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

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.

/RA/

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

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

Donna-Beth Howe, NMSS
301-415-7848
E-mail: dbh@nrc.gov

Roberto J. Torres, NMSS
301-415-8112
E-mail: rjt@nrc.gov

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

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Susan N. Frant Acting Division Director for:
/RA/
Donald A. Cool, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

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

Donna-Beth Howe, NMSS
301-415-7848
E-mail: dbh@nrc.gov

Roberto J. Torres, NMSS
301-415-8112
E-mail: rjt@nrc.gov

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LIST OF RECENTLY ISSUED
NMSS INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
2001-03	Incident Reporting Requirements for Radiography Licensees	04/06/01	All industrial radiography licensees
2001-01	The Importance of Accurate Inventory Controls to Prevent the Unauthorized Possession of Radioactive Material	03/26/01	All material licensees
2000-22	Medical Misadministrations Caused by Human Errors Involving Gamma Stereotactic Radiosurgery (GAMMA KNIFE)	12/18/00	All medical use licensees authorized to conduct gamma stereotactic radiosurgery treatments
2000-19	Implementation of Human Use Research Protocols Involving U.S. Nuclear Regulatory Commission Regulated Materials	12/05/2000	All medical use licensees
2000-18	Substandard Material Supplied by Chicago Bullet Proof Systems	11/29/2000	All 10 CFR Part 50 licensees and applicants All category 1 fuel facilities All 10 CFR Part 72 licensees and applicants
2000-16	Potential Hazards Due to Volatilization of Radionuclides	10/5/2000	All licensees that process unsealed byproduct materia.
2000-15	Recent Events Resulting in Whole Body Exposures Exceeding Regulatory Limits	9/29/2000	All radiography licensees
2000-12	Potential Degradation of Firefighter Primary Protective Garments	9/21/2000	All holders of licenses for nuclear power, research, and test reactors and fuel cycle facilities
2000-11	Licensee Responsibility for Quality Assurance Oversight of Contractor Activities Regarding Fabrication and Use of Spent Fuel Storage Cask Systems	8/7/2000	All U.S. NRC 10 CFR Part 50 and Part 72 licensees, and Part 72 Certificate of Compliance holders

OL = Operating License
CP = Construction Permit

LIST OF RECENTLY ISSUED
NRC INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
2001-07	Unescorted Access Granted Based on Incomplete and/or Inaccurate Information	05/11/01	All holders of nuclear reactor operating licenses who are subject to Section 73.56 of Title 10, of the Code of Federal Regulations (10 CFR 73.56), "Personnel Access Authorization Requirements of Nuclear Power Plants."
2001-06	Centrifugal Charging Pump Thrust Bearing Damage not Detected Due to Inadequate Assessment of Oil Analysis Results and Selection of Pump Surveillance Points	05/11/01	All holders of operating licenses for nuclear power reactors, except those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor
2001-05	Through-Wall Circumferential Cracking of Reactor Pressure Vessel Head Control Rod Drive Mechanism Penetration Nozzles at Oconee Nuclear Station, Unit 3	04/30/01	All holders of operating licenses for pressurized water nuclear power reactors except those who have ceased operations and have certified that fuel has been permanently removed from the reactor vessel
2001-04	Neglected Fire Extinguisher Maintenance Causes Fatality	04/11/01	All holders of licenses for nuclear power, research, and test reactors and fuel cycle facilities
2001-03	Incident Reporting Requirements for Radiography Licensees	04/06/01	All industrial radiography licensees
2001-02	Summary of Fitness-for-Duty Program Performance Reports for Calendar Years 1998 and 1999	03/28/01	All holders of operating licenses for nuclear power reactors, and licensees authorized to possess or use formula quantities of strategic special nuclear material (SSNM) or to transport formula quantities of SSNM

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