UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
612 EAST LAMAR BLVD, SUITE 400
ARLINGTON, TEXAS 76011-4125

December 10, 2010

EA-2010-182

Sanford Medical Center
dba Sanford USD Medical Center
ATTN: Karen Tobin, Vice President
Heart and Vascular Center of Excellence
P.O. Box 5039
Sioux Falls, South Dakota 57117-5039

SUBJECT: NRC INSPECTION REPORT 030-03249/10-001 AND NOTICE OF VIOLATION

Dear Ms Tobin:

This refers to the routine, unannounced inspection conducted on July 29, 2010, at Sanford Medical Center located in Sioux Falls, South Dakota, with continued in-office review through December 9, 2010. The inspection was an examination of activities conducted under your license as they relate to radiation safety and security, and to compliance with the Commission's rules and regulations, as well as the conditions of your license. Within these areas, the inspection consisted of a selected examination of procedures and representative records, observations of activities, and interviews with personnel. The inspector discussed the preliminary inspection findings with you and members of your staff at the conclusion of the onsite portion of the inspection. A final exit briefing was conducted telephonically with you on December 9, 2010. The enclosed report presents the results of this inspection.

During the telephonic exit briefing, Ms. Vivian Campbell and Mr. Rick Muñoz of my staff informed you that the NRC was considering escalated enforcement for an apparent violation of NRC requirements. The apparent violation involved a failure to adequately lock and secure the high dose-rate remote (HDR) afterloader brachytherapy unit within the treatment room when the unit was not in use or unattended. The circumstances surrounding the apparent violation, the significance of the issue, and the need for lasting and effective corrective actions were discussed with you at the inspection exit briefing. You have initiated corrective actions to address the violation. The corrective actions are documented in this report. Ms. Campbell also informed you that the NRC has sufficient information regarding the apparent violation and your prompt corrective actions to make an enforcement decision without the need for a predecisional enforcement conference or a written response from you. You agreed that a predecisional enforcement conference or additional written response was not needed.

Based on the information developed during the inspection, the NRC has determined that a violation of NRC requirements occurred. The violation is cited in the enclosed Notice of

Violation (Notice) and the circumstances surrounding it is described in detail in the inspection report. As noted above, the violation involved a failure to secure the HDR unit in the treatment room when not in use or unattended.

The NRC considers this violation significant because the security requirements provide a reasonable assurance that licensed material stored in controlled or unrestricted areas will be secured from unauthorized use, removal, or access. Therefore, this violation is categorized in accordance with the NRC Enforcement Policy as a Severity Level III violation. The NRC Enforcement Policy may be found on the NRC's Web site at www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html.

In accordance with the NRC Enforcement Policy, a base civil penalty of $3,500 is considered for each Severity Level III violation.

Because your facility has not been the subject of escalated enforcement action within the last two inspections, the NRC considered whether credit is warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section VI.C.2 of the Enforcement Policy. Based on your prompt and comprehensive corrective actions, the NRC has determined that *Corrective Action* credit was warranted. Your corrective actions included immediately securing the door to the HDR storage cabinet and enhancing the locking mechanisms with a more robust system. In addition, the oncology department revised its Standard Operating Procedure and Quality Management chart form to assure the security of the HDR unit. This revised policy included instructions for securing the unit and checking the effectiveness of the locking mechanism on a daily basis. All radiation oncology staff was trained on the new security policy on August 9, 2010.

Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this Severity Level III violation constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that 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 was achieved is already adequately addressed on the docket in the letter dated August 06, 2010 received via electronic mail. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's “Rules of Practice,” a copy of this letter, its enclosures, and your response if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC's Web site at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy,

proprietary, or safeguards information so that it can be made available to the public without redaction. If 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). The NRC also includes significant enforcement actions on its Web site at http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/.

Should you have any questions regarding this letter, the enclosed report, or the enclosed Notice, please contact Ms Vivian H. Campbell, Chief, Nuclear Materials Safety Branch A at (817) 860-8287.

