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

January 21, 2010

EA-09-290

John C. Kinna
Chief Administrative Officer
Great Falls Clinic
1400 29th Street South
P.O. Box 5012
Great Falls, MT 59403

SUBJECT: NRC INSPECTION REPORT 030-35944/09-001 AND NOTICE OF VIOLATION

Dear Mr. Kinna:

This refers to the routine, unannounced inspection conducted on October 29, 2009, at Great Falls Clinic located in Great Falls, Montana, with continued in-office review through December 10, 2009. 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 at the conclusion of the onsite portion of the inspection. Additional inspection items were discussed with Mr. Ralph Young of your staff via telephone and electronic mail from October through December 2009. The NRC conducted a final exit briefing telephonically with you on January 7, 2010. The enclosed report presents the results of this inspection.

During the telephonic exit briefing, Messrs. Anthony Gaines and Jason Razo of my staff informed you that the NRC was considering escalated enforcement for two apparent violations of NRC requirements. The apparent violations involved: 1) a failure to secure from unauthorized removal or access licensed materials that were stored in controlled or unrestricted areas and 2) a failure to secure the high dose-rate remote afterloader unit, the console, the console keys, and the treatment room when not in use or unattended. The circumstances surrounding these apparent violations, the significance of the issues, 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 violations. These corrective actions are documented in this report. Mr. Gaines also informed you that the NRC had sufficient information regarding the apparent violations and your corrective actions to make an enforcement decision without the need for a predecisional enforcement conference or a written response from you. You agreed that neither a predecisional enforcement conference nor a written response were needed.

Based on the information developed during the inspection, the NRC has determined that two violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the inspection report. As noted above, the violations involved: (1) a failure to secure from unauthorized removal or access licensed materials that were stored in controlled or unrestricted areas, and (2) a failure to secure the high dose-rate unit, the console, the console keys, and the treatment room when not in use or unattended. Specifically, an high dose-rate remote afterloading unit containing licensed material was not secured from unauthorized removal while in storage, and the console keys were found unsecured at the console and the unit keys were found in the high dose-rate unit.

The NRC considers these violations significant because these requirements provide a reasonable assurance that licensed materials stored in controlled or unrestricted areas will be secured from unauthorized use, removal, or access. Therefore, these violations are categorized collectively in accordance with the NRC Enforcement Policy as a Severity Level III problem. 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 $3500 is considered for a Severity Level III problem.

Because your facility has not been the subject of escalated enforcement actions within the last two inspections, the NRC considered whether credit was 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 is warranted. Your corrective actions included immediately securing the door to the high dose-rate suite and securing the unit and console keys in the medical physicist's office. In addition, a security policy was developed by the radiation safety officer and approved by the physician authorized to use the high dose-rate unit. This policy included instructions for securing the unit and keys when not in use. All radiation oncology staff was trained on the new security policy on October 30, 2009.

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 problem constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance was achieved is already adequately addressed on the docket in the facsimile dated October 30, 2009, and the electronic mail dated November 23, 2009. 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 Mr. Anthony Gaines, Chief, Nuclear Materials Safety Branch A, at (817) 860-8252.

Sincerely,

/RA/

Elmo E. Collins
Regional Administrator

Docket: 030-35944
License: 25-27721-01

Enclosures:
1. Notice of Violation
2. NRC Inspection Report 030-35944/09-001

cc w/Enclosures 1 and 2:
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Licensing Bureau Chief
Division of Quality Assurance
Department of Public Health and
Human Services
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P.O. Box 202953
Helena, MT 59620-2953

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Hard copy:
RIV Materials Docket File (5th Floor)

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ADAMS	☐ No	***X Yes***	***X SUNSI Review Complete***	***Reviewer Initials: JMR***
X Publicly Available	☐Non-publicly Available		☐Sensitive	**X Non-sensitive**
Category – **KEYWORDS**:	EA-09-290 NOV Great Falls Clinic			

RIV:DNMS:NMSB-A	C:NMSB-A	C:NMSB-B	ACES	RC
JMRazo	ADGaines	JEWhitten	MCMaier	KFuller
/RA/	***/RA/***	***/RA/***	***/RA/***	***/RA/***
12/14/09	12/15/09	12/15/09	12/17/09	01/08/10

DD:DNMS	DRA	OE	RA	
ATHowell	CACasto	NHilton	EECollins	
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01/12/10	01/14/10	01/19/10	01/21/10	

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NOTICE OF VIOLATION

Great Falls Clinic.
Great Falls, Montana

Docket: 030-35944
License: 25-27721-01
EA-09-290

During an NRC inspection conducted on October 29, 2009, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. 10 CFR 20.1801 requires that the licensee shall secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

Contrary to the above, on October 29, 2009, the licensee failed to secure from unauthorized removal or access licensed materials that were stored in controlled or unrestricted areas. Specifically, the licensee stored a high dose-rate remote afterloader unit containing licensed material in a designated controlled area, and did not secure the radioactive material from unauthorized removal or access.

