Jeb Bush
Governor

FLORIDA DEPARTMENT OF HEALTH

Robert G. Brooks, M.D.
Secretary

July 2001

Bureau of Radiation Control
RADIOACTIVE MATERIALS SECTION
Information Notice 2001-03

Information on the Misadministrations in Panama

This information notice is applicable to all medical radioactive material licensees and broad scope medical licensees who may use treatment-planning computers for teletherapy and brachytherapy.

Attached is the NRC IN 2001-08 dated June 1, 2001, and a supplement IN 2001-08 dated June 6, 2001, concerning the misadministration that occurred in Panama. Twenty-eight people are known to have been treated with a cobalt 60 teletherapy unit with incorrect treatment data entered in the treatment planning computer system. The doses were 20 to 100 percent higher than prescribed and resulted in the death of eight patients. The primary finding of the investigation was that the overexposures were caused by a change in the procedure for entering treatment data into the treatment planning software. The change, combined with the lack of a verification that the correct treatment dose was being calculated and delivered, allowed the overdoses to occur.

Each licensee should evaluate the information for applicability at his or her institution. This notice requires no specific action or written response. If additional information is provided we will notify each licensee as appropriate. If you have any questions, please contact our office at (850) 245-4545.

No specific actions nor written response is required. If you have any questions or need additional information, please contact us.

http://www.doh.state.fl.us/environment/radiation/
Phone (850) 245-4545 (SC) 205-4545
Bureau of Radiation Control • Radioactive Materials Section
Bin #C21 • 4052 Bald Cypress Way • Tallahassee, FL 32399-1741
Fax (850) 921-6364 (SC) 291-6364

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

June 6, 2001

NRC INFORMATION NOTICE 2001-08, SUPPLEMENT 1: UPDATE ON THE INVESTIGATION OF PATIENT DEATHS IN PANAMA, FOLLOWING RADIATION THERAPY OVEREXPOSURES

Addressees

All medical licensees.

Purpose

The U.S. Nuclear Regulatory Commission (NRC) is issuing this supplement to information notice (IN) 2001-08, to inform addressees of the preliminary findings from the International Atomic Energy Agency (IAEA) investigation of patient overdoses received during radiation therapy treatments at the National Oncology Institute (ION) in Panama. 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 or written response is required.

Description of Circumstances

On June 1, 2001, NRC issued IN 2001-08 to promptly alert licensees to an ongoing investigation concerning cancer patients in Panama who had received excessive radiation therapy doses. As noted in IN 2001-08, ION representatives announced on May 18, 2001, that 28 patients treated at the institute for colon, prostate, and cervical cancer may have received radiation doses from 20 to 100 percent above what was prescribed. Eight patients are reported to have died, and five of the deaths have been attributed to the excess radiation received during the treatments. Panamanian authorities initiated an investigation of the cause of the radiation overdoses and patient deaths. Subsequently, the Panamanian government requested IAEA assistance, and IAEA sent an investigation team to Panama on May 26, 2001.

On June 2, 2001, the IAEA issued an Advisory Information Notice (attached) on the initial findings of the investigation. The notice indicates that the apparent cause of the radiation overexposures was the incorrect entry of data into the computer used for the treatment planning system, resulting in incorrectly calculated radiation doses. The team determined that the radiotherapy equipment itself worked properly. An associated report, issued by the Panamanian government, states that the therapy unit and associated computerized treatment planning system worked properly and were not the cause of the incident.

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The IAEA notice suggests that users of computerized treatment planning systems for radiotherapy should ensure that treatments are performed in accordance with an appropriate quality assurance program. This is consistent with 10 CFR 35.32, which requires NRC medical licensees to establish and maintain a written quality management program.

NRC is continuing to evaluate this incident, and plans to update this IN if additional findings or significant information become available.

This IN requires no specific action or 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/Susan M. Frant
For

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. IAEA Advisory Information Notice, dated June 2, 2001

Attachment 1
IN 2001-08, Supp. 1

2001-06-02 01:00 UTC

ADVISORY INFORMATION

RADIOLOGICAL EMERGENCY IN PANAMA

On 22 May 2001, the IAEA informed Contact Points identified under the Convention on Early Notification of a Nuclear Accident ("Early Notification Convention") and the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency ("Assistance Convention") of a radiological emergency at the National Oncology Institute in Panama affecting 28 patients undergoing radiotherapy. 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 patients. The IAEA received a request for assistance from the Panamanian Government under the auspices of the Assistance Convention and you were informed that an expert team was being sent to Panama.

The IAEA team, composed of experts in radiation protection, radiopathology, radiotherapy, radiology and medical physics, from France, Japan, the United States of America and the IAEA, joined by an expert from the Russian Federation representing the World Health Organization, has in the meantime reached preliminary conclusions on the factors contributing to the emergency and the consequences thereof. There is concordance between the findings of the international team of experts and those of national experts.

The team reported that of the 28 affected patients, eight have died, the deaths of five of whom are probably attributable to radiation overexposure. Of the other three deaths, one was considered to have been related to the patient's cancer, while there was insufficient information to draw conclusions with respect to the other two. Of the 20 patients who are alive, some have developed serious radiopathological complications.

The team of experts found that the radiotherapy equipment had been working properly and that it was adequately calibrated. A preliminary assessment of the situation by the team suggests that the apparent cause of the emergency lay with the entering of data into the computer used for the treatment planning system. The computerized treatment planning system used in the National Oncology Institute requires that the data on the spatial co-ordinates of shielding blocks used to protect healthy tissue during radiotherapy be entered into the system one block at a time, following a certain sequence and subject to a limitation on the number of blocks. It is reported that, as from August 2000, the practice used at the National Oncology Institute was changed whereby, in the case of the affected patients, the co-ordinates for all of the blocks were entered as a single block, resulting in incorrect calculated radiation doses and, consequently, treatment times. Together with an apparent lack of written procedures, and of a manual check when the data input procedure was changed, the combination of circumstances resulted in substantial over-exposure to radiation of the patients involved.

The Ministry of Health of Panama has just been briefed by the team on these preliminary conclusions and has agreed that the lessons identified should be shared on an urgent basis with the international community in order to prevent overexposures wherever this configuration of treatment might be in use. While the team's final report has not yet been completed, under the arrangements set out in the Emergency Notification and Assistance Technical Operations Manual (ENATOM), the IAEA is informing Contact Points about the essential facts that have come to its attention surrounding this emergency in order that national authorities and users of computerized treatment planning systems for radiotherapy, including those similar to that involved in this situation, are informed of the unfortunate circumstances that occurred at the National Oncology Institute in Panama. The Contact Points are urged to draw this matter to the attention of the relevant national authorities and users, who are encouraged to check that any relevant systems are being operated in accordance with an appropriate quality assurance programme.

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.

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.

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