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Quality Assurance in Radiotherapy

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In order to obtain the best possible results from radiotherapy, a programme of quality assurance is essential. Such a programme aims to ensure consistency of the medical prescription and the safe fulfilment of that prescription, as regards dose to the target volume, together with minimal dose to normal tissue and minimal exposure of personnel.

This guide, which was prepared following an international workshop, summarizes the factors to be considered in establishing a programme of quality assurance at local or national level. In addition to the operational aspects of the programme, it covers the physical and technical checks needed to verify the correct functioning of the equipment, and the clinical aspects of quality assurance, aimed at ensuring the best possible patient management. This book will be invaluable to radiotherapists, medical physicists, radiotherapy technicians, and health administrators in charge of radiotherapy programmes.

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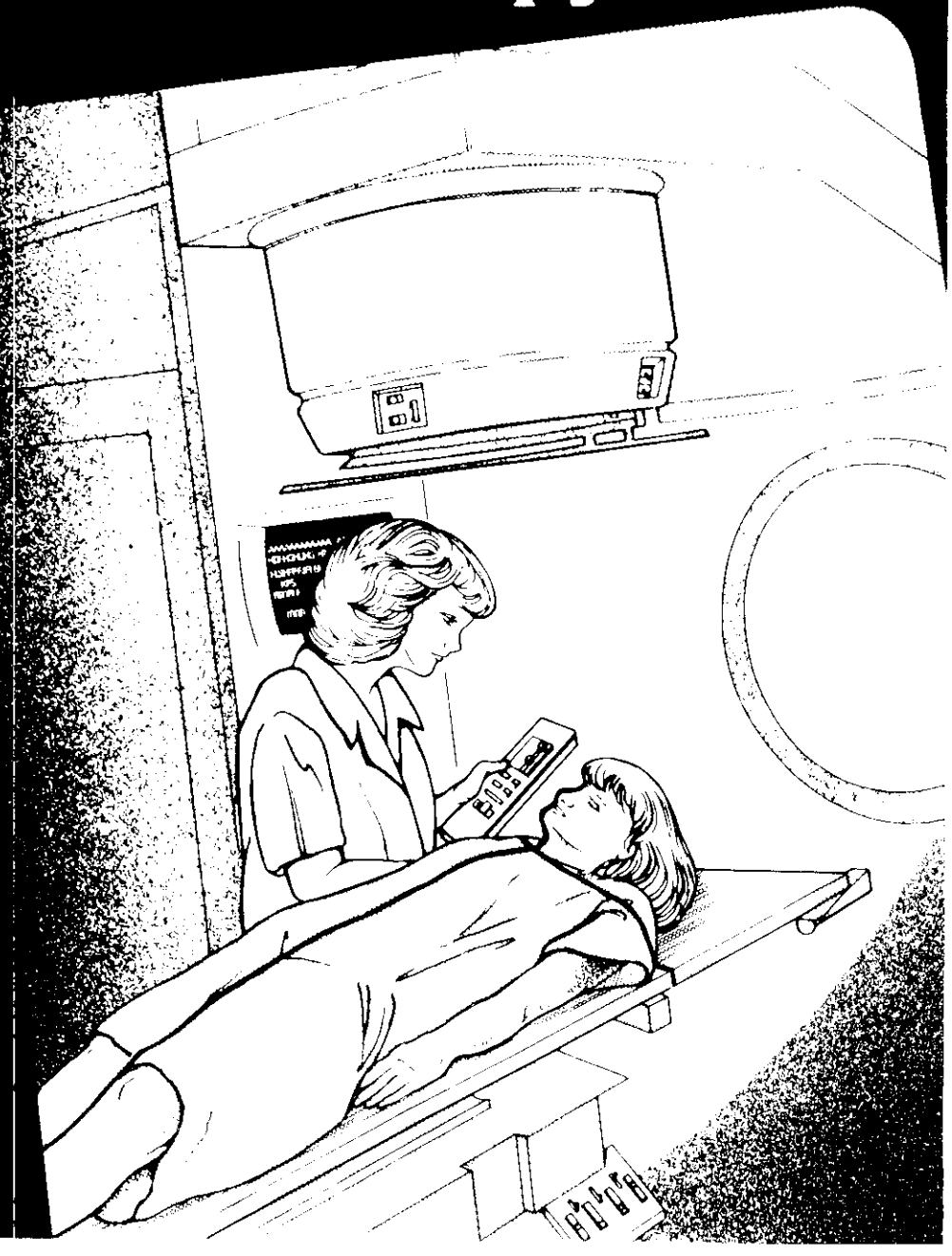

The World Health Organization is a specialized agency of the United Nations with primary responsibility for international health matters and public health. Through this organization, which was created in 1948, the health professions of some 165 countries exchange their knowledge and experience with the aim of making possible the attainment by all citizens of the world by the year 2000 of a level of health that will permit them to lead a socially and economically productive life.

