From: JHM@nrc.gov
To: <stp-announcements@nrc.gov>
Date: 6/7/01 13:00 EST
Subject: SUPPLEMENTAL INFORMATION NOTICE ON EVENT IN PANAMA

To: STP - ANNOUNCEMENTS - SUBSCRIBERS
Date: 06/07/01 13:00 EST
Subject: Supplement to IN 2001-08, on the Panama Event

The attached supplement to IN 2001-08 (final and issued) provides additional information on the Panama event, and the results of the IAEA investigation. Attachment 1 to the IN is an IAEA Advisory Information Notice (dated 6/2/2001), which provides the preliminary findings of the investigation. Additional information obtained from a report issued by the Panamanian government is also included in the IN.

The primary finding of the investigation was that the overexposures were caused by a change in the procedure for entering treatment data into then 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. We plan to issue an additional supplement to the IN if significant new information or other investigation findings are made available.

As indicated when the original IN was issued, the intent of this supplement is to allow for the early notification of our licensees of the IAEA investigation findings. As with the original IN, the supplement will be distributed to all medical licensees and master material licensees.

We encouraged the regions to immediately distribute (e.g., via e-mail, FAX, etc.) the supplement to licensees that have the highest potential of being affected by this issue (primarily teletherapy licensees and those using Multidata software in their treatment planning systems).

Regards,

Jim Myers
STP Webmaster
jhm@nrc.gov

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
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and Medical Nuclear Safety
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Attachments:
1. IAEA Advisory Information Notice, dated June 2, 2001
2. List of Recently Issued NMSS Information Notices
3. List of Recently Issued NRC Information Notices

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.

LIST OF RECENTLY ISSUED
NMSS INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
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.
2000-12	Potential Degradation of Firefighter Primary Protective Garments	9/21/2000	All holders of licenses for nuclear power, research, and test reactors and fuel cycle facilities.

LIST OF RECENTLY ISSUED
NRC INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
2001-08	Treatment Planning System Errors Result in Deaths of Overseas Radiation Therapy Patients	06/01/01	All medical licensees
2001-07	Unescorted Access Granted Based on Incomplete and/or Inaccurate Information	05/11/01	All holders of nuclear reactor operating licenses who are subject to Section 73.56 of Title 10, of the Code of Federal Regulations (10 CFR 73.56), "Personnel Access Authorization Requirements of Nuclear Power Plants."
2001-06	Centrifugal Charging Pump Thrust Bearing Damage not Detected Due to Inadequate Assessment of Oil Analysis Results and Selection of Pump Surveillance Points	05/11/01	All holders of operating licenses for nuclear power reactors, except those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor
2001-05	Through-Wall Circumferential Cracking of Reactor Pressure Vessel Head Control Rod Drive Mechanism Penetration Nozzles at Oconee Nuclear Station, Unit 3	04/30/01	All holders of operating licenses for pressurized water nuclear power reactors except those who have ceased operations and have certified that fuel has been permanently removed from the reactor vessel
2001-04	Neglected Fire Extinguisher Maintenance Causes Fatality	04/11/01	All holders of licenses for nuclear power, research, and test reactors and fuel cycle facilities
2001-03	Incident Reporting Requirements for Radiography Licensees	04/06/01	All industrial radiography licensees

OL = Operating License
CP = Construction Permit