UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF FEDERAL AND STATE MATERIALS
AND ENVIRONMENTAL MANAGEMENT PROGRAMS
WASHINGTON, DC 20555

August 28, 2009

NRC INFORMATION NOTICE 2009-17: REPORTABLE MEDICAL EVENTS INVOLVING TREATMENT DELIVERY ERRORS CAUSED BY CONFUSION OF UNITS FOR THE SPECIFICATION OF BRACHYTHERAPY SOURCES.

## ADDRESSEES

All U.S. Nuclear Regulatory Commission (NRC) medical use licensees and NRC master materials licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers.

## PURPOSE

The NRC is issuing this information notice (IN) to alert addressees to treatment delivery errors and associated medical events caused by confusion of units for the specification of low-energy photon-emitting brachytherapy sources implanted into patients. The NRC expects recipients to review the information for applicability to their facilities and to consider actions, as appropriate, to avoid similar problems. However, suggestions contained in the IN are not new NRC requirements; therefore, no specific action or written response is required. The NRC is providing this IN to the Agreement States for their information and for distribution to their medical licensees as appropriate.

## DESCRIPTION OF CIRCUMSTANCES

The NRC has received reports of numerous medical events caused by errors in confusing the units of source strength in the specification of sources—specifically, units of air-kerma strength and apparent activity in units of millicurie (mCi). Although the details of the medical events varied, human error, not the design or functioning of the equipment, caused all of these events. These events illustrate the following three main areas of concern:

(1) data entry error, whereby the source strength was entered into a computerized treatment planning system in units not used by the system

(2) ordering error, whereby sources of an incorrect source strength were delivered and used because either the licensee or the manufacturer made an error in the requested units

(3) conversion error, whereby a conversion between two different units was omitted or performed incorrectly

The NRC recognizes that other pathways may lead to treatment delivery errors, such as the mislabeling of source strength or errors in patient dose calculations caused by incorrect programming of the treatment planning software (e.g., incorrect conversion factor or decay correction values within the software programming). However, this IN only addresses events caused by errors in the use of differing source-strength units.

Data Entry Error

One recent data entry error for a manual implant of iodine-125 resulted in the patient receiving a dose higher than the intended dose when the wrong units were entered into the treatment planning system.

Another event reported to the NRC in which the patient received a higher-than-intended dose because of a data entry error was caused by a licensee staff member who entered the numerical value for mCi instead of the default units of air-kerma strength used in the treatment planning system. Based on the 27-percent lower activity per source entered, the treatment planning system calculated a higher quantity of seeds to deliver the intended dose.

Both events were avoidable human errors associated with entering information into a treatment planning system using the wrong units to specify the source strength of the brachytherapy sources.

Ordering Error

As a result of a licensee error when ordering brachytherapy sources, a patient received a 27-percent overdose. The treatment planning system calculated the source strength in air-kerma strength per seed; however, when placing the order, the licensee specified the source activity in mCi per seed using the same numerical value.

A similar medical event occurred at another facility when the licensee ordered the brachytherapy sources in units of mCi per seed instead of ordering them with the same numerical value but in units of air-kerma strength per seed. Because of this error, 10 different patients received doses 27 percent higher than those prescribed in the written directive.

The NRC also received reports of medical events that were caused by differences in the units used by the individual who ordered the sources and the vendor that supplied them. In one such case that resulted in a 28-percent overdose, a seed manufacturer delivered seeds in units of mCi per seed, but the individual who had ordered the sources actually requested the seeds of the same numerical value but in units of air-kerma strength per seed.

Conversion Error

In the case of a medical event involving an interstitial brachytherapy treatment using iridium-192 seeds, the conversion from units of milligram radium-equivalent (mg Ra-eq) to units of air-kerma strength was omitted before the numerical value was entered into the treatment planning system. The numerical value in mg Ra-eq was entered into the treatment planning system using units of air-kerma strength. This medical event was further compounded by the use of a dose rate factor being based on the wrong isotope because the licensee omitted acceptance

testing of the treatment planning software for iridium-192. Together, these two errors resulted in a delivered dose of 4,590 centigray (cGy), rather than the intended 2,500-cGy dose.

In a separate medical event, four different patients received overdoses of 56 to 78 percent higher than those prescribed when the conversion from mg Ra-eq to activity in units of mCi was omitted before entry into the treatment planning system.

**DISCUSSION**

Human error, not the design or functioning of the equipment, was the cause of all of these events. To prevent these types of occurrences, licensees should have the written directive and treatment plan readily available when they order brachytherapy seeds from the manufacturer and when they receive the seeds from the manufacturer for comparison with the calibration certificate. Licensees should use written forms that capture key data (i.e., dates, quantities, and units) rather than relying on verbal telephone orders when ordering brachytherapy seeds from a manufacturer to limit the potential for miscommunication and minimize the likelihood of errors. However, if licensees order brachytherapy seeds by telephone, they could request that the manufacturer fax or e-mail a copy of the order for their immediate review. This procedure would allow licensees to find discrepancies before the manufacturer transfers the sources to them.