Sincerely,

/RA/

Elmo E. Collins
Regional Administrator

Docket: 030-03249
License: 40-12378-01

Enclosures:
1. Notice of Violation
2. NRC Inspection Report 030-03249/10-001

cc w/Enclosures:
Robert J. Stahl, Administrator
South Dakota Radiation Control
Program Director
Office of Health Care Facilities
Licensure & Certification
615 E. 4th Street
Pierre, SD 57501

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Final: R:_DNMS

ADAMS	☐ No	☒ Yes	☒ SUNSI Review Complete	Reviewer Initials: RRM
☐Publicly Available		☒Non-publicly Available	☒Sensitive	☐ Non-sensitive
Category –**A.7 - Sensitive Internal**				

RIV:DNMS:NMSB-A	C:NMSB-A	C:NMSB-B	ACES	RC
RRMuñoz	VHCampbell	JEWhitten	RLKellar	KFuller
/RA/ C.Cain for	***/RA/ by email***	***/RA/C.Cain for***	***/RA/***	***/RA/***
11/22/2010	11/17/2010	11/22/2010	11/24/2010	11/30/2010

DD:DNMS	DRA	OE	RA	
RJCaniano	ATHowell	RJSummers	EECollins	
/RA/ C.Cain for	***/RA/BH for***	***/RA/by email***	***/Ra/***	
11/22/2010	12/01/2010	12/8/2010	12/10/2010	

OFFICIAL RECORD COPY T=Telephone E=E-mail F=Fax

NOTICE OF VIOLATION

Sanford Medical Center
Sioux Falls, South Dakota

Docket 030-03249
License 40-12378-01
EA-2010-182

During an NRC inspection conducted on July 29, 2010, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

> License Condition 19.A of byproduct materials License 40-12378-01 requires, in part, that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures in the license application dated November 01, 2004.
>
> Section 3.3.1.1 of Standard Operating Procedure NM-X2, "Radiation Safety Procedures for the Nucletron Microselectron HDR, Version-2," of the license application specifies, in part, that the high dose remote (HDR) afterloader unit will be secured, when the unit is not in use.
>
> Contrary to the above, from June 15 through July 29, 2010, the licensee failed to secure the HDR unit from unauthorized removal or access from its storage area when the unit was not in use. Specifically, the licensee failed to secure the Nucletron Microselectron HDR unit, which was stored in the linear accelerator room. Although the unit was placed in its storage cabinet using a mechanical locking mechanism, the system failed to function as designed, leaving the unit unsecured.
>
> This is a Severity Level III Violation (Supplement VI).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to be taken to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in the letter dated August 6, 2010, received via electronic mail. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, clearly mark your response as a "Reply to a Notice of Violation; EA-2010-182, and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region IV, within 30 days of the date of the letter transmitting this Notice.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

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

Dated this 10th day of December 2010.

U.S. Nuclear Regulatory Commission
Region IV

Docket:	030-03249
License:	40-12378-01
Report:	030-03249/2010-001
EA:	EA-2010-182
Licensee:	Sanford Medical Center dba Sanford USD Medical Center
Facility:	Sanford USD Medical Center
Location:	Sioux Falls, South Dakota
Date:	July 29, through December 9, 2010
Inspector:	Rick Muñoz, Health Physicist Nuclear Materials Safety Branch A
Approved By:	Vivian H. Campbell, Chief Nuclear Materials Safety Branch A
Attachment:	Supplemental Inspection Information

EXECUTIVE SUMMARY

Sanford Medical Center
NRC Inspection Report 030-03249/2010-001

This was an unannounced inspection of licensed activities involving the use and storage of byproduct material at the Sanford Medical Center in Sioux Falls, South Dakota. The inspection was an examination of activities conducted under NRC Materials License 40-12378-01. The inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel. This report describes the findings of the inspection.

