UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 E. LAMAR BLVD.
ARLINGTON, TX 76011-4511

July 25, 2017

Mr. Greg Haar
Administrator
Siouxland Urology Center, LLC
455 Sioux Point Road
Dakota Dunes, SD 57049

SUBJECT: NOTICE OF VIOLATION AND NRC INSPECTION REPORT 030-36922/2017-001

Dear Mr. Haar:

This letter refers to the reactive inspection conducted on March 23-24, 2017, at your facility in Dakota Dunes, South Dakota, with continued in-office review of the causal factors of the event, through July 5, 2017. The inspection was conducted in response to Siouxland Urology Center's report of a medical event (Event Notification 52614) that was initially reported as an overexposure to a patient undergoing prostate seed brachytherapy. The inspection was an examination of activities conducted under your license as they relate to radiation safety and compliance with the U.S. Nuclear Regulatory Commission's (NRC) rules and regulations, and with the conditions in your license. Within these areas, the inspection consisted of a selected examination of procedures and representative records relevant to the medical event, observations of activities and facilities, and interviews with personnel. At the conclusion of the onsite portion of the inspection, the preliminary inspection findings were discussed with you and members of your staff. A final exit briefing was conducted telephonically with you on July 5, 2017. The enclosed report presents the results of this inspection.

Based on the results of this inspection, the NRC has determined that one Severity Level IV violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy which can be found at the NRC's Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The violation is cited in the enclosed Notice of Violation (Notice), and the circumstances surrounding it are described in detail in the subject inspection report. The violation involved Siouxland Urology Center's failure to maintain and implement written procedures to provide high confidence that each administration is in accordance with the written directive. The violation is being cited in the enclosed Notice because it was identified by the NRC during the inspection. The NRC's review determined that this failure was isolated and did not represent a programmatic weakness in Siouxland Urology Center's manual brachytherapy program.

You are required to respond to this letter and must 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: https://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html. 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 achieved should be addressed. The NRC 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. 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.

Should you have any questions concerning this letter or the enclosed Notice, please contact Mr. James Thompson at 817-200-1538 or Ms. Vivian Campbell at 817-200-1455.

Sincerely,

/RA by LLHowell Acting For/

Mark R. Shaffer, Director
Division of Nuclear Materials Safety

Docket: 030-36922
License: 40-34223-01

Enclosures:
1) Notice of Violation (Notice)
2) NRC Inspection Report 030-36922/2017-001

cc: w/Enclosures:
South Dakota Radiation Control Program Director

NOTICE OF VIOLATION AND NRC INSPECTION REPORT 030-36922/2017-001 - DATED JULY 25, 2017.

DISTRIBUTION:
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ADAMS ACCESSION NUMBER: ML17170A088

☒ SUNSI Review By: **JLT** ADAMS: ☒ Yes ☐ No ☐ Non-Publicly Available ☒ Publicly Available ☒ Non-Sensitive ☐ Sensitive Keyword: NRC-002

OFFICE	RIV:MLIB	C:MLIB	D:DNMS			
NAME	JLThompson	VHCampbell	MRShaffer			
SIGNATURE	***/RA/***	***/RA/***	***/RA by LLHowell Acting For/***			
DATE	7/5/2017	07/17/17	07/25/17			

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NOTICE OF VIOLATION

Siouxland Urology Center, LLC
Dakota Dunes, South Dakota

Docket: 030-36922
License: 40-34223-01

During the U.S. Nuclear Regulatory Commission (NRC) inspection conducted from March 23, 2017, through July 5, 2017, 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 that, for any administration requiring a written directive, licensees 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.
>
> 10 CFR 35.41(b)(2 and 3) require, in part, that the procedures required by paragraph (a) above must address the following items: (2) verifying that the administration was in accordance with the treatment plan and written directive; and (3) checking both manual and computer-generated dose calculations.
>
> Contrary to the above, as of March 16, 2017, for an administration requiring a written directive, the licensee failed to develop, implement, and maintain written procedures to provide high confidence that each administration was in accordance with the written directive. Specifically, the licensee's procedures related to prostate seed brachytherapy treatments failed address the need to verify that the administration was in accordance with the written directive and the need to check both manual and computer-generated dose calculations. On March 16, 2017, the manual and computer-generated calculations performed by the licensee's physicist for a prostate brachytherapy treatment were not checked prior to the administration, which resulted in a patient receiving an administration that was not in accordance with the written directive.
>
> This is a Severity Level IV violation (Section 6.3(d)(1))

