

CONCLUSION

The reported medical event involved the first of two planned administered doses to the patient's right coronary artery using a 40 millimeter (mm) strontium-90 source train in a Novoste Beta-Cath System. The physician authorized user prescribed 18.4 gray (Gy) to two areas of the patients' right coronary artery using the Novoste System. A kink in the delivery catheter caused the source to not reach the intended area of the patients's right coronary artery. The licensee recognized the error following the first attempted treatment and a second attempted was made, however again the device failed again. The authorized user physician did not expect any adverse health effects to the patient as a result of this event.

To reduce the likelihood of similar events, the licensee committed to the following: (1) having the device manufacturer representative and a trained cardiology coordinator present to perform the stopwatch timer verification for all IVB procedures ; (2) meet with all the authorized radiation oncologists and medical physicists to review the proper preparation and the written directive, proper confirmation of the written directive prior to the start of the treatment, emergency procedures, and error prevention; (3) trained 10 cardiology coordinators on the proper procedure for documenting and confirming the treatment plan, including the treatment time and timer setting prior to the start of the procedure; (4) instructed each member of the IVB team to ensure that four team members (i.e., radiation oncologists, medical physicist, cardiologist, cardiology coordinators, and device manufacturer's representatives) are present prior to the start of a patient treatment; (5) committed to always have a device manufacturer's representative present, when the full-time coronary brachytherapy physicist is not present; and (6) implemented a new checklist to document each of the treatment parameters (vessel, diameter, injury length, catheter size, treatment device, treatment time and time programmed onto the stopwatch), (7) prior to any IVB procedure, visually inspect the delivery catheter for any unusual bends or kinks. The licensee's corrective actions were adequate to preclude recurrence of similar events. Subsequent discussions with the device manufacturer, they do not consider the device as "defective", the cause of the source hang-up was due to a kinked delivery catheter.

ACTION REQUIRED

Subsequently this event was considered to not be a reportable event. A TAR was sent to NRC HQ to request guidance regarding this issue.

NAME OF PERSON DOCUMENTING CONVERSATION

Darrel Wiedeman

SIGNATURE



DATE

8/24/2009
