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.

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

Technical Contacts: 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. 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

June 22, 2001

URGENT
Medical Device Safety Alert

Dear U.S. and International Customers of Multidata Systems:

This letter informs you of radiation overexposures and deaths associated with Multidata radiation treatment planning software. It explains our actions to investigate and follow up on the overexposure incidents and reinforces the need for you to conduct adequate quality assurance. Provide this letter to medical physicists, radiologists, clinical engineers, and risk managers at your facility.

Radiation Overexposures

Multidata became aware of a radiological emergency in Panama when the International Atomic Energy Agency (IAEA) and the U.S. Nuclear Regulatory Commission (US NRC) released reports of an IAEA investigation of multiple radiation overexposures and deaths. Two IAEA reports and two US NRC Information Notices (IN2001-8 and IN2001-8 Supplement 1) indicate the National Oncology Institute in Panama was using a Theratron 780-C cobalt-60 teletherapy machine and a Multidata Systems computerized treatment planning system to calculate the radiation doses delivered to the patients. The reports are available on our website at http://www.multidata-systems.com .

In related reports, Panama's Health Minister Fernando Garcia said health officials changed their procedures in administering the radiation treatment in order to get better results and ended up giving the patients more radiation than they should have. The incident involved 28 patients who were treated at the center from August 2000 through February 2001 for colon, prostate, and cervical cancer. Eight patients died, and five deaths are attributed to excess radiation received during the treatments.

The eight year old treatment planning system in use at the time (RTP version 2.2) has a limitation on the number of shielding blocks that can be used in a treatment plan. It was reported the practice at the facility was changed in August 2000 to enter data in such a way as to appear to allow the treatment system to exceed its limitation on shielding blocks, even though the user manual for the treatment planning system not only specifies the limit, but also recommends that the results be verified by measurement before using.

Multidata Actions

Multidata is in the process of obtaining information on this incident and is collaborating with the various regulatory agencies, including the US NRC and the U.S. Food and Drug Administration. At this time we do not have sufficient information to duplicate the circumstances that led to the incident in Panama or to determine which versions of the radiation treatment planning software may have a similar problem. Because the specific reason for the overexposures is still unknown, we are notifying all users of the RTP and

DSS software, regardless of software version or therapy modality (sealed-source teletherapy or linear accelerator).

Multidata will continue to evaluate these circumstances and attempt to duplicate the problem. We will provide all users additional information describing the problem as soon as the specific sequence of events involving the interaction between the user and the system are found. If a corrective action is required as a result of this incident, Multidata will make this correction available to all customers.

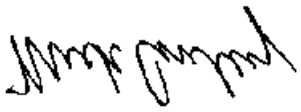
Your Response

In the meantime, Multidata urges all customers to maintain quality assurance and review their operating procedures. Particular emphasis should be given to the following:

- Follow the instructions in the user manual. The calculation modules, other programs, and data on radiation used in the treatment planning system have certain limitations, which are specified in the user manual. Do not attempt to operate the system outside these limitations, as the software could produce misleading or incorrect results.
- Follow a written quality assurance procedure for changes in treatment protocol, which should include independent verification of dose to the prescription points as calculated by the computer for each individual patient and before the first treatment.
- Perform verification measurements using a phantom, or other procedures as may be required for those exceptional cases of complicated treatments for which manual calculations may not be practical or difficult to interpret.

We ask that you confirm receipt of this letter by July 6, 2001. Notify Jennifer Davis by telephone at (800) 225-1130, by facsimile (FAX) at (314) 968-6443, or by E-mail at jdavis@multidata-systems.com. Let us know if you are aware of any problems similar to the incident in Panama. If you no longer use the treatment planning system, let us know so that you can be removed from the user list. If you have any questions, concerns, or doubt about the proper operation of the treatment planning system, please contact us.

Multidata Systems International Corp.



Mick Conley
General Business Manager

August 10, 2001

Urgent Notice

For All Users of Multidata Treatment Planning Systems

Dear Customer of Multidata Systems:

The attached *Notice for All Users of Multidata's Treatment Planning Systems* is a follow up to the recently distributed *Medical Device Safety Alert*. It explains an improper entry of block shapes and its effect on dose calculation results. In short, as long as the block outline does not cross itself, the dose calculations should correlate with the results obtained by an appropriate method of independent validation. For the Multidata Treatment Planning System, such methods include hand calculations or calculations using the central axis dose calculation program (CHT) or the irregular fields utility (IRF).

