PART I. BACKGROUND

2. HISTORY OF THE ACCIDENT

The accident occurred at a radiotherapy Alcyon II unit of the radiotherapy facility of the San Juan de Dios Hospital in San José, Costa Rica. The unit is equipped with a cobalt-60 (Co-60) source. (The hospital facility is also equipped with another radiotherapy unit, a Theratron-80). The accident can be dated from a change of radioactive source that the unit underwent on Thursday 22 August 1996. When the new source was calibrated, an error was made in calculating the dose rate. Operation of the unit for the treatments of patients resumed after this change of source on Monday 26 August. The miscalculation resulted in the administration to patients of significantly more radiation than had been prescribed.

2.1. EVENTS PRIOR TO THE ACCIDENT

The IAEA/WHO thermoluminescence dosimetry (TLD) postal dose check service had since 1977 repeatedly revealed significant differences between the dose value reported by the San Juan de Dios Hospital and the value obtained by the IAEA's Dosimetry Programme from TLD dosimeters irradiated at the same hospital. (It should be noted that results are treated confidentially and that actions upon the results of this postal dose check service are not binding on participating institutions.) Details of the results are provided in Annex I.

Since no satisfactory explanation for the differences was available, an expert was engaged to investigate the reasons for them and to evaluate the physical aspects of quality assurance in radiotherapy, as well as to check the degree of application of IAEA Technical Reports Series No. 277 [8] on the Determination of the Absorbed Dose in Photon and Electron Beams and of compliance with the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, Safety Series No. 115 [9].

The expert engaged made a review on 8–19 July 1996. She found that no records had been kept on the calibration of radiation beams, and there was no information on the equipment used, the working conditions, the dose determination protocols followed, the results obtained or the calculation of what appears as 'rendimiento' ('output' in the radiotherapeutical jargon, or absorbed

dose rate in technical terms) in a computer program purposely written for the calculation of the time.

Differences of up to 8% in the calculated time were found, for the same irradiation conditions, when a calculation method based on percentage depth dose (PDD) as well as tissue air ratio (TAR) was used. A first analysis showed that the same value of the 'rendimiento' had been used for both methods; this revealed a confusion between the concepts of 'dose in air' and 'dose to water' at the depth of maximum ionization.

The expert brought to the attention of the radiation oncologists and the person in charge of dosimetry at the San Juan de Dios Hospital the results of the TLD postal dose check service since 1989, which the radiation oncologists said were unknown to them, as well as of the conceptual errors in the calculations. They seemed greatly surprised and also sceptical, maintaining that "if it were so, we should have noticed in the clinical results" [10]. The expert explained that in all cases the doses delivered to the patients with open radiation fields (that is, without organ shielding) had been lower than planned. It is well known that underdosage can only be clinically noted after months or years, in contrast to overdosage.

2.2. DISCOVERY OF IRREGULARITIES

According to the information obtained during the expert review in July 1996, the radiation oncologist of the Calderón Guardia Hospital noticed that there were unusually severe effects in some of the patients treated using the Alcyon II unit of the San Juan de Dios Hospital and followed up on the observation. The effects related to the skin and low digestive tract, such as diarrhoea, abdominal pain and reddened skin. He compared the dose rates of both machines (Theratron and Alcyon II) registered in the records and pointed out to the person in charge of dosimetry at the San Juan de Dios Hospital that the dose rate of the Alcyon II was lower than that from the Theratron, despite the fact that the activity was higher.

On 27 September 1996, after one month of working with the new source, the person in charge of dosimetry at the San Juan de Dios Hospital contacted the physicist of the Hospital de México and asked him to measure the absorbed dose rate of the machine, in order to compare the results with his

own measurements. The value obtained was 2.02 Gy/min at the point of maximum dose to water, while the value that had been assumed for treatment had been 1.22 Gy/min.

While comparing the results, the person in charge of dosimetry at the San Juan de Dios Hospital asked questions about the time associated with 0.3 units of the timer on the control panel. The reply was that 0.3 units corresponded to 0.3 min, i.e. 18 s. It then emerged that, instead of 18 s, the value of 30 s seemed to have been used to determine the dose rate. This would imply, on this basis alone, an overestimation of the exposure time by a factor of 30/18 = 1.66. As a result, the dose rate would have been underestimated by the same factor, and therefore the dose to patients would consequently have been higher than intended.

2.3. REGULATORY ACTIONS

On 3 October 1996, the person in charge of dosimetry at the San Juan de Dios Hospital contacted the Section for Control of Ionizing Radiation of the Ministry of Health of Costa Rica, responsible for monitoring compliance with the regulations on radiation protection. He informed the staff there that there was a difference between the dose rate measured by him and the value on the certification of the radiation source provided by the manufacturer. The Ministry immediately ordered the unit to cease operations and initiated an investigation.

