Accidental Overexposure of Radiotherapy Patients in San José, Costa Rica

ACCIDENTAL OVEREXPOSURE
OF RADIOTHERAPY PATIENTS
IN SAN JOSE, COSTA RICA

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The Agency's Statute was approved on 23 October 1956 by the Conference on the Statute of the IAEA held at United Nations Headquarters, New York; it entered into force on 29 July 1957. The Headquarters of the Agency are situated in Vienna. Its principal objective is "to accelerate and enlarge the contribution of atomic energy to peace, health and prosperity throughout the world''.

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FOREWORD

Radiotherapy is well established as an indispensable means of treatment in national cancer control programmes in both developing and developed countries. In radiotherapy, radiation is used directly to destroy malignant tissue. As radiation penetrates into the body, it also destroys healthy tissue. The success of radiotherapy therefore depends on achieving a radiation dose that is high enough to kill malignant tissue yet sufficiently low to preserve healthy tissue. This delicate balance is achieved by means of a carefully selected combination of treatment geometry and fractionated delivery of the dose for an optimal dose distribution within the body and over time.

With respect to radiation protection, radiotherapy is unique in a number of ways. It is the only application in which high radiation doses are delivered intentionally to a particular part of the human body. For this purpose, either the patient is placed directly in line with a radiation beam or radiation sources are placed in contact with body tissue. No structural barrier is placed between the radiation source and the target tissue, and any mistake made in the radiation source or the beam may have severe consequences. In addition, not only may doses administered at a higher level than those intended have harmful effects, but doses applied at a lower level than those planned may also be detrimental to the patient.

Review of radiological accidents and their causes, and dissemination of the lessons to be learned and recommendations, have proved to be a valuable tool for accident prevention. With a view to preventing accidents, the IAEA initiated a project under which reports have been issued on radiological accidents in industrial or research applications of radiation that have occurred in Belarus, El Salvador, Israel and Viet Nam, as well as accidents involving abandoned or insecurely stored sources in Brazil and Estonia.

Drawing up and disseminating the lessons to be learned from accidents are potentially extremely valuable for radiotherapy. The accident that occurred in Costa Rica in 1996, with fatal consequences for some radiotherapy patients, is the first time that the IAEA has had the opportunity of evaluating the causes and consequences of severe overexposure in radiotherapy. A dosimetric evaluation was made and a medical assessment performed that notably included the examination of patients and medical data by an international medical team.

The review was conducted at the generous invitation of the Government of Costa Rica which, through this report, has made an invaluable contribution to knowledge on radiotherapy accidents; such information can be applied to accident prevention in radiotherapy worldwide. The IAEA expresses its gratitude to the Government of Costa Rica and its authorities for their kind co-operation.

CONTENTS

PREFACE

The report summarizes the assessment made of an accidental overexposure of radiotherapy patients that occurred at the San Juan de Dios Hospital in San José, Costa Rica, in August and September 1996. The assessment was carried out by an Expert Team convened by the IAEA in July 1997 at the request of the Government of Costa Rica.

An overview provides background information on radiotherapy in general and the situation in Costa Rica in particular. It also contains a description of the biological effects of radiotherapeutic exposure, the framework for radiation protection in radiotherapy and the role of the IAEA in this area.

The report summarizes the history of the accident. An account of previous investigations in Costa Rica, made both before and after the accident, is presented. The circumstances and causes of the accident are also detailed.

The findings of the Expert Team's assessment in July 1997 are presented in two parts:

(1) An evaluation of the doses to patients by analysing the treatment records and physical measurements;
(2) A medical evaluation of patients, together with the autopsy findings for those who died.

Finally, conclusions and recommendations are presented.

Two Appendices detail the treatment parameters and doses for the patients, and summarize the individual medical findings. An Annex sets out the elements of the combined IAEA/WHO thermoluminescence dosimeter postal dose quality audit. An Addendum contains more detailed evaluation of the doses given to the normal tissue of patients with marked adverse effects.

EXECUTIVE SUMMARY

In July 1997, the IAEA received a request from the Government of Costa Rica to assist in an assessment of overexposure of radiotherapy patients in San José, Costa Rica. The initiating event occurred at the San Juan de Dios Hospital in San José on 22 August 1996, when a ^{60}Co radiation therapy source was replaced. When the new source was calibrated, an error was made in calculating the dose rate. This miscalculation resulted in the administration to patients of significantly higher radiation doses than those prescribed.

This was a major radiation accident. It appeared that 115 patients being treated for neoplasms by radiotherapy were affected. The error was realized on 27 September 1996, and treatments were stopped. Officially, the radiotherapy machine was closed down on 3 October 1996.

Shortly after the accident, an initial evaluation was made by the Ministry of Health of Costa Rica and by a physicist from and a physician designated by the Pan American Health Organization. This evaluation confirmed that overexposures had occurred.

Following a request for assistance from the Government of Costa Rica, the IAEA assembled an Expert Team composed of international and Costa Rican experts, including physicians and physicists. The Team assessed the event between 7 and 11 July 1997, and concluded its assessment in a meeting held at the IAEA Headquarters from 1 to 6 September 1997.

Measurements on the machine in question and a review of the patients' charts made by the Expert Team also confirmed that the exposure rate had been greater than assumed, by about 50–60%. Examination and evaluation of 70 of the 73 patients who remained alive at the time of the review in July 1997 were carried out. It was concluded that, at that time, four patients were suffering from catastrophic consequences and that a further 16 patients were experiencing major adverse effects resulting from the overexposure and would be at high risk in the future. Twenty-six patients showed effects that were not severe, but would be at some risk of suffering effects in the future. Twenty-two patients had no discernible effects and were considered to be at low risk of future effects, because many had undergone only a small part of their therapy with the replaced source. At least two patients were underexposed. Three patients were not examined.

As of 7 July 1997, i.e. within 9 months of the accident, 42 of the patients had died. Data on 34 of these patients were reviewed by the Expert Team. While the final answers must await full autopsies and a review of the clinical records, it appears that three patients may have died as a direct result of overexposure and another four patients were considered to have died with radiation overexposure probably a major contributory cause of death. Twenty-two patients appeared to have died as a result of their disease rather than radiation exposure, while information

on the other five deaths was either inconclusive or unavailable. Information on all the patients, including that on eight deceased patients which could not be reviewed by the Expert Team, has been appended to this report.

It is clear that, while many patients showed obvious effects of radiation overexposure, the full consequences of the overexposure are not yet evident, and that irreversible radiation effects and complications resulting from this accident are likely to appear in patients in the coming years.

Updated regulations for radiological safety, approved in 1995, were in the implementation phase in Costa Rica at the time of the accident. The radiotherapy machine itself was in good working order, as was the dosimetry equipment. The proximate cause appears to have been an arithmetical mistake. However, a contributing factor (and root cause) was the inadequacy of the hospital's radiation protection programme which, specifically, was lacking in a quality assurance (QA) programme, accident prevention measures, and an education and training programme.

This accident has served to confirm a number of lessons that were already widely known from previous incidents, and also provided specific lessons to be learned:

(1) Radiation accidents with severe and even fatal consequences do occur in medical facilities;

(2) Human error is the most common cause of radiation accidents;

(3) Prior to the accident, external auditing had detected the poor quality of record keeping, the lack of redundancy in procedures, and inadequate education and training; had actions been taken on these findings, the accident might have been prevented;

(4) Investigation of radiation accidents generally reveals faults that should be corrected;

(5) When there is high incidence/severity of acute effects during radiotherapy treatment, the treatment should be stopped and the source calibration checked immediately;

(6) In radiotherapy accidents, the tumour dose may not be the parameter of primary interest. Often, the biologically equivalent 2 Gy/fraction dose (the dose that would be biologically equivalent had it been delivered in fractions of 2 Gy) to sensitive structures such as the spinal cord, heart and intestine is more important;

(7) Accepted radiotherapy protocols have very little margin for error, since both normal and malignant cells are killed; significant overdoses (errors much greater than 10%) will result in an unacceptable incidence of severe consequences;

(8) Radiotherapy administered in fewer than the normal number of treatments with higher doses per treatment results in an excessive number of early and, particularly, late complications;

(9) When radiation therapy sources are replaced, the calibration should be done by appropriately trained persons, and independently checked;

(10) A properly operating machine does not guarantee good radiotherapy treatment; adequate ancillary equipment, education and training, staffing and management are essential;

(11) Regulations should cover the level of training and competence required to deal with potentially hazardous radiation sources;

(12) Specific training should be given after an individual working in a radiotherapy unit has received a thorough basic education, and should not consist of simply attending occasional short courses;

(13) Radiotherapy records should be uniform, clear, consistent and complete;

(14) Early and reliable information and communication are crucial for the good management of radiation accidents;

(15) Radiation accidents can have major short and long term psychosocial consequences.

In the light of its investigation of this accident, the Expert Team made the following specific recommendations to the Government of Costa Rica:

(a) Radiation therapy is necessary and should be continued in Costa Rica;

(b) In general, radiotherapy should be improved to avoid unnecessary and unacceptable harmful outcomes;

(c) Existing radiation protection regulations should be implemented, enforced as soon as possible and kept up to date;

(d) QA programmes should be developed and implemented;

(e) Education and training for radiation therapy staff should be improved;

(f) Record keeping in radiotherapy charts should be improved;

(g) If external auditing, such as (confidential) dose check services, reveals significant, persistent and continuing problems, another channel of communication to the authorities should be sought;

(h) Major medical and psychosocial support should be provided to many patients, and will probably be needed for at least the next 5 years;

(i) A registry of data on these patients should be set up.

The Expert Team further recommended that the IAEA publish this report in the literature so as to foster information exchange with a view to preventing similar accidents elsewhere in the future.

1. OVERVIEW OF RADIOTHERAPY AND RADIATION PROTECTION

1.1. USE OF RADIOTHERAPY

The recorded incidence of cancer is increasing in most countries, for several reasons. With growing public awareness, more and more cancers will be diagnosed at an earlier stage and the need for radical (curative) treatments (surgery and/or radiotherapy) will rise. There is also an increasing demand for organ saving procedures, e.g. for breast cancers and head and neck cancers, which require high quality integrated cancer surgery and radiotherapy. Furthermore, developments in palliative care have greatly improved the quality of life for those patients with advanced cancers that cannot be cured. Radiotherapy plays an important part in the management of such patients.

It has been estimated that in the United States of America and the European Union radiotherapy is useful for 50% or more of cancer patients, initially or during the course of progressive disease. This level of use of radiotherapy has been reached in only a limited number of countries.

1.2. RADIOTHERAPY IN COSTA RICA

Costa Rica, in Central America, has a total area of 50 900 km^2. In 1993, the reported population of Costa Rica was about 3.22 million, of which about 1.63 million were male and 1.59 million female. According to a 1991 report, the capital, San José, had 1.11 million inhabitants. About 60% of the Costa Rican population resides in urban areas and 40% in rural areas. Life expectancy in the period between 1990 and 1995 was 75.2 years. Medical coverage, provided by the Costa Rican Social Security System (Caja Costarricense del Seguro Social (CCSS)), reaches about 90% of the people.

The status of cancer and radiotherapy has been summarized by the Grupo Latino de Curieterapia (curietherapy) as follows. Some 4198 cancer cases were diagnosed in 1992, with an incidence rate of 132.8 cases per 100 000 inhabitants. Of these, 2217 cases were in females and 1981 in males. Skin cancer appeared to be most common among Costa Rican women, with 373 diagnosed cases in 1992. The second most common occurrence was breast cancer, with 323 cases, followed by uterine cervical cancer with 265 cases, in situ cervical cancer with 232 cases and stomach cancer, in fifth place, with 180 cases. The remaining 844 cases among females corresponded to various other types of cancer. For males, skin cancer also had the highest incidence with 392 cases, followed by stomach cancer

with 386 cases, prostate cancer with 269 cases, lung cancer with 87 cases and leukaemia with 82 cases. The remaining 765 cases in males were various other types of cancer.

In 1993, the general mortality rate in Costa Rica was 12 543 deaths, tumours being the most common direct cause, with 2608 cancer deaths, or a rate of 20.79% of all deaths, and approximately 81 cancer deaths per 100 000 inhabitants. Cancer was rated second, after 3930 deaths related to ailments of the circulatory system. Of these 2608 cancer deaths, stomach cancer was the main cause in 604 cases, i.e. 23.14% of all cancer deaths. The next four most common types of fatal cancer were lung cancer (209 cases), prostate cancer (162 cases), breast cancer (140 cases) and uterine cervical cancer (135 cases).

Analysing by gender, 1385 males and 1223 females died of cancer. The first five causes in males were stomach cancer (386 cases), prostate cancer (162 cases), lung cancer (143 cases), pancreatic cancer (72 cases) and liver cancer (70 cases). For females, stomach cancer was also the foremost cause of death in 218 cases, followed by breast cancer (140 cases), uterine cervical cancer (135 cases), lung cancer (66 cases) and pancreatic cancer (65 cases). As the population ages, the prevalence of cancer will increase.

There are 28 hospitals throughout the country, of which six are national referral hospitals for the rest of the country, and 22 are regional or provincial hospitals. There are three hospitals in the capital devoted to the integral treatment of cancer; these also function as referral centres for different parts of the country: the San Juan de Dios Hospital, the México Hospital and the Dr. Rafael Angel Calderón Guardia Hospital, with 882, 630 and 522 beds, respectively.

Two hospitals, the San Juan de Dios Hospital and the México Hospital, offer radiotherapy facilities. There is a radiotherapist at the Calderón Guardia Hospital, but no equipment for radiotherapy treatment is available, so the radiotherapy patients are moved daily to the San Juan de Dios Hospital. Five radiotherapy oncologists work for the CCSS; there are no radiotherapists available in private medical institutions. In total, there are one physicist and nine radiotherapy technicians in Costa Rica.

There are three radiotherapy units available, all with cobalt sources: two Theratron-80 models and one Alcyon CGR II model. The San Juan de Dios Hospital is equipped with one Theratron-80 and one Alcyon CGR II machine, and the México Hospital has a Theratron-80 unit. One of the Theratron machines was acquired in 1969, the other in 1973. The Alcyon CGR II machine was manufactured in 1987 and donated to Costa Rica in 1992.

Currently, there are two orthovoltage machines, both in the same hospital; a Toshiba simulator is also available. There is no computer based planning for radio-therapy in the country, and there are no styrofoam cutters for use in manufacturing the protective lead blocks.

For brachytherapy, only five beds are available for the application of intra-cavitary implants. There is currently a large inventory of capsules and radium needles that have not been used since 1974. With the limited brachytherapy material and equipment it is impossible to carry out timely treatment, and the waiting time for intracavitary radiotherapy is 3 months.

The human and technical resources for radiotherapy currently available in Costa Rica are inadequate to meet needs, and the radiotherapy equipment, including the ancillary equipment, is of inadequate quality.

1.3. BIOLOGICAL EFFECTS OF RADIOTHERAPEUTIC EXPOSURE

To be effective, radiation therapy must reach doses that are toxic to malignant cells. At these dose levels, a substantial number of normal cells will also be killed. The number of cells killed is the result of the total dose, i.e. the dose per treatment and the number of treatments. The effects of killing normal cells can be minimized by: (1) centring the radiation beam on the tumour while including as little normal tissue as possible; (2) using multiple fields so that the sum of the doses at the centre of the tumour is higher than that at any point on the surface; and (3) dividing (fractionating) the treatment into about 25 days (usually treatment with each radiation field every day). Usual fractionation schemes give doses of 1.5–2 Gy/d, 4–5 days per week. Even when these measures are taken and when practice is good, radiotherapy complications will develop. A serious complication rate of 5% is usually considered acceptable and is anticipated because of individual variations in sensitivity to radiation. If the radiation doses received are lower, then fewer, if any, complications will arise, but this also implies that there will be fewer cures. On the other hand, higher doses will result in potentially more cures, but also more complications.

If the total dose is increased, more cells will be killed. Also, if the total dose remains the same but the dose per fraction is increased and the number of fractions reduced, more cells will be killed. For many tissues, reducing the number of fractions and increasing the dose per fraction will cause a disproportionate increase in chronic effects compared with acute effects. Under these circumstances, relying on acute effects for the prediction of late effects would result in underestimation of the actual extent of the effects.

There are well known tolerance levels for radiation for many normal tissues. These are given in Table I [1] and are the result of achieving certain total doses with the usual fractionation schemes. For the accident under review, as the number of fractions was often lower and the dose per fraction higher, the tolerance doses for many of these patients will be lower than those given in the

TABLE I. RADIATION TOLERANCE DOSES (rad)[a]

Organ	Injury (at 5 years)	1–5% (TD 5/5)[b]	25–50% (TD 50/5)[c]	Volume or length
Skin	Ulcer, severe fibrosis	5500	7000	100 cm^3
Oral mucosa	Ulcer, severe fibrosis	6000	7500	50 cm^3
Oesophagus	Ulcer, stricture	6000	7500	75 cm^3
Stomach	Ulcer, perforation	4500	5500	100 cm^3
Intestine	Ulcer, perforation	5000	6500	100 cm^3
Colon	Ulcer, stricture	4500	6500	100 cm^3
Rectum	Ulcer, stricture	5500	8000	100 cm^3
Salivary gland	Xerostomia	5000	7000	50 cm^3
Liver	Hepatitis	2500	4000	Whole
Kidney	Nephrosclerosis	2000	2500	Whole
Bladder	Ulcer, contracture	6000	8000	Whole
Ureter	Stricture, obstruction	7500	10 000	5–10 cm
Testes	Permanent sterilization	500–1500	2000	Whole
Ovary	Permanent sterilization	200–300	625–1200	Whole
Uterus	Necrosis, perforation	>10 000	>20 000	Whole
Vagina	Ulcer, fistula	9000	>10 000	5 cm
Breast (child)	No development	1000	1500	5 cm^3
Breast (adult)	Atrophy and necrosis	>5000	>10 000	Whole
Lung	Pneumonitis, fibrosis	4000	6000	Lobe
Lung		1500	2500	Whole
Capillaries	Telangiectasia, sclerosis	5000–6000	7000–10 000	—
Heart	Pericarditis, pancarditis	4500	5500	60%
Bone (child)	Arrested growth	2000	3000	10 cm^3
Bone (adult)	Necrosis, fracture	6000	15 000	10 cm^3
Cartilage (child)	Arrested growth	1000	3000	Whole
Cartilage (adult)	Necrosis	6000	10 000	Whole
			Absorbed dose	—
Brain	Necrosis, infarction	5000	>6000	Whole
Spinal cord	Necrosis, transection	4500	>5500	10 cm^3
Eye	Panophthalmitis, haemorrhage	5500	10 000	Whole
Cornea (L.b.)	Keratitis	5000	>6000	Whole
Lens	Cataract	500	1200	Whole
Ear (inner)	Deafness	>6000	—	Whole
Vestibular	Meniere's syndrome	6000	10 000	Whole
Thyroid gland	Hypothyroidism	4500	15 000	Whole
Adrenal gland	Hypoadrenadism	>6000	—	Whole
Pituitary gland	Hypopituitarism	4500	20 000–30 000	Whole
Muscle (child)	No development	2000–3000	4000–5000	Whole
Muscle (adult)	Atrophy	>10 000	—	Whole
Bone marrow		250	450	Whole
Bone marrow		3000	4000	Localized
Lymph nodes	Atrophy	4500	>7000	—
Lymphatic gland	Sclerosis	5000	>8000	—
Foetus	Death	200	400	Whole

[a] Data adapted from Dalrymple, G.V., et. al., Medical Radiation Biology, Saunders (1973), Table 1-13 (page 23) of Ref. [1], and reproduced here with the permission of the W.B. Saunders Company, Philadelphia, PA, United States of America.

[b] TD 5/5 = tolerance dose of 5% in 5 years.

[c] TD 50/5 = tolerance dose of 50% in 5 years.

Note: No dose data were available for the pancreas, gall bladder or aorta.

table[1]. Specific values for different fractionation schemes are quoted in this report where available and applicable.

It should be pointed out that, while it is possible to calculate doses quite precisely, there are significant individual variations in response among patients. Calculated doses should only be used to provide general guidelines and not to reach firm conclusions concerning the causation of adverse effects. There are a few rare individuals who may demonstrate exceptional radiosensitivity (e.g. patients who are homozygous for ataxia telangiectasia).

1.4. PROCEDURES IN RADIOTHERAPY

Successful radiotherapy programmes must meet a number of criteria:

(1)   The selection of patients and the clinical work-up have to be adequate to permit an appropriate prescription of radiotherapy.
(2)   To deliver the prescribed dose (a range of approximately ±7% is acceptable) to the relevant tumour and critical tissues (an uncertainty of around ±5 mm is often accepted), a number of instruments are necessary, or at least useful:

   (a)   Treatment machines that can deliver at least one high energy and one low energy photon beam are necessary (e.g. ^{60}Co machines and orthovoltage machines). Further improvements can be achieved with accelerators that can provide a selection of photon energies as well as electron beams of different energies.
   (b)   Brachytherapy (intracavitary or interstitial) plays an instrumental role, especially for gynaecological cancers. For the radiation protection of personnel, dedicated instruments are needed.

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[1] In some palliative situations, use of a lower number of fractions over a short period of time has some advantages. Such treatments reduce the patients' stay at the hospital and allow them to spend more time at home. The available (limited) resources of the radiotherapy department can then be used to treat other patients. Examples of such schedules are 30 Gy given in 10 fractions of 3 Gy each, or even 20 Gy in two fractions of 10 Gy, one week apart. However, such palliative treatments (with a small number of fractions) have to be limited to certain situations, such as when the expected survival is short (weeks or, at most, a few months) and when the treatment does not affect organs at risk such as the central nervous system (CNS), the lungs and the intestine. Otherwise, the palliative effects may be outbalanced by radiation induced side effects such as pneumonitis, gastrointestinal (GI) upset, or even CNS complications. In practice, this means that this type of fractionation should only be used for patients with widespread and rapidly deteriorating disease, and then for mainly skeletal metastases from cancers with a very short expected survival.

(c) Positioning and immobilization systems for patients must be available in order to minimize the irradiation of healthy tissue.

(d) Treatment planning (dose computation) can be done at different levels of thoroughness. At level 1, only the dose delivered at points along a treatment beam can be estimated. At levels 2 and 3, complete dose distributions for areas or volumes can be estimated. For this purpose, treatment planning computers are necessary. Information gained at level 1 provides only an approximate estimate.

(e) To check that the beam geometry complies with the prescription, imaging systems are needed for daily clinical routine; a simulator is very useful for this purpose.

(f) A number of dosimetry systems can be used to check the dose within and at the patient (in vivo), e.g. thermoluminescence dosimetry (TLD) or diode dosimetry.

(g) A QA system must be in place in order to conform with the precision requirements stated earlier; an example of a QA programme is given in Ref. [2].

Radiotherapy procedures involve a number of steps, as shown in Fig. 1 [3]. For optimal use of resources it is necessary that the quality of procedures is equal or similar at each step.

The initial selection of patients for curative (radical) radiotherapy must be based on an evaluation of the condition of the patient, the site and size of the tumour, and the use of any medication that would modify the response to radiation (e.g. in cancer chemotherapy).

The next major step is a complete clinical work-up, including the site and extent of the tumour, its stage, etc.

Use of cancer staging classification (TNM) is mandatory. According to the clinical information available, external beam therapy may be selected, as well as the possible use of brachytherapy alone, or before, or after external irradiation. The next step must be the precise localization and simulation of the treatment of the tumour and determination of its size and shape (Fig. 2) [3, 4]. Anatomical data are used as a basis for dose planning. Once the tumour volume is known, the next step is to delineate the full target and then to determine the planning target volume and simulate the treatment.

The prescription of curative radiotherapy includes:

(i) Definition of the organs/tissues to be treated (e.g. right tonsil and lymph nodes on the right side of the neck); this anatomical prescription can be codified;

(ii) Prescription of dose and fractionation (e.g. 68 Gy for the right tonsil, given in daily fractions of 2 Gy, plus 50 Gy to the lymph nodes, with the same fractionation);
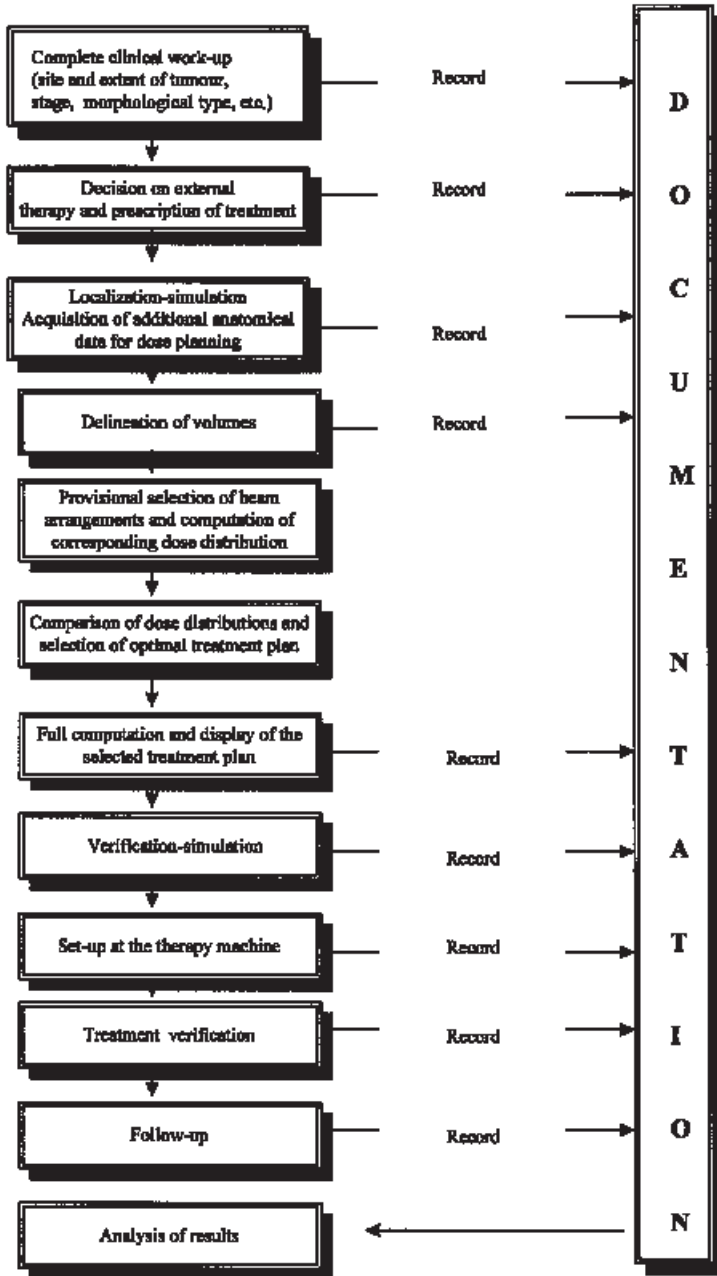
FIG. 1. Steps in the radiotherapy procedure. (It should be noted that there must be continuous feedback between all the different steps. Any difficulties at a given point may question all the decisions made at previous steps [3].) (This figure is reproduced here with the permission of the International Commission on Radiation Units and Measurements, Bethesda, MD, USA.)
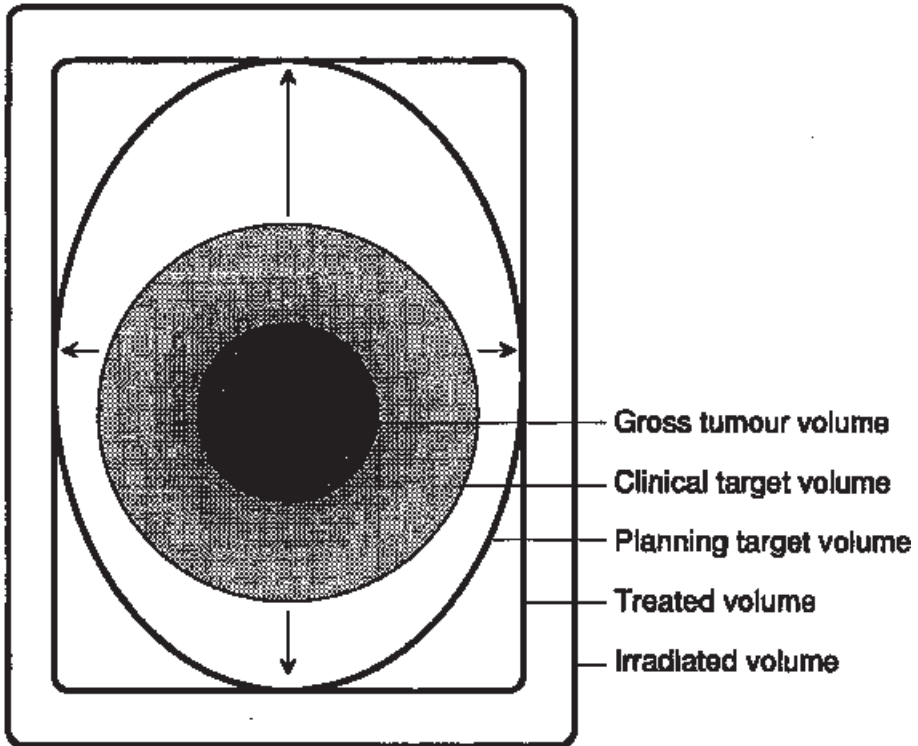
FIG. 2. Schematic illustration of the different volumes. Gross tumour volume (GTV) denotes the demonstrated tumour. Clinical target volume (CTV) denotes the demonstrated tumour (when present) and also a volume with a suspected (subclinical) tumour (e.g. the margin around the GTV and, for example, regional lymph nodes (according to the cancer staging classification (TMN) [4] considered to need treatment). The CTV is thus a purely anatomical-clinical concept. The planning target volume (PTV) consists of the CTV(s) and a margin to account for variations in size, shape and position relative to the treatment beam(s). The PTV is thus a geometrical concept used to ensure that the CTV receives the prescribed dose, and it is (like the patient and/or tissues concerned) defined in relation to a fixed co-ordinate system. Note that in the example shown the magnitude of foreseen movements of the CTV is different in different directions. The treated volume is the volume that receives a dose which is considered important for local cure or palliation. The irradiated volume is the volume that receives a dose which is considered important for normal tissue tolerance (other than those specifically defined for organs at risk). (Adapted from Ref. [3].) (This figure is reproduced here with the permission of the International Commission on Radiation Units and Measurements, Bethesda, MD, USA.)

(iii)   Description of the organs at risk (e.g. cervical spinal cord, at most 48 Gy with daily 2 Gy fractions).

The data obtained are then used to design an appropriate dose distribution by means of a computerized planning system (CPS). If no such system is available, less sophisticated methods must be used.

It is important to formulate at least two dose distributions in order to be able to make the best choice. Once the treatment plan is chosen, it is verified by means of film radiographs in the therapy unit in the first session. In vivo verification should be done before the actual treatment commences; this applies for every treatment. This is achieved by using in vivo dosimetry[2], applying TLD detectors and/or diodes.

In the prescription procedure, a number of additional issues, including fractionation, will have to be addressed. Unless otherwise stated it is assumed [3, 5] that all fields are treated at each fraction, and that five fractions are given each week; usually, this is considered to be standard treatment.

The methods used to reduce the number of fractions (often because of limited radiotherapy resources) will have implications for tumour eradication; the frequency and severity of early normal tissue reactions (acute side effects); and the frequency and severity of late normal tissue reactions (complications). It is important to understand that these endpoints depend on a number of factors, such as the dose at each fraction, the number of fields per fraction, the total (cumulative) dose, the total number of days of treatment and any additional intervals.

Recent advances in radiobiology indicate that there is a difference between the cellular mechanisms for early and late normal tissue reactions. In this respect, cancer cells follow the early reaction tissues, and the relation between effect and dose is more or less linear (alpha type). On the other hand, late reactions (such as late ulcers and scarring) are related to the square of the dose (beta type).

It follows from this that, if the total dose to be administered (i.e. the dose considered necessary for tumour control) is divided into fewer and fewer treatments (fractions), a greater number of late complications will occur. The same result will be seen with a schedule in which only one field is treated at each fraction.

With standard treatment it is thus good practice to treat all the fields at each fraction and to use standard doses at each fraction (e.g. a 2 Gy target dose five times per week, in all 34 fractions, to give a total of 68 Gy, all fields treated at each fraction). It is recommended that treatments beginning on Fridays should be avoided because any prolongation of total treatment time will necessitate a larger total dose (and thus more complications) if the cure rate is to remain unchanged.

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[2] Dose verification, usually applying TLD detectors or diodes, on the patient or in the patient's cavities, in order to detect deviations in the delivery of a treatment or to document doses to critical structures.

It is well known that there are several sources of uncertainty and error that cannot be shown by adequate calibration of the beam output from the machine. In vivo dose measurements can reveal several of these sources of error by measuring the true dose given to the patient (e.g. at the beam entry point in the mouth or in the rectum). Use of such in vivo dosimetry is highly recommended and should be part of the routine QA programme. It is good practice to have a system for in vivo patient dose measurements that supplements (but never substitutes for) calibration of the treatment machines.

Control of set-up precision is needed using simulator based portal films[3] against which treatment verification films obtained during treatment can be checked. Such controls should reveal any significant deviation in the patient–beam geometry during the whole treatment procedure. It is good practice to have a system for checking the patient–beam geometry, and it is recommended that a film be taken every week, or at least one film initially, and another at the middle of the treatment.

It is necessary to record the parameters at all steps during the whole procedure (for legal purposes, among other reasons), during the prescription, during the planning and execution of therapy, and also during the follow-up. For reporting it is necessary to use internationally accepted codes of nomenclature. It is an advantage if the same codes are used in all departments, since this will reduce the risk of ambiguity, and even mistakes.

For brachytherapy practice in gynaecology, the following steps are desirable:

(1) Obtain a complete clinical history, including the clinical stage, extension and the histological type of the tumour;
(2) Make a good selection of the patients expected to benefit from brachytherapy;
(3) Obtain adequate information on the extent of the disease and on the anatomy of the patient to ensure correct dose planning;
(4) Take films to localize and simulate the radioactive sources;
(5) Delineate the volume to be irradiated;
(6) Use a CPS for calculating the dose to the tumour and to the anatomical points, as recommended in International Commission on Radiation Units and Measurements (ICRU) Publication No. 38 [6];
(7) Use adequate rooms, guaranteeing radiological protection;
(8) Apply the recommendations of ICRU Publication No. 38 [6];
(9) Prohibit the use of radium;
(10) Ensure adequate follow-up of patients.

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[3] Portal films consist of pictures taken to verify the beam orientation to the patient's anatomy and are obtained with X rays (in the case of simulators) or with high energy photons (in the case of treatment machines).

1.5. RADIATION PROTECTION

It is important to understand the internationally accepted framework for radiation protection and safety in medicine (ICRP 73) [7] in order to be able to observe where the breakdowns occurred in this accident. The basic concepts were published by the International Commission on Radiological Protection (ICRP) in 1991 (ICRP 60) [8].

The elements in the framework begin with *justification of the practice*. The initial step is to justify the practice proper (in this case, radiotherapy for a given disease). Obviously, radiotherapy usually does more good than harm and is therefore justified for the treatment of various diseases such as Hodgkin's disease and breast, lung and cervical cancer. It is not justified to use radiotherapy for the treatment of other diseases such as acne.

After justification of the practice proper, there has to be individual justification. This means that the treatment needs to be justified for the stage of the disease, and the particular circumstances. For example, if a patient has Hodgkin's disease at a stage that is better treated by chemotherapy, then radiotherapy would not be justified.

The second component of the framework is the *optimization of protection*[4]. This refers to steps that can reasonably be taken to reduce the dose to non-tumour tissues. Optimization is normally applied at two levels: (1) design and construction of equipment and installations; and (2) day to day methods of working.

Radiation safety or *accident prevention* is the third important component of radiation protection and safety that is usually specifically addressed. The underlying principle of accident prevention is defence in depth (i.e. multiple safeguards to prevent an accident). For radiation therapy equipment, specific recommendations have included that calibration be done after installation and modification, and that key decisions be subject to independent review and confirmation.

A final component involves *institutional arrangements*. This is important, since safety depends critically on the performance of people, and institutional arrangements can greatly affect their performance. Governments have the responsibility for establishing a framework of policy on radiological protection.

The institutional arrangements necessary also cover the need to verify compliance with procedures and fulfilment of objectives; this includes QA programmes and record keeping.

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[4] Optimization of protection is an inherent component of optimization of radiotherapy itself, which is aimed at achieving control of the tumours and preserving normal tissue. This implies that doses to normal tissue should be maintained as low as possible.

1.6. THE ROLE OF THE IAEA

In relation to the subject of this report, the IAEA has, as one of its main statutory functions, *"to establish... standards of safety for protection of health... and to provide for the application of these standards... at the request of a State"*. The Agency has established, jointly with the Food and Agriculture Organization of the United Nations (FAO), the International Labour Organization (ILO), the Nuclear Energy Agency of the OECD (OECD/NEA), the Pan American Health Organization (PAHO) and the World Health Organization (WHO), the International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources (issued by the IAEA in 1996 as Safety Series No. 115) [9], which include detailed requirements for the protection of patients undergoing therapeutic radiation exposure. The Agency provides for the application of these standards, usually by fostering information exchange; encouraging education and training; co-ordinating research and development; rendering services on request, including radiological assessments; and providing technical co-operation and assistance.

The programme of technical co-operation (TC) at the Agency is a major vehicle for strengthening radiotherapy and radiation protection infrastructures in its Member States, including those for the protection of patients undergoing therapeutic radiation exposure. A relevant TC project in this regard is the Model Project on Upgrading Radiation and Waste Safety Infrastructures.

The Agency also has a number of promotional projects on applied radiation biology and radiotherapy, and on dosimetry. These include projects on the upgrading of radiation oncology in developing countries; advanced techniques in radiotherapy; development of criteria for human responsiveness to radiation for use in treatment planning; QA in clinical radiotherapy; combined radiation therapy of cancer; collaboration in radiotherapy protocols for improved cancer cure; a secondary standards dosimetry laboratory network; dose intercomparison and assurance; and transfer of dosimetry techniques.

In addition, the IAEA plays a major role under the terms of the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency. Under the Convention, the Agency has to co-operate with those States that are parties to this Convention, facilitating prompt assistance in the event of a radiological emergency in order to minimize its consequences and to protect life. The Agency, moreover, has inter alia to assist, to make available appropriate resources, and to offer its good offices to a requesting State party in the event of a radiological emergency.

In the case of the radiological accident in Costa Rica, the Agency responded to a request for assistance by the Government of Costa Rica. Costa Rica is a Member State of the IAEA and has received technical co-operation from the Agency in different areas, including radiotherapy and dosimetry. Costa Rica is part of the IAEA TC Model Project on Upgrading Radiation and Waste Safety Infrastructures. Within its

project on dose intercomparison and assurance, the Agency has rendered mailed dosimetry services for radiotherapy centres in Costa Rica in order to verify the dose delivered by the sources in machines for external and internal radiotherapy treatment (see Annex to this report). Costa Rica is also a State party to the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency.

Part I

BACKGROUND

2. HISTORY OF THE ACCIDENT

2.1. INTRODUCTION

The accident occurred in the radiotherapy Alcyon II unit of the radiotherapy facility at the San Juan de Dios Hospital in San José, Costa Rica. The unit is equipped with a ^{60}Co 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. After this source change, operation of the unit for the treatment of patients resumed on Monday, 26 August 1996. The miscalculation resulted in the administration to patients of significantly more radiation than that prescribed.

2.2. EVENTS PRIOR TO THE ACCIDENT

IAEA/WHO TLD postal dose quality audits 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 the results are treated confidentially and that actions upon the results of this postal dose quality audit 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 their occurrence, to evaluate the physical aspects of QA in radiotherapy, and to check the degree of application of Technical Reports Series No. 277 [10] and of compliance with Safety Series No. 115 [9].

The expert carried out a review between 8 and 19 July 1996. She found that no records had been kept on the calibration of radiation beams, and that no information was available on the equipment used, the working conditions prevailing, the dose determination protocols followed, the results obtained or the calculation of what appears as 'rendimiento' ('output' in radiotherapeutical jargon, or absorbed dose rate in technical terms) in a computer program purposely written for calculating the time.

Differences of up to 8% in the calculated time were found, for the same irradiation conditions, when a calculation method based on the percentage depth dose (PDD) and the tissue air ratio (TAR) was used. First analysis showed that the same 'rendimiento' value had been used for both methods; this revealed 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 quality audits that had been carried out since 1989 (which were unknown to the radiation oncologists), as well as the conceptual errors in calculation. The radiation oncologists seemed greatly surprised, and also sceptical, maintaining that "if it were so, we would have noticed in the clinical results" [11]. The expert explained that in all cases the doses delivered to patients with open radiation fields (i.e. without organ shielding) had been lower than those planned. It is well known that underdosage can only be clinically noted after months or years (a decrease in the tumour control rate and therefore an increase in tumour recurrence), in contrast to overdosage.

2.3. DISCOVERY OF IRREGULARITIES

According to the information obtained during the expert review in July 1996, the radiation oncologist at the Calderón Guardia Hospital had noticed that there were unusually severe effects in some of the patients treated with the Alcyon II unit at the San Juan de Dios Hospital, and followed up on the observation. These effects were related to the skin and low digestive tract, e.g. diarrhoea, abdominal pain and reddened skin. He compared the recorded dose rates of both machines (Theratron and Alcyon II), 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 unit was lower than that of the Theratron, despite the fact that the activity was higher.

On 27 September 1996, after 1 month of working with the new source, the person in charge of dosimetry at the San Juan de Dios Hospital contacted the physicist at 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 correspond to 0.3 min, i.e. 18 s. It then emerged that, instead of 18 s, a value of 30 s seems to have been used to determine the dose rate. This implies that, on this basis alone, the exposure time had been overestimated 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 that intended.

2.4. 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, which is responsible for monitoring compliance with the regulations on radiation protection. He informed the staff 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 certification of any academic degree; he had only attended a number of training courses and fellowships.

2.5. INVESTIGATIONS PRIOR TO THE EXPERT TEAM'S ASSESSMENT

According to the information received from a Costa Rican member of the Expert Team, the CCSS proposed to the Ministry of Health that assistance be requested from 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" [12], and J.C. Jiménez to classify the patients in order "to determine those who needed the resumption of radiotherapy treatment from others needing continued clinical observation" [13]. The early investigation was made from 15 to 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 a depth of 0.5 cm in water) from the ^{60}Co Alcyon II unit yielded a value of 190.72 cGy/min (1.9072 Gy/min) at a distance of 80.5 cm for a field size of 10×10 cm. The group concluded that there had been an overdosage to patients of 73%. It also showed that a computer program to interpolate the 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 the 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 (CEA) (Atomic Energy Commission of Costa Rica), who is Adviser to the Resident Representative of Costa Rica to the IAEA and normally the Costa Rican technical counterpart for the Agency, officially informed the IAEA 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 the 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 1996, the Minister of Health of Costa Rica faxed a note to the IAEA referring to the request of the President of the CEA 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 CEA 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 CEA 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, the Defensoría de los Habitantes reiterated the required assistance to the CEA. On 3 June 1997, the Director General of the CEA repeated the request for assistance from the 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 to the effect 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 an Expert Mission to Costa Rica to assess the accident and to 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 the CEA.

