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

October 7, 2005

NRC INFORMATION NOTICE 2005-27: LOW-DOSE-RATE MANUAL BRACHYTHERAPY--EQUIPMENT-RELATED MEDICAL EVENTS

ADDRESSEES

All medical licensees.

PURPOSE

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice (IN) to inform addressees of recently reported medical events that occurred during an NRC licensee's implementation of low-dose-rate (LDR) manual brachytherapy procedures. 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, the information contained in this IN does not constitute new NRC requirements; therefore, no specific action nor written response is required.

DESCRIPTION OF CIRCUMSTANCES

On March 28, 2005, an NRC licensee reported to NRC its identification of two medical events involving radiation doses to unintended treatment sites of two patients. The licensee had administered LDR manual brachytherapy treatments to the patients in February and March 2004 and, during a subsequent review, licensee staff determined that the treatments had resulted in medical events, as defined in NRC's regulations. During a special NRC inspection conducted on March 30, 2005, to review the circumstances of the two medical events reported by the licensee, the inspector identified three additional patients who had treatments similar to those that resulted in the reported medical events. One of those additional patients exhibited observable side effects, as did the two patients involved in the medical events reported by the licensee. As a result, NRC upgraded the special inspection to an Augmented Inspection Team (AIT) on March 31, 2005. The purpose of the AIT was to examine the conditions and circumstances surrounding the medical events to determine the probable causes and contributing factors of the events.

The AIT concluded that five LDR manual brachytherapy treatments had resulted in medical events, as defined in Title 10 of the Code of Federal Regulations (CFR) Part 35. Three of the patients developed skin lesions on the upper thighs from radiation doses to the skin of the upper thighs, an unintended treatment site. The nature of the lesions indicated that the doses were greater than 1100 centigray (cGy) (1100 rads). The other two patients did not exhibit any unintended radiation effects. Therefore, those two patients received unintended doses to the

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thighs that were below the threshold for observable radiation effects. The AIT also determined that the root cause of these medical events was the licensee staff use of radioactive sources with smaller diameters than that specified in the instructions distributed with the brachytherapy applicator employed in all five cases. This error allowed the sources to move from their intended position within the applicator to a position that resulted in the unintended doses to the skin of the five patients.

The applicator involved in the five medical events was a Mick Radio-Nuclear Instruments, Inc. Wang Front-Loading Vaginal Applicator, Model 8524 (applicator), intended for use with cesium-137 sources, to treat patients. See the attached diagram of the Wang applicator. The instructions provided with the applicator specified the use of sources manufactured by the 3M Company (3M), and the applicator was marked with the appropriate source dimensions.

The applicator design allowed the sources to be inserted into the applicator after the applicator had been positioned in the patient for treatment (i.e., “afterloaded”), thereby reducing the radiation dose to brachytherapy staff. After the applicator was positioned within the patient, one of the sources was placed into a hinged insert, referred to as a “bucket,” and subsequently positioned within the applicator, perpendicular to two sources to be positioned in the tandem portion of the applicator. The tandem sources were loaded into a closable flexible carrier tube, and a coil spring was inserted into the tube, to hold the sources in position. Once the loaded flexible carrier tube was closed, the tube was placed into the applicator.

During each of the first five brachytherapy treatments performed by the licensee with the Wang applicator, that resulted in medical events, licensee staff selected G.E. Healthcare (formerly known as Amersham; hereafter referred to as Amersham) sources for use in the tandem portion of the applicator. The Amersham sources were different in a critical dimension from the 3M sources specified in the instructions - they were too small in diameter, being 2.6 millimeter (mm) (0.10 inch) in diameter, when 3.1 mm (0.12 inch) diameter sources were specified. As a result, the tandem sources slid down to the opposite end of the applicator’s flexible carrier tube whenever the applicator was tilted more than 20 degrees off-level (i.e., the tandem sources moved out of their intended position whenever a patient moved more than 20 degrees off-level (e.g., sat up) during treatment), resulting in irradiation of the skin on the patient’s thighs. The Amersham sources moved through the center of the applicator’s carrier tube spring because the diameter of the sources was smaller than the inner diameter of the coil spring.

The licensee became aware of the error in April 2004, after the authorized user observed effects during examinations of the three patients who exhibited skin injury. The authorized user requested that licensee staff investigate the possible cause of the injuries. During this investigation, licensee staff reviewed the instructions that came with the applicator, noticed that the instructions specified the use of 3M sources, recognized that the sources that had been used were Amersham sources, not 3M sources, and discovered the mobility of Amersham sources when used in the applicator’s tandem source holder.

