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

March 24, 1999

NRC INFORMATION NOTICE 99-09: PROBLEMS ENCOUNTERED WHEN MANUALLY EDITING TREATMENT DATA ON THE NUCLETRON MICROSELECTRON-HDR (NEW) MODEL 105.999

Addressees:

All medical licensees authorized to conduct high-dose-rate (HDR) remote after loading brachytherapy treatments.

Purpose:

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice to alert addressees to the potential for patient misadministrations that may result from inadvertent changes to source step size that can occur when editing dwell time data. It is expected that recipients will review the information for applicability to their facilities and consider actions, as appropriate, to address these issues. However, suggestions contained in this information notice are not new NRC requirements; therefore, no specific action, nor written response, is required.

Description of Circumstances:

On February 26, 1999, an NRC licensee reported a misadministration that had occurred in the first fraction of a planned treatment of two fractions of 500 cGy (500 Rads) each for an HDR vaginal treatment. The sequence of events leading up to this misadministration began with the licensee encountering difficulty in electronically transferring the treatment plan, for this patient, from its Nucletron treatment planning system to their Nucletron microSelectron HDR treatment system. After several unsuccessful attempts at electronically transferring the patient's treatment plan to the treatment system, the licensee elected to manually enter the treatment plan directly into the treatment system's control station. This was accomplished without apparent difficulty.

On reviewing the printout of the treatment plan, before beginning treatment, the radiation oncologist noted that the planned source dwell times were incorrect and instructed that the plan be revised to the correct dwell times. While making the

required manual entry changes to edit the source dwell times, the keystrokes used in completing the data entry field changes caused the source step size to change from 2.5 mm to 10 mm. The licensee did not notice this change and the patient, therefore, was treated using

the incorrect step size. This resulted in the dose to the intended treatment site being less than 50 percent of the intended dose and considerable unintended dose to tissue distal to the intended treatment site. The licensee attributes this unintended and unnoticed change in step size to a software problem with the software used in the Nucletron treatment control station (TCS). However, had the licensee properly reviewed the complete final treatment plan, immediately before treatment, this misadministration could have been prevented.

Discussion:

A review of the preliminary inspection information related to this misadministration indicated that there were two software problems that contributed to this event: one with the Nucletron Plato Treatment Planning system; and, one with the microSelectron-HDR treatment control station. The documented problem with the treatment planning system was the inability to transfer the treatment plan to the HDR treatment system from the treatment planning system via disk or electronically. The microSelectron-HDR treatment system problem was the heretofore undetected possibility of making unintended and unnoticed changes to the source step size, while editing an unrelated parameter.

The manual data entry into, and subsequent editing of these data on, the Nucletron TCS were necessitated by the licensee's inability to transfer the original treatment plan for the Nucletron Plato treatment planning system to the TCS via either the network interface or floppy disk. Attempts to perform either type of transfer produced a "Error writing to file" with no indication of what is causing the problem.

A Nucletron service engineer investigated the cause of this transfer problem and found it to result from an undocumented limitation on the maximum number of combined patient and applicator points that can be transferred. When a treatment plan has more than 24 combined patient and applicator points, the treatment planning system refuses to write the treatment plan data file to either the hard disk or the floppy disk. TCS accesses PLATO's hard disk when a transfer via the network is required. If such a failure does occur, and the user subsequently reduces the combined patient and applicator points to a total of 24 or less, then the reduced data set can be successfully transferred. However, if it is necessary to transfer a treatment plan, to the HDR TCS, that contains a total of more than 24 patient and applicator points, then it will be necessary to enter either all or part of the treatment plan into the TCS manually.

