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# NRLSD BULLETIN NO. 93-05 RADIATION INCIDENTS RELATED TO BRACHYTHERAPY TREATMENT

## A. ADDRESSEES

All holders of radioactive material license in brachytherapy.

## B. PURPOSE

This bulletin is issued to inform licensees of recent incidents published by the United States Nuclear Regulatory Commission (USNRC) which resulted in unnecessary radiation exposure to radiation workers, the patient and the public. It is expected that concerned licensees will review this bulletin and consider actions, as appropriate, to avoid similar problems in their own facilities.

## C. DESCRIPTION OF CIRCUMSTANCES

**Section 21 of Part 3 of the Code of PAEC Regulations (CPR)** provides that each licensee shall establish and implement a radiation protection program that describes its organization, operating procedures and practices, conduct of operation, and emergency plans, and a policy that clearly states written standards and instructions for strict adherence to radiation protection requirements and periodic evaluations of radiation protection performance and effectiveness.

Below are incidents which occurred mainly as a result of insufficient training and instructions on the part of the medical staff.

### Case 1

On October 21, 1992, while reviewing the shipping documents associated with the implant performed on August 19, 1992, the licensee's dosimetrist noted a discrepancy in the units of measurement between what she had received. The licensee ordered brachytherapy ribbons containing 0.79 millicurie per ribbon. However, the vendor delivered

brachytherapy ribbons containing 0.79 milligrams radium equivalent (1.36 millicurie) per ribbon. When the shipment was received, the dosimetrist checked the prescription order against what was received and noted that the quantities (0.79) matched, but she failed to note that the amount received was measured in milligrams radium equivalent rather than the requested millicurie units. As a result, the radiation dose to the patient's prostate gland was 5,669 rads rather than the prescribed 3,258 rads.

The referring physician was notified and chose not to inform the patient.

The patient was examined during subsequent follow-up visits and has shown no adverse effects due to the increased radiation exposure. The licensee does not anticipate any significant effects to the patient as a result of the misadministration.

The cause is attributed to human error by the licensee's staff resulting in the failure to perform an adequate verification of source strengths prior to implanting the brachytherapy sources. The licensee's dosimetrist had checked the prescription order against the receipt records but failed to note the discrepancy in units of measurement. Miscommunication between the licensee and the vendor also appears to have contributed to the error.

To prevent recurrence, revised procedures have been implemented. An implant checklist has to be completed and initialed to ensure that units of measurement received correspond to that which was ordered and the licensee's physicist has to verify source strengths by direct measurement prior to implantation.

**Case 2**

During a brachytherapy implant, radioactive seeds (a total of 25, each containing 3.5 millicurie of iridium-192) were spaced at 0.5-cm intervals and located in a ribbon that was inserted through the patient's nose into an endobronchial catheter positioned in the patient's bronchi. The Ir-192 ribbon became dislodged from the catheter during the night (11 p.m. to 7 a.m.) shift. A nurse observed the ribbon outside the patient's nose at 2 a.m. The nurse did not realize that the seeds were within the ribbon. She handled the ribbon with her bare hands and taped it to the patient's face, which contributed to the consequence of the misadministration and resulted in unnecessary radiation exposure of approximately 17.8 rem to the nurse's hands. Before the nurse taped the ribbon, it dangled in front of the patient's face and, for an unidentified interval, the patient repositioned the ribbon in her hair. The patient received an estimated dose of 1032 rad to the left side of the face.

A root cause of the misadministration was failure of the licensee to instruct the nurse concerning radiation safety precautions associated with the care of the patient who

had received the brachytherapy implant. The nurse had attended training sessions on such implants, but had not been provided specific instructions nor assigned primary responsibility for care of an endobronchial implant patient.

