PREFACE

This report summarizes an assessment 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 made by a senior Expert Team convened by the IAEA in July 1997 at the request of the Government of Costa Rica.

A preamble to the report provides background information on radiotherapy in general and in Costa Rica, in particular. It 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 begins by providing a summary history of the accident. An account of previous investigations in Costa Rica, made both before and after the accident, is also 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 through the analysis of treatment records and physical measurements;
2. A medical evaluation of patients together with autopsy findings for those who died.

Finally, conclusions and recommendations are presented.

Two appendices detail the treatment parameters and doses for the patients as well as summaries of individual medical findings. An annex sets out the elements of the combined IAEA/WHO thermoluminescence dosimeter postal dose check service.

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EXECUTIVE SUMMARY

In July 1997, the International Atomic Energy Agency (IAEA) received a request from the Government of Costa Rica to assist in an assessment of an 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 Co-60 radiation therapy source was replaced. When the new source was calibrated, an error was made in calculating the dose rate. The miscalculation resulted in the administration to patients of significantly higher radiation doses than had been prescribed.

This was a major radiation accident. It appears 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 for use 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 (PAHO). 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 on 7–11 July 1997 and concluded its assessment in a meeting at the IAEA headquarters on 1–6 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%. The Team examined and evaluated 70 of the 73 patients who remained alive at that time of the review in July 1997. It was concluded that, at that time, four patients were suffering from catastrophic consequences and a further 16 were suffering major adverse effects owing to the overexposures and would be at high risk in the future. Twenty-six showed effects that were not severe but they will 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 for future effects. This was because many of these 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, within nine months of the accident, 42 of the patients had died. Data on 34 of the 42 patients who had died were reviewed by the Expert Team. While the final answers must await full autopsies and review of the clinical records, it appears that three patients may have died as a direct result of the 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 and not owing to radiation exposure. Information on the other five deaths was either inconclusive or unavailable. Information on all patients, including information 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 overexposures are not yet evident. Irreversible radiation effects and complications due to this accident are likely to continue to appear in patients over 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 condition, 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 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 has also provided specific lessons to be learned:

- Radiation accidents with severe and even fatal consequences do occur in medical facilities.
- Human error is the most common cause of radiation accidents.
- 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.
- The investigation of radiation accidents generally reveals faults that should be corrected.

- When there is a high incidence and severity of acute effects during radiotherapy treatment, the treatment should be stopped and the source calibration checked immediately.
- In radiotherapy accidents, the tumour dose may not be the parameter of primary interest. Often the biologically effective dose to sensitive structures such as the spinal cord, heart and intestine are more important.
- 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.
- Radiotherapy 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.
- When radiation therapy sources are replaced, the calibration should be done by appropriately trained persons and the calculations should be independently checked.
- A properly operating machine does not guarantee good radiotherapy treatment. Adequate ancillary equipment, education and training, staffing and management are essential..
- Regulations should cover training and competence required to deal with potentially hazardous radiation sources.
- Specific training should be given after an individual working in a radiotherapy unit has received a thorough basic education and should not consist simply in attending occasional short courses.
- Radiotherapy records should be uniform, clear, consistent and complete.
- Early and reliable information and communication are crucial for good management of radiation accidents.
- Radiation accidents can have major short and long term psychosocial consequences.

The Expert Team, in the light of its investigation of this accident, makes the following specific recommendations to the Government of Costa Rica:

- Radiation therapy is necessary and should be continued in Costa Rica.
- Radiotherapy in general should be improved to avoid unnecessary and unacceptable harmful outcomes.
- Existing radiation protection regulations should be implemented, enforced as soon as possible, and kept up to date.
- Quality assurance programmes should be developed and implemented.

- Education and training for radiation therapy staff should be improved.
- Record keeping in radiotherapy charts should be improved.
- If external auditing, such as (confidential) dose check services, discovers significant, persistent and continuing problems, another channel of communication to the authorities should be sought.
- Major medical and psychosocial support should be provided now to many patients and will probably be needed for at least the next five years.
- A registry of data on these patients should be set up.

The Expert Team further recommends that the IAEA publish this report in the open literature so as to foster information exchange to help prevent similar accidents elsewhere in the future.

1. PREAMBLE: 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 such as 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 patients with advanced cancers who cannot be cured. Radiotherapy plays an important part in the management of such patients.