Program Overview

Sanford Medical Center was authorized to use and store byproduct material for performance of nuclear medicine and radiation therapy activities at its facilities located in Sioux Falls, South Dakota. (Section 1)

Inspection Findings

The licensee failed to secure a high dose-rate remote (HDR) afterloader unit containing licensed material while it was in storage. (Section 2)

Corrective Actions

- Upon discovery, the licensee immediately locked the HDR cabinet. (Section 3)

- As an interim measure, a new lock equipped with an automatic spring was installed on the cabinet on July 29, 2010. This lock was durable in structure and secure in design with a steel connection plate to ensure that each of the double doors are secured. (Section 3)

- A communication was sent on July 29, 2010, by the Chief Medical Physicist to the cancer therapy staff regarding a change in procedure for checking the HDR cabinet to ensure it is locked and secure. The therapy staff will check the HDR cabinet doors during daily start up and shut down of the linear accelerator. The morning security check is electronically recorded in the licensee's computer quality control software. (Section 3)

- The Radiation Oncology Department Standard Operating Procedure for Quality Assurance was revised to reflect documentation that the HDR cabinet door is secured after each treatment. This policy change was completed on July 30, 2010. (Section 3)

- After consulting with the Director of Security, two separate locking mechanisms (one on each of the adjacent storage closet doors) were installed on August 5, 2010, to provide an added level of security and prevent an inadvertent error by failing to attach the connecting plate. (Section 3)

- A cancer therapy staff in-service meeting was held on August 9, 2010, to reinforce the security training and procedural changes. (Section 3)

- As of August 13, 2010, a cable was installed to secure the HDR unit to the floor inside of the HDR cabinet acting as a secondary physical security measure. (Section 3)

- An emergency drill involving the HDR source was completed on August 13, 2010. Sanford Medical Center security and safety officers participated as responders and observed the drill. (Section 3)

Report Details

1 Program Overview

1.1 Inspection Scope

The inspector reviewed the organization and scope of licensed activities including the nuclear medicine, manual brachytherapy, high dose-rate remote (HDR) afterloader brachytherapy, and positron emission tomography (PET) programs.

1.2 Observations and Findings

Sanford Medical Cancer was authorized for the medical use of radioactive material for diagnostic and therapeutic procedures. A written directive was required for therapeutic administrations. Two use locations were authorized on the license, which included the main hospital campus, and the cancer center located across the street but contiguous with the main campus. The Novoste A1000 intravenous brachytherapy device was returned to the manufacturer and removed from the license in April 2007.

The radiation safety officer (RSO) was an authorized user and chaired the radiation safety committee (RSC), which meets quarterly or as needed. The radiation protection program has strong support from hospital management who was well represented in every RSC meeting. The department has a certified nuclear medicine technologist (technologists) supervisor and a lead technologist. Sanford Medical Center also contracts the services of a medical physicist to assist the RSO. The brachytherapy department was managed by one of the licensee's medical physicists.

Sanford Medical Center operated a 24-hour department with 19 technologists and 13 authorized users performing 7,000 scans per year in five imaging rooms and one PET dual head camera. The department received single unit doses and bulk technetium-99m from a radiopharmacy for standard nuclear medicine diagnostic studies. Iodine-131 in doses greater than 30 millicuries was administered approximately 15-20 times per year, all in capsule form. Outpatients were released in accordance with the requirements in 10 CFR 35.75 (NUREG 1556, Vol. 9, App U and Regulatory Guide 8.39). All technologists rotate through the nuclear medicine department, the hot lab, and the cancer center. A smaller pool of technologists rotate through the PET facility located at the cancer center performing 1,200 scans per year.

The HDR unit was stored and used in the linear accelerator treatment room in the cancer center. The HDR was used once every 2-3 weeks. The cancer center performed 3-5 implants per month, primarily with iodine-125 and palladium-103 seeds. The brachytherapy sources were stored in the nuclear medicine hot lab and were inventoried on a quarterly schedule. All requirements for manual brachytherapy appeared to have been met.

All waste generated was disposed of by decay-in-storage and maintained in the hot lab. Radioactive material waste-storage areas were well secured. Access to all use and

storage areas were controlled. A storage area was also located in the basement of the PET area.

The RSO reviewed written directives on a quarterly schedule and reviewed the radiation safety program annually. Problems identified were tracked, corrected, documented, and followed-up by the medical physicist and RSC. The review of the dosimetry records revealed that the PET technologists received higher radiation exposure than the nuclear medicine technologists. Maximum exposures recorded for the PET technologists during calendar year 2009 were 1029 mRem total effective dose equivalent, and 5400 mRem extremity compared to the recorded exposures for the nuclear medicine technologists of 202 mRem total effective dose equivalent and 1960 mRem extremity doses.