Pursuant to the provisions of 10 CFR 2.201, Siouxland Urology Center, LLC, 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 for the violation: (1) the reason for the violation or, if contested, the basis for disputing the violation 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 was, or 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 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, U.S. 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.

Dated this 25th day of July 2017

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U.S. NUCLEAR REGULATORY COMMISSION

Region IV

Docket:	030-36922
License:	40-34223-01
Report:	2017-001
Licensee:	Siouxland Urology Center, LLC
Facilities:	Main Office
Location:	455 Sioux Point Road Dakota Dunes, South Dakota
Date:	March 23 through July 5, 2017
Inspectors:	James L. Thompson, Senior Health Physicist Materials Licensing and Inspection Branch
Approved By:	Vivian H. Campbell, Chief Materials Licensing and Inspection Branch
Attachment:	Supplemental Inspection Information

Enclosure 2

EXECUTIVE SUMMARY

Siouxland Urology Center, LLC
NRC Inspection Report 030-36922/2017-001

This was an announced, reactive inspection performed in response to a medical event at Siouxland Urology Center (Siouxland) located in Dakota Dunes, South Dakota, that was reported to the NRC on March 16, 2017 (Event Notification 52614). The medical event was related to the treatment of a patient using palladium-103 (Pd-103) brachytherapy seeds for treatment of the prostate, which resulted in the patient receiving a greater radiation dose to the prostate than prescribed. The reactive inspection focused on the causes of the medical event, as well as a review of previous prostate treatments performed by Siouxland, in an effort to determine whether this medical event was an isolated occurrence. This report describes the findings of the reactive inspection.

Radiation Dose Assessment

The licensee reported that the patient received an additional radiation dose of approximately 58 percent to the target volume of the prostate. Although an overexposure to the target volume of the prostate occurred, the licensee does not expect any adverse effects to the patient, because this overexposure was isolated to only the target volume of the prostate and not to other organs. (Section 4)

Direct, Contributing, and Root Causes

The direct cause of the medical event was the Authorized User implanting 110 Pd-103 seeds into the prostate rather than 80 Pd-103 seeds due to a miscalculation in the determination of activity per seed. (Section 5.3.1)

Several factors contributed to the medical event, including the proceduralized verbal notification of measurements and calculations and the medical physicist performing self-checks on his calculations. Additionally, the medical physicist was using a newly developed spreadsheet and failed to clear previously-entered data before the use of this spreadsheet on the day of the medical event. (Section 5.3.2)

The NRC determined that the root cause of the medical event was the licensee's failure to perform independent verifications of the data being used in the calculation of activity and number of seeds to be implanted, which was partly due to the failure of the licensee to develop written operating procedures to require this independent check prior to the administration of licensed material. (Section 5.3.3)

Inspection Findings

The NRC identified one violation of 10 CFR 35.41 involving the failure of the licensee to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. The licensee's procedures did not ensure that the administration was in accordance with the treatment plan and written directive, nor did the procedures address checking both manual and computer-generated dose calculations. (Section 6)

Corrective Actions

The licensee instituted immediate and long-term corrective actions to prevent recurrence of this type of event. These corrective actions included, but were not limited to: introducing an additional manual check of dose calculations, revising procedures to use a blank spreadsheet, and institution of a “time-out” to cross-check parameters with independent sources prior to future administrations. (Section 7)

Report Details

1 Program Overview (87132)

1.1 Inspection Scope

The inspector reviewed the NRC license and Siouxland's documentation related to the medical event, interviewed licensee staff, and observed Siouxland's re-enactment of the events that led to the medical event. Additionally, the inspector reviewed previous prostate brachytherapy administrations to identify whether this medical event represented an isolated occurrence.

