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

January 7, 1991

NRC INFORMATION NOTICE NO. 91-02: BRACHYTHERAPY SOURCE MANAGEMENT

Addressees:

All Nuclear Regulatory Commission (NRC) medical licensees authorized to use byproduct material for medical purposes.

Purpose:

This information notice is intended to emphasize to medical use licensees the potential radiation hazards resulting from improper handling of brachytherapy sealed sources. Licensees are expected to review this information for applicability to their radioactive sealed source procedures, distribute the notice to those responsible for radiation safety and quality assurance, and consider actions, if warranted, to establish procedures to prevent similar problems from occurring at their facilities. However, suggestions contained in this notice do not constitute any new NRC requirements, and no writter response is required.

Description of Circumstances:

The following cases are recent events reported to NRC that have resulted in unintended radiation doses to humans as a result of improper handling of radioactive sealed sources:

<u>Case 1</u>: On December 14, 1989, during preparation for a brachytherapy procedure, the medical physicist noted that there were only two scurces present within the source storage safe drawer, instead of the expected three sources. The missing source contained 53 millicuries of cesium-137. The Radiation Safety Officer was notified, and together with the physicist, made a physical search and radiation survey of the area. Radiation surveys were performed with a Geiger Mueller meter and a gamma scintillation detector. The search and survey were expanded to the remainder of the facility, but the source was not found. After a review of the brachytherapy source inventory records, it was determined that the source had not been returned to the source storage safe after completion of a brachytherapy procedure on October 19, 1989. The root cause of the loss of the source was the failure to return all brachytherapy sources to the source storage area promptly after removal from the patient, and failure to document that transfer procedure. A contributing factor was the white color of some sources, which are easy to lose among white linens, paper, and debris. At this facility, all sealed sources are color-coded according to their nominal activity. For example, 20-mg sources are color-coded in white.

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The licensee speculated that the 20-mg (white) source may have been mistaken for cut pieces of white nylon spacers, and may have been inadvertently placed in normal trash. The licensee failed to perform radiation surveys of disposable waste material at the completion of the October 19, 1989 procedure. Personnel monitoring devices did not indicate unusual levels of radiation exposure, although one technologist who was involved in the October procedure did not wear the required ring badge. Since no information exists to document who came into contact with the source, or for how long, additional dose estimates would be unreliable. In conclusion, the source is probably in a local landfill, and if there, is buried in an active burial area and is approximately 25-40 feet below the surface.

Case 2: A patient to receive an endobronchial iridium-192 treatment received an unintended therapy dose to the face. The misadministration occurred when a nylon ribbon, containing 25 seeds of 3.5 millicuries each of iridium-192, was inserted via a catheter into the patient's bronchi. The nylon ribbon became completely dislodged from the catheter, was expelled outside of the lung, and came to rest next to the patient's face. The catheter remained in place in the lung. The duty nurse noticed the dislodged source at approximately midnight, but took no action at that time. At 2:00 a.m. that same night, the duty nurse, using bare hands, taped the end of the ribbon containing the iridium-192 seeds to the left side of the patient's face. At approximately 4:15 a.m., the charge nurse, while attending the patient, noticed the dislodged source. The charge nurse called the Radiation Safety Officer, who directed the removal of the ribbon, using a remote handling tool. The sources were removed from the patient, and placed in a shielded container. The estimated dose to the patient was: 1,032 rem to a portion of the left side of the face, 282 rem to the eyes, and 357 rem to the scalp (at one point the patient had folded the ribbon back into her hair). The duty nurse received an estimated 17.6 rem to her hands. In addition to the source becoming dislodged, the cause of this event was the inappropriate response of the duty nurse to the dislodged source. The root cause is the failure of the licensee to provide radiation safety instruction to all personnel caring for a patient undergoing implant therapy. Corrective actions undertaken included: removing the duty nurse from the care of patients receiving brachytherapy implant therapy until additional training has been completed, and a written examination of personnel, after training, that requires an 80% passing score. In addition, the catheter that contains the iridium-192 seeds will be crimped to prevent the seeds from leaving the catheter.

