Radioactive Materials Unit
625 Robert Street North
PO Box 64975
St. Paul, MN 55164-0975

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To: All MDH Licensed Users of Sealed Sources for Brachytherapy

From: Radioactive Materials Unit

Subject: Treatment Errors Caused by the Confusion of Units for the Specification of Brachytherapy Sources

Information Notice 2009-04

PURPOSE

The Minnesota Department of Health (MDH) is issuing this information notice 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 issues were reported to the US Nuclear Regulatory Commission (NRC). MDH 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 information notice are not new requirements; therefore, no specific action or written response is required.

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.

MDH recognizes that treatment delivery errors may result from errors in patient dose calculations caused by incorrect conversion factors, decay correction values, or from other mislabeling of source strength. However, this information notice 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 capture key data (i.e., dates, quantities, and units) in writing 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:

- all dates;
- radioactive decay;
- numerical values;
- quantities; and
- 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).

The 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. A standard of practice would be established if all licensees and manufacturers specify the intensity of brachytherapy sources in units of air-kerma strength for every order and treatment plan. That would reduce the number of medical events caused by confusing the units of source strength in the specification of sources.