UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 E. LAMAR BLVD.
ARLINGTON, TX 76011-4511

September 15, 2014

Jeremy Evans, Vice President,
Professional Services
Kootenai Health
2003 Kootenai Healthway
Coeur d'Alene, ID 83814-2611

SUBJECT: NRC INSPECTION REPORT NO. 030-32264/2014-001 AND NOTICE OF VIOLATION

Dear Mr. Evans

This letter refers to the routine, unannounced inspection conducted on August 18, 2014, at your facility at 2003 Kootenai Healthway, Coeur d'Alene, Idaho. The inspection continued with in-office reviews until September 09, 2014. 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 an interview with your staff. Preliminary inspection findings were discussed with you and your staff at the conclusion of the onsite inspection. A final telephonic exit briefing was conducted with Mr. Robert Matthews, PhD of your staff on September 10, 2014.

Based on the results of this inspection, the NRC has determined that one Severity Level IV violation 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 it was identified by the NRC during the inspection. The violation involved the failure to ensure that an authorized user dated and signed written directives prior to the administration of I-131 sodium iodide greater than 1.11 megabecquerels (30 microcuries), as required by Title 10 of the Code of Federal Regulations (CFR) Section 35.40(a) and License Condition 12.C. of NRC License 11-27307-01. Specifically, the licensee was under the impression that physicians that were being supervised by an authorized user of I-131, which included reviewing the written directive, could date and sign the written directive. Therefore, for the period reviewed during the inspection, the inspector noted that there were written directives that were dated and signed by physicians that were not authorized by License Condition 12.C. for the use of I-131 in quantities greater than 30 microcuries.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC's

review of your response to the Notice will also 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, its enclosure, and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management 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.

Should you have any questions regarding this letter or the enclosed Notice, please contact Mr. Anthony Gaines at 817-200-1252 or the undersigned at 817-200-1130.

Sincerely,

/RA/

G. Michael Vasquez, Chief
Nuclear Materials Safety Branch A
Division of Nuclear Materials Safety

Docket No.: 030-32264
License No.: 11-27307-01

Enclosure:
Notice of Violation (Notice)

cc w/encl: State of Idaho, Radiation Control Program Director

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G. Michael Vasquez, Chief
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cc w/encl: State of Idaho, Radiation Control Program Director

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X SUNSI Review By: **ADG**		ADAMS **X** Yes ☐ No	**X** Publicly Available ☐ Non-Publicly Available		**X** Non-Sensitive ☐ Sensitive		Keyword:
OFFICE	NMSB-B	C:NMSB					
NAME	ADGaines	GMVasquez					
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OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Kootenai Health
Coeur d'Alene, Idaho

Docket: 030-32264
License: 11-27307-01

During the U.S. Nuclear Regulatory Commission (NRC) inspection conducted from August 18, 2014, with continued in-office reviews through September 09, 2014, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

A. 10 CFR 35.40(a) states, in part, that a written directive must be dated and signed by an authorized user before the administration of iodine-131 (I-131) sodium iodide greater than 1.11 mega becquerels (MBq) (30 microcuries).

Condition 12.C. of NRC License No. 11-27307-01 lists the individuals who are authorized users for medical use as indicated above.

Contrary to the above, from September 19, 2012, to August 18, 2014, written directives were not dated and signed by an authorized user before administration of I-131 sodium iodide greater than 30 microcuries. Specifically, the licensee administered I-131 in quantities greater than 30 microcuries to patients and some of the written directives were dated and signed by physicians, who were not listed in Condition 12.C. for the use of I-131. The physicians were working under the supervision of an authorized user listed in Condition 12.C. for the use of I-131, who as part of the supervision reviewed the written directives.

This is a Severity Level IV violation (Section 6.3).

Pursuant to the provisions of 10 CFR 2.201, Kootenai Health, 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 two working days.

Dated this 15th day of September 2014.

Enclosure