<u>Case 3</u>: A total of seven seeds in nylon ribbon, each containing 7.2 millicuries of iridium-192, were acquired to be used in the treatment of a patient with lung cancer. It was decided that only five of the seven seeds would be needed to deliver the prescribed dose. On July 5, 1990, the ribbon was cut into two pieces. The two ribbons, one containing two seeds, and the other containing five seeds, were placed in a storage/transport container and taken to the patient's room. The five seed ribbon was implanted into the patient and

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explanted 10 hours later. The two seed ribbon was left in the storage container in the patient's room during the 10-hour treatment period. At the time of source removal, the radiation therapy physician counted the seeds removed from the patient and verified that it matched the number of seeds implanted. At the completion of the explantation procedure, a radiation survey of the patient's room was conducted, and showed no detectable radiation above background. On July 27, 1990, an inventory of the seeds, in preparation for their return to the supplier, revealed that the ribbon containing two seeds was missing. A search revealed the two seeds within a crack between the carpeting and the wall, in the patient's room where the July 5th brachytherapy procedure took place. It is assumed that the seeds were pushed into the crack when the room was vacuumed, after the patient was released on July 6, 1990. The seeds remained in the room for 22 days before being recovered. The room remained empty until July 26, 1990, when another patient was admitted to the room. The patient and his wife remained in the room for the next 15 hours, at which time the sources were found and removed. The cause of this incident was the failure to promptly conduct a source inventory, after removing them from the patient, as described in 10 CFR 35.406. Documenting the return of the sources as required would have made it obvious that not all the sources that had been removed from storage had been returned.

Licensees are reminded of the importance of ensuring the safe performance of licensed activities in accordance with NRC regulations, requirements of their licenses, and accepted medical practice. Sealed sources for therapeutic use are capable of delivering significant unintended exposures to patients, health care workers, and members of the general public, when source management procedures are not followed. The lost sources in Cases 1 and 3 may have caused significant unintended exposure to a number of people during the time they were out of the licensees' control.

In view of these and other recent incidents involving mismanagement of brachytherapy sources, licensees are reminded of their responsibilities to:

- 1. Provide radiation safety instruction to all personnel caring for the patient undergoing implant therapy, and ensure that the instructions meet the requirements of 10 CFR 35.410.
- 2. Maintain a record log for brachytherapy source use, that includes the names of individuals properly trained, instructed, and permitted to handle the sources as described in 10 CFR 35.406(b)(1).
- 3. Immediately after implanting the sources in a patient, make a radiation survey of the patient and the area of use to confirm that no sources have been misplaced. A record shall be made of each survey as described in 10 CFR 35.406(c).

- 4. After the sources are removed from the patient, conduct a radiation survey of the patient to confirm that all sources have been removed as required in 10 CFR 35.404(a), and survey the area of use, to include linens, disposables, and debris, to prevent the inadvertent disposal of a source into regular trash.
- 5. Return brachytherapy sources to the storage area promptly upon their removal, and count the number returned to ensure that all sources taken from storage have been returned as required by 10 CFR 35.406(a).
- 6. Maintain a record to include the number and activity of sources removed date of removal and return, the number and activity of sources remaining in storage after removal and return, and the initials of the individuals who removed and returned the sources as described in 10 CFR 35.406(b)(?).

No specific written response is required by this information notice. If you have any questions about this matter, please contact the appropriate regional office or this office.

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

Technical Contact: Sally Merchant, NMSS (301) 492-0637

Attachments:

- 1. List of Recently Issued NMSS Information Notices.
- 2. List of Recently Issued NRC Information Notices.