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

3.2. THE EXPERT TEAM

Nominations for the following experts were endorsed by the Government of Costa Rica:

Bermúdez Jiménez, L., Sección Radiaciones Ionizantes, Ministerio de Salud, San José, Costa Rica;

Kutcher, G.J., Medical Physics Department, Memorial Sloan-Kettering Cancer Center, New York, United States of America;

Landberg, T., Department of Oncology, Malmö University Hospital, Malmö, Sweden;

Marenco Zúñiga, H., Caja Costarricense del Seguro Social, Servicio de Oncología, Hospital de México, San José, Costa Rica;

Medina Trejos, F., Caja Costarricense del Seguro Social, Servicio de Oncología, Hospital Calderón Guardia, San José, Costa Rica;

Mettler, F.A., Jr. (*Chairman*), Department of Radiology, Health Sciences Center, School of Medicine, University of New Mexico, Albuquerque, New Mexico, USA;

Mora Rodríguez, P., Universidad de Costa Rica, Miembro de la Junta Directiva de la Comisión de Energía Atómica, San José, Costa Rica;

Nénot, J.-C., Institut de protection et de sûreté nucléaire, Fontenay-aux-Roses, France;

Ortiz López, P. (*Scientific Secretary*), Division of Radiation and Waste Safety, IAEA, Vienna;

Pacheco Jiménez, R., Sección Radiaciones Ionizantes, Ministerio de Salud, Miembro de la Junta Directiva de la Comisión de Energía Atómica, San José, Costa Rica;

Pérez Ulloa, V., Universidad de Costa Rica, Defensoría de los Habitantes, Servicio de Oncología, Hospital México, San José, Costa Rica.

3.3. SUPPORT AND LOGISTICS FOR THE EXPERT TEAM

Other Costa Rican experts (physicians, psychologists and lawyers) made valuable contributions to the work, including R.C. Cheng, San Juan de Dios Hospital; X.M. Méndez, Calderón Guardia Hospital; and M.B. 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: S. Piszk, Defensora de los

Habitantes; L. Arrieta and C.J. Valerio, Quality of Life Department; J. Tischler Fuchs, Universidad de Costa Rica; L. Sell, Escuela Fernando Centeno Güel, assigned to collaborate with the Defensoría in evaluating emotional damage; and A. Benison and R. Nassar, interpreters. The support group from the Defensoría de los Habitantes helped with the logistics (in collecting all the 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 BRIEFING OF 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:

(1) Circumstances and causes of the accident;
(2) Details of the accident;
(3) What follow-up should be done for the patients, and the prognosis;
(4) Effects resulting from radiation exposure and those caused by the tumour under treatment, or possibly both;
(5) Recommendations to improve the application of radiotherapy;
(6) Recommendations on QA;
(7) Psychosocial issues;
(8) Safety of the technologist and other staff outside the irradiation room;
(9) Check of the actual dosimetry at the time of assessment.

3.5. SCHEDULE FOR THE EXPERT TEAM

The schedule for the Expert Team was as follows:

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 the San Juan de Dios Hospital and the Calderón Guardia Hospital
18:00–20:00	Committee meeting to review the progress made and to determine the work schedule

Tuesday, 8 July 1997

07:30–08:30	Team meeting

| 09:30–17:00 | Work at the San Juan de Dios Hospital and the Calderón Guardia Hospital |
| 18:00–19:30 | Team meeting |

Wednesday, 9 July 1997

09:30–17:00	Work at the San Juan de Dios Hospital and the Calderón Guardia Hospital
18:00–19:30	Meeting with the attorney for the criminal defence
21:00–22:30	Team meeting

Thursday, 10 July 1997

08:30–15:00	Medical team work at the mortuary
08:30–15:00	Physics work at the San Juan de Dios Hospital
16:00–18:00	Team meeting to review the data collected and to outline the report

Friday, 11 July 1997

08:00–13:00	Work on the draft report
14:00–15:00	Meeting with the Minister of Health to discuss the summary of preliminary findings
16:00–18:00	Meeting of the full committee to discuss the format and content of the draft report

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

Part II

FINDINGS OF THE EXPERT TEAM

4. ASSESSMENT OF THE DOSIMETRY AND THE STATUS OF THE EQUIPMENT AND THE FACILITY

4.1. CALIBRATION OF THE BEAM

The absorbed dose to water from the beam of the Alcyon II ^{60}Co unit was determined by the Expert Team in accordance with IAEA Technical Reports Series No. 277 [10]. Three different ionization chambers were used for these measurements. The values, obtained on 10 July 1997, were corrected for two factors:

(1) There was a 10 month decay correction (back to 10 September 1996) to reconstruct the doses delivered to patients over the period end of August to end of September 1996 (correction factor of 1.115).
(2) A distance correction was also made in order to reproduce the conditions of the actual treatments. The reason for this correction was that, according to E. Castellanos's report and the report on early investigations after the accident, there had been an error of –2 cm in the optical distance indicator. This correction from source–skin distance (SSD) = 80 cm to SSD = 78 cm (e.g. 80.5 cm to 78.5 cm at maximum dose) was 1.053, which included a small factor of about 0.2% for the increase in beam opening, i.e. the same field size of 10×10 cm, from a distance of 80 cm to 78 cm.

In addition, the IAEA/WHO TLD postal dose quality audit was used once more to verify the calibration measurements, which provided agreement within 1.5% (see Table I.I of Appendix I). The detailed measurements and calculation spreadsheets are given in Table I.II of Appendix I.

Table II summarizes the results of all the measurements made with the three different ionization chambers.

4.2. CONDITION OF THE ALCYON II ^{60}Co UNIT

Alcyon II was in a good condition, and the geometrical parameters were within the acceptable tolerances for treating patients. The parameters controlled were (see Table I.III of Appendix I): the axial coincidence of the collimator; the isocentre; the optical distance indicator; the coincidence between the field size indicator on the collimator and the light beam size; and the congruence of the light and/or radiation beam.

Deficiencies in the treatment couch were found in the expert review in July 1996. The couch was replaced at the beginning of 1997, and no further deficiencies were found in the Expert Team's assessment in July 1997. However, the Team

TABLE II. DOSE RATES FROM THE ALCYON II Co-60 UNIT (Gy/min)[a]

Ion chamber	10 July 1997		10 month decay correction		
	D_w (4.82, 80, 10 × 10)	D_{max} (0.5, 80, 10 × 10)	D_w (4.82, 80, 10 × 10)	D_{max} (0.5, 80, 10 × 10)	D_{max} (0.5, 78, 10 × 10)
PTW30001	1.344	1.687	1.578	1.881	1.980
PTW30002	1.334	1.674	1.566	1.867	1.966
Farmer	1.338	1.680	1.571	1.873	1.972

[a] D_w and D_{max} = (depth (cm); SSD (cm); and field size (cm)).

detected by touch a leakage of electric current between the irradiation head and the couch. Electrical safety, e.g. electrical grounding, needs to be verified and ensured according to the International Electrotechnical Commission's IEC-601 standard.

4.3. IRRADIATION ROOM

A visual inspection of facility interlocks and signals was performed during the mission. The findings were as follows:

(1) The red light signals indicating source on/off at the entrance to the irradiation room were in working order, but the green light had failed; the signals should be larger and more clearly visible;
(2) The door switch functioned when opening the door: the audio alarm switched on and the source returned to the shielded position; however, a signal interlocked with a radiation monitor placed at the end of the maze would be desirable;
(3) The emergency push buttons that make the source move to the off position were working properly.

4.4. RADIATION SHIELDING

Dose rate measurements were made in different locations outside the irradiation room. From the results obtained, and assuming a normal workload for this room of about 500 Gy/week and a use factor of 30% with the unattenuated beam directed towards the ceiling, the radiation levels in the room above would be 1 Sv/a. This room is occupied by patients staying for extended periods of time, visitors and the attendant hospital staff. The shielding is not acceptable. In particular, the ceiling of this room was not designed for radiotherapy (see Fig. I.1 of Appendix I).

Since the shielding cannot be increased, one solution that merits a feasibility study would be to exchange use of this room with use of the shielded room for the Theratron-80, since the latter has a beam stopper with an attenuation factor of about 1000.

4.5. DOSE MONITORING FOR PERSONNEL

Radiotherapy staff wear individual TLD dosimeters that are measured monthly by the Ministry of Health. These records were not reviewed by the Expert Team.

4.6. WRITTEN PROCEDURES

The working procedures for normal conditions were not available. The emergency procedures were not able to be viewed at the time of the Expert Team's assessment.

4.7. PATIENTS' CHARTS AND CLINICAL DOSIMETRY

4.7.1. Status of the charts

A total of 113 patient therapy charts were reviewed, of which nine were from the Children's Hospital, 37 from the Calderón Guardia Hospital and the remaining 67 from the San Juan de Dios Hospital.

The therapy charts were reviewed at the San Juan de Dios Hospital and at the law courts. None of those persons in charge at the time of the accident, including the dosimetrist, the radiation therapist from the San Juan de Dios Hospital and the person who performed the initial calculation and calibration, were available for an interview in an effort to reconstruct the charts.

The treatment time was transcribed from a purpose written computer program. The name of the person who had made the calculation was also on the computer sheets. There was no documentation on how calculation of the treatment time had been made after the source had been changed: by using a ratio or by using the new measured dose rate. There was also no indication that any review had been made of the treatment time calculation. The back page of the chart contained the daily record, listing the fraction number, date, session dose and total dose. The doses entered were the maximum dose per field and the total maximum dose per field. For most patients, single or parallel opposed fields were used and patients were treated with one field per day.

There was no running record of the tumour dose or the time used at each fraction, nor was there any indication of who treated the patient on a given day, or whether portal films had been acquired and when. On a few charts, two treatment times were given on the front page: one for the Alcyon and one for the Theratron. Since there was no daily record of the time, it was not always possible to know which fractions had been used on which machine. There was no indication that a chart review had been carried out during the course of the therapy. The charts for the Calderón Guardia patients were better documented, with diagrams showing the site of the fields and the blocking. The treatments also appeared more in keeping with better practice. Treatment at two fields per day was more common, and many were isocentric.

4.7.2.   Aim of the dose reconstruction and the assumptions made

Since over 100 charts needed some form of dose reconstruction, it was not possible in the time allotted during the Expert Assessment to reconstruct the maximum and minimum doses to the planning target volume and to the relevant points for all the patients individually. Furthermore, calibration of the Alcyon by the Expert Team was in progress during the same week. A simplified dose reconstruction was therefore attempted. The prescribed dose, the number of fractions prior to the source change and the number of fractions following the source change were extracted from the charts, in addition to other important parameters. The number of fractions following the source change was counted from Monday, 26 August 1996. For those charts where a Theratron treatment time had been entered on the front page in addition to the Alcyon treatment time it was assumed that the Alcyon had been used for all the treatments, since there was no record of when the Theratron had been used. In addition, prior compilation of the doses after the source change, made by H. Marenco Zúñiga, was also used to obtain other parameters.

The total tumour dose was reconstructed by adding the prescribed dose multiplied by the number of fractions administered before the source change to the estimated dose administered after the source change. The dose administered after the source change was estimated by multiplying the prescribed dose by a factor of 1.55 and by the number of fractions administered.

The factor of 1.55 was derived in the following way:

(1)   A sample of patients was taken;
(2)   The dose rate at d_{max} for a 10×10 cm field at an SSD of 78 cm was taken from the measurements made and   corrected for decay to September 1996 (see Section 4.1); the value was rounded to 2 Gy/min, with the distance of 78 cm corresponding to a nominal value of 80 cm in view of the error of 2 cm in the optical distance indicator at the time of the accident;
(3)   The tumour dose was calculated by multiplying the dose rate $d_{max} = 2$ Gy/min by the field size factor and the PDD;
(4)   The derived dose at the depth of the tumour was divided by the prescribed dose to obtain the overexposure factor;
(5)   The result for the sample of patients was 1.55; this value was used for all the patients to obtain Table I.IV in Appendix I;
(6)   It was assumed that all the patients were treated at a nominal SSD of 80 cm, unless otherwise indicated;
(7)   The maximum entrance dose was also calculated in those cases where it was evident that this would pose an unusual problem, for example, if there was only one field, if the prescribed dose was deep inside the patient, if the prescribed

dose per treatment was large, if the field size was large, or if the patient's tissue reaction indicated it.

In addition to the approach of using a common factor (1.55) for all the patients, a specific calculation was made for a number of selected patients. This calculation, based on individual treatment times (where available) and the measured dose rate (see Section 4.1), includes doses to the organs at risk. These patients represent the greater part of the cases described in Section 5 (medical effects). The values are presented in Table I.V of Appendix I.

To assess how the dose per fraction, being higher than normal, might influence the late (chronic) effects, the biologically effective dose (BED) [14–16] was calculated for a small sample of patients using the linear–quadratic (LQ) model for cell killing. The BED was then used to derive the dose that would be biologically equivalent had it been delivered in fractions of 2 Gy (see Table I.VI of Appendix I). For example, for *Patient No. 54*, who had received approximately 52 Gy to the spinal cord in 15 fractions of 3.5 Gy each, this treatment was calculated to be biologically equivalent to a total dose of about 72 Gy, delivered in 36 fractions of about 2 Gy. This is especially relevant when comparing with the tissue tolerance doses. Such equivalent dose comparisons can only be made for late normal tissue reactions, where no effect of the overall time is expected.

In extreme cases, such as *Patient No. 44*, for which only two fractions with a dose per fraction higher than 10 Gy were given, the results of the LQ calculations using BED to derive the equivalent 2 Gy/fraction dose had to be taken only as an approximate value, since the high dose/fraction exceeded the validity range of the model, which is normally thought to be between 1 and 10 Gy/fraction.

The following alpha/beta ratios for late normal tissue reactions were used with the LQ model, with no allowance for the overall time of the treatment: 2 Gy for the CNS; 3 Gy for the skin; and 5 Gy for the bowel.

5. MEDICAL EFFECTS OF RADIATION EXPOSURE OF THE PATIENTS

5.1. INTRODUCTION

The Expert Assessment included the examination of 70 of the 73 surviving patients and a review of the information that was available on those patients who had died over the previous 9 months. The specific results of the examinations and review can be found in Appendix II. Each patient was examined by at least two, and usually

three, physicians from the Expert Team, and a Costa Rican physician was present at each examination. The findings for all patients presented in this report represent a review made and consensus conclusions reached by all the physicians. The conclusions were arrived at independently of the findings reached during the investigations carried out by PAHO, which were not made available to the Expert Team until after the assessment had been completed. The available autopsy results were also reviewed by all the physicians.

On the basis of temporal characterization of the effects of radiation exposure at the high levels used in radiotherapy as *acute* (first appearing within 6 months of exposure), *subacute* (first seen between 6 and 12 months after exposure) and *chronic* (first appearing 12 months or more after exposure) it was found that the effects observed in the surviving patients irradiated in the accident were predominantly subacute and chronic.

Many of the overexposed patients initially displayed reactions such as skin ulceration, severe mucositis, nausea, vomiting and diarrhoea, although the nature of the acute effects initially manifested depended on the part of the body irradiated. Many of these effects had healed, but some have persisted.

In general, the effects observed in the patients examined by the Expert Team, and those anticipated in the future, had resulted from overexposure of specific sensitive tissues or a diminution in vascular blood supply. (The most chronic effects of radiation exposure are consequences of an irreversible narrowing of the lumina of small blood vessels (arterioles): the thickness of the arteriolar walls is increased, thereby diminishing the size of the lumina and reducing the vascular supply. As a result, tissues can become thin or atrophic and, if diminution of the blood supply is severe, they become necrotic. The vascular changes may be progressive and may continue for years after radiation exposure.) It should therefore be clear that effects will occur in these patients which are not yet apparent. However, future effects could be predicted to some extent if the conditions of exposure were better known.

Assessment of all the patients was complicated by a number of factors. One major task was to differentiate the adverse radiation effects from those caused by malignant disease. Determining radiation effects can often be accomplished with the knowledge of the radiation sensitivity of tissues, the time course of expression of radiation effects, and the known radiation dose, fractionation scheme, radiation location and field size. While chemotherapy can cause some potentiation of radiation effects, few of the patients concerned were concurrently undergoing chemotherapy.

As stated in Section 1, the effect of radiotherapy treatment in killing normal cells can be minimized by use of multiple radiation fields and fractionation of the radiation treatment in order to maintain the percentage of severe complications at a level considered acceptable. If the total dose is increased above the normal level, more cells will be killed. Also, if the number of fractions is reduced and the dose per fraction increases correspondingly, even though the total dose stays the same, more

cells will be killed. Both of these circumstances were present in this accident. For many tissues, reducing the number of fractions and increasing the dose per fraction will cause a disproportionate increase in chronic effects in comparison to acute effects. Under these circumstances, relying on acute effects for the prediction of late effects will result in underestimation of the actual extent of the effects.

In the situation under consideration, the Expert Team noted differences in the radiation therapy practices and protocols for the same disease. Some of the protocols involved very large fields, with treatment of each field every other day. More than half the prescribed radiation therapy treatments had fewer than the normally accepted number of fractions. These practices undoubtedly aggravated some of the adverse radiation effects (see footnote 1).

The current and critical physical problems caused by the overexposure of these patients relate to several specific body systems: first, the CNS; second, the skin; third, the GI system; and fourth, the cardiovascular system. These systems are of critical importance in this accident, because of their tissue sensitivity to radiation and because the tumours being treated were generally in the head and neck, or of mediastinal or pelvic origin. Even though the Expert Team singled out these categories for special attention, many other effects may develop in these patients in the future as a result of radiation exposure. Each patient involved in this accident had a very different risk factor and therefore needs to be evaluated individually using at least the data in the Appendices as well as each medical record presenting the symptomatology and clinical evolution.

The Expert Team's examination represents an evaluation of the patient population at only one point in time. Any compensation and medical care should not be based solely on this report, since patients suffered acute effects and some died before the investigation. Similarly, many patients may develop adverse effects that are not yet apparent.

5.2. CENTRAL NERVOUS SYSTEM

Several patients are already experiencing difficulties, or may be expected to do so in the future, as a result of irradiation of the brain, spinal cord and peripheral nerves.

In general, radiotherapy of the brain results in cortical atrophy in a large number of cases [17]. Of the children who received 20–65 Gy (with fractions of less than 2 Gy/d), over half will develop cortical atrophy, 26% will exhibit white matter changes (leukoencephalopathy) (Photograph 1) and 8% will suffer from calcifications. It appears that the younger the child at irradiation, the worse the atrophy. Some patients will also develop mineralizing microangiopathy (Photograph 2). Clinical findings after routine radiotherapy may relate to poor school performance and
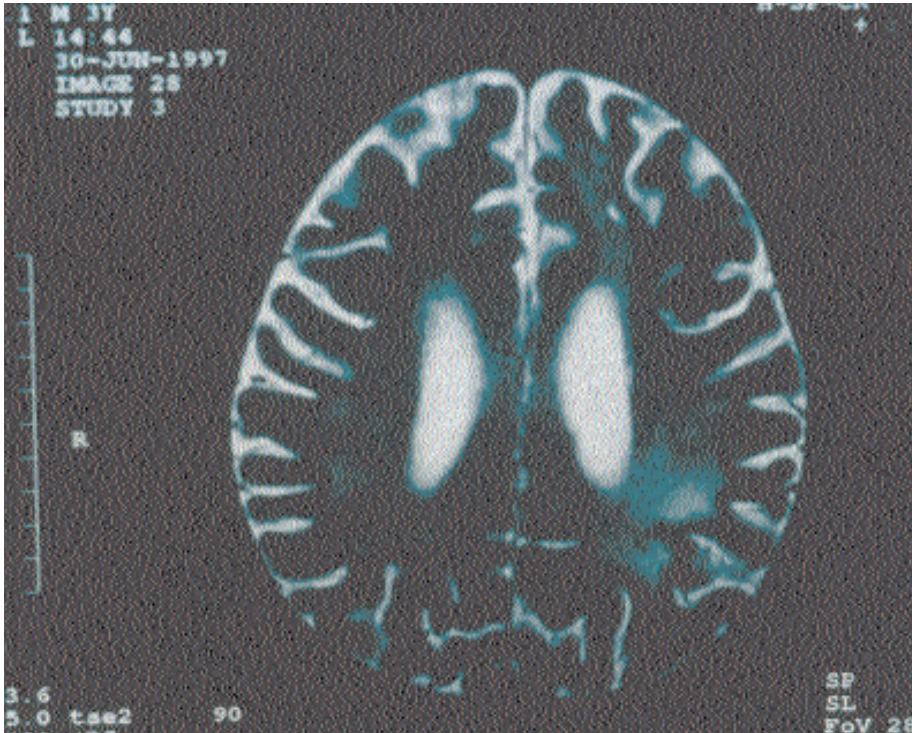
Photograph 1. A T_2 weighted nuclear magnetic resonance (NMR) scan of the brain showing characteristic white matter changes in leukoencephalopathy.

dysfunction of the pituitary gland and hypothalamus. If there is overexposure, the adverse effects may be severe and can include lethargy, ataxia, spasticity and progressive dementia (Photograph 3). Radiation induced changes in the brain are potentiated by methotrexate and other chemotherapy administered before, during or after radiotherapy.

Cerebral necrosis is a serious and irreversible complication of radiation induced vascular disease. It is usually diagnosed 1–5 years after irradiation, but can occur up to a decade later. Radiation induced necrosis occurs with moderate probability when therapy schemes exceed 40 Gy in 10 fractions, 50 Gy in 20 fractions, 60 Gy in 30 fractions over a period of 5 weeks, or when individual fractions exceed 3 Gy. There is a very high probability of necrosis when treatment schemes exceed 50 Gy in 15 fractions, 60 Gy in 20 fractions or 70 Gy in 30 fractions. Brain necrosis may be manifested by headaches, increased intracranial pressure, seizures, sensory deficits and psychotic changes.
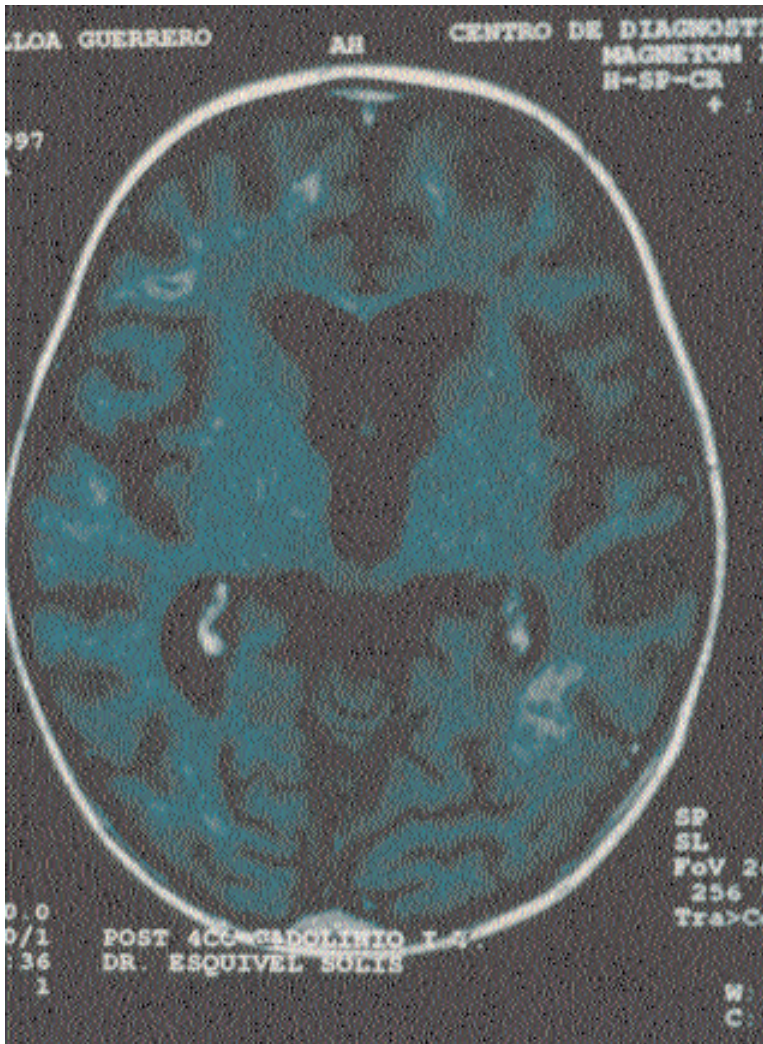
Photograph 2. A T$_1$ weighted NMR showing the cortical changes in microangiopathy (white areas at top left and bottom right), cortical atrophy and ventricular enlargement.

Photograph 3. A young child post-treatment and after radiotherapeutic overexposure for treatment of a brain tumour (Photographs 1 and 2 are from this patient).

Optic nerve damage and blindness can also occur 1–5 years later in more than 20% of the patients who receive 42 Gy in 15 fractions, 55 Gy in 25 fractions, 60 Gy in 30 fractions or 70 Gy in 40 fractions.

Loss of hearing has been reported after irradiation. Sensory neural hearing loss rarely occurs with standard fractionation schemes and doses of 55 Gy or less, but it is often encountered after total doses of 65 Gy in standard fractions (Photograph 4). Higher doses or shorter fractionation schemes can also result in necrosis of the ossicles.
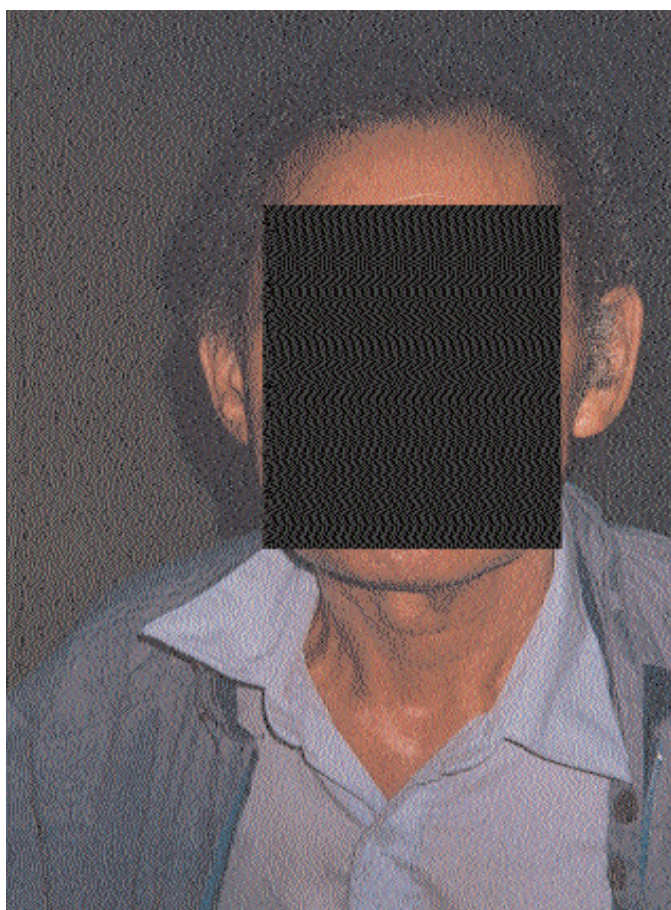
Photograph 4. Patient treated for a carcinoma near the right eye who now has deafness and drainage in the right ear.

A number of the patients examined will be at risk of brain necrosis or loss of hearing (and in at least one case, blindness) for years to come. The identification numbers and treatment particulars of some of these patients are as follows:

(1) *Patient No. 109*, who was about 3 years old and had received 58 Gy to the cranium in 20 fractions; this treatment scheme is calculated to be biologically equivalent to about 36 fractions of 2 Gy each, for a total dose of about 72 Gy (see Table I–VI);

(2) *Patient No. 105*, who was a child and had received 50 Gy to the cranium in 18 fractions;

(3) *Patient No. 58* (age 30), who had received 58 Gy to the posterior fossa in 22 fractions;

(4) *Patient No. 54* (age 35), who had received 60 Gy to the posterior fossa in 25 fractions and 52 Gy to the spinal cord in 15 fractions; the former treatment is calculated to be biologically equivalent to about 33 fractions of 2 Gy each, for a total dose of about 66 Gy;

(5) *Patient No. 47* (age 38), who had received 68 Gy to the pituitary area in 28 fractions;

(6) *Patient No. 106*, who was a child and had received 63 Gy to the posterior fossa in 25 fractions.

Spinal cord irradiation can result in radiation myelitis, which may be transient or permanent. Acute transient myelitis often appears 2–4 months after irradiation. The lesions appear to be caused by transient demyelination of the ascending motor neurons. Patients affected by myelitis usually present Lhermitte's sign, which occurs with neck flexion or other movements of the body that stretch the spinal cord. Reversal of transient myelopathy occurs between 8 and 40 weeks and does not necessarily progress to late delayed necrosis.

Delayed myelopathy occurs following a mean latent period of 20 months. Nevertheless, this period may be shorter if the doses and the dose per fraction are high. This is usually manifested by discontinuous deterioration, and is irreversible. In the cervical and thoracic regions, sensory dissociation develops, followed by spastic paresis and then flaccid paresis. In the lumbar spinal cord, flaccid paresis is dominant. There is a high fatality rate, depending on the location of spinal cord irradiation. Mortality from cervical or high thoracic lesions reaches 70%, with death resulting from pneumonia or infection of the urinary tract.

About 10% of the total number of patients are at very high risk of spinal cord effects; some are already paralysed. The spinal cord is a relatively radiosensitive structure and overexposure can have disastrous consequences. As with other tissues, the total dose, the number of fractions and the volume (or length) of spinal cord irradiation are all important. The overall time during which irradiation is undergone is insignificant compared with the dose/fraction (number of fractions). Reference [18]

has published information on the tolerance curves for 25–50% incidence of thoracic myelopathy. The data show the following:

Dose/fraction (Gy)	Total dose (Gy)
1	80
2	60
3	40
4	35
5	30–35
6	25

Among the patients examined by the Expert Team, a number of individuals had received about 47 Gy (in 11 fractions, or 4.3 Gy per fraction), including *Patient No. 97*. From the above data it can be seen that this patient is well over the total dose tolerance level for the spinal cord (about 30–35 Gy for this fraction size). *Patient No. 80* had received 50 Gy in 16 fractions (or about 3.1 Gy per fraction). The total tolerance dose for this fraction size is 40 Gy. These two patients are paralysed. Other patients examined by the Expert Team are not paralysed, but are nonetheless at major risk.

Some examples of the patients at very high risk or with current problems in this regard were:

(a) *Patient No. 54*, who had received 52 Gy in 15 fractions of 3.5 Gy per fraction to the spine; this places the patient above the 25–50% level of risk;

(b) *Patient No. 41*, who had received 57 Gy in 15 fractions (or 3.8 Gy per fraction); any dose over 40 Gy with this fractionation scheme puts the patient at extremely high risk; the patient was experiencing early partial paralysis (*the patient subsequently died*);

(c) *Patient No. 40*, who had received a calculated spinal cord dose of 51 Gy in 17 fractions (3 Gy per fraction), which is well over the 25–50% complication level of 35–40 Gy total dose; she showed some early signs of spinal cord injury when examined, and has subsequently experienced significant neurological difficulty.

Peripheral nerves can be affected by radiation, although they are typically quite resistant. Doses in the range of 50 Gy in 25 fractions over 5 weeks can cause brachial plexus injury in 5% of patients. Many of the patients examined by the Expert Team complained of sacral pain and had received high doses to the sacrum. It is possible that scarring about the nerves may have resulted in neuropathy. These problems are not usually encountered, since in many countries rotational techniques have replaced the box treatment technique for pelvic tumours. However, the box technique was utilized for all the patients examined.

5.3. SKIN

With high doses of radiation, acute exudative skin reaction is often followed by transient regeneration. Thus, healing of the initial reaction should not be taken as a sign that no significant overexposure has occurred or that late effects can be ruled out. Delayed effects on the skin may become apparent 6 months after radiation exposure and then progress slowly for up to 10 years. The changes that may occur include telangiectasia, thin dry semi-translucent pigmentation (sometimes depigmentation) and fibrosis with a limitation in motion. Those portions of the skin that are moist and subject to friction, such as the axilla, groin and skin folds, are the most sensitive (Photograph 5). With chronic radiation changes, the skin breaks down as a result of

Photograph 5. Breakdown of the skin in the gluteal folds as a result of overexposure.

minor trauma (mechanical and ultraviolet). The skin becomes infected easily, is difficult to heal and may have chronic ulceration (Photograph 6). These ulcers do not heal well and require intensive and prolonged dermatological treatment or plastic surgery. Furthermore, they should be regarded as precancerous.

With megavoltage radiotherapy techniques, the most common indication that skin tolerance has been exceeded is subcutaneous fibrosis. This is usually a hard

Photograph 6. Severe non-healing ulceration (grade 3 necrosis) of the vulva as a result of overexposure; the actual dose was about 30 Gy in two fractions of 15 Gy each.

Photograph 7. Severe pigmentation, atrophy and skin fibrosis over the sacrum. Such skin is easily broken down with minimal trauma and is difficult to heal. Most of these patients also had sacral plexus nerve and bowel complaints.
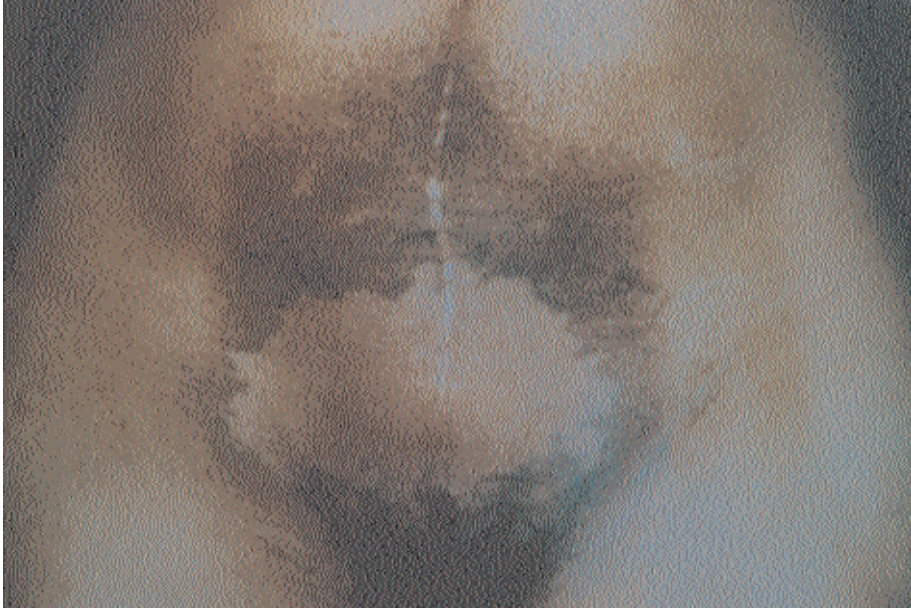
Photograph 8. Deep pigmentation, with central scarring of the skin. Overexposure of the underlying sensitive bowel has caused significant problems, including persistent bloody diarrhoea, bowel obstruction and anaemia.

plaque below the pigmented skin surface (Photograph 7) and is most pronounced where there is a layer of subcutaneous fat (Photographs 8 and 9). The incidence of skin reactions is greatly influenced by the number of treatment fractions and the volume of irradiation. For example, severe fibrosis will develop in 20% of post-mastectomy patients who received 46 Gy (1.9 Gy per fraction) using the standard five fractions per week treatment scheme and in 80% of those who received 52 Gy (2.1 Gy per fraction). These figures can be compared against the data for two weekly fractions, where 20% of the patients developed severe fibrosis at 37 Gy (3.7 Gy per fraction) and 80% at 41 Gy (4.1 Gy per fraction).

Many of the patients examined had received skin doses in excess of 52 Gy, often with fewer than 20 fractions. This aggravated the effects even further. These higher doses resulted in severe fibrosis, with fixed skin in some patients and skin necrosis in others. For quite a number of the patients examined, the skin effects were exacerbated by treatment with the anterior field one day and the posterior field the following day, rather than treating with each field every day. This effectively reduced by half the number of skin and superficial tissue fractions listed on the physics sheet. This should be borne in mind when the total doses are examined.
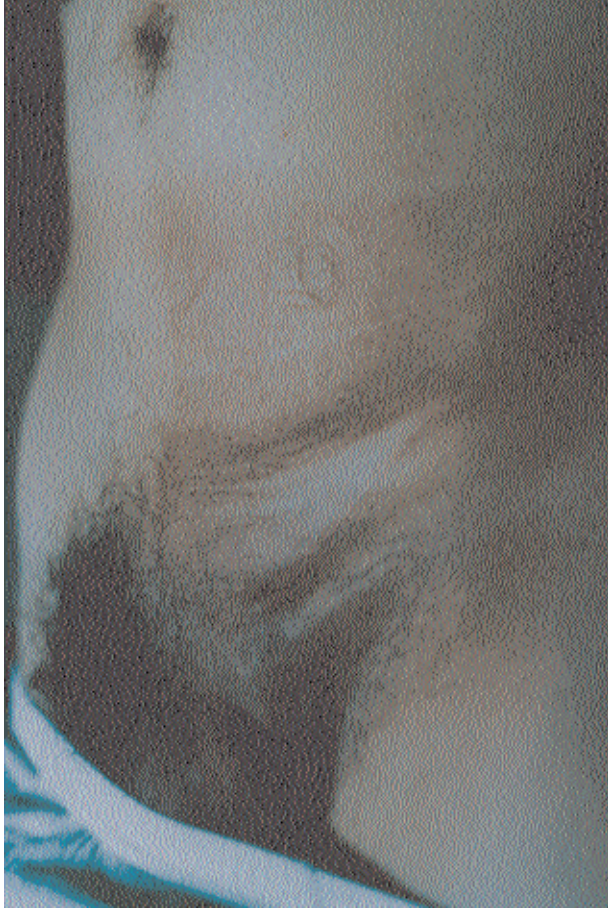
Photograph 9. Permanent epilation, pigmentation and severe subcutaneous fibrosis after irradiation of the left groin. The patient also had limited movement of the left hip as a result of overexposure.

Regrowth of hair often occurs even when radiation doses to the skin are high. A number of patients had permanent epilation, which attests to the high skin doses they had received (Photographs 10 and 11). Examples of such cases included:

(1)　*Patient No. 44*, who had received 31 Gy in two fractions, or 15.5 Gy per fraction. This patient had ulceration of the vulva on both sides. This treatment is calculated to be biologically equivalent to about 57 fractions of 2 Gy each for a total dose of above 110 Gy (with the limitations of the LQ method for such a high dose/fraction, as indicated in Section 4.7.2).

Photograph 10. Patient with permanent epilation as a result of overexposure, and at high risk of late brain necrosis and spinal cord injury.

Photograph 11. Another patient with permanent epilation as a result of exposure, and at high risk of late brain necrosis and spinal cord injury.

(2) *Patient No. 8*, who had received 70 Gy in 20 fractions, but with alternating day treatment. Effectively, the skin had received 56 Gy in 10 fractions, or 5.6 Gy per fraction. This patient had severe sacral fibrosis.

(3) *Patient No. 62*, who had received more than 43 Gy in 15 fractions (more than 2.85 Gy per fraction). This patient may have received alternating fields, resulting in fractions of at least 6.2 Gy each to the skin, and had severe sacral fibrosis.

(4) *Patient No. 39*, who had received about 58 Gy in 14 fractions (about 4.1 Gy per fraction). This patient had severe deep fibrosis of the inguinal region, with a limitation in motion; there was also permanent epilation.

(5) *Patient No. 106*, who was a child, had received 62 Gy in 25 fractions (2.5 Gy per fraction in alternating fields), and had permanent epilation.

(6) *Patient No. 109*, who was a child, had received 58 Gy in 20 fractions (3 Gy per fraction) to the cranium, and had permanent epilation.

5.4. GASTROINTESTINAL SYSTEM

The intestine is very sensitive to radiation. In this accident, a number of patients were irradiated to rather large fields of the lower abdomen at relatively high doses, with few fractions. Severe chronic radiation injury of the small bowel usually presents constipation and abdominal pain, often with stenosis, and frequently an acute abdomen with ulcerations, infarction, fistulas and perforation. Surgery is the only form of treatment for injuries to the small intestine. Small bowel injury can also be present as a malabsorption syndrome with anaemia.

Radiation injury of the rectum and sigmoid often results in rectal bleeding 6–12 months after irradiation. If the injury extends into the sigmoid colon, bloody diarrhoea is often present. Treatment is usually conservative and surgery is not recommended. Even a biopsy can cause massive haemorrhage. Rectal stenosis can also occur. The scoring system used for radiation injury of the gut is shown in Table III [18]. The dose–effect curve for severe complications of the large bowel is very steep. With standard treatment fractionation, the incidence of severe complications is 10% at 50 Gy and 40% at 60 Gy. Larger fraction sizes weigh more heavily in the incidence of chronic effects than of acute effects. The incidence of complications is also directly dependent on the volume treated. Large treatment fields were often used for these patients.

