UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 EAST LAMAR BOULEVARD
ARLINGTON, TEXAS 76011-4511

May 31, 2018

NMED No. 180198

Paulette Davidson, President
Rapid City Regional Hospital, Inc.
353 Fairmont Blvd.
Rapid City, SD 57701

SUBJECT: NRC INSPECTION REPORT 030-03231/2018-001 AND NOTICE OF VIOLATION

Dear Ms. Davidson:

This letter refers to the announced inspection conducted on April 2-3, 2018, at your facility in Rapid City, South Dakota. The inspection continued with in-office reviews until May 11, 2018. The inspection was an examination of activities conducted under your license as they relate to public health and safety, to confirm compliance with the U.S. Nuclear Regulatory Commission's (NRC's) rules, regulations, and with the conditions of your license. Within these areas, the inspection consisted of a selected examination of procedures and representative records, and interviews with personnel. The preliminary inspection findings were discussed with you and members of your staff at the conclusion of the onsite portion of the inspection. A final telephonic exit briefing was conducted with your radiation safety officer, Mr. Jim McKee, on May 11, 2018.

Based on the results of this inspection, the U.S. Nuclear Regulatory Commission (NRC) has determined that one violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy and meets the criteria for a Severity Level IV because the violation was characterized as being an isolated event, it did not demonstrate programmatic weaknesses in implementation, and had limited medical consequences. The current Enforcement Policy is included on the NRC's Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. To summarize, the violation involved the failure by Rapid City Regional Hospital, Inc., to implement and maintain written procedures to provide high confidence that each administration was in accordance with the written directive, as required by Title 10 of the *Code of Federal Regulations* (CFR) 35.41(a). The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it is described in detail in the subject inspection report.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful in preparing your response. You can find the Information Notice on the NRC website at: http://pbadupws.nrc.gov/docs/ML0612/ML061240509.pdf. Information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance will be (was) achieved should be addressed. The NRC's review of your response to the Notice will also determine

whether further enforcement action is necessary to ensure compliance with regulatory requirements.

To the extent possible, your response should not include any personal privacy or proprietary information so that it can be made available to the Public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such information, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter, its enclosure, and your response, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Should you have any questions regarding this letter or the enclosed Notice, please contact Michelle Simmons at 817-200-1590, or the undersigned at 817-200-1145.

Sincerely,

/RA/

Michael C. Hay, Chief
Materials Licensing and Inspection Branch
Division of Nuclear Materials Safety

Docket: 030-03231
License: 40-00238-01

Enclosures:
1. Notice of Violation
2. NRC INSPECTION
   REPORT 030-03231/2018-001

cc:
T. McCaskell, Administrator
State of South Dakota

NRC INSPECTION REPORT 030-03231/2018-001 - DATED MAY 31, 2018.

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☒SUNSI Review: By: MRS5	ADAMS: ☒ Yes ☐ No	☐ Non-Publicly Available ☒ Publicly Available	☒Non-Sensitive ☐ Sensitive	Keyword:

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NOTICE OF VIOLATION

Rapid City Regional Health, Inc.
Rapid City, SD

Docket No. 030-03231
License No. 40-00238-01

During an NRC inspection conducted on April 2 through May 10, 2018, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

> 10 CFR 35.41(a) states, "For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:
>
> (1) The patient's or human research subject's identity is verified before each administration; and
>
> (2) Each administration is in accordance with the written directive.
>
> Contrary to the above, on March 8 and 12, 2018, the licensee failed to develop, implement and maintain written procedures that provided high confidence that the administration was in accordance with the written directive. These deficiencies resulted in the licensee administering approximately 3.5Gy (after two fractions) to a patient that was not in accordance with the written directive which prescribed 10Gy (5Gy for each fraction).

This is a Severity Level IV violation (Section 6.3 of the NRC Enforcement Policy).

Pursuant to the provisions of 10 CFR 2.201, Rapid City Regional Health, Inc., is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Regional Administrator, Region IV, 1600 E. Lamar Blvd., Arlington, Texas 76011, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include: (1) the reason for the violations, or, if contested, the basis for disputing the violations or severity level; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance will be achieved.

Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued requiring information as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Your response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agencywide Documents Access and Management 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 or proprietary information so that it can be made available to the public without redaction.

