UNITED STATES
NUCLEAR REGULATORY COMMISSION
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ALL AGREEMENT STATES, PENNSYLVANIA, VIRGINIA

NRC INSPECTION VALUE ADDED FINDING: HIGH DOSE RATE REMOTE AFTERLOADER MEDICAL EVENT (STP-06-047)

Purpose: To share with the Agreement States NRC's inspection findings that could be useful in their respective inspection programs.

Background: The NRC Regional Offices routinely share with other NRC offices good practices they have incorporated into their inspection programs. Recently, the Office of State and Tribal Programs (STP) received information detailing such good practices from the NRC Region III Office and determined that the information could be useful to the Agreement States. STP plans to continue to share such information.

High Dose Rate Remote Afterloader Medical Event Discovered During Routine NRC Inspection (VAF)-2006-11: During a routine inspection of Community Hospitals of Indiana, Inc. (an NRC licensee), an inspector noted an event that involved a high dose rate remote afterloader (HDR) treatment that was subsequently identified as a medical event.

On November 8, 2005, the medical event occurred during the last fraction of a palliative HDR treatment. The root cause of the medical event was the licensee's failure to attach a metal interface connector (connector) to the end of a catheter used to position non-radioactive "dummy" sources inside of the patient during treatment simulation and planning. However, during the HDR treatment, the connector was used to attach the catheter to the HDR. The connector effectively added a 0.7 centimeter distance between the source and the end of the catheter. Therefore, the treatment resulted in the HDR source, and the associated radiation dose contour, being erroneously positioned by 0.7 centimeters relative to the treatment plan/written directive.

The licensee identified the error immediately; however, failed to perform an adequate evaluation to determine whether the event met the definition of a "medical event" per NRC regulations. Because the physician/authorized user indicated that no adverse patient consequences were anticipated, the licensee did not adequately evaluate whether the event constituted a medical event. Instead, the licensee documented the issue as a "reportable event" in the Radiation Safety Committee Meeting minutes.

The inspector identified the event during a routine review of the licensee's Radiation Safety Committee Meeting minutes. The inspector requested the licensee conduct an evaluation to determine if the event met the definition of a medical event.

The licensee conducted the evaluation and confirmed that a medical event had occurred. Specifically, the licensee identified that, during the third fraction of the HDR treatment, the patient received a dose to an unintended site that exceeded 50 rem to tissue and was greater than 50 percent of the dose expected from the administration as defined in the written directive. In addition, the licensee identified that, during the third fraction of the HDR treatment, the total dose administered to the treatment site differed from the prescribed dose by more than 20 percent (underdose). Additionally, the licensee identified that its failure to establish and implement written procedures requiring the use of the connector on the catheter during treatment simulations was a contributing cause of the medical event.

This finding illustrates the importance of verifying licensee assumptions and ensuring that licensees perform adequate evaluations to determine whether or not NRC requirements have been followed.

For additional information, please contact Michael LaFranzo, 630-829-9865.

If you have any questions on this correspondence, please contact me or the individual named below.

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