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

November 20, 2001

NRC INFORMATION NOTICE 2001-08, SUPPLEMENT 2: UPDATE ON RADIATION THERAPY OVEREXPOSURES IN PANAMA

Addressees

All medical licensees.

Purpose

The U.S. Nuclear Regulatory Commission (NRC) is issuing this supplement to information notice (IN) 2001-08, to provide additional information related to the radiation therapy overexposures that recently occurred in Panama. All persons in your institution who are involved with radiation therapy should review this notice. It is expected that recipients will review this 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

IN 2001-08, dated June 1, 2001, and Supplement 1, dated June 6, 2001, describe an incident in Panama, involving radiation overexposures of 28 teletherapy patients, resulting in multiple deaths. The International Atomic Energy Agency (IAEA) recently published its report entitled "Investigation of an Accidental Exposure of Radiotherapy Patients in Panama," which concluded that the cause of the radiation overexposures was the way the shielding block data were entered into the computerized treatment planning system. The report is available from IAEA, and can be ordered from its web site at:
http://www.iaea.org/worldatom/Books/NewReleases/book26.shtml.

The company that supplied the treatment planning software, Multidata Systems International Corporation (Multidata), in St. Louis, Missouri, issued a "Medical Device Safety Alert" on June 22, 2001 (Attachment 1), and an "Urgent Notice" on August 10, 2001 (Attachment 2). The "Urgent Notice" explains that certain improper data entries will be accepted by the software, but will result in incorrect dose calculations. Multidata is developing a "filter program" to address this problem.

Discussion

According to the IAEA report, one method the Panamanian hospital staff used for the data entry of shielding blocks caused the treatment planning system to calculate incorrect treatment times.

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Specifically, the staff modified its procedures and entered data for multiple shielding blocks together ("digitized" the blocks), as if they were a single block. The data were accepted by the treatment planning system, but the software calculated incorrect treatment times. Using incorrect treatment times resulted in significant radiation overexposures to patients. The hospital staff did not perform independent verification of the computer-calculated treatment times, so the errors were not identified before treatment. The IAEA report states that there were several characteristics of the computerized treatment planning system that made it relatively easy for the error to occur. These were:

1) Several different ways of digitizing blocks were accepted by the computer treatment planning system;

2) There was no warning on the computer screen when blocks were digitized in an unacceptable way (i.e., any way that is different from the one prescribed in the manual); and

3) When blocks were digitized incorrectly, the treatment planning system produced a diagram that was the same as that produced when the data were entered correctly, thereby giving the impression that the calculated results were correct.

The "Multidata Medical Device Safety Alert," dated June 22, 2001, urges customers to follow the instructions in the user manual, and emphasizes that users should not attempt to operate the system outside the limitations stated in the user manual.

All persons involved in radiation therapy are encouraged to review both the information related to this incident, and your treatment planning procedures, to ensure that both your procedures and written quality management program, required by 10 CFR 35.32, are adequate to avoid similar radiation therapy errors. The event in Panama demonstrates that licensees should always be alert to the possibility of introducing unintended errors into the treatment planning process. In particular, note the importance of independent verification of computer-generated patient treatment plans.

In addition, if you are a Multidata customer, you should have received notices from the firm about this incident. If you have not received the attached communications from Multidata, you should contact its Helpdesk at 1-800-225-1130 or helpdesk@multidata-systems.com.

The U.S. Food and Drug Administration (FDA) is investigating this incident, and NRC is cooperating with its investigation. 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 those that may be software related, you are strongly encouraged to report such events to MedWatch, the FDA's voluntary reporting program. You may submit voluntary reports to MedWatch through:

* Phone at 1-800-FDA-1088;
* FAX at 1-800-FDA-0178;

* The Internet at http://www.fda.gov/medwatch/ ; or,
* Mailing your report to MedWatch, Food and Drug Administration, 5600 Fishers Lane (HF-2), Rockville, MD 20857.

Also note that under the Safe Medical Devices Act of 1990, user facilities must comply with 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, through telephone at (301) 594-2735.

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

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

Technical Contacts: Robert Ayres, NMSS
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Roberto J. Torres, NMSS
(301) 415-8112
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Attachments:
1. Medical Device Safety Alert, June 22, 2001
2. Urgent Notice, August 10, 2001
3. List of Recently Issued NMSS Information Notices
4. List of Recently Issued NRC Information Notices

* The Internet at http://www.fda.gov/medwatch/ ; or,
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DOCUMENT NAME:
Package ML012990347 contains ML012390161 (Information Notice text), ML012990318 (Attachment 1), ML012990328 (Page 1 of Attachment 2) and ML012990335 (Page 2 of Attachment 2)

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See ML012990318

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See ML012990328

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LIST OF RECENTLY ISSUED
NMSS INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
2001-11	Thefts of Portable Gauges	07/13/2001	All portable Gauge licensees.
2001-08, Supplement 1	Update on the Investigation of Patient Deaths in Panama, Following Radiation Therapy Overexposures	06/06/01	All medical licensees.
2001-08	Treatment Planning System Errors Result in Deaths of Overseas Radiation Therapy Patients	06/01/01	All medical licensees.
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 material.
2000-15	Recent Events Resulting in Whole Body Exposures Exceeding Regulatory Limits	9/29/2000	All radiography licensees.

LIST OF RECENTLY ISSUED
NRC INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
2001-16	Recent Foreign and Domestic Experience with Degradation of steam Generator Tubes and Internals	10/31/2001	All holders of operating licenses for pressurized-water reactors (PWR), except those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor
2001-15	Non-Conservative Errors in Minimum Critical Power Ratio Limits	10/29/01	All holders of operating licenses or construction permits for boiling water reactors (BWRs)
2001-14	Problems with Incorrectly-Installed Swing-Check Valves	10/03/01	All holders of operating licenses or construction permits for nuclear power reactors except those who have ceased operations and have certified that fuel has been permanently removed from the reactor vessel
2001-13	Inadequate Standby Liquid Control System Relief Valve Margin	08/10/01	All holders of operating licenses for boiling water reactors
2001-12 (ERRATA)	Hydrogen Fire at Nuclear Power Stations	8/08/01	All holders of operating licenses or construction permits for nuclear power reactors except those who have ceased operations and have certified that fuel has been permanently removed from the reactor vessel
2001-12	Hydrogen Fire at Nuclear Power Stations	7/13/01	All holders of operating licenses or construction permits for nuclear power reactors except those who have ceased operations and have certified that fuel has been permanently removed from the reactor vessel

OL = Operating License
CP = Construction Permit