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

September 12, 1994

NRC INFORMATION NOTICE 94-65: POTENTIAL ERRORS IN MANUAL BRACHYTHERAPY DOSE CALCULATIONS GENERATED USING A COMPUTERIZED TREATMENT PLANNING SYSTEM

Addressees

All U.S. Nuclear Regulatory Commission medical licensees.

Purpose

NRC is issuing this information notice to alert addressees to an event involving errors in the calculation of dose tables and isodose curves for several brachytherapy treatments and to the potential for errors in computer-generated dose calculations for brachytherapy treatment plans. It is expected that recipients will review the information for applicability to their operation and consider action, as appropriate, to avoid similar problems. However, information contained in this notice does not constitute new NRC requirements; therefore, no specific action nor written response is required.

Description of Event

Recently, NRC was notified of several events, at two NRC-licensed facilities, involving multiple patients receiving manual cesium-137 (Cs-137) brachytherapy treatments. The radiation dose administered to eleven patients was calculated to be in excess of the dose prescribed by the authorized users, by 5 to 30 percent.

The licensees used a Theratronics Theraplan/TP11 treatment planning system to perform the dosimetry calculations for linear Cs-137 sources. Through a detailed review of backup versions of the data files and discussion with Theratronics, the licensees determined that at some point before September 1992, the treatment planning system users re-entered data for Cs-137 as linear sources because a data file had been inadvertently deleted from the system. The Theraplan system, as supplied, contains sample data for radium-226 (Ra-226), iodine-125, and palladium-103 as linear sources, but no similar data for Cs-137. The user must enter 10 parameters to characterize linear sources other than those supplied by the vendor. The user manual and software offers, as an alternative, direct entry of a data table from a published source. However, due to a known "bug" in the version of the program used by this licensee, that option was not available. The computer-generated dose tables that were computed using erroneous data were in error by as much as 20 to 25 percent.

When the treatment planning system was originally set up, the vendor's representative assisted the licensee in entering the treatment parameters, and

the correct values were used. However, based on information provided by Theratronics, review of data files and testing of the software, it appears that when the users re-entered data for the Cs-137 source files in 1992, they entered the value of zero for the filter attenuation coefficient (to correct for attenuation by the source capsule). The software recognized the keyboard entry of zero as selection of an option to use an existing non-zero default value. The users relied upon the screen prompts to reenter the data.

In the case at hand, the software program displayed the value "0.0" both to the user on the screen and in the hard copy printout of the linear source data table entered by the user. The information displayed to the user on the computer monitor for this program did not indicate that the "0.0" was, in fact, a default value. The instructions in the technical manual regarding the use of default values were in a chapter on external beam treatment planning. The user was not aware that a default value selection option existed in this portion of the program, nor that the value zero would not be accepted as a valid numerical entry.[1]

Data tables for radium with a platinum filter are commonly used for non-radium sources at some facilities when the sources or treatments are described in milligrams-radium-equivalent (mgRaeq). The Cs-137 line sources with stainless steel filters (source encapsulation wall material) are comparable to Ra-226 sources filtered with 0.5 mm platinum. In this case, the users entered a gamma constant that was equivalent to Ra-226, as filtered by 0.5 mm of platinum. However, because of the default value selected for the attenuation factor when "0.0" was entered, a non-zero value was selected.

The users erroneously checked the computer-generated dose tables against along-and-away dose tables (Quimby tables[2]) developed for Ra-226 sources filtered by 1.0 mm of platinum. There was a failure to identify the error in the computer-generated dose values that were lower than would have been generated using correct parameters to characterize the Cs-137 sources. If the correct table (for Ra-226 sources filtered by 0.5 mm of platinum) had been used to check the calculations, the discrepancy in the computer-generated dose values would have been identified and could have been adjusted by adjusting the data elements. Coincidentally, the net result of the user's data re-entry and use of an incorrect data table for verification, was that the dose rate

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[1] A zero entry might be considered by the user during the process of fitting data computed by the treatment planning system to published data. That process involves an iterative adjustment to fitting factors among the ten data elements entered into the IMPLNT.DAT file until an adequate fit to measured data is obtained. First, it would be typical to adjust the gamma constant (i.e., exposure rate constant) entered into the IMPLNT.DAT file and have the computer recalculate data for comparison with published data. Depending on the success of adjustments to the gamma constant, the next data element to be adjusted would be the filter attenuation coefficient, and that adjustment process might reasonably be expected to include an entry of zero.

[2] Goodman, Quimby, et al, Physical Foundations of Radiology, Harper and Row

tables calculated by the treatment planning system appeared accurate within approximately 5 percent.

One of the licensees discovered, through routine verification of a patient treatment plan, that the computer-generated dose table had values lower than expected when compared with published dose tables for Cs-137 (Krishnaswamy tables[3]). After subsequent review and investigation, the licensee detected the error in the selection of one parameter used to define the physical characteristics of the Cs-137 sources.

Although both licensees had a written Quality Management Program (QMP), the treatment planning system that was involved in these events was owned and located at a cancer center that is jointly financed by the two licensees. Because the individual who performed the calculations was employed by the cancer center, neither licensee had detailed procedures to address the treatment planning as part of the QMP. The licensees assumed that the authorized users had responsibility for oversight of all aspects of the patients' treatments and that the licensee need only be aware of those aspects of the treatment actually conducted at the licensee's facility.