1.2 Observations and Findings

Siouxland is authorized under NRC License 40-34223-01, Amendment 4, to use byproduct material to perform therapeutic medical administrations including permanent manual brachytherapy procedures in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 35.400.

Siouxland is a small private practice specializing in prostate seed brachytherapy implant treatments. The main office where the performance of prostate seed implants occurs is in Dakota Dunes, South Dakota. The only authorized user and the medical physicist are located in Sioux City, Iowa, approximately five miles away. There have been 13 patient treatments using Pd-103 since June 16, 2016, and all of these administrations were reviewed. During this review, no additional medical events or excessive radiation exposures involving prostate brachytherapy treatments were identified.

2 Background (87132, 87103)

The patient arrived at Siouxland on March 16, 2017, to undergo a treatment for prostate cancer; the patient had been previously diagnosed with adenocarcinoma of the prostate. The procedure was a Pd-103 prostate implant using a Mick applicator, which is a device that is used with multiple needles that are implanted into the prostate, and then the desired number of seeds are loaded into the needles. The procedure was performed with the urologist and radiation oncologist taking a series of trans-rectal ultrasound images which together assisted in the determination of the volume of the prostate. Using this data, the physicist used a nomogram that compared the volume of the patient's prostate gland to a corresponding total activity of Pd-103 that should be implanted into the prostate to achieve the desired dose of 125 Gy as was listed on the written directive. This total activity was then compared to the activity of Pd-103 in each seed to ascertain the number of seeds required to be implanted into the prostate. The physicist then entered this information into the newly developed spreadsheet, which calculated that 14 needles would be placed into the periphery of the prostate and 8 needles to the interior of the prostate. The periphery needles were to be loaded with 5-6 seeds each, and the interior needles were to be loaded with 3-4 seeds each. The physicist then verbally transmitted this data to the urologist and the oncologist.

For this particular procedure, since the activity of each seed was 1.67 millicuries, the oncologist should have implanted 80 seeds to achieve the prescribed dose of 125 Gy to the target volume of the prostate; instead, due to a calculation error made by the physicist, the oncologist implanted 110 seeds which delivered a dose to the target volume of the prostate of approximately 58 percent higher than the prescribed dose.

3 Event Chronology (87103)

3.1 Inspection Scope

The NRC inspector conducted interviews with licensee personnel and reviewed procedures and treatment plans. These inspection activities were conducted in an effort to reconstruct the events surrounding the medical event that occurred on March 16, 2017.

3.2 Observations and Findings

The following is a sequence of events that preceded the medical event referenced in this section:

October 11, 2016:

- The patient was diagnosed with an adenocarcinoma of the prostate, and the prostate was measured as 57 cubic centimeters (cc).
- The patient was placed on a three-month Lupron protocol to downsize the prostate for the full-strength Pd-103 implant.

March 16, 2017:

- The patient arrived at the licensee's facility to have a prostate treatment with Pd-103 seeds implanted to the prostate.
- The patient was escorted to the operating room where he was prepped, given general anesthesia, positioned on the table and cleansed in the implantation area.
- The medical physicist, urologist, and radiation oncologist (authorized user) arrived in the operating room and prepared the ultrasound transducer for placement to determine the new prostate volume, post Lupron protocol.
- The prostate volume was verbally transmitted to the medical physicist (23cc) who entered it into the excel spreadsheet. The spreadsheet was set up to calculate the number of needles and seeds to be placed in various locations of the prostate.
- The medical physicist failed to notice that the per-seed activity in the spreadsheet was already filled in and was different from the actual activity per-seed for the seeds being used on the day of the procedure on March 16, 2017. The spreadsheet had an activity of 1.26 millicuries per seed and the actual seed activity was 1.67 millicuries per seed. This error resulted in more seeds being implanted into the prostate (110 seeds) than were necessary (80 seeds) to deliver the intended dose of 125 Gy.
- The physician then used fluoroscopy to verify that the seeds had not been inadvertently placed in the bladder.
- The patient was released from the operating room. At this point, the medical physicist realized the error and notified the authorized user.
- The authorized user then reported the event to the NRC, and notified the urologist and the patient of the event.

