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NRC STAFF SENDS DIRECTIVE ON CERTAIN DEVICE
USED FOR TREATING CANCER PATIENTS

The Nuclear Regulatory Commission has sent a directive to all NRC licensees authorized to use a specific device (Omnitron Model 2000 High Dose Rate Afterloader) used for treating patients suffering from cancer with radioactive sources. Licensees are to, within 15 days, discontinue use of the device or take certain steps in regard to its use.

The action is being taken after an outpatient was treated on November 16 using the device at the Indiana, Pennsylvania, Regional Cancer Center of Oncology Services Corporation and was returned to a nearby nursing home with the radioactive iridium source remaining in the patient's body.

The patient died on November 21 and the NRC staff's consultant physician, based on an examination of the patient's medical records, has preliminarily concluded that the patient either died as a result of exposure to radiation or that radiation exposure was a major contributor to death. Until the radioactive source was removed from the nursing home, after the patient's death, it also subjected residents, staff and visitors to radiation exposures which still are being evaluated.

Cancer Center personnel had experienced difficulty with the placement of the radioactive source in one of the patient's five treatment catheters and, because they thought the signal was false, ignored a wall monitor alarm indicating the presence of a radiation field. No survey of the patient was conducted using a hand-held survey instrument to determine if the radioactive source remained in the patient. It later was determined that a short piece of cable, containing the iridium source, had broken off and remained in the catheter.

On December 7, a source again separated from the cable drive of the same kind of device during treatment of a patient at the Greater Pittsburgh Cancer Center of Oncology Services Corporation. In that case, the source separation was detected at the end of treatment and the source was recovered.

The NRC staff and the Food and Drug Administration are conducting ongoing investigations into the cause of the failures associated with device and, until the investigations are completed, it is unclear whether the manufacturer will be required to recall the device, implement design modifications and/or conduct field retrofits. Therefore, licensees are being directed to either discontinue use of the Omnitron 2000 unit or immediately implement the following actions if the units are used:

(1) Make radiation surveys of patients with an appropriate radiation detection survey instrument to confirm that all sources have been removed. This survey is to be done in addition to any indication of radiation levels provided by an area monitor. The surveys are to be done immediately after completion of the therapy procedure prior to removal of the patient from the shielded treatment room and appropriately documented with initials and/or signatures.

(2) Refrain from conducting any procedure for which a decoupled source cannot be expeditiously removed from a patient and placed in a shielded condition. Have written emergency procedures describing actions to be taken, including surgical intervention, should the source not return to the shielded container at the conclusion of treatment. Assure that appropriate staff and equipment are available immediately, at the location a procedure is performed, to implement the written emergency procedures. Have equipment available to carry out the emergency procedures including shielded storage containers, remote handling tools and, if appropriate, supplies to help surgically remove sources from a patient including scissors and cable cutters. Emergency source removal procedures should minimize exposure to healthcare personnel while maximizing safety to the patient.

(3) Ensure that personnel are trained in both the routine use of the device and emergency procedures to return the source to a safe condition. Training is to be provided immediately for new personnel and retraining provided semiannually for all personnel. The records of the training are to be retained by the licensee for a period of three years.

Licensees are to report in writing, within 15 days, whether the actions have been taken or the use of the Omnitron 2000 device has been discontinued.

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