CONVERSATION RECORD

TIME 9:40 am | DATE 8/12/2009

○ VISIT ○ CONFERENCE X TELEPHONE

0 INCOMING

X OUTGOING

NAME OF PERSON(S) CONTACTED OR IN CONTACT	ORGANIZATION (OFFICE, DEPT.ETC.)	TELEPHONE NO.
Dennis Szmania, RSO-Munson Medical Center		(231) 935-7100
Craig Reed- Novoste (Best Vascular)		(770) 335-1042

SUBJECT

Telephone contact to resolve questions associated with a IVB brachytherapy event.

SUMMARY

On July 30, 2009, the licensee was in the process of treating a patient's occluded coronary arteries with a Novoste Intra-Vascular Brachytherapy (IVB) device. The radioactive source in the device was a 40 millimeter source train containing 16 sources with a total activity of 1.7 GBq (45 millicuries) of strontium-90. Prior to the procedure the authorized user (physician) completed a written directive prescribing two treatment sites to be treated for 3 minutes and 41 seconds which would deliver a dose of 18.4 gray (Gy) for each of the two treatment sites. One treatment to the diagonal left anterior descending coronary artery and one treatment to the proximal left anterior descending coronary artery. Normal preparation procedures for an IVB treatment were followed. Included in these procedures were radiation surveys of the patient, catheter and Novoste treatment device, visually verifying the presence of the source train in the Novoste device, attaching a water collection pouch to the Novoste treatment device and passing the treatment device off to the authorized user (radiation oncologist). The Cardiologist previously determined the number of lesions to be treated, their locations, and vessel sizes and provided this information to the authorized user so he could include this information in the written directive.

A 3.5 French beta-rail catheter was advanced to the first treatment area, with the Indicator of Source Train (IST) dummy markers in the catheter. The position of this catheter was verified via fluoroscopy by the authorized user. Source delivery was attempted for the first treatment site, but the authorized user stated that the source train never left the Novoste device. The licensee held a "time-out" and there was a discussion about whether the Toughy valve was open or closed. They re-checked the valves and verified that they were in the correct position. Another attempt to send the source train was made and this time the source train did leave the Novoste device but did not arrive at the treatment site as expected. The authorized user verified that the source train did not arrive to the treatment site by observing the treatment markers with the use of fluoroscopy.

The authorized user attempted to return the source train to the Novoste treatment device but was unsuccessful. The licensee initiated their emergency bail-out procedures and the catheters were removed from the patient and placed in a temporary storage container. The AU then changed the written directive to indicate that the dose to the sites was zero. The authorized user then assumed that the Novoste IVB device was malfunctioning and decided to discontinue any further attempts to treat the patient. The licensee initially assumed that the source train entered the patient's large vessels (aorta) and caused an unintended exposure to the aorta, however, it was subsequently determined by the manufacturer (Best Vascular) that a minute kink in the delivery catheter caused the source train to stop approximately 6-8 inches from the Novoste device which would be outside the patient's body. Dose to the patient's skin and thigh were considered negligible. At the termination of the attempted procedure the authorized user physician revised the written directive to indicate that that the dose to the treatment sites was changed to zero (0) Gy because he was unable to transfer the sources to the treatment sites.

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 havie 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	SIGNATURE	DATE
Darrel Wiedeman		8/24/2009