Additional precautions that licensees may take include developing and implementing working procedures that require independent confirmation of key processes, a system of redundant checks, and reviews of the treatment plan. Independent confirmations should include an independent verification of the accuracy of the dose calculation algorithms. Redundant checks should include checking the quantity of seeds, numerical values, and units for specifying the source strength of the seeds before ordering from the manufacturer and upon receipt of the seeds. Treatment plan reviews should include verifying the consistency and accuracy of the following information among the written directive, treatment plan, and calibration certificate: (1) all dates, (2) radioactive decay, (3) numerical values, (4) quantities, and (5) units. Furthermore, licensees should check that the correct data was entered into the treatment planning system. A good standard of practice accepted by many physicists is that an individual other than the person who entered the data perform these redundant checks.

Users of treatment planning systems are reminded to refer to the software manufacturer's instructions for appropriate data entry methods. Effective communication among all involved persons (e.g., licensee staff, the seed manufacturer, and the treatment planning software manufacturer) is vital to an effective process.

As an additional reference for specifying the source strength, licensees may refer to guidance and practical standards contained in the American Association of Physicists in Medicine (AAPM) Report No. 21, "Specification of Brachytherapy Source Strength," Report of AAPM Task Group No. 32, issued 1987 (http://www.aapm.org/pubs/reports/rpt 21.pdf).

NRC's Advisory Committee on Medical Uses of Isotopes endorses the concept of using air-kerma strength when ordering brachytherapy sources and in patient treatment planning. By all licensees and manufacturers specifying the intensity of brachytherapy sources in units of air-kerma strength for every order and treatment plan, a standard of practice would be established

that would reduce the number of medical events caused be errors in confusing the units of source strength in the specification of sources.

**CONTACT**

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

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Division of Materials Safety
and State Agreements
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Enclosure:
List of Recently Issued Office of Federal and State Material and Environmental Management Programs Generic Communications

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**ML080710054**

| **OFC** | MSSA/MSEA | MSSA/MSEA | QTE | OGC |
|---|---|---|---|---|
| **NAME** | CFlannery: sxg6 | AMcIntosh | KAzariah-Kribbs | BJones |
| **DATE** | 05/27/09 | 06/01/09 | 06/03/09 | 08/11/09 |
| **OFC** | MSEA | MSSA | MSSA | |
| **NAME** | CEinberg | JLuehman | RLewis | |
| **DATE** | 08/11/09 | 08/18/09 | 08/28/09 | |

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**List of Recently Issued Office of Federal and State Material and Environmental Management Programs Generic Communications**

| Date | GC No. | Subject | Addressees |
|---|---|---|---|
| 01/12/09 | IN-2008-22 | Molybdenum-99 Breakthrough in Molybdenum-99/Technetium-99m Generators | All NRC medical, radiopharmacy, molybdenum-99/ technetium-99m generator manufacturers, and master materials licensees authorized to manufacture or use generators. All Agreement State Radiation Control Program Directors and State Liaison Officers. |
| 01/22/09 | IN-2009-01 | National Response Framework | All holders of operating licenses or certificates for nuclear power plants, research and test reactors, independent spent fuel storage installations, fuel cycle facilities, and radioactive materials. All holders of operating licenses for uranium recovery facilities and all holders of licenses or certificates for the following types of facilities undergoing decommissioning: nuclear power plants, research and test reactors, fuel cycle facilities, and uranium recovery facilities. |
| 02/03/09 | IN-2009-05 | Contamination Events Resulting from Damage to Sealed Radioactive Sources during Gauge Dismantlement and Nonroutine Maintenance Operations | All NRC materials licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers. |
| 03/30/09 | IN-2009-07 | Withholding of Proprietary Information from Public Disclosure | All current holders of and potential applicants for licenses, certificates of compliance, permits, or standard design certifications and any other persons submitting a request that information be withheld from public disclosure under the provisions of Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390, "Public Inspections, Exemptions, Requests for Withholding." |
| 05/07/09 | RIS-2009-07 | Status Update for the Implementation of NRC Regulatory Authority for Certain Naturally Occurring and Accelerator-Produced Radioactive Material | All NRC material and fuel cycle licensees. All Radiation Control Program Directors and State Liaison Officers. |
| 07/13/09 | RIS-2009-09 | Use of Multiple Dosimetry and Compartment Factors in Determining Effective Dose Equivalent from External Radiation Exposures | All NRC licensees, Agreement State Radiation Control Program Directors, and State Liaison Officers. |

Note: This list contains the six most recently issued generic communications issued by the Office of Federal and State Materials and Environmental Management Programs. A full listing of all generic communications may be viewed at the NRC public Web site at the following address: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/index.html.