

REPLY TO A NOTICE OF VIOLATION; EA-09-071**May 28, 2009****FedEx Overnight Mail**

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Regional Manager
Washington, DC 20555-001

With Copy To:
Regional Administrator
Region IV
612 East Lamar Blvd.
Arlington, TX 76011-4125

To Whom It May Concern:

Please accept this letter from Memorial Hospital of Sweetwater County (Hospital) as written **Reply to a Notice of Violation; EA-09-071** received subsequent to an unannounced inspection conducted on February 12, 2009. We take regulatory compliance matters very seriously and had, prior to receipt of your call and subsequent written notification of the violation, conducted a thorough review of the circumstances that led to the violation, identified the root cause of the violation, and taken prompt corrective actions to address the immediate concerns and prevent recurrence of the violation. Many such actions were taken prior to the exit of the inspector on the day of the inspection.

In reply to the Notice of Violation; EA-09-071, we provide the following information as per NRC guidelines noted in the Notice of Violation, Enclosure 1, page 1:

1. Reason for Violation

- A. The violation occurred secondary to an unintentional oversight by the Nuclear Medicine Technologist on duty resulting in failure to secure access to licensed materials which are stored in the Nuclear Medicine Hot Lab.

REPLY TO A NOTICE OF VIOLATION; EA-09-071

2. Corrective Steps Taken and Results Achieved

- A. February 12, 2009: Conducted a physical inspection and concluded that the hot lab and storage areas were locked when not in use.

Results Achieved

- (1) Verification that failure to secure access was not a routine occurrence.
- (2) Assessment of current security processes, identification of additional mechanisms that could provide greater security and remove some of the reliance on staff behavior to assure that the hot lab and storage areas remain locked when not in use.

- B. February 12, 2009: Retraining of the two Nuclear Medicine Technologists occurred. This training included security procedures for controlling the radioactive material in the hot lab.

Results Achieved

- (1) Assurance and verification that the Nuclear Medicine technologists are aware of the importance of securing radioactive materials.
- (2) Assurance and verification that the Nuclear Medicine technologists know and are committed to following the process for assuring security of the hot lab and storage areas.

- C. February 12, 2009: A sign was posted on the door to the hot lab to remind staff to close and secure the hot lab area upon exiting the area.

Results Achieved

- (1) Reminder provided to all medical imaging staff that the main nuclear medicine door is to be closed when someone enters or exits the room
- (2) Reminder provided to all medical imaging staff that the hot lab door is to be closed at all times to secure the area.

- D. February 23, 2009: A policy regarding the storage and security of all radioactive material was drafted and implemented by the technologists immediately. This policy will be used as part of the annual refresher training.

Results Achieved

- (1) Process for security and storage of all radioactive material is now available for anyone who may need to know the information.
- (2) The policy helps to assure consistency in providing for security and storage of all radioactive material.

- (3) The policy provides an additional tool for use in annual refresher training for staff.

3. Corrective Steps Taken to Avoid Further Violations

- A. April 1, 2009: Automatic door closures were installed on both the hot lab and main entry doors to the Nuclear Medicine room.
- B. April 29, 2009: Keyless Lock Pad, requiring authorized personnel ID badge for entry, was installed on the main Nuclear Medicine door. This includes a mechanism for automatic closure of the door.
- C. All personnel working with the licensed material receive annual training regarding security of radioactive materials which is a continuing practice of our radiation safety program. A new policy has been adopted to specify this practice.
- D. RSO will continue to monitor the security of the hot lab storage area on a weekly basis, and will keep a record as part of our weekly performance improvement.
- E. Employee counseling occurred as result of admitted knowing failure to follow policy and procedure to secure access to licensed materials stored in the Nuclear Medicine Hot Lab.

4. Date Full Compliance will be Achieved

- A. Full compliance was achieved April 29, 2009.

In conclusion, Memorial Hospital of Sweetwater County takes very seriously compliance with regulatory standards. Your feedback as to our compliance is welcomed and we are willing to provide any additional information you may require as you evaluate our reply. We appreciate the opportunity to reply to the Notice of Violation; EA-09-071.

Respectfully,



Bruce James
Chief Executive Officer



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

May 14, 2009

EA-09-071

Bruce James
Chief Executive Officer
Memorial Hospital of Sweetwater County
1200 College Drive
Rock Springs, Wyoming 82901

SUBJECT: NOTICE OF VIOLATION AND NRC INSPECTION REPORT 030-13672/09-001

Dear Mr. James:

This refers to the unannounced inspection conducted on February 12, 2009, at Memorial Hospital of Sweetwater County in Rock Springs, Wyoming. The inspection was an examination of activities conducted under your license as they relate to safety and compliance with the Commission's rules and regulations. 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 your staff at the conclusion of the onsite portion of the inspection. The inspector conducted a final exit briefing telephonically with you on April 17, 2009. The enclosed report presents the results of this inspection.