The sequence of events that led to the erroneous step size change occurred as follows:

1. The treatment plan that eventually produced the erroneous step size was entered into the TCS manually because of the previously described inability to transfer it electronically;

2. The radiation oncologist discovered that the dwell times of this treatment plan were in error, when he reviewed the plan;

3. During the subsequent manual editing of the treatment plan on the TCS, to correct the erroneous source dwell times, the licensee used the "Tab" key twice in an attempt to move from one dwell time position to the next. This action inadvertently selected the step size option;

4. When the previous action had no effect on the selection of the next dwell time position to be edited, the licensee tried the "arrow" key twice in an attempt to select the desired dwell time data. This had the effect of changing the source step size from 2.5 mm to 10 mm;

5. The licensee did not notice the unintended selection of the step size option and subsequent change to the value of the step size. This change to the step size would have also resulted in changing the scale and overall length of the "loading grid ruler" above the channel one dwell positions, as well as the "treatment length value" per channel;

6. The licensee then used the mouse to select the next dwell time position(s) to be edited and successfully made the necessary corrections to the source dwell times.

7. The radiation oncologist reviewed and approved the revised treatment plan without noticing the altered step size. The patient was subsequently treated using this incorrect source step size.

The licensee did not discover the error in the step size for the first treatment until one week later, when it was preparing the treatment plan for the second of the two fractions to be administered to this patient. When the previous treatment plan was brought up in preparation for the second treatment, the licensee discovered the increased step size. At this point, the licensee corrected the erroneous step size and adjusted the written directive, and corresponding treatment plan, to compensate for the under dosage to the intended treatment site that occurred in the first fraction.

How did the licensee not notice this step size change? First, in attempting to select the dwell positions to be edited, by the inappropriate use of the "Tab" and "arrow" keys, the licensee did not expect this to have any affect on other (unrelated) treatment plan parameters. This expectation was reinforced by the lack of any cautions or other instructions, in the Nucletron microSelectron-HDR v1.2X manual, that would indicate otherwise. More importantly, the licensee expected to see a confirmation message that would have required it to acknowledge any changes to the treatment plan step size, in accordance with the information on page 4-23 of the users manual. Secondly, since the licensee did not anticipate that any of the other treatment plan parameters would change it did not check any parameters other than the source dwell times on the final printed treatment plan.

Nucletron has confirmed that this acknowledgment prompt, and corresponding warning message, only appears when the step size parameter is changed for the first time to a treatment plan that either: (1) has been electronically transferred from the treatment planning system; or, (2) has previously had a reference dose entered into TCS. Subsequent changes to the step size, or changes to the step size in manually entered treatment plans, do not generate the indicated confirmation box or warning unless you have entered the reference dose on the previous screen. This behavior is contrary to what would be expected, given the information provided on page 4-23 of the Nucletron microSelectron HDR users manual, which does not place any conditions on the expected confirmation prompt from the system. Also, the descriptions given in the Nucletron TCS manual for the functions of the "Tab" and "arrow" keys do not include the ability to use these keys for changing treatment plan parameters. Based on these manual descriptions, the licensee would appear justified in its assumption that no parameters were inadvertently changed by their inappropriate use of these keys.

This event highlights the importance that, when making changes to treatment plans, licensees should always be alert to the possibility that other unintended changes can also occur. If such an unintended change should occur, whether this change were to occur through user error or system software problems, the potential adverse consequences to the patient remain the same. Thus, after making any changes to a pre-existing treatment plan, the final treatment plan should be reviewed for not only for the correctness of the changed parameters but also for its total overall correctness.

Often device users are the first to discover problems with marketed medical devices. If you encounter device malfunctions or product problems involving radiation therapy devices or radiation therapy treatment planning systems, particularly Y2K problems or those which may be software related, you are strongly encouraged to report such events to MedWatch, the Food and Drug Administration's (FDA) voluntary reporting program. You may submit voluntary reports to MedWatch:

- by phone at 1-800-FDA-1088;
- by FAX at 1-800-FDA-0178;
- over the Internet at http://www.fda.gov/medwatch/ ; or,
- by mailing your report to MedWatch, Food and Drug Administration, 5600 Fishers Lane (HF-2), Rockville, MD 20857.

You are also reminded that under the Safe Medical Devices Act of 1990, user facilities have specific mandatory reporting time frames and requirements when they become aware that a medical device may have caused or contributed to a patient death or serious injury/illness.

