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

September 5, 2017

Attention: Document Control Desk

Subject: Reply to a Notice of Violation

To Whom It May Concern,

This letter is in response to the NRC Notice of Violation dated August 21, 2017. Notice of Violation is a result from the NRC inspection conducted on July 25, 2017 at Eastern Idaho Regional Medical Center (EIRMC). The Idaho Cancer Center (ICC) at EIRMC acknowledges the findings of the inspection: a non-compliant condition of NRC requirements, pertaining to a single treatment performed on May 25, 2017. While the violation was an isolated event, programmatic review of procedures and an internal audit of treatments was completed and raised awareness identifying the existing procedures in place at that time of the finding were not adequate when applied to a certain subset of treatment types. The ICC and EIRMC have implemented immediate corrective changes to workflow and procedure to prevent the identified non-compliant scenario. This written response is to confirm and inform the NRC of implemented improvements to workflow and procedure, ensuring compliance to the cited standard (10 CFR 35.40(a).

Violation as stated in the August 21, 2017 Notice of Violation:
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, on May 25, 2017, the licensee failed to have a written directive dated and signed by an Authorized User prior to the administration of a therapeutic dose of radiation from byproduct material. Specifically, for a skin treatment using a Valencia applicator, a written directive was not dated and signed by an Authorized User prior to the administration of a therapeutic dose of radiation from an iridium-192 sealed source in a high dose rate remote afterloader unit. This was the only time that this applicator was used for this type of treatment, and represented an isolated failure to have written directive dated and signed by an Authorized User prior to the administration of a therapeutic dose of radiation from byproduct material.

Reason for Violation
An immediate internal audit of treatment documentation was completed and it was determined that the non-compliant violation was truly an isolated event. The treatment in question was unique to a Valencia applicator where hand calculations and spreadsheets were performed in place of the standard treatment planning system, which is utilized for all other treatment modalities at the center. At the time of this report, an error exists with the interface of the Mosaiq record and verify system and the treatment unit. This error prohibits ordinary use of the record and verify system, which normally only allows treatments that are associated with a digitally signed and dated written directive to be sent to the treatment unit. In the case of treatments not planned using the designated treatment planning system, to date, being just Valencia skin treatments, the treatment is manually programmed into the treatment unit and manually updated in the record and verify system; this process bypasses the digital record and verify requirement for a written directive to be signed and dated. On May 25, 2017 the Authorized User was directly involved in the planning and treatment process, and verbally approved the treatment with staff; however, the written directive was documented and signed shortly after the treatment rather than before treatment. The ICC believes that reliance on the Mosaiq record and verify system combined with a treatment modality infrequently performed at the center, which requires working outside of routine standard procedures, creates an opportunity for treatment prior to verification that a written directive has been completed and signed.

Prevention of Future Violations
Prior to the non-compliant finding, the ICC engaged the vender to mitigate the error between the Mosaiq record and verify system, and the treatment unit. This would allow certain benefits of the system, such as the requirement of a signed written directive before treatment, to apply to all brachytherapy treatment modalities. The violation on May 25, 2017 demonstrates that until routine use of the system applies to all treatment modalities, a more robust policy must be followed to ensure written directives are completed and signed by the Authorized User before any treatment delivery.

Effective immediately, a digitally time stamped assessment will be performed by the ICC prior to all brachytherapy treatments that do not allow use of the digital workflow within the Mosaiq record and verify system.

The assessment will include (but not limited to):

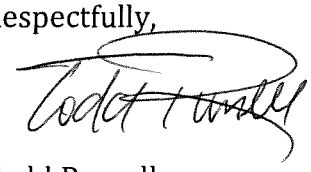
1. Time Out Performed (correct patient: name, birthdate, scheduled treatment, resources available)
2. Correct plan, with plan directives approved by AU prior to treatment
3. Treatment location and transfer tubes verified to connect correct channels to correct catheters by AU and/or AMP
4. Rx signed and dated (with a warning that treatment plans not imported from the Mosaiq record and verify system require manual verification that the Rx is signed)

The ICC will conduct documented blind random audits to ensure all patients treated follow the process outlined in the proposed action plan. Audits of all HDR patients treated each month over the next 12 months will be audited. Audit results will be available upon request.

The staff and administrative management at the ICC and EIRMC have implemented these changes to policy. Staff at the ICC believe that indicated changes are effective and beneficial, specifically during the interim time-period while digital workflow processes are corrected within the Mosaiq system. The ICC is committed to ensure compliance is consistent with current NRC requirements, specifically 10 CFR 35.40(a), currently and in the future. The ICC will receive appropriate oversight and involvement from EIRMC leadership and Radiation Safety Committee to the support the current action plan and any future amendments that may be needed to policy and procedure. All staff at the ICC have been informed of the non-compliant condition and resulted finding / violation. Education around the enhanced workflow and changes to written directive procedure with the Valencia applicator have been acknowledged and completed.

We appreciate your time and efforts to review our proposed action plan. Please let me know if you have any additional questions or concerns.

Respectfully,



Todd Russell
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cc:
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