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

January 31, 1992

NRC INFORMATION NOTICE 92-10: BRACHYTHERAPY INCIDENTS INVOLVING IRIDIUM-192 WIRE USED IN ENDOBRONCHIAL TREATMENTS

Addressees

All Nuclear Regulatory Commission (NRC) licensees authorized to use iridium-192 for brachytherapy; manufacturers and distributors of iridium-192 wire for use in brachytherapy.

Purpose

This information notice describes two events in which iridium-192 wire attached to an unirradiated, flexible guide wire became detached from the guide wire. The use of iridium-192 wire for intracavity brachytherapy treatment is not authorized under 10 CFR 35.400, and may only be authorized by a customized license review and amendment. In one event, a portion of the iridium-192 wire remained in the patient's thorax. It is expected that licensees will review this information for applicability to their programs, distribute it to members of the Radiation Safety Committee and to responsible staff and hospital management, and consider actions, if appropriate, to prevent similar incidents from occurring at their facilities. Suggestions contained in this information notice do not constitute new NRC requirements, and no written response to the notice is required.

Description of Circumstances

Two brachytherapy incidents have been reported that involved endobronchial treatment of patients using iridium-192 wire. The brachytherapy device consisted of activated iridium-192 wire of specified activity content attached to a nonradioactive guide wire.

On January 6, 1989, an iridium-192 wire used for an endobronchial brachytherapy treatment of a patient was not retrievable and had to be removed surgically. When the iridium-192 wire was received by the hospital staff, it was not encased in the closed-end nylon tube, described in the manufacturer's instructions. The unencased wire, attached to a flexible nonradioactive guide wire, was placed in an opened-end catheter and the catheter was introduced into the patient's thorax through a bronchoscope. The calibrated activity of the iridium-192 wire was 86.9 millicuries, and the length was 7 centimeters.

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While inserting the wire into the catheter, personnel noticed that the wire could not travel down as far as they had planned. The wire was pulled back to determine the cause of the obstruction. Approximately 5 cubic centimeters of saline solution were introduced into the catheter to facilitate removal of any possible obstruction and reinsertion of the wire. However, before a second attempt was made to reinsert the wire, personnel noticed that the wire was markedly shorter than its original length. At that point, personnel presumed that the radioactive part of the wire was withdrawn but broken off in the catheter. After withdrawing the catheter, personnel found that the missing radioactive part had slipped through the catheter and remained in the patient. The bronchoscope was withdrawn. Surveys conducted on the patient's chest revealed an elevated exposure rate confirming that a portion of the iridium-192 wire remained in the patient's thorax.

A bronchoscope was re-introduced into the patient, and several unsuccessful attempts were made to locate and remove the wire. A thoracotomy was performed on the patient and the wire was removed with no further complications. In this event, the iridium-192 was neither encased in a nylon tube when it arrived at the hospital, nor was it placed in a closed-end tube.

On July 7, 1989, at a different facility, an iridium-192 wire for an endobronchial treatment was received unencased and then used in an open-end catheter. The wire had a calibrated activity of 157.7 millicuries and a length of 4 centimeters.

Upon completion of the treatment, the guide wire was withdrawn from the patient and placed in the shielded transport container. The patient was immediately surveyed, in accordance with procedures, with a Geiger counter that showed readings in excess of 300 mR/hr. Assuming that the iridium-192 wire had remained lodged in the patient, the personnel involved in this procedure immediately withdrew the open-end catheter used to contain the wire. A subsequent survey of the patient showed background readings. A wipe test of the room and the guide wire that was attached to the iridium-192 wire showed no removable contamination.

An autoradiograph of the catheter showed that it contained the intact 4-centimeter iridium-192 wire. Personnel concluded that the radioactive wire became detached from the guide wire when it was being withdrawn from the patient and remained inside the catheter.

Discussion

Although neither of these incidents was a reportable misadministration, the first incident resulted in an unanticipated surgery and constituted a health risk to the patient. In each of the two events, all or part of an iridium-192 source attached to a nonradioactive guide wire became detached from the guide

wire. The involved licensees adopted the following procedural measures to prevent this type of event from reoccurring:

The iridium-192 wire will be inspected and tested in the hot laboratory prior to implantation.

The iridium-192 wire for brachytherapy endobronchial treatments will be inserted using fluoroscopy.

The licensees will contact the manufacturer about the possibility of obtaining an iridium-192 wire encased in a closed-end tube.

If resistance is encountered while the iridium-192 wire is being withdrawn, no force will be used to remove it, because such force may break or dislodge the radioactive wire. Instead, the catheter containing the wire will be removed.

This information notice requires no specific action or written response. If you have any questions about the information in this notice, please contact the technical contact listed below or the appropriate regional office.

Richard E Cunningham

Richard E. Cunningham, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Technical contact: Harriet Karagiannis, AEOD
(301) 492-4258

Attachments:
1. List of Recently Issued NMSS Information Notices
2. List of Recently Issued NRC Information Notices

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*See previous concurrences.
EKraus, Tech Editor 10/08/91

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