, Director
Division of Nuclear Materials Safety

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

Enclosures:
1. IR No. 03002077/2014001(DNMS)
2. Factual Summary of Office of Investigations Report 3-2015-011

cc w/encl: Timothy Allen McKnight, D.O.
Radiation Safety Officer
Bethany Parish, BSBT(T),
Director, Cancer Center
State of Michigan

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,

/RA/

John B. Giessner, Director
Division of Nuclear Materials Safety

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cc w/encl: Timothy Allen McKnight, D.O.
Radiation Safety Officer
Bethany Parish, BSBT(T),
Director, Cancer Center
State of Michigan

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See next page

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NAME	JHeck		KNorman [1] (via-e-mail)		LBaer [1] (via-e-mail)		JGiessner	
DATE	6/1/2016		6/9/2016		6/8/2016		10/12/2016	

[1] (HQ) review and concurrence received via e-mail from (KNorman) on (06/09/16)

OFFICIAL RECORD COPY

Letter to David Gaffney from John Giessner dated October 12, 2016.

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03002077/2014001(DNMS) AND INVESTIGATION REPORT 3-2015-011 – BOTSFORD GENERAL HOSPITAL

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U.S. Nuclear Regulatory Commission

Region III

Docket No.:	030-02077
License No.:	21-08892-01
Report No.:	03002077/2014001(DNMS)
EA No.:	EA-16-066
EN No.:	50369
Licensee:	Botsford General Hospital
Facility:	27900 and 28050 Grand River Avenue Farmington Hills, Michigan
Inspection Dates:	August 28 and 29, 2014, with in-office review through May 12, 2016
Exit Meeting Date:	May 16, 2016
Inspectors:	Geoffrey Warren, Senior Health Physicist Ryan Craffey, Health Physicist
Approved By:	Aaron T. McCraw, Chief Materials Inspection Branch Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

Botsford General Hospital
NRC Inspection Report 03002077/2014001(DNMS)

The purpose of this inspection was to review the facts and circumstances surrounding a medical event reported to the U.S. Nuclear Regulatory Commission (NRC) by Botsford General Hospital (the licensee) on August 14, 2014. In addition, the inspectors reviewed the licensee's implementation of the radiation safety program in nuclear medicine and the cancer center.

On July 10, 2014, a physicist performed a high dose-rate remote afterloader (HDR) administration. The physicist appeared to have loaded an incorrect treatment plan into the treatment console by mistake. Based on later calculations and discussions, this resulted in a medical event. Upon recognizing the error, the physicist appeared to have attempted to hide that the medical event had occurred, creating documentation indicating that the procedure had been performed correctly, and not informing other personnel about the error. Through their audit program, the licensee later identified inconsistencies in the treatment record and investigated, identifying the error and terminating the physicist from employment.

The cause of the medical event was that the licensee's written procedure for HDR administrations did not require sufficient verification that the proper treatment plan was loaded into the treatment system prior to administration. Contributing factors included a lack of a standard naming convention for treatment plans and not removing previous plans from the folder on a network drive where they were available for import to the treatment console.

The licensee's apparent failure to develop a written procedure to sufficiently address ensuring that the proper treatment plan was selected is an apparent violation of Title 10 of the *Code of Federal Regulations* (CFR) Section 35.41(a)(2), which requires that for any administration requiring a written directive, the licensee develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. The cause of the apparent violation was an oversight on the licensee.

As corrective action for the medical event and apparent violation, the licensee committed to: (1) modify the written procedure to require that a second person verify that the approved treatment plan is correctly imported into the treatment console, (2) work with hospital staff to have previous treatment plans removed from the network drive folder into a backup folder to ensure that only current plans are maintained in that folder, and (3) set up a standard naming convention for treatment plan files to match the convention for naming planning files. According to several discussions with licensee staff, these actions were complete soon after the onsite inspection, and licensee staff were trained on the revisions to the written procedure.

In addition, the licensee identified a violation of 10 CFR 35.61(a) concerning the failure to calibrate two radiation survey instruments annually and took corrective action to reduce the likelihood of recurrence. This non-repetitive, non-willful, licensee-identified, and corrected violation is being treated as a Non-Citied Violation, consistent with Section 2.3.2.b of the Enforcement Policy.

REPORT DETAILS

1 Program Overview and Inspection History

Botsford General Hospital was authorized under U.S. Nuclear Regulatory Commission (NRC) Materials License No. 21-08892-01 to use licensed material for medical procedures. At the cancer center, licensee staff performed HDR administrations. At the main nuclear medicine area, technologists performed a variety of diagnostic nuclear medicine procedures. Radiopharmaceutical therapy procedures used primarily iodine-131 and radium-223 chloride.

The licensee was not subject to any escalated enforcement action from the most recent inspections in February 2011 and December 2012.

2 Sequence of Events

2.1 Inspection Scope

The inspectors reviewed the events surrounding the medical event reported to the NRC on August 14, 2014. This review included interviewing staff, reviewing selected records, and observing activities relating to the medical event.

