



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 EAST LAMAR BLVD
ARLINGTON, TEXAS 76011-4511

January 14, 2013

Chuck Wright
Chief Executive Officer
St. James Healthcare
400 S. Clark Street
P.O. Box 3300
Butte, Montana 59702

SUBJECT: NRC INSPECTION REPORT 030-12143/2012-001

Dear Mr. Wright:

This refers to the routine unannounced inspection that was conducted on December 20, 2012, at your facility in Butte, Montana. 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 and with the conditions of the license. Within these areas, the inspection consisted of selected examination of procedures and representative records and interviews with personnel. Inspection findings were discussed with Mr. Gary Bailey, Senior Director Imaging, Cardiology, and Pulmonary Services, at the conclusion of the inspection.

Based on the results of this inspection, the NRC has determined that one Severity Level IV violations of NRC requirements occurred. The violation was 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 violation is cited in the enclosed Notice of Violation (Notice) because they were identified by the NRC during the inspection, rather than being self-identified by the licensee. The violation involved a failure to amend your license to include an authorized user who was performing thyroid treatments.

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. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, Enclosure 1 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 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).

Should you have any questions regarding this letter or the enclosed Notice, please contact Mr. Don Stearns at 817-200-1176 or the undersigned at 817-200-1130.

Sincerely,

/RA/

G. Michael Vasquez, Chief
Nuclear Materials Safety Branch A

Docket: 030-12143
License: 25-13173-02

Enclosures:

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

cc w/Enclosure 1:
Montana Radiation Control Program Director

Internal distribution w/Enclosure 1:

E. Collins, RA
 S. Reynolds, DRA
 V. Campbell, D:DNMS
 J. Whitten, C:DNMS/NMSB-B
 M. Herrera, Fee Coordinator
 R4DNMS_MS-A

Hard copy:
 RIV Materials Docket File
 Administrative Assistant Area

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R:_DNMS\2012\ St James Healthcare IR 12-001.docx

MLXXXXXXXX

ADAMS: <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes		<input checked="" type="checkbox"/> SUNSI Review Complete	Reviewer Initials: DLS
		<input checked="" type="checkbox"/> Publicly Available	<input checked="" type="checkbox"/> Non-Sensitive
		<input type="checkbox"/> Non-publicly Available	<input type="checkbox"/> Sensitive
KEYWORD:			
RIV:DNMS/NMSB-A	C:NMSB-A		
DLStearns	MVasquez		
/RA/	/RA/		
01/09/13	01/14/13		

OFFICIAL RECORD COPY

T=Telephone

E=E-mail

F=Fax

NOTICE OF VIOLATION

St. James Healthcare
Butte, Montana

Docket: 030-12143
License: 25-13173-02

During an NRC inspection conducted on December 20, 2012, one violation of NRC requirements was identified. In accordance with NRC Enforcement Policy, the violation is listed below:

10 CFR 35.40(a) states, in part, "A written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 megabecquerels (MBq), any therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material"

Contrary to the above, on at least two occasions, written directives were not dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 megabecquerels (MBq). Specifically on September 24, 2011, and November 8, 2012, written directives were dated and signed by an individual who was not listed as an authorized user on the license.

This is a Severity Level IV violation (Section 6.3)

Pursuant to the provisions of 10 CFR 2.201, St. James Healthcare, 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.

In accordance with 10 CFR 19.11, you may be required to post this Notice within 2 working days. However, you are reminded to review your NRC security orders for superseding requirements that limit the release of information to certain individuals.

Dated this 14 day of January 2013

Enclosure 1