Discussion of Root Cause and Contributing Factors

An NRC team consisting of two risk assessment engineers, a medical physicist, and a radiation oncologist identified multiple causes of this event, including: the selection of an inappropriate reference table to check the computer-generated output dose calculations; use of the same incorrect table during the manual checks of the treatment plans; the inadvertent use of the default function for the filter attenuation factor used by the planning computer; lack of an independent review of treatment plans; lack of formal policies to control or record the modification of the planning software; lack of clear, formal policies governing the use of the computerized planning system; lack of oversight by the Radiation Safety Officer (RSO) or Radiation Safety Committee (RSC) at either hospital over the treatment planning for the brachytherapy procedures performed at their facilities; and poor software design and documentation. The team identified software deviations from many accepted standards of user-computer interface design.

Root Cause: The root cause of the brachytherapy events was a failure to adequately validate the data used in the computer planning system. Specifically, an error was made in performing an independent verification of computer-generated dose tables and patient treatment plans.

Software and Erroneous Data Files: Although the validation error in the use of an inappropriate reference table was the root cause of the brachytherapy errors, there was also an error in the data parameter entry such that the computer-generated dose values were too low. According to the licensee, this problem has been corrected in subsequent versions of the software.

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[3] V. Krishnaswamy, "Dose Distributions about Cs-137 Sources in Tissue," Radiology 105:181-184, 1972.

A meeting was held between NRC and FDA to discuss the computer software problems associated with these events. At the time of the incident, FDA(had an Import Alert in effect on the Theraplan treatment planning system resulting from a review of the manufacturer's Good Manufacturing Practices. However, on July 26, 1994, FDA cleared the Theraplan V05B/TP-11 V09B treatment planning system which will allow modifications to be made to existing software, as well as the import of new software. In addition, FDA is working with NRC in its review of this incident.

Other Contributing Factors: There were several other contributing factors as described above. There was no independent review or check of the treatment plans until the patient treatment in which the error was identified. Secondly, there were no formal policies and barriers to control or record the modification of the software or governing the use of the computerized planning system. Formal policies on file modification, and password or key protection may have prevented the loss of the original Cs-137 parameter set. In addition, formal policies governing the use of the planning system could have included mechanisms to handle inadvertent data loss such as use of backup or archived files or use of the technical manual for data reentry. Finally, there was little or no oversight by the RSO or RSC at either hospital over the treatment planning for the brachytherapy procedures performed at their facilities. Furthermore, the inspection findings revealed that the RSO/RSC for both licensees appeared to act as if the manual-afterloading treatment planning performed at the cancer center did not fall under their hospitals' NRC licenses.

General Discussion

This case highlights the importance of verifying data entry and performing independent checks of computer-generated dose tables and treatment plans. In addition, when data files are deleted, by whatever means, users should consider comparing data entry with older versions of the file, if backup files are available, to provide a second means of verifying data entry. This case also emphasizes the need for the manufacturer to provide adequate training for the user, regarding the use of the software in order to understand the logic of programs used in treatment planning systems and the need to be familiar with the conventions used by any software manufacturer for data entry. Although there were instructions in the technical manual indicating that when a default value was available as an option that entering zero or using the return key would result in use of the default value, they were only described in a chapter regarding external beam treatment planning.

Licensees using the Theraplan treatment planning system are encouraged to review computer-generated dose tables for linear sources other than Ra-226, or other sources for which data files have been manually entered, and to review the parameters currently in use on the treatment planning system, to verify their accuracy. In addition, users should ensure that they are familiar with the conventions used for accepting default values and with all parameters for which default values exist.

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Licensees are also reminded of the importance of appropriate oversight of the licensee's radiation safety program and QMP. Radiation therapy has changed in recent years and frequently involves multiple individuals from potentially separate organizations in the planning and administration of radioactive material to patients. In addition, if authorized users treat patients at more than one facility, each facility might have different QMPs. It is critical that licensee management ensure that individuals are properly instructed in the licensee's written QMP and that there are adequate mechanisms for oversight in place to determine that the QMP is effectively implemented by the appropriate individuals to provide high confidence that byproduct material is administered as directed by the authorized user.

This information notice requires no specific action nor or written response. If you have any questions about the information in this notice, please contact the technical contacts listed below, or the appropriate NRC regional office.

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Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material
Safety and Safeguards

Technical contacts: Patricia K. Holahan, NMSS
(301) 415-7847

Linda L. Kasner, RIV
(817) 860-8213

*See attached concurrence ** See previous concurrence

OFC	IMAB	E	RIV**	E	IMAB**	E	IMAB**	E	IMOB**	E
NAME	PKholahan		LKasner		LWCamper		JEGlenn		FCCombs	
DATE	08/30/94		06/03/94		06/27/94		07/06/94		07/11/94	

OFC	OGC		DD/IMNS		D/IMNS		TechEd*	
NAME	STreby		EWBrach		CJPaperiello		EKraus	
DATE	06/ /94		08/31/94		08/30/94		05/24/94	

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