**Case 3**

During a brachytherapy implant procedure, two ribbons, each containing six Ir-192 seeds, with a total activity of 48.25 mCi, were implanted into two catheters inserted into the patient's common bile duct, through an abdominal incision. During the night shift, the patient's dressings on the wound were wet and loose. A licensed practical nurse (LPN), who responded to the patient, found the Ir-192 ribbons dislodged and lying loose on the patient's abdomen. The LPN, not realizing that the Ir-192 seeds were in the ribbon, changed the patient's dressing and bed, and coiled each Ir-192 ribbon around her hand and taped them to the patient's abdomen. The oncologist had left verbal orders with the day shift charge nurse "not to change the dressing" but these orders were not passed on to the LPN. A routine x-ray identified that the seeds were no longer implanted, and the coiled ribbons were removed by a physician.

The patient's abdominal skin received an unnecessary exposure over various areas ranging from 172 rad to 1032 rad. The skin exposure to the hand of the LPN was 7.6 rad.

The misadministration was caused by:

1) lack of oversight of the procedure by the licensee's Radiation Health and Safety Officer; and

2) inadequate training of the nursing staff in that they were unable to identify the brachytherapy ribbon and handle them appropriately if, and when, they become dislodged.

To prevent recurrence, the licensee initiated an expanded training program that includes:

1) familiarization of personnel with the size and appearance of the radioactive sources used in brachytherapy treatments at the licensee's facility;

2) naming a new RHSO who could devote sufficient time to the radiation safety program;

3) developing a nurses' procedure manual;

4) conducting formal in-service training in radiation safety with all nursing unit

workers; and

5) requiring a written directive be initiated before ordering radioactive material.

**Case 4**

In Indiana University Medical Center, a 31-month old patient, being treated for a brain tumor, was to receive two Cobalt-60 teletherapy treatments of 150 rads each for a total dose of 300 rads to reduce swelling behind the patient's eye. The dosimetrist mistakenly prepared the dose calculations for 300 rads per treatment. The patient was treated November 13 and 14, 1992, with 300 rads per treatment for a total dose of 600 rads.

Prior to the treatment, the treatment plan was reviewed by the treating physician. Following the treatments, the dose calculations were reviewed by a medical physicist and approved. The error was discovered by a student technologist during a monthly chart review on December 2, 1992.

The error was caused by the mistaken calculations by the dosimetrist and by the apparent inadequate review by the physician before the treatment began. The doses normally used for this type of treatment are 300 rads per treatment, and this further contributed to the failure to identify the error before the treatments occurred. There was also a problem with the legibility and format of the treatment plan.

To prevent recurrence, the licensee has provided additional training to treatment personnel to eliminate the types of problems that contributed to the misadministration.

**Case 5**

A 35-millicurie brachytherapy source was recovered after it was found missing earlier that day. The source had probably been lost before or during a brachytherapy treatment, resulting in a therapeutic misadministration. A female patient, approximately 39 years old, was to receive 1,848 rads to the cervix for cancer treatment. One of the sources that was prescribed was either never inserted or was removed from the applicator during treatment. Assuming maximum deviation from the planned treatment, the actual dose to the patient was only 1,235 rads. The licensee stated that a source was also misplaced and was in contact with one of the patient's legs for a period of time, resulting in an estimated dose to the leg of 260 rads. The physicians responsible for the treatment, after reviewing the dose estimates, decided no additional treatments were necessary.

The misplaced source was inadvertently put with hospital linen. The linen with the

brachytherapy source was taken to an off-site laundry facility, from which it was subsequently recovered. The referring physician and patient were notified of the misadministration.

The cause of the misadministration was failure of the licensee to recognize the significance to radiation safety of a procedural change that eliminated the use of disposable pads in favor of reusable linen pads. Previously, the licensee disposed pads by putting them in infectious waste, which stayed in the room until after the final radiation survey was performed, after removal of the radiation sources. The reusable pads, when changed, were placed in laundry bags in the hallway, which were taken to the laundry facility daily. The nursing staff failed to follow the procedure that prohibited removing anything from the patient's room that had not been checked for the presence of a brachytherapy source.