By means of direct technical cooperation with its Member States, and by stimulating such cooperation among them, WHO promotes the development of comprehensive health services, the prevention and control of diseases, the improvement of environmental conditions, the development of health manpower, the coordination and development of biomedical and health services research, and the planning and implementation of health programmes.

These broad fields of endeavour encompass a wide variety of activities, such as developing systems of primary health care that reach the whole population of Member countries; promoting the health of mothers and children; combating malnutrition; controlling malaria and other communicable diseases, including tuberculosis and leprosy; having achieved the eradication of smallpox, promoting mass immunization against a number of other preventable diseases; improving mental health; providing safe water supplies, and training health personnel of all categories.

Progress towards better health throughout the world also demands international cooperation in such matters as establishing international standards for biological substances, pesticides, and pharmaceuticals; formulating environmental health criteria; recommending international non-proprietary names for drugs; administering the International Health Regulations; revising the International Classification of Diseases, Injuries, and Causes of Death; and collecting and disseminating health statistical information.

Further information on many aspects of WHO's work is presented in the Organization's publications.

QUALITY ASSURANCE IN RADIOTHERAPY

Quality Assurance in Radiotherapy

A guide prepared following a workshop held at
Schloss Reisensburg,
Federal Republic of Germany, 3–7 December 1984,
and organized jointly by

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and

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Preface

IN 1982, in an effort to improve the quality of the medical use of ionizing radiation, WHO issued publications on quality assurance in diagnostic radiology[a] and nuclear medicine.[b] As a further stage in this programme, WHO initiated and organized jointly with the Institute of Radiation Hygiene, Federal Health Office, Federal Republic of Germany, a Workshop on Quality Assurance in Radiotherapy, held at Schloss Reisensburg, Federal Republic of Germany, from 3 to 7 December 1984.

The workshop was attended by 35 participants from 15 countries as well as by representatives of the International Atomic Energy Agency (IAEA), the International Organization for Medical Physics (IOMP), the European Federation of Organizations of Medical Physics (EFOMP), the Nordic Association of Clinical Physics (NACP), the American Association of Physicists in Medicine (AAPM), and the Center for Devices and Radiological Health, USA; the list of participants is given in Annex 1.

Radiotherapy is an area where there is an urgent need for quality assurance and cooperative efforts at international, regional and national levels should therefore be strongly supported and encouraged.

The radiotherapy performed today in radiological or oncological departments in different countries is not uniform in quality and the end results obtained in treating malignant tumours at the same site, and of the same type and stage, differ widely.

Attempts by WHO and IAEA to introduce some uniformity in the physical measurement of the output of radiotherapy machines date back to 1969–70, when the thermoluminescent dosimetry (TLD) postal dose intercomparison was introduced and the network of secondary standard dosimetry laboratories (SSDL) established.

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[a] World Health Organization. *Quality assurance in diagnostic radiology*. Geneva, 1982.

In its 17 years of existence, the TLD postal dose intercomparison has given approximately 600 radiotherapy departments in 85 countries the possibility of checking the output of teletherapy machines and of reducing somewhat the discrepancy between the dose calculated or measured at each department and that measured by a primary standard dosimetry laboratory (the National Physical Laboratory, Teddington, England, and the Physikalisch-Technische Bundesanstalt, Braunschweig, Federal Republic of Germany), used as a reference by IAEA.

This limited aspect of quality assurance in radiotherapy, although very important, does not cover the multitude of factors involved in good radiotherapy practice. Various specialized organizations such as the International Commission on Radiological Units and Measurements (ICRU) and the International Electrotechnical Commission (IEC) have begun preparing specific recommendations for the physical, mechanical, and other parameters of radiotherapy equipment and procedures, including radiation protection. Reference should also be made to the International Symposium on Quality Assurance in Radiation Therapy, Clinical and Physical Aspects, held in Washington, DC, in 1983.[c]

[c] *International journal of radiation oncology, biology, physics*, **10** (Suppl. 1) (1984)

1. Operational aspects

1.1 Treatment modalities for malignant disease

THREE main modalities are used in treating malignant disease: surgery, radiotherapy and chemotherapy (including hormonal therapy). These may be used separately or in combination in order to eradicate the tumour (curative treatment) or to relieve the symptoms associated with it (palliative treatment).

