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

August 8, 2016

Mr. Todd Russell
Director of Medical Imaging & Radiation Oncology
Eastern Idaho Health Services, Inc.
dba Eastern Idaho Regional Medical Center
P. O. Box 2077
Idaho Falls, ID 83403

SUBJECT: NRC INSPECTION REPORT 030-32290/2016-001 AND NOTICE OF VIOLATION

Dear Mr. Russell:

This letter refers to the routine, unannounced inspection conducted on July 15, 2016, at your facilities in Idaho Falls, Idaho. The inspection was an examination of activities conducted under your license as they relate to public health and safety, to confirm compliance with the U.S. Nuclear Regulatory Commission's (NRC) rules, regulations, and with the conditions of your license. Within these areas, the inspection consisted of a selected examination of procedures and representative records, observation of licensed activities, independent radiation measurements, and interviews with personnel. The preliminary inspection findings were discussed with Jeff Sollis, Chief Operations Officer, Paula Cutler, Medical Imaging Manager, and you at the conclusion of the onsite portion of the inspection. A final telephonic exit briefing was conducted with you on July 27, 2016.

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, which can be found at the NRC's Web site at www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The violation is cited and described in the enclosed Notice of Violation (Notice). The violation involved the failure to have written directives dated and signed by an Authorized User (AU) prior to the administration of therapeutic doses of radiation from byproduct material. The violation was identified in April 2016 by one of the licensee's Authorized Medical Physicists (AMP). As a corrective action, the AMP initiated implementation of an additional quality check item on a "Quality Check List" for high dose rate brachytherapy. The quality check item is for the AMP to verify that the written directive is dated and signed by an AU prior to the initiation of the therapeutic procedure. The NRC inspector confirmed that there have been no recurrences of the violation since the corrective action was initiated in April 2016. However, the NRC believes that this corrective action may not be sufficient or lasting in order to prevent future recurrences of the violation, such as when different AMPs or AUs are involved with a therapeutic procedure. The enclosed Notice, which requires a response in writing, provides you with the opportunity to further describe any additional corrective actions taken and/or planned in order to prevent recurrence of the violation.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The guidance in NRC Information Notice 96-28, “Suggested Guidance Relating to Development and Implementation of Corrective Action,” may be helpful in preparing your response. You can find the Information Notice on the NRC website at: http://pbadupws.nrc.gov/docs/ML0612/ML061240509.pdf. Information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance will be (was) achieved should be addressed. The NRC will review your response to the Notice 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 "Agency Rules of Practice and Procedure," 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 Janine F. Katanic, PhD, CHP, at 817-200-1151 or the undersigned at 817-200-1191.

Sincerely,

/RA/

Ray L. Kellar, P.E., Chief
Nuclear Materials Safety Branch A
Division of Nuclear Materials Safety

Docket: 030-32290
License: 11-27346-01

Enclosure:
Notice of Violation

cc w/Enclosure:
Mr. Mark Dietrich
State of Idaho
Radiation Control Program Director

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Ray L. Kellar, P.E., Chief
Nuclear Materials Safety Branch A
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Docket: 030-32290
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Notice of Violation

cc w/Enclosure:
Mr. Mark Dietrich
State of Idaho
Radiation Control Program Director

DISTRIBUTION:

S. Morris	M. Shaffer	L. Howell
R4DNMS_MS-A	R4DNMS_MS-B	

ADAMS ACCESSION NUMBER:

Cover Letter (w/ Enclosure) X SUNSI Review by: JFK	ADAMS X Yes ☐ No	X Publicly Available ☐Non-Publicly Available	X Non-Sensitive ☐Sensitive	Keyword: N/A	
OFFICE	RIV:NMSB-A	RIV:C:NMSB-A			
NAME	JFKatanic	RLKellar			
SIGNATURE	***/RA/***	***/RA/***			
DATE	08/08/16	08/08/16			

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Eastern Idaho Health Services, Inc.
dba Eastern Idaho Regional Medical Center
Idaho Falls, Idaho

Docket No. 030-32290
License No. 11-27346-01

During an NRC inspection conducted on July 15, 2016, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

> 10 CFR 35.40(a) requires, in part, that a written directive must be dated and signed by an Authorized User before the administration of any therapeutic dose of radiation from byproduct material.
>
> Contrary to the above, from June 16, 2015, to July 15, 2016, the licensee failed to have written directives dated and signed by an Authorized User before the administration of any therapeutic dose of radiation from byproduct material. Specifically, from June 16, 2015, to July 15, 2016, written directives were not dated and signed by an Authorized User for seven procedures, before the administration of a therapeutic dose of radiation from an iridium-192 sealed source in a high dose rate remote afterloader unit.
>
> This is a Severity Level IV Violation (Section 6.3.d)

Pursuant to the provisions of 10 CFR 2.201, Eastern Idaho Health Services, Inc., 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: (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 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 requiring information 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.

Your response will be made available electronically for public inspection in the NRC Public Document Room or in 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. 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).

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

Dated this 8th day of August 2016