It has been estimated for the United States of America (USA) and for the European Union (EU) that radiotherapy is useful for up to 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 these, about 1.63 million were male and 1.59 million female. According to a 1991 report, the capital San José then had 1.11 million inhabitants. About 60% of the Costa Rican population resides in urban areas and 40% in rural areas. Life expectancy at birth in Costa Rica in the period 1990 to 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 for each 100,000 inhabitants. Of these 4198, 2217 cases were in females and 1981 cases were in males. Skin cancer appeared to be the most common cancer among Costa Rican women, with 373 diagnosed cases in 1992. The second most common was breast cancer, with 323 cases, followed by uterine cervix cancer with 265 cases, in situ cervix 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 were various other types of cancer in males.

The general mortality rate in Costa Rica for 1993 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 the second cause of death in Costa Rica, after 3930 deaths related to ailments of the circulatory system. For these 2608 cancer deaths, stomach cancer was the main cause of death, in 604 cases, 23.14% of all cancer deaths. The next four most common types of fatal cancer were lung cancer with 209 cases, prostate cancer (162 cases), breast cancer (140 cases) and uterine cervical cancer (135 cases).

Analysing by gender causes of death, 1385 males and 1223 females died of cancer. The first five causes of cancer death in males are stomach cancer, with 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 cancer death in 218 cases, breast cancer in 140 cases, uterine cervical cancer in 135 cases, then 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, which also function as referral centres for different parts of the country. These are San Juan de Dios Hospital, México Hospital and Dr. Rafael Angel Calderón Guardia Hospital, with 882, 630 and 522 beds respectively.

Two hospitals, San Juan de Dios Hospital and México Hospital, offer radiotherapy facilities. There is a radiotherapist in Calderón Guardia Hospital, which does not have equipment for radiotherapy treatment, so radiotherapy patients are moved daily to the San Juan de Dios Hospital. Five radiotherapy oncologists work for the state social security system (CCSS); there are no radiotherapists available in private medical institutions. There is one physicist and there are nine radiotherapy technicians in total in Costa Rica.

There are three radiotherapy units available, all with cobalt sources: two Theratron-80 models and one Alcyon CGR II model. San Juan de Dios Hospital is equipped with one Theratron-80 and one Alcyon CGR II machine, 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. There is also a Toshiba simulator. There is no computer based planning for radiotherapy in the country, and there are no styrofoam cutters for use in manufacturing the protective lead blocks.

For brachytherapy, there are only five beds for applications of intracavitary 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 three months.

The human and technical resources for radiotherapy presently 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

In order to be effective, radiation therapy must reach doses that are toxic to the malignant cells. At these levels of dose, a substantial number of normal cells will also be killed. The number of cells killed is the result of the total dose; that is, 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 in the centre of the tumour is higher than at any point on the surface; and (3) dividing (fractionating) the treatment into 25 days (usually treating with each different radiation field every day). Usual fractionation schemes give doses of 1.5–2.0 Gy per day, four to five days per week. Even with these measures taken and when practice is good, complications of radiotherapy will develop. A serious complication rate of 5% is usually considered acceptable and is anticipated owing to individual variation in sensitivity to radiation. If the radiation doses received are lower, there will be fewer, if any, complications due to radiation, but this also implies that there will be fewer cures. On the other hand, higher doses will cause potentially more cures but also more complications.

If the total dose is increased, more cells will be killed. Also, if the total dose stays the same but the dose per fraction is increased and the number of fractions is 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 in comparison 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 shown in Table I and are the result of achieving certain total doses with the usual fractionation schemes. In the case of this accident, 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 that shown in the table. Specific values for different fractionation schemes will be quoted further in this report when available and applicable.

It should be pointed out that, while it is possible to calculate doses quite precisely, there is significant individual variation in response among patients. Calculated doses should only be used to provide a general guide and not firm conclusions concerning causation of adverse effects. There are a few rare

TABLE I. RADIATION TOLERANCE DOSES (in rad)

Organ	Injury at 5 years	1-5% (TDs/5)	25-50% (TDso/s)	Volume or length
Skin	Ulcer, severe fibrosis	5500	7000	100 cm3
Oral mucosa	Ulcer, severe fibrosis	6000	7500	50 cm3
Oesophagus	Ulcer, stricture	6000	7500	75 cm3
Stomach	Ulcer, perforation	4500	5500	100 cm3
Intestine	Ulcer, perforation	5000	6500	100 cm3
Colon	Ulcer, stricture	4500	6500	100 cm3
Rectum	Ulcer, stricture	5500	8000	100 cm3
Salivary	Xerostomia	5000	7000	50 cm3
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 cm3
Breast (adult)	Atrophy and necrosis	>5000	>10,000	Whole
Lung	Pneumonitis, fibrosis	4000	6000	Lobe
		1500	2500	Whole
Capillaries	Telangiectasia, sclerosis	5000-6000	7000-10,000	–
Heart	Pericarditis, pancarditis	4500	5500	60%
Bone (child)	Arrested growth	2000	3000	10 cm3
Bone (adult)	Necrosis, fracture	6000	15,000	10 cm3
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 cm3
Eye	Panophthalmitis, hemorrhage	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	Hypothyroidism	4500	15,000	Whole
Adrenal	Hypoadrenadism	>6000	—	Whole
Pituitary	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
		3000	4000	Localized
Lymph nodes	Atrophy	4500	>7000	–
Lymphatics	Sclerosis	5000	>8000	–
Foetus	Death	200	400	Whole