The decision as to which type of treatment to use must be based on the realization that a multidisciplinary approach is essential in managing malignant tumours. Thus radiotherapy is closely related to the other treatment modalities and, although this publication deals specifically with quality assurance in radiotherapy, it should not be seen as advocating a unilateral approach to cancer treatment. On the contrary, in accordance with WHO's recommendation that a multidisciplinary approach should be adopted in the management of cancer patients, it is hoped that this report may stimulate the application of quality assurance to the other treatment modalities.

1.2 Definitions

The following definitions are used throughout this publication:

Quality assurance: all those planned and systematic actions necessary to provide adequate confidence that a structure, system or component will perform satisfactorily in service (definition adopted by the International Organization for Standardization) (ISO 6215-1980) (*1*);

Quality assurance in radiotherapy: all those procedures that ensure consistency of the medical prescription and the safe fulfilment of that prescription as regards dose to the target volume, together with minimal dose to normal tissue, minimal exposure of personnel, and adequate patient monitoring aimed at determining the end result of treatment;

Quality assessment: the operations carried out to measure or evaluate the performance of the radiotherapy process;

Quality control: the measures taken to restore, maintain and/or improve the quality of treatment.

1.3 Need for quality assurance in radiotherapy

According to the replies to a WHO questionnaire on quality assurance in radiotherapy received from 56 institutions in 52 countries, a quality assurance programme in radiotherapy is necessary for the following reasons:

(i) quality assurance minimizes errors in treatment planning and dose delivery and thereby improves the results of therapy by increasing remission rates and decreasing complication and recurrence rates;
(ii) quality assurance permits the meaningful intercomparison of results both among radiotherapy centres within a country and internationally by ensuring more uniform and accurate dosimetry and treatment delivery;
(iii) the superior performance of modern radiotherapy equipment cannot be fully exploited unless a high degree of accuracy and consistency is reached, as is possible through quality assurance;
(iv) in the developing world, the application of radiotherapy will increase greatly in the near future and quality assurance programmes will be necessary to ensure that treatment is of acceptable quality.

1.4 Sources of errors in radiotherapy

As pointed out above, a comprehensive quality assurance programme is necessary because of the importance of accuracy in dose delivery in radiotherapy. The dose response curve is quite steep in certain cases, and there is evidence that a 7–10 % change in the dose to the target volume may result in a significant change in the probability of controlling the tumour (*2*). Similarly, such a dose change may also result in a marked change in the incidence and severity of radiation-induced morbidity.

Surveying the evidence on effective and excessive dose levels, Herring & Compton (*3*) concluded that the therapeutic system should be capable of delivering a dose to the target volume within 5 % of that prescribed, a conclusion that is supported by a number of studies (*2*). This figure does not take into account the dose variations within the target volume.

The uncertainty in the dose delivered is due to errors that may occur at different steps in the radiotherapy process, as follows:

(i) determination of patient anatomy (errors in obtaining outline, patient positioning, defining organs at risk, estimating tissue inhomogeneities, etc.);

(ii) definition of target volume(s) (shapes and location, failure to take into account movements of organs or tissues due to circulation and respiration and/or of the whole patient, etc.);
(iii) treatment planning (errors in beam data, beam models, computer software and hardware, etc.);
(iv) treatment delivery (errors in machine calibration, patient set-up, improper machine settings, etc.);
(v) patient data (identification, diagnosis, treatment prescription, records of previous treatment given, portals of entry, etc.).

These errors, which may be either random or systematic, may be the result of mistakes, inattention, misunderstanding or misjudgement, or of mechanical or electrical failure.

The above enumeration of the possible sources of error indicates the complexity of quality assurance in radiotherapy and emphasizes the fact that, if the best possible therapeutic results are to be obtained, a quality assurance programme is essential.

1.5 Content of quality assurance programmes in radiotherapy

The content of a quality assurance programme will differ with the level at which it is applied; three main levels are recognized here:

- radiotherapy department;
- country;
- international.