Some examples of the patients examined with these complications included:

(1) *Patient No. 83*, who had received a total dose of 72 Gy (AP/PA) to the bowel in 25 fractions and 12 Gy from lateral fields in five fractions. The patient had

TABLE III. ACUTE AND LATE RADIATION MORBIDITY SCORING CRITERIA (RTOG/EORTC) [18][a,b]

Organ/tissue	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4
Acute radiation morbidity scoring criteria					
Upper GI	No change	Anorexia with ≤5% weight loss from the pretreatment baseline; nausea that does not require anti-emetics; abdominal discomfort that does not require parasympatholytic drugs or analgesics	Anorexia with >15% weight loss from the pretreatment baseline; nausea and/or vomiting that requires anti-emetics; abdominal pain that requires analgesics	Anorexia with >15% weight loss from the pretreatment baseline that requires a nasogastric tube or parenteral support; vomiting that requires a nasogastric tube or parenteral support; abdominal pain that is severe, despite medication; haematemesis or melena; abdominal distension (flat plate radiograph demonstrates distended bowel loops)	Ileus, subacute or acute obstruction, perforation, GI bleeding that requires transfusion; abdominal pain that requires tube decompression or bowel diversion
Lower GI, including pelvis	No change	Increased frequency or change in the quality of bowel habits that does not require medication; rectal discomfort that does not require analgesics	Diarrhoea that requires parasympatholytic drugs; mucus discharge that does not necessitate sanitary pads; rectal or abdominal pain that requires analgesics	Diarrhoea that requires parenteral support; severe mucus or blood discharge that necessitates sanitary pads; abdominal distension (flat plate radiograph demonstrates distended bowel loops)	Acute or subacute obstruction, fistula or perforation, GI bleeding that requires transfusion; abdominal pain or tenesmus that requires tube decompression or bowel diversion
Late radiation morbidity scoring criteria					
Small/large intestine	None	Mild diarrhoea; mild cramping; bowel movement five times daily; slight rectal discharge or bleeding	Moderate diarrhoea and colic; bowel movement more than five times daily; excessive rectal mucus or intermittent bleeding	Obstruction or bleeding that requires surgery	Necrosis; perforation; fistula
Liver	None	Mild lassitude; nausea; dyspepsia; slightly abnormal liver function	Moderate symptoms; some liver function tests that are abnormal; serum albumin that is normal	Disabling hepatic insufficiency; liver function tests that are grossly abnormal; albumin that is low; oedema or ascites	Necrosis; hepatic coma, encephalopathy

[a] Data taken from Table 11.1 (page 321) of Ref. [18] and reproduced here with the permission of the Springer-Verlag, Heidelberg, Germany.

[b] Grade 5: death directly related to the radiation effect.

continual rectal bleeding, diarrhoea, anaemia and weight loss. This treatment is calculated to be biologically equivalent to about 50 fractions of 2 Gy each for a total dose of about 100 Gy to the bowel.

(2)   *Patient No. 78*, who had received 68 Gy to the pelvis in 25 fractions (2.7 Gy per fraction). The patient had continual diarrhoea and a 2×2 cm infected skin ulcer.

(3)   *Patient No. 85*, who had received more than 49 Gy in 18 fractions, but with alternating fields every other day. The patient had rectal pain with ulceration and perirectal ulceration.

(4)   *Patient No. 8*, who had received 56 Gy in 20 fractions (2.8 Gy per fraction), but with alternating fields every other day. The patient had occasional diarrhoea.

(5)   *Patient No. 44*, who had received 25 Gy to the bowel in two fractions (12.5 Gy each). This treatment is calculated to be biologically equivalent to about 31 fractions of 2 Gy each, with a total dose to the bowel of about 62 Gy.

5.5.   CARDIOVASCULAR SYSTEM

Radiation induced changes in the heart have been reported in patients treated for Hodgkin's disease. Cardiomyopathy rarely occurs with standard fractionation schemes and doses of less than 40 Gy. Above this level, up to half of the patients will experience pericarditis. Patients show a more than 50% incidence of complications when the dose exceeds 60 Gy (standard fractionation). Increasing the dose per fraction has been shown to significantly increase the complications and incidence. At 50 Gy of standard fraction-ated radiotherapy (2 Gy per fraction), about 25–35% of the patients will develop reduced ventricular function. Pericardial effusions resulting from radiation usually occur between 1 and 6 months after irradiation and in over 50% of the patients who have received more than 60 Gy of standard fraction radiotherapy (Photograph 12). At least one patient exam-ined clearly had pericarditis and a pericardial effusion requiring surgery. *Patient No. 40*, who had received 53 Gy in 17 fractions (3.1 Gy per fraction) to the mediastinum, subsequently developed pericardial effusion.

Radiation can also affect the major blood vessels. It causes an increase in coronary artery disease and a higher incidence of arteriosclerosis of the carotid arter-ies, brachial vessels, aorta and pelvic vessels. These changes typically occur between 3 and 10 or more years after irradiation.

A number of the patients examined may be expected to experience these late complications. Thirty per cent of the patients who received 50 Gy of standard fractionated radiation (20–25 fractions) to the neck will develop moderate or severe lesions compared with 6% for the controls. This equates to 2–2.5 Gy per fraction. Ten per cent of the patients who received 26 Gy of standard fractionated radiotherapy for seminoma will develop vascular abnormalities.
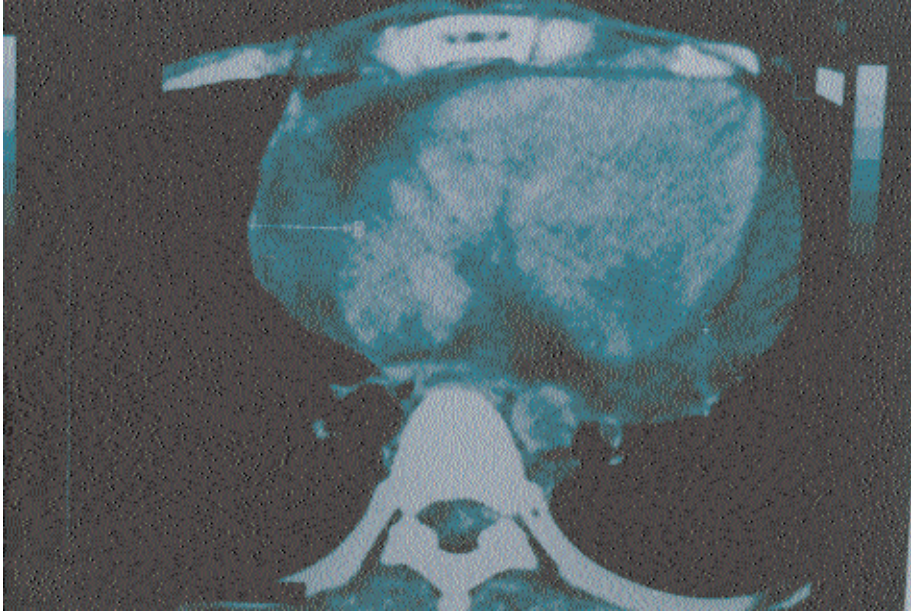
Photograph 12. Computed tomography X ray image of a patient showing pericardial effusion.

Examples of the patients with these characteristics were as follows:

(1)   *Patient No. 39*, who was being treated for seminoma and had received 58 Gy in
       14 fractions (about 4.1 Gy per fraction) to the inguinal area (potential femoral
       artery disease and aseptic necrosis of the hip);
(2)   *Patient No. 26*, who had received 54 Gy to the neck in 14 fractions (3.9 Gy per
       fraction) (potential carotid artery disease);
(3)   *Patient No. 97*, who had received 47 Gy to the neck in 11 fractions (4.3 Gy per
       fraction) (potential carotid artery disease);
(4)   *Patient No. 70*, who had received 72 Gy in 25 fractions to the left neck
       (potential carotid artery disease).

5.6.   UNDEREXPOSURE OF PATIENTS

An additional, perhaps unappreciated, problem is undertreatment owing to
the fact that, following the discovery of the problem with the source, treatment was
halted and not resumed. While most of the patients who were starting treatment at the
time the problem was discovered did receive the necessary additional radiotherapy, at

least two patients did not, probably resulting in less than optimal therapy. In at least one instance this was the choice of the patient, and not because additional therapy was not offered.

5.7. PSYCHOSOCIAL EFFECTS

The patients treated by radiotherapy are from a population of modest financial means, with a monthly average income of about US $160. Their level of education is low and they live principally in rural and suburban areas. The majority of patients were women (approximately 60%) who did domestic chores, whereas the greater part of the men were farmers. The average number of children per family in this population group is five. In addition, minors were also part of this group of irradiated patients. Minors experienced the highest death rate in the initial stages of the accident. The majority were schoolchildren in the public school system.

The psychosocial problems associated with this accident were clearly evident: (1) the issue of radiation exposure without somatic effects; (2) issues related to having been involved in an accident; and (3) issues related to the direct effects of radiation on tissues.

Patients exposed accidentally to any radiation may have concerns related to the unfamiliarity of radiation. Often these issues can be resolved somewhat by information and education. Persons who are involved in an accident are often thought to have post-traumatic stress disorder (PTSD). Experience with the population around Chernobyl in the former USSR has shown that the effects and the patient manifestations of PTSD are not exactly the same. PTSD occurs after an event, e.g. an earthquake, that is large, sudden and then over. A term proposed as a result of study of the psychological issues at Chernobyl is 'chronic environmental stress disorder' as a result of the continued presence of, and exposure to, environmental radioactive contamination.

In this and other radiation accidents involving serious overexposure, patients have to live with the knowledge that the potential effects may not be over, or even evident, for years. Many of the patients in this accident who were subjected to cranial and spinal overexposure may suffer from significant neurological consequences, including quadriplegia, which will require major psychosocial support. Another large group of patients that fits into the third category are those who received large pelvic overexposure and still suffer from severe bloody diarrhoea. Having to wear diapers, and to suffer this, is very damaging to the self- esteem, and makes daily life very difficult. Finally, in contrast to most other radiation accidents, the majority of these patients were under tremendous stress as a result of their tumours. Many already knew that their life span was limited because of neoplasm, a situation that was further complicated by this accident. For a number of patients, the quality of their remaining life and their life expectancy had been significantly reduced.

It was encouraging to learn that the patients involved in this accident had formed a self-help committee. This is a positive sign and should be encouraged. The vast majority of patients examined by the Expert Team were quite rational, but were nevertheless concerned about their future and the extra risks and effects of the radiation. The Ministry of Health is to be commended on the prompt notification of the accident to the public. In spite of this openness on the part of the authorities, a large number of patients appeared to have lost confidence in the health care system because of the inaction they faced relative to their complaints and problems. In addition, some had partially lost confidence in certain of their physicians. This was apparently quite physician specific and can be explained by the fact that when the patients had initially complained of severe side effects during the treatments, they felt that they had been either ignored or taken too lightly.

The Expert Team was impressed by the attitudes and activities of the relatives of many of the patients. Many were obviously very concerned and had spent a great deal of time and energy dealing with the problems directly related to the accident. These relatives were often very anxious about and stressed by the intensive care needed by the patients; in fact, many were themselves in need of psychosocial and logistical support.

The Expert Team did receive reports that some patients with psychological problems prior to the accident, such as depression, felt that their problems had recurred or been exacerbated as a result of the accident. The issue of depression is complex. Many patients who are undergoing radiation therapy or who are involved in accidents complain of fatigue. Whether this is a direct effect of radiation, a psychological manifestation of stress, or a result of associated disease is a matter of debate. At present, the symptom is felt to be multidimensional in nature and multifactorial in origin. The literature suggests that 70% of the patients who receive radiotherapy complain of fatigue, even long after the treatment has ceased. There is also evidence that psychotherapy may result in a reduction in reported symptoms. As an example of the extent of psychological effects, 5 years after the Chernobyl accident, over 80% of the persons surveyed reported fatigue, even in villages with essentially no radioactive contamination.

Part III

CONCLUSIONS AND RECOMMENDATIONS

6. CONCLUSIONS AND RECOMMENDATIONS

6.1. GENERAL CONSIDERATIONS

This accident has confirmed a number of lessons that were well known from previous incidents, and also yielded specific lessons. Lessons of a more general character can be summarized as follows:

(1) Investigation of radiation accidents generally reveals faults that should have been corrected;
(2) Radiation accidents with severe and even fatal consequences do occur in medical facilities;
(3) Human error is the most common cause of radiation accidents;
(4) A properly operating machine does not guarantee good radiotherapy treatment; adequate ancillary equipment, education and training, staffing and management are essential;
(5) Radiation accidents can have major short and long term psychosocial consequences;
(6) Accepted radiotherapy protocols have very little margin for error, since both normal and malignant cells are killed; significant overdoses (errors much larger than 10%) will result in an unacceptable incidence of severe consequences;
(7) Doses administered in fewer than the normal number of treatments with higher doses per treatment result in an excessive number of early and, particularly, late complications;
(8) When radiation therapy sources are replaced, calibration should be done by appropriately trained persons, and independently checked;
(9) Regulations should cover the training and competence required to deal with potentially hazardous radiation sources;
(10) Specific training should be given after an individual working in a radiotherapy unit has received a thorough basic education and should not consist of simply attending occasional short courses;
(11) When there is high incidence/severity of acute effects during radiotherapy treatment, the treatment should be stopped and the source calibration checked immediately;
(12) In radiotherapy accidents, the tumour dose may not be the parameter of primary interest; often the biologically equivalent 2 Gy/fraction dose (the dose that would be biologically equivalent had it been delivered in fractions of 2 Gy) to sensitive structures such as the spinal cord, heart and intestine is more important;

(13) Early and reliable information and communication are crucial for good management of radiation accidents;

(14) Radiotherapy records should be uniform, clear, consistent and complete.

The following subsections contain the conclusions and recommendations that are specific to this accident. They were classified following ICRP Publication No. 73 [7].

6.2. FRAMEWORK FOR RADIATION PROTECTION

The application of radiation protection and safety in radiotherapy in Costa Rica is adequate in terms of justification, but is deficient in several areas, particularly optimization of protection, accident prevention and institutional arrangements.

6.3. JUSTIFICATION OF THE PRACTICE

6.3.1. Conclusions

Radiation therapy is unquestionably necessary for the population of Costa Rica and it must be provided within the country. The patients assessed had received very good clinical evaluation and diagnostic/staging procedures. Every patient that received radiotherapy clearly needed it.

6.3.2. Recommendations

No recommendations are necessary in this regard.

6.4. OPTIMIZATION OF PROTECTION

6.4.1. Conclusions

It is well known that radiotherapy administered in fewer than the normal number of treatments with higher doses per treatment results in an excessive number of early and, particularly, late complications.

There are deficiencies in the optimization of protection in radiotherapy in Costa Rica relating to: (1) the design and construction of the facility; and (2) the day to day working methods:

(1) The shielding was inadequate, as a result of which the beam directed to the ceiling could not be used safely; therefore, the treatment geometry was severely restricted;

(2) In day to day practice, no planning had been done for doses or wedges, organ shielding, immobilization devices or other ancillary equipment that could be tailored to individual patients to reduce unnecessary doses, and thus complications. This exacerbated the harmful consequences of the accident.

6.4.2. Recommendations

It is recommended that the Costa Rican authorities strengthen radiation therapy in these areas, especially by improving the installation of the Alcyon II unit so that its use can be unrestricted, and make more use of accessories and ancillary devices to individually tailor and optimize the treatments.

6.5. ACCIDENT PREVENTION

6.5.1. Conclusions

There was inadequate defence in depth[5] in the radiotherapy service in the San Juan de Dios Hospital. The fact that there was no redundant and independent calibration, e.g. for determining the absorbed dose, made it possible for a mistake to remain undiscovered until it resulted in an accident. With an appropriate degree of defence in depth, the accident might have been prevented.

Prior to the accident, IAEA/WHO TLD postal dose quality audits had detected discrepancies in the absorbed dose rate determinations. In addition, external auditing had detected the poor quality of record keeping, the lack of redundancy in procedures, and the inadequate level of education and training. Had actions been taken on these findings, the accident might have been prevented.

6.5.2. Recommendations

Defence in depth for safety critical tasks should be introduced. For example, redundancy, independence and diversity should be applied to safety critical tasks such

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[5] The term defence in depth may not be familiar to radiation oncologists and medical physicists; however, provisions for redundant and independent verification of the critical parameters are usually part of a good QA programme for radiotherapy treatment. Use of defence in depth methodology is of benefit in testing and ensuring that the QA programme contains sufficient safety layers to make accidents very unlikely.

as calibration at commissioning and after a source change. Redundancy and independence can be achieved by two persons making independent determinations of the absorbed dose rate. This is feasible by using resources rationally and for selected tasks. Diversity can be achieved by cross-checking the results of the beam calibration against the certificate of the source manufacturer, corrected for decay.[6]

6.6. INSTITUTIONAL ARRANGEMENTS

6.6.1. Conclusions

Some deficiencies related to the institutional arrangements (responsibilities, management, education and training, and compliance with regulations) were indirect causes of the accident.

The fact that discrepancies were detected and not corrected reveals that the responsibilities were not properly delegated or exercised, and that managerial problems of supervision existed. Education of the responsible persons was inadequate, and there was no QA programme. Record keeping was also a problem, although this did not contribute directly to the accident. The Expert Assessment in July 1997, and the previous expert review conducted in July 1996, prior to the accident, noted deficiencies in both these areas.

Regulations were promulgated in March 1995 in Costa Rica through Executive Decree, Reglamento de protección contra las radiaciones ionizantes (Regulations for protection against ionizing radiation). These regulations establish that the Section for Radiation Control of the Ministry of Health is the regulatory authority. The regulations require authorization for radiation sources and installations as well as for those persons that handle the radiation sources. They include radiation protection requirements for medical practice, e.g. the existence of a QA programme. At the time of the accident, the regulations had just begun to be implemented, but it should be noted that more than 1 year after their promulgation fewer than half the requirements had apparently been met.

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[6] Despite differences stemming from the collimation used at the source manufacturer's laboratory and that of the therapy machine (which influence the absorbed dose rate), a cross-check should point out any major inconsistencies.

6.6.2. Recommendations

Responsibilities should be well defined, procedures developed and compliance with procedures supervised. Additional educational programmes should be implemented for those staff that are engaged in radiotherapy. The existing regulations should be implemented, monitored and enforced as soon as possible. A safety culture should be established and fostered, and education and training provided.

A QA and record keeping programme should be implemented. Particular attention should be directed towards ensuring that QA programmes are operational. These programmes should include:

(1) Verification of the physical arrangements (sources, beam and geometry) and clinical aids (patients' charts) used in the treatment of patients;
(2) Verification of the appropriate calibration and conditions of operation of dosimetry equipment, and confirmation that the absorbed dose determination is traceable to a standards dosimetry laboratory;
(3) Implementation of regular and independent quality audit reviews of the programme;
(4) Participation in intercomparison exercises such as the IAEA/WHO TLD postal dose quality audit, combined with the establishment of positive procedures for taking actions if a prescribed deviation is found.

Radiotherapy records should be uniform, clear, consistent and complete.

6.7. MEDICAL EFFECTS OF OVEREXPOSURE

A wide range of effects of overexposure to radiation were noted in the 115 patients, varying from minimal detected or expected adverse effects to clearly developed catastrophic effects and several deaths. At least two-thirds of the patients were, or are, at significant risk. The circumstances of the accident can be expected to result in a high incidence of serious late effects. Psychological, social and other harmful effects for many patients were, are, or will be major.

Many of the surviving patients may be expected to develop further effects over the next 5 years. The medical and psychological needs of these patients will be very great. Owing to the location of the tumours in some patients and to the sensitivity of certain tissues, the incidence of effects relating to the CNS and to the GI, cardiovascular and skin effects was, and will continue to be, high.

Table IV summarizes the findings from the direct examination of patients, while Table V summarizes the findings from the review of records of the deceased patients (see Appendix II).

TABLE IV. FINDINGS FROM THE DIRECT EXAMINATION OF PATIENTS

No. of patients	Adverse effects in surviving patients
4	Severe or catastrophic effects
16	Marked effects, with high risk of future effects
26	Radiation effects that were not severe at the time of examination; some risk of future effects
22	No definite effects of significance at the time of examination; low risk of future effects
2	Underexposed patients as therapy was discontinued (when the error was discovered)
3	Could not be seen; one possibly at risk of future effects

Total 73

TABLE V. FINDINGS FROM THE REVIEW OF RECORDS OF DECEASED PATIENTS

No. of fatalities	Findings in deceased patients
3	Exposure as the major factor in causing death
4	Exposure as a substantial contributory factor
22	Death related to a tumour or cause other than exposure
5	Not enough data to judge
8	Data on patients not reviewed by the Expert Team

Total 42

6.8. FOLLOW-UP OF PATIENTS

6.8.1.   Recommendations

Since these radiation problems are unique and rare, it is strongly recommended that all those patients with specific radiation related problems be referred to certain specialists rather than to many different specialists.

The follow-up for patients should be structured to allow for both optimal individual care and scientific evaluation.

Baseline data should be compiled according to internationally recognized systems (e.g. RTOG/ESTRO for normal tissue effects and the ICRU for doses/fractionation).

Data should be stored in a special database to permit continuous upgrading. Data that are already available should also be placed in the database (data on the patients at the Calderón Guardia Hospital have largely already been obtained and stored). Additional factors such as the results of biopsies may prove to be important. Structured information obtained by post-mortem examinations on cancers and normal tissue is also extremely important for determining the cause of death and for evaluating future accidents.

It is recommended that one physician (or, better, two physicians) be responsible for running this registry, and be assigned the resources and the authority to do so.

6.9. FUTURE WORK

It is important that a report be issued on this accident in order to help prevent such accidents in the future. After several years, further investigation will be necessary to determine the full extent of the consequences of this accident.

6.10. USE OF THIS REPORT

This report presents the situation of the patients as of July 1997. Any analysis of patients for medical care compensation should take into account the early effects, the current medical evaluation and the risk of specific future effects, in addition to those that are described in this report.

6.11. RECOMMENDATIONS

The following recommendations were made to the Government of Costa Rica:

(1)   Radiation therapy is necessary and should be continued in Costa Rica;
(2)   Existing regulations should be implemented and enforced as soon as possible;
(3)   QA programmes should be developed and implemented;
(4)   Education and training for radiation therapy staff should be improved;
(5)   Record keeping in radiotherapy charts should be improved;
(6)   In general, radiotherapy should be improved to avoid unnecessary and unacceptable harmful outcomes;
(7)   If external auditing reveals significant, persistent and continuing problems, another channel of communication to the authorities should be sought;
(8)   Major medical and psychosocial support should be provided to many patients immediately, and will probably be needed for at least 5 years;
(9)   A registry of data on patients should be set up.

APPENDICES, ANNEX
AND ADDENDUM

Appendix I

RESULTS OF THE DOSIMETRIC FINDINGS
AND THE STATUS OF THE EQUIPMENT AND THE FACILITY

This Appendix contains detailed data on the calibration of the ^{60}Co beam, clinical dosimetry and quality control of the equipment by the Expert Team. In addition, it contains the layout and radiation levels in the spaces adjoining the emplacement of the Alcyon II radiotherapy unit.

Table I.I [10] gives the results of the IAEA/WHO TLD postal dose quality audit for the dosimeters irradiated after beam calibration performed during the IAEA Expert Mission. Table I.II [10] shows the computer spreadsheets, with the results of the beam calibration performed by the Expert Team. Table I.III gives the results of the quality control of the Alcyon II unit performed during the IAEA Expert Mission. Table I.IV provides the patient dose data, covering all the patients. Table I.V shows the dose to the organs at risk for selected patients. Table I.VI gives the calculated doses in 2 Gy fractions that would be biologically equivalent to the doses actually delivered. Figure I.1 shows the layout of the irradiation room of Alcyon II and adjoining spaces, with the measured dose rate levels of the radiation fields.

TABLE I.I. CERTIFICATE OF THE IAEA/WHO TLD POSTAL DOSE QUALITY AUDIT OF THE IRRADIATION CARRIED OUT AFTER THE EXPERT MISSION [10]

IAEA/WHO TLD POSTAL DOSE QUALITY AUDIT

Institution: San Juan de Dios Hospital
Address: District Hospital, San José

Country: Costa Rica

TLD batch No.:   SR 971
TLDs irradiated by: R. Pacheco Jiménez
Date of irradiation: 5 August 1997
Evaluation: 18 August 1997

RESULTS OF THE TLD MEASUREMENTS FOR Co-60 AND HIGH ENERGY PHOTONS

Beam	Radiation unit	No. of TLD set	User stated dose (Gy)	IAEA measured dose[a] (Gy)	IAEA mean measured dose (Gy)	% deviation relative to the IAEA mean measured dose[b]	IAEA mean measured dose / User stated dose
Co-60	Alcyon II	SR 97101	2.00	1.98 1.98 1.98	1.97	1.5	0.98

[a] The uncertainty in the TLD measurement of the dose is 1.8% (1 standard deviation); this does not include the uncertainty intrinsic to the dosimetry protocol (see IAEA Technical Reports Series No. 277 [10]).

[b] % deviation relative to the IAEA mean measured dose = 100 × (the user stated dose – the IAEA mean measured dose)/the IAEA mean measured dose. A relative deviation with a negative (positive) sign indicates that the user estimates a lower (higher) dose than that measured; a patient would therefore receive a higher (lower) dose than that intended by the factor given in the last column. Agreement within ±5% between the user stated dose and the IAEA measured dose is considered satisfactory.

J. Izewska   Date: 18 August 1997   **P. Andreo**

TLD Officer — Dosimetry and Medical Radiation Physics Section, IAEA   Head — Dosimetry and Medical Radiation Physics Section, IAEA

Important note: This information is provided only as an independent verification of beam output and *not* as a machine calibration, nor as an alternative to frequent calibrations by a qualified physicist. *It does not constitute a conclusive statement with regard to the quality of radiotherapy.*

Determination of the absorbed dose to air chamber factor $N_{D,air}$ for a cylindrical chamber

Responsible physicist: ▓▓▓▓▓▓▓▓   Date: ▓▓▓▓▓▓▓▓

1. Ionization chamber

Chamber model : PTW 30001 PMMA/Al Farmer ▼ | Serial no. ▓▓▓▓▓▓▓

Cavity inner radius (mm):   3.05

Wall material:	PMMA	thickness (g/cm^2)	0.045
Buildup cap material:	PMMA	thickness (g/cm^2)	0.541
		total thickness	0.586

Central electrode: aluminium

2. Chamber calibration data

Calibration laboratory: ▓▓▓▓▓▓▓▓   Date: ▓▓▓▓▓▓▓▓

Calibration factor ref chamber (N_K/N_X; units) | NK ▼ | ▓▓▓▓▓ | Gy/div ▼

Calibration factor ref chamber (N_K):   4.723E-02   Gy/div

given at	Pressure, P_o	▓▓▓▓	kPa
	Temperature, T_o	▓▓▓▓	°C
	Relative humidity	▓▓▓▓	%
	Polarizing volt	▓▓▓▓	V
	Field size	▓▓▓▓	cm x cm
	Source-chamber dist	▓▓▓▓	cm

3. Constants and factors

$k_{att} k_m$ =	0.972	
W/e =	33.97	
1-g =	0.997	(for Co-60 gamma radiation)

4. Absorbed dose to air chamber factor

Calibration factor ref chamber ($N_{D,air}$):   45.769E-3   Gy/div

given at	Pressure, P_o	101.3 kPa
	Temperature, T_o	20 °C
	Relative humidity	50.0 %
	Polarizing volt	-250.0 V

TABLE I.II. (cont.)

Determination of the absorbed dose to water in a Co-60 beam

Responsible physicist: ▓▓▓▓▓▓▓▓▓▓▓▓▓ Date: ▓▓▓▓▓▓▓

1. Radiation treatment unit and reference conditions for Dw determination

Co-60 unit ▓▓▓▓▓▓▓

Reference phantom: water
Reference field size: 10x10 cm x cm at S.S.D. = ▓▓▓▓▓▓▓▓▓ cm
Depth in water of the center of the chamber, $z(ctr)$ = ▓▓▓▓▓▓▓ cm
he shift of the effective point of measurent is 0.6 r
Reference depth in water of the P_{eff} of the chamber, z_{ref} = 4.8 cm

2. Ionization chamber

Chamber model PTW 30001 PMMA/Al Farmer Serial no. 1423
Wall material: PMMA thickness (g/cm^2) 0.045
Central electrode: aluminium

Electrometer model : ▓▓▓▓▓▓▓▓▓▓▓ Serial no. ▓▓▓▓▓▓▓

Absorbed dose to air ch factor $N_{D,air}$ (Gy/div)= 45.769E-3
given at P_o 101.3 kPa
T_o 20.0 °C
R.H. 50.0 %
Polarizing volt -250.0 V

3. Electrometer reading corrections

All readings should be corrected for leakage
Pressure, P (kPa) ▓▓▓▓▓▓▓ p_{TP} = 1.151
Temperature, T (°C) ▓▓▓▓▓▓ M_o = ▓▓▓▓▓▓ div/min
Recombination correction (continuous radiation; fig 13) [10] p_s = ▓▓▓▓▓▓
Average of chamber readings (div/min) M_u = 25.91

4. Absorbed dose to water

Stopping-power ratio, water/air (Table XIII) [10] $s_{w,air}$ = 1.133
Perturbation factor (eq (25), Tables XX, XXI) [10] p_{wall} = 1.001
α = 0.414
$s_{wall,air}$ = 1.102
$(\mu_{en}/\rho)_{w,wall}$ = 1.030
Central electrode correction = p_{cel} = 1.000
$D_w(z_{ref})$ = 1.3447 Gy/min
$D_w(z_{max})$ = 1.6873 Gy/min (%DD zref)= 79.697

%DD Co-60 10x10

	SSD	60	80	100
z=	4	81.5	83.7	85.0
z=	5	76.2	78.8	80.4

TABLE I.II. (cont.)

Determination of the absorbed dose to air chamber factor $N_{D,air}$ for a cylindrical chamber

Responsible physicist: _____   Date: _____

1. Ionization chamber

Chamber model : | PTW 30002 C/C Farmer | ▼ | Serial no. | _____
Cavity inner radius (mm):   3.05

Wall material:	graphite	thickness (g/cm^2)	0.079
Buildup cap material:	PMMA	thickness (g/cm^2)	0.541
Buildup cap material:		total thickness	0.620
Buildup cap material:	graphite		

2. Chamber calibration data

Calibration laboratory: _____   Date: _____

| NK | ▼ | | _____ | Gy/div | ▼ |

                          4.623E-02

Pressure, P$_a$ _____   **Gy/div**
Temperature, T$_a$ _____   kPa
                                                  °C

Relative humidity _____ %
Polarizing volt _____ V
Field size _____ cm x cm
Source-chamber dist _____ cm

3. Constants and factors

$k_{att} k_m$ =   0.982
W/e =   33.97
$1-g$ =   0.997   (for Co-60 gamma radiation)

4. Absorbed dose to air chamber factor

Calibration factor ref chamber ($N_{D,air}$):   45.262E-3   Gy/div
given at   Pressure, P$_a$ 101.3 kPa
Temperature, T$_a$ 20.0 °C
Relative humidity   50.0 %
Polarizing volt   -250.0 V

TABLE I.II. (cont.)

Determination of the absorbed dose to water in a Co–60 beam

Responsible physicist: ▮▮▮▮▮▮▮▮▮▮▮▮▮▮ Date: ▮▮▮▮▮▮▮▮

1. Radiation treatment unit and reference conditions for Dw determination

Co-60 unit ▮▮▮▮▮▮▮

Reference phantom: water
Reference field size: 10x10   cm x cm   at S.S.D. = ▮▮▮▮▮▮▮ cm
                            Depth in water of the center of the chamber, $z(ctr)$ = ▮▮▮▮▮▮ cm
                            he shift of the effective point of measurent is 0.6 r
                            Reference depth in water of the P_{air} of the chamber, z_{ref} =   4.8   cm

2. Ionization chamber

Chamber model   PTW 30002 C/C Farmer   Serial no. 152
Wall material: graphite   thickness (g/cm^2) 0.079
Central electrode: graphite

Electrometer model : ▮▮▮▮▮▮▮▮▮▮▮▮ Serial no. ▮▮▮▮▮▮▮▮

Absorbed dose to air ch factor $N_{D,air}$ (Gy/div)=   45.262E-3
                    given at P_o 101.3 kPa
                              T_o 20.0 °C
                              R.H.   50.0 %
                              Polarizing volt -250.0 V

3. Electrometer reading corrections
All readings should be corrected for leakage

Pressure, P (kPa)   ▮▮▮▮▮▮▮ p_{TP} =   1.151
Temperature, T (°C)   ▮▮▮▮ M_o = ▮▮▮▮▮ div/min
Recombination correction (continuous radiation; fig 13) [10] p_s = ▮▮▮▮▮
Average of chamber readings (div/min) M_o =   26.26

4. Absorbed dose to water

Stopping-power ratio, water/air (Table XIII) [10] $s_{w,air}$ = 1.133
Perturbation factor (eq (25), Tables XX, XXI) [10] p_{wall} =   0.990
                            α =   0.609
                            $s_{m,air}$ =   1.002
                            $(\mu_{en}/\rho)_{w,m}$ = 1.113
Central electrode correction = p_{cel} =   1.000
                    $D_w(z_{ref})$ =   1.3339   Gy/min
                    $D_w(z_{max})$ =   1.6737   Gy/min   (%DD zref)=   79.697

%DD Co-60 10x10

	SSD	60	80	100
z=	4	81.5	83.7	85.0
z=	5	76.2	78.8	80.4

TABLE I.II. (cont.)

Determination of the absorbed dose to air chamber factor $N_{D,air}$ for a cylindrical chamber

Responsible physicist: Date:

1. Ionization chamber

Chamber model : NE 2505/3, 3B '74-present ▼ | Serial no.

Cavity inner radius (mm):	3.15		
Wall material:	nylon 66	thickness (g/cm^2)	0.041
Buildup cap material:	PMMA	thickness (g/cm^2)	0.551
		total thickness	0.592
Central electrode:	aluminium		

2. Chamber calibration data

Calibration laboratory: Date:

Calibration factor ref chamber (N_K/N_X; units)   NK   ▼   Gy/div ▼

Calibration factor ref chamber (N_K):   8.677E-03   Gy/div

given at	Pressure, P_o	kPa
	Temperature, T_o	°C
	Relative humidity	%
	Polarizing volt	V
	Field size	cm x cm
	Source-chamber dist	cm

3. Constants and factors

$k_{att} k_m =$	0.965	
W/e =	33.97	
1-g =	0.997	(for Co-60 gamma radiation)

4. Absorbed dose to air chamber factor

Calibration factor ref chamber ($N_{D,air}$):   8.348E-3   Gy/div

given at	Pressure, P_o	101.3 kPa
	Temperature, T_o	20.0 °C
	Relative humidity	50.0 %
	Polarizing volt	-250.0 V

TABLE I.II. (cont.)

Determination of the absorbed dose to water in a Co-60 beam

Responsible physicist: ▓▓▓▓▓▓▓▓▓▓▓▓   Date: ▓▓▓▓▓▓

1. Radiation treatment unit and reference conditions for Dw determination

Co-60 unit ▓▓▓▓▓▓▓▓

Reference phantom: water
Reference field size: 10x10   cm x cm   at S.S.D. = ▓▓▓▓▓ cm
            Depth in water of the center of the chamber, z(ctr) = ▓▓▓▓ cm
            The shift of the effective point of measurent is 0.6 r
            Reference depth in water of the P_{eff} of the chamber, z_{ref} =   4.8   cm

2. Ionization chamber

Chamber model   NE 2505/3, 3B '74-present   Serial no. 19
Wall material: nylon 66   thickness (g/cm^2) 0.041
Central electrode: aluminium

Electrometer model : ▓▓▓▓▓▓▓▓▓▓   Serial no. ▓▓▓▓▓▓

        Absorbed dose to air ch factor $N_{D,air}$ (Gy/div)=   8.348E-3
            given at P_o 101.3 kPa
            T_o 20.0 °C
            R.H.   50.0 %
            Polarizing volt   -250.0 V

3. Electrometer reading correction

All readings should be corrected for leakage

Pressure, P (kPa)   ▓▓▓▓▓▓ p_{TP} =   1.151
Temperature, T (°C)   ▓▓▓▓▓▓ M_o = ▓▓▓▓ div/min
Recombination correction (continuous radiation; fig 13) [10] p_r = ▓▓▓▓
Average of chamber readings (div/min) M_a =   140.25

4. Absorbed dose to water

Stopping-power ratio, water/air (Table XIII) [10] $s_{w,air}$ =   1.133
Perturbation factor (eq (25), Tables XX, XXI) [10] p_{wall} =   1.009
                α =   0.386
                $s_{wall,air}$ =   1.142
                $(\mu_{en}/p)_{w,wall}$ =   1.015
Central electrode correction = p_{cel} =   1.000
        $D_w(z_{ref})$ =   1.3384   Gy/min
        $D_w(z_{max})$ =   1.6787   Gy/min   (%DD zref)=   79.726

%DD Co-60 10x10

	SSD	60	80	100
z=	4	81.5	83.7	85.0
z=	5	76.2	78.8	80.4

TABLE I.III. QUALITY CONTROL OF THE ALCYON II UNIT

Officials who carried out the measurements
L. Bermúdez Jiménez
H. Marenco Zúñiga
R. Pacheco Jiménez

(1)   *Reticle in collimator axis* (*tolerance: ±1 mm*)

x	Place collimator in horizontal position
x	Turn on light simulator system
x	Rotate collimator through 360°

Does the projection remain stationary in a plane 80 cm away from the source?

x Yes   ☐ No

(2)   *Isocentre verification* (*tolerance: 2 mm*)

x	Rotation of the collimator: original angle
x	Set a 30 × 30 cm field
x	Using a pointed object, find the position of the rotation axis

Note the distances between the cross and the isocentre in the following four positions:

0°	90°	180°	270°
0 mm	0.5 mm	0 mm	0 mm

Is the isocentre rotation within the margin of tolerance?

x Yes   ☐ No

(3)   *Optical distance indicator (ODI)* (*tolerance: 2 mm; s*ource axis distance: SAD)

| x | Collimator at 0° |
| x | Arm at 0° |

| *SAD = 70 cm* | *SAD = 80 cm* | *SAD = 90 cm* |
(25 cm from the cross)	*(35 cm from the cross)*	*(45 cm from the cross)*
ODI: 70 cm	ODI: 80 cm	ODI: 90 cm
Actual distance: 69.6 cm	Actual distance: 80 cm	Actual distance: 90 cm
Not acceptable	Acceptable	Acceptable

TABLE I.III. (cont.)

(4) *Verification of correspondence between the light field dimensions and the dimensions measured at 80 cm (tolerance: ±2 mm)*

x   Collimator at 0°
x   Arm at 0°
x   Plane at SAD = 80 cm, graph paper of at least 35 × 35 cm

Field selected		Light field dimensions			
		X jaw		Y jaw	
X jaw	Y jaw	Nominal	Error	Nominal	Error
5.0	5.0	4.5	0.5	4.8	0.2
10.0	10.0	10.0	0.0	10.0	0.0
15.0	15.0	15.0	0.0	15.0	0.0
20.0	20.0	20.0	0.0	20.0	0.0
25.0	25.0	25.0	0.0	25.0	0.0
30.0	30.0	30.0	0.0	30.0	0.0

Is this within the tolerance?

x Yes   ☐ No

(5) *Verification of the coincidence of the light beam with the radiation beam (control plate)*

x   Project a light field of 10 × 10 cm
x   Arm at 0°
x   Plane at SAD = 80 cm on a radiographic plate for cobalt
x   Using a pin, mark the points of the field on the shield
x   Place a 3 mm acrylic sheet on the plate and irradiate for 0.1 min

TABLE I.IV. PATIENT DOSE DATA[a]

Patient No.	Dd	Site	FS (cm)	No. of fields	Pd (cGy)	FX<	Depth (cm)	d> (cGy)	FX>	D (cGy)	$d_{max}<$ (cGy)	$D_{max}>$ (cGy)	Comments
1		Posterior axilla	12 × 12	1	200	0	7	310	4	1240	292	1810.4	
2		Larynx	18 × 13	2	100	0	6	155	6	930			Two fields/day
		Neck	22 × 8	1	200	0	3	310	6	1860	230	2139	
4		Pelvis	18 × 16	2	200	0	9	310	12	3720			Two fields/day isocentric
6	Yes	Pelvis	15 × 15	2	200	0	8.5	310	5	1550			Two fields/day isocentric
8		Lateral pelvis	12 × 7	2	200	—	16	310	5	1550	552		
		Pelvis	15 × 15	2	200	20	10	310	5	5550	342		
10		Pelvis	15 × 15	2	200	0	10	310	6	1860	343		
11	Yes	Costal ribs	9 × 4	1	400	0	0.5	620	5	3100	400	3100	Previous breast irradiation
12		Neck	8 × 9	2	200	0	4.5	310	12	3720			Two fields/day
13		Pelvis	15 × 15	2	200	0	10.5	310	8	2480	354		
		Lateral pelvis	12 × 10	2	267	5	16	413.85	0	1335			Two fields/day
14		Femur	31 × 12	2	200	0	6.5	310	4		270		After calibration corrected
		Spine	11 × 6	1	300	0	6	465	10		413		After calibration corrected
15	?	Pelvis	14 × 14	2	200	9	10	310	6	3660	343		
16	Yes	Mediastinum	17 × 14	2	200	0	9	310	4	1240	327		
		Inverted Y	24 × 18	2	150	0	10	232.5	9	2092.5	247		
17		Foot	16 × 7	2	200	0	3.5	310	11	3410			
18	Yes	Pelvis	15 × 15	2	200	0	11	310	12	3720	366	6807.6	
19		Shoulder	14 × 11	2	300	1	7	465	2	1230	429		

TABLE I.IV. (cont.)

Patient No.	Dd	Site	FS (cm)	No. of fields	Pd (cGy)	FX<	Depth (cm)	d> (cGy)	FX>	D (cGy)	$d_{max}<$ (cGy)	$D_{max}>$ (cGy)	Comments
20		Oblique lateral left head	7 × 7	1	134	0	5	207.7	4	830.8			Isocentric
		Oblique posterior head	7 × 7	1	66	0	11	102.3	4	409.2			Isocentric
21		Pelvis	15 × 15	2	200	0	11	310	8	2480	366		
22	Yes	Scrotum	16 × 14	1	200	0	4	310	10	3100	240		
23		Upper arm	21 × 10	2	200	0	4.5	310	13	4030	243		
24	Yes	Neck	12 × 9	1	300	0	0.5	465	10	4650	305	4727.5	
25		Costal ribs	8 × 13	1	800	1	0.5	1240	4	5760	800	5760	
26		Neck	13 × 14	1	250	0	0.5	387.5	14	5425	250	5425	Deaf
		Eye	5 × 6	1	250	0	0.5	387.5	14	5425	255	5534	
27	Yes	Oesophagus	12 × 6	2	200	5	8.5	310	15	5650			Two fields/day isocentric
28	Yes	Mediastinum	15 × 10	2	200	11	12	310	9	4990	404		
29		Right shoulder	15 × 8	1	400	0	5	620	5	3100	510	3953	
	Yes	Spine	19 × 7	1	300	0	5	465	3	1395	382	1776	
30	Yes	Lumbar spine	15 × 7	1	300	0	5	465	8	3720	382	4737	
31		Dorsal ribs	16 × 10	1	267	3	4	413.9	12	5767	318	6869	
32		Spine	12 × 6	1	400	0	4	620	5	3100	490	3798	
33	Yes	Pelvis	19 × 17	2	300	0	8.5	465	10	4650	463		
34	Yes	Pelvis	18 × 18	1	400	0	7	620	5	3100	565	4379	
35		Anterior pelvis	8 × 8	1	200	0	8	310	20	6200	320	9920	
36		Spine	15 × 6	1	267	11	5	413.9	3	4179	340	5321	
37		Prostate	14 × 14	2	200	17	9	310	4	4640			
		Boost	8 × 8	1	200	0	6	310	12	3720			D_{max} (prostate) = 8200 cGy

TABLE I.IV. (cont.)

