Hello Dante,

NRC is currently working on the AO report. One event that Region III would like to add to the AO report is the VA San Diego event. I think this event is in NMED but, it is not marked as a potential AO because not enough information was provided. It appears the Region did a Reactive Inspection and in that inspection report, which I believe is nonpublic, more information is provided to determine a potential AO. Therefore, could you please use the attached AO write-up to update the event record and mark this event as a potential AO in NMED. If you have any questions please let me know.

Thanks,

Duane

NRC09-XX **Medical Event at the Veterans Affairs San Diego Health Care System in San Diego, California**

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site shall be considered for reporting as an AO.

Date and Place – September 21, 2009, San Diego, California

Nature and Probable Consequences - On September 26, 2009, the Department of Veterans Affairs (licensee), National Health Physics Program (NHPP) notified the NRC of a medical event at the VA San Diego Health Care System that involved a therapeutic administration of iodine-131 for the treatment of metastatic cancer. On September 21, 2009, a dosage of 6.9 Gbq (187 mCi) of iodine-131 was administered to a patient through an existing feeding tube. Daily radiation measurements of the patient indicated only small decreases in radiation measurement readings that were consistent with physical decay, but not the expected biological elimination. The feeding tube was replaced on September 25, 2009. A subsequent investigation indicated that the majority of the dosage, 6.1 Gbq (166 mCi), was administered to the wrong orifice of the feeding tube. As a result, the dosage remained in the balloon of the feeding tube and irradiated the patient's stomach instead of the metastatic cancer sites around the body. Based on the location of the radioactive material within the balloon of the feeding tube, the patient's stomach received a dose of approximately 16 to 19 Gy (1,600 to 1,900 rad).

The NRC-contracted a medical consultant to review the case; however, at the time of this report the consultant's findings were not available.

Cause(s) – The VA San Diego Health Care System identified three root causes as a result of this event: (1) inadequate training of staff, (2) inadequate procedures, and (3) the licensee's written policy and procedures did not provide a procedure to adequately verify that during administrations involving feeding tubes the administered dosage is in

accordance with the written directive.

Actions Taken To Prevent Recurrence

Licensee – Corrective actions taken by the VA San Diego Health Care System included: (1) The licensee immediately suspended any further gastric tube administrations until the direct cause of the medical event could be identified, (2) the licensee suspended one individual's participation in administrations requiring a written directive, (3) the RSO provided informal training to the nuclear medicine technologists, and (4) the licensee developed (draft) written policies and procedures specific to administering I-131 through a gastric tube.

NRC – The NRC Region III Office conducted a reactive inspection on November 3, 2009. Based on the results of this inspection, five apparent violations of NRC requirements were identified. Enforcement action is pending.

This event is closed for the purpose of this report.