1.5.1 *Quality assurance programme in a radiotherapy department*

The general content of a departmental quality assurance programme and the responsibilities of the various staff members are shown in Table 1. The head of the radiotherapy programme has the main responsibility for establishing such a programme. He or she must be personally convinced that the radiotherapy process, i.e., patient treatment, is conducted to a standard that is acceptable at the local, national or international level.

A major problem in any departmental quality assurance programme is that of ascertaining whether and when a certain quality assurance task, whether clinical or physical, has been performed. The head of the radiotherapy department must therefore insist that the results of quality assurance tasks, calibration results and patient-related information are properly recorded and that records are kept for an appropriate length of time. Such procedures are necessary for the purposes of follow-up investigations and to avoid possible litigation.

Since a radiotherapy department is a clinical and technical entity it is important that the head radiotherapist delegates certain quality assurance responsibilities to those individuals in the department with appropriate professional skills. It thus becomes a team effort to ensure

Table 1. Content of departmental quality assurance programme and responsibilities of staff members

Purpose	Quality control of		Staff member responsible
Establishment of programme (including legal and other aspects of record keeping, and delegation of responsibilities)	Radiotherapy process (including assessment and corrective action)		Head of radiotherapy department
Patient dose control (assessment and corrective actions)	Dosimetric errors	Metrological equipment	Physicist
		Teletherapy and brachytherapy sources and equipment	Physicist, radiotherapist
	Geometrical (geographical) errors	Patient positioning (marking, verification)	Radiotherapist, technician
		Patient data acquisition (definition of target volume, critical organs, etc.)	Radiotherapist, physicist
	Treatment planning errors	Dose calculations, *in vivo* dosimetry	Physicist
		Patient chart (record) review	Radiotherapist, physicist, technician
Patient safety	Dose outside target volume and treatment beam		Radiotherapist, physicist, technician
	Equipment interlock systems (radiation, mechanical, collision avoidance) Patient monitoring and communication Electrical hazards (grounding, etc.) Mechanical failures, risk of falling parts, etc. Ozone, freon, radioactivity, toxic fumes		Physicist, technician
Personnel safety	Facilities (room), shielding (photons, neutrons) Personnel monitoring (photons, charged particles, neutron contamination radio active contamination)		Physicist
	Electrical safety (exposed high voltage, earthing of equipment) Systems interlocks (doors, lights, emergency switches, room monitors, therapy equipment) Mechanical attachment		Physicist, technician

that the radiotherapy prescription is safely implemented with the desired accuracy and precision. The head radiotherapist and other responsible individuals must motivate personnel at all levels to cross-check computations and eliminate errors in the process.

Depending on national or local conditions, policies and resources, departments may vary in their degree of specialization and therefore in the specialized professionals on their staff. In addition to one or more radiotherapists, they must also have one or more qualified medical radiological physicists (or similar personnel) and qualified radiotherapy technologists (full or part time).

Since full or part-time access to these three categories of professionals is necessary for the safe functioning of a radiotherapy department, the responsibilities arising from the quality assurance programme must be divided among them.

One important component of a departmental quality assurance programme is patient dose control (see Table 1). This should be effected by controlling the accuracy and precision of the dosimetric procedures (calibration of dosimetric equipment and source output, which should be referred to a national or international standard laboratory), and the geometry and alignment of source equipment and patient anatomy; an understanding of the causes of treatment planning errors is also necessary so that they can be reduced. These are all good examples of tasks where a team effort is necessary, and the need for the chief radiotherapist to delegate responsibility to skilled specialists is obvious.

Another component of the quality assurance programme is that of patient safety. The radiotherapy technologist who positions the patient on the treatment table, positions blocks and wedges, and finally delivers the treatment, plays an important role in patient safety. Minimizing the dose to points outside the target volume again calls for a team effort, requiring the radiotherapist to prescribe the limiting dose to critical organs, the radiotherapist and physicist to design a treatment plan, the physicist to design the shielding blocks, and the technologist to execute the prescription.

The final quality assurance task relates to personnel safety. This is an area where the involvement of the head of the department should be greater than is perhaps usually the case. Non-compliance with local or national labour laws and safety requirements can be very costly. It is, however, also an area where the radiotherapist must usually delegate responsibility and rely upon the technical staff.