Patient No.	Dd	Site	FS (cm)	No. of fields	Pd (cGy)	FX<	Depth (cm)	d> (cGy)	FX>	D (cGy)	d_max< (cGy)	D_max> (cGy)	Comments
38		Cranium	5 × 5	2	200	15	7	310	10	6100			
39		Inguinal groin	18 × 14	1	170	0	9	263.5	14	3689	270	5859	
40		Mediastinum	19 × 18	2	200	0	9	310	17	5270	296		
41		Posterior T11	19 × 6	1	250	0	5	387.5	15	5813	318	7394	Dose depth (5 cm) = 5600 cGy
42		Parotid gland	6 × 10	2	200	0	4	310	23	7130			Wedge pair, two fields/day
43	Yes	Cranium	18 × 15	2	300	0	7	465	9	4185	416		
44		Pelvis	10 × 10	1	1000	0	0.5	1550	2	3100	1000	3100	
45		Pituitary gland	5 × 5	2	200	18	7	310	7	5770	311		
46	Yes	Face	8 × 7	2	200	5	0	310	20	7200	266		
		Neck	16 × 7	1	200	0	0.5	310	20	6200	204		
47		Pituitary gland	5 × 5	2	200	5	7	310	23	8130[b]	311		
48		Mediastinum	10 × 6	2	267	0	8	413.9	15	6208	425		
49		Oesophagus	4 × 8	2	200	0	9	310	17	5270	2480		Two fields/day
50		Anterior neck	11 × 8	1	200	0	0.5	310	17	5270	204	5375	
51		Pelvis	15 × 15	2	200	9	11.5	310	10	4900			1 lateral right = 16 600 cGy
52	Yes	Tonsil	13 × 9	2	200	9	4	310	24	9240	242		
53		Pelvis	14 × 14	2	200	0	10.5	310	15	4650	354		
54	Yes	Fossa	15 × 12	2	200	16	7	310	9	5990	283		
		Thoracic spine	31 × 16	1	200	0	4	310	15	4650	240	5580	
		Lumbar spine	19 × 6	1	200	0	5	310	15	4650	255	5929	
55		Neck	18 × 19	1	200	0	0.5	310	13	4030	200	4030	
56		Pelvis	14 × 14	2	200	1	9.5	310	11	3610			
57	Yes	Abdomen	29 × 23	1	160	12	2	248	10	4400	170	4675	

TABLE I.IV. (cont.)

Patient No.	Dd	Site	FS (cm)	No. of fields	Pd (cGy)	FX<	Depth (cm)	d> (cGy)	FX>	D (cGy)	$d_{max}<$ (cGy)	$D_{max}>$ (cGy)	Comments
58		Posterior fossa	17 × 14	2	200	9	6.5	310	13	5830	274		
		Spine	16 × 5	1	200	3	6	310	6	2460	276	3395	Overlap?
		Spine	33 × 5	1	200	3	6	310	6	2460	274	3370	
59	Yes	Neck	12 × 20	1	200	0	0.5	310	20	6200	204	6324	Spinal cord dose?
60	Yes	Left face naso	13 × 8	1	44	0	7	68.2	24	1637			lrradiation on same day
		Right face	13 × 8	1	110	0	7	170.5	24	4092			
		Anterior face	9 × 7	1	66	0	9	102.3	24	2455	115	4278	
		Neck	25 × 10	1	200	0	0.5	310	24	7440	200	7440	
61	Yes	Pelvis	15 × 15	2	200	0	9	310	9	2790	321		
		Right tonsil	8 × 11	1	125	0	5	193.8	15	2906			Two fields/day
		Left tonsil	8 × 11	1	75	0	5	116.3	15	1744			
62		Pelvis	15 × 15	2	200	0	11	310	15	4650	366		
63	Yes	Pelvis	14 × 14	2	200	0	8.5	310	14	4340	311		
64		Pelvis	15 × 15	2	200	10	11.5	310	8	4480	378		
65	Yes	Left arm	20 × 10	1	500	0	0.5	775	5	3875	500	3875	
66		Mantle	16 × 16	2	200	0	10	310	11	3410	348		2-1 anterior
67	Yes	Abdomen	31 × 22	2	200	0	9	310	16	4960			Isocentric
68	Yes	Pelvis	18 × 17	2	200	0	10	310	19	5890			Two fields/day isocentric
69		Hockey stick+ D28	14 × 14	1	200	12	7	310	13	6430	224	7202	Brachyplexis?
70		Parotid gland	15 × 9	1	200	5	3	310	20	720	229	8244	
71	Yes	Lateral pelvis	10 × 7	2	200	0	18	310	5	1550			5000 cGY AP/PA previously
72	Yes	Thorax	15 × 19.5	2	200	0	11	465	10	4650			Two fields/day isocentric

TABLE I.IV. (cont.)

Patient No.	Dd	Site	FS (cm)	No. of fields	Pd (cGy)	FX<	Depth (cm)	d> (cGy)	FX>	D (cGy)	$d_{max}<$ (cGy)	$D_{max}>$ (cGy)	Comments
73	Yes	Pelvis AP	15 × 15	2	200	9	8	310	16	6760			One field/day isocentric
74		Pelvis AP	20 × 26	2	200	10	10	310	11	5410			Two fields/day isocentric
75		Right axilla	15 × 19	1	200	0	4	310	17	5270	239		
		Forearm	13 × 6	1	200	0	5	310	7	2170			
76		Lateral thorax	19 × 4	2	200	0	13	310	7	2170			Two fields/day, previously 600 cGy
77		Pelvis AP	15 × 14	2	200	7	9	310	18	6980			Two fields/day isocentric
78		Pelvis AP	15 × 15		200	9	10	310	16	6760			Isocentric
79		Pelvis AP	15 × 16	2	200	0	10	310	14	4340			Two fields/day isocentric
80		Lateral naso	12 × 17	2	200	0	7	310	16	4960	219		
		Neck	23 × 8	1	200	0	3	310	16	4960	230	5704	
81		Right neck	10 × 10	1	77	12	6	119.4	8	1879			
		Left neck	10 × 10	1	33	12	6	51.15	8	805			
82	Yes	Pelvis AP	14 × 14	2	338	0	6.5	523.9	6	3143			Isocentric
83		Pelvis AP	16 × 20	2	200	5	9.5	310	20	7200			Two fields/day
		Lateral pelvis	10 × 10	2	200	0	16	310	5	1550			Two fields/day
84	Yes	Thorax AP	26 × 15	2	200	0	8.5	310	20	6200			Two fields/day isocentric
85		Pelvis AP	18 × 15	2	200	6	10	310	12	4920[b]			Two fields/day isocentric
86	Yes	Mantle	32 × 35	2	200	0	10	310	14	4340			Two fields/day
87		Thoracic spine	5 × 32	1	200	2	4	310	4	1640	240	1968	
		Lumbar spine	5 × 7	1	200	2	4	310	4	1640	247	2025	

TABLE I.IV. (cont.)

Patient No.	Dd	Site	FS (cm)	No. of fields	Pd (cGy)	FX<	Depth (cm)	d> (cGy)	FX>	D (cGy)	$d_{max}<$ (cGy)	$D_{max}>$ (cGy)	Comments
88		Nasal	3 × 3	1	200	0	3	310	5	1550	236	1829	Previous dose of 5000 cGy
89		Pelvis AP	16.5 × 15	2	200	0	10	310	11	3410			Two fields/day isocentric
92	Yes	Pelvis AP	24 × 29	2	200	14	9	310	11	6210			One field/day isocentric
94	Yes	Anterior neck	21 × 5	1	200	0	3	310	15	4650	232	5394	
		Lateral neck	12 × 17	2	200	0	5.5	310	15	4650	256		
95		Pelvis AP	16 × 14	2	100	0	9	155	14	2170			Isocentric
96	Yes	Neck	14 × 21	1	200	3	3	310	14	4940	227	5607	
		Anterior sinus	9.5 × 11	1	100	3	8	155	14	2470	156		
		Lateral sinus	11 × 11	1	100	3	8	155	14	2470	153		
97		Anterior neck	7 × 31	1	200	11	3	310	8	4680	230		
		Lateral naso	12 × 17	2	200	11	6	310	8	4680	270		
98		Internal mammary nodes	14 × 5	1	200	0	3	310	23	7130	230		
100		Posterior parietal	6 × 7	1	100	16		155	14	3770			Wedge, two fields/day
		Lateral parietal	9 × 7	1	100	16		155	14	3770			
101		Forehead	6 × 8	2	143	24		221.7	6	4762			Two fields/day
102		Cranium	14 × 18	2	200	4	6.5	310	8	3280	274		
		Thoracic spine	28 × 5	1	200	0	5	310	6	1860	258	2399	
		Lumbar spine	14 × 15	1	200	0	5	310	6	1860	261	2427	
103		Left testis	4 × 4	1	200	9	0.5	310	2	2420	200	2420	
104	Yes	Right clavicle	6 × 6	1	250	0	0.5	387.5	18	6975			
105		Cranium	10 × 17	2	200	2	7.75	310	16	5360	297		
		Lumbar spine	16 × 5	1	200	0	6	310	6	1860	279	2595	
		Thoracic spine	23 × 5	1	200	0	6	310	6	1860	276		

TABLE I.IV. (cont.)

Patient No.	Dd	Site	FS (cm)	No. of fields	Pd (cGy)	FX<	Depth (cm)	d> (cGy)	FX>	D (cGy)	d_{max}< (cGy)	D_{max}> (cGy)	Comments
106		Posterior fossa	15 × 12	2	200	13	6	310	12	6320	265		
		Spine	33 × 5	1	200	0	4	310	10	3100	240	3720	
107	Yes	Cranium	14 × 16	2	200	28	7.75	310	5	7150	270		
108	Yes	Left hip	10 × 8	1	267	0	0.5	413.9	15	6208	267	6208	
109		Cranium	16 × 9	2	200	4	7	310	16	5760	282		
110	Yes	Left cranium	16 × 18	2	200	7	7	310	6	3260	283		
111		Anterior lung	16 × 10	2	200	18	10	310	2	4220	362		
		Lung	13 × 10	1	300	3	10	465	0	900	527	1581	
112	Yes	Clitoris	5 × 5	1	300	0	0.5	465	11	5115	300		
		Pelvis	14 × 14	1	200	0	9.5	310	5	1550	331		
113	Yes	Neck	11 × 17	1	600	0	0.5	930	5	4650			
		Arm	8 × 7	1	600	0	0.5	930	5	4650			
		Posterior abdomen	10 × 4	1	400	0	0.5	620	3	1860			
		Posterior abdomen	12 × 4	1	600	0	0.5	930	5	4650			
114	Yes	Spine	15 × 12	1	300	6	5	465	2	2730		0	
		?	5 × 5	1	300	0	0.5	465	5	2325		0	
115		Lumbar spine	18 × 6	1	300	0	5	465	10	4650	382	5921	
		Thoracic spine	20 × 5	1	300	0	5	465	10	4650	388	6014	
116	Yes	Pelvis	17 × 17	2	100	0	10	155	2		110		
117		Pelvis	16 × 15	2	100	0	9		3				Two fields/day

a Dd = deceased; FS = field site; Pd = prescribed dose per fraction; FX< = number of fractions before source change; d> = dose per fraction after source change; FX> = number of fractions after source change; D = grand total dose; d_{max} < = dose per fraction at maximum dose depth before source change; and D_{max}> = total dose at maximum dose depth (0.5 cm) after source change.

b In these cases, the dose obtained with the factor 1.55 differs significantly from the dose calculated from the recorded treatment time.

TABLE I.V. DOSE TO THE ORGANS AT RISK FOR SELECTED PATIENTS[a]

| Patient No.	Site	FS (cm)	No. of fields	Pd (cGy)	FX<	D< (cGy)	Depth (cm)	EqFS (cm × cm)	FSF	DD or TAR	Time (min)	d> (cGy)	FX>	D> (cGy)	D (cGy)	Dose organ (cGy)	Critical organ
8	Lateral pelvis	12 × 7	2	200	—	0	16	8.8	0.988	0.359	4.3	303.3	5	1516	1516.3		
	Pelvis	15 × 15	2	200	20	4000	10	15	1.035	0.592	2.6	311.4	5	1557	5557.1		
26	Neck	13 × 14	1	250	0	0	0.5	13.5	1.025	1	1.9	387.7	14	5428	5427.7	4179	Cervical spine
	Eye	5 × 6	1	250	0	0	0.5	5.5	0.947	1	2.1	395.5	14	5537	5537.1		Eye (with lead block)
	Ear															8500	Ear dose due to overlap
39	Inguinal groin	18 × 14	1	170	0	0	9	16	1.04	0.631	2	259.9	14	3638	3637.9	5800	Inguinal vessels
40	Mediastinum	19 × 18	2	200	0	0	9	18.5	1.048	0.638	2.3	300.3	17	5105	5105.4	5105/5105	Thoracic spine/heart
41	Thoracic and lumbar spine	19 × 6	1	250	0	0	5	8.9	0.99	0.783	2.5	381.8	15	5727	5726.6	4349	Thoracic and lumbar spine
44	Pelvis	10 × 10	1	1000	0	0	0.5	10	1	1	7.9	1548.4	2	3097	3096.8	2500/1220	Gut, bladder, rectum
47	Pituitary gland	5 × 5	2	200	5	1000	7	5	0.94	0.647	2.1	251.6	23	5787	6786.9	6787 (to both organs)	Eye nerve/ears
58	Posterior fossa	17 × 14	2	200	9	1800	6.5	15.3	1.037	0.74	2.1	311.4	13	4048	5848.4	5848	Cerebellum
	Lumbar spine	16 × 5	1	200	3	600	6	7.6	0.987	0.722	2.2	310.3	6	1862	2461.5	2462	Lumbar spine
	Spine	33 × 5	1	200	3	600	6	8.3	0.985	0.727	2.1	301.9	6	1811	2411.3	2411	Thoracic spine
62	Pelvis	15 × 15	2	200	0	0	11	15	1.036	0.553	2.6	290.1	15	4351	4351	4351	Gut, bladder, rectum
78	Pelvis AP	15 × 15	2	200	9	1800	10	15	1.035	0.779	2	324.0	16	5184	6984.3	6984 (to all three organs)	Gut, bladder, rectum
80	Lateral naso	12 × 17	2	200	0	0	7	13.7	1.03	0.708	1.1	321.8	16	5149	5148.8	5149	Cervical spine
	Neck	23 × 8	1	200	0	0	3	11.4	1.06	0.891	1.8	327.5	16	5239	5239.4		Spine block

TABLE I.V. (cont.)

Patient No.	Site	FS (cm)	No. of fields	Pd (cGy)	FX<	D< (cGy)	Depth (cm)	EqFS (cm × cm)	FSF	DD or TAR	Time (min)	d> (cGy)	FX>	D> (cGy)	D (cGy)	Dose organ (cGy)	Critical organ
85	Pelvis AP	18 × 15	2	200	6	1200	8.5	16.3	1.04	0.853	1.1	395.0	12	4740	5939.6	5940	Gut, bladder, rectum
97	Anterior neck	7 × 31	1	200	11	2200	3	10	1	0.887	1.8	307.5	8	2460	4660.3		
105	Cranium	10 × 17	2	200	2	400	7.7	12.4	1.02	0.658	2.2	290.9	16	4654	5054.1	5054	Brain and cerebellum
	Dorsal column	23 × 5	1	200	0	0	6	8	0.983	0.726	2.2	310.7	6	1864	1864.2	1864	Spine
	Lumbar column	16 × 5	1	200	0	0	6	7.6	0.98	0.723	2.3	316.9	6				
106	Posterior fossa	15 × 12	2	200	13	2600	6	13.3	1.023	0.751	2	302.7	12	3632	6232.4	6232	Cerebellum
	Spine	33 × 5	1	200	0	0	4	8.3	0.983	0.822	1.9	299.3	10	2993	2992.6	2993	Whole spine
109	Cranium	16 × 19	2	200	4	800	7	17.3	1.044	0.7255	2.1	313.3	16	5014	5813.5	5814	Brain and cerebellum

[a]   FS = field site; Pd = prescribed dose per fraction; FX< = number of fractions before source change; D< = total tumour before source change; EqFS = equivalent square of a field; FSF = field size factor; DD = depth dose ratio; TAR = tissue air ratio; d> = dose per fraction after source change; FX> = number of fractions after source change; D> = total tumour dose after source change; and D = grand total dose.

TABLE I.VI. BIOLOGICALLY EQUIVALENT DOSE (D(2))
IN 2 Gy FRACTIONS[a]

Patient No.	d< (Gy)	FX<	D< (Gy)	d> (Gy)	FX>	D> (Gy)	D (Gy)	Alpha/beta (Gy)	Tissue	D(2) (Gy)	
44	0	0	0	15.5	2	31.0	31.0	3	Skin	114.70	
	0	0	0	12.5	2	25.0	25.0	5	Bowel	62.50	
47	2	5	10	2.5	23	57.7	67.7	2	Brain	75.09	
54	2	16	32	3.0	9	27.0	59.0	2	Brain	65.75	
	2	0	0	3.5	15	52.1	52.1	2	Thoracic spine	71.18	
83	2	5	10	3.1	20	62.0	72.0	5	Bowel	81.74	*Total*
	0	0	0	3.3	5	16.6	16.6	5	Bowel	19.73	101.47
109	2	4	8	3.1	16	50.1	58.1	2	Brain	72.23	

[a] d< = dose per fraction before source change; FX< = number of fractions before source change; D< = total tumour dose before source change; d> = dose per fraction after source change; FX> = number of fractions after source change; D> = total tumour dose after source change; D = grand total dose; and D(2) = total dose given in fractions that would be biologically equivalent to D.

Radiometric survey (m Sv/h)

❶ ^	❷	❸	❹	❺	❻
4	0.02	0.015	0.00	0.02	0.25
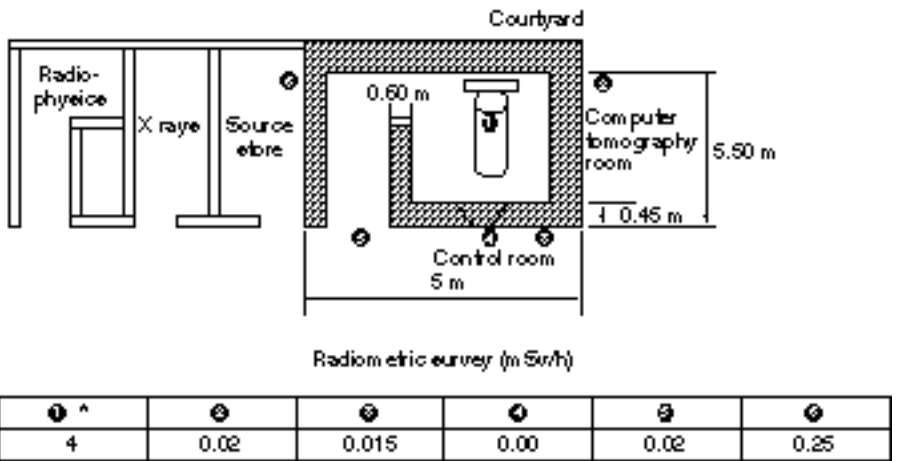
Notes: Readings were taken with an open collimator on a 30 × 30 cm field without a phantom or patient (direct beam); ^ reading in the room above at the height of the gonads.

FIG. I.1. *Layout of the irradiation room of Alycon II and adjoining spaces, with the measured dose rate levels of the radiation fields.*

Appendix II

DATA ON PATIENTS

The data and findings below represent one point in time in the evolution of a complex situation for these patients. Many had significant lesions and reactions that had healed during the acute phase. What we see now are the subacute and some chronic findings. Many of these patients will have continuing evolution of radiation effects. Many will also have additional difficulties owing to tumour extension, prior surgery and chemotherapy. In addition, it is clear that each of these patients has psychosocial needs that cannot be commented upon specifically.

In summary, 70 patients were examined with the following results: four patients had severe or catastrophic effects; 16 patients had marked effects, with high risk of future effects; 26 patients had radiation effects that are not severe at this time, with some risk of future radiation effects; 22 patients had no definite adverse effects of significance at this time, with low risk of future effects; two patients were under-exposed because their therapy was discontinued; and three patients were not seen, of whom one may be at high risk of adverse effects.

Patients with major catastrophic effects
of overexposure at this time

Identification Nos: 97, HCG—, 1-320-763
Age: 52
Tumour history: Non-Hodgkin's lymphoma of the nasopharynx; received chemotherapy
Dates of therapy:
Prescribed dose: Anterior neck, 7 × 31 cm, and lateral nasopharynx, 12 × 17 cm
*Estimated dos*e: 47 Gy to the anterior neck in 11 fractions and 47 Gy to the nasopharynx in 14 fractions
Findings: Dry mouth and loss of taste; therapy covered the cervical spine and the patient showed classic signs associated with spinal cord demyelination
Conclusions: Possible severe spinal cord complications as a result of radiotherapy; the spinal cord dose needs to be calculated

Identification Nos: 44, HSJD—, 107806
Age: 81
Tumour history: Epidermoid carcinoma of the cervix, stage IIIB
Dates of therapy: 4 and 12 September 1996
Prescribed dose: 10 Gy each fraction, in two fractions, 10 × 10 cm, palliative only
Estimated dose: 31 Gy in two fractions, 1 week apart
Findings: Patient had severe ulceration of the vulva on both sides following radiotherapy; after healing, it broke out again in December, and has since not healed; blood often appears in stools; picture taken
Conclusions: Severe radiation effects

Identification Nos: 80, HSG 35, 6-276-803

Age: 20

Tumour history: At age 19 the patient was pregnant, and at 27 weeks was diagnosed to have an undifferentiated carcinoma of the pharynx; the patient waited until the end of pregnancy to begin therapy, undergoing six cycles of chemotherapy

Dates of therapy:

Prescribed dose:

Estimated dose: 50 Gy in 16 fractions, two fields for the lower neck and pharynx, lateral fields

Findings: Patient is a quadriplegic, and is reported to have had magnetic resonance imaging (MRI) that showed radiation changes in the spinal cord (C1–C7)

Conclusions: Severe adverse reaction as a result of overexposure, causing quadriplegia

Identification Nos: 109, Hospital de Niños

Age: 3 years and 5 months

Tumour history: A yolk sac tumour of the right testicle was diagnosed in January 1995. Subsequently, the patient developed a large mediastinal mass, which was resected, reportedly completely. In July 1996, he had a seizure and a computer tomography (CT) scan revealed a large lesion, with surrounding oedema over the right cortex. The patient received intrathecal methotrexate, as well as radiotherapy

Dates of therapy: 12 August to 16 September 1996

Prescribed dose:

Estimated dose: 58 Gy in 20 fractions to the cranium, four with the old source and 16 with the new source

Findings: The patient has permanent epilation. He has lost all ability to speak and is confined to a wheelchair. He was apparently able to walk, dance and sing before the radiotherapy. He has minimal motor skills with his hands, and often drifted off to sleep during our examination. His mother gives him physical therapy. Current MRI scans do not show evidence of a tumour, but there is evidence of periventricular leukoencephalopathy, as well as mineralizing micro-angiopathy and atrophy, with dilated ventricles

Conclusions: Severe changes as a result of overexposure, probably additionally potentiated by methotrexate. Detailed dose evaluation is needed

**Patients with moderate to severe effects
of local overexposure at this time:
At high risk of additional future effects**

Identification Nos: 8, HJJD—, 6-005-80347

Age: 54

Tumour history: Carcinoma of the cervix, stage IIIB, July 1996

Dates of therapy: 24 July to 23 August; 26 August to September 1996

Prescribed dose: D_{max} of 3.4

Estimated dose: 16 Gy lateral port and 56 Gy AP/PA, 20 fractions of AP/PA, 15×15 cm every other day + lateral fields of 12×7 cm, 13 fractions of AP, 12 fractions of PA, three to the right, two to the left (550 cGy each, lateral)

Findings: Initially, diarrhoea with cramps; grade 2 cystocele; normal pelvis recently reported. Now, occasional diarrhoea, a small amount of ascites. Lost 9 kg in weight. Complains of diarrhoea 3 days per week. Since January 1997, pain in the hips that radiates down both legs. No prior back problems or difficulties in walking or bending. Severe sacral pigmentation; picture taken

Conclusions: Probable recurrent tumour in abdomen, sacral fibrosis

Identification Nos: 85, HCG—, 6-333-390

Age: 66

Tumour history: Rectal cancer with surgery in November 1995 and chemotherapy in September 1996. In January, a recurrence was suspected, with a biopsy showing questionable fibrosis and inflammation

Dates of therapy: 9 August to 19 September 1996

Prescribed dose:

Estimated dose: 49 Gy, 18 fractions, six with the old source and 12 with the new source, 18×15 cm, pelvis AP/PA, two fields each day

Findings: Ulceration and significant rectal pain. No diarrhoea, deep induration of the superficial pelvic tissues. Significant perirectal ulceration, with possible superimposed infection and/or necrosis

Conclusions: Significant post-radiation pelvic complications

Identification Nos: 77, HCG 9, 1-471-189

Age: 39

Tumour history: Moderately differentiated cancer of the cervix, stage IB. Initially given three cycles of chemotherapy followed by surgery, which disclosed positive lymph nodes, leaving the residual tumour

Dates of therapy: 5 August to 24 September 1996

Prescribed dose: Pelvis, 15×15 cm, 25 fractions

Estimated dose: 70 Gy in 25 fractions, seven with the old source and 18 with the new source

Findings: Patient now has ascites, with positive cytology. Significant skin changes exist, with marked anterior and posterior induration. Also, the patient has continuous bloody diarrhoea

Conclusions: Severe skin and subcutaneous changes, as well as GI complications as a result of overexposure

The patient died in mid-August 1997 from sindroma occlusivum following an operation

Identification Nos: 58, HSJD 12, 786095, 270-130-149-00667646

Age: 30

Tumour history: CT scan in April 1996, left cerebellar lesion and surgery for desmoplastic medulloblastoma of the cerebellum

Dates of therapy: 30 July to 19 August; 26–27 September 1996

Prescribed dose: Alternating lateral fields each day, 12 on the right spine, 8 August to

27 September 1996, 16 × 5 cm on the lumbar spine, 33 × 5 cm on the thoracic spine. Spine treated every fourth day at 2.75 cGy/d, nine fractions per field
Estimated dose: 58 Gy on the posterior fossa, 25 Gy on the lumbar spine, 25 Gy on the thoracic spine, opposed laterals, posterior fossa, 17 × 14 cm
Findings: Suffers from headaches and parasthaesia in both lower limbs
Conclusions: Possible or probable spinal cord changes owing to overexposure

Identification Nos: 54, HSJD 27, 1-581-341
Age: 35
Tumour history: In 1993, carcinoma in situ of the cervix. In 1994, hysterectomy and right oopherectomy. In 1996, headaches and CT revealed posterior fossa lesion, hydrocephalus and compression of the fourth ventricle
Dates of therapy: 23 July to 19 August 1996, 16 treatments, posterior fossa; 26 August to 16 September 1996, 16 fractions to the spinal cord
Prescribed dose:
Estimated dose: Posterior fossa, 60 Gy in 16 fractions, 15 × 12 cm. Fields on alternate days. Spinal fields, 31 × 6 cm on the thoracic spine, 47 Gy, 19 fractions and 19 × 6 cm on the lumbar spine
Findings: Patient reports continuing problems with nausea and dizziness. Residual epilation, which is worse on the right side
Conclusions: Patient is still at risk of neurological sequelae

Identification Nos: 47, HSJD 31, 6-137-437
Age: 38
Tumour history: In May 1996, large pituitary adenoma, with transsphenoidal hypophysectomy
Dates of therapy: 13–19 August 1996, five fractions; 28 August to 26 September 1996, 28 fractions
Prescribed dose:
Estimated dose: 68 Gy, 5 × 5 cm, lateral opposed, one field per day
Findings: Complex symptoms, some hair regrowth, decreased hearing and otitis
Conclusions: Patient is at high risk of neurological sequelae

Identification Nos: 66, HSJD 32, 2-465-815
Age: 25
Tumour history: NS (nodular sclerosis) Hodgkin's disease, stage IIIA, with bulky mediastinal disease, chemotherapy, COPP × 6 in January 1996
Dates of therapy: 13–27 September 1996
Prescribed dose:
Estimated dose: 34 Gy, 16 × 16 cm, mantle, alternating fields, 2 days anterior then 1 day posterior
Findings: No spinal changes now apparent, regrowth of hair, ventral pigmentation
Conclusions: Care needs to be continued for potential cardiac effects and increased risk of breast cancer

Identification Nos: 41, HSJD 13, 5-01210805

Age: 49

Tumour history: In 1992, breast cancer, T4N2M1, multiple skeletal metastases. In 1996, hepatic metastases and T11 collapse

Dates of therapy: 24–26 September 1996

Prescribed dose: 19 × 6 cm, posterior T11

Estimated dose: 58 Gy depth and 73 Gy skin with 477 cGy daily treatment to the spinal cord T 12-S1, 15 fractions

Findings: At the time of radiotherapy the patient had no back pain, only pain in the hips and legs. There was a severe skin reaction that healed within a few months, and she has experienced intestinal cramps and bladder problems. Practically no reaction on the skin now, but has developed 50–70% paralysis of legs, which is difficult to evaluate because of pain. Subcutaneous tumour nodules on the anterior chest, and leg reflexes are almost gone

Conclusions: Partial paralysis, with extensive metastatic disease. Potential spinal cord changes need to be followed up

Subsequent to the Expert Mission in July 1997, paralysis became total and severe bleeding developed. The patient died at the end of August 1977

Identification Nos: 106, Hospital de Niños

Age: 5

Tumour history: Medulloblastoma of the posterior fossa, patient had eight courses of chemotherapy, surgery and radiation

Dates of therapy: 27 July to 10 September 1996

Prescribed dose:

Estimated dose: 63 Gy posterior fossa (25 fractions, 13 with the old source and 12 with the new source) and 31 Gy to the spine (10 fractions with the new source)

Findings: There is permanent epilation over the posterior half of the skull. The motor skills are good, but there are psychological worries about permanent epilation

Conclusions: Changes have occurred as a result of overexposure. The Expert Team is concerned about possible radiation necrosis of the brain tissues over the next year or two. Follow-up and very careful dose estimation will be needed

Identification Nos: 78, HCG 30, 5-069-0434

Age: 62

Tumour history: In 1991, the patient had epidermoid carcinoma of the cervix, with a recurrence in 1996

Dates of therapy: 6 August to 16 September 1996

Prescribed dose: AP pelvis, 15 × 15 cm

Estimated dose: 68 Gy, 25 fractions, 16 with the old source and nine with the new source

Findings: Patient has continuing diarrhoea, a 2 × 2 cm infected ulceration of the skin and also an ulcerated vaginal lesion

Conclusions: Infected ulcerations as a result of overexposure

Identification Nos: 83, HCG 16, 6-099-1017

Age: 44

Tumour history: Carcinoma of the cervix, stage IIIB

Dates of therapy: 12 August to 27 September 1996

Prescribed dose:

Estimated dose: 72 Gy, AP pelvis, 25 fractions, five with the old source and 20 with the new source, 16×25 cm, 10 Gy lateral ports in five fractions

Findings: Initially, the patient had grade 3 GI toxicity. Now has 10 kg weight loss, anaemia, continuing rectal bleeding and diarrhoea, and must wear a diaper

Conclusions: Severe GI complications as a result of overexposure

Identification Nos: 40, HSJD 8, 1-828-057

Age: 25

Tumour history: In February 1996, Hodgkin's disease, stage IIB, was diagnosed. CT showed a 5 cm superior anterior mediastinal mass. The patient received six cycles of chemotherapy

Dates of therapy: 5–27 September 1996

Prescribed dose: Treatment to anterior and posterior mediastina up to the level of the larynx, 19×18 cm

Estimated dose: 53 Gy in 17 fractions

Findings: Patient developed a pericardial effusion at 9 months post-therapy, which required mediastinoscopy and a pericardial window. A chest X ray from January 1997 also showed superior mediastinal and medial lung radiation pneumonitis or fibrosis. She suffers from fatigue and is often cold, and also reports mininal neurological findings

Conclusions: Changes as a result of radiation overexposure have occurred. The patient may have resultant hypothyroidism, which should be checked; she may also have some cervical and thoracic spinal cord changes. Detailed dosimetry needs to be done in this case

This patient developed walking problems and became incontinent

Identification Nos: 26, HSJD 7, 1-216-306

Age: 64

Tumour history: In 1996, it was noted that the patient had a squamous cell carcinoma of the right eye (outer canthus) and metastatic disease to the right neck. Neck dissection

Dates of therapy: 9–26 September 1996

Prescribed dose:

Estimated dose: Neck, 13×14 cm, 54 Gy in 14 fractions; and eye, 5×6 cm, 54 Gy in 14 fractions

Findings: The patient has limited motion of his jaw, and fibrosis of the right face and neck. An unexpected finding was drainage from the right ear and complete deafness after radiotherapy

Conclusions: This patient had a lateral and an anterior field. If there was an overlap, this could account for his ear problems. The treatment films need to be reviewed, if available

Identification Nos: 39, HJSD 45, 2-404-003

Age: 31

Tumour history: Left testicular seminoma (T1N0M0), followed by orchiectomy

Dates of therapy: 10–27 September 1996, 14 fractions

Prescribed dose: Inguinal, 18×4 cm

Estimated dose: 36.9 Gy, but a D_{max} of 59 Gy

Findings: The serum markers and two CT scans were normal. Patient has permanent epilation on left pubis and severe woody induration anteriorly, involving the entire inguinal canal. The patient reports limited range of motion of the hip

Conclusions: Issues related to the long term risks of femoral head asceptic necrosis, lymphoedema and vascular stenosis

Identification Nos: 62, HSJD

Age: 69

Tumour history: Carcinoma of the cervix, stage IIIB

Dates of therapy: 9–27 September 1996

Prescribed dose:

Estimated dose: Pelvis, 15×15 cm, 47 Gy in 15 fractions

Findings: The patient chart shows rectal bleeding, moist dermatitis, nausea and vomiting, and rectal bleeding during radiotherapy. She now has severe woody induration over the sacrum, with dark induration (picture taken). Also, a barium enema report showed narrowing of the rectosigmoid. Reportedly, the patient had a normal pelvic examination 1 month previously

Conclusions: Changes have occurred as a result of overexposure, with concern about skin breakdown with minimal trauma, difficult healing and rectal narrowing

Identification Nos: 95, HSG 36, 2-101-083

Age: 76

Tumour history: Carcinoma of the cervix, stage IIIB

Dates of therapy:

Prescribed dose: Pelvis, 14×16 cm, AP/PA

Estimated dose: 21.7 Gy in 23 fractions

Findings: Patient had an initial grade 3 GI reaction, and now has deep subcutaneous induration and marked skin changes; continuing diarrhoea until now

Conclusions: Marked skin reaction and GI effects as a result of overexposure. This does not match the estimated dose very well, therefore the dosimetry needs to be reassessed

Patients with effects attributable to radiotherapy
but not severe at this time:
At some risk of future effects

Identification Nos: 13, 1-035-705-88

Age: 48

Tumour history: Adenocarcinoma of the endometrium, with surgery for a total abdominal hysterectomy and bilateral salpingo oophorectomy (TAH and BSO)

Dates of therapy: 18–27 September 1996

Prescribed dose: 300 cGy, AP one day, PA the next. Additional therapy with lateral ports, 1–7 November 1996, in five fractions

Estimated dose: 24 Gy AP/PA in eight fractions and lateral 14 Gy in five fractions

Findings: The patient chart indicated grade 2 GI toxicity. Initially, there was skin breakdown, now there is not much pigmentation, except for a central small scar from skin healing over the upper sacrum; the patient reports pain here. Also, the patient complained of pain and tenderness over the entire abdomen; now she has intermittent diarrhoea

Conclusions: Intermittent diarrhoea as a result of the radiation therapy

Identification Nos: 35, HSJD 22, 5-105-383

Age: 52

Tumour history: In September 1994, the patient was found to have a carcinoma of the endometrium, diagnosed as grade 2, followed by TAH and BSO. In 1996, there was a positive inguinal node and metastases to the vulva

Dates of therapy: 2–27 September 1996

Prescribed dose: Anterior pelvis, 8×8 cm

Estimated dose: 62 Gy to the tumour in 20 fractions

Findings: Patient now has colitis and intermittent diarrhoea; she also has minor skin breakdown; picture taken

Conclusions: Minor skin breakdown and intermittent diarrhoea as a result of radiotherapy

Identification Nos: 61, HSJD 42, 1-205-006

Age: 66

Tumour history: An epidermoid carcinoma of the right vocal cord was diagnosed in 1985; radiotherapy was carried out at that time. In 1996, another epidermoid carcinoma was found on the right tonsil. The patient received two cycles of chemotherapy with 5-FU

Dates of therapy: 9–27 September 1996

Prescribed dose:

Estimated dose: 75 Gy

Findings: The patient reports a dry mouth and loss of taste, with fibrosis appropriate to standard radiotherapy; saliva in mouth was adequate upon examination

Conclusions:

Identification Nos: 10, HSJD 34, 2-303-591

Age: 42

Tumour history: Prior cancer of the left breast, with a positive node; mastectomy was performed. In 1996, an invasive carcinoma of the cervix was diagnosed and a TAH performed

Dates of therapy: 20–27 September 1996, followed by ^{137}Cs brachytherapy in December 1996

Prescribed dose: Pelvis, 15×15 cm, AP/PA each day, 40 Gy of caesium

Estimated dose: 18.6 Gy in six fractions

Findings: Patient now has tense swelling of the entire right leg. Doppler ultrasound was used to clear the vessels, and now the patient awaits a lymphangiogram or MRI scan

Conclusions: The patient may have residual disease, although unilateral oedema can occur after radiotherapy

Identification Nos: 7, HSJD 38, 1-124-333

Age: 78

Tumour history: A well differentiated carcinoma of the cervix, stage IIIB, with right hydronephrosis
Dates of therapy: 17–27 September 1996
Prescribed dose: Pelvis, 15 × 15 cm
Estimated dose: 27 Gy in nine fractions
Findings: Patient had diarrhoea, nausea and vomiting during therapy. She now has occasional diarrhoea, but no bleeding
Conclusions: Minimal diarrhoea as a result of radiotherapy

Identification Nos: 31, HSJD 10, 1-228-173
Age: 62
Tumour history: In July 1996, the patient had a right posterior (sixth?) lytic rib lesion biopsied, which turned out to be a large cell carcinoma. There was concurrent radiation therapy and chemotherapy, with cis-platinum and velban (one cycle)
Dates of therapy: 2 August to 11 September 1996
Prescribed dose: 12 × 12 cm
Estimated dose: 58 Gy, 15 fractions, D_{max} of 69 Gy
Findings: The patient has pain and limited motion of the right shoulder. The treatment port included inferior medical glenoid to the midline and inferior to the right hilum. Chest X rays showed infiltrate in the right mid-lung and volume loss. The CT scan showed the posterior lytic rib lesion, a right infiltrate sparing the upper lobe (not geometrical). There is also a 2 cm nodular density just posterior and lateral to the right pulmonary artery
Conclusions: Owing to the volume loss, changes have occurred that are consistent with normal radiotherapy. The infiltrate and nodular density are worrisome for a tumour

Identification Nos: 74, HCG 11, 5-080-817
Age: 50
Tumour history: In April 1996, the patient was operated upon for carcinoma of the vulva. The lymph nodes were 1/7 positive
Dates of therapy: 5–19 August 1996 and 26 August to 9 September 1996
Prescribed dose: Pelvis, AP, 20 × 26 cm
Estimated dose: 54 Gy in 21 fractions
Findings: Patient has some rectal bleeding now, but aetiology is uncertain; thrombosis of the left leg
Conclusions: No definite severe effects from overexposure

Identification Nos: 100, HCG 26, 1-533-824
Age: 41
Tumour history: In 1995, the patient had a seizure and was found to have a right occipital grade 2 oligodendroglioma, which was partially resected
Dates of therapy: 30 July to 13 September 1996
Prescribed dose: 60 Gy
Estimated dose: 38 Gy anterior and 38 Gy lateral in 30 fractions, 16 with the old source and 14 with the new source

Findings: CT showed that the patient is now free of disease
Conclusions: Some concern about long term potential necrosis, but the patient is currently well

Identification Nos: 89, HSG 39
Age: 59
Tumour history: Endometrial carcinoma in 1995, followed by TAH and BSO, which showed lymphatic infiltration
Dates of therapy: 16–25 September 1996
Prescribed dose: Pelvis, 16×15 cm
Estimated dose: 35 Gy, 11 fractions, AP/PA fields, both done each day
Findings: Initially reported as grade 3 GI reaction; now, thin skin over the sacrum but no other effects or complaints
Conclusions: No adverse effects of exposure, but potential skin breakdown and GI effects

Identification Nos: 70, HCG—, 3-075-321
Age: 74
Tumour history: Carcinoma of the left parotid, with surgery in March 1996
Dates of therapy: 12 August to 20 September 1996
Prescribed dose:
Estimated dose: 72 Gy in 25 fractions, five with the old source and 20 with the new source, 15×9 cm, D_{max} of 83 Gy
Findings: Patient has difficulty in hearing on the left side, but there is cerumen plugging. Initially, it was felt that grade 3 otitis was present immediately after therapy
Conclusions: No definite adverse effects, only limited ear examination was carried out

Identification Nos: 50, HSJD 20, 3-185-023
Age: 42
Tumour history: In 1982, non-Hodgkin's lymphoma was diagnosed. In 1991, the patient had left axillary adenopathy and received CHOP and bleomycin. In 1996, he had a relapse in the neck
Dates of therapy: 5–22 September 1996
Prescribed dose:
Estimated dose: 53 Gy, 11×18 cm, 17 fractions to the anterior neck, 11×28 cm
Findings: Some skin fibrosis and pigmentation, which are not serious; patient has a significant suntan
Conclusions: No adverse effects of overexposure

Identification Nos: 64, HSJD 29, 733-77215-434
Age: 44
Tumour history: Stage IIB carcinoma of the cervix, with TAH and BSO
Dates of therapy: 28 August to 20 September 1996
Prescribed dose:
Estimated dose: 45 Gy, 18 fractions to the pelvis, 15×15 cm, AP 13 sessions and posterior 12 sessions. First 10 fractions on the Theratron and only eight on the Alycon

Findings: Patient has mild diarrhoea, with minimal occasional bleeding. Mild skin pigmentation

Conclusions: No severe radiation effects; only eight treatments with the new source

Identification Nos: 55, HSJD—, 105-850639
Age: 35
Tumour history: In March 1993, mass in supraclavicular, with non-Hodgkin's lymphoma diagnosis, stage IIIA, chemotherapy. In 1996, splenomegaly and retroauricular and mesenteric nodes, therapy of the left axilla in April 1996
Dates of therapy: 11–27 September 1996
Prescribed dose: 13 fractions of the left base of the neck, 18×9 cm, one field per day
Estimated dose: 40 Gy
Findings: Widespread disease (lymphoma in abdomen). Dry mouth, which should return to normal, but fractionation was small for the total dose
Conclusions: No major adverse effects; apparently the CT shows widespread abdominal disease, which is untreatable because of bone marrow depression from previous chemotherapy

Identification Nos: 45, 1-044120145
Age: 43
Tumour history: Patient with years of Cushing's disease
Dates of therapy: 29 July to 23 August: nine fractions to the right and nine fractions to the left head, one field per day. 26 August to 3 September 1996: four fractions to the right and three fractions to the left. Total of 25 fractions
Prescribed dose:
Estimated dose: 58 Gy in 14 fractions, 5×5 cm
Findings: Hair had fallen out completely, but has partially regrown. Difficulty in chewing, probably as a result of fibrosis (picture of left side and portal film with ID marker)
Conclusions: Expected fibrosis as a result of radiotherapy. Long term effects on the brain and optic nerves

Identification Nos: 105, Hospital de Niños
Age: 7
Tumour history: Acute lymphatic leukaemia diagnosed, with meningeal involvement
Dates of therapy: 16 August to 16 September 1996
Prescribed dose:
Estimated dose: 54 Gy, 18 fractions to cranium, and 19 Gy, six fractions to the thoracic spine, 23×5 cm, and the lumbar spine, 16×5 cm
Findings:
Conclusions:

Identification Nos: 37, HSJD—, 1-01610363
Age: 29
Tumour history: Adenocarcinoma of the prostate, Gleason 2, with TURP
Dates of therapy: 22 July to 19 August, and 28 August to 9 September 1996

Prescribed dose:

Estimated dose: 47 Gy + 37 Gy = 74 Gy, 8 × 8 cm, first treatment, AP/PA, 21 fractions with one field each day, 14 × 14 cm, and second treatment, 8 × 8 cm rotational field

Findings: Abdominal cramps, but no GI bleeding or haematuria. Slight fibrosis, AP and PA fields only

Conclusions: No adverse effects observed now. Potentially, rectal or bladder problems should be followed up

Identification Nos: 38, HSJD—, exp 502551

Age: 38

Tumour history: In August 1995, a visual field defect and a pituitary adenoma appeared, with transsphenoidal resection

Dates of therapy: First treatment, 24 July to 19 August 1996; and second treatment, 26 August to 6 September 1996

Prescribed dose:

Estimated dose: 61 Gy: first treatment, 15 fractions; second treatment, 10 fractions, 5 × 5 cm, 13 fractions from the right and 12 from the left

Findings: 90% epilation in portal areas; the patient has various problems, mainly related to endocrinology

Conclusions: Not totally out of risk for optic nerves, etc.