2.2 Observations and Findings

On July 10, 2014, a physicist (Physicist A) performed the second of two fractions for an interstitial HDR procedure. The two fractions were to be performed using different plans, and the first fraction had been performed according to plan. However, Physicist A appears to have re-loaded the plan for the first fraction into the treatment system instead of loading the plan for the second fraction. The plans differed in the number of catheters placed into the patient. Each plan had more than eighteen catheters, so the physicist would treat the first eighteen catheters, then remove the previous catheters and place the remaining catheters before treating the remaining catheters. After switching the catheters for the second part of the procedure, Physicist A appears to have recognized that the number of catheters did not match, implying that he had loaded the incorrect plan. At this point, he appears to have stopped the procedure. Based on later calculations and discussions, this resulted in a medical event, an underdose to a portion of the treatment volume.

The cause of the medical event was that the licensee's written procedure for HDR administrations did not require sufficient verification that the proper treatment plan was loaded into the treatment system prior to administration. One contributing factor was that the licensee had no standard naming convention for treatment plans. Another factor was that treatment plans were exported from the planning system to a folder on a network drive from which they were imported into the treatment console; such plans were never removed from the folder so there were a large number of such files in the folder.

The licensee's apparent failure to develop a written procedure to sufficiently address ensuring that the proper treatment plan was selected is an apparent violation of 10 CFR 35.41(a)(2), which requires that for any administration requiring a written directive, the licensee develop, implement, and maintain written procedures to provide

high confidence that each administration is in accordance with the written directive. The cause of the apparent violation was an oversight on the licensee. Specifically, the licensee did not recognize the need for such specificity in the written procedure.

As corrective action for the medical event and apparent violation, the licensee committed to: (1) modify the written procedure to require that a second person verify that the approved treatment plan is correctly imported into the treatment console, (2) work with hospital staff to have previous treatment plans removed from the network drive folder into a backup folder to ensure that only current plans are maintained in that folder, and (3) set up a standard naming convention for treatment plan files to match the convention for naming planning files. According to several discussions with licensee staff, these actions were complete soon after the onsite inspection and licensee staff were trained on the revisions to the written procedure.

After identifying the issue and halting the procedure, Physicist A did not inform any other licensee staff about the issue, instead stating that the procedure was complete and that there had been no issues. Physicist A later appears to have created a document by cutting and pasting information that indicated incorrectly that the treatment had been performed as planned.

A second physicist (Physicist B) was performing a routine audit two weeks later and noticed that the number of catheters in the treatment plan did not match the number of catheters in the treatment record. He also noted that the date of the document was not the date of the procedure. He asked Physicist A about these observations but Physicist A did not provide any explanation except that he had reprinted the document because he had misplaced the original. Physicist B then requested information by email and later through the cancer center manager, but Physicist A provided no additional information.

Licensee management then brought in a contract physicist (Physicist C) from an outside company to review the case. Physicist C identified that the record that Physicist A had provided showed signs of tampering, that the record in the treatment system was inconsistent with the provided record, and other issues. Based on this information, Physicist A was put on suspension while the licensee's investigation continued. As part of this investigation, licensee staff identified the cut-and-pasted document in Physicist A's office.

Following the licensee's investigation, licensee management held a meeting with Physicist A to discuss the results. Physicist A was invited to provide an explanation, but declined to do so. Based on this and the evidence presented, Physicist A was terminated from employment.

Because of the claim of falsification of documentation, the NRC initiated an investigation into the facts of the case. The results of the investigation are summarized in Enclosure 2 to the letter transmitting this inspection report.

2.3 Conclusions

The inspectors identified an apparent violation of 10 CFR 35.41(a)(2) concerning the licensee's apparent failure to develop a written procedure to provide high confidence that HDR administrations are in accordance with the written directive.

3 Licensee Notification to the NRC

3.1 Inspection Scope

The inspectors interviewed the radiation safety officer and cancer center staff and management personnel concerning the initial notification to the NRC about the medical event and the written report. In addition, the inspectors reviewed the documentation of the notifications for required information.

3.2 Observations and Findings

Upon initial review of the case on August 14, 2014, Physicist C contacted the NRC to report a possible medical event. This report was made prior to the licensee determining whether it constituted a medical event. The report to the NRC contained all required information. In addition, the licensee notified the referring physician and the patient about the possible medical event the same day, as required by 10 CFR 35.3045(e).

On October 23, 2014, the licensee provided a written report discussing all topics required by 10 CFR 35.3045(d) concerning the possible medical event. Although the written report was provided to the NRC more than 15 days after the initial notification, this does not constitute a violation of NRC requirements. The licensee, in conjunction with the NRC, was still evaluating the dosimetry of this case to determine with some degree of certainty whether or not the event met the NRC's medical event criteria. There were complexities to this type of interstitial administration and limitations with the treatment planning software that required substantial, additional review.

In April 2015, the licensee, in discussion with the NRC, made a conservative decision that this event met the definition of a medical event under 10 CFR 35.3045(a)(1), as an underdose to a portion of the treatment volume.