Taken from Ref. [1].
Note: There are no dose data available for the pancreas, gall bladder or aorta.

individuals in populations 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:

- The selection of patients and the clinical work-up has to be adequate in order to permit an appropriate prescription of radiotherapy.
- In order to deliver the prescribed dose (a range of approximately plus or minus 7% being accepted) to the relevant tumour and critical tissues (an uncertainty of around plus or minus 5 mm often being accepted), a number of instruments are necessary, or at least useful:
  - Treatment machines that can deliver at least one high energy and one low energy photon beam are necessary (e.g., Co-60 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.
  - Brachytherapy (intracavitary or interstitial) plays an instrumental role, especially for gynaecological cancers. For the radiation protection of personnel, dedicated instruments are needed.
  - Positioning and immobilization systems for patients must be available in order to minimize the irradiation of healthy tissue.
  - 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 gives only an approximate estimate.
  - In order 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.
  - A number of dosimetry systems can be used in order to check the dose within and at the patient (*in vivo*), such as thermoluminescence dosimetry (TLD) or diode dosimetry.
  - Different quality assurance (QA) systems must be in routine use in order to conform with the requirements for precision 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. For optimal use of resources, it is necessary that the quality of the procedures be maintained 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).

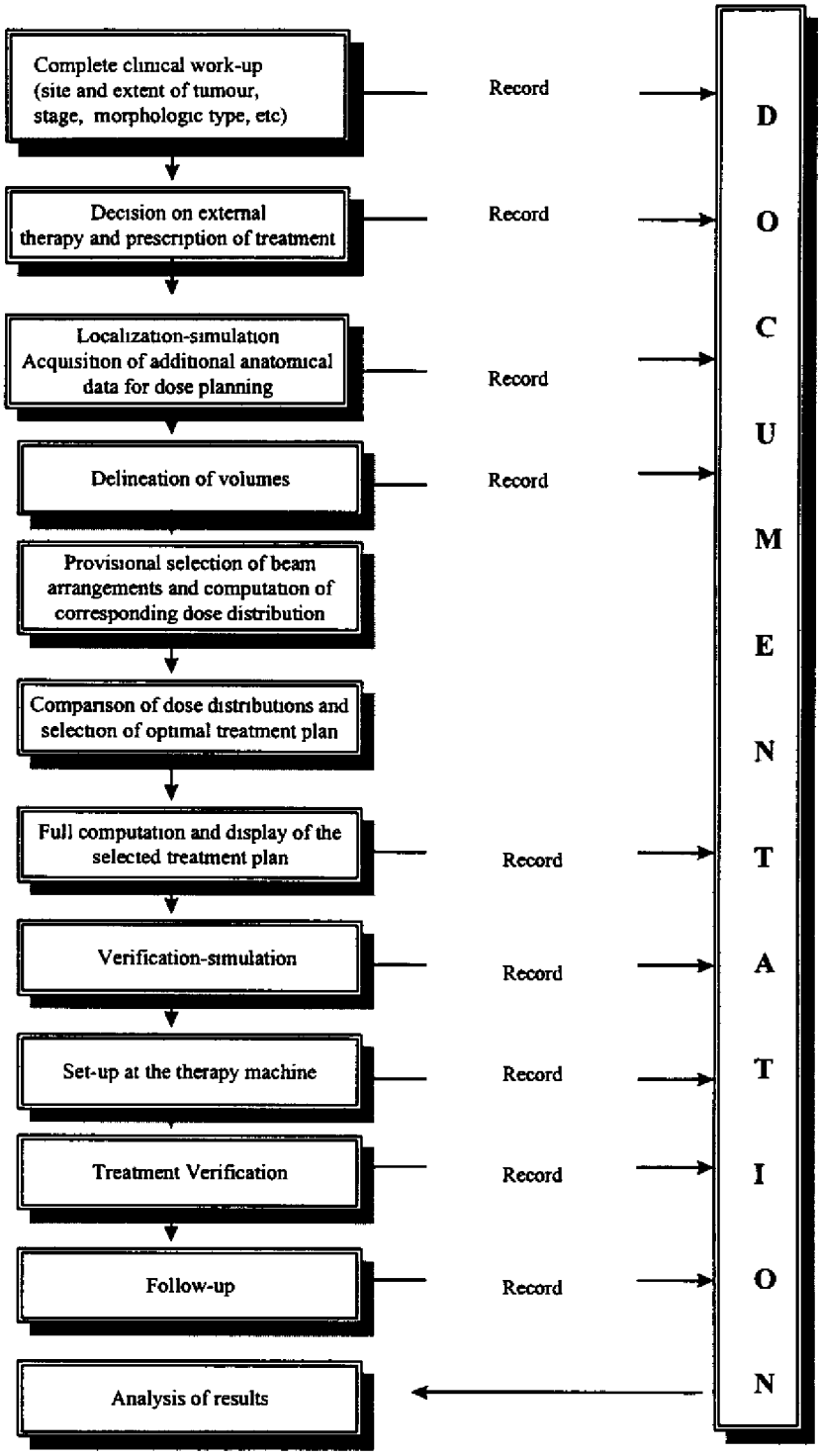

Fig. 1. Steps in the radiotherapy procedure. *NB.* There should be a continuous feed-back between all the different steps. A difficulty at a given point may question all the decisions made at previous steps. (From ICRU Report 50, 1993).

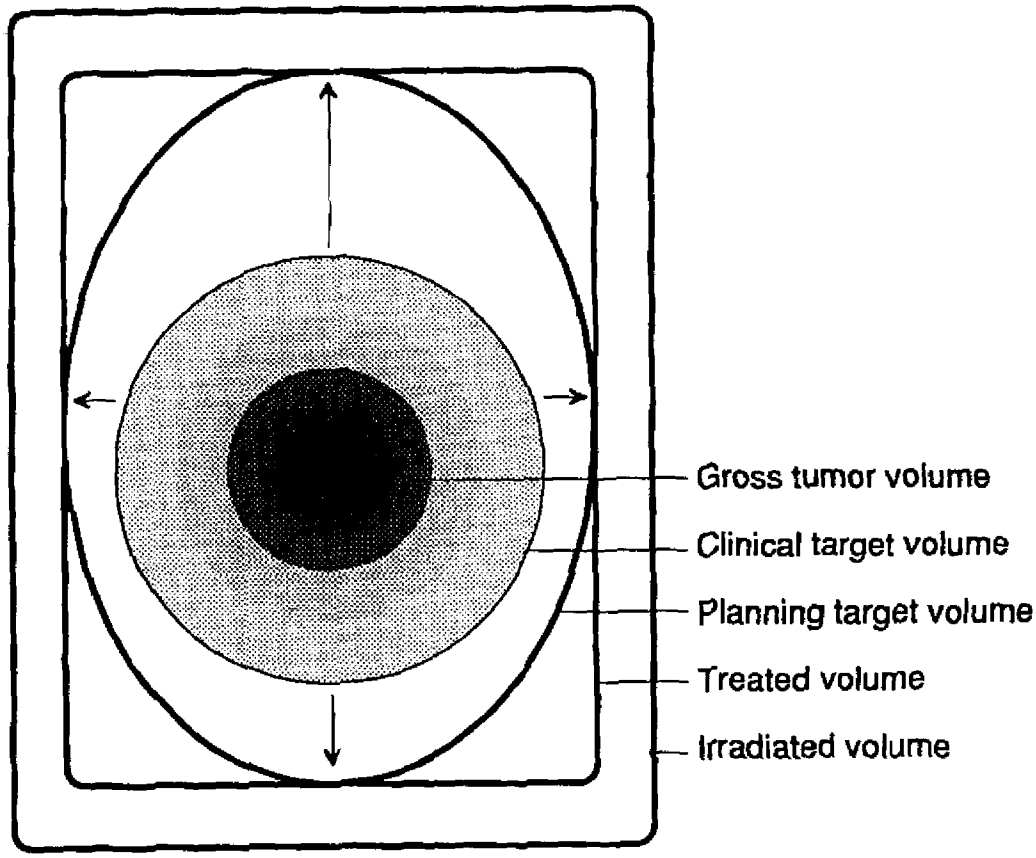

FIG. 2. Schematic illustration of the different volumes. Gross tumour volume (GTV) denotes the demonstrated tumour. Clinical target volume (CTV) denotes the demonstrated tumour (when present) and also a volume with suspected (subclinical) tumour (e.g. the margin around the GTV and, for example, regional lymph nodes, NO (according to the TNM classification [3] *considered to need treatment). The CTV is thus a purely anatomical-clinical concept. 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. Treated volume is the volume that receives a dose that is considered important for local cure or palliation. Irradiated volume is the volume that receives a dose that is considered important for normal tissue tolerance (other than those specifically defined for organs at risk). (Adapted from ICRU Report No. 50, 1993* [4].*)*