Identification Nos: 76, HCG—, 1-128-601

Age: 76

Tumour history: Epidermoid carcinoma of the oesophagus, lower third, inoperable. Chemotherapy 1 week in July 1996. Right lung removed 30 years ago for tuberculosis

Dates of therapy: 3 July to 14 August 1996

Prescribed dose:

Estimated dose: 22 Gy, but from medical records, 62 Gy, 50 Gy with the old source and 12 Gy with the new source, 30 fractions, AP, 12 + 11 lateral, seven fractions, 19 × 4 cm

Findings: Seems quite well

Conclusions: Small potential problem with remaining lung, but no significantly adverse effects. The dosimetry in the medical record did not match the Expert Team's records

Identification Nos: 56, HCG

Age: 72

Tumour history: Anaplastic carcinoma of the bladder, with lymph node invasion, partial resection

Dates of therapy: 23 August to 17 September 1996

Prescribed dose:

Estimated dose: 36 Gy, 12 fractions, instead of the 30 prescribed. When treatment was interrupted, the patient did not want any further therapy. AP, pelvis, 14 × 14 cm

Findings: Diarrhoea is well controlled by medication, and skin is good. Significant psychological problems

Conclusions: Significant psychological problems probably as a result of the accident, even though the patient did not receive significant overexposure and has no somatic effects

Identification Nos: 115

Age: 51

Tumour history: In 1990, breast cancer, T3N1M0, with 2/17 nodes positive. Had radical surgery and six cycles of chemotherapy. Received radiotherapy for pain in the neck and back related to arthrosis, but there were no known metastases

Dates of therapy: 6–20 September 1995 (10 fractions, lumbar spine), 16–23 August 1996 (six fractions, dorsal), 26–29 August 1996 (four fractions, dorsal)

Prescribed dose:

Estimated dose: 46 Gy in 10 fractions to the lumbar spine, 18×6 cm, and the thoracic spine, 20×5 cm

Findings: Lumbar region fine after treatment in 1995. Dorsally, there is induration and fibrosis from treatment with the miscalibrated source

Conclusions: No major adverse effects at this time

Identification Nos: 102, Hospital de Niños

Age: 11

Tumour history: Acute lymphatic leukaemia diagnosed, with meningeal involvement. The patient received chemotherapy and radiotherapy

Dates of therapy: 12 August to 12 September 1996

Prescribed dose: 32 Gy to the cranium and 12 Gy to the spine

Estimated dose:

Findings:

Conclusions: Probable decreased school performance as a result of the therapy. A more detailed dose evaluation would be useful

Identification Nos: 87, Hospital de Niños

Age: 13

Tumour history: Medulloblastoma diagnosed in April 1996. The patient had two courses of chemotherapy, followed by radiotherapy, and then another six courses of chemotherapy and surgery

Dates of therapy: 1 July to 30 August 1996

Prescribed dose: 50 Gy to the posterior fossa and 20 Gy to the spine

Estimated dose: 16.4 Gy to the thoracic spine and 16.2 Gy to the lumbar spine in eight fractions each

Findings: Thin hair all over, probably as a result of chemotherapy

Conclusions: No definite effects of overexposure yet. Much of the therapy was before the source was changed. This case should be followed up

Identification Nos: 42, HSJD 40, 2-298-967

Age: 41

Tumour history: Left parotid gland, mixed malignant tumour. The patient had surgery and then radiotherapy because of capsular invasion

Dates of therapy: 27 August to 27 September 1996

Prescribed dose:

Estimated dose: 71 Gy in 23 fractions

Findings: The patient showed post-surgical changes to the left side. It is reported that he has no ability to taste salt, bitter or sweet foods. He has also been tested and been shown to have decreased (but not absent) hearing in the left ear

Conclusions: Mild changes caused by radiation exposure. Taste may or may not return. Hearing needs to be followed up

Identification Nos: : 63, HSJD 21, 2-150-961

Age: 72

Tumour history: Carcinoma of the prostate, no surgery

Dates of therapy: 27 August to 13 September 1996

Prescribed dose:

Estimated dose: 46 Gy, 14 × 14 cm, 14 fractions

Findings: During therapy the patient had skin ulceration, cramps, tenesmus, grade 3 cystitis and diarrhoea. He now has marked skin pigmentation, with woody induration evident, particularly over the sacrum

Conclusions: Skin changes from overexposure. Worry about late breakdown as a result of minor trauma with difficult healing. The patient may also have rectal changes, but this would require further study

Identification Nos: 36, HSJD, 2-80-5-9957-2217

Age: 54

Tumour history: In 1994, the patient was found to have infiltrating ductal breast cancer, T4N1M0. Chemotherapy and radiotherapy at that time. In 1996, low back pain with sclerotic lesion L5

Dates of therapy: 8–28 August 1996

Prescribed dose: Spine

Estimated dose: 42 Gy, 14 fractions, 15 × 6 cm

Findings: Subjectively, there are no problems, hyperpigmentation in field, without ulceration, reflexes normal

Conclusions: No major adverse effects at this time

Identification Nos: 48, HSJD 40, 1-141-308

Age: 75

Tumour history:

Dates of therapy:

Prescribed dose: Mediastinum, 10 × 6 cm

Estimated dose: 62 Gy in 23 fractions

Findings: Patient visited at home, apparently terminal, clinically anorexic

Conclusions: Oesophageal/tracheal fistula, probably due to the tumour

The patient died in July 1997, before this report was finalized

Patients without obvious effects at this time:
At low risk of future effects

Identification Nos: 75, HSG 37, 9-004-0129

Age: 60

Tumour history: Epidermoid carcinoma of the forearm, surgery showed 4/23 positive axillary nodes

Dates of therapy:

Prescribed dose: Right axilla and forearm

Estimated dose: 52 Gy to the right axilla in 21 fractions, and 22 Gy to the forearm in 12 fractions

Findings: The patient is in a terminal state as a result of tumour metastases, and is bedridden and currently on morphine

Conclusions: Terminal state due to tumour. No definite adverse effects as a result of radiation exposure

The patient died in mid-August 1997, following the Expert Mission and prior to the drafting of this report

Identification Nos: 17, HCG

Age: 72

Tumour history: Pleomorphic fibrous histiocytoma of the tibia, with surgical resection in July 1996

Dates of therapy: 13 July to 27 September 1996

Prescribed dose: 60 Gy

Estimated dose: 34 Gy, only received 11 fractions instead of the prescribed 30, 16×7 cm

Findings: Poor healing after radiotherapy, and reoperated in December 1996. Now, good healing and thin skin

Conclusions: No adverse effects of radiation

Identification Nos: 101

Age: 40

Tumour history: Brain astrocytoma

Dates of therapy: 9 July to 3 September 1996

Prescribed dose:

Estimated dose: 62 Gy in 30 fractions, 25 with the old source and five with the new source, anterior 6×8 cm and lateral 6×8 cm

Findings: No obvious problems related to radiotherapy. Patient initially appeared angry, but was ultimately fine

Conclusions: No obvious adverse effects of overexposure

Identification Nos: 79, HCG 14, 1-284-257

Age: 57

Tumour history: Granulosa cell carcinoma of the ovary diagnosed in 1991, with recurrences in 1995 and 1996

Dates of therapy: 24 August to 12 September 1996
Prescribed dose:
Estimated dose: 44 Gy, 15 × 16 cm, 14 fractions
Findings: Initially had grade 3 intestinal reaction. Now, no definite complications
Conclusions: No definite complications from radiotherapy

Identification Nos: 19, HSJD—, 201650544
Age: 62
Tumour history: In March 1996, the patient suffered from a pain in the rectum, with an enlarged prostate. The diagnosis was carcinoma, with metastases to the bone and lymph nodes. Treated with hormones, orchiectomy and radiotherapy. The bone scan is positive in many areas. Later, pelvic radiotherapy (December 1996)
Dates of therapy: 25–27 September 1996
Prescribed dose:
Estimated dose: 12 Gy in three fractions, two anterior and one posterior, right shoulder
Findings: No problems of radiation effects, generalized bone pain, patient on morphine, films of the pelvis show generalized diffuse osseous metastases
Conclusions: No radiation effects, widespread metastatic disease

Identification Nos: 15, HSJD 47, 2-088-65-19
Age: 80
Tumour history: Transitional cell carcinoma of the bladder (TxN0M0)
Dates of therapy: 20–27 September 1997
Prescribed dose: Pelvis, 14 × 14 cm
Estimated dose: 36.6 Gy, six fractions, treatment halted because of the accident
Findings: Initial diarrhoea and bleeding during therapy, now without significant colitis complaints
Conclusions: No evidence of problems related to overexposure, treatment was stopped early because of the accident

Identification Nos: 25, HSJD 18, 1-513-542
Age: 38
Tumour history: Mastectomy in 1995, with a recurrence in 1996, and thoracostomy for a metastatic lesion. The patient had received chemotherapy in 1993 and radiation therapy in April 1996. She had a peritoneal fluid tap in January 1996, which revealed malignant cells, and a bone scan in July 1996, which showed many osseous metastases
Dates of therapy: 5–10 August 1996
Prescribed dose: The patient received five fractions to the right hemipelvis (anterior and posterior) and five fractions to the right and lateral lower ribs
Estimated dose: 8 × 13 cm, 58 Gy, five fractions
Findings: Minimal skin pigmentation over right hemipelvis
Conclusions: No adverse effects of overexposure

Identification Nos: 23, HSJD17, 1-511-043
Age: 38

Tumour history: Left arm tumour in deltoid, diagnosis was aggressive angiomyoma

Dates of therapy: 12–27 September 1996 and January 1997

Prescribed dose: 21 × 10 cm of entire humerus

Estimated dose: 40 Gy in 13 fractions

Findings: Little evidence of skin pigmentation, surgical scar over lateral inferior deltoid, no epilation. Patient says that he has some stiffness and pain in the anterior deltoid when raising his elbow

Conclusions: No adverse effects of overexposure

Identification Nos: 12, HSJD, 1-0182-0436

Age: 69

Tumour history: 70 carton per year smoking history. In August 1996, hypopharynx epiglottis and arytenoid carcinoma T3N0M0. Treated with concurrent chemotherapy and radiation therapy. In hospital during therapy with severe mucositis

Dates of therapy: 11–27 September 1996

Prescribed dose: Neck, 8 × 9 cm, two fields

Estimated dose: 37 Gy in 12 fractions

Findings: No adverse effects

Conclusions: No apparent adverse effects

Identification Nos: 49, HSJD 19, 1-205-006, 201610813

Age: 64

Tumour history: In 1988, seizure, CT lesion compatible with infarct. In June 1996, gastroscopy showed oesophageal carcinoma, chemotherapy

Dates of therapy: 29 July to 23 August 1996, 18–27 September 1996

Prescribed dose:10 × 10 cm, mediastinum anterior and posterior each day, both fields, 1 Gy/field, then two angled fields (1.8 Gy) treated each day to oesophagus, 4 × 8 cm

Estimated dose: 25 Gy, 20 + eight additional treatments

Findings: The October gastroscopy findings were normal. The patient reported pain in the legs, but an MRI of the entire spinal cord was normal. There is posterior and anterior epilation, and very mild skin changes

Conclusions: No definite radiation effects

Identification Nos: 117, HCG—, 3-173-015

Age: 48

Tumour history: Carcinoma of the cervix, stage IB, with chemotherapy in 1995; tumour felt to be cured, but it reappeared in August 1996 as stage IIIB

Dates of therapy: 25–27 September 1996, therapy later completed in January 1997. In April 1997, it was thought that the patient had a residual or recurrent tumour

Prescribed dose: 16 ×15 cm, 12 fractions

Estimated dose: 11.2 Gy with the new source

Findings: Large abdominal mass, pain in abdomen and vomiting

Conclusions: No findings related to the adverse effects of radiotherapy

Identification Nos: 53, 9-0041-0020
Age: 52
Tumour history: Adenocarcinoma of the rectum, AP resection and colostomy, post-operative radiation therapy
Dates of therapy: 9–22 September 1996, pelvic region
Prescribed dose:
Estimated dose: 47 Gy, AP, 14 × 14 cm, PA, 14 × 14 cm, one field each day, good portal film, anterior eight fractions, posterior seven fractions, total 15 fractions
Findings: Pain in the groins after treatment, with some intestinal cramps, some minimal fibrosis and tanning, posterior, very little abnormal, no urinary symptoms (picture of the anterior field taken)
Conclusions: No special problems anticipated

Identification Nos: 14, HSJD 24, 5-111-580
Age: 52
Tumour history: Unknown primary tumour, with osseous metastases, lesions of the left femur, humerus, but not with metastatic disease to the brain
Dates of therapy: 19 August 1996
Prescribed dose: To the left femur, four fractions, and to the spine, 10 fractions, palliation
Estimated dose:
Findings: No changes as a result of radiation
Conclusions: Palliated and no changes because the patient only received four and ten treatments
Patient died of osseous metastases at the end of August 1996

Identification Nos: 21, 1-0530-0604
Age: 36
Tumour history: Cervical carcinoma, vaginal application of caesium, 25 Gy, 54 hours
Dates of therapy: 18–22 September1996
Prescribed dose:
Estimated dose: 25 Gy, AP/PA, 15 × 15 cm, four fractions anterior and four posterior, one field per day at 3.65 cGy D_{max} per day
Findings: Skin fine, but the patient complains of diarrhoea
Conclusions: No future problems expected, radiotherapy unlikely to be responsible for intestinal problems

Identification Nos: 103, Hospital de Niños
Age: 10
Tumour history: Acute lymphatic leukaemia diagnosed in 1990 at the age of 3, with meningeal involvement. Testicular relapse in 1992. Received 24 Gy to the cranium, 24 Gy to the testicles and 12 Gy to the spine. In July 1996, there was another testicular relapse
Dates of therapy: 6–18 August 1996
Prescribed dose: 24 Gy to the testicles
Estimated dose:

Findings: Testicles present, but slightly small, minimal skin pigmentation, no other findings
Conclusions: No adverse effects, probably because most of the treatment was completed before the new source was installed

Identification Nos: 22, HSJD
Age: 46
Tumour history: Diagnosed in August 1996, with a pure seminoma in the left testicle, stage I
Dates of therapy: 16–27 September 1996
Prescribed dose: 24 Gy
Estimated dose: 31 Gy, 16 × 14 cm, left groin, 10 fractions
Findings: Slight oedema, otherwise fine
Conclusions: No adverse effects seen or expected

Identification Nos: 32, HSJD 25, 1-221-976
Age: 64
Tumour history: Adenocarcinoma of the cervix diagnosed in 1989. In January 1990, the patient had radiotherapy for a large left parametrial mass. In 1996, there was a pathological fracture of the upper humerus. Now has additional metastases
Dates of therapy: 20–22, 26 August to 2 September 1996
Prescribed dose:
Estimated dose: 31 Gy, 12 × 6 cm, a total of 11 fractions to the lumbar spine
Findings: Some pigmentation and skin fibrosis, persistent diarrhoea
Conclusions: No unexpected findings from overexposure

Identification Nos: 88, HCG —, 1-700-088
Age: 88
Tumour history: In 1989, basal cell carcinoma of the nose. Now with recurrence verses keratosis
Dates of therapy: 27 June to 9 September 1996
Prescribed dose:
Estimated dose: 15.5 Gy in eight fractions, three with the old source and five with the new source, 3 × 3 cm nasal field, prior dose of 50 Gy
Findings: The patient has some very focal necrosis of the inferior lateral left nares that is felt to be the result of the tumour, no definite radiation changes
Conclusions: No definite adverse effects, probable minimal necrosis as a result of the tumour

Identification Nos: 69, HCG—, 1-781-758
Age: 68
Tumour history: In 1996, T1 breast cancer, with 1/15 nodes positive, chemotherapy and surgery before radiation therapy
Dates of therapy: 24 July to 27 September 1996
Prescribed dose: Hockey stick, 14 × 14 cm
Estimated dose: 66 Gy, 25 fractions, 12 with the old source and 13 with the new source, D_{max} of 72 Gy

Findings: No adverse effects noted
Conclusions: No adverse effects at this time

Identification Nos: 98, HCG 43, 1-332-999
Age: 50
Tumour history: Breast cancer in inner quadrant, chemotherapy before radiotherapy
Dates of therapy: 25 July to 3 September 1996
Prescribed dose:
Estimated dose: 71 Gy, 23 fractions, 18 with the old source and seven with the new source. Anterior only field was along the right lateral aspect of the sternum to cover the internal mammary nodes
Findings: Patient has minimal skin pigmentation, no other effects now
Conclusions: No adverse effects of overexposure

Identification Nos: 81, HCG 41, 9-055-935
Age: 72
Tumour history: T4 epidermoid cancer of the mouth, with left radical neck dissection in 1995. Patient initially treated in May 1996 with 15 fractions, and then no follow-up until 29 July
Dates of therapy: 29 July to 4 September 1996
Prescribed dose:
Estimated dose: Five fields, 20 fractions, 12 with the old source and eight with the new source. Right neck 19 Gy, and left neck 8 Gy. Doses on other fields not estimated
Findings: Post-surgical neck dissection changes. The patient complains of a dry mouth, but upon examination saliva appears to be adequate. Patient also has mild dysphagia
Conclusions: No definite adverse effects as a result of overexposure

Identification Nos: 2, HCG 46, 9-003-211
Age: 58
Tumour history: Cancer of the nasopharynx, treated initially in June 1996 with three cycles of chemotherapy
Dates of therapy: 20–27 September 1996
Prescribed dose: Larynx and neck
Estimated dose: 19 Gy to the neck and 10 Gy to the larynx, six fractions only. Treatment ceased because of the accident. Continued the remainder of the therapy after 3 months
Findings: No radiation related adverse effects noted
Conclusions: No radiation related adverse effects noted

Patients underexposed

Identification Nos: 1, HSJD 33, 1-431-892
Age: 43
Tumour history: In 1992, left breast cancer, with a mastectomy in 1993. Radiation therapy December 1993 to January 1994 with tangential fields. Supraclavicular recurrence in 1996

Dates of therapy: 24–27 September 1996
Prescribed dose:
Estimated dose: 13 Gy , 12 × 11 cm, four fractions before discovery of the accident
Findings: No adverse effects
Conclusions: No adverse effects, since the patient only received four fractions

Identification Nos: 20 , HCG 23, 6-108-780
Age: 42
Tumour history: In 1993, a left olfactory meningioma was diagnosed, which was operated upon three times, but with persistent recurrences
Dates of therapy: 24–27 September 1996
Prescribed dose: Oblique fields
Estimated dose: 13 Gy, four fractions only. Treatment ceased because of the accident. No further radiotherapy
Findings: The patient is blind in the right eye as a result of prior surgery. Recurrent tumour noted on CT scan in the ethmoid sinuses, invading the orbits and destroying the bone. Moderate left exophthalmos as a result of the tumour. Patient is currently contemplating more surgery
Conclusions: No adverse effects of radiation exposure

Patients not seen

Identification Nos: 120, HCG—, 3-129-199
Age: 59
Tumour history: Right parotid, hyperpigmentation, with alteration of taste. Cutaneous atrophy in the area irradiated, regrowth of hair, no indication of local relapse. Dermatitis actinica following overexposure, with yellowish secretion and 40% perforation
Dates of therapy:
Prescribed dose:
Estimated dose:
Findings: The patient did not come to be examined and does not appear to be on the main list
Conclusions: Patient treated prior to the change of the source

Identification Nos: HSJD 15, 2-114-280
Age: 74
Tumour history: Cancer of the cervix
Dates of therapy: 26 August to 10 September 1996
Prescribed dose: Pelvis, 15 × 15 cm
Estimated dose: 49 Gy, in 19 fractions
Findings: The patient did not come to be examined
Conclusions:

Identification No: 111
Age:

Tumour history:
Dates of therapy:
Prescribed dose: Lung
Estimated dose: 43 Gy, 12 fractions, 16 × 10 cm
Findings: The patient was out of the country at the time of the Expert Mission, therefore not seen
Conclusions:

Deceased patients

Data on 34 of the 42 deceased patients (about 80%) were reviewed.

In seven cases, the autopsies are complete. In others, the autopsies are in progress and we were able to review photographs of specimens and the patients. In some cases, only fragmentary data were available, while in others our judgement was based on the hospital records or the magnitude, location and fractionation of the radiation received.

The cause of death in a tumour patient is difficult to assess without complete autopsy data, as well as data on the circumstances at the time of death. Since all the patients received radiation therapy, almost all will have histopathological changes related to radiation exposure. However, this does not imply that radiation was always a proximate cause or major contributor to death. The judgements of the Expert Team are based on data available at the time, are very preliminary, and should not be construed as the final answer.

A summary of these patients (total 42) is as follows: three patients, where radiation was the major factor in the cause of death; four patients, where radiation was a substantial contributor to death; 22 patients, where death was related to a tumour or cause other than radiation; five patients, where not enough data were available to make a judgement; and eight patients, where data could not be reviewed by the Expert Team.

Patients who died
with radiation exposure as the probable major cause

Identification Nos: 57, 96-2137, 307613592
Age: 79
Date of death: 22 December 1996
Cause of death:
Tumour history: Chronic lymphatic leukaemia, patient was in hospital 14 days before death
Dates of therapy:
Prescribed dose:

Estimated dose: 44 Gy, 29 × 23 cm, abdominal field, 12 fractions with the old source and 10 with the new source. Hospital charts showed a much lower dose than that calculated by the Expert Team

Findings: The patient was embalmed, but photographs appear to show GI haemorrhage

Conclusions: Death probably radiation related

Identification Nos: 59, 96-1774, 2174632, 21740632

Age: 61

Date of death: 28 October 1996

Cause of death: Necrotizing tracheobronchitis and bilateral upper lobe pneumonia

Tumour history: Malignant lymphoma

Dates of therapy: 26 August 1996

Prescribed dose: Anterior chest and neck

Estimated dose: 62 Gy anterior, and 50 Gy exit dose, 20 fractions

Findings: Autopsy complete. Necrosis of the pharynx and larynx, epilation over the posterior fossa from the exit dose, path slides also show necrosis and haemorrhage in the thyroid and denudation of tracheal mucosa. Possible radiation pneumonitis as well, complicated by bacteria

Conclusions: Radiation was the major cause of death. This was also the conclusion of the coroner

Identification Nos: 18 , 96-1719

Age: 64

Date of death: 19 October 1996

Cause of death: Upper GI bleeding

Tumour history: Carcinoma of the cervix, stage IIB

Dates of therapy: 5–29 September 1996

Prescribed dose:

Estimated dose: 38 Gy tumour dose, D_{max} of 68 Gy, 15 × 15 cm, 12 fractions

Findings: Patient had haemorrhage and diarrhoea before therapy was completed. Was hospitalized and never left the hospital. Photographs show colonic haemorrhage with perforation, small bowel petechiae, and haemorrhage of cervix and uterus

Conclusions: Radiation was the major cause of death. This was also the conclusion of the coroner

Patients in whom radiation appeared to have played a major role

Identification Nos: 67, 97-987, 5-0960984

Age: 54

Date of death: To forensics on 19 June 1997

Cause of death:

Tumour history: Retroperitoneal sarcoma, with incomplete surgery

Dates of therapy:

Prescribed dose: Right abdomen, 31 × 22 cm, two fields, 16 fractions with the new source

Estimated dose: 50 Gy

Findings: Gastric ulceration, hyperpigmentation of the skin on the right abdomen, necrosis of

the right colon, 4500 g extensive tumour

Conclusions: Radiation may have played a major role because of the changes in the right colon in the therapy area

Identification Nos: 60, 96-1851
Age: 60
Date of death: 8 November 1996
Cause of death: Acute necrotic colitis, moderately differentiated lymphocitic lymphoma, pharyngitis, and acute and necrotic tracheitis as a result of irradiation
Tumour history: Non-Hodgkin's lymphoma
Dates of therapy:
Prescribed dose:
Estimated dose: Face, 13 × 8 cm, lateral fields, 24 fractions in total, 16 Gy to the left side and 40 Gy to the right side. Anterior face, 9 × 2 cm, 24 fractions, 24 Gy; anterior neck, 25 × 10 cm, 24 fractions, 72 Gy
Findings: No skin ulceration, mucosa and oedema, and some necrosis of the pharynx and trachea
Conclusions: Radiation may have been a major contributor to death

Identification Nos: 46, 97-187, 1-203-954
Age: 72
Date of death: To forensics on 26 January 1997
Cause of death: Cancer of the tongue, mucositis and oesophagitis
Tumour history: Carcinoma of the tongue
Dates of therapy:
Prescribed dose:
Estimated dose: 72 Gy, face, 8 × 7 cm, five fractions with the old source and 20 with the new source. 62 Gy, neck, 16 × 7 cm, one field, 20 fractions, all with the new source
Findings: Photographs of gross autopsy show facial oedema, swelling at the base of the tongue and larynx, no obvious tumour
Conclusions: Radiation may well have been a major contributor to death

Identification Nos: 52, 97-110, 4-051-822
Age: 73
Date of death:
Cause of death:
Tumour history: Cancer of the hypopharynx, May 1996
Dates of therapy:
Prescribed dose: 13 × 9 cm , two fields, nine fractions
Estimated dose: 92 Gy, neck
Findings: Gross autopsy findings: hard swollen neck, marked tanning with depigmentation over the larynx, oedema of the piriform sinuses and the base of the tongue, with fibrous changes
Conclusions: Radiation may have been a major contributory cause of death

Patients in whom radiation did not appear to have played a major role

Identification Nos: 27, 97-15, 1-209-835
Age: 65
Date of death: 2 January 1997
Cause of death: Cancer of the oesophagus
Tumour history: Cancer of the oesophagus
Dates of therapy: 13 August to 25 September 1996
Prescribed dose:
Estimated dose: 55 Gy, 12×6 cm, five fractions with the old source and 15 fractions with the new source
Findings: The completed autopsy report and pictures were reviewed
Conclusions: The official coroner's report concluded that there was no relation to radiation. The Expert Team agreed

Identification Nos: 71, 97-42
Age: 65
Date of death: 13 February 1997
Cause of death:
Tumour history: Adenocarcinoma of the rectum
Dates of therapy:
Prescribed dose: Pelvis, 10×7 cm
Estimated dose: 16 Gy in 10 fractions
Findings: Autopsy, 8×8 cm, sigmoid tumour, and 8×8 cm, rectal neoplasm
Conclusions: The dose was too low for radiation to have had an effect

Identification Nos: 11, 97-122, 01-0122-0518
Age: 74
Date of death: 17 January 1997
Cause of death:
Tumour history: Breast cancer
Dates of therapy:
Prescribed dose:
Estimated dose: 31 Gy in six fractions, one with the old source and five with the new source, right ribs, 9×4 cm
Findings:
Conclusions: The dose was too low, the field size small and the location not critical. Pictures show no major skin reaction

Identification Nos: 28, 96-2096, 06-0034-0653
Age: 66
Date of death: 19 December 1996
Cause of death:
Tumour history: Lung cancer T4N2M0

Dates of therapy:

Prescribed dose:

Estimated dose: 50 Gy to the mediastinum, 15 × 10 cm, 20 fractions, 11 with the old source and nine with the new source

Findings: Autopsy. The patient had oesophagitis, but died from pericardial and other wide-spread metastases

Conclusions: Radiation was not a major contributory cause of death

Identification Nos: 29, 96-2123

Age: 53

Date of death: 22 December 1996

Cause of death:

Tumour history: Breast cancer

Dates of therapy:

Prescribed dose:

Estimated dose: 30 Gy to the right shoulder, 10 fractions, 13 Gy to the spine, 19 × 7 cm, eight fractions, five with the old source and three with the new source

Findings:

Conclusions: The dose was too low to be a significant factor

Identification Nos: 65, 97-73, 6-01030081

Age*: 43*

Date of death: To forensics in November 1996

Cause of death:

Tumour history: Breast cancer

Dates of therapy:

Prescribed dose:

Estimated dose: 39 Gy to the left arm, one field, 20 × 10 cm, five fractions

Findings:

Conclusions: Not related to radiation to the arm, dose also low

Identification Nos: 30, 97-17, 3-142-0078

Age: 56

Date of death: 2 January 1997

Cause of death: Breast cancer

Tumour history: Breast cancer

Dates of therapy: 18–26 September 1996

Prescribed dose: Spine irradiated, L4

Estimated dose: 36 Gy to the spine in 13 fractions, five with the old source and eight with the new source, 15 × 7 cm

Findings: Metastatic tumour to the lungs, heart, liver, bone, spleen and lymph nodes

Conclusions:

Identification Nos: 108, 96-79 97-25

Age: 2

Date of death: 13 October 1996
Cause of death:
Tumour history: Abdominal neuroblastoma
Dates of therapy: 6 Gy with the new source
Prescribed dose: Left hip, palliative treatment
Estimated dose: 62 Gy, 10 × 8 cm, 15 fractions
Findings: Originally, tumour of the right kidney, mass on left buttock
Conclusions: Palliation to hip only, death not due to overexposure

Identification Nos: 16, 97-25, 3-272-271
Age: 32
Date of death: 23 December 1996
Cause of death:
Tumour history: Hodgkin's disease, stage IVB
Dates of therapy: 23–27 September 1996 (dates did not match the fractions on the physics chart)
Prescribed dose:
Estimated dose: 12 Gy, mediastinum,13 fractions, inverted Y, 20 Gy, 19 fractions
Findings:
Conclusions: Death not radiation related because the dose was too low

Identification Nos: 107, 97-076
Age: 10
Date of death: 9 January 1997
Cause of death:
Tumour history: Rhabdomyosarcoma
Dates of therapy:
Prescribed dose:
Estimated dose: Cranial irradiation, 14 × 16 cm, right and left sides, 71 Gy, 28 fractions with the old source and five with the new source, total dose of 72 Gy, mostly with the old source
Findings: The gross autopsy results were reviewed
Conclusions: No significant adverse radiation changes

Identification Nos: 110, 96-78, 6-117-0751
Age: 40
Date of death:
Cause of death:
Tumour history: Cancer of the uterus, brachytherapy in 1993, secondary occipital tumour (medulloblastoma versus metastases)
Dates of therapy:
Prescribed dose:
Estimated dose: 32 Gy, 13 fractions, six with the new source, 16 × 18 cm, cranial fields laterally
Findings: No autopsy
Conclusions: Dose was too low for radiation to be a major cause of death

Identification Nos: 97-26, 260-7462
Age: 70
Date of death: 12 September 1996
Cause of death:
Tumour history: Malignant fibrous histiocytoma
Dates of therapy: 10–12 September 1996
Prescribed dose:
Estimated dose:
Findings: No autopsy
Conclusions: Two fractions only, death within 2 days of starting radiotherapy, not radiation related
The patient was irradiated prior to the change of source

Identification Nos: 82, 97-74
Age: 82
Date of death:
Cause of death:
Tumour history: Cancer of the cervix
Dates of therapy: 1 August to 4 September 1996 (dates did not match the physics information)
Prescribed dose: Pelvis, AP
Estimated dose: 31 Gy, six fractions with the new source, 14 × 14 cm, two fields
Findings:
Conclusions: The dose was probably too low to have had any major adverse effects

Identification Nos: 43, 96-1953
Age: 50
Date of death: 26 November 1996
Cause of death:
Tumour history: Breast cancer
Dates of therapy: 17 September to 2 October 1996
Prescribed dose: Cranium, 18 × 15 cm, two fields
Estimated dose: 40 Gy, nine fractions
Findings:
Conclusions: The dose to the cranium should not have had lethal consequences

Identification Nos: 119-2018, 1-2590077, 48.546
Age: 50
Date of death: 6 December 1996
Cause of death: Cardiopulmonary arrest, autopsy not complete
Tumour history: Breast cancer, surgery 1980. Radiation therapy in 1980, 40 Gy breast and 50 Gy axilla. In 1994, dsyphagia and stenosis of the oesophagus and pericarditis were felt to be due to prior radiation. In 1995, bone metastases, oesophageal carcinoma, for which the patient received radiotherapy, and gastrostomy
Dates of therapy: Unclear from the data available

Prescribed dose: 30 Gy to pelvis, 10 fractions for palliation

Estimated dose:

Findings:

Conclusions: Death not related to radiation exposure primarily on the basis of the dose and perhaps the treatment dates

Identification Nos: 92, 97-058, 4-044-0909

Age: 77

Date of death: 7 January 1997

Cause of death:

Tumour history: Carcinoma in the vulva

Dates of therapy:

Prescribed dose: Pelvis, 24 × 29 cm

Estimated dose: 61 Gy, 14 fractions with the old source and 11 with the new source

Findings: Post-mortem, massive tumour, ascites, no obvious radiation therapy changes in the abdominal organs

Conclusions: Death was probably the result of the tumour

Identification Nos: 93, 97-901

Age: 65

Date of death: 18 May 1997

Cause of death:

Tumour history: Carcinoma in the cervix

Dates of therapy: 23–29 September 1996

Prescribed dose: 15 × 15 cm, two fields

Estimated dose: 15.5 Gy

Findings:

Conclusions: Death was not radiation related because the patient only received three to four fractions and the dose was too low for adverse radiation effects

Identification Nos: 86, 96-2022

Age: 19

Date of death: 7 December 1996

Cause of death:

Tumour history: Hodgkin's disease

Dates of therapy: 9–26 September 1996

Prescribed dose: Mantle, 32 × 35 cm, two fields, 14 fractions

Estimated dose: 43 Gy

Findings:

Conclusions: The dose was within a range such that it should not have caused death

Identification Nos: 24, 96-1878

Age: 76

Date of death: 13 November 1996
Cause of death:
Tumour history: Multiple myeloma
Dates of therapy:
Prescribed dose: Neck, 12 × 9 cm and 10 × 14 cm
Estimated dose: 46.5 Gy, 10 fractions with the new source
Findings: Brain oedema
Conclusions: Death was probably not radiation related

Identification Nos: 112, 96-72, 01-0342-0435
Age: 33
Date of death: 4 October 1996
Cause of death: Upper GI bleeding
Tumour history: Gastric adenocarcinoma with metastases
Dates of therapy: 6–27 September 1996
Prescribed dose:
Estimated dose: Perineal field, 5 × 5 cm, 49 Gy, pelvis, 14 × 14 cm, 15 Gy in five fractions
Findings:
Conclusions: Death was probably not radiation related

Identification Nos: 118, 97-375
Age: 74
Date of death: 21 February 1997
Cause of death:
Tumour history: Cancer of the nasopharynx
Dates of therapy:
Prescribed dose:
Estimated dose:
Findings: Moderate skin reaction on neck, mucosa in the neck region that appeared to be relatively normal
Conclusions: Death was probably not radiation related

Identification Nos: 73, 97154
Age: 56
Date of death: 20 November 1996
Cause of death: Chronic diarrhoea, actinic enteritis, carcinoma of the colon
Tumour history: Carcinoma of the colon
Dates of therapy:
Prescribed dose:
Estimated dose:
Findings:
Conclusions:

120

Patients for whom data were insufficient to make an informed judgement

Identification Nos: 116, 97-879
Age: 71
Date of death: To forensics on 16 May 1997, died at home
Cause of death:
Tumour history: Pelvis
Dates of therapy:
Prescribed dose:
Estimated dose:
Findings:
Conclusions:

Identification Nos: 72, 96-1780, 3-0210076
Age: 76
Date of death:
Cause of death:
Tumour history: Lung cancer
Dates of therapy: 10–24 September 1996
Prescribed dose:
Estimated dose: 48 Gy, 20 fractions
Findings: Referred for palliation of haemoptysis, grade 2 skin reaction at the time of radiotherapy, as well as vomiting
Conclusions: Insufficient information

Identification Nos: 104, 97-154
Age: 2
Date of death: 21 January 1997
Cause of death: Tumour activity with toxicity as a result of overexposure
Tumour history: Neuroblastoma radiation and chemotherapy
Dates of therapy:
Prescribed dose: 6 × 6 cm, supraclavicular
Estimated dose: 70 Gy, 18 fractions with the new source
Findings: Liver, pulmonary and pleural metastases, erosion of the dura and bone
Conclusions: Insufficient information

Identification No: 114
Age: 60
Date of death:
Cause of death:
Tumour history:
Dates of therapy:
Prescribed dose: Spine, 15 × 12 cm, one field, and another field, 5 × 5 cm

Estimated dose: 27.3 Gy, eight fractions, 15 × 12 cm, spine, two with the new source, and 23 Gy, five fractions with the new source, 5 × 5 cm
Findings:
Conclusions:

Identification Nos: 33, 96-2188
Age: 51
Date of death: 29 December 1996
Cause of death:
Tumour history: Breast cancer
Dates of therapy: 28 August to 10 September 1996
Prescribed dose: Pelvis, 19 × 17 cm, two fields
Estimated dose: 46.5 Gy, 10 fractions
Findings:
Conclusions: Death was probably not radiation related

Patient data not reviewed by the Expert Team

Identification No: 94
Age: 81
Date of death: 4 January 1997
Cause of death:
Tumour history: Hypopharynx carcinoma
Dates of therapy: 9–27 September 1996
Prescribed dose:
Estimated dose: 47 anterior and 47 lateral, 15 fractions, 2 Gy to hypopharynx and all of the neck
Findings:
Conclusions:

Identification No: 34
Age: 66
Date of death: 26 February 1997
Cause of death: Autopsy not available
Tumour history: Kidney tumour
Dates of therapy:
Prescribed dose:
Estimated dose:
Findings:
Conclusions:

Identification No:
Age: 68

Date of death: 19 September 1996
Cause of death: Autopsy not available
Tumour history: Axillary cancer
Dates of therapy:
Prescribed dose:
Estimated dose:
Findings:
Conclusions:

Identification No: 113
Age: 67
Date of death: 13 January 1997
Cause of death:
Tumour history: Metastatic melanoma of the skin
Dates of therapy:
Prescribed dose:
Estimated dose:
Findings:
Conclusions:

Identification No: 96
Age: 50
Date of death: Not available
Cause of death: Autopsy not available
Tumour history: Carcinoma of the right maxillary antrum
Dates of therapy: Treatment ended on 13 September 1996
Prescribed dose: 17 fractions, 2 Gy to the right antral area and all of the neck
Estimated dose: 50 Gy, 14 fractions to the neck and 25 fractions to the sinus anterior
Findings:
Conclusions:

Identification No: 4
Age: 48
Date of death:
Cause of death:
Tumour history: Cancer of the cervix
Dates of therapy: 12–27 September 1996
Prescribed dose:
Estimated dose: 38 Gy, 12 fractions
Findings:
Conclusions:

Identification No:
Age: 72

Date of death: 16 December 1996
Cause of death:
Tumour history: Lung cancer
Dates of therapy: 2–27 September 1996
Prescribed dose:
Estimated dose: 20 fractions, 2 Gy to upper lobe of the left lung, mediastinum and left supra-clavicular neck
Findings:
Conclusions:

Identification Nos: 68, 97-115
Age: 52,
Date of death:
Cause of death:
Tumour history: Stage IB carcinoma of the cervix, incomplete surgery
Dates of therapy:
Prescribed dose: Pelvis, 18 × 17 cm, 10 fractions with the old source and 19 with the new source
Estimated dose: 59 Gy
Findings:
Conclusions:

Annex

RECORDS ON THE PARTICIPATION
OF THE SAN JUAN DE DIOS HOSPITAL
IN THE IAEA/WHO TLD POSTAL DOSE QUALITY AUDIT

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A-1. THE IAEA/WHO TLD POSTAL DOSE QUALITY AUDIT

The IAEA operates a service facility to verify the calibration of radiotherapy units in hospitals and oncology centres in Member States. This service was established in 1969. The dose quality audits of radiotherapy centres (sometimes referred to as intercomparisons) are performed using TLDs sent by post. The TLDs are provided by the Agency and irradiated by hospital users under predetermined reference conditions, using radiation doses of clinical relevance. The dose absorbed in the dosimeter is determined at the IAEA's Dosimetry Laboratory and the result compared with the value stated by the user. The service has been used for 30 years to check more than 2600 radiotherapy beams in 850 hospitals. In many instances, significant errors have been detected in the calibration of therapy beams; these have sometimes been related to patient mistreatment. In all instances, the service provides an independent and impartial quality audit of the dosimetry procedures used in hospitals.

