



BAY REGION

1900 Columbus Ave.
Bay City, MI 48708

August 4, 2015

Materials Licensing
United States Nuclear Regulatory Commission
Region III
2443 Warrenville Road Suite 210
Lisle, IL 60532-4352

**RE: Response to the Apparent Violation in Inspection Report No. 03013900/2015001(DNMS);
EA-15-111**

To Whom It May Concern:

This letter is written to provide additional information as requested in Inspection Report No. 03013900/2015001 (DNMS) dated June 23, 2015. Please find our responses below:

(1) Reason for the apparent violation:

The apparent violation occurred because a policy and procedure was not developed specific to High Dose-Rate (HDR) applicator devices that employ a close-ended transfer tube catheter providing high confidence that treatments are delivered in accordance with the written directive. In this setup the extent of the transfer tube catheter determines the distal treatment position. The transfer tube catheter position was not visible with radiographs.

(2) Corrective steps that have been taken and the results achieved:

A policy and procedure was established for applicators that use a close-ended transfer tube catheter. The procedure requires the authorized user to verify the position of the transfer tube catheter using a CT radiograph and radio-opaque markers positioned inside the transfer tube catheter. Staff members were trained and all subsequent treatments have been performed with high confidence of Ir-192 source positions.

(3) Corrective steps that have been taken to avoid further violations:

In the new policy the authorized user is required to visually verify and sign off on the position of the transfer tube catheter. A secondary time-out check is documented prior to commencing treatment, confirming that the authorized user has reviewed and approved the catheter position. For all other devices that do not employ the close-ended transfer tube, policies and procedures had already been in place to verify treatment position and provide high confidence that HDR treatments are delivered in accordance with the written directive.

(4) Date when full compliance was achieved:

Full compliance and training was completed on February 9th, 2015.

If you have any questions or require additional information, please contact myself or our Medical physicist, Matthew Buczek, at 989-667-6675.

Sincerely,

Clarence Sevillian
President and CEO
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989-894-3000

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