To prevent recurrence, the licensee has taken the following steps:

1. Physicians have been instructed to visually confirm that sources are properly loaded into applicators;

2. Dosimetrist have been instructed to observe the loading process and confirm that applicators are correctly loaded;

3. A linen hamper will be placed in each brachytherapy patient's room so that linen will not be removed until after the final room survey to confirm that no sources have been lost;

4. Soiled linen that cannot be left in the room until the end of treatment will be surveyed to ensure that no sources are in the linen prior to its removal from the patient's room;

5. Physicians have been instructed to visually check for the presence of sources at the time they are removed from the patients.

**Case 6**

An elderly patient was treated for anal carcinoma with an Omnitron Model 2000 High Dose Rate (HDR) After loading Brachytherapy unit, at the **Indiana Regional Cancer Center** (IRCC) in Indiana, Pennsylvania, of Oncology Services Corporation (OSC). The treatment took place on November 16, 1992, and the patient died on November 21, 1992.

During the treatment, which was the first of a series of three 600-rad treatments

planned by the physician, 4.3 Ci of Iridium-192 source was placed at various positions in each of the five catheters that were to remain in the patient for subsequent treatments. The IRCC personnel experienced difficulty with source placement in one of the patient's five treatment catheters. Although a wall-mounted area monitor alarmed at various times when the source should have been retracted, the licensee's staff did not conduct a survey for radiation levels with the available portable radiation survey instrument. The only action taken was to check the control console of the HDR remote afterloader. Because the console indicator showed "safe", they believed the source to be fully retracted into the lead shield and assumed the area radiation monitor was malfunctioning. They were unaware that a short piece of the cable containing the Iridium source had broken off and remained in one of the catheters in the patient. The patient was transported to a nearby nursing home. The source remained in the patient's body for four days when the catheter fell out. It was placed in a medical biohazard bag (red bag) in a storage room by nursing home personnel who did not know it contained the radioactive source. The catheter containing the source was moved to another storage location at the nursing home and placed in a box with other red bags. Numerous residents, employees, and visitors to the nursing home were unknowingly irradiated. A driver from **Browning-Ferris Industries** (BFI) picked up the red-bag biowaste and transported it to a BFI facility in Carnegie, Pennsylvania and transported it to a BFI medical waste incinerator where fixed radiation monitors identified radiation emanating from the trailer, and, on facility personnel direction, the trailer was returned to Carnegie. The BFI staff searched the truck for the radiation source and identified the box with the radiation source. They identified a name found with the red-bag waste in the box, and traced it to the nursing home.

After being notified by BFI, the nursing home called the IRCC. The cancer center had not used the HDR afterloader after the single treatment on November 16, 1992. The medical physicist determined that no source was present in the HDR afterloader and informed the NRC of this fact. The physician and the medical physicist drove to Carnegie and retrieved the source.

The cause of death of the patient, as listed in the official autopsy report, is "Acute Radiation Exposure and Consequences Thereof." Until the source was recovered after the patient's death, it subjected nursing home residents and staff, as well as visitors, to radiation exposure. Radiation doses to the 94 individuals associated with the event ranged from 40 mrem to 22 rem.

No personnel or property contamination occurred and no occupational worker received a whole body radiation dose above 1.25 rem. While members of the public received radiation doses above applicable limits, no one received a dose at which acute radiation injury or clinical signs are expected to occur.

The Incident Investigation Team (IIT) of the USNRC reported that the event was caused by the following:

1. OSC had weaknesses in their radiation safety program that were a major contributing cause of the seriousness of the event and radiation exposure consequences. Because of the rapid expansion in their HDR brachytherapy program from one facility to ten facilities in less than a year, the Radiation Health and Safety Officer failed to ensure that the staff at all facilities received adequate radiation safety training and that all management instructions relating to HDR were being followed;

2. A number of weaknesses were found in the design and testing of the Omnitron 2000. Weaknesses were identified in the testing and validation of source-wire design, and in the design of certain safety features of the HDR afterloader. These could allow the undetected retraction and further use of a broken wire with no warning to the user;

3. The safety culture at IRCC contributed significantly to the event. Technologists routinely ignored the PrimAlert-10 alarm. Its problems were worked around and not fixed. Technologists did not survey patients, the afterloader, or the treatment room following HDR treatments. The authorized user failed to wear a film badge on both occasions when the source was encountered;

4. Overall regulatory oversight was weak. NRC regulations do not directly address HDR brachytherapy to the extent that teletherapy and low dose rate brachytherapy are addressed.