1.3 Conclusions

Licensee performed activities as authorized by NRC materials License 40-12378-01.

2 Inspection Findings

2.1 Inspection Scope

Information was collected through discussions with licensee personnel, tours of the facility, observations of licensed activities, demonstrations of procedures, and a review of records. Licensed activities were assessed as they related to the safety and security of the radioactive material and the licensee's policies and procedures for handling licensed materials. The areas evaluated included, but were not limited to, training, personnel dosimetry, instrumentation, security, postings, audits, and radiation surveys.

2.2 Observations and Findings Considered for Escalated Enforcement

License Condition 19.A of NRC License 40-12378-01 required, in part, that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures in the license application dated November 1, 2004. Section 3.3.1.1 of Standard Operating Procedure M-X2, "Radiation Safety Procedures for the Nucletron Microselectron HDR, Version-2," of the license application specified, in part, that the HDR unit would be secured, when the unit was not in use.

Upon arriving at Sanford Medical Center's cancer center, the NRC inspector walked with licensee representatives into the control panel area. The medical physicist gave the inspector a brief overview of the radiation safety program, and then he and the inspector proceeded into the HDR treatment room. The licensee's HDR afterloader unit was operated in a shared space with the linear accelerator. The inspector and medical physicist approached the HDR's storage cabinet. The 4-foot square HDR cabinet, which was a two door built-in closet configuration, was located in the corner of the room.

Before the medical physicist inserted the key into the double door locking mechanism, the inspector tested the door to verify that it was locked and secured. The door swung

open with little effort, demonstrating that the doors to the HDR cabinet, although closed, were not properly locked and secured.

Although the doors to the storage cabinet were equipped with one mechanical lock on one of the doors, the inside manual latch on the opposite door was not engaged. This resulted in a failure of the locking configuration, therefore, making the locking system ineffective and not functioning in the manner in which it was designed. Specifically, although the mechanical lock was turned to the lock position, the latch on the opposite inside door was not engaged, which resulted in both doors opening with relative ease when the inspector checked to verify if the doors were properly locked.

The layout of the treatment area provided limited control into the treatment room. Unless there was a treatment scheduled, there was no one in or around the treatment room or control panel area to provide constant surveillance of the licensed material. However, there was staff at the registration desk in the department controlling access to the department. The licensee stated that it would be unlikely that a member of the public could reach the HDR without a member of the cancer center staff stopping them and asking why they were there. Nevertheless, the hallway directly adjacent to the treatment room could be publically accessed.

The HDR unit was used approximately twice per month. Based on a record review, the last time the unit was used prior to the inspection was on June 15, 2010. It appeared that the key was turned to activate the locking mechanism, but the licensee authorized personnel failed to engage the manual dead bolt and failed to verify that the doors were adequately secured. The licensee did not have procedures in place for verifying that the locking mechanism for the double doors HDR cabinet was functioning after a treatment was completed, and when the room was left unattended. The root cause of this violation appears to be human error.

It was determined that since the last use of the HDR on June 15, 2010, through July 29, 2010, the licensee failed to secure the HDR unit from unauthorized removal or access from its storage area. Although the storage cabinet was equipped with a mechanical locking mechanism, the system failed due to human error, leaving the unit unsecured. This was identified as a violation of License Condition 19.A of NRC License 40-12378-01. (030-03249/2010-001-001)

2.3 Conclusions

The inspection identified a Severity Level III violation. The violation involved the failure to secure from unauthorized removal and limit access to licensed materials stored in a controlled or restricted area when not in use or unattended. No actual security consequence occurred. However, the NRC considers this violation significant because the requirement to secure a device while in storage provides a fundamental assurance that radioactive materials will not be compromised.