The TLD postal service, known as the IAEA/WHO TLD postal dose quality audit, is conducted through collaboration between the IAEA, WHO and, in Latin America, PAHO. The Dosimetry and Medical Radiation Physics Section of the IAEA's Division of Human Health is responsible for the technical aspects of the TLD system, for the reference irradiations, and for the collection and evaluation of dosimeters. WHO/PAHO oversee the distribution of TLDs to radiotherapy institutions, using WHO national or regional affiliated centres. The IAEA and WHO establish the connection with participants through the health ministries of Member States, which ordinarily have authority over radiotherapy centres.

Originally, the service was developed for ^{60}Co therapy units. Recently, however, it has been extended to high energy photon and electron beams produced in clinical accelerators. Within this programme, activities in collaboration with other organizations provide redundant QA to the laboratory tasks performed at the IAEA. All the TLD procedures receive the support of the Bureau international des poids et mesures

(BIPM), various primary standard dosimetry laboratories (the Bundesamt für Eich- und Vermessungswesen, Vienna, Austria, the Physikalisch-Technische Bundesanstalt, Braunschweig, Germany, etc.), and certain advanced radiotherapy centres and institutions in Europe and the USA. These institutes provide reference irradiations for the TLD sets, acting as an external quality control arm of the IAEA's TLD dosimetry service.

A-2. IMPORTANT COMMENT

The IAEA/WHO TLD postal dose quality audit warranties the confidentiality of the results, and only those persons that are responsible for the radiotherapy departments or for the calibrations have access to the outcome of verification. The open discussion and dissemination of the results given below constitute an exceptional case, and the decision to release these results has been adopted in the light of the important social consequences of the accident under consideration.

A-3. RESULTS OF THE IAEA/WHO TLD POSTAL DOSE QUALITY AUDITS FOR THE SAN JUAN DE DIOS HOSPITAL, SAN JOSE, COSTA RICA

The San Juan de Dios Hospital participated 14 times in the IAEA/WHO TLD postal dose quality audit between 1977 and 1995. During this period, 17 checks of

TABLE A-I. TLD CHECKS CARRIED OUT AT THE SAN JUAN DE DIOS HOSPITAL

Year	Beam	Deviation[a] (%)
1990	Co-60/1	20.5
1991	Co-60/1	7.1
1992	Co-60/1	26.3
	Co-60/2	25.9
1994	Co-60/1	68.9
	Co-60/2	69.8
1995	Co-60/1	38.3
	Co-60/2	25.5
1995 (blind test)	Co-60/1	–5.9
(blind test)	Co-60/2	–7.2

[a] Relative deviation (%) = 100 × (user stated dose – IAEA measured dose)/IAEA measured dose.

beam calibrations were performed; on only four occasions were the results within the acceptance limit of ±5%. The results of the participation in the TLD checks between 1990 and 1995 are given in Table A-I.

With regard to this table it should be noted that deviations in positive values indicate that the user stated dose is higher than the value measured by the IAEA; this corresponds to a situation where the patient would receive a dose that is lower than that intended. In contrast, deviations in negative values indicate that a patient would receive a dose that is higher than that intended.

Until 1995, the person in charge of dosimetry at the San Juan de Dios Hospital was informed by the IAEA, through PAHO, of the results obtained in the different participations in the TLD checks. This was the standard procedure of the IAEA/WHO TLD postal dose quality audit at the time, and the participants were requested to take steps to improve their beam calibration.

However, in 1995, when the IAEA observed that the large deviations found had not diminished, a second set of dosimeters was sent under so called 'blind test' conditions, i.e. the participants are not informed of the exact deviation measured by the IAEA, only that the results are outside the acceptance limit. Confirmation of an anomalous situation, indicated by the inconsistency of the two sets of results, prompted the IAEA to field an expert with a view to investigating the status of calibration of the beams. Simultaneously, three TLD sets were sent to the hospital in July 1996 to verify calibration of the two ^{60}Co therapy units, a Theratron-80 and an Alcyon. Replacement of the ^{60}Co sources of the two machines had been planned for July–August 1996. It was requested that the TLDs should be irradiated immediately after calibrating the machines with the new sources, and before initiating treatment of the patients.

The following is a short summary of the TLD results for the two ^{60}Co therapy units.

A-3.1. Theratron-80

After source replacement, calibration of the beam was performed by an IAEA expert, E. Castellanos, using dosimetry equipment available at the hospital. On the basis of the two calibration factors of the equipment, the expert irradiated two TLD sets on 19 July 1996 and returned them to the IAEA's Dosimetry Laboratory for evaluation. The TLDs were received on 1 August 1996 and evaluated on 2 August 1996. The results in terms of the deviation of the IAEA measured and user stated dose values (D_{IAEA} and D_{stated}, respectively) were within the acceptance limits of ±5%:

(a)   *TLD set No. SR 96201*

$D_{stated} = 2.000$ Gy
$D_{IAEA} = 2.047$ Gy

The deviation, relative to the IAEA measured values, was –2.3%, which corresponds to a dose ratio IAEA measured/user stated dose of 1.024.

(b) TLD set No. SR 96202

D_{stated} = 2.000 Gy
D_{IAEA} = 2.068 Gy

The deviation, relative to the IAEA measured values, was –3.3%, which corresponds to a dose ratio IAEA measured/user stated dose of 1.034.

A-3.2. Alcyon

A TLD set to be used with this machine was left in Costa Rica by the expert with instructions for to the local physicist to irradiate immediately after exchanging the ^{60}Co source and prior to initiating treatment of the patients. The irradiated TLD set was returned to the IAEA's Dosimetry Laboratory on 18 October 1996, only after the accident had been reported. The TLDs were evaluated on the day of their arrival. The accompanying data sheet had been filled in by J. Cabezas, the person in charge of dosimetry at the hospital. He did not indicate the date of irradiation of the TLDs, but provided only the date of the beam output measurement (calibration) using an ionization chamber, i.e. 22 August 1996.

From analysis of the accompanying data sheet it was observed, first, that the user stated dose D_{stated} = 2.000 Gy (pertaining to the date of 22 August 1996) corresponded in reality to a depth of 0.5 cm, and not to the depth of 5 cm in water, where the TLD capsules had been placed for irradiation. Therefore, the user stated dose had to be reduced by a factor equal to 0.787 (obtained from the ^{60}Co percentage depth dose data given in Ref. [19]), corresponding to attenuation of the beam by 4.5 cm of water. This yielded a 'depth corrected' stated dose D'_{stated} = 1.576 Gy (on 22 August 1996). The shape of the TLD glow curve, however, demonstrated that the TLDs had been irradiated only a few days before their dispatch by post to the IAEA. The above depth corrected stated dose was therefore subsequently modified to account for the decay of the ^{60}Co source for approximately 2 months, yielding a more accurate estimate of the user stated dose D''_{stated} = 1.544 Gy.

Because of lack of clarity in the information provided for the TLD irradiation procedure, two results are given below (TLD set No. SR 96203), one relative to the user stated dose D_{stated}, and the other relative to the best estimate of the user stated dose D''_{stated}:

(1) D_{stated} = 2.000 Gy (user stated dose)
D_{IAEA} = 2.812 Gy

The deviation, relative to the IAEA measured values, was –28.9%, which corresponds to a dose ratio IAEA measured/user stated dose of 1.406.

(2) $D''_{stated} = 1.544$ Gy (IAEA estimated user stated dose)
     $D_{IAEA} = 2.812$ Gy

The deviation, relative to the IAEA measured values, was –45.1%, which corresponds to a dose ratio IAEA measured/estimated user stated dose of 1.821.

From the above data it can be concluded that the TLD results for the Alcyon machine indicate an overexposure of the order of 80%, which applies exclusively to the reference conditions used in the beam calibration (10 × 10 cm field size, 5 cm depth in water). The overexposure of patients will vary from this amount, depending on the conditions used for the radiotherapy treatments (field size, secondary collimation, use of wedges, etc.). The estimated overexposure for the reference conditions agrees well (within the uncertainties of the TLD system, estimated to be 2.5%, k = 1) with the result measured by PAHO for the same configuration, using a calibrated ionization chamber.

Addendum

RECONSTRUCTION OF THE DOSES TO NORMAL TISSUE FOR PATIENTS WITH MARKED ADVERSE EFFECTS

A.1. INTRODUCTION

The report reproduced in this Special Publication was delivered by the Director General of the IAEA to the Government of Costa Rica on 26 September 1997.

As stated in the findings and conclusions of the Data on Patients (Appendix II), further evaluation of the doses to normal tissue was desirable for some of the patients. To make this evaluation, a two dimensional reconstruction of the dose distributions was undertaken, using a computerized treatment planning system (TPS), by the IAEA, in co-operation with P. Binder of the General Hospital (Allgemeines Krankenhaus (AKH)), Vienna, Austria, and with the advice of C. Serrano, Hospital Ramón y Cajal, Madrid, Spain. In addition, estimation of the biologically equivalent dose for late effects, if administered at 2 Gy/fraction, based on the LQ model, was made in collaboration with G.G. Steel of the Institute of Cancer Research, Sutton, Surrey, United Kingdom, and J. Fowler, Belgium and the UK.

A.2. METHOD AND DISCUSSION

Cross-sectional images (of the actual patients in the area of interest) that were suitable for clinical dosimetry were only available in a few cases (indicated by (P) in Table A.I of this Addendum). Most of the dose reconstructions had to be made using standard images from an anatomy atlas [20].

The images were entered into the TPS by means of a television camera and the scale was fitted digitally to the actual body thickness of the patient, taken from his/her charts. The influence of anatomical differences on the uncertainties introduced when selecting the isodose curve that crosses a given tissue is estimated to be within ±10% because the distance between two consecutive isodose curves (drawn in steps of 10%) is about 2 cm.

The data for a ^{60}Co beam available in the TPS of the General Hospital in Vienna correspond to those for a Theratron-80. The differences to the Alcyon II are not significant, except in the penumbra region. Calculation of doses to tissue within the penumbra of the beams was therefore avoided.

Dose reconstructions were made for patients falling into the following groups:

(1)   Four patients (alive), with severe or catastrophic effects from radiation;

(2)   Sixteen patients (alive), with marked effects and with high risk of future effects from radiation;

(3)   Three patients (deceased), with radiation considered to be the major factor in their death;

(4)   Four patients (deceased), with radiation considered to be a substantial contributor to their death.

The two dimensional relative dose distributions were calculated in planes containing the centre of the beam. The absolute dose values to the organs and tissues at risk were obtained using standard methods of clinical dosimetry, as explained in the following subsections.

A.2.1.   Determination of absolute doses to the organs and tissues at risk

A.2.1.1. Dose received by the tissue of interest before the source change

The dose to the organs at risk was estimated from the prescribed dose to the target by applying a conversion factor. The conversion factor was obtained by comparing the isodose from the TPS that corresponds to the tumour with the isodose that corresponds to the organs at risk (d<) (see Table A.I).

A.2.1.2. Dose received after the source change

The dose to the organs at risk was estimated from the actual treatment time (from patients' charts), the time to deliver 1 Gy to the 100% isodose and the relative dose distributions from the TPS.

When more than one field is applied (in the present case, two opposite, equally weighted, parallel fields), the time obtained corresponds to one of the fields, e.g. 0.5 min/Gy indicates that 0.5 min for each field (in total, 1 min) is necessary to produce 1 Gy.

The steps were:

(1)   The time/Gy (T) for the Theratron-80 to deliver 1 Gy was converted to the time/Gy (A) for the Alcyon II source, given the dose rate from the two sources;

(2)   The actual treatment time was taken from the patients' charts;

(3)   From the two values, and from the isodose that crosses the tissue at risk, the dose per fraction (d>), e.g. the daily dose, was obtained;

(4)   The total dose with the new source (D>) was obtained from the number of fractions indicated in the patients' charts.

TABLE A.I. DOSE RECONSTRUCTION TO THE ORGANS AND TISSUES AT RISK, USING A COMPUTERIZED
TREATMENT PLANNING SYSTEM[a]

ID	Tissue	% isodose	d<	FX<	D<	T (min/Gy)	A (min/Gy)	min/field	d>	FX>	D>	D	Range of alpha/beta		Range of D(2)		Medical findings
8	Rectum, lower ileum, part of sigmoid colon	100	2	20	40	0.7	0.42	1.29	3.1	5	15.5	55.5	2	4	59.8	58.4	Diarrhoea about threee times a week
	Rectum, part of sigmoid colon (from lateral fields)	100				1.1	0.72	2.17	3.0	6	18.1	18.1	2	4	22.8	21.2	Diarrhoea about three times a week
18	Bowel, cervix and uterus	100			0	0.7	0.44	1.29	2.9	12	35.1	35.1	2	4	43.2	40.5	Colonic haemorrhage with perforation, small bowel petechiae, haemorrhage of cervix and uterus
26	Ear (assuming overlap)	80			0	0.5	0.28	2.02	5.7	14	79.8	79.8	2	4	154	129	Drainage of the right ear and complete deafness (since the eye was shielded, only a 3 cm anterior field was included)
39	Skin, inguinal and subcutaneous tissue (P)	100			0	0.8	0.49	2.01	4.1	14	57.3	57.3	2	4	87.2	77.2	Severe woody induration anterior
	Femoral head (P)	80			0	0.8	0.49	2.01	3.3	14	45.8	45.8	2	4	60.4	55.5	Femoral head aseptic necrosis
40	Heart (P)	100			0	0.6	0.38	1.14	3.0	17	51.3	51.3	2	4	64.3	60	Pericardial effusion
	Spinal cord (P)	100			0	0.6	0.38	1.14	3.0	17	51.3	51.3	2	4	64.3	60	May have cervical and thoracic spinal cord changes
41	Thoracic spine	75			0	0.8	0.51	2.5	3.7	15	55.1	55.1	1.5	2.5	81.5	75.6	Potential spinal cord changes
44	Skin folds	100			0	0.8	0.50	7.86	15.6	2	31.2	31.2	2	4	137	102	Ulceration in the vulva
	Bowel	75			0	0.8	0.50	7.86	11.7	2	23.4	23.4	2	4	80.1	61.2	Blood in stools
46	Skin and subcutaneous tissue (from lateral fields)	100	2	5	10	0.6	0.37	1.08	3.0	20	59.1	69.1	2	4	83.2	78.5	Facial oedema (if the anterior neck field overlapped, the dose to the face would be about 50 Gy higher)

TABLE A.I. (cont.)

ID	Tissue	% isodose	d<	FX<	D<	T (min/Gy)	A (min/Gy)	min/field	d>	FX>	D>	D	Range of alpha/beta		Range of D(2)		Medical findings
46	Base of tongue (from lateral fields)	100				0.6	0.35	1.08	3.1	20	62.3	62.3	2	4	79.7	73.9	Swelling of the base of the tongue and larynx (if the anterior field overlapped and organ shielding was not used, the dose would be nearly doubled)
47	Brain	100	2	5	10	0.7	0.41	1.05	2.6	23	59.0	69.0	1.5	2.5	78.5	76.4	High risk of neurological sequelae
52	Base of tongue	100	2	9	18	0.6	0.35	1.1	3.2	23	73.0	91.0	2	4	112	105	Oedema of the piriform sinuses and fibrous changes
54	Brain	100	2	16	32	0.6	0.35	1.06	3.0	9	27.0	59.0	1.5	2.5	66.8	65.1	Risk of neurological sequelae
	Thoracic spine	77				0.8	0.51	2.13	3.2	12	38.6	38.6	1.5	2.5	51.9	49	
	Lumbar spine	77				0.8	0.51	2	3.0	15	45.3	45.3	1.5	2.5	58.4	55.5	
57	Gastrointestinal system	95	1.6	12	19.2	0.7	0.43	0.96	2.1	10	21.0	40.2	2	4	38.8	39.2	Haemorrhage GI (estimated dose did not seem to match medical findings)
58	Cervical spine	100	2	16	32	0.6	0.35	1.07	3.0	9	27.2	59.2	1.5	2.5	67.1	65.3	Risk of neurological sequelae
	Thoracic spine	75				0.8	0.51	2.13	3.1	6	18.8	18.8	1.5	2.5	24.8	23.5	
	Lumbar spine	75				0.8	0.51	2	2.9	6	17.6	17.6	1.5	2.5	22.36	21.3	
59	Trachea	90				0.8	0.49	1.57	2.9	20	57.5	57.5	2	4	70.1	65.9	Necrosis of the pharynx, larynx and epilation over posterior fossa. *Note*: According to the patient's chart, shielding in the centre of the beam was planned from fraction 16; this would reduce the dose by 14 Gy
60	Face (from lateral left field)	70				0.6	0.36	0.91	1.8	24	42.6	42.6	2	4	40.2	41	Oedema and some necrosis of the pharynx and trachea
	Face (from lateral right field)	70				0.6	0.36	0.37	0.7	24	17.3	17.3	2	4	11.8	13.6	Possible overlap with anterior field in the trachea

TABLE A.I. (cont.)

ID	Tissue	% isodose	d<	FX<	D<	T (min/Gy)	A (min/Gy)	min/field	d>	FX>	D>	D	Range of alpha/beta		Range of D(2)		Medical findings
60	Neck (anterior field)	95				0.8	0.49	1.53	3.0	24	71.0	71.0	2	4	88	82.3	(If the anterior field overlapped, the dose would be approximately doubled)
62	Rectum	100				0.7	0.44	1.29	2.9	15	43.9	43.9	2	4	54	50.6	Rectal narrowing
66	Heart (P)	105				0.7	0.44	1.36	3.2	11	35.6	35.6	1.5	2.5	48.2	45.4	Potential cardiac effects
67	Right colon	100				0.5	0.31	0.96	3.1	16	49.8	49.8	2	4	63.6	59	Necrosis of the right colon
77	Sink and subcutaneous tissue	100	2	7	14	0.5	0.32	0.98	3.1	18	56.0	70.0	1.5	2.5	87.8	83.8	Severe skin changes and GI complications
80	Spinal cord (from lateral fields) and nasopharynx	100				0.6	0.35	1.12	3.2	16	51.7	51.7	1.5	2.5	69.9	65.9	Quadriplegia (if the anterior field overlapped and organ shielding was not used, the dose would be nearly doubled)
83	Intestine (from AP/PA fields) (P)	100	2.2	5	11	0.5	0.33	0.94	2.8	20	56.3	67.3	2	4	79.3	75.3	Grade 3 GI toxicity initially, weight loss, anaemia, continual rectal bleeding and diarrhoea, and must wear a diaper
	Rectum (from lateral fields) (P)	100	2.2	5	11	0.5	0.33	0.94	2.8	20	56.3	67.3	2	4	79.3	75.3	Continual rectal bleeding
	Rectum (from lateral fields) (P)	90				0.9	0.59	1.61	2.5	5	12.4	12.4	2	4	13.8	13.3	Continual rectal bleeding
85	Rectum	100	2	6	12	0.5	0.30	1.13	3.7	12	44.8	56.8	2	4	76.3	69.8	Perirectal ulceration, with possible infection/necrosis
95	Skin and subcutaneous tissue	100				0.5	0.32	1.08	3.4	14	47.1	47.1	2	4	63.1	57.7	Diarrhoea, skin induration
97	Spinal cord (from lateral fields)	95	1.9	11	20.9	0.5	0.33	1.02	2.9	8	23.5	44.4	1.5	2.5	50.2	48.9	Spinal cord demyelination (if the anterior field overlapped and organ shielding was not used, the dose would be approximately doubled)

TABLE A.I. (cont.)

ID	Tissue	% isodose	d<	FX<	D<	T (min/Gy)	A (min/Gy)	min/field	d>	FX>	D>	D	Range of alpha/beta		Range of D(2)		Medical findings
106	Brain (P)	100	1.9	13	24.7	0.5	0.34	1	2.9	12	35.3	60.0	1.5	2.5	68.7	66.8	Concern about possible radiation necrosis of the brain
	Thoracic spine (P)	88				0.8	0.52	1.88	3.2	10	32.0	32.0	1.5	2.5	43	40.6	
109	Temporal lobes	100	2	4	8	0.5	0.33	1.05	3.1	16	50.3	58.3	1.5	2.5	74.8	71.1	Lost ability to speak and walk; periventricular leucoencephalopathy, mineralizing microangiopathy, atrophy

a   d< = dose per fraction before source change; FX< = number of fractions before source change; D< = total tumour dose before source change; T = Theratron-80; A = Alycon II; d> = dose per fraction after source change; FX> = number of fractions after source change; D> = total tumour dose after source change; D = grand total dose; and D(2) = total dose given in fractions of 2 Gy that would be biologically equivalent to D.

Note: (P) = cross-sectional images taken from actual patients.

A.2.2. Determination of the equivalent 2 Gy/fraction dose D(2)

The dose per fraction to the tissues at risk was higher than normal for the following reasons:

(1) Miscalibration of the beam, leading to doses higher than those prescribed (higher dose per fraction and higher total dose);
(2) Prescription of higher fractional doses and a lower number of fractions;
(3) Use of alternating fields instead of both fields every day.

The effect of these factors has been explored in the example trials presented in Tables A.II(a) to (d).

A.2.2.1. Effect of a higher dose per fraction

The effect of a higher dose per fraction and a lower number of fractions, with the same total dose, is shown in Table A.II(a). In the range of doses relevant to this report, use of three instead of five fractions per week, during the whole treatment, leads to an increase of more than 30% in D(2). Use of two rather than five fractions, with the same total dose, leads to an increase of about 75% in D(2).

If a higher dose per fraction is used and the total dose is increased, which was the effect of the miscalibration, the increase in D(2) is accordingly higher, depending on the proportion of treatment conducted with the new source.

These effects are reflected in the results given in Table A.I: instead of a single alpha/beta value for each tissue, the following ranges of values were used: 1.5–2.5 for the brain and spinal cord; and 2–4 for all the other tissues. These ranges lead to the range of values for D(2) presented in the relevant columns of Table A.I. The D(2) values are usually higher than the estimated absorbed dose delivered (D).

A.2.2.2. Effect of applying alternating fields versus both fields

The effect of applying alternating fields every other day instead of treating both fields every day (for two opposite parallel fields) was explored.

Tissues located at mid-depth receive the same daily dose, regardless of whether the treatment has been applied with both fields every day or with alternating fields. Therefore, the biological effect of treating both fields every day or not is not significant, since d and D would be the same.

The greatest difference would be expected for tissues that one day are close to the beam entrance and the following day are close to the beam exit. Examples of these tissues are subcutaneous tissue (at D_{max}) and tissue from the skin folds, the rectum, the bladder, and the thoracic and lumbar spinal cord.

TABLE A.II. EXAMPLE TRIALS[a]

(a) Influence of dose per fraction and the number of fractions per week for the same total dose per week

	d	FX	D	Alpha/beta	D(2)	Increase factor
Five fractions/week (2 Gy/fraction)	2	30	60	2	60.0	
Three fractions/week (3.33 Gy/fraction)	3.333	18	60	2	80.0	1.33
Two fractions/week (5 Gy/fraction)	5	12	60	2	105.0	1.75

(b) Influence of treating fields every day versus alternating fields (skin)

	d1	FX1	D1	d2	FX2	D2	D	Alpha/beta	D(2)	Increase factor
Two parallel opposite fields every day (30 fractions)	2	30	60				60.0	3	60.0	
Skin in the head region (factor 2 (e.g. d1 is nearly double that of d2))	2.7	15	40.5	1.3	15	19.5	60.0	3	62.9	1.05
Skin in abdominal region (factor 3 (e.g. d1 is nearly three times that of d2))	3	15	45	1	15	15	60.0	3	66.0	1.10

(c) Influence of treating all fields every day versus alternating fields (rectum)

	d1	FX1	D1	d2	FX2	D2	D	Alpha/beta	D(2)	Increase factor
All fields every day	2	30	60				60	3	60.0	
Examples of rectum (factor 2 (e.g. d1 is nearly double that of d2))	2.7	15	40.5	1.30	15	19.5	60	3	62.9	1.05

(d) Influence of treating all fields every day versus alternating fields (spinal cord)

	d1	FX1	D1	d2	FX2	D2	D	Alpha/beta	D(2)	Increase factor
All fields every day (factor 2 (e.g. d1 is nearly double that of d2)	2	30	60				60	2	60.0	
	2.7	15	40.5	1.30	15	19.5	60	2	63.7	1.06

[a] d = dose per fraction; FX = number of fractions per week; D = total dose per week; D(2) = total dose given in fractions of 2 Gy that would be biologically equivalent to D.

Note: d1, d2, etc.: 1 = field 1; 2 = field 2 (see Section A.2.2.2 for further explanation).

TABLE A.III. ESTIMATED DOSE AND EQUIVALENT 2 Gy/FRACTION DOSE (SKIN AND SUBCUTANEOUS TISSUE IN THE ABDOMINAL REGION) FOR PARALLEL, OPPOSITE, ALTERNATING FIELDS[a]

ID	Tissue	d1<	FX1<	D1<	d2<	FX2<	D2<	min/field	d1>	FX1>	D1>	d2>	FX2>	D2>	D	Range of alpha/beta	Range of D(2)	Medical findings
8	Skin and subcutaneous tissue in the sacral region	3.3	10	33	1	10	10	2.58	5.25	3	15.8	1.6	2	3.2	61.9	2	4	82.6 75.7	Severe sacral pigmentation
62	Skin and subcutaneous tissue in the pelvic region							2.57	5.23	8	41.8	1.3	7	9.2	51.0	2	4	83.2 72.5	Woody induration, concern about skin breakdown
78	Skin and subcutaneous tissue in the sacral region	3.3	5	16.5	1	4	4	2.04	4.15	8	33.2	1.2	8	10.0	63.7	2	4	84.0 77.2	Infected ulceration as a result of overexposure of the skin, and also an ulcerated vagina

[a] d1< = dose per fraction; FX1< = number of fractions before source change; D1< = total tumour dose before source change; d1> = dose per fraction after source change; FX1> = number of fractions after source change; D1> total tumour dose after source change; D = grand total dose; and D(2) = total dose given in fractions of 2 Gy that would be biologically equivalent to D.

Note: d1, d2, etc.: 1 = field 1; 2 = field 2 (see Section A.2.2.2 for further explanation).

The results of the calculation experiment are given in Tables A.II(b), (c) and (d). In these tables, the value d1 stands for the dose received when the tissue is located closer to the beam entrance, while d2 stands for the dose received when the tissue is located closer to the beam exit. The table shows that the biological effect of using alternating fields is about 5–6%, except for skin in the abdominal region, where the ratio between the entrance dose and the exit dose may be as much as 3–4, depending on the body thickness of the patient and D(2) increases of about 10% or more.

This consideration was therefore only applied to the skin folds and sub-cutaneous tissue of patients treated in the abdominal region with parallel, opposite fields, alternating every other day, namely, *Patient Nos. 8, 62* and *78*. The results are presented in Table A.III.

REFERENCES

[1]   METTLER, F.A., Jr., Medical Effects of Ionizing Radiation, Saunders, Philadelphia, PA (1996).

[2]   AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE, Comprehensive Quality Assurance for Radiation Oncology, Task Group 40, Med. Phys. **21** 4 (1994).

[3]   INTERNATIONAL COMMISSION ON RADIATION UNITS AND MEASURE-MENTS, Prescribing, Recording and Reporting Photon Beam Therapy, ICRU Publication No. 50, ICRU, Bethesda, MD (1993).

[4]   INTERNATIONAL UNION AGAINST CANCER, TNM Classification of Malignant Tumours, 4th edn, Springer-Verlag, Berlin (1987).

[5]   INTERNATIONAL COMMISSION ON RADIATION UNITS AND MEASURE-MENTS, Dose Specificity for Reporting External Beam Therapy with Photons and Electrons, ICRU Publication No. 29, ICRU, Bethesda, MD (1978).

[6]   INTERNATIONAL COMMISSION ON RADIATION UNITS AND MEASURE-MENTS, Dose and Volume Specifications for Reporting Intracavitary Therapy in Gynecology, ICRU Publication No. 38, ICRU, Bethesda, MD (1985).

[7]   INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Radio-logical Protection and Safety in Medicine, ICRP Publication No. 73, Ann. ICRP **26** 2 (1996).

[8]   INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, 1990 Recommendations of the International Commission on Radiological Protection, ICRP Publication No. 60, Ann. ICRP **21** (1991) 1–13.

[9]   FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANISATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, WORLD HEALTH ORGANIZATION, International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources, Safety Series No. 115, IAEA, Vienna (1996).

[10]   INTERNATIONAL ATOMIC ENERGY AGENCY, Absorbed Dose Determination in Photon and Electron Beams: An International Code of Practice, Technical Reports Series No. 277, 2nd edn, IAEA, Vienna (1997).

[11]   CASTELLANOS, E., Mission Report to the IAEA, 1996.

[12]   BORRAS, C., Mission Report to the Expert Team, 1996.

[13]   JIMENEZ, J.C., Mission Report to the Expert Team, 1996.

[14]   FOWLER, J., Brief summary of radiobiological principles in fractionated radiotherapy, Semin. Radiat. Oncol. J. **2** (1992) 16–21.

[15]   FOWLER, J., The linear–quadratic formula and progress in fractionated radiotherapy, Br. J. Radiol. **62** (1989) 679–694.

[16]   Basic Clinical Radiobiology (STEEL, G.G., ARNOLD. E., Eds), Medical Marketing Department, Arnold, London (1997).

[17]   Radiation Injury to the Nervous System (GUTIN, P.H., LEIBEL, S.A., SHELINE, G.E., Eds), Raven Press, New York (1991).

[18]   Radiopathology of Organs and Tissues (SCHERER, E., STREFFER, C., TROTT, K.R., Eds), Springer-Verlag, Heidelberg (1991).

[19] Central Axis Depth Dose Data for Use in Radiotherapy, Supplement 17, Br. J. Radiol. (1983).

[20] Atlas of Cross-Sectional Anatomy (Computed Tomography and Magnetic Resonance Imaging), Georg Thieme Verlag, Stuttgart (1994).

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Vienna, Austria: 1–6 September 1997