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151 Richard Cunningham, Director Division of Industrial and Medical Nuclear Safety Office of Nuclear Material Safety and Safeguards Technical Contact: Sally Merchant, NMSS (301) 492-0637 Attachments: 1. List of Recently Issued NMSS Information Notices. 2. List of Recently Issued NRC Information Notices. Distribution NRC File Center IMNS Central Files SMerchant NMSS r/f RECunningham IMAB r/f GS job lom NMSS Dir r/f JEG1enn LWCamper IMOB Tech. Editor, CTrottier E. Kraus 12/ /90 12/06/90 *-~ Dreviau-IMNSX : IMNSX OFC : IMAB* : IMAB* : IMAB* NAME:SMerchant:LCamper :JEGlenn :GSjoblom :RCunningham DATE: 12/20/90 : 12/20/90 : 12/20/90 : 12/20/90 : 12/27/90

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LIST OF RECENTLY ISSUED NMSS INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
90-82	Requirements for Use of Nuclear Regulatory Comm- ission-(NRC-)Approved Transport Packages for Shipment of Type A Quanti- ties of Radioactive Materials.	12/31/90	All registered users of NRC-approved packages.
90-81	Fitness for Duty	12/24/90	All U.S. Nuclear Regulatory Commission (NRC) and non-power reactor licensees.
90-75	Denial of Access to Current Low-Level Radio- active Waste Disposal Facilities	12/5/90	All Michigan holders of NRC licenses.
90-71	Effective Use of Radiation Safety Committees to Exercise Control Over Medical Use Programs	11/6/90	All NRC licensees authorized to use byproduct material for medical purposes.
90-70	Pump Explosions Involving Ammonium Nitrate	11/6/90	All uranium fuel fabrication and conversion facilities.
90-38, Supp. 1	License and Fee Require- ments for Processing Fin- ancial Assurance Submittals for Decommissioning	11/6/90	All fuel facility and materials licensees.
90-67	Potential Security Equip- ment Weaknesses	10/29/90	All holders of OLs or CPs for nuclear power reactors and Category 1 fuel facilities.
90-63	Management Attention to the Establishment and Maintenance of A Nuclear Criticality Safety Program	10/03/90	All fuel cycle licensees possessing more than critical mass quantities of special nuclear material

OL = Operating License CP = Construction Permit

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LIST OF RECENTLY ISSUED NRC INFORMATION NOTICES

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Information Notice No.	Subject	Date of Issuance	Issued to
91-01	Supplier of Misrepresented Resistors	01/04/91	All holders of OLs or CPs for nuclear power reactors.
90-82	Requirements for Use of Nuclear Regulatory Comm- ission-(NRC-)Approved Transport Packages for Shipment of Type A Quanti- ties of Radioactive Materials.	12/31/90	All registered users of NRC-approved packages.
90-81	Fitness for Duty	12/24/90	All U.S. Nuclear Regulatory Commission (NRC) material and non-power reactor licensees.
90-80	Sand Intrusion Resulting in Two Diesel Generators Becoming Inoperable	12/21/90	All holders of OLs or CPs for nuclear power reactors.
90-79	Failures of Main Steam Isolation Check Valves Resulting in Disc Separation	12/20/90	All holders of OLs or CPs for nuclear power reactors.
90-78	Previously Unidentified Release Path from Boiling Water Reactor Control Rod Hydraulic Units	12/18/90	All holders of OLs or CPs for boiling water reactors (BWRS). 7
90-77	Inadvertent Removal of Fuel Assemblies from the Reactor Core	12/12/90	All holders of OLs or CPs for pressurized- water reactors (PWRS).
88-23, Supp. 3	Potential for Gas Binding of High-Pressure Safety Injection Pumps During A Loss-Of-Coolant Accident	12/10/90	All holders of OLs or CPs for pressurized- water reactors (PWRs).
90-76	Failure Of Turbine Overspeed Trip Mechanism Because of Inadequate Spring Tension	12/7/90	All holders of OLs or CPs for nuclear power reactors.

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