

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

August 29, 2016

Subject: Reply to a Notice of Violation

Easter Idaho Regional Medical Center / Idaho Cancer Center Action Plan:

Violation Description:

The NRC conducted an unannounced inspection on July 15, 2016, at the Idaho Cancer Center at Eastern Idaho Regional Medical Center, EIRMC. A Severity Level IV Violation (Section 6.3.d) was cited, under 10 CFR 35.40 (a) "failure to have written directives dated and signed by the Authorized User (AU) prior to the administration of therapeutic doses of radiation from byproduct material".

Initial Corrective Steps:

Issue was originally discovered in April of 2016 by staff. Upon discovery, workflow changes and Quality Checklists, were created within the record and verify software, Mosaiq. The implemented Quality Checklists eliminated the possibility of patients receiving an HDR treatment without a physician signed written directive. No treatments have occurred without the physician signed written directive since.

Background of Vendor Connectivity Issue:

When EIRMC purchased the HDR unit there was a specified line item purchase that stated connectivity between Mosaiq and the HDR. The original quote is dated July 29, 2014. The HDR unit was installed and operational in October of 2015. At that time the vendor of Mosaiq, Elekta, disclosed there was a "bug" in the connectivity software and there was no date provided for correction. The connectivity is a critical piece of the treatment delivery workflow that inherently ensures physician signatures are in place before treatment delivery can be administered.

NRC INSPECTION REPORT 030-32290/2016-001 AND NOTICE OF VIOLATION
Docket No.: 030-32290
License No.: 11-27346-01
Control No.: 590849

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Off-Campus Locations:

Behavioral Health Center
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208.227.2100

The Cancer Center
3245 Channing Way
208.227.2700

The Imaging Center
1670 John Adams Pkwy
208.535.4555

Physical Therapy Specialties
2840 Channing Way
208.529.7999

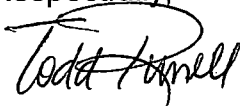
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(RGV-IV)

Corrective Steps and Full Compliance:

Elekta currently has resolved the connectivity issue, and provides a resolution for the connectivity software. EIRMC has been in constant discussion with the vendor, and is in the process of implementing the resolution. The first step in completing this process is to upgrade the service pack for the Mosaik software, which is scheduled for September 23rd, 2016. Upon completion of the service pack upgrade, Elekta software engineers will come on-site to connect Mosaik to the HDR unit. This is scheduled for October 5th–7th 2016. When connectivity is completed on October 7, 2016 the system will not be capable to administer a treatment without the Radiation Oncologist written directive appropriately completed. This will prevent the 10 CFR 35.40 (a) finding from occurring. The Idaho Cancer Center at Eastern Idaho Regional Medical Center will be in full compliance of the cited findings. As a second layer of assurance, EIRMC will continue the manual Quality checklist items that are were originally implemented and currently in place. The AMP who implemented the manual Quality checklist has provided education on the current workflow to ensure any covering AU's or AMP's will follow the same specified workflow process.

Please let me know if you have any additional questions or concerns.
Thank you.

Respectfully,



Todd Russell
Director of Medical Imaging & Radiation Oncology
Eastern Idaho Regional Medical Center

cc:
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