Other personnel who, in number and qualifications, vary greatly depending on local conditions, may also be involved. For example, medical dosimetrists usually perform treatment planning dose calculations, under supervision, and mould work, while engineers may be responsible for the maintenance of therapy equipment. For the purposes of this publication, however, it cannot be assumed that such personnel are widely available. Moreover, it is recommended that the responsibility for a quality assurance programme should rest with only a few highly

skilled individuals in a department; personnel in other categories may have a secondary and advisory role in the implementation of that programme.

1.5.2 *Quality assurance programmes at country level*

The implementation of quality assurance programmes in radiotherapy will be facilitated if the appropriate organizations at the country level are made responsible for:

(1) providing technical assistance and coordination in the setting up of quality assurance programmes at radiotherapy department level and in particular in the testing of newly commissioned radiotherapy equipment;
(2) ascertaining the adequacy of quality assurance programmes at radiotherapy department level and advising accordingly;
(3) developing, adapting and disseminating recommendations, codes of practice, regulations, norms, etc., produced by national authorities or international bodies, professional organizations, etc.;
(4) ensuring the provision of, or access to, calibration facilities for the test equipment used in local quality assurance programmes, e.g., to the IAEA/WHO network of secondary standard dosimetry laboratories or perhaps the primary dosimetry laboratories, and the IAEA/WHO TLD postal dose intercomparison;
(5) providing assistance in the analysis of the results of quality assurance programmes at local level and in finding technical means of improving performance;
(6) organizing training on quality assurance in radiotherapy for the staff of the radiotherapy department, in collaboration with scientific or professional societies at national or international level and/or arranging for participation in training programmes offered at international level.

1.5.3 *Quality assurance programmes at international level*

The role of international organizations and of international scientific or professional societies is to stimulate and motivate national organizations and specialists in radiotherapy departments to establish and apply quality assurance programmes.

International bodies can play an active role in the following areas:

—organization of training at international or regional level, in particular for small countries having only one or a few radiotherapy facilities, which do not have the technical capacity to organize national training activities;
—organization of the intercomparison of quality assurance programmes at international level and facilitating participation in such programmes;

—publication of guidelines, recommendations, and information on techniques related to the performance of quality assurance in radiotherapy;
– organization of meetings, seminars, workshops or special sessions at international meetings or congresses, where quality assurance programmes and their results can be discussed.

1.6 Legislation and regulations

Quality assurance in radiotherapy has not yet been the subject of extensive national or international legislation. Regulatory measures or recommendations have, in the main, been prepared by various intergovernmental or non-governmental bodies, e.g., for radiotherapy equipment, dosimetric equipment, dosimetry, protective devices, etc. The International Electrotechnical Commission (IEC) has produced a number of publications dealing with the safety of, and compliance tests on, radiotherapy equipment and dosimetric equipment (see Annex 2).

The International Commission on Radiological Protection (ICRP) has emphasized the need for quality assurance in radiotherapy in its publications (see Annex 2) while the International Commission on Radiation Units and Measurements (ICRU) also refers to this subject in a number of reports (see Annex 2). Other scientific and professional organizations, such as the American Association of Physicists in Medicine, the Nordic Association of Clinical Physicists, the Hospital Physicists Association (United Kingdom), and the Société Française des Physiciens d'Hôpital, to quote but a few, have published or prepared protocols, recommendations or guidelines on quality assurance in radiotherapy, some of which are also listed in Annex 2.

It will be seen from the above that the regulation of quality assurance in radiotherapy is still at an early stage of development, and there is a need, at both the national and international levels, for efforts to be made to establish appropriate and easily adaptable regulations.

It is also clear that the recommendations that have been made are based on the experience accumulated over a long period of time by specialists, who are therefore in a position to decide what deviations from them are acceptable. Before any substantial changes are made in the standards, norms or regulations prepared by the various international or national organizations, therefore, evidence will have to be presented to show that such changes are justified.

As far as the performance of radiotherapy equipment is concerned, the acceptance test when such equipment is commissioned, or following major repairs or alterations, is of particular importance. It should be standard practice for manufacturers to participate and offer full support to the users in the performance of such tests. At the same time, the manufacturer should provide, with the invoice for the machine, a complete specification of its technical parameters, which will also constitute the basis for the acceptance testing when the machine is commissioned. If the principal parameters of the machine deviate from the specification to such an extent that the tolerances recommended by IEC or ICRU, or prescribed in the regulations adopted by the country concerned, are exceeded, it must not be accepted. Manufacturers should also provide information on the length of time during which spare parts will be available for the radiotherapy equipment they have sold.