IMAGES

*Images that have captions marked with (P) (see also Table A.I)
were taken from actual patients.
The remaining images were taken from the
Atlas of Cross-Sectional Anatomy
(Computed Tomography and Magnetic Resonance Imaging) [20]
and have been reproduced here with the permission
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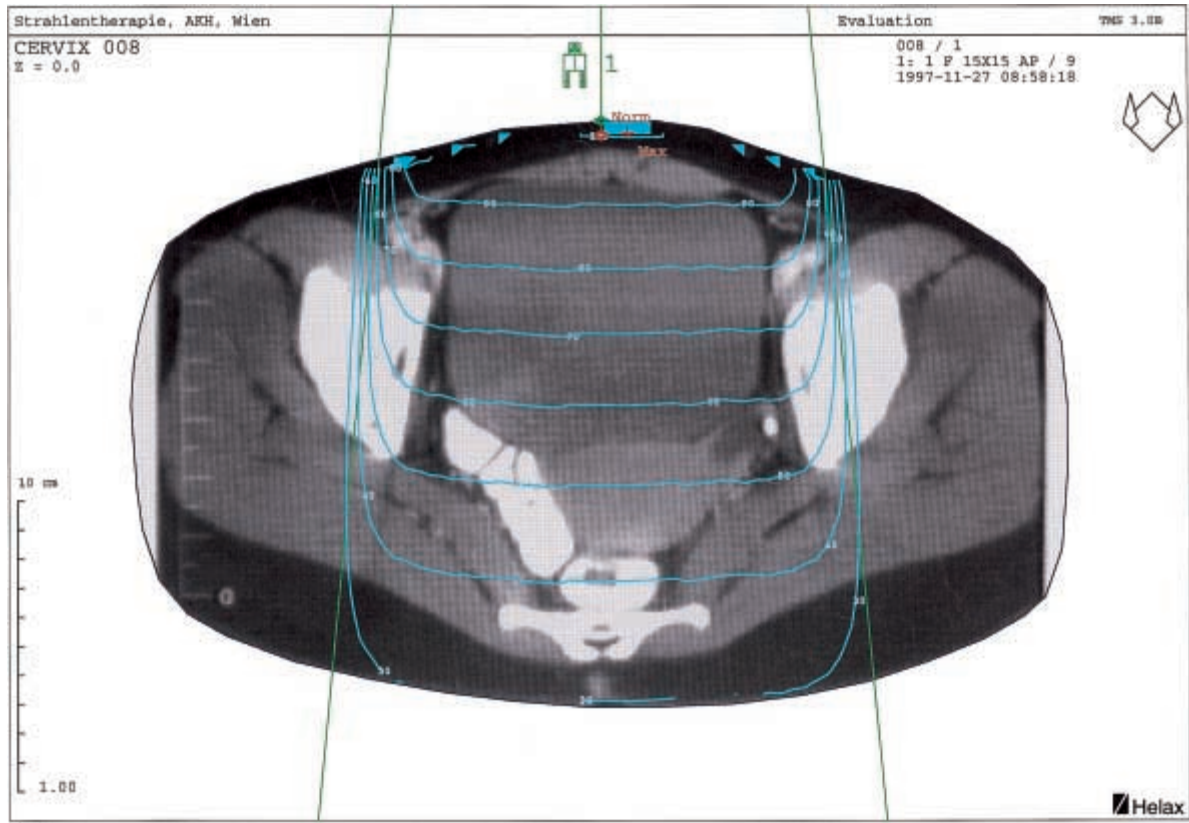
Image 1. Patient No. 8: cervix (AP field). The calculations for the AP and PA fields were made separately in order to estimate (using a biologically equivalent dose of 2 Gy/fraction) the effect on the skin of treating alternating fields every other day.
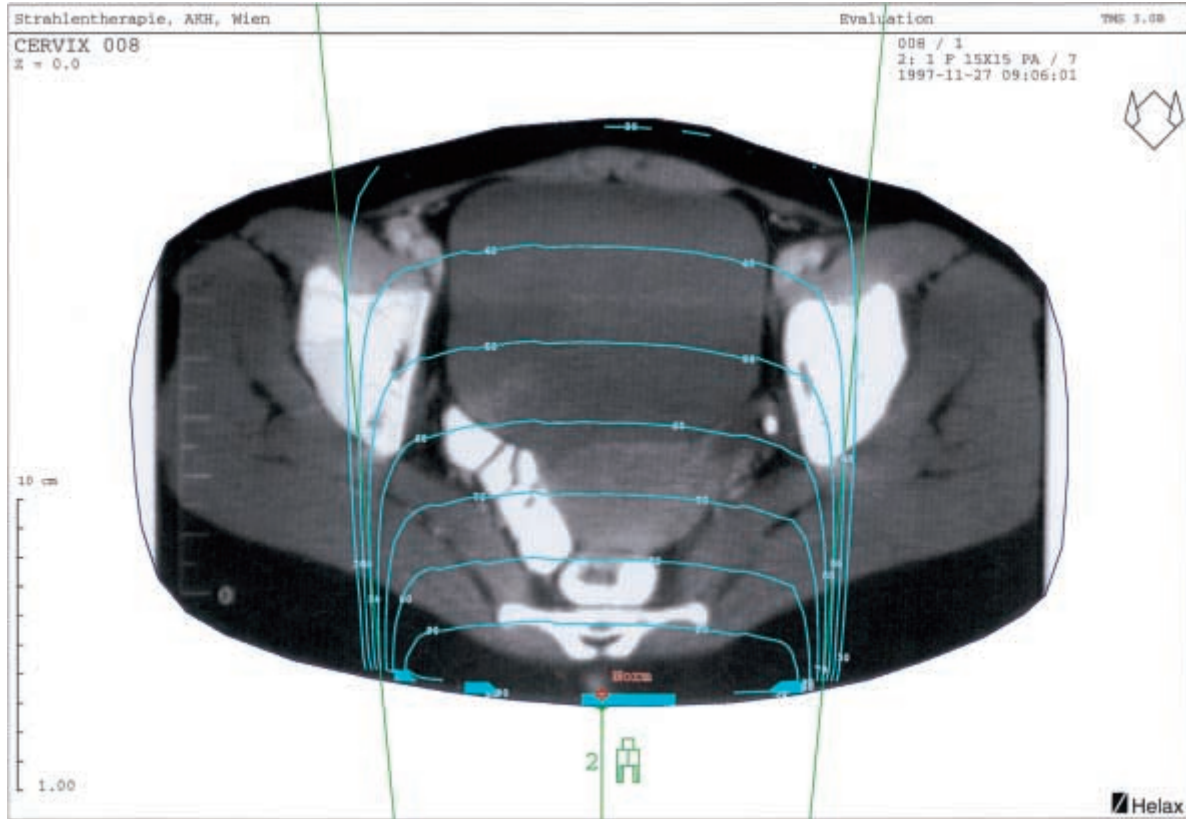
Image 2. Patient No. 8: cervix (PA field). The calculations for the AP and PA fields were made separately in order to estimate (using a biologically equivalent dose of 2 Gy/fraction) the effect on the skin of treating alternating fields every other day.
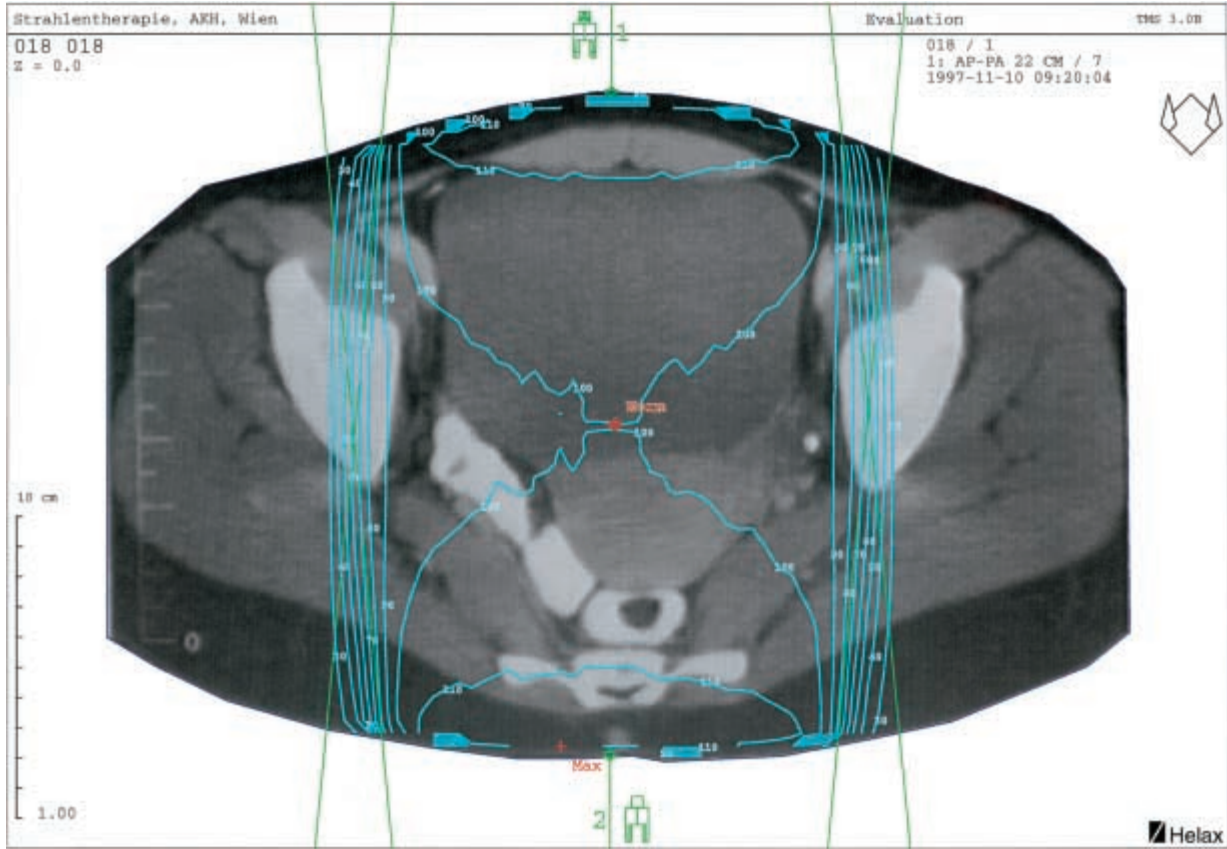
Image 3. Patient No. 18: cervix, uterus and bowel.
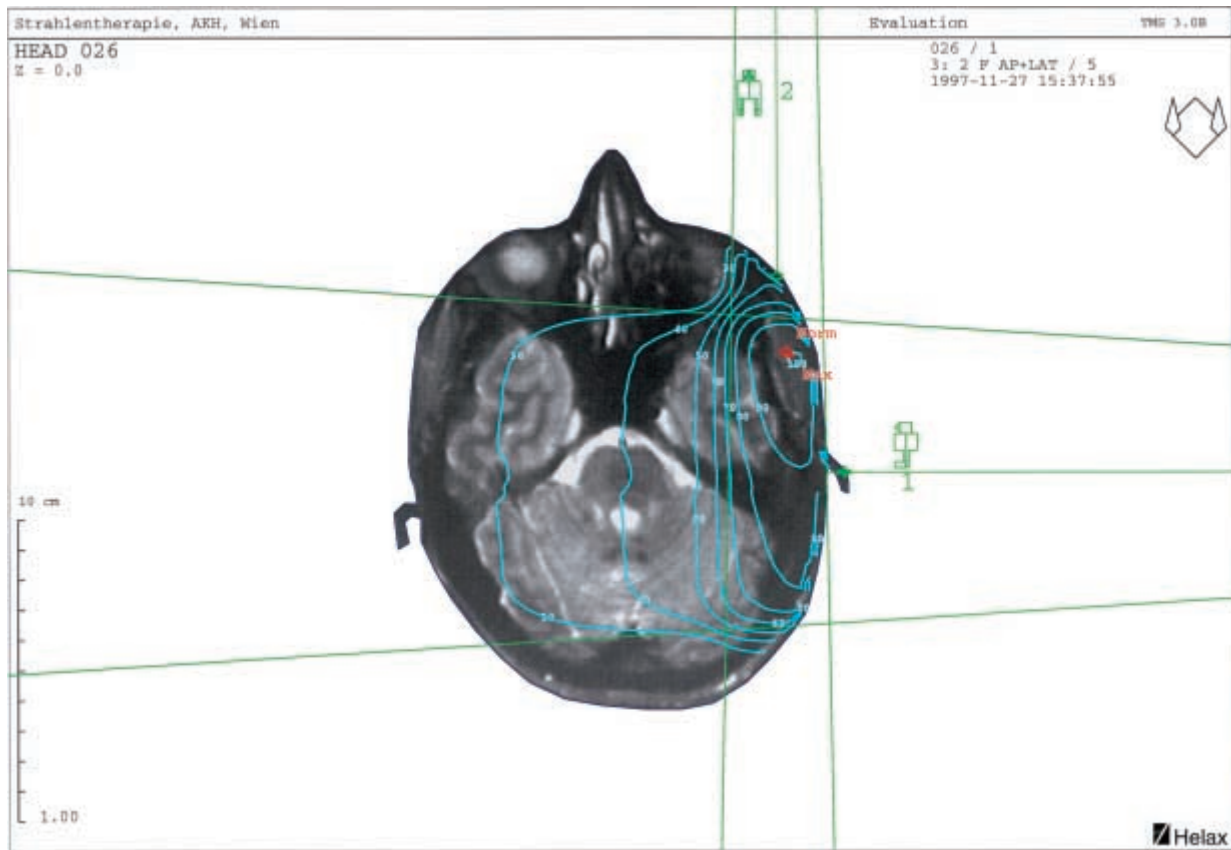
Image 4. Patient No. 26: head (overlap in the ear area).
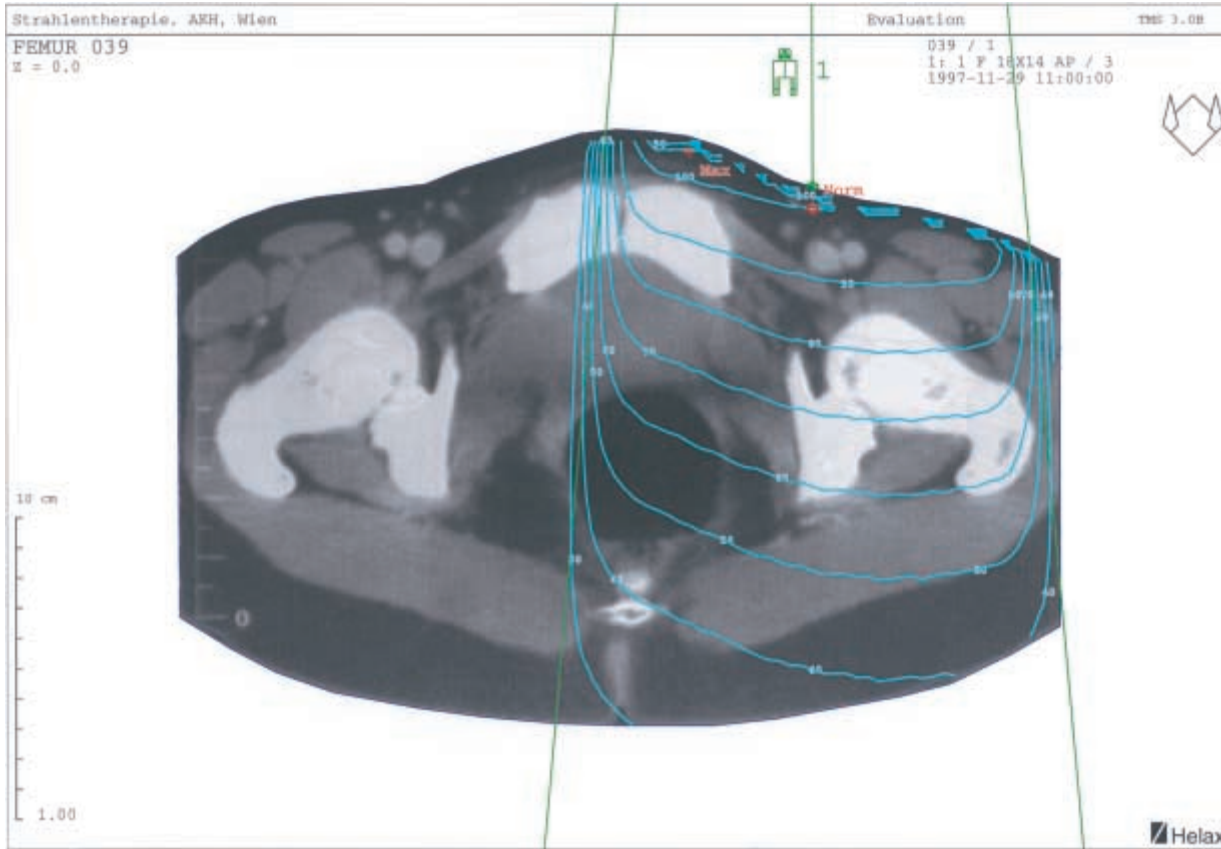
Image 5. Patient No. 39: femur, inguinal subcutaneous tissue and femoral artery (P).
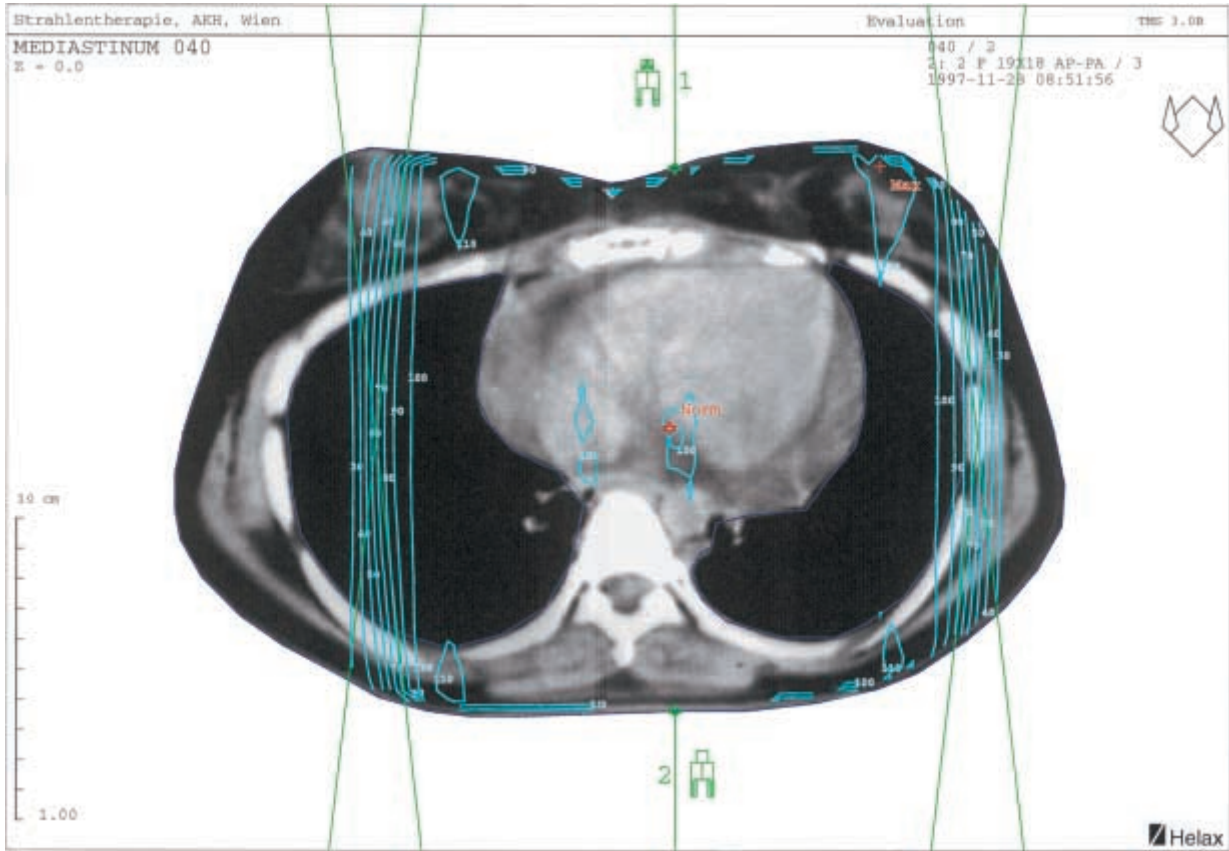
Image 6. Patient No. 40: mediastinum (heart and spinal cord) (P).
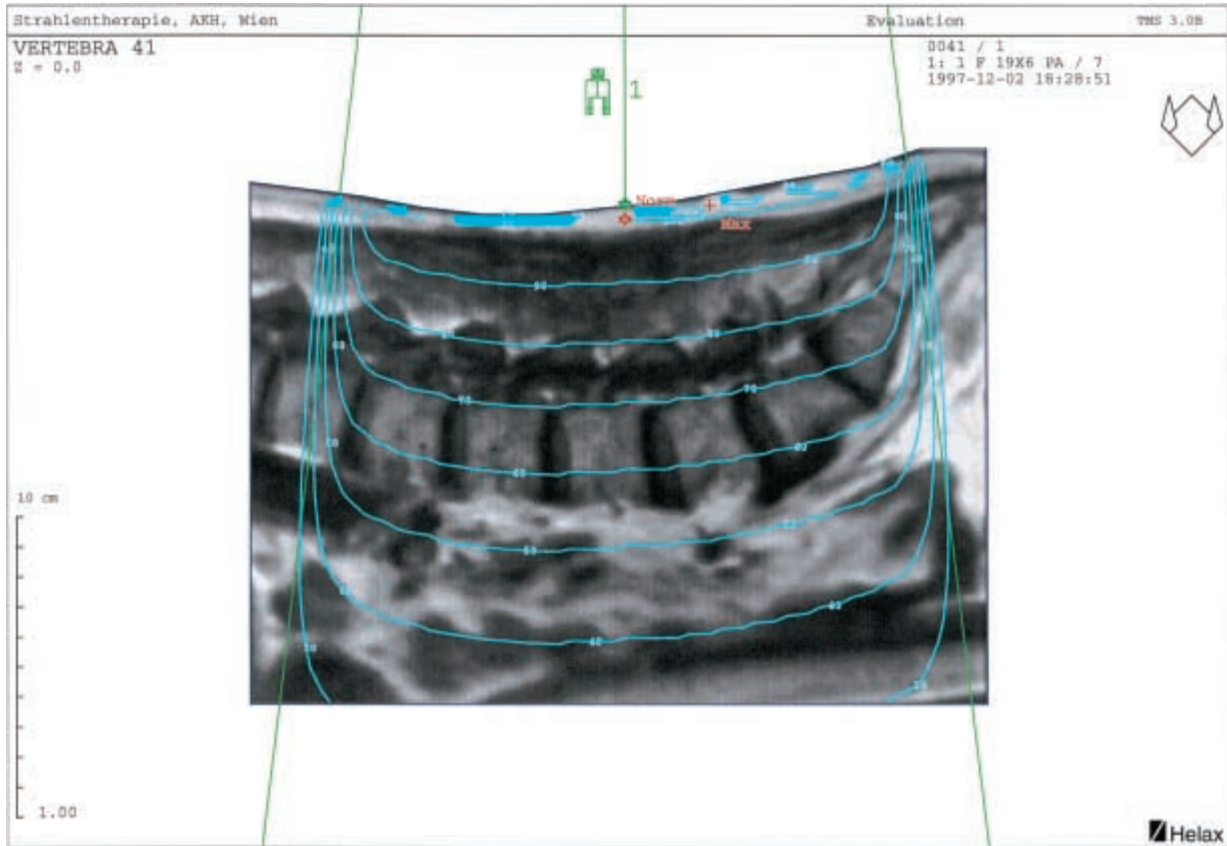
Image 7. Patient No. 41: thoracic spine.
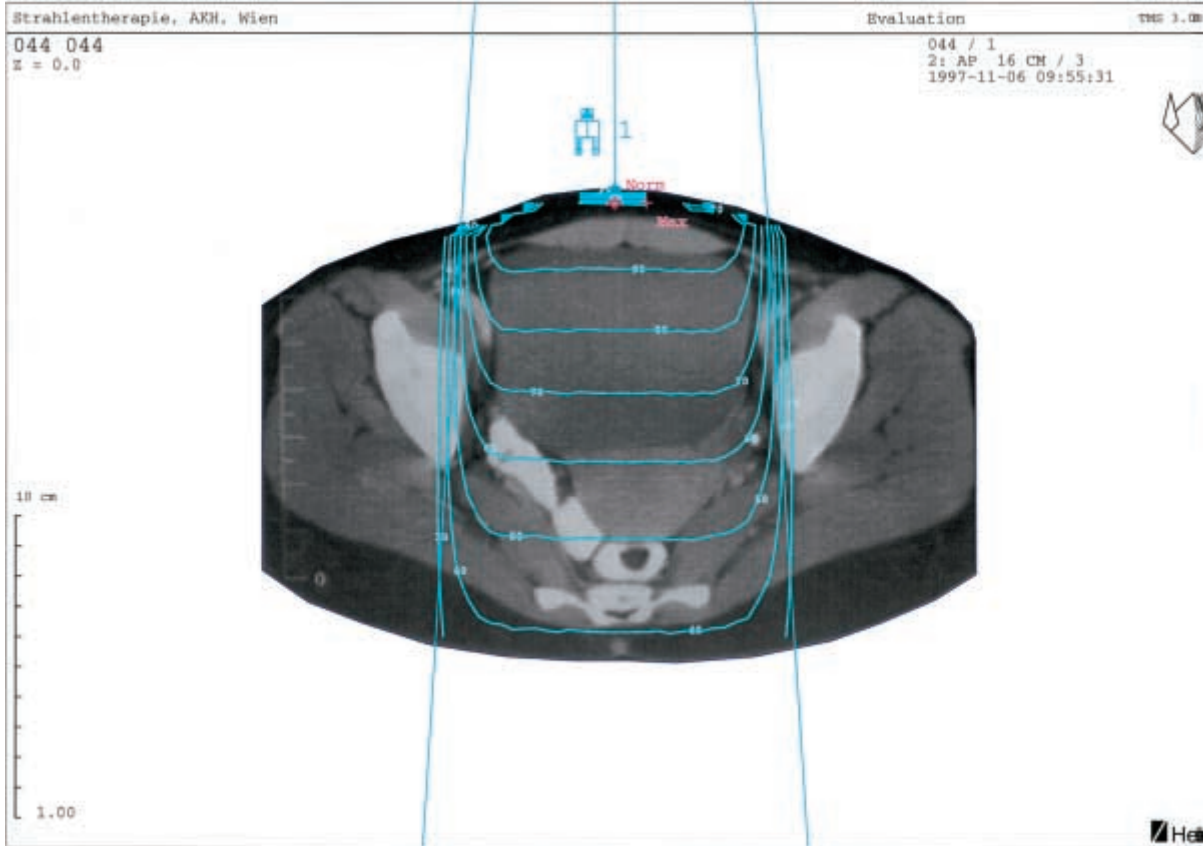
Image 8. Patient No. 44: cervix (skin folds and bowel).

TONGUE 046
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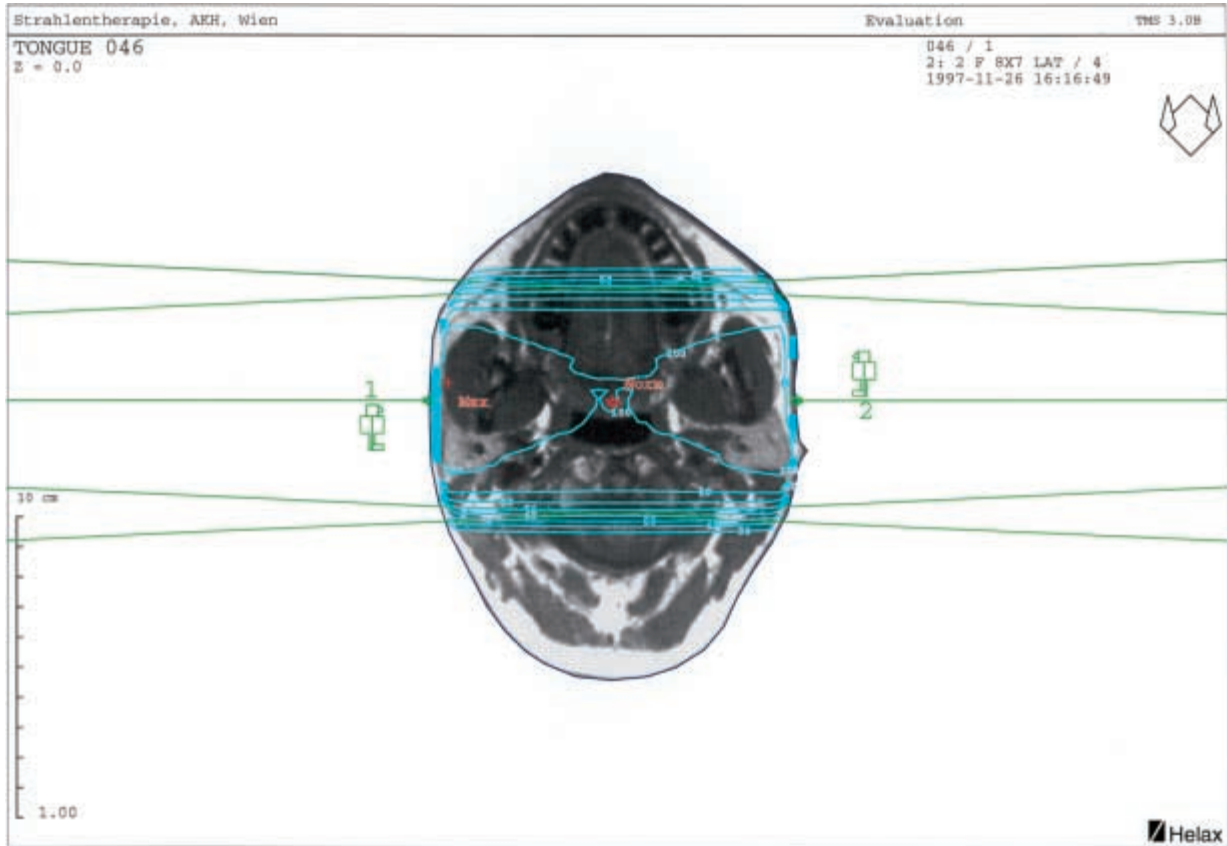
Image 9. Patient No. 46: tongue (skin and subcutaneous tissue).
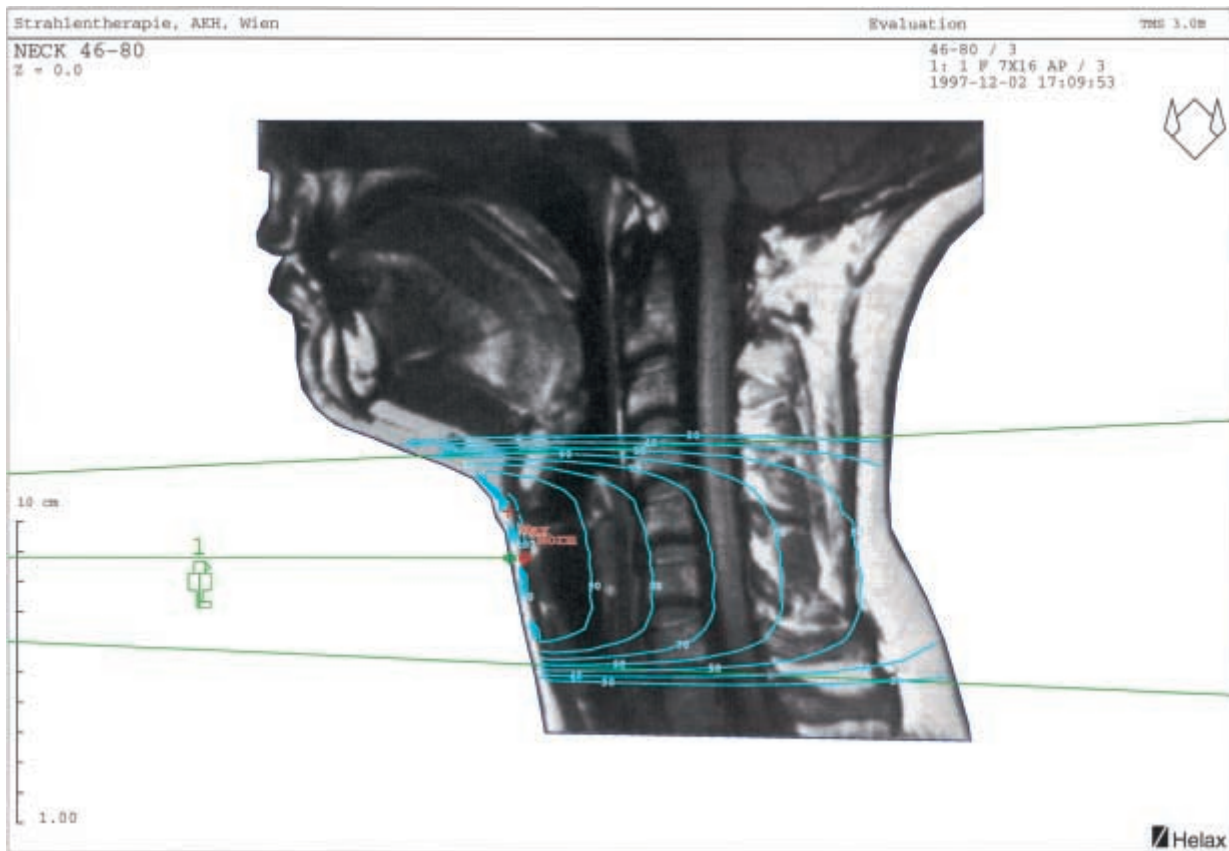
Image 10. Patient Nos 46 and 80: neck.

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10 CM

1.00

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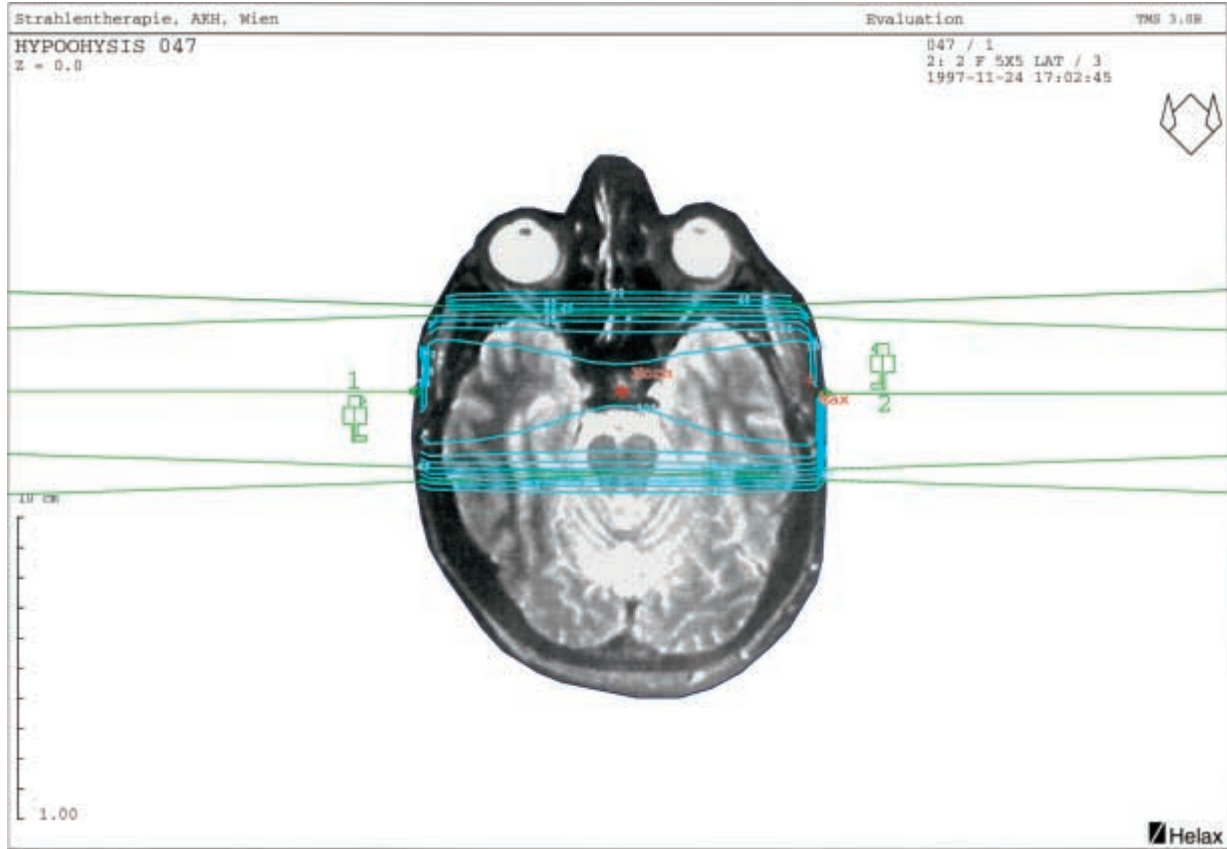
Image 11. Patient No. 47: hypophysis.
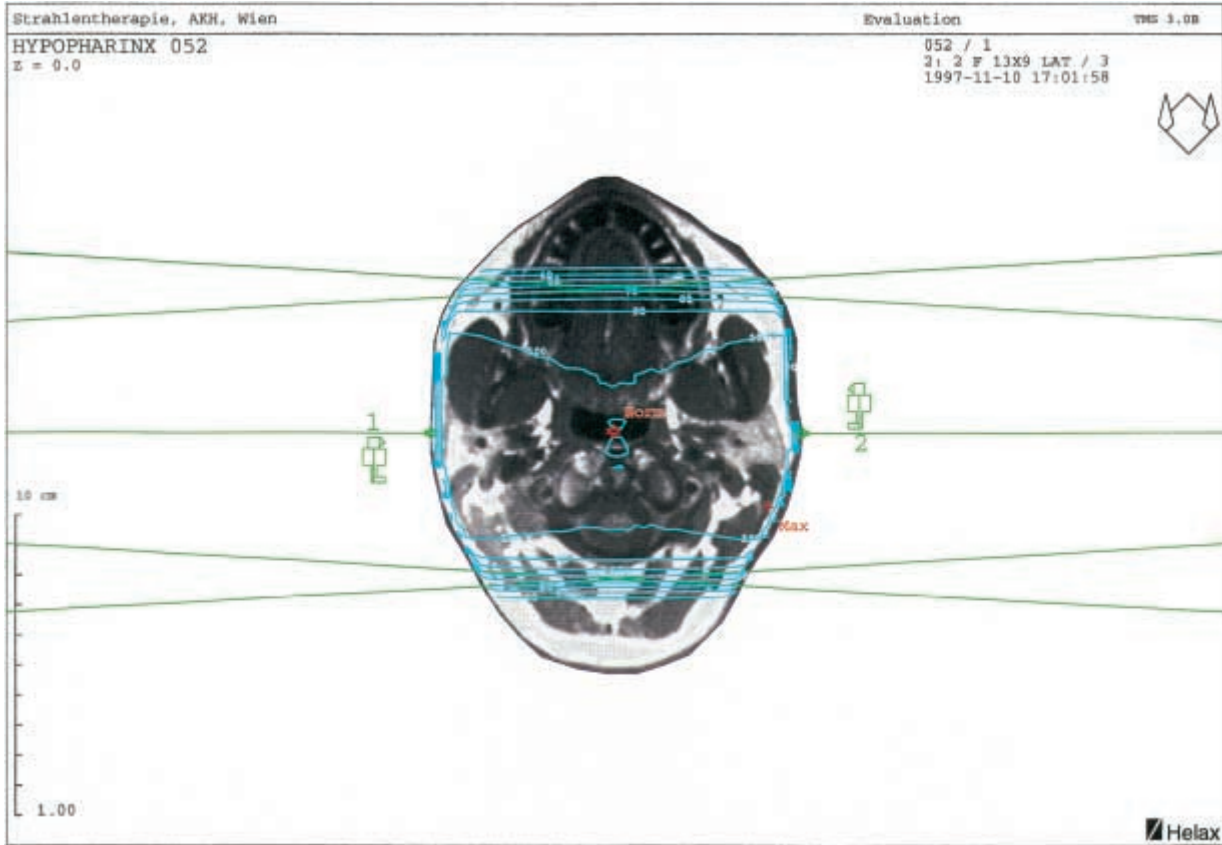
Image 12. Patient No. 52: hypopharynx.

Image 13. Patient No. 54: head.
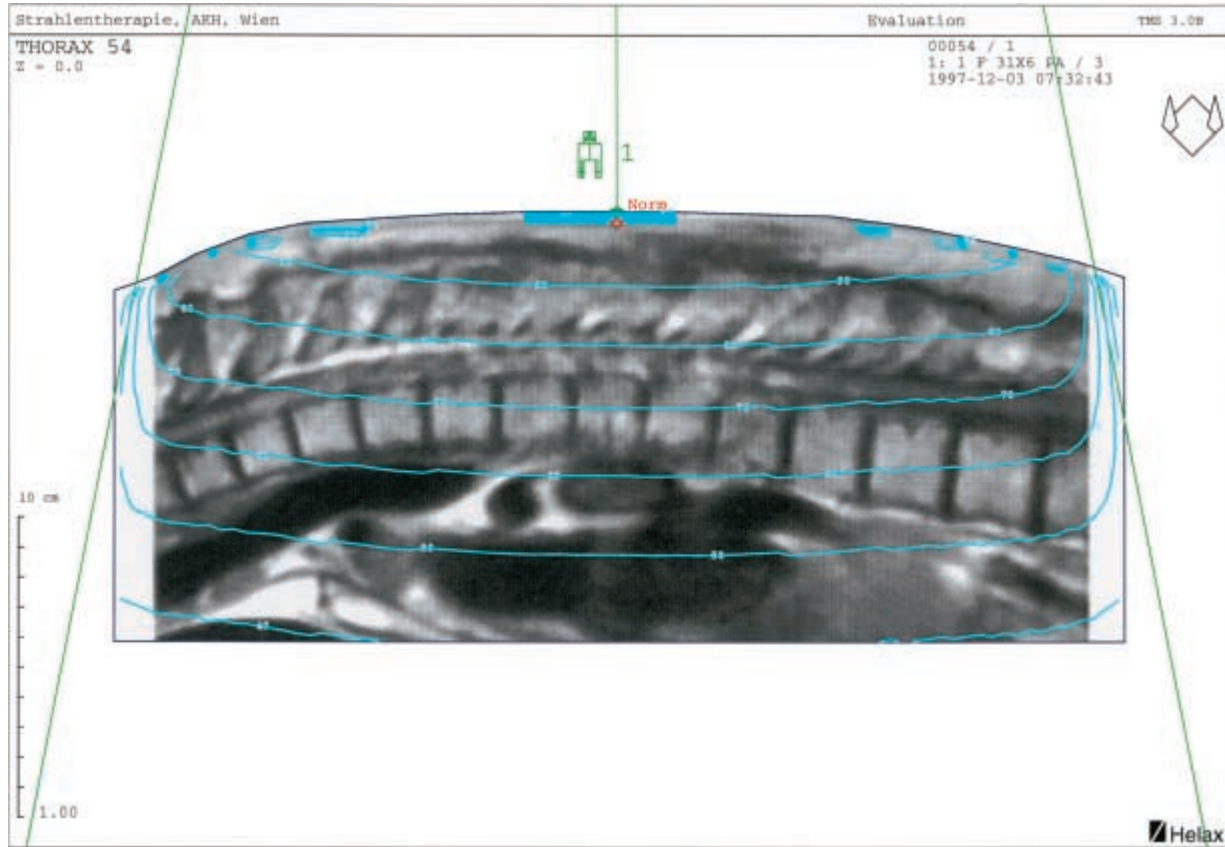
Image 14. Patient No. 54: thorax.

