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.

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