



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

August 30, 2011

ATTN: Barry Scott Monfore, M.D.
Radiation Safety Officer
St. Mary's Healthcare Center
800 East Dakota
Pierre, South Dakota 57501

SUBJECT: NRC INSPECTION REPORT 030-12639/2011-001 AND NOTICE OF VIOLATION

Dear Dr. Monfore:

This refers to the inspection conducted on July 26, 2011, at your facility in Pierre, South Dakota. During this inspection, the NRC examined activities conducted under your license as they relate to public health and safety and with the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel. Preliminary inspection findings were discussed with you at the conclusion of the onsite portion of the inspection. A final telephonic exit briefing was conducted with Mr. Benjamin Shoup of your staff on August 4, 2011.

Based on the results of this inspection, the NRC has determined that two Severity Level IV violations of NRC requirements occurred. The first violation involved a failure to maintain adequate security of check sources in the nuclear medicine department hotlab. The second violation involved the failure to perform contamination wipes on incoming packages.

These violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The violations are cited in the enclosed Notice of Violation (Notice). The violations are being cited in the Notice because they were identified by the NRC during the inspection.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. For your consideration and convenience, NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," is enclosed. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

St. Mary's Healthcare Center
Pierre, South Dakota

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In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," 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 document 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.

Sincerely,

/RA/

G. Michael Vasquez, Chief
Nuclear Material Safety Branch A

Docket: 030-12639
License: 40-07328-03

Enclosures:

1. Notice of Violation
2. NRC Information Notice 96-28

cc w/ Enclosure 1:

South Dakota Radiation Control Program Director

St. Mary's Healthcare Center
Pierre, South Dakota

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bcc w/Enclosure 1:

R. Caniano, D: DNMS

V. Campbell, DD: NMSB-A

C. Cain, SMA: DNMS

G.M. Vasquez, C: NMSB-A

J. Whitten, C: NMSB-B

NMSB-A

M. Herrera, Fee Coordinator

Hard Copy:

RIV Materials Docket File (5th Floor)

Hard copy:

RIV Materials Docket File (5th Floor)

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R:_DNMS

ADAMS	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input checked="" type="checkbox"/> SUNSI Review Complete	Reviewer Initials: JMR	
<input checked="" type="checkbox"/> Publicly Available		<input type="checkbox"/> Non-publicly Available		<input type="checkbox"/> Sensitive	<input checked="" type="checkbox"/> Non-sensitive
Category – KEYWORD:					
DNMS:NMSBA	DNMS:NMSBA:BC				
JMR5	GMVasquez				
/RA/	/RA/				
08/08/11	08/30/11				

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T=Telephone

E=E-mail

F=Fax

NOTICE OF VIOLATION

St. Mary's Healthcare Center
Pierre, South Dakota

Docket: 030-12639
License: 40-07328-03

During an NRC inspection conducted from July 26, 2011, through August 4, 2011, 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 secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

Contrary to the above, on July 26, 2011, the licensee did not secure from unauthorized removal or limit access to cesium-137, barium-133, and cobalt-57 sources located in the nuclear medicine hotlab, which is a controlled area. Specifically, the licensee failed to secure the door of the hotlab, and no licensee staff was present to prevent unauthorized removal or access to licensed materials.

This is a Severity Level IV violation (Section 6.7).

- B. 10 CFR 20.1906(b) requires each licensee to monitor the external surfaces of packages labeled with a Radioactive White I, Yellow II, or Yellow III label for: (1) radioactive contamination, unless the package contains only radioactive material in the form of a gas or in special form as defined in 10 CFR 71.4; and (2) radiation levels, unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in 10 CFR 71.4 and Appendix A to Part 71.

10 CFR 20.1907(c) requires licensees to perform the monitoring required by paragraph (b) above, as soon as practicable, but not later than 3 hours after receipt of the package if it is received during the licensee's normal working hours, or not later than 3 hours from the beginning of the next working day if it is received after working hours.

Contrary to the above, from July 12, 2005, through July 26, 2011, the licensee received packages labeled with Radioactive White I and Yellow II labels during working hours, the packages were not exempt from the monitoring requirement for radioactive contamination, and the licensee did not perform the required monitoring. Specifically, the packages received by the licensee contained unit doses of technetium-99m and iodine-123 containing up to 45 mCi each in unsealed form.

This is a Severity Level IV violation (Section 6.7).

Pursuant to the provisions of 10 CFR 2.201, St. Mary's Healthcare Center is hereby required to submit a written statement or explanation within 30 days of the date of the letter transmitting this Notice of Violation (Notice) to:

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555-0001

with a copy to:

U.S. Nuclear Regulatory Commission
ATTN: Regional Administrator
612 E. Lamar Blvd., Suite. 400
Arlington, TX 76011-4125

This reply should be clearly marked as a "Reply to a Notice of Violation" 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, 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:

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 Web site at <http://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 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). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

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

Dated this 30th day of August 2011