ABDOMEN 057

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1997-11-08 17:23:30

10 cm

1.00

Helax
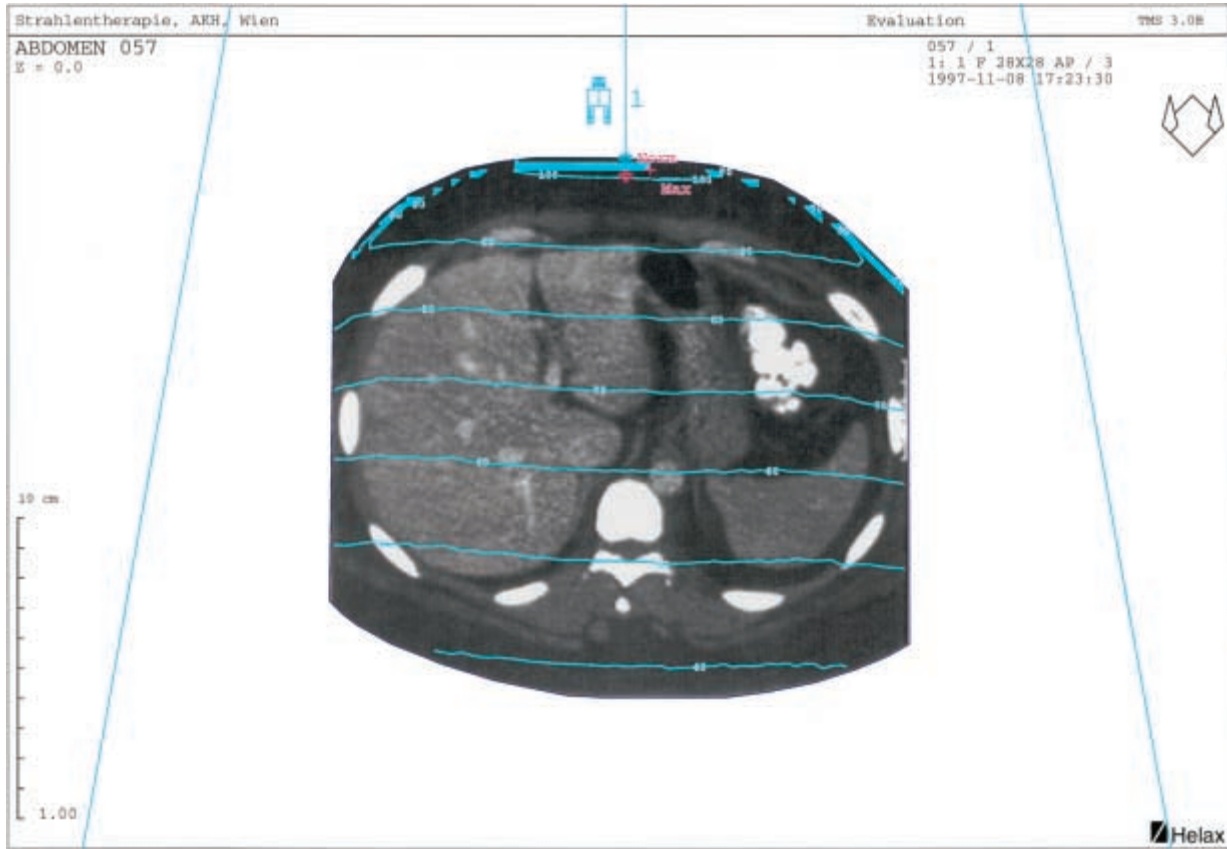
Image 15. Patient No. 57: abdomen.
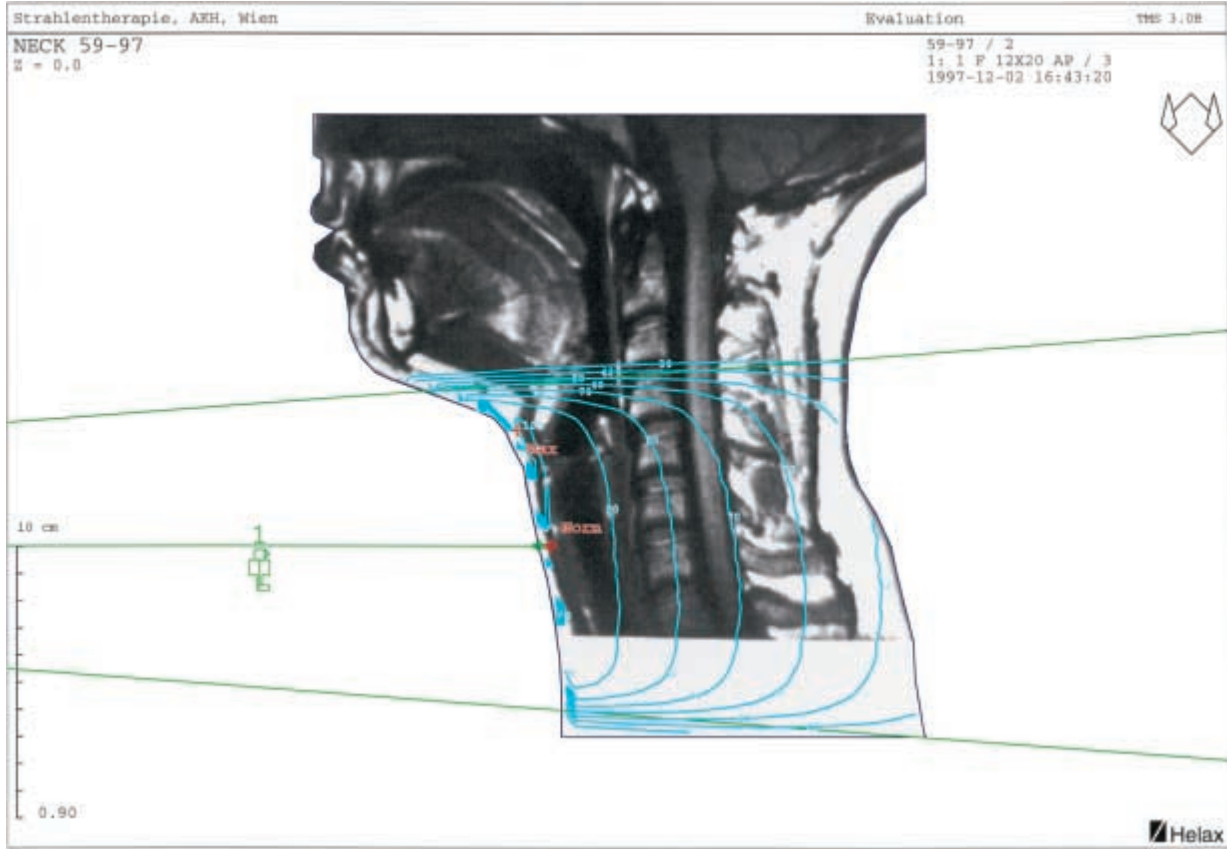
Image 16. Patient Nos 59 and 97: neck.
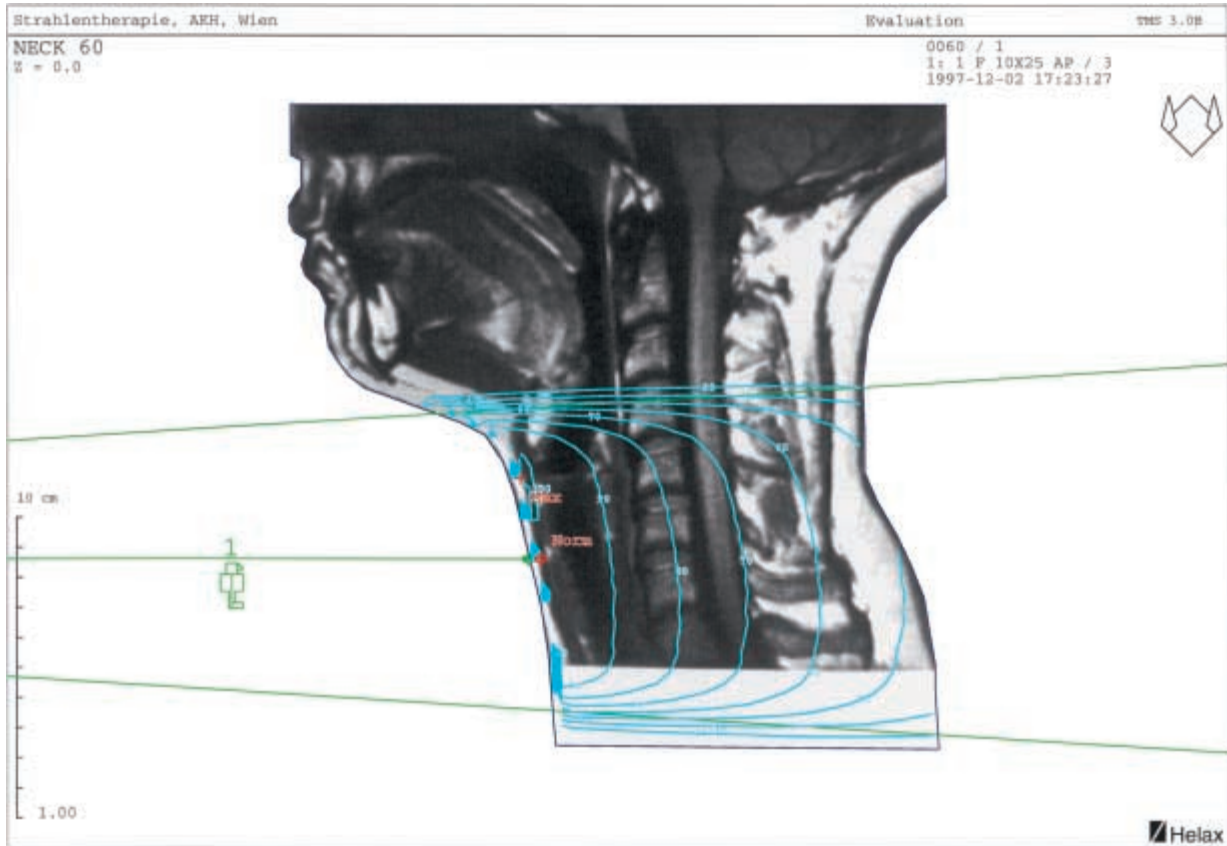
Image 17.   Patient No. 60: neck.
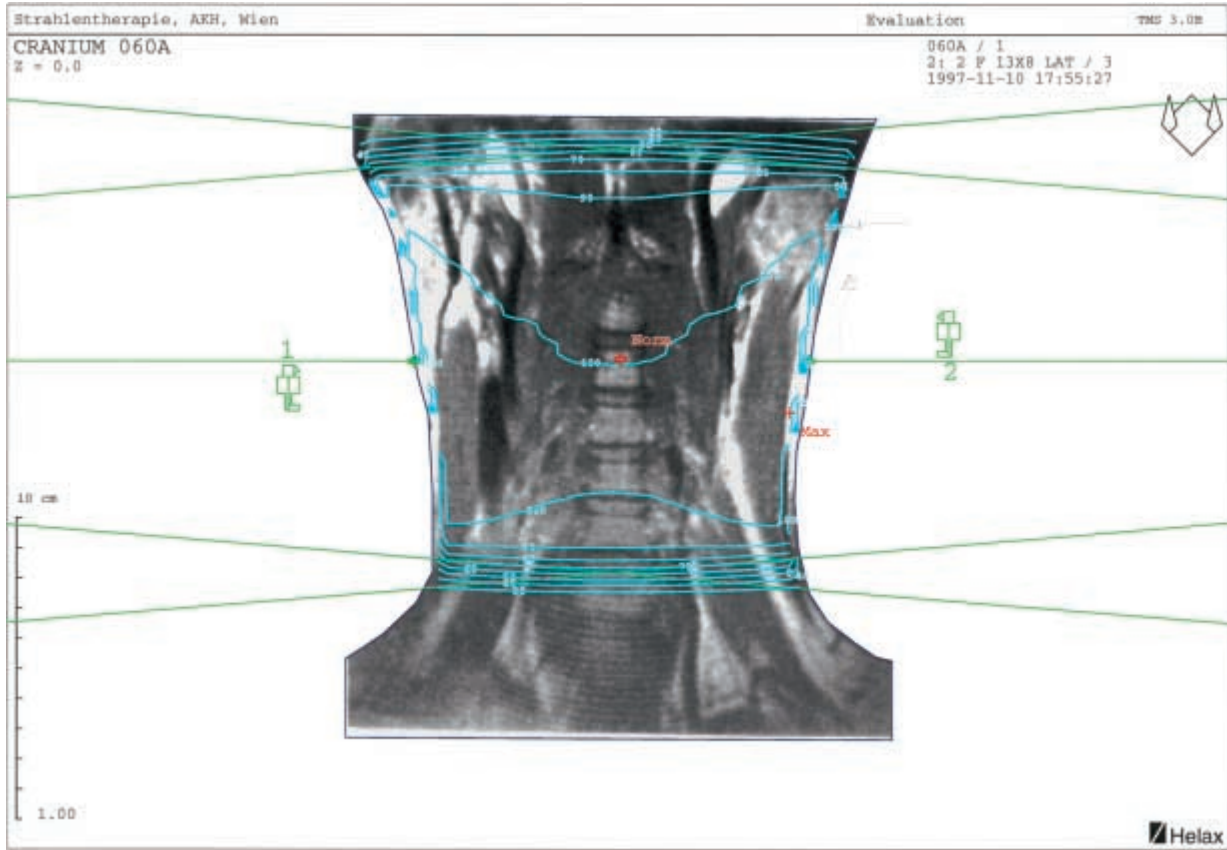
Image 18. Patient No. 60: neck.
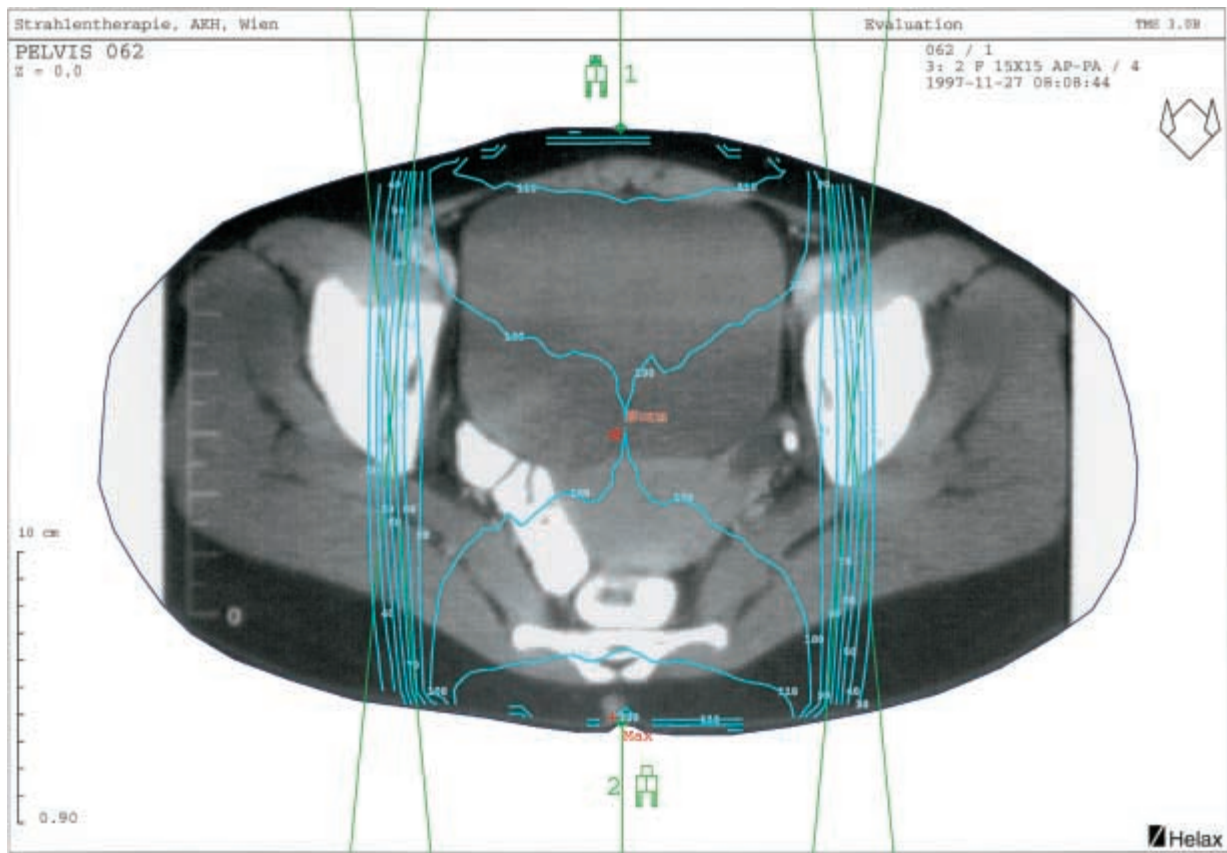
Image 19. Patient No. 62: pelvis, rectum.
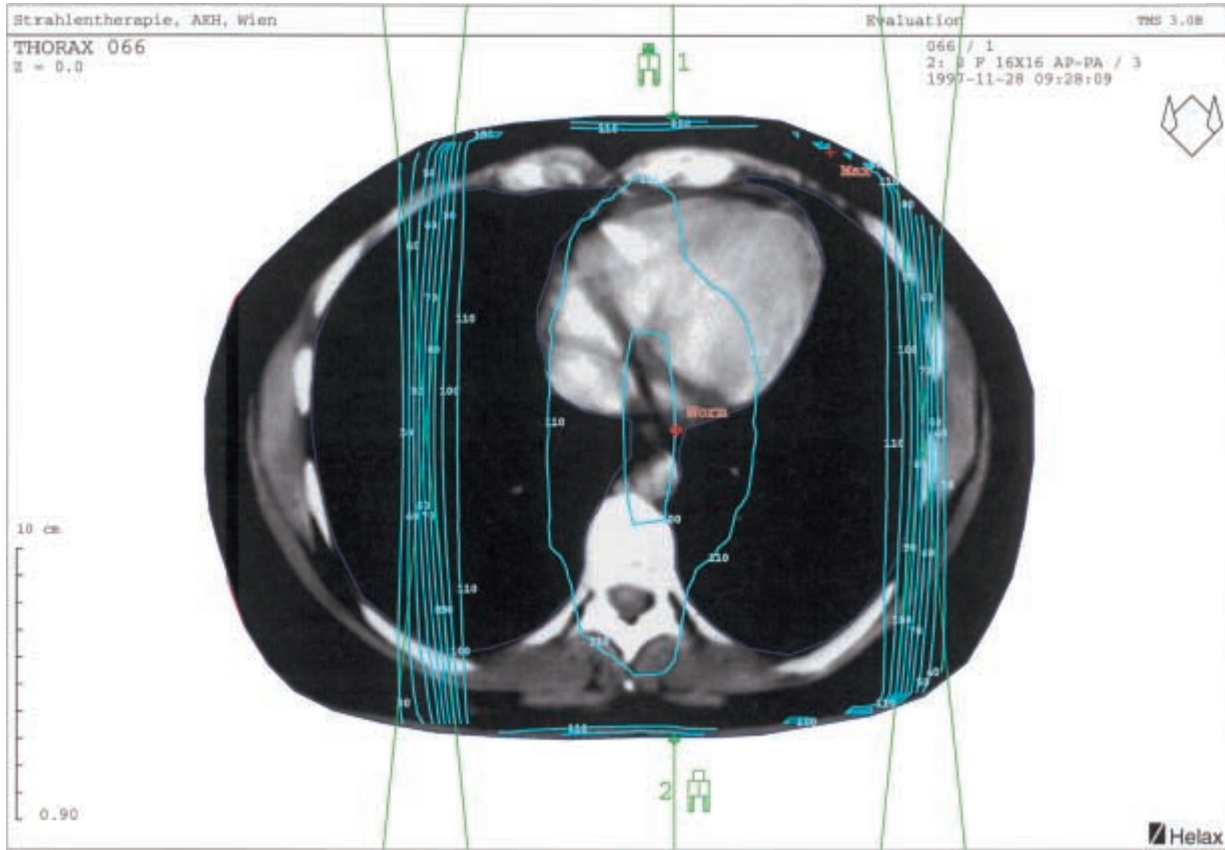
Image 20.   Patient No. 66: thorax, heart (P).
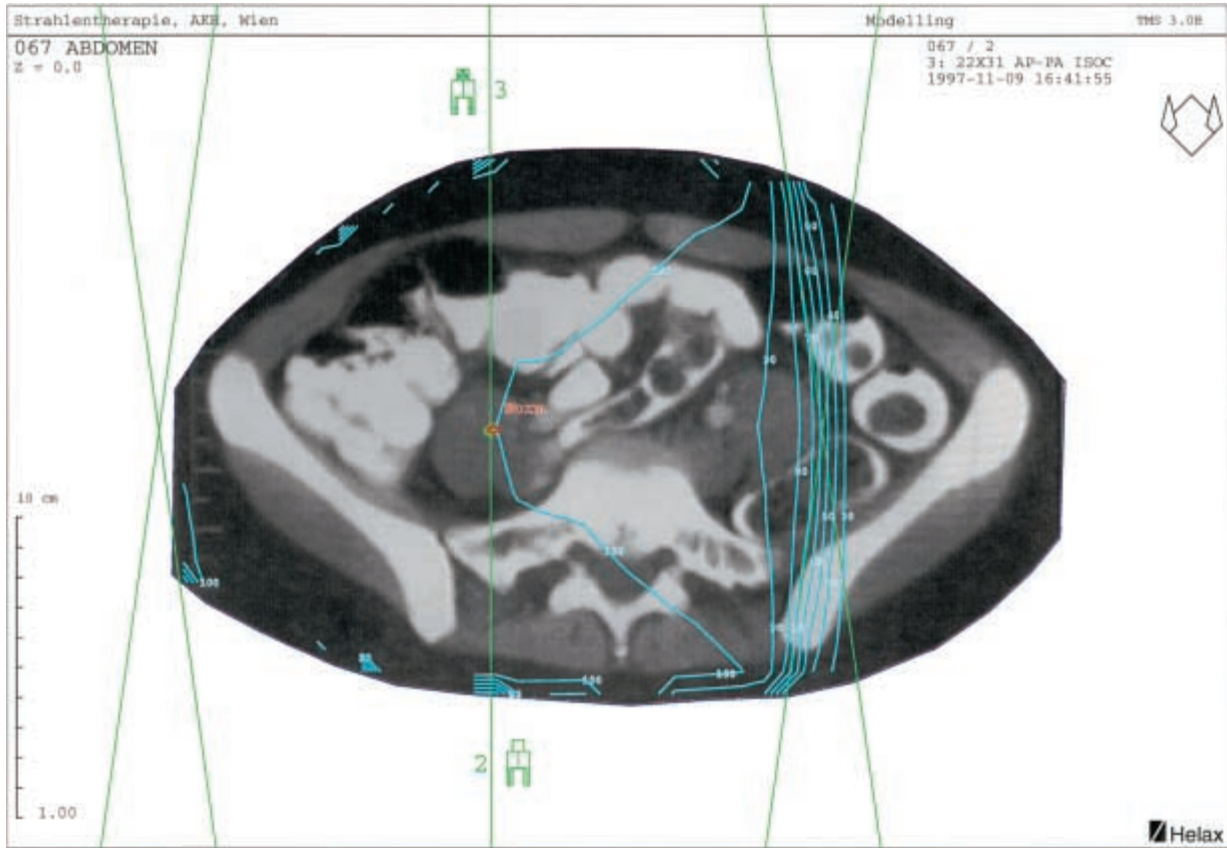
Image 21. Patient No. 67: abdomen, right colon.
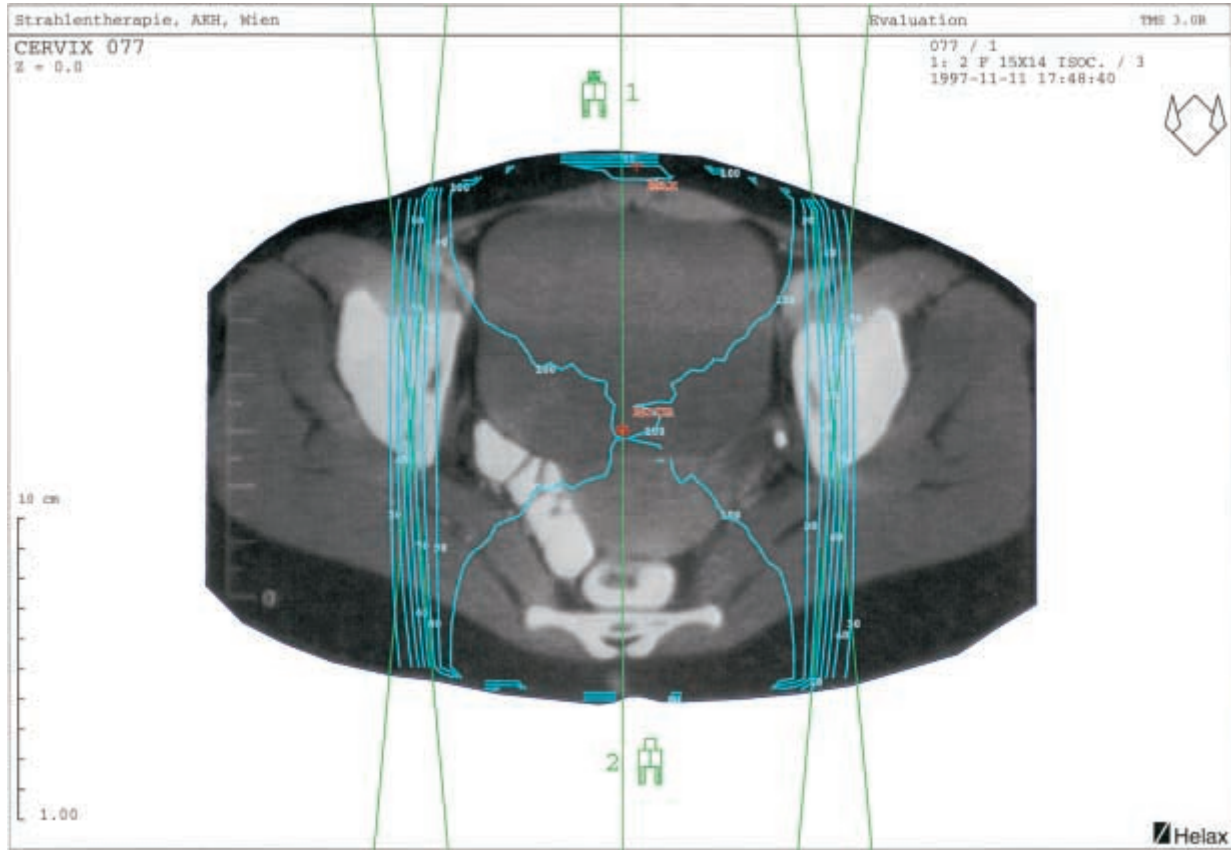
Image 22. Patient No. 77: cervix, subcutaneous and GI tissue.
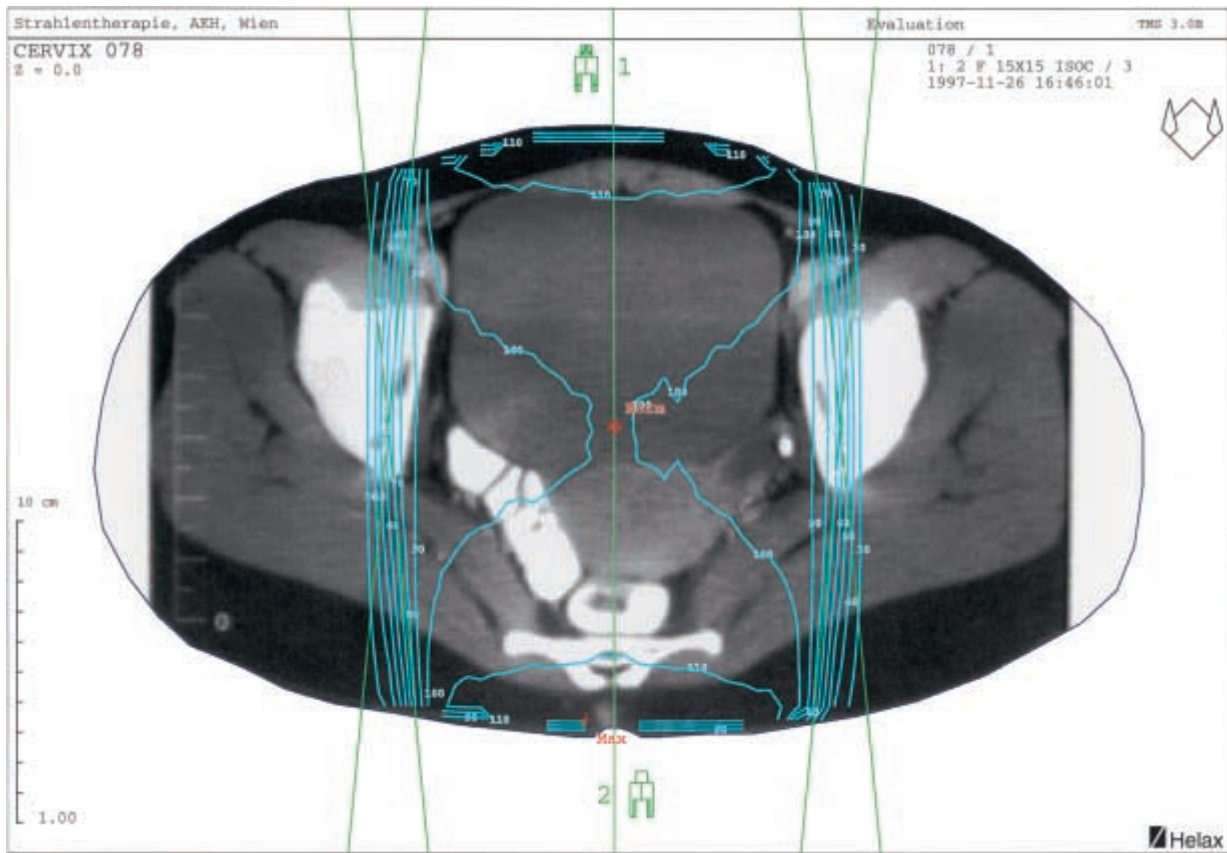
Image 23. Patient No. 78: cervix.
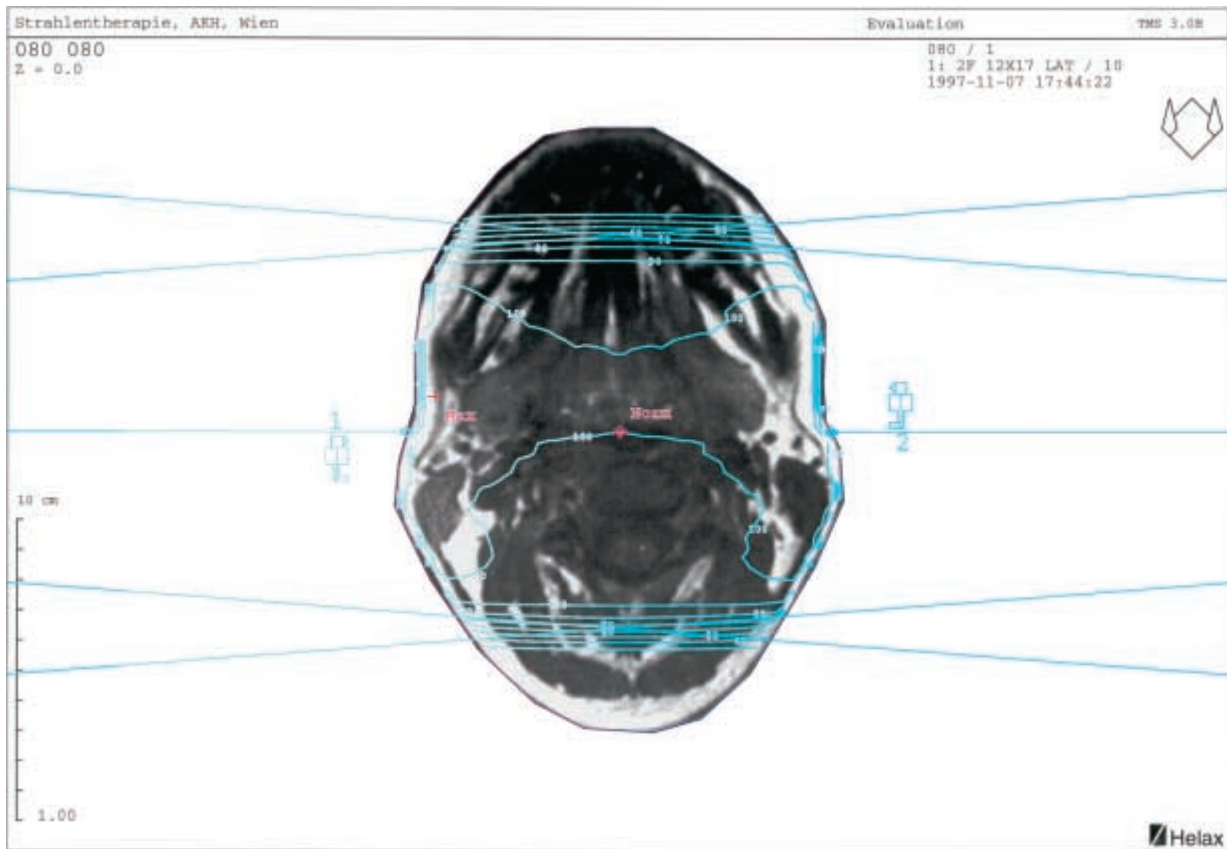
Image 24. Patient No. 80: neck.
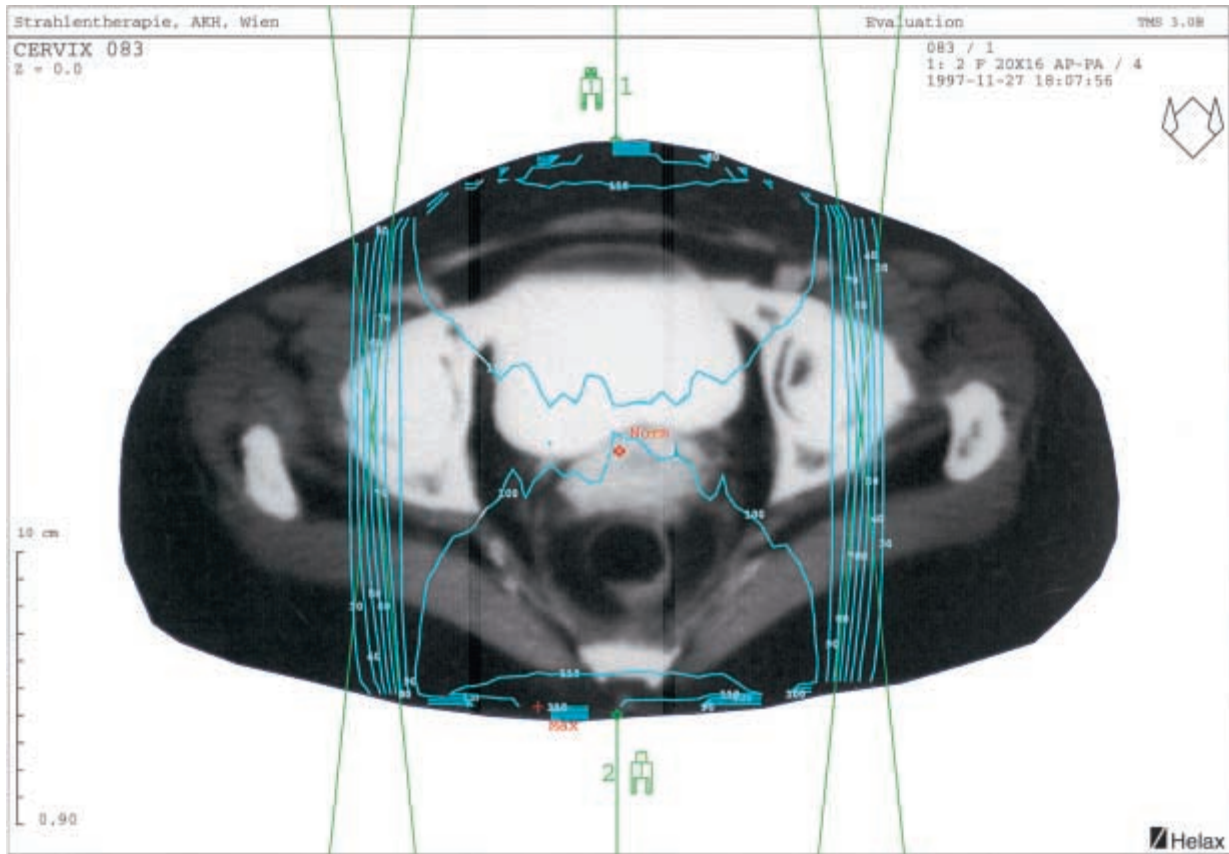
Image 25. Patient No. 83: cervix, bowel, rectum (P).
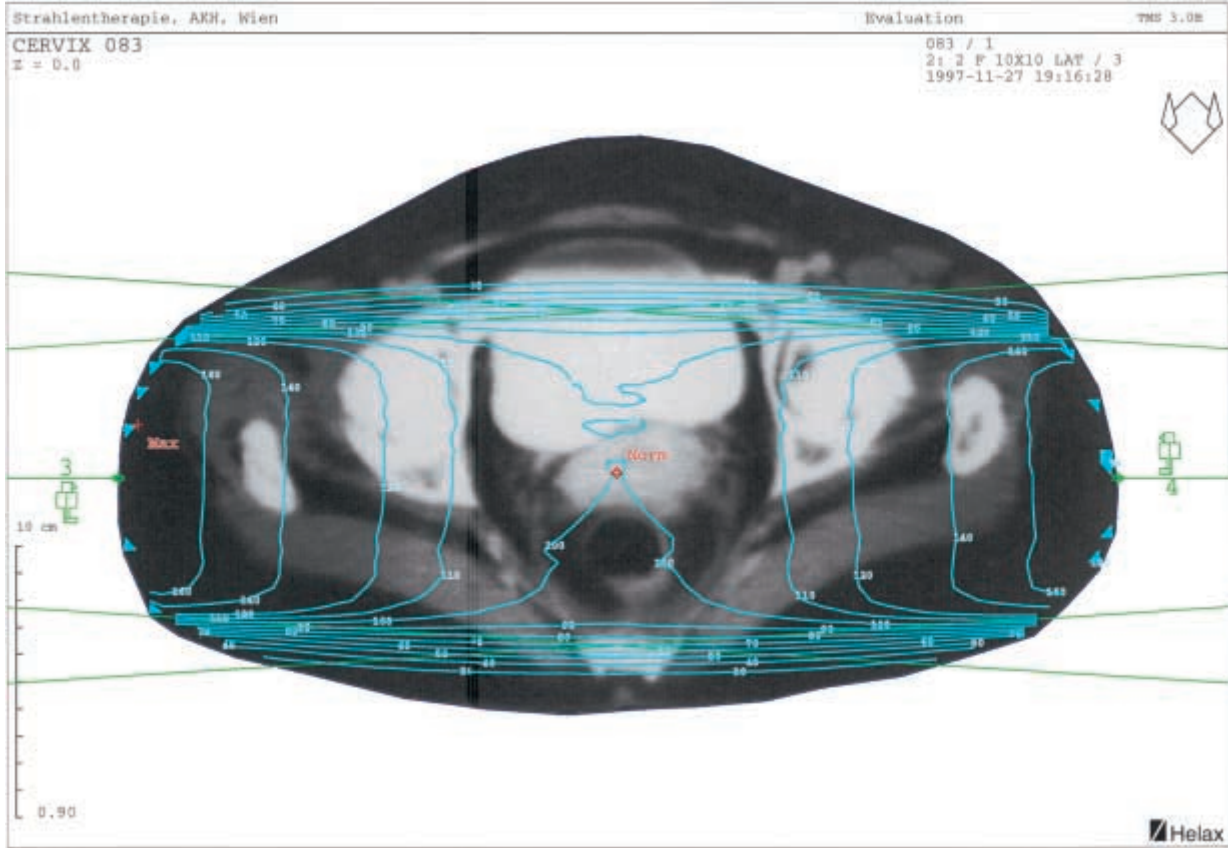
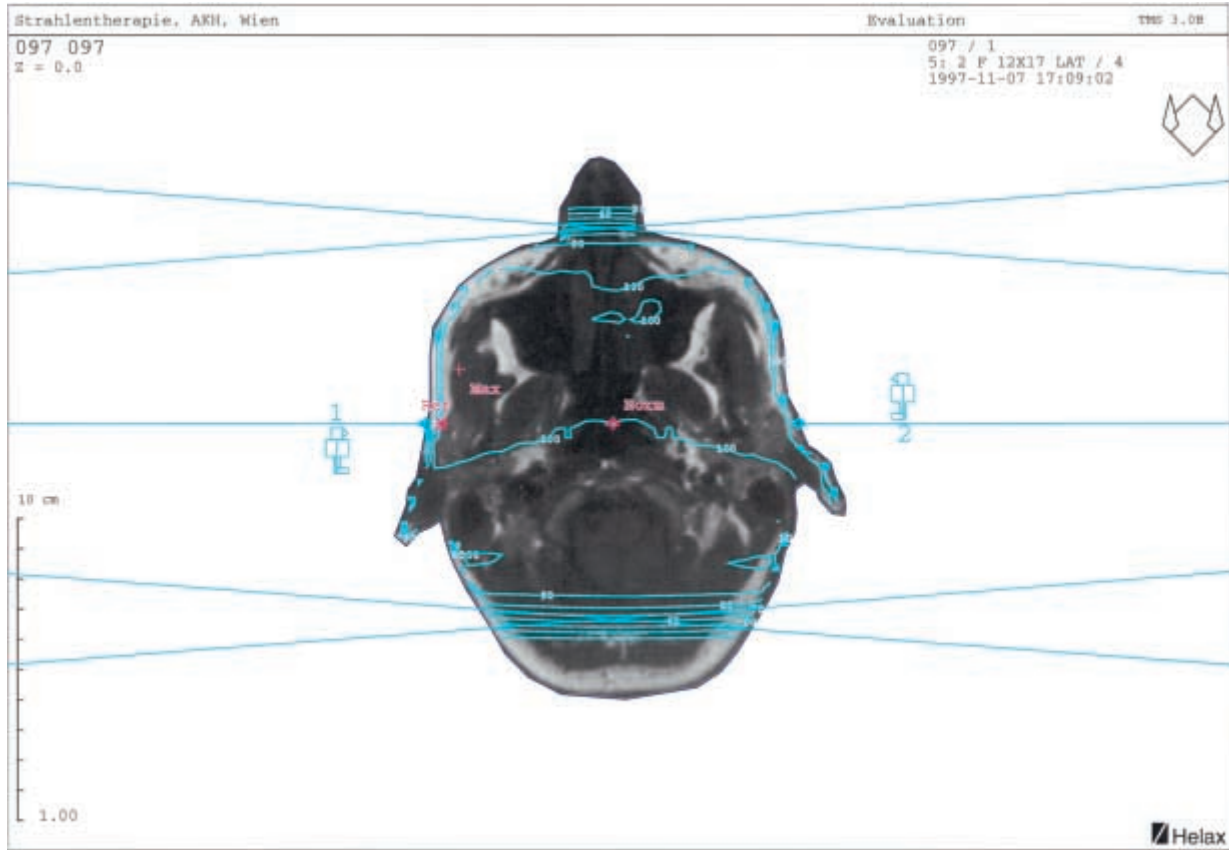*Image 26. Patient No. 83: cervix, rectum.*
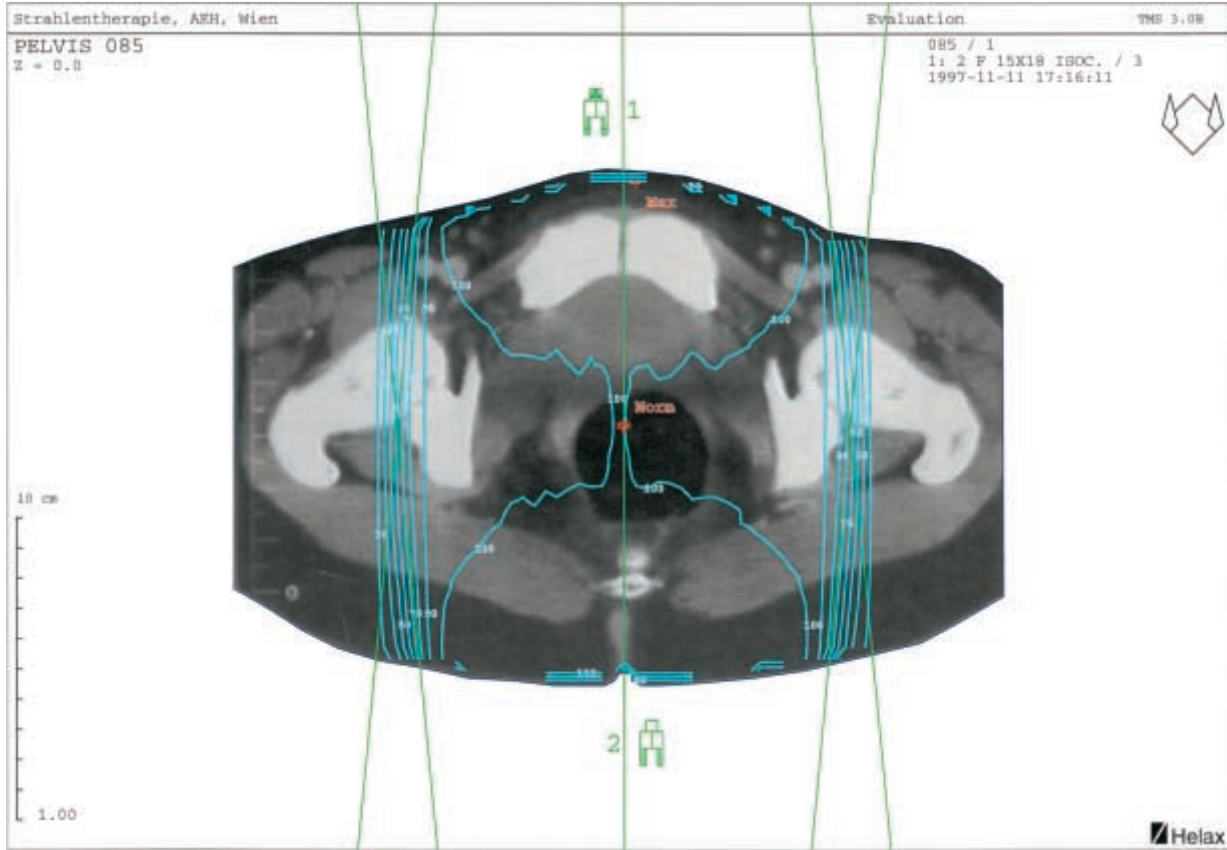
Image 27.   Patient No. 85: pelvis, rectum.
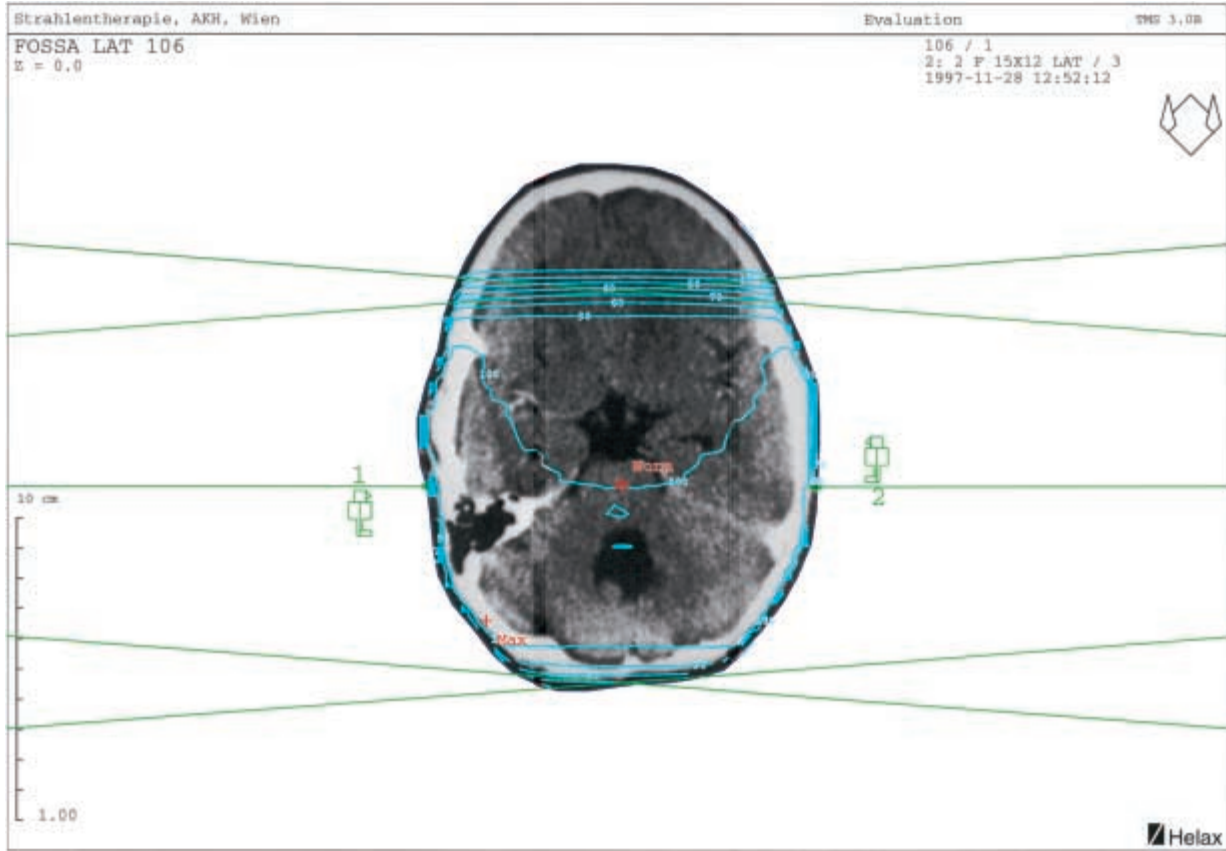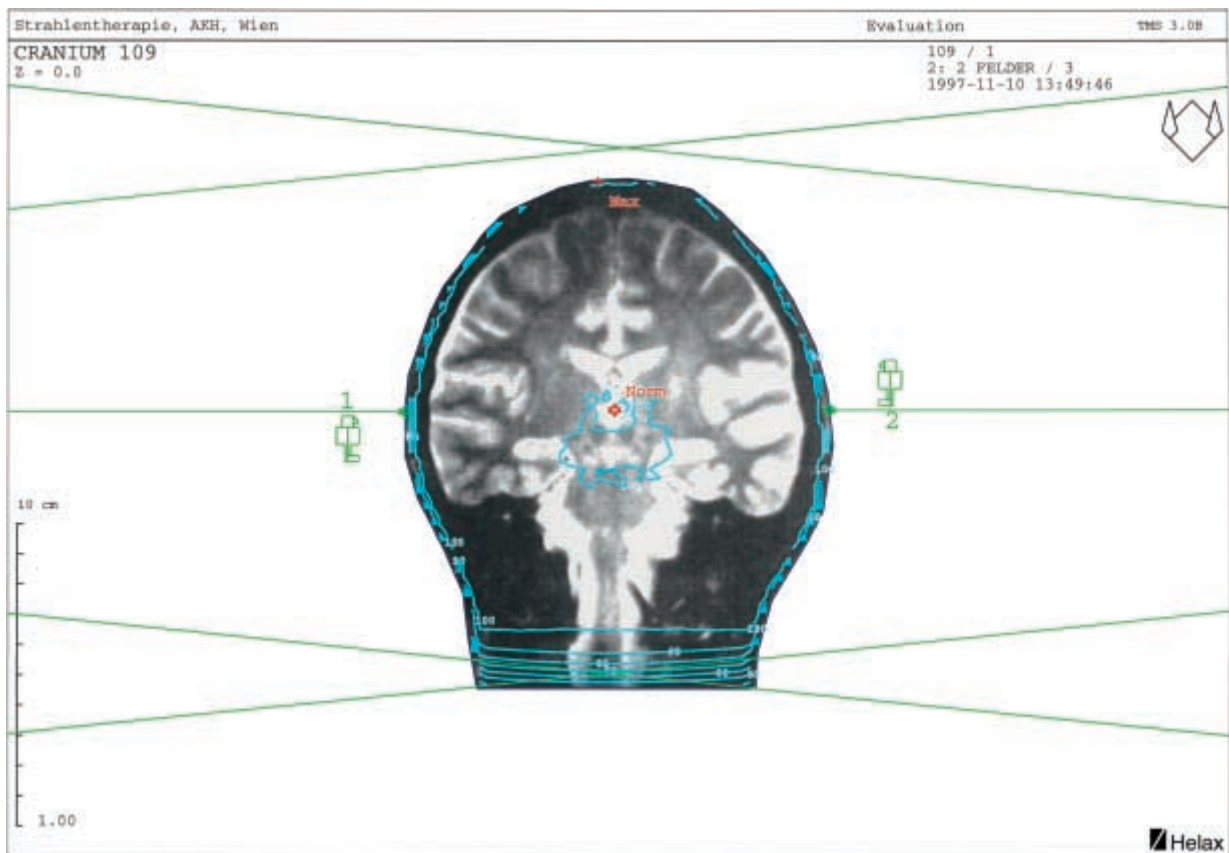
Image 28. Patient No. 97: cranium.

Image 29.   Patient No. 106: posterior fossa (P).

Image 30. Patient No. 109: cranium.