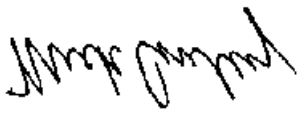
Multidata shares the concern that an improper data entry sequence was permitted as input. Therefore, through its Project Safeguard, Multidata has identified a data entry sequence that creates a self-intersecting shape outline (See Fig. 1 on the attached sheet) as what is not acceptable. Digitizing direction and exceeding the limitations on the number of blocks, numbers of points per block or the block shape have no unexpected effect on the dose calculation. For information about specific limitations as to the number of blocks or points used in a particular plan, please refer to the user manual provided with your version of the software.

A filter program which automatically rejects an improper data entry sequence as an unacceptable outline, on the basis that it is not a true polygon, has been developed and is currently being tested. Once the project is complete, Multidata will make this program available to all customers in the form of an easy to install update. It is expected that this safeguard program will be compatible with any software version in use.

Your Response

We ask that you confirm receipt of this letter by August 24, 2001. Notify Multidata Helpdesk by telephone at (800) 225-1130, by facsimile (FAX) at (314) 968-6443, or by E-mail at helpdesk@multidata-systems.com. If you no longer use the treatment planning system, let us know so that you can be removed from the user list. If you have any questions, concerns, or doubt about the proper operation of the treatment planning system, please contact us.

Multidata Systems International Corp.



Mick Conley
General and Business Manager

Urgent Notice for Users of Multidata's Treatment Planning Systems

Multidata has determined that its treatment planning system will accept blocks that are entered improperly (in a manner other than that specified in the user manual). When a block is entered improperly, the results may differ from those expected by the user.

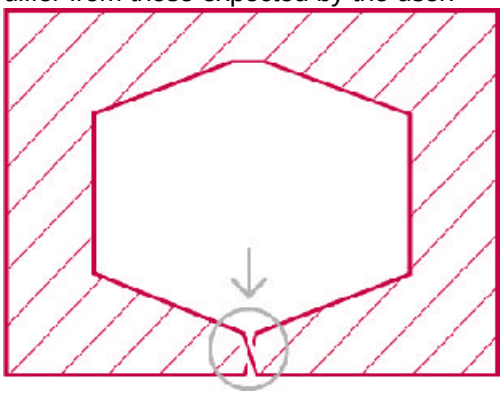


Fig. 1: **Incorrect crossing block outline**

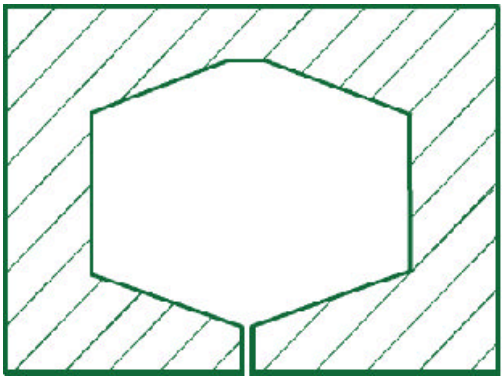
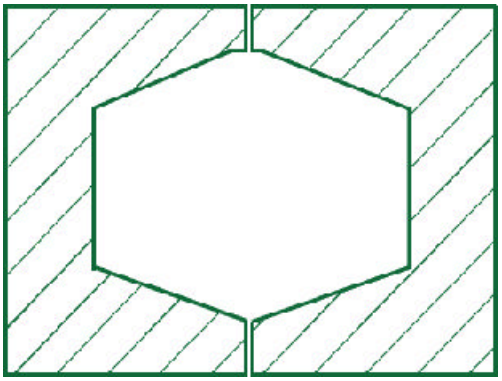


Fig. 3: Safe aperture definition with a single continuous line



In BEV, regardless of the direction in which the block is entered or the shape of the block, when the block outline crosses itself (see Fig 1, left) an improper block is created (i.e. not a true polygon.)

These improper blocks will produce substantially higher values (50 to 500% for MU or TIME-ON) than what one would expect by partially blocking an open field.

Any time a beam shaping technique alters the MU by more than the Open Field Output Factor range, the plan configuration must be investigated.

When an improper block (not a true polygon) has been entered, a solid line connects the two block icons in the slice (transverse) view (Fig 2) as shown below.

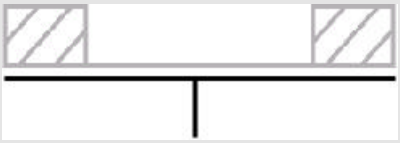


Fig 2. Solid line connecting block icons in the transverse view

Whenever this solid line is present, the data entered and plan results should be verified to determine that the results are valid and as expected. Please note that some properly entered blocks, including those that extend over three sides of the field (Fig 3), will also display this solid line.

To assure that data entry defining an aperture shape is correct, one should use two blocks (Fig 4). Note that outlines of different blocks may overlap; however, if only one block is used, it is essential to verify that the block outline does not cross itself (Fig 3).

Fig. 4: Recommended aperture definition using two separate blocks