4 Radiation Dose Assessment (87103, 87132)

The licensee described in their 15-day written report dated March 31, 2017 (ADAMS ML17101A660), that, as previously discussed, the prescribed dose of 125 Gy was expected to have been delivered to the prostate with an implanted activity of 135 millicuries of Pd-103; however, a different calculation was made which led to the implant of 184.8 millicuries. This was due to the wrong seed activity being used in the calculation.

On March 28, 2017, a post-implant volume study was performed on the patient to determine the actual dose to the prostate and surrounding organs due to the implanted activity of Pd-103 exceeding the desired activity. The volume study was performed using the Varian VariSeed treatment planning system. The licensee had a planning goal for 90% of the volume of the prostate (D-90) to receive a minimum 100% of the prescribed dose; this served as the lower bound for radiation dose to the prostate. The actual D-90 was determined to have been 157.81% of the prescribed dose. The plan also called for less than 50% of the target volume of the prostate to receive 150% or more (V-150) of the prescribed dose; this served as the upper bound for radiation dose to the prostate. The volume study revealed that the actual V-150 for this administration was 91.69%, which exceeded the planned V-150 by approximately 42%.

Additionally, the planning goal included a dose to the hottest 2 cc of the rectum to receive less than 100% of the prescribed dose to the prostate. The volume study showed that the dose to the hottest 2 cc of the rectum actually received 106% of the prescribed dose to the prostate (131.5 Gy).

Although this error resulted in the patient receiving a greater radiation dose to the prostate gland than was initially planned, the licensee concluded, based on these estimates, that the patient would experience no unusual side effects due to the additional radiation dose. This is based partly on the fact that the D-90 is a minimum dose projection to a portion of the prostate and not a maximum dose projection to the entire prostate. The licensee has been in weekly contact with the patient since the medical event that occurred on March 16, 2017, and only the normal and expected side effects of the procedure have been reported by the patient.

5 Causal Analysis (87103)

5.1 Inspection Scope

The inspector performed a root cause analysis, using the Events and Conditional Factors and 5 Why's analyses methods to review human factors, policies and procedures, management oversight, and operational characteristics of the brachytherapy preparation, planning, and treatment system program.

5.2 Siouxland's Causal Analysis

In the licensee's letter dated March 31, 2017, Siouxland performed a root cause analysis of the event and determined that the root cause of the medical event was that a second independent verification of the input data being used in the physics calculations was not being performed. Siouxland also determined that using a blank spreadsheet rather than a previously used copy would have prevented the miscalculations.

5.3 NRC's Independent Causal Analysis

The NRC determined that there were multiple causes for this medical event. The causes included, but were not limited to, human error, a lack of or inadequate procedures, and inattention to detail.

5.3.1 Direct Cause

The direct cause of the medical event was due to the oncologist implanting too many Pd-103 seeds into the patient's prostate as a result of the physicist's error in documenting the activity of the Pd-103 seeds.

5.3.2 Contributing Causes

One contributing cause of the medical event was the use of new software to calculate the number of seeds needed for the prostate treatment. Previously, the physicist would perform the calculations manually using a calculator the day of each procedure. On the day of the medical event, the physicist was using a newly developed spreadsheet which would perform the calculations for the number of seeds needed based on specific program inputs, such as seed activity and volume of the prostate.

Additionally, the physicist failed to clear the spreadsheet of all input parameters prior to the procedure. The physicist had mistakenly left the seed activity the same value as the practice run that had been performed the night before and failed to catch the error during the actual calculation for the prostate brachytherapy procedure the morning of March 16, 2017.