Several months after the accident, the person in charge of dosimetry presented to the Section for Control of Ionizing Radiation an application to be registered as a radiation physicist. In none of the documents presented was there a certification of any academic degree. He had attended a number of training courses and fellowships.

2.4. INVESTIGATIONS PRIOR TO THE EXPERT TEAM'S ASSESSMENT

According to information received from a Costa Rican member of the Expert Team, the Costa Rican Social Security System (CCSS) proposed to the Ministry of Health that assistance be requested from the Pan American Health Organization (PAHO), which sent C. Borrás "to assess the doses received by the radiotherapy patients in the San Juan de Dios Hospital over the period 21 August to 3 October 1996" [11] and J.C. Jiménez to classify the patients in order "to determine those who needed the resumption of radiotherapy treatment from the others needing continued clinical observation." [12]. The early investigation was made on 15–22 October 1996.

In addition to C. Borrás from PAHO, the group investigating the dosimetry included H. Marenco Zúñiga from the Hospital de México and L. Bermúdez Jiménez from the Ministry of Health of Costa Rica. Determination of the maximum dose rate (at 0.5 cm depth in water) from the Co-60 unit Alcyon II yielded the value of 190.72 cGy/min (1.9072 Gy/min) at 80.5 cm distance for a field size of 10 cm x 10 cm. The group concluded that there had been an overdosage to patients of 73%. It also showed that a computer program to interpolate percentage depth–dose values, developed by the person in charge of dosimetry, had errors of the order of 5% and that there was an error of 2 cm in the optical distance indicator. Over the week of 23–27 June 1997, F. Moreno (on behalf of PAHO) examined a number of the affected patients at the San Juan de Dios Hospital and Calderón Guardia Hospital in co-operation with local physicians in internal medicine.

3. EXPERT ASSESSMENT ORGANIZED BY THE IAEA

3.1. REQUEST TO THE IAEA TO UNDERTAKE AN EXPERT ASSESSMENT

On 16 October 1996, the President of the Comisión de Energía Atómica de Costa Rica (Atomic Energy Commission of Costa Rica, CEA), who is Adviser to the Resident Representative of Costa Rica to the IAEA and normally the Costa Rican technical counterpart for the Agency, informed the IAEA officially of the accident and requested "the support and collaboration of the IAEA as a matter of urgency, in order to do whatever was appropriate". In doing so, he relayed a request to CEA by the then Co-ordinator of an "ad hoc group for the administrative process" established by the CCSS. However, one day after this request, on 17 October, the Minister of Health of Costa Rica faxed a note to the IAEA referring to the request of the President of the Atomic Energy Commission, and informing the IAEA that the Ministry of Health was the sole entity responsible for medical matters in Costa Rica and that neither the President of the Atomic Energy Commission nor the Co-ordinator of the group established by the CCSS had any authority to request the assistance of the IAEA. The Minister thus cancelled the request for assistance. On 18 October 1996, the IAEA sent a letter to the President of the Atomic Energy Commission assuring him that the IAEA was ready to assist Costa Rica but that any request should be co-ordinated with and endorsed by the Government.

On 20 April 1997, the Defensoría de los Habitantes of Costa Rica (Costa Rican Ombudsman) requested the assistance of the CEA in evaluating the accident, and repeated this request on 8 May. On 23 May 1997, the Director General of the CEA requested assistance from the IAEA's Department of Technical Co-operation in the form of radiotherapeutical expertise for assessing a number of matters associated with the accident in order, among other things, to provide the assistance requested by the Defensoría de los Habitantes. On 30 May 1997 la Defensoría de los Habitantes reiterated the required assistance to CEA. On 3 June 1997, the Director General of CEA reiterated the request for assistance from IAEA, referring to discussions held with the IAEA Director of Technical Co-operation: Project Management.

On 6 June 1997, in view of the urgency indicated in the various requests received, the IAEA wrote to the Minister of Foreign Affairs of Costa Rica that the IAEA had to presume that the wish of the Government of Costa Rica was now to request assistance and that, unless the Government indicated to the contrary, the IAEA would organize a Senior Expert Mission to Costa Rica to assess the accident and prepare a report to the Government, which would eventually be published by the IAEA.

On 16 June 1997 the IAEA received an official letter from the Director General of Foreign Affairs Policy of Costa Rica welcoming the IAEA's assistance. A similar letter was received on 19 June 1997 from the President of CEA.

After an exchange of several letters with the Costa Rican, a senior Expert Team was convened by the IAEA in San José to assess the accident from 7 to 11 July 1997. The Expert Team finalized its work at a meeting at the IAEA headquarters from 1 to 6 September 1997.

I.2.2. THE EXPERT TEAM

The nominations of Costa Rican experts were endorsed by the Government of Costa Rica.