In a telephone conversation on April 17, 2009, Ms. Vivian Campbell, Mr. Jason Razo, and Mr. Mark Haire 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 secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas. The circumstances surrounding this apparent violation, the significance of the issue, and the need for lasting and effective corrective action were discussed with members of your staff at the inspection exit briefing. Additionally, you have initiated corrective actions, some of which are documented in this report, to address the violation. Further, we provided you an opportunity to (1) respond to the apparent violation addressed in this inspection report within 30 days of the date of this letter or (2) request a predecisional enforcement conference. Ms. Campbell and Messrs. Haire and Razo also informed you that the NRC had sufficient information regarding the apparent violation 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 a predecisional enforcement conference or 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 are described in detail in the subject inspection report. As noted above, the violation involved a failure to secure licensed materials that are stored in controlled or unrestricted areas. Licensed materials used in the nuclear medicine department were stored in the nuclear medicine hot lab. While the nuclear medicine technologist was away from the area for approximately 2 minutes to check a work schedule, the hot lab door remained ajar. The technologist failed to fully secure, and then lock the hot lab door. The circumstances surrounding the apparent violation, the significance of the issue, and the need for lasting and effective corrective action was discussed with members of your staff at the inspection exit meeting.

The NRC considers this violation significant because this security requirement provides a reasonable assurance that licensed material stored in controlled or unrestricted areas will be secured from unauthorized removal or access. Therefore, this violation has been categorized in accordance with the NRC Enforcement Policy at Severity Level III. 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 in the amount of \$3,500 is considered for a Severity Level III violation.

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 and locking the hot lab door, promptly retraining current nuclear medicine technologists regarding the security policies and procedures of the department and adding training on security procedures to the annual refresher training provided to the technologists.

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.

You are required to respond to the Notice and should follow the instructions specified in the enclosed Notice when preparing your response. The information provided in the excerpt from NRC Information Notice 96-28 may be helpful when preparing your response. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

Memorial Hospital of Sweetwater County - 3 -
EA-09-071

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and 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 <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 www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html.

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

Sincerely,


Elmo E. Collins
Regional Administrator

Docket No. 030-13672
License No. 49-17940-01

Enclosures:

1. Notice of Violation
2. NRC Inspection Report 030-13672/09-001
(w/Attachment)
3. NRC Information Notice 96-28

cc w/Enclosures 1 and 2:
Scott W. Ramsay
Radiation Safety Officer
Wyoming Office of Homeland Security
2421 E. 7th Street
Cheyenne, WY 82001

NOTICE OF VIOLATION

Memorial Hospital of Sweetwater County
Rock Springs, Wyoming

Docket No. 030-13672
License No. 49-17940-01
EA 09-071

During an NRC inspection conducted on February 12, 2009, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

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 February 12, 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 radioactive materials, authorized for medical use, in a hospital hot lab, a designated controlled area, and did not secure the radioactive materials therein from unauthorized removal or access by failing to lock the hot lab door.

This is a Severity Level III violation (Supplement IV).

Pursuant to the provisions of 10 CFR 2.201, Memorial Hospital of Sweetwater County is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-001 with a copy to the Regional Administrator, Region IV, 612 East Lamar Blvd., Arlington, Texas 76011-4125 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; EA-09-071" and should include for each 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 to avoid further violations, 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 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.

Because 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, to the extent possible, it 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, proprietary, or safeguards 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 are required to post this Notice within 2 working days.

Dated this 14th day of May 2009.

U.S. Nuclear Regulatory Commission
Region IV

Docket No.: 030-13672
License No.: 49-17940-01
Report No.: 030-13672/09-001
EA No.: 09-071
Licensee: Mémorial Hospital of Sweetwater County
Facilities: Main Office
Location: Rock Springs, Wyoming
Date: February 12, 2009
Inspector: Jason Razo, Health Physicist
Nuclear Materials Safety Branch A
Approved By: Vivian Campbell, Chief
Nuclear Materials Safety Branch A
Attachment: Supplemental Inspection Information

EXECUTIVE SUMMARY

Memorial Hospital of Sweetwater County
NRC Inspection Report 030-13672/09-001

This was a routine, unannounced inspection of licensed activities involving the use and storage of byproduct material at Memorial Hospital of Sweetwater County. The inspection was an examination of activities conducted under NRC Materials License 49-17940-01, as they relate to radiation safety and to compliance with the Commission's rules and regulations, and the conditions of the license. Within these areas, 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

Memorial Hospital of Sweetwater County is authorized under its NRC License to possess and use byproduct material for medical diagnostic imaging and therapy procedures. Activities primarily are conducted in the nuclear medicine imaging room and material is stored and prepared in the hot lab area. (Section 1)

Inspection Findings Considered for Escalated Enforcement

- The licensee failed to secure from unauthorized removal or access licensed materials that were stored in the hot lab, a controlled area. This was identified as a violation of 10 CFR 20.1801. (Section 2.2)

Corrective Actions

- On February 12, the licensee ensured by physical inspection that the hot lab and storage areas were locked when not in use.
- On February 12, the licensee retrained all nuclear medicine technologists on security procedures for controlling the radioactive material and hot lab.
- On February 12, the licensee posted a sign on the door to the hot lab to remind staff to close and secure the door upon leaving the hot lab.