B. 10 CFR 35.610 (a)(1) requires that the licensee shall secure the unit, the console, the console keys, and the treatment room when not in use or unattended.

Contrary to the above, on October 29, 2009, the licensee failed to secure the unit, the console, the console keys, and the treatment room when not in use or unattended. Specifically, the console and unit were found in the designated controlled area, which was unattended and not secured. The console was found with its key inserted.

This is a Severity Level III problem (Supplements IV and VI).

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to be taken to correct the violations and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in the facsimile dated October 30, 2009, and the electronic mail dated November 23, 2009. 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-09-290, 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 of Violation.

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's Web site at www.nrc.gov/reading-rm/pdr.html or 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.

Dated this 21st day of January 2010

U.S. Nuclear Regulatory Commission
Region IV

Docket:	030-35944
License:	25-27721-01
Report:	030-35944/09-01
EA:	EA-09-290
Licensee:	Great Falls Clinic
Facility:	Great Falls Clinic Specialty Center
Location:	Great Falls, Montana
Date:	October 29, 2009
Inspectors:	Jason Razo, Health Physicist Nuclear Materials Safety Branch A
Approved By:	Anthony Gaines, Chief Nuclear Materials Safety Branch A
Attachment:	Supplemental Inspection Information

EXECUTIVE SUMMARY

Great Falls Clinic
NRC Inspection Report 030-35944/09-01

This was an unannounced inspection of licensed activities involving the use and storage of byproduct material at the Great Falls Clinic in Great Falls, Montana. The inspection was an examination of activities conducted under NRC Materials License 25-27721-01. 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

Great Falls Clinic is authorized to use and store byproduct material for performance of nuclear medicine and radiation therapy activities at its facilities located in Great Falls, Montana. (Section 1)

Inspection Findings

- The licensee failed to secure a high dose-rate remote afterloader containing licensed material while it was in storage. (Section 2.2)

- The licensee failed to secure the high dose-rate unit, the high dose-rate console, the high dose-rate console keys, and the treatment room when unattended by trained personnel. (Section 2.2)

Corrective Actions

- On October 29, 2009, the dosimetrist retrieved the two sets of keys (unit and console), and closed and locked the only entrance into the high dose-rate suite before leaving the area. (Section 3)

- On October 30, 2009, the authorized user and the radiation safety officer trained the staff on a new security policy for the high dose-rate unit and treatment room. (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, and high dose-rate remote (HDR) afterloader brachytherapy programs.

1.2 Observations and Findings

Great Falls Clinic is a community clinic, authorized for 10 CFR 35.100, 35.200, 35.300, 35.400, and 35.600 activities as authorized in NRC materials license 25-27721-01.

The nuclear medicine department performs a full range of diagnostic and therapeutic studies. The licensee receives a technetium-99m generator every three weeks or as supplies allow. Other radioisotopes used by the department include indium, gallium, and iodine. There are two full-time technologists with another part-time technologist that assists when necessary. The licensee has an agreement with a positron emission tomography imaging provider that brings a mobile truck to the licensee's address once per week. Licensee uses therapeutic quantities of iodine-131 on an outpatient basis; written directives are used in conformance with licensee procedures and NRC regulations.

The Clinic Cancer Care performs HDR afterloader brachytherapy using a Varian Medical Systems afterloader that contained 5.2 curies of iridium-192 at the time of the inspection. The medical physicist also coordinates use of permanent implant seeds for manual brachytherapy. The dosimetrist provides support services for both functions.

1.3 Conclusions

Licensee performs activities as authorized by NRC materials license 25-27721-01.