- BERMÚDEZ JIMÉNEZ, Luis, Sección Radiaciones Ionizantes, Ministry of Health, Costa Rica
- KUTCHER, Gerald J., Medical Physics Department, Memorial Sloan-Kettering Cancer Center, New York, USA
- LANDBERG, Torsten, Department of Oncology, Malmö University Hospital, Malmö, Sweden
- MARENCO ZÚÑIGA, Hugo, Radiofísico, Caja Costarricense del Seguro Social, Servicio de Oncología, Hospital de México, San José, Costa Rica
- MEDINA TREJOS, Fernando, Radioterapeuta, Caja Costarricense del Seguro Social, Servicio de Oncología, Hospital Calderón Guardia, Costa Rica
- METTLER, Fred A., Jr. (*Chairman*), Professor and Chairman, Department of Radiology, Health Sciences Center, School of Medicine, University of New Mexico, Albuquerque, New Mexico, USA
- MORA RODRÍGUEZ, Patricia, Físico Médico, Universidad de Costa Rica, Miembro de la Junta Directiva de la Comisión de Energía Atómica, Costa Rica
- NÉNOT, Jean-Claude, Institut de Protection et Sûreté Nucléaire, Fontenay-aux-Roses, France
- ORTIZ LÓPEZ, Pedro (*Scientific Secretary*), Division of Radiation and Waste Safety, IAEA, Vienna
- PACHECO JIMÉNEZ, Ronald, Subjefe Sección Radiaciones Ionizantes, Ministry of Health, Miembro de la Junta Directiva de la Comisión de Energía Atómica, Costa Rica
- PÉREZ ULLOA, Vinicio, Radioterapeuta, Universidad de Costa Rica, Defensoría de los Habitantes, Servicio Oncología del Hospital México, Costa Rica

3.3. SUPPORT AND LOGISTICS FOR THE EXPERT TEAM

Other Costa Rican experts provided valuable contributions to the work, including Roxana Chan Cheng, San Juan de Dios Hospital; Xinia Madrigal Méndez, Calderón Guardia Hospital; and Marco Bruno Ramírez, San Juan de Dios Hospital. The members of the Defensoría de los Habitantes who assisted in terms of logistics throughout the Expert Team's work were: Sandra Piszk (Defensora de los Habitantes); Lilliana Arrieta, Director, Quality of Life Department; Carlos José Valerio, Lawyer, Quality of Life Department; Jaha Tischler Fuchs, Psicóloga de la Universidad de Costa Rica and Lidiette Sell, Psicóloga de la Escuela Fernando Centeno Güel, assigned to collaborate with the Defensoria in evaluating the emotional damage Audrey Benison and Rossana Nassar, interpreters. The support group from the Defensoría de los Habitantes helped with the logistics (in collecting all relevant information related to the accident). However, it did not participate directly in the medical or technical (radiotherapy related) aspects of the report.

3.4. INITIAL MEETING AND SCHEDULE FOR THE EXPERT TEAM

An initial briefing took place on Sunday 6 July 1997 to review the Expert Team's terms of assignment and the detailed expectations of the Costa Rican authorities. The following is a summary of the issues raised:

- Circumstances and cause of the accident.
- Details of the accident.
- What follow-up should be done for the patients and the prognosis.
- Effects due to radiation exposure and those due to the tumour under treatment or possibly to both.
- Recommendations to improve the application of radiotherapy.
- Recommendations on quality assurance (QA).
- Psychosocial issues.
- Safety of the technologist and other staff outside the irradiation room.
- Check of the actual dosimetry at the time of the assessment.

3.5. SCHEDULE FOR THE EXPERT TEAM

Monday 7 July 1997	
08:00–09:30	Committee meeting to review information on radiotherapy in Costa Rica and post-accident dose calibration
09:30–17:00	Work at San Juan de Dios Hospital and Calderón Guardia Hospital
06:00–20:00	Committee Meeting to review progress and determine the work schedule
Tuesday 8 July 1997	
07:30–08:30	Team work meeting
09:30–17:00	Work at San Juan de Dios Hospital and Calderón Guardia Hospital
06:00–19:30	Team work meeting
Wednesday 9 July 1997	
09:30–17:00	Work at San Juan de Dios Hospital and Calderón Guardia Hospital
06:00–19:30	Meeting with attorney for the criminal defence
09:00–22:30	Team work meeting
Thursday 10 July 1997	
08:30–15:00	Medical Team work at mortuary
08:30–15:00	Physics work at San Juan de Dios Hospital
16:00–18:00	Team meeting to review data collected and outline report
Friday 11 July 1997	
08:00–13:00	Work on draft report
14:00–15:00	Meeting with Minister of Health to discuss summary of preliminary findings
16:00–18:00	Meeting of full committee to discuss format and content of draft report

The agreed schedule was met in its entirety and in addition two meetings were held, one with the Medical Director (Gerente Médica) of the CCSS and one with the Minister of Health.