## D. REQUIRED LICENSEE ACTIONS

1. Information contained in this Bulletin does not constitute a new requirement. In the interest of safety, all brachytherapy licensees are however enjoined to consider the instructions stated in **Appendix A** to be followed by facility staff and personnel who are involved in the use and handling of radioactive materials.

2. The licensee should evaluate its training programs to determine if these are sufficient to ensure proper performance of radiation safety activities. The licensee, through the **RHSO**, should ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's radioactive material program. The RHSO should implement written policy and procedures for training personnel who work in or frequent areas where radioactive material is used or stored.

3. Licensees using HDR afterloaders are enjoined to immediately implement the actions stated in **Appendix B**.

**This bulletin shall be posted** in a place where it could be read by everyone concerned. If there are further questions, please contact the person listed below:

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September 28, 1993

## APPENDIX A

## INSTRUCTIONS TO USERS OF RADIOACTIVE MATERIAL IN BRACHYTHERAPY

1. The licensee should instruct individuals working in or frequenting any portion of a restricted radiation area on the health protection problems associated with exposure to radioactive materials or radiation, on precautions or procedures to minimize exposure, and on the purposes and functions of protective devices employed.

2. The licensee should provide radiation safety instruction to all personnel assigned to care for patients undergoing implant therapy. This instruction must include information on the size and appearance of the brachytherapy sources; procedures for patient and visitor control; and safe handling and shielding instructions in case of a dislodged source.

## APPENDIX B

## RECOMMENDATIONS FOR LICENSEES USING HDR AFTERLOADERS*

1. The licensee, upon removal of the source, should make a radiation survey of the patient with an appropriate radiation detection survey instrument to confirm that all sources have been removed. For surveys associated with HDR procedures, the licensee must use a portable radiation measurement survey instrument, capable of measuring dose rates of **1 millirem per hour to at least 1000 millirem per hour**. It is important to use calibrated survey instruments with appropriate sensitivity, since the high exposure rates associated with these sources can easily overload some survey instrument detectors, resulting in a false low reading. This survey of the patient must be done whether or not there is any indication of radiation levels provided by an area radiation monitor. The surveys shall be performed immediately after completion of the therapy procedure before removal of the patient from the treatment room.

   The required area monitor provides an immediate indication of a possible problem and thus serves a useful function as an early warning device. The area monitor will provide a visible indication of an exposed or partially exposed source, and must be observable immediately on entry into the treatment vault. It must be equipped with an independent source of backup power and checked with a dedicated check source for proper operation each day of use of the HDR device.

2. The licensee should 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. The licensee should not begin any treatment procedure for which a decoupled or jammed source cannot be removed expeditiously from the patient and placed in a shielded condition. The licensee should ensure that appropriate staff and equipment are available immediately, at the location that the HDR procedure is performed, to implement the written emergency procedures. Equipment shall include shielded storage containers, remote handling tools, and, if appropriate,

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*A High-Dose-Rate (HDR) afterloader is a remote afterloading brachytherapy unit capable of producing exposure rates in excess of 500 rads (centigray) per hour at one centimeter.

supplies necessary to surgically remove applicators or sources from the patient, to include scissors and cable cutters. The emergency source removal procedure should minimize exposure to health care personnel while maximizing safety of the patient.

3. During all patient treatments, both the authorized user and either the medical physicist or Radiation Health and Safety Officer must be physically present. Physical presence, for this purpose, is defined as within audible range of normal human speech.

4. The licensee should ensure that personnel are trained in both the routine use of the HDR afterloading device and emergency procedures necessary to return the source to a safe condition. Training should include emergency procedures and dry runs, for coupled and decoupled sources that either remain in the patient or remain exposed external to the patient. Training should be provided immediately for new personnel, and retraining provided semiannually, for all personnel.