In April 2004, immediately after the licensee identified that the Amersham sources could change position in the Wang applicator’s tandem source carrier tube during brachytherapy treatments, the licensee initiated actions to prevent similar unintended patient exposures. The

licensee modified the applicator by using different hardware to keep the radioactive sources in proper position during brachytherapy treatments. The licensee's modification of the applicator was effective.[1] However, the licensee misinterpreted the medical event reporting requirements in 10 CFR 35.3045(a)(3) and failed to promptly identify, in April 2004, that multiple medical events had occurred. Reporting of medical events (2) to NRC was delayed until March 2005, when, following patient reexaminations, the licensee determined that treatment side effects for two patients were more severe than previously observed.

DISCUSSION

NRC staff reviewed the instructions associated with use of the Wang applicator and identified several issues of generic concern that staff believes may result in improper use of the device. For example:

- Instructions explaining the use of alternate sources were not clear. Portions of the instructions provided with the applicator indicated that only 3M sources should be used with the applicator. However, other portions of the instructions indicated that the tandem portion of the applicator may be loaded with sources manufactured by other suppliers, and it referenced an attachment with source comparisons. The attachment was not clear regarding what other sources could be used (e.g., it did not indicate the source manufacturers' names or the technical limitations on source physical dimensions).

- Instructions explaining the proper configuration of sources were not clear. The instructions indicated that the applicator used three sources in a "T" configuration (e.g., one in the bucket and two in the tandem portion of the applicator). However, another section stated that up to four sources could be used in the tandem portion of the applicator.

- Instructions did not clearly alert the user to proper action that must be taken if the spring in the tandem portion of the applicator required shortening. The distal end of the applicator coil spring was designed with an inward bend, to prevent source movement down the center of the spring. The instructions stated that the applicator spring could be shortened. This would be necessary if more than two sources were used in the tandem portion of the applicator. The instructions did not provide a warning to the user not to cut the distal end of the spring with the inward bend, if shortening of the spring was necessary. Such an action could result in source movement down the center of the spring.

The licensee had not used more than two sources in the tandem portion of the applicator for any of the five similar brachytherapy treatments completed. Therefore, the licensee did not cut the applicator spring. However, the spring supplied with the licensee's applicator did not include the inward bend at the distal end, which increased the potential for source movement under certain circumstances. The Amersham sources could, and did, for the five patients involved in

[1]Such a user modification is not regulated by the Food and Drug Administration (FDA).

medical events, move down the center of the spring to the opposite end of the tandem portion of the applicator when the patients undergoing treatment raised up from horizontal positions.

NRC referred the generic-concern issues of the applicator instructions and this licensee's experience with the applicator spring to the FDA for its review and evaluation. Presently, FDA's review and evaluation of these issues is in progress and has not been completed.

The medical events involved errors in selection of ancillary equipment--sealed radioactive sources--required for use of the afterloader applicator employed in the treatments, resulting in failure of the sealed sources to remain in their intended positions throughout the specified treatment times. Licensees performing LDR manual brachytherapy procedures are expected to review this IN and:

- Assure that radioactive sources and any other ancillary devices to be used with an LDR manual brachytherapy applicator for a therapeutic procedure are designed for use with, or are known to be compatible with, the LDR applicator to be used during the procedure;

- Assure that all LDR manual brachytherapy applicator users are familiar with the operating procedures and applicable usage restrictions of all equipment to be employed in a therapeutic procedure, before actual use of such devices, associated radioactive sources, and any other ancillary equipment;

- Encourage device and equipment users to review all vendors' pertinent documentation and clarify any concerns with the vendors, regarding particular devices, sources, or equipment, before the devices, sources, or equipment are used for patient treatments. Licensees are expected to clarify any uncertainties, discrepancies, or potential errors in usage directions provided in vendor-supplied documentation and/or through verbal discussion with a vendor or on-site vendor representative before use of the device(s), sources, or equipment; and

- Promptly report: 1) any and all medical events, to NRC; and 2) all equipment malfunctions or problems, to the vendors and, if required, to the licensing authorities.

CONTACTS

This information notice does not require any specific action or written response. Please direct any questions about this matter to the technical contact below, or the appropriate regional office.