1.7 Education and training

Quality assurance in radiotherapy, in the broad sense of the term, has always been the main objective of the joint efforts of radiotherapists, medical physicists and other personnel. Up to the present time, however, this subject has not been taught on a routine basis to persons working in this field. It is essential, therefore, that training programmes on quality assurance procedures in radiotherapy should be established for the various categories of personnel mentioned above.

The professional groups concerned should also be encouraged to emphasize questions of quality assurance in their basic education, and such education should, in the future, incorporate the fundamental concepts underlying quality assurance programmes.

1.7.1 *Categories of personnel and training required*

In view of the differences in the background and responsibilities of the various categories of personnel to be trained in quality assurance procedures, the training provided will vary accordingly, although certain fundamentals will be common to all the curricula. Four main categories of personnel can be distinguished, as follows:

(i) *Radiotherapists (radiation oncologists)*, responsible for the clinical definition of target volume, treatment prescription, patient monitoring during therapy and follow-up, and monitoring of results.

The radiotherapist, or radiation oncologist, is a medical practitioner who specializes in the use of radiation in the treatment of cancer. He or she must be familiar with the various methods for the diagnosis of malignant as well as certain non-neoplastic diseases. The best modern cancer care requires a team approach to the care of the patient, using the skills of both medical and other personnel; the radiation oncologist is the leader of the team. In addition to being well qualified in his or her own speciality, the radiation oncologist must have sufficient knowledge of the therapeutic capabilities and limitations of surgery, chemotherapy, and hormonal therapy or other biological approaches in order to be able to judge when radiotherapy will be most useful as a curative agent, either alone or in combination with other modalities, as a palliative or as an adjuvant to other modes of treatment.

After graduation from medical school, the radiation oncologist should have at least 3–4 years of further education, training and experience within a large oncological teaching centre, with specialized training in all aspects of oncology, radiation biology, pathology, radiation physics and

dosimetry, and radiation protection. He or she should have a knowledge of diagnostic imaging techniques, and sufficient general medical experience to undertake the inpatient care of patients with malignant disease. He or she should hold an appropriate certificate, usually awarded by a national authority, and should be a full-time practitioner of radiation oncology. There should be provision for the continuing education of the radiation oncologist throughout his/her working life.

(ii) *Medical radiation physicists*, responsible for the physical aspects of irradiation techniques, treatment planning, dosimetry, radiation protection, etc.

A medical radiation physicist, in the context of this publication is a physicist trained in the medical applications of radiation, and possessing a thorough knowledge of radiation physics, including radiation generation, dosimetry, treatment planning and protection. It is desirable that he or she should have a basic knowledge of human anatomy, physiology, radiobiology and oncology.

The medical radiation physicist must possess a university degree or equivalent qualification in a physical science and have special training in radiological physics as well as practical experience in radiotherapy applications. The training should include theoretical course work and practical experience, including dealing with patients. The course of study should last for 3 years and lead to certification.

The medical radiation physicist should be responsible for radiation dosimetry, the physical aspects of treatment planning, radiation protection, the design and construction of equipment, such as beam-directing or beam-limiting devices, the supervision of quality assurance, and advice on the choice of radiotherapy equipment, radiation shielding and building design. As a rule, dosimetrists or equivalent personnel will be under the supervision of the medical physicist.

(iii) *Engineers*, responsible for the technical performance of treatment units, dosimetry equipment, etc. The engineers should have a basic technical education with additional training on the equipment used in the department. Initial training is usually offered by the manufacturer and should be followed by continuing refresher training. The technical problems to be dealt with might be related to mechanical or electronic faults, as well as to radiation aspects.

(iv) *Medical radiotherapy technicians/technologists (radiographers)*, responsible for the routine performance of patient irradiation, including machine set-up, positioning of the patient and of the wedge filters, blocks, etc., and for treatment monitoring and data recording.

The radiotherapy technician should have at least the equivalent of a secondary (higher) school education, followed by a course of study in radiotherapy technology of at least 2 years' duration; this should include anatomy, physiology, pathology, oncology, radiation physics, radiation biology, radiation protection, treatment planning, radiation response of normal tissues and care of the patient.

The instruction should be such as to allow the radiographer intelligently and compassionately to carry out the above duties. The course of study should lead to certification, preferably after an examination.

