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FILE

MEMO TO : All Medical Use Licensees

FROM : Terry L. O'Clair, P.E.
Director
Division of Air Quality

RE : NRC Information Notice 2003-09: "Source Positioning Errors and System Malfunctions During Administration of Intravascular Brachytherapy"

DATE : August 4, 2003

Enclosed is a copy of the United States Nuclear Regulatory Commission (NRC) Information Notice 2003-09: "Source Positioning Errors and System Malfunctions During Administration of Intravascular Brachytherapy". This information notice was issued to inform licensees of four recently reported medical events that have occurred during the conduct of intravascular brachytherapy (IVB) procedures.

As indicated in the notice, it is expected that you will review this information for applicability to your licensed activities and consider actions, as appropriate, to ensure the safe and legal use of radioactive materials in the State of North Dakota.

This notice is for your information only. No specific action nor written response is required. If you have any questions concerning this issue, please contact the Radiation Control Program at 701-328-5188.

TLO/JMG:csc
Enc:

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555-0001

July 16, 2003

NRC INFORMATION NOTICE 2003-09: SOURCE POSITIONING ERRORS AND SYSTEM MALFUNCTIONS DURING ADMINISTRATION OF INTRAVASCULAR BRACHYTHERAPY

Addressees:

All medical licensees.

Purpose:

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice (IN) to inform addressees of four recently reported medical events, with two separate device types, that have occurred during the conduct of intravascular brachytherapy (IVB) procedures. These medical events involved errors in positioning the IVB sources or system malfunctions, resulting in administration of the dose to the wrong treatment site. Two events involved inadequate understanding of source positioning details for the most recent device being employed. The third event involved catheter malfunction and inadequate visualization of the active source and the fourth event involved system malfunction.

It is expected that recipients will review this information for applicability to their licensed operations and consider actions, as appropriate, to avoid similar problems. However, suggestions contained in this IN are not new NRC requirements; therefore, no specific action nor written response is required.

Description of Circumstances:

NRC has received four recent medical event reports involving administration of IVB doses to the wrong treatment sites. The events are summarized below.

In the first event, the licensee had been using a Guidant Galileo IVB system and had recently received an upgraded software system, the Guidant Galileo III. The old system was updated, in part, to allow delivery of the dose in two parts to the distal and proximal ends of the lesion. The new system automatically sends out an inactive wire with a marker that should align with a marker on the catheter placed in the patient. To reach exact alignment, the user may need to manually "fine tune" the positioning. With the old system, the positioning is accomplished essentially the same way. On the day of the first use of the upgraded system, the vendor's representative arrived on site to provide training. However, the first patient had already been prepped to undergo the treatment and the formal training for the new version was not delivered prior to the treatment. During the initial use of the upgraded system, the source delivery unit sent out the inactive wire to a point where its distal marker stopped in the approximate area of

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the catheter's distal marker. Since the users had not received formal training, nor had they reviewed the training manual, they questioned whether they had to manually "fine tune" the positioning of the inactive wire to align it with the distal end of the catheter. The vendor's representative had not used the upgraded system often and did not fully understand the importance of the marker alignment, and therefore, assured the users that the position of the inactive wire was acceptable and that the system would advance the active wire to cover the desired area without any "fine tuning". As a result, when the source delivery unit sent out the active wire, the wire traveled 3 to 6 millimeters short of its intended location. The users retracted the source, were again assured by the vendor's representative that the active wire would go to the desired position, and attempted to treat again. The active source wire was run out a second time and again did not reach the desired treatment position. Subsequently, the inactive wire was run out and this time the users manually adjusted it to align with the catheter's distal marker, and the treatment was administered.

In the second event, the licensee had been using the Novoste Beta-Cath 5 French IVB system and had recently received the 3.5 French system. One of the differences between the two units is the method for locating positional markers. The vendor's representative was present for the procedure and had provided training to the licensee's staff prior to staff performing a patient treatment with the new unit. However, both the vendor's representative and the Authorized User were in the room but not in a position to see the source train positioning in the new catheter which was inserted by the interventional cardiologist. Following insertion of the active source train, the interventional cardiologist determined, via fluoroscopy, that the source train was incorrectly positioned and did not cover the desired treatment site. The source train was withdrawn after 60 seconds of treatment. The catheter was then correctly positioned and treatment was given to the proper area of the vessel.