/RA/ Patricia K. Holahan, for
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Attachments:
1. Diagram of Wang Applicator
2. List of Recently Issued NMSS Generic Communications

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Recently Issued NMSS Generic Communications

Date	GC No.	Subject	Addressees
2/11/05	BL-05-01	Material Control and Accounting at Reactors and Wet Spent Fuel Storage Facilities	All holders of operating licenses for nuclear power reactors, decommissioning nuclear power reactor sites storing spent fuel in a pool, and wet spent fuel storage sites.
8/25/05	RIS-05-18	Guidance for Establishing and Maintaining a Safety Conscious Work Environment	All licensees, applicants for licenses, holders of certificates of compliance, and their contractors subject to NRC authority
8/10/05	RIS-05-16	Issuance of NRC Management Directive 8.17, “Licensee Complaints Against NRC Employees”	All licensees and certificate holders.
8/3/05	RIS-05-15	Reporting Requirements for Damaged Industrial Radiographic Equipment	All material licensees possessing industrial radiographic equipment, regulated under 10 CFR Part 34.
7/13/05	RIS-05-13	NRC Incident Response and the National Response Plan	All licensees and certificate holders.
7/11/05	RIS-05-12	Transportation of Radioactive Material Quantities of Concern NRC Threat Advisory and Protective Measures System	Licensees authorized to possess radioactive material that equals or exceeds the threshold values in the Additional Security Measures (ASM) for transportation of Radioactive Material Quantities of Concern (RAMQC) under their 10 CFR Part 30, 32, 50, 70, and 71 licenses and Agreement State licensees similarly authorized to possess such material in such quantities under their Agreement State licenses.
7/11/05	RIS-05-11	Requirements for Power Reactor Licensees in Possession of Devices Subject to the General License Requirements of 10 CFR 31.5	All holders of operating licenses for nuclear power reactors and generally licensed device vendors.

Date	GC No.	Subject	Addressees
6/10/05	RIS-05-10	Performance-Based Approach for Associated Equipment in 10 CFR 34.20	All industrial radiography licensees and manufacturers and distributors of industrial radiography equipment.
4/18/05	RIS-05-06	Reporting Requirements for Gauges Damaged at Temporary Job Sites	All material licensees possessing portable gauges, regulated under 10 CFR Part 30.
4/14/05	RIS-05-04	Guidance on the Protection of Unattended Openings that Intersect a Security Boundary or Area	All holders of operating licenses or construction permits for nuclear power reactors, research and test reactors, decommissioning reactors with fuel on site, Category 1 fuel cycle facilities, critical mass facilities, uranium conversion facility, independent spent fuel storage installations, gaseous diffusion plants, and certain other material licensees.
2/28/05	RIS-05-03	10 CFR Part 40 Exemptions for Uranium Contained in Aircraft Counterweights - Storage and Repair	All persons possessing aircraft counterweights containing uranium under the exemption in 10 CFR 40.13(c)(5).
7/29/05	IN-05-22	Inadequate Criticality Safety Analysis of Ventilation Systems at Fuel Cycle Facilities	All licensees authorized to possess a critical mass of special nuclear material.
6/23/05	IN-05-17	Manual Brachytherapy Source Jamming	All medical licensees authorized to possess a Mick applicator.
5/17/05	IN-05-13	Potential Non-conservative Error in Modeling Geometric Regions in the Keno-v.a Criticality Code	All licensees using the Keno-V.a criticality code module in Standardized Computer Analyses for Licensing Evaluation (SCALE) software developed by Oak Ridge National Laboratory (ORNL)
5/17/05	IN-05-12	Excessively Large Criticality Safety Limits Fail to Provide Double Contingency at Fuel Cycle Facility	All licensees authorized to possess a critical mass of special nuclear material.

Date	GC No.	Subject	Addressees
4/7/05	IN-05-10	Changes to 10 CFR Part 71 Packages	All 10 CFR Part 71 licensees and certificate holders.
4/1/05	IN-05-07	Results of HEMYC Electrical Raceway Fire Barrier System Full Scale Fire Testing	All holders of operating licenses for nuclear power reactors, except those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel, and fuel facilities licensees.
3/10/05	IN-05-05	Improving Material Control and Accountability Interface with Criticality Safety Activities at Fuel Cycle Facilities	All licensees authorized to possess a critical mass of special nuclear material.

Note: NRC generic communications may be found on the NRC public website at http://www.nrc.gov, under Electronic Reading Room/Document Collections.