The technician assists the radiotherapist in executing treatment and observing the patient at the time of each treatment. The duties include preparing equipment for daily use, ensuring proper insertion of beam-modifying aids, positioning the patient, preparing and using positioning aids, obtaining field localization and verification films, measuring the clinical dose, maintaining treatment records, and assisting in the therapeutic use of radioactive isotopes.

1.7.2 *Quality assurance in education and training*

It is recommended that, in future, quality assurance should be integrated in the education and training programmes for the various categories of personnel mentioned above. It should be part of postgraduate education and in-service training, and should be practically oriented with a minimum of formal teaching, i.e., it should be devoted to the direct application of the proper procedures and the evaluation of the results.

In the case of personnel already working in radiotherapy departments, whose training did not include quality assurance, special training programmes in quality assurance procedures should be established. At the same time it would be valuable to review the existing curricula of institutions where radiotherapists, medical physicists, engineers, and radiotherapy technicians are trained, to ensure that the teaching of quality assurance in radiotherapy is included.

Teaching methods must be flexible and accommodate such factors as variations in the background knowledge of trainees and in the facilities available locally. The curriculum must include practical demonstrations of quality assurance procedures. The effectiveness of the training should be assessed in an appropriate manner.

Use of instruction manuals and teaching aids should be an integral part of the training programme. The production and regular updating of such manuals should be encouraged. A training manual on quality assurance procedures for technologists and instructors was published by the American College of Radiology, with the support of the National Cancer Institute, in 1982 (*4*).

Comparative studies on important parameters of quality assurance on a local, regional, or international basis are important, and the results of such studies should be taken into account in defining the aims of training and in developing and maintaining quality assurance programmes.

The complexity of the advanced radiotherapy equipment in use at the present time is such that training in maintaining and servicing it should be provided by the manufacturer to the staff responsible for its operation. Such training should be offered not only when the equipment

is installed, but also throughout its entire lifetime, particularly when major technical updating is carried out.

1.7.3 *National versus international training*

Because training in quality assurance is so varied and highly specialized, it may not always be possible to cover it fully within a particular country. It is desirable, however, that basic-level training in quality assurance procedures should be organized nationally. Medical physicists, engineers, and technicians can then be trained in countries where adequate knowledge and suitable facilities exist. If this is not possible, such training will have to be organized on an international basis. Efforts should be made at the international level to identify the places where courses can be held, draw up appropriate curricula and training programmes, arrange the courses, and encourage countries to send their personnel for training. Once trained, such personnel can initiate quality assurance programmes in their own countries and can also train local staff.

1.8 Terminology

The dissemination of knowledge and exchange of data calls for uniform terminology that is generally acceptable. Terms and concepts as defined, e.g., by ICRU, ICRP, International Union Against Cancer (UICC) and other similar international organizations or agencies, should be adopted. For those areas where international recommendations are lacking, efforts should be made to work out widely acceptable definitions.

This also implies the standardization of hospital and radiotherapy records to ensure that reliable scientific background information is collected, and a more coherent approach to the diagnosis and staging of tumours, treatment protocols, and patient follow-up is adopted. Clinical parameters are changing continuously with the rapid progress in diagnostic techniques and therapeutic modalities, so that internationally coordinated efforts are necessary to establish minimal standards of good radiotherapy practice for major cancer sites and types.

1.9 Expression of treatment results

The ultimate outcome of radiotherapy, as applied to a particular group of patients, should be expressed in terms of the remission rate, complication rate, and recurrence rate, as defined by WHO (*5*). The results should be presented in such a way that enough information is available to enable the patient group, treatments given (all modalities), and methods used to assess the outcome to be fully characterized. The methods of analysis used should be stated. Procedures must be adopted to ensure that as few patients as possible are lost to follow-up, otherwise the validity of the results will be adversely affected.

2. Physical and technical aspects

2.1 Introduction

THIS chapter is concerned with the physical and technical aspects of quality control in radiotherapy. Five major areas can be identified:

—mechanical and geometrical aspects of external therapy machines and simulators;
—dosimetry;
—treatment planning system;
—brachytherapy;
—safety.

For each of these areas, the quality assurance programme should include:

—the specification to be drawn up when the equipment is ordered;
—acceptance tests after the purchase of the equipment and the determination of a baseline standard;
—the initial calibration;
—periodic constancy checks and special tests after major repairs.

