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U.S. Nuclear Regulatory Commission
Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352 Copy of response to Document Control Desk

Response to Apparent Violations in Inspection Report Nos. 030-01625/06-001 and 002(DNMS); EA-06-101

Dear Sir or Madam:

Apparent violation (1): Failure to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.

The incident involved a shift in the location of an HDR treatment field caused by the failure to include the interface connector on the treatment catheter before the localization markers were inserted and filmed for treatment simulation.

Incident Follow-up: The authorized user (AU) and radiation safety officer (RSO) were notified of the treatment variation the same day the event occurred. The RSO interviewed the physicist who planned the treatment and the nurse who was involved in the simulation process in the radiation oncology department. From these interviews it was determined that the radiation oncology nurse was the usual person to verify that the catheter setup was correct and in place for bronchial HDR simulation and treatment. This role assignment was not documented in the written HDR simulation/ treatment procedure.

The **root cause** of this apparent violation was failure to provide unequivocal task assignment as part of the written procedure. Contributing factors included: placement of the catheter in the patient outside the radiation oncology department using non-departmental nursing staff; inexperience of the radiation oncology nurse in that this was the second bronchial procedure that this individual had participated in without supervision by more experienced nursing staff.

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Corrective Action: All staff involved in HDR treatments was made aware of the incident and the cause. The written policy was modified to include role assignment such that the nursing staff was made responsible to complete catheter preparation and insertion of appropriate radiographic markers. The therapist performing the imaging must verify correct marker placement prior to imaging. Physics staff must oversee the localization process. Additionally the written addendum to the HDR policy describes the requirement of the metal connector and the placement of the radiographic marker.

The documentation for HDR treatments of like site and in chronologic proximity were reviewed along with staff interviews. It was determined that this was an isolated event not a systemic occurrence. The incident and the corrective actions were submitted to the Radiation Safety Committee during the December 22, 2005 meeting. The modified written procedure was formulated and placed in the procedure manual November 9, 2005, the day after the event occurred. Compliance with corrective action, November 9, 2005.

Apparent violation (2): Failure to appropriately identify and report the medical event to the NRC by the next calendar day after discovery.

Though the event was discovered the day it occurred, it was not recognized as a reportable event because the authorized user indicated that in this specific case, generous margins were drawn on the simulation film. In the AU's opinion, a treatment shift of up to 1 cm would still have treated the area of interest. She did not require an additional treatment to increase the dose to the area that received the under-dose, nor did she anticipate that the area that received the overdose would result in a negative outcome. The intent of the treatment was palliative in nature and a boost to the dose from external beam treatment. Based on the AU's opinion, the RSO did not conduct a more thorough evaluation to determine if the requirements of 10 CFR 35.3045(a)(3) were met requiring that the event be reported.

Root cause: Failure to follow the requirements of 10CFR 35.3045(a)(3) in evaluating the event for report potential.

Corrective Action: Title 10 CFR Part 35.3045(a)(3) was reviewed by the RSO and the radiation therapy chief medical physicist. An evaluation of the shifted dose distribution was conducted and found to be such that the dose distribution at the superior end of the treatment area was greater than 50% more than the expected dose from administration as defined in the written directive. The OPS center was notified by phone at 13:31 EDST 4/5/06 and assigned event number 42474. A written report was submitted to the Region III office on 4/13/06. The referring physician was notified of the event on 4/13/06. The patient was deceased. Any

future event will be evaluated in accordance with 10 CFR 35.3045(a)(3). If criteria for event reporting are met, the event will be reported by telephone and in writing as required. If there is uncertainty regarding whether the event meets requirements, the NRC Region III office will be consulted for assistance. Understanding of 10 CFR 35.3045 requirements and appropriate reporting of event completed April 13, 2006.

Sincerely,

William R. Corley, President
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