3 Corrective Actions

Upon discovery of the unsecured HDR unit, an authorized medical physicist listed on the license for the cancer center took action by immediately locking the HDR cabinet. As an interim measure, a new lock was installed on the cabinet while NRC was still on site. Pictures of the newly installed locking mechanism were taken and sent via electronic mail to the NRC inspector on July 29, 2010. This lock was durable in structure and secure in design with a steel connection plate to ensure that each of the double doors are secured. This lock has a spring action that will positively secure both doors without the problems of the previous locking system.

To validate that an appropriate lock was selected for securing the HDR unit, the Director of Security was consulted to inspect the cabinet and lock in order to provide a recommendation. Security advised that rather than utilizing one lock with a steel plate connection, two separate locking mechanisms should be used (one on each of the adjacent doors) to provide an added level of security and prevent an inadvertent error by failing to attach the connecting plate. This new locking system was installed on August 5, 2010. Photographs of the new installation were provided to NRC on August 6, 2010.

On July 29, 2010, a communication was sent by the Chief medical physicist to the cancer therapy staff regarding a change in procedure for checking the HDR cabinet to ensure it is locked and secure. The therapy staff will now check the HDR cabinet doors during daily start up and shut down of the linear accelerator. The morning security check will be electronically recorded in Argus, the licensee's computer QC software. A cancer therapy staff in-service meeting was held on August 9, 2010, by the medical physicist, to reinforce the security training and procedural changes. A screen capture of the new Argus QC page for the linear accelerator sharing the vault with the HDR was provided to NRC as an attachment to the August 6, 2010 letter.

The Radiation Oncology Department Standard Operating Procedure Q-003, Section 3.1.2.2, for quality assurance was revised to reflect documentation that the HDR cabinet door will be secured and checked after each treatment. This policy change was completed on July 30, 2010. On August 13, 2010, a metal security cable was installed to lock the HDR unit to the floor inside of the HDR cabinet, which acts as a secondary physical security measure. A copy of the revised security procedure was provided to NRC as an attachment to the August 6, 2010 letter.

In addition, an emergency drill involving the HDR source was completed on August 13, 2010. Sanford Medical Center security and safety officers participated as responders and observed the drill.

4 Exit Meeting Summary

A preliminary exit briefing was conducted on July 29, 2010, at the conclusion of the onsite inspection with administration, the radiation safety officer, and technical staff. A final telephonic exit briefing was conducted with hospital administration, the radiation safety officer and technical staff on December 9, 2010, to review the inspection findings as presented in this report. Sanford Medical Center acknowledged the inspector's findings. No proprietary information was identified.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

Jennifer Stapleton, CNMT, Nuclear Medicine Supervisor
Fred Linton Lovrien, M.D., Radiation Safety Officer/ Authorized User
Richard Massoth, Ph.D., Medical Physicist
Jeffrey P. Masten, M.S. Chief Medical Physicist
Traci Hollingshead, Medical Health Physicist/Consultant
Forest Weston, CNMT, Lead Technologist
Michele Strasser, Clinical Manager
Diana Berkland, CNO
Randy Bury, COO
Kay Santema, VP Sanford Cancer Center
Marsha Daner, Nursing Coordinator
Dani Reiff, RN/Floor Nurse
Steve Moeckly, Dosimetrist
Ann Myers, CNMT/PET Center
Mark Heath, CNMT/PET Center
Robin Rayman, CNMT/PET Center
Mark Palpka, CNMT/Diagnostic
Tracey Hollingshead, CNMT/Diagnostic
Ashley Hanson, CNMT/Diagnostic
Kenna Furgeson, SNMT/Diagnostic
Nancy Anderson, Executive Assistant

INSPECTION PROCEDURES USED

87131	Nuclear Medicine, Written Directive required
87132	Brachytherapy

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-03249/10-001	VIO	A violation involving a failure to secure a high dose-rate remote (HDR) afterloader unit containing licensed material while it was in storage.

Closed

None

Discussed

None

LIST OF ACRONYMS USED

CFR	Code of Federal Regulations
CNMT	Certified Nuclear Medicine Technologist
EA	Enforcement Action
HDR	High Dose-Rate Remote Afterloader Unit
NRC	Nuclear Regulatory Commission
VIO	Violation