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FILE

MEMO TO : All Medical Licensees

FROM : Jeffrey L. Burgess, P.E.
Director, Division of
Air Quality

RE : NRC Notice 2001-08: "Treatment Planning System Errors Result in Deaths of Overseas Radiation Therapy Patients"

DATE : June 19, 2001

Enclosed is a copy of the United States Nuclear Regulatory Commission (NRC) information notice 2001-08: "Treatment Planning System Errors Result in Deaths of Overseas Radiation Therapy Patients". This information notice was issued to inform licensees of a significant event that may be applicable to any medical facility performing therapeutic radiation treatments using treatment planning software.

As indicated in the notice, it is expected that you will review this information for applicability to your licensed activities and consider actions, as appropriate, to ensure the safe and legal use of radioactive materials in the State of North Dakota.

This notice is for your information only. No specific action nor written response is required. If you have any questions concerning this issue, please contact the Radiation Control Program at (701)328-5188.

JLB/JMG:saj
Enc:

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

JUN 2001
Received
Air Quality

June 1, 2001

NRC INFORMATION NOTICE 2001-08: TREATMENT PLANNING SYSTEM ERRORS RESULT IN DEATHS OF OVERSEAS RADIATION THERAPY PATIENTS

Addressees

All medical licensees.

Purpose

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice (IN) to inform licensees of a significant event that may be applicable to any medical facility in the United States performing therapeutic radiation treatments using treatment planning software. Although the treatment planning software involved in this event was used in conjunction with external beam therapy, similar treatment planning software may be used in therapeutic modalities other than external beam therapy. NRC is issuing this prompt IN before receipt of more detailed information because of the significant consequences associated with this event. The NRC will update this IN when more detailed information is available. In the meantime, licensees are reminded of the need to ensure that the use of treatment planning systems result in applied doses consistent with the written directive.

It is expected that recipients will review the information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. However, suggestions contained in this IN are not new NRC requirements; therefore, no specific action nor written response is required.

Description of circumstances

On May 21, 2001, the International Atomic Energy Agency (IAEA) notified the NRC Office of International Programs (OIP) of an ongoing investigation in Panama of patients who received radiation therapy doses of up to 100 percent above what was prescribed. At a press conference on May 18, 2001, representatives from the National Oncology Institute (ION) in Panama announced that 28 patients treated for colon, prostate, and cervical cancer may have received radiation doses between 20 to 100 percent above what was prescribed. A newspaper reported that human error and the failure of the treatment planning software to warn the user of possible errors may have contributed to the event. Five patients treated at ION were reported to have died at that time, but the causes of their deaths were under investigation. It is NRC's understanding that some of the deaths are directly attributable to the excess radiation received during treatment.

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The 28 patients received external beam therapy treatments from what is believed to be a Cobalt-60 Theratron 780-C teletherapy unit at the ION between August and December 2000, but the additional doses were not confirmed by the ION until March 2001. The Government of Panama requested the IAEA assistance with an investigation of the event. NRC will update this IN when the IAEA team's findings are available.

The manufacturers of the therapy unit and the treatment planning software (Multidata in St. Louis, MO) were contacted and provided information to the IAEA team. The use of the therapy unit in the United States is jointly regulated by the U.S. Food and Drug Administration (FDA) and NRC, whereas the use of the treatment software falls under the jurisdiction of the FDA. The FDA and NRC have initiated a joint followup investigation at this time.

Discussion

NRC's Nuclear Materials Event Database from 1990 to March 2001 was reviewed for reported misadministrations associated with the use of therapy devices (brachytherapy sources, high-dose-rate remote afterloaders, gamma stereotactic radiosurgery units, and teletherapy units), and the patient treatment systems used with these devices.

Although most past misadministrations involving patient treatment systems or computer-driven devices were caused by data entry errors, some were more directly related to the structure and function of the treatment planning software. These previous treatment-planning-system-related misadministrations resulted from the software's default to set parameters (wedge factor, step increment, catheter lengths, or treatment dose) not provided by the user; changes to new treatment systems that required data input in different or newer measurement units (millimeters instead of centimeters, millicuries instead of milligram radium equivalents, air kerma strength instead of milligram radium equivalents, and SI units instead of non-SI units); and software programming errors (editing one parameter resulted in an unintended change to another parameter; double-hitting the enter key doubled the step increment; an incorrect attenuation factor used in the program). The manufacturer's corrective actions for the events described above included correction of the identified errors by for example, adding warning screens to notify users of the use of critical default values.

One recurring root cause for single- and multiple-patient teletherapy misadministrations was the improper use of wedges. The most common error was omitting the use of a wedge when it was required for the treatment. Other errors occurred from improper calculation of wedge factors, software defaulting to an inappropriate wedge factor, and using a wedge factor for all treatments in a series when one treatment did not involve use of a wedge.

Related NRC requirements

The Quality Management Program provisions of 10 CFR 35.32 require NRC licensees to ensure that the final treatment plans and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the applicable written directive. Licensee staff using treatment planning systems should understand the system's software, including whether the system will provide automatic warnings for typical or potentially significant data entry errors. Additional attention should be paid when new personnel, new treatment equipment, or new treatment planning software are placed into service.

This IN 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
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and Safeguards

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