In the third event, during a treatment with a Novoste Beta-Cath 3.5 French IVB system, the source train did not travel the entire way to the treatment site and was 40 millimeters proximal to the treatment site. The immediate cause of the event was a small kink in the delivery catheter which kept the source train from traveling to the correct site, even though the kink was not substantial enough to affect the flow of the sterile water used to send/retrieve the sources. The error was identified the next day during the medical physics quality assurance checks of the films taken during the treatment. The review revealed that the proximal end of the source train was hidden inside the guiding catheter and was not properly visualized by fluoroscopy during source placement. The licensee also noted that the proximal and distal markers of the source train are the same size and shape and are not distinguishable from each other. Therefore, the distal end of the source train was mistaken as the proximal end and the entire dose was delivered to an area 40 millimeters proximal to the intended treatment site. During on-site review of the event, NRC inspectors observed the licensee conducting a treatment with the 3.5 French IVB system. Again, the licensee had to remove the catheter from the patient, due to kinking of the catheter. As in the earlier treatment, the kinking was not substantial enough to affect the flow of the sterile water. However, the source train remained stuck in the catheter, requiring removal of the catheter containing the source train from the patient. The manufacturer is evaluating the system.

In the fourth event, there was a malfunction of the drive mechanism with a Guidant Galileo III IVB system. A vendor's representative was present for the treatment. During the treatment the inactive source successfully reached the proper position (confirmed visually via fluoroscopy) and returned. The active source was then advanced into the catheter. The licensee noted that the source movement light continued to blink well after the anticipated transit time. The licensee attempted to locate the source position via fluoroscopy; however, the source was not viewed. The licensee performed surveys that confirmed that the source stopped inside the patient. The licensee assumed a machine malfunction had occurred and initiated emergency procedures. The indicator light on the console continued to indicate the source was in transit even after the licensee confirmed the source was in the patient and not at the treatment site. While attempting to return the source to the shielded position, the licensee was unable to retract the source using the machine interrupt, the system stop button, or the manual hand-wheel. Therefore, the licensee manually removed the catheter and source from the patient. After the power cord was removed from the wall receptacle, the source was retracted back to its shielded position. The device is being evaluated for proper operation by the manufacturer. In addition, the licensee did not contact the State regulatory authority, as required.

Discussion:

In two of the four cases, the licensees received new designs for systems they had been using, and did not fully appreciate any differences in the methods used by the new designs for positioning the active source trains. In addition, a vendor's representative was present in both cases, but in one case, the representative did not fully understand the source positional differences between systems, and in the other case, the representative could not adequately view the treatment to verify whether correct positional methods were used.

In another case, two issues resulted in the wrong area being treated. First, the catheter kinked, restricting the source train from traveling to the intended treatment site. Second, the proximal and distal markers for the source train are the same size and shape. During fluoroscopy of the treatment area for source placement verification, the licensee's staff believed that both the proximal and distal markers had been visualized. However, only the distal marker had been visualized.

In the last case, there was complete failure in safety systems when emergency procedures were implemented. The system appears to have malfunctioned both in its ability to recognize the location of the active source and its ability to retract the active source wire with emergency features. Although investigation of this reported event is ongoing, presently available information suggests that the console touch screen used to control the treatment "froze" and did not display the touch screen interrupt button. In addition, the licensee did not notify the regulatory authority of this event. Prompt notification of regulatory authorities is essential for these types of events to ensure that immediate actions are taken to prevent recurrences of such medical events by this and other device users.

Licensees performing IVB are expected to review this IN and:

- Assure that vendor training has been provided to all users prior to their actual use of new devices or re-designs of devices;

- Encourage device users to review all of the vendors training documentation and clarify any concerns with the vendors regarding particular devices prior to using the devices for patient treatments. If direction provided by the on-site vendor's representatives is believed to be in error, licensees are expected to clarify any discrepancies with the manufacturers prior to use.

- Report all system malfunctions to the vendors; and if required, to the licensing authorities expeditiously; and

- Consider performing quality assurance checks of the films taken during the treatment to identify whether correct placements of active sources were achieved.

This IN requires no specific action nor written response. If you have any questions about the information in this notice, please contact the technical contacts below, or the appropriate regional office.

/RA/

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and Safeguards

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Attachments:
1. List of recently issued NMSS Information Notices
2. List of recently issued NRC Information Notices