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To Dante C Huntsman <Dante.Huntsman@inl.gov>
cc Michele Burgess <Michele.Burgess@nrc.gov>
bcc
Subject Closure information for NMED Event No. 080119

On February 20, 2008, you requested additional information on the above NMED Record. On July 2, 2008, the licensee's response to an NOV was placed in ADAMS (ML081840117).

(1) What was the cause of the event?

The cause of the event was the improper assembly of the device, i.e., human error. The three-way stopcock was put in backwards causing crimping of the outlet tubes and restricting flow of the microspheres to the patient.

(2) What corrective action(s) were taken by the licensee to prevent a recurrence?

The licensee reviewed the event with all personnel concerned and staff that might be part of a future procedure. The three-way stopcock was modified locking it in place. Directional arrows were placed on the device to ensure proper assembly.

(3) What was the activity of the Y-90 given to the patient and prescribed to the patient?

The Y-90 activity given to the patient was 0.58 GBq (16 gray) and prescribed was 1.42 GBq (38 Gray).

(4) Did the patient receive the remainder of the treatment at a future date?

Yes, the patient received a treatment on March 4, 2008, of 3.2 GBq (85 Gray) to complete the treatment.

The inspection letter and report may be found at ML081640166 and ML081640177. Please change Investigation to Yes as the inspection was completed on June 3, 2008. If you require no further information for this record, you may close the record. NRC management believes it has all the information that it needs concerning the event.