Questions concerning FDA's mandatory user facility reporting requirements can be directed to FDA's Center for Devices and Radiological Health, Office of Surveillance and Biometrics, by calling (301) 594-2735.

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

Donald A. Cool, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Technical Contact: Robert L. Ayres, NMSS
(301) 415-5746
E-mail: rxa1@nrc.gov

Attachments:
1. List of Recently Issued NMSS Information Notices
2. List of Recently Issued NRC Information Notices

LIST OF RECENTLY ISSUED NMSS INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
99-06	1998 Enforcement Sanctions as a Result of Deliberate Violations of	3/19/99	All U. S. Nuclear Regulatory Commission licensees.
99-05	Inadvertent Discharge of Carbon Dioxide Fire Protection System and Gas Migration	3/8/99	All holders of licenses for nuclear power, research, and test reactor, and fuel cycle facilities
99-04	Unplanned Radiation Exposures to Radiographers, Resulting from failures to follow Proper Radiation Safety Procedures	3/8/99	All radiography licensees.
99-03	Exothermic Reactions Involving Dried Uranium Oxide Powder (Yellowcake)	1/29/99	All operating uranium recovery facilities that produce oxide powder (U_3O_8) (yellowcake)
99-02	Guidance to Users on the Implementation of a New Single-Source Dose-Calculation Formalism and Revised Air-Kerma Strength Standard for Iodine-125 Sealed Sources	1/21/99	All medical licensees authorized to conduct brachytherapy treatments.
99-01	Deterioration of High-Efficiency Particulate Air Filters in a Pressurized Water Reactor Containment Fan Cooler Unit	1/20/99	All holders of licences for nuclear power, research and test reactors; and fuel cycle facilities.
98-33 Regulatory	NRC Regulations Prohibit Agreements that Restrict or Discourage an Employee from Participating in Protected Activities	8/28/98	All holders of a Nuclear Commission license
98-30	Effect of the Year 2000 Computer Problem on NRC Licensees and Certificate Holders	8/12/98	All material and fuel cycle licensees and certificate holders

LIST OF RECENTLY ISSUED NRC INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
99-08	Urine Specimen Adulteration	3/24/99	All holders of operating licenses For nuclear power reactors and Licensees authorized to possess Or use formula quantities of strategic special nuclear material (SSNM)
99-07	Fire Proctection Preaction Preaction Sprinkler System Deluge Valve Failures and Potenetial Testing Deficiencies	3/22/99	All NRC licensees
99-06	1998 Enforcement Sanctions as a Result of Deliberate Violation on NRC Employee Protection Requirements	3/19/99	All U.S. Nuclear Regulatory Commission licensees
99-05	Inadvertent Discharge of Carbon Dioxide Fire Protection System and Gas Migration	3/8/99	All holders of licenses for nuclear power, research, and test reactor, and fuel cycle facilities
99-04	Unplanned Radiation Exposures to Radiographers, Resulting from failures to follow Proper Radiation Safety Procedures	3/8/99	All radiography licensees.
99-03	Exothermic Reactions Involving Dried Uranium Oxide Powder (Yellowcake)	1/29/99	All operating uranium recovery facilities that produce oxide powder (U_3O_8) (yellowcake)
99-02	Guidance to Users on the Implementation of a New Single-Source Dose-Calculation Formalism and Revised Air-Kerma Strength Standard for Iodine-125 Sealed Sources	1/21/99	All medical licensees authorized to conduct brachytherapy treatments.

OL = Operating License
CP = Construction Permit

Questions concerning FDA's mandatory user facility reporting requirements can be directed to FDA's Center for Devices and Radiological Health, Office of Surveillance and Biometrics, by calling (301) 594-2735.

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OFC	MSB		TechED		MSB		D/IMNS	
NAME	RAyres/ll		EKraus(FAX)		LWCamper		DACool	
DATE	03/ 05 /99		3/8/99		3/17/99		3/17/99	

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DATE	03/ 05 /99		3/8/99		3/ 17 /99		03/ 17 /99	

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