2 Inspection Findings

2.1 Inspection Scope

Information was gathered through discussions with cognizant personnel, tours of the facility, observations of licensed activities, demonstrations of procedures, and a review of records. Licensed activities were examined as they relate 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

Upon arriving at the Clinic Cancer Care of Great Falls Clinic, the NRC inspector walked into the office area to locate licensee personnel. After walking around the office area for a few minutes, a receptionist directed the inspector to the dosimetrist. The dosimetrist gave the inspector a brief overview of the radiation safety program, and then he stated that the authorized medical physicist, who was also the radiation safety officer, would be in later that morning.

Before heading to the nuclear medicine department, the inspector asked the dosimetrist to show him the HDR suite. The HDR/CT Sim suite was not far from the medical physicist's office. When the dosimetrist and inspector arrived at the suite, the door was ajar, and no licensee personnel were directly present to provide surveillance of the HDR unit that was in storage in the suite. In addition, the keys that were used to secure the source in the unit and to operate the console were both found unsecure and unattended at the unit and console respectively.

The NRC regulations in 10 CFR 20.1801 require licensees to secure licensed materials when they are in storage and not in use. When the inspector and dosimetrist arrived at the HDR/CT Sim suite that morning, the HDR unit was in storage, was not in use, was not being supervised by an authorized employee, and the suite was not locked. This was identified as a violation of 10 CFR 20.1801. (030-33184/09-001)

Furthermore, the NRC regulations in 10 CFR 35.610(a)(1) supplement the security requirements in 10 CFR 20.1801 by requiring, in part, that licensees secure the unit and console keys when not in use. At the time of the suite tour with the dosimetrist, the NRC inspector observed that the unit keys were inserted in the unit, and the console keys were inserted in the console in the control room and the HDR suite was not secured. Neither the unit nor the set of keys were under the control of an authorized user. This was identified as a violation of 10 CFR 35.610(a)(1). (030-33184/09-002)

No actual security consequence occurred. However, compliance with the above regulations provides a fundamental assurance that radioactive materials will not be compromised while in storage at a licensee's facility.

A root cause of these violations appears to be a failure to implement the conditions of the amendment submitted to the NRC to add the HDR unit in 2005. The amendment contained procedures that were adequate to satisfy the regulations, but they were not implemented to a satisfactory degree to meet compliance with the above regulations.

2.3 Conclusions

The inspection identified a Severity Level III problem. The problem involved: a 1) failure to secure from unauthorized removal and limit access to licensed materials stored in controlled or unrestricted areas, and 2) a failure to secure the unit, the console, the console keys, and the treatment room when not in use or unattended.

3 Corrective Actions

During the inspection at the Clinic Cancer Care office in Great Falls, Montana, the dosimetrist retrieved the two sets of keys (unit and console), closed and locked the only entrance into the HDR/CT Sim suite, and secured the keys in the medical physicist's office. On October 30, 2009, the authorized user and the radiation safety officer wrote a formal policy for securing the HDR unit, suite, and console. On that same day, the radiation oncology staff was trained in the new procedure. This policy and the list of trained staff were included in the facsimile dated October 30, 2009. Further, the radiation safety officer committed to perform audits of the implementation of the new security policy via periodic walk-downs of the HDR/CT Sim suite. Failures to comply with the policy would include counseling and retraining of the staff. In addition, the keys to the unit and console are to remain under the custody of the authorized user when not in use. These actions were discussed in an electronic mail dated November 23, 2009.

4 Exit Meeting Summary

A preliminary exit briefing was conducted at the conclusion of the on site inspection with the radiation safety officer and your administrative staff. A final telephonic exit briefing was conducted with the radiation safety officer on January 7, 2010, to review the inspection findings as presented in this report. He acknowledged the inspector's findings. No proprietary information was identified.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

Ralph D Young, Radiation Safety Officer
Jeffery A Stephenson, MD, Authorized User
John C. Kinna, Chief Administrative Officer
Sue Reppe, Director of Oncology Services
Gayle Knudson, Director of Radiology
Mark Tucker, Dosimetrist

INSPECTION PROCEDURES USED

87131	Nuclear Medicine, Written Directive required
87132	Brachytherapy

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-35944/09-001	VIO	A violation involving a failure to secure from unauthorized removal or limit access to licensed materials that are stored in controlled or unrestricted areas.
030-35944/09-002	VIO	A violation involving the failure to secure the high dose-rate unit, the console, the console keys, and the treatment room when not in use or unattended.

Closed

None

Discussed

None

LIST OF ACRONYMS USED

CFR	Code of Federal Regulations
EA	Enforcement Action
HDR	High Dose-Rate Remote afterloader unit
NRC	Nuclear Regulatory Commission
VIO	Violation