If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 31st of May 2018.

U.S. NUCLEAR REGULATORY COMMISSION
Region IV

Docket:	030-03231
License:	40-00238-04
Report:	2018-001
Licensee:	Rapid City Regional Hospital, Inc.
Facilities:	John T. Vucurevich Regional Cancer Care Institute
Location:	353 Fairmont Blvd. Rapid City, South Dakota
Date:	April 2, 2018 through May 11, 2018
Inspector:	Michelle Simmons, Health Physicist Materials Licensing and Inspection Branch
Approved By:	Michael Hay, Chief Materials Licensing and Inspection Branch Division of Nuclear Materials Safety
Attachment:	Supplemental Inspection Information

EXECUTIVE SUMMARY

Rapid City Regional Hospital, Inc.
NRC Inspection Report 03003231/2018001

This was an announced, reactive inspection in response to a reported event at the Rapid City Regional Hospital, Inc. (RCRH), located in Rapid City, South Dakota. The reactive inspection was a review of the event with focus on the direct, contributing, and root causes and the licensee's high dose rate remote afterloader unit (HDR) skin brachytherapy program. This report describes the findings of the reactive inspection.

Summary of Event

The event was an administration during a skin brachytherapy treatment using a HDR. A patient was prescribed 8 fractions of 5Gy to the temple area. During the third fraction, the physician noticed the first two fractions were performed incorrectly. The first two fractions were performed with an incorrect setup, and the patient received less than 50 percent of the prescribed dose to the temple.

Direct, Contributing, and Root Causes

The direct cause was the failure to properly recreate the initial patient setup.

The contributing causes included the authorized medical physicist's inexperience with using custom immobilization device during HDR treatments. This was only the second brachytherapy patient to use a custom immobilization device. Both authorized medical physicists were not present during the treatment pre-planning simulation. During the pre-planning simulation, the authorized medical physicist, radiation therapist, and authorized user develop a plan for treating the patient. This includes the setup of all devices that will be used on the day of treatment. (Section 4.2)

The root cause of the medical event was the licensee's failure to implement and maintain procedures for HDR skin brachytherapy that would minimize or eliminate the possibility of administering an incorrect dose to the patient. (Section 4.2).

Inspection Findings

A violation of 10 CFR 35.41(a) was identified involving the failure to implement and maintain procedures that provided high confidence that each administration would be conducted in accordance with the written directive. (Section 6.2)

Corrective Actions

The licensee's immediate and long-term corrective actions to prevent recurrence included (1) creating procedures for HDR skin brachytherapy; (2) during pre-planning simulation, any custom immobilization used in brachytherapy will be photographed with and without the patient to ensure that each piece of the custom device can be clearly visualized; (3) installing a computer monitor, keyboard, and mouse in the HDR treatment vault to support verification of the setup in the treatment room; and (4) implementing a bar code scanning system to track custom setup devices. (Section 7.2)

Report Details

1 Program Overview (87103, 87132)

1.1 Inspection Scope

The inspectors interviewed licensee personnel, reviewed the license application, supporting documentation, treatment plans, and other records maintained by the licensee.

1.2 Observations and Findings

The RCRH was authorized under NRC License 40-00238-04, Amendment 104, to use byproduct material to perform both diagnostic and therapeutic medical administrations, including the use of iridium-192 sealed sources for HDR.

The RCRH conducted the majority of its cancer treatments at the John T. Vucurevich Regional Cancer Care Institute, which was connected to the main hospital. At the time of the event, RCRH employed three authorized medical physicists, one of whom was the radiation safety officer. In addition, the treatment planning and implantation team consisted of an authorized user and a radiation therapist. The RCRH performed approximately 25 HDR procedures from 2017 through the date of the onsite inspection. An active radiation safety committee oversaw radiation safety operations at the cancer center and the hospital.

2 Background (87103, 87132)

There were two primary methods for treating skin cancer at RCRH. The first involves the use of a linear accelerator. The linear accelerator is used for areas of the body where the surface is mostly flat. The HDR unit is used to treat the areas of the body where the surface has some curvature. The authorized user determines which method is best for the patient.

