

Multidata Responds to IAEA Reports on Radiological Emergency in Panama

In public documents released by the International Atomic Energy Agency (IAEA) and the US Nuclear Regulatory Commission (US NRC) Multidata has become aware of a radiological emergency in Panama.

In a preliminary report issued on June 2, 2001, the IAEA reported on a radiological emergency at the National Oncology Institute of Panama. The emergency involved a radiotherapy unit using a cobalt-60 teletherapy machine and a computerized treatment planning system for calculating the radiation doses to be delivered to the patient. The US NRC Information Notice (IN2001-8) identified the teletherapy machine as a Theratron 780-C and identified Multidata Systems as the manufacturer of the treatment planning system.

Related reports issued by the Panamanian government state that the therapy unit and the associated computerized treatment planning system worked properly and were not the cause of the incident. The report blamed human error for the overdoses, which were detected in February. 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 between 20% and 100% more radiation than they should have. As reported, the incident involved 28 patients who were treated at the center from August 2000 through February 2001 for colon, prostate and cervical cancer. Eight of the patients are reported to have died, and five of the deaths have been attributed to the excess radiation received during the treatments.

The eight year old treatment planning system in use at the time has a limitation on the number of shielding blocks that can be used in a treatment plan. It was reported that in August 2000 the practice at the facility was **changed 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 clearly specifies the limit, but also recommends that the results be verified by measurement before using.**

Multidata is still in the process of obtaining information on this incident and is fully collaborating with the various regulatory agencies. Based on the information obtained to date and using the current software, Multidata has not been able to duplicate the circumstances that led to the incident in Panama. **Multidata will continue to evaluate these circumstances and will inform all users as additional information becomes available.** Should a corrective action be required as the result of this incident, Multidata will make this correction available to all customers. In the meantime, Multidata supports the regulatory goal for every customer to review their operating procedures in this area. Particular emphasis should be given to the following:

- 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. Attempting to “fool” the system to exceed these limitations could produce misleading or incorrect results. Follow the instructions in the user manual.
- 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.