Report Details

1 Program Overview (87131)

1.1 Inspection Scope

The inspector reviewed the license and supporting documentation, interviewed licensee staff, and examined storage and use locations at Memorial Hospital of Sweetwater County (MHSC). Collectively, the documents reviewed described the licensee's implementation of its NRC license requirements and its radiation safety program.

1.2 Observations and Findings

Under its NRC byproduct materials license, MHSC operates a nuclear medicine imaging department that administers radiopharmaceuticals in unsealed form to patients. Many imaging and localization studies use the radioisotope technetium-99m. The licensee obtains the technetium-99m from a molybdenum-99 generator that it receives once per week. In addition, MHSC is authorized to receive sodium iodide containing iodine-131 in the form of capsules for therapy procedures. Certified nuclear medicine technologists (CNMTs) are responsible for the preparation, safety, and security of the radioactive material on a daily basis. The lead technologist also serves as the radiation safety officer and provides oversight and direction to the radiation safety program.

2 Inspection Findings (87131)

2.1 Inspection Scope

Interviews with licensee staff and observations of the nuclear medicine department and its storage locations constituted the bulk of the inspection. 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 inspector evaluated training, shipping/receiving, audits, instrument calibrations, dosimetry, and storage of licensed material.

2.2 Observations and Findings Considered for Escalated Enforcement

2.2.1 Material Security and Control

The NRC's regulation, 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.

The inspector entered the hospital around 7:30 a.m. MDT through the main entrance. The inspector followed signs to the Diagnostic Medical Imaging Department and proceeded down the hallways toward the nuclear medicine imaging room. Upon arrival at the imaging room, the inspector noted that the exam room door was ajar. The inspector knocked then entered the imaging room and determined that no one was

present. The inspector then walked over to the hot lab entrance that was at the rear of the exam room. The inspector observed that the hot lab door was also open and not secured.

The inspector then immediately exited the hot lab and began to exit the exam room. As the inspector was staged to exit the exam room, the CNMT on duty was entering.

The CNMT immediately challenged the inspector and asked him to identify himself. The inspector did so and proceeded to interview the CNMT. The inspector determined that he had walked down the hallway to check the work schedule for a coworker that had recently called him and that the total time that the hot lab was left unattended and unsecured by the CNMT was approximately two minutes.

Both the nuclear medicine imaging room door and the hot lab room door had locking mechanisms, but neither was engaged at the time the inspector arrived. Based on the physical arrangement of the nuclear medicine facility, if either door had been closed and secured, no security violation would have occurred.

At the time of the inspection, radioactive materials including a generator containing 0.300 curies of molybdenum-99 and sealed check sources were present in the hot lab and hot lab storage area.

On February 12, 2009, the licensee failed to secure from unauthorized removal or access licensed materials that were stored in the nuclear medicine hot lab, a designated controlled area. This instance was identified as an example of a violation of 10 CFR 20.1801. (030-13672/09-001)

2.3 Conclusions

The inspection identified one violation for failing to secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas in the nuclear medicine hot lab.

3 **Corrective Actions (87131)**

During the inspection, MHSC took many immediate corrective actions. On February 12, 2009, the licensee ensured that the hot lab and storage areas were locked when not in use. The inspector observed the nuclear medicine staff close and secure the hot lab when licensed activities involving materials in the hot lab (e.g., administering radiopharmaceuticals to a patient) were not being conducted and when access to the hot lab area was not needed to perform the inspection.

In addition, on February 12, 2009, the radiation safety officer retrained all nuclear medicine technologists on security procedures for the radioactive material and the control of the hot lab.

Also on February 12, 2009, the radiation safety officer posted a sign on the door to the hot lab to remind staff of security procedures for the hot lab and radioactive materials. Specifically, the instructions stated, in part, that staff must close and secure the hot lab door upon leaving the hot lab.

Further, the radiation safety officer will ensure that annual refresher training for radiation workers includes training on MHSC's security procedures.

4 Exit Meeting Summary

A preliminary exit briefing was conducted at the conclusion of the on site inspection with the Vice President of Operations, the Director of Medical Imaging, and the Radiation Safety Officer. A final telephonic exit briefing was conducted with representatives of MHSC on April 17, 2009, to review the inspection findings as presented in this report. Licensee representatives acknowledged the inspector's findings. No proprietary information was identified during the inspection.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

Bruce James, Chief Executive Officer
Linda Minh, Vice President of Operations
Tracie Suller, Director of Medical Imaging
Keith Carnahan, Radiation Safety Officer
Joe Faigl, Nuclear Medicine Technologist

INSPECTION PROCEDURES USED

87131 Nuclear Medicine Programs, Written Directive Required

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-13672/09-001 VIO A violation involving the failure to secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas

Closed

030-13672/05-001 VIO A violation involving the failure to post copies of the regulations or a notice describing them and where they can be found

Discussed

None

LIST OF ACRONYMS USED

CFR Code of Federal Regulations
CNMT Certified Nuclear Medicine Technologist
EA Enforcement Action
MDT Mountain Daylight Time
MHSC Memorial Hospital of Sweetwater County
NRC Nuclear Regulatory Commission
VIO Violation