In February 2018, the authorized user determined that the patient would benefit from undergoing skin brachytherapy treatment using the HDR unit instead of the linear accelerator since the skin lesion was located on the patient's temple. The prescribed dose was eight fractions. A dose of 5Gy for each fraction for a prescribed total dose of 40Gy.

The treatment plan called for the use of a custom setup that included a plastic head rest, an AccuForm custom head rest, a custom AquaPlast mask, and a Freiburg Flap. This setup ensures that the patient is in the correct position during treatment and restricts movement. The authorized medical physicist performing the first two fractions did not use the AccuForm custom head rest. This resulted in the patient receiving a dose to the intended area more than 50 percent less than the prescribed dose.

The RCRH radiation safety officer notified the NRC's Regional office and Headquarters operations officer within 24 hours of identifying the error that resulted in the event (NMED 180198).

3 Event Chronology (87103)

The inspectors interviewed licensee personnel, reviewed procedures and corresponding documentation, and inspected equipment to reconstruct the sequence of events.

February 15, 2018

The patient had a Computer Tomography (CT) simulation (pre-planning). A custom setup was created using a plastic head rest, an AccuForm custom head rest, a custom AquaPlast mask, and a Freiburg Flap.

March 7, 2018

The treatment plan was completed and approved

March 8, 2018

The first treatment was delivered by the first authorized medical physicist.

March 12, 2018

The second treatment was delivered by the first authorized medical physicist.

March 15, 2018

The third treatment was delivered by the second authorized medical physicist. After the completion of the third treatment, the difference in setup was noticed by the authorized medical physicist who delivered the first two treatments. The decision was made by the staff to perform another CT simulation plan when the patient returned for the fourth treatment. This time without the AccuForm head rest, so the actual dose delivered to the patient during the first two treatments could be calculated.

March 19, 2018

The patient returned for the fourth treatment. The fourth treatment was performed using the correct custom setup. At the completion of the fourth treatment, another CT simulation plan was performed. The plan was reconstructed using the same parameters as the original plan except for the AccuForm head rest. At this time, the licensee discovered that the patient received an underdose by more than 50 percent in each of the first two fractions.

The RCRH notified the NRC of the medical event.

March 22- March 29, 2018

The patient received three more treatments.

April 2, 2018 – April 19, 2018

The patient received a treatment.

The NRC conducted an onsite inspection.

April 5, 2018
The patient received the final treatment.

April 9, 2018

The license submitted a 15-day report.

April 19, 2018

The licensee submitted a final report.

4 Causes of the Medical Event (87103)

4.1 Inspection Scope

The inspectors conducted interviews with licensee personnel, observed demonstrations of protocols, reviewed policies and procedures, and analyzed records related to HDR skin brachytherapy treatments to determine the direct, contributing, and root causes of the medical event.

4.2 Direct, Contributing, and Root Causes

In a letter dated April 19, 2018, RCRH submitted its root cause analysis to the NRC. The direct cause was a failure to use the AccuForm custom immobilization headrest during the HDR skin brachytherapy treatment. There was no checklist or procedure to instruct the authorized medical physicist through this process.

Contributing causes included:

- The authorized medical physicist's inexperience with using custom immobilization device during HDR treatments. This was only the second HDR skin brachytherapy performed at RCRH and it was the first time the AccuForm head rest was used.

- Both authorized medical physicists were not present during the CT simulation pre-planning. During the CT simulation pre-planning, the authorized medical physicist, radiation therapist, and authorized user developed a plan for treating the patient. The plan included the setup of all the devices that were to be used on the day of treatment.

The root cause was determined to be the licensee's failure to implement and maintain HDR skin brachytherapy procedures that would minimize or eliminate the possibility of administering an incorrect dose to the patient.

4.3 NRC Review of the Root Cause Analysis

The NRC determined that the licensee's root cause analysis was adequate and included comprehensive corrective actions sufficient to address the cause of this event.

5 Radiation Dose Assessment (87103, 87132)

The patient was prescribed an additional fraction of 5Gy to make up the difference from the doses received during the first two fractions that were below those intended. The patient's total dose after nine fractions was 40Gy, which was the original prescribed dose.