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

The use of a 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 the determination of its size and shape (Fig. 2). The anatomical data are used as a basis for the 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:

- A definition of the organs/tissues to be treated (for example, 'right tonsil and lymph nodes on the right side of the neck'). This anatomical prescription can be codified.
- A prescription of dose and fractionation (for example '68 Gy for the right tonsil, given in daily fractions of 2 Gy, plus 50 Gy to the lymph nodes with the same fractionation').
- A description of organs at risk (for example '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. 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 choose the best one. Once the treatment planning is chosen, it is verified by means of film radiographs in the therapy unit. The first session and in vivo verification should be done before the actual treatment commences and this applies for every treatment. This is achieved by the use of in vivo dosimetry[1] with the use of TLD detectors and/or diodes.

[1] Dose verification, usually by the application of 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.

In the prescription procedure, a number of additional issues, including fractionation, will need to be addressed. Unless otherwise stated, it is assumed (see ICRU Reports Nos 29 and 50) that all fields are treated at each fraction, and that five fractions are given each week, which is usually considered standard treatment.

Methods to reduce the number of fractions (often due to limited radiotherapy resources) will have implications for:

1. tumour eradication;
2. frequency and severity of early normal tissue reactions ('acute side-effects');
3. frequency and severity of late normal tissue reactions ('complications').

It is important to understand that endpoints 1, 2 and 3 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 distinct 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, in the case of late reactions (such as late ulcers and scarring), these are related to the square of the dose (beta type).

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

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

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). The 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 which supplements (but never substitutes for) calibration of the treatment machines.

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

It is necessary to record parameters at all the steps in the whole procedure (for legal purposes, among other reasons), during the prescription as well as during 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 histological type of the tumour.
2. Make a good selection of patients expected to benefit from brachytherapy.
3. Obtain adequate information about the extent of the disease and the anatomy of the patient in order to ensure correct dose planning.
4. Take films to localize and simulate radioactive sources.
5. Delineate the volume to be irradiated.
6. Use a computerized planning system for the calculation of dose to the tumour and to anatomical points as recommended in ICRU Publication No. 38 [5].
7. Use adequate rooms, guaranteeing radiological protection.

8. Apply the recommendations of ICRU Publication No. 38 [5].
9. Prohibit the use of radium.
10. Ensure adequate follow-up of patients.

1.5. RADIATION PROTECTION

It is important to understand the internationally accepted framework for radiation protection and safety in medicine [6] (ICRP 73) in order to see where the breakdowns occurred in this accident. The basic concepts were published by the International Commission on Radiological Protection (ICRP) most recently in 1996 [7] (ICRP 60).

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 some other diseases, such as acne.

After justification of the practice proper there needs 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*. This refers to steps that can reasonably be taken to reduce 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 the recommendation 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 that performance. Governments have the responsibility for establishing a framework of policy on radiological protection.

The institutional arrangements necessary also include the need to verify compliance with procedures and fulfilment of objectives. This would include quality assurance programmes as well as record keeping.

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 FAO, ILO, OECD-NEA, PAHO and 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), 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) of the Agency is a major vehicle for strengthening radiation protection infrastructures in the Agency Member States, including infrastructures 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 has also a number of promotional projects on applied radiation biology and radiotherapy and on dosimetry. They include projects on: upgrading of radiation oncology in developing countries; advanced techniques in radiotherapy; development of criteria for human responsiveness to radiation for use in treatment planning; quality assurance in clinical radiotherapy; combined radiation therapy of cancer; collaboration in radiotherapy protocols for improved cancer

cure; secondary standards dosimetry laboratory network; dose intercomparison and assurance; and transfer of the dosimetry techniques.

In addition, the Agency has 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 States parties to that 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 -- among other things -- to assist, make available appropriate resources, and offer its good offices to a requesting State party in case 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 Agency and has received technical co-operation from the Agency in different areas including radiotherapy and dosimetry. Costa Rica is part of the Agency TC Model Project on Upgrading Radiation and Waste Safety Infrastructure. Within the Agency 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 sources in machines for external and internal radiotherapy treatment (see Annex to this report). Costa Rica is also a State party to the Convention in Assistance in the case of a Nuclear Accident or Radiological Emergency.