5.3.3 Root Cause

The root cause of the medical event was determined to be Siouxland's failure to perform independent verifications of the data being used in the calculation of activity and number of seeds to be implanted, which was due to the failure of the licensee to develop written operating procedures to require these independent verifications prior to the administration of licensed material.

5.4 NRC Conclusions

The NRC concluded that there were multiple causes for this medical event which included, but were not limited to, human error, a lack of or inadequate procedures, and inattention to detail. The NRC's independent causal analysis was in basic agreement with the licensee's causal analysis.

6 Inspection Findings Associated With the Medical Event (87132)

6.1 Inspection Scope

The inspector reviewed the NRC license and documentation related to the medical event to include the patient's treatment chart and a representative sample of other patient treatment charts using the same protocol of treatment. The inspector also reviewed Siouxland's operating procedures for performing manual brachytherapy.

Additionally, the inspector interviewed licensee staff, including the radiation safety officer (RSO), the authorized user (oncologist) assigned to treat the patient involved in the medical event, and the medical physicist.

6.2 Observations and Findings

10 CFR 35.41(a) states that, for any administration requiring a written directive, licensees 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.

10 CFR 35.41(b)(2 and 3) require, in part, that the procedures required by paragraph (a) above must address the following items: (2) verifying that the administration was in accordance with the treatment plan and written directive; and (3) checking both manual and computer-generated dose calculations.

On March 16, 2017, the licensee failed, for an administration requiring a written directive, to develop, implement, and maintain written procedures to provide high confidence that each administration was in accordance with the written directive. Specifically, the licensee's procedures related to prostate seed brachytherapy treatments failed address the need to verify that the administration was in accordance with the written directive and treatment plan, as well as the need to check both manual and computer-generated dose calculations. On March 16, 2017, the manual and computer-generated calculations performed by the licensee's physicist for a prostate brachytherapy treatment were not independently reviewed for accuracy prior to the administration which resulted in a patient receiving an administration that was not in accordance with the written directive.

6.3 Conclusions

The NRC identified one violation of 10 CFR 35.41(a) and (b)(2 and 3), involving the licensee's failure to develop, implement, and maintain written procedures to provide high confidence that each administration was in accordance with the written directive and the treatment plan.

7 Corrective Actions (87132)

Siouxland implemented numerous short-term corrective actions to prevent recurrence of this type of event, to include the following:

- The introduction of a new secondary hand calculation designed to confirm the original input values;
- A revision of their procedures for any physicist using Excel spreadsheets to require the use of a blank spreadsheet template as the starting point to all patient treatments;
- A revision of their procedures to include a verbal "timeout" to independently confirm the physicist's input parameter values for the dose calculations for each patient administration.

The licensee's long-term corrective actions, such as initial and recurrent training requirements for these changes to their procedures, will be addressed in the licensee's response to the Notice of Violation associated with this inspection report, as discussed with the licensee during the final exit briefing, described below.

8 Exit Meeting Summary

A preliminary exit briefing was conducted at the conclusion of the on-site portion of the inspection on March 24, 2017, with members of the licensee's staff. A final telephonic exit briefing was performed on July 5, 2017, with Greg Haar, Administrator. Licensee representatives acknowledged the reactive inspection findings. No proprietary information was identified.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

Greg Haar, Administrator
Kenneth McCalla, M.D., Urologist
Greg Naden, M.D., Radiation Oncologist
Russ Rupolo, M.S., Medical Physicist

INSPECTION PROCEDURES USED

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

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-36922/17001-01	VIO	Violation involving the failure to develop procedures to provide high confidence that the administration was in accordance with the written directive and treatment plan

Closed

None

Discussed

None

LIST OF ACRONYMS USED

CFR	*Code of Federal Regulations*
Gy	Gray
NRC	Nuclear Regulatory Commission
RSO	radiation safety officer
cc	cubic centimeter

Attachment