6 Inspection Findings Associated With the Event (87103, 87132)

6.1 Inspection Scope

The inspector reviewed RCRH's NRC license and documentation related to the event to include the patient's treatment chart and a representative sample of other patient's treatment charts using the same protocol of treatment. The inspectors reviewed RCRH's standard operating procedures for other HDR treatments. Additionally, the inspectors interviewed licensee staff, including the authorized medical physicists, the authorized user, a nurse, a radiation therapist, and management representatives.

6.2 Observations and Findings

The requirements for written directives are in 10 CFR 35.40, and for procedures that cover written directives in 10 CFR 35.41. Interviews with the authorized user and authorized medical physicists indicated that there were standard practices used to implement the written directive. However, the HDR skin brachytherapy practices were not documented in a formal policy at RCRH.

The failure to implement and maintain written procedures to provide high confidence that each administration was in accordance with the written directive and treatment plan was identified as a violation of 10 CFR 35.41(a). (03003231/2018-001)

6.3 Conclusions

The NRC identified a violation of 10 CFR 35.41(a) for the failure to implement and maintain written procedures to provide high confidence that each administration was in accordance with the written directive.

7 Corrective Actions (87103, 87132)

7.1 Inspection Scope

The inspectors reviewed records and interviewed staff in order to evaluate the effectiveness of the licensees root cause analysis and associated corrective actions. The inspectors reviewed RCRH's 15-day report (ML18145A230), its root cause analysis and HDR skin brachytherapy procedures (ML18145A227).

The inspectors reviewed and evaluated the immediate and long-term corrective actions initiated by RCRH.

7.2 Observations and Findings

The inspector determined the licensee adequately performed a root cause analysis. As previously discussed the root and contributing causes consisted of the following:

- The licensee's failure to implement and maintain HDR skin brachytherapy procedures that would minimize or eliminate the possibility of administering an incorrect dose to the patient.

- The authorized medical physicist's inexperience with using custom immobilization device during HDR treatments.

- Both authorized medical physicists were not present during the CT simulation pre-planning.

To address these causes, the licensee implemented the following corrective actions:

- Reviewed the other HDR skin brachytherapy treatment performed to determine whether other possible medical events occurred with the same or similar circumstances; none were identified.

- Developed HDR skin brachytherapy procedures.

- To ensure that each piece of the custom device can be clearly visualized, any custom immobilization used will be photographed with and without the patient, during pre-planning simulation.

- Installed a computer monitor, keyboard, and mouse in the HDR treatment vault. This will support the verification of the setup used in the treatment room.

- Implemented a bar code scanning system, to track custom setup devices.

7.3 Conclusions

The RCRH implemented immediate and long-term corrective actions that provide reasonable assurance that similar events will not occur in the future and that patient treatments will be in accordance with the written directive and treatment plan.

8 Exit Meeting Summary

A preliminary exit briefing was conducted at the conclusion of the on-site inspection on April 3, 2018, to review the inspection findings as presented in this report. A final exit briefing was conducted telephonically with your radiation safety officer, Mr. Jim McKee, on May 11, 2018. Licensee representatives acknowledged the inspection findings. No proprietary information was identified.

SUPPLEMENTAL INFORMATION

PARTIAL LIST OF PERSONS CONTACTED

Licensee

Paulette Davidson, President
John Pierce, Vice President
Paul Clemments, Director Regional Cancer Care Institute
Nancy Klunder, Systems Director of Corporate Responsibility
James McKee, M.S., Authorized Medical Physicist and Radiation Safety Officer
Charles Carver, M.S., Authorized Medical Physicist
Daniel Petereit, M.D., Authorized User
Cheryl Achbach, Nurse
Tina Scott, Radiation Therapist

INSPECTION PROCEDURES USED

87132	Brachytherapy Programs
87103	Inspection of Material Licensees Involved in an Incident

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-03231/2018-001	VIO	One violation of 10 CFR 35.41(a) was cited for the failure to implement and maintain their procedures in a way that provided high confidence that each administration was in accordance with the written directive.

Closed

Notice of Violation from inspection report 030-03231/2018-001

Discussed

None

LIST OF ACRONYMS USED

CFR	*Code of Federal Regulations*
CT	Computer Tomography
Gy	gray
HDR	High Dose Rate Remote Afterloader Unit
NRC	U.S. Nuclear Regulatory Commission
RCRH	Rapid City Regional Hospital
RSO	radiation safety officer
VIO	Violation