3.3 Conclusions

The inspectors did not identify any violations concerning the licensee's reporting of the medical event to the NRC.

4 Other Areas Inspected

4.1 Inspection Scope

The inspectors observed routine licensee activities and demonstrations, reviewed selected documentation, and interviewed licensee staff concerning the radiation safety program.

4.2 Observations and Findings

The inspectors identified that the licensee secured radioactive materials appropriately and tracked materials through inventory checks. The licensee performed leak tests at the required intervals, and reports of the leak tests showed no evidence of leakage. Dosimetry records showed no exposures of regulatory concern. Licensee staff wore appropriate personal protective equipment during medical procedures. Confirmatory

surveys showed radiation levels consistent with licensee records and postings. Licensee staff were trained in radiation safety routinely. Interviews with licensee staff showed adequate knowledge of radiation safety concepts and protocols.

In early August 2014, the licensee identified that two Fluke 451P radiation survey meters at the cancer center were out of calibration. One had not been calibrated since September 18, 2012, and the other since December 5, 2012. The meters were routinely used until the time the licensee identified this issue. The inspectors determined that, despite being past their calibration due dates, the meters read approximately correct values of radiation levels.

This is a violation of 10 CFR 35.61(a), which requires, in part, that licensees calibrate survey instruments used to show compliance with 10 CFR Parts 35 and 20 annually. As corrective action, the licensee borrowed and used replacement meters and set the meters aside, marked not to use, until they could be sent in for calibration. This non-repetitive, non-willful, licensee-identified, and corrected violation is being treated as a Non-Citied Violation, consistent with Section 2.3.2.b of the Enforcement Policy.

4.3 Conclusions

The licensee had identified a violation of 10 CFR 35.61(a) concerning the failure to calibrate certain survey instruments annually and took corrective action to reduce the likelihood of recurrence. This non-repetitive, non-willful, licensee-identified, and corrected violation is being treated as a Non-Citied Violation, consistent with Section 2.3.2.b of the Enforcement Policy.

5 Exit Meeting Summary

The NRC inspector presented preliminary inspection findings following the onsite inspection on August 29, 2014. The licensee did not identify any documents or processes reviewed by the inspectors as proprietary. The licensee acknowledged the findings presented. The NRC inspectors presented the final inspection findings during a final inspection exit meeting by telephone on May 16, 2016.

LIST OF PERSONNEL CONTACTED

Sandy Adkins, Supervisor, Nuclear Medicine
James Fontanesi, M.D., Radiation Oncologist
Misbah Gulam, Medical Physicist
David Gaffney, Vice President, Imaging Sciences, Beaumont
Krystal Hanson, Chief Radiation Therapist
Holly Hufeld, Executive Assistant
Teresa Kolacz, Dosimetrist
Timothy McKnight, D.O., Radiation Safety Officer
Nicholle Mehr, Director, Cancer Center (previous)
Teamour Nurushev, Medical Physicist
Bethany Parish, Director, Cancer Center (current)
Purushottam Sharma, Medical Physicist
And additional nuclear medicine and cancer center staff

Attended telephonic exit meeting on May 16, 2016.

FACTUAL SUMMARY OF OFFICE OF INVESTIGATIONS REPORT 3-2015-011

On April 30, 2015, the U.S. Nuclear Regulatory Commission's (NRC) Office of Investigations (OI), Region III Field Office, initiated an investigation to determine whether a medical physicist at Botsford General Hospital falsified a medical treatment report. The NRC completed its investigation on March 18, 2016. The NRC conducted the investigation in response to the licensee reporting a potential medical event. The licensee identified the error through their chart auditing process and conducted their own internal investigation. During the course of their investigation, the licensee discovered that the computer record of the second fraction of the high dose rate therapy treatment did not match the treatment plan documentation. The physicist who administered the dose refused to admit any error and appears to have falsified the treatment report to indicate that the procedure had been completed correctly.

Specifically, on July 10, 2014, a medical physicist delivered the second fraction of a high dose rate remote after loader (HDR) treatment to a patient. During the course of the treatment, the physicist selected the treatment plan for the first fraction in the HDR computer and used this plan during the second fraction treatment rather than the plan developed for the second fraction. The licensee's procedure "HDR GYN MUPIT Policy," which applies to the treatment in question, did not use a standard naming convention to clearly identify changed plans for different fraction treatments on the same patient or include a step to have a second individual verify that the correct treatment plan was loaded into the HDR computer.

Based on the evidence gathered during the OI investigation, it appears the licensee failed to develop procedures that provide high confidence that the administration was in accordance with the written directive. Specifically, the licensee's "HDR GYN MUPIT Policy" did not require a standard naming convention for treatment plans or independent verification that the proper treatment plan was loaded into the HDR computer prior to administration. Therefore, the licensee apparently violated 10 CFR 35.41(a)(2), which requires that, in part, that for any administration requiring a written directive, the licensee develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.