The physical and technical aspects of the quality assurance programme are the responsibility of the physicist, even if some of the checks may be performed by technologists or dosimetrists. However, as the therapeutic decision and the treatment planning, starting with the simulation, the prescription of the dose and the performance of the treatment, are the responsibility of the radiation oncologist, close cooperation between the latter and the physicist is absolutely essential in order to ensure the highest possible quality of the treatment as a whole.

2.2 Quality assurance programme

2.2.1 *Documentation*

It is essential that quality assurance procedures as well as the results of initial and periodic checks should be properly documented and dated. A

log book should be kept at each therapy machine or simulator console, so that the radiotherapy technician can immediately document problems that may affect machine performance. Similar log books should also be used for the other pieces of equipment, such as dosimeters, treatment planning systems, etc., and for radioactive sources used in brachytherapy.

2.2.2 *Acceptance tests*

Before a periodic test programme can be defined, a baseline standard must be established.

In the case of new equipment, this baseline standard is established during the process of commissioning the unit in what is often referred to as the acceptance test, in which a comparison is made with the prepurchase specification of the equipment. However, in most radiotherapy departments old equipment is already in use when a quality assurance programme is being prepared. For such equipment, tests similar to acceptance tests should be performed. After everything possible has been done to improve the equipment, a baseline standard should be established for use in the performance of constancy checks.

Every piece of equipment, on receipt or after major repair, should undergo extensive baseline tests before clinical use in order to check compliance with the pre-purchase specifications; such tests include all those listed later in Tables 2–4. They should be performed by a well qualified physicist, or by a technician under his or her direct supervision, under several geometrical and irradiation conditions so as to ensure agreement over the full range of conditions in clinical use in the department. Those parameters not complying with the specification must be corrected and rechecked.

When it is not possible to ensure that old equipment complies with the original specification, the new specification accepted should be recorded and the radiation oncologists and radiotherapy technicians in charge of patient treatment warned accordingly.

IEC and ICRU are preparing reports, to be published in the near future, on performance characteristics, test procedures and test conditions for acceptance tests and constancy checks. These will contain proposals for optimal values of maximum deviations for each parameter. All manufacturers should prepare, for each piece of equipment, lists of specifications in accordance with these recommendations. *In future, therefore, users should request the manufacturer to provide these detailed specifications before purchasing any new piece of equipment.*

2.2.3 *Constancy checks*

The frequency with which constancy checks are performed and the method used must be consistent with the tolerances accepted following the baseline test. These checks may be restricted to only one or two

geometrical conditions or radiation qualities in order to provide a rapid yes or no answer, and may be performed by a qualified technologist under the supervision of a qualified physicist. More detailed constancy checks should also be performed, but with a lower frequency, for several geometrical conditions and radiation qualities covering the full range of clinical conditions in use in the department. Such comprehensive checks should be performed by a qualified physicist so as to ensure that subtle changes have not occurred which might have been missed during the simpler tests.

Special attention should be given to the parameters that have shown the largest deviations from the baseline during the previous constancy checks, and the frequency of the checks on those parameters should be increased.

Average intervals between tests are shown in Tables 2–4, but these intervals should be adapted to the special requirements of each facility and can be considered as the minimum intervals in a new quality assurance programme. However, after a few months or years of experience with a given piece of equipment, different intervals may be adopted, depending upon the constancy of the parameters.

2.3 Mechanical and geometrical characteristics of external therapy equipment

2.3.1 *General*

Radiotherapy equipment is complex, expensive and liable to break down. The various components of the equipment are described in sections 2.3.2–2.3.8, while section 2.3.9 describes testing programmes for mechanical and geometrical parameters. The parameters related to the radiation beam performance and to the accuracy of the light field are covered in section 2.4. Cyclotrons and neutron generators are not considered here, but the recommendations relating to electron accelerators may be applied to them with only minor modifications. Tests on mechanical and geometric performance are summarized in Table 2.

2.3.2 *Isocentric and non-isocentric units*

Teletherapy equipment is either isocentric or non-isocentric. At a WHO meeting of investigators held in 1978 on the optimization of radiotherapy, the use of isocentrically mounted machines was strongly recommended (6). The additional complication and expense of isocentric mounting, as compared with vertical mounting, is justified for the treatment of deeply seated tumours. However, non-isocentric equipment is still in use in all parts of the world, providing radiotherapy of a good standard.

Table 2. Tests on mechanical and geometric performance

Performance characteristic or item of equipment tested	Remarks	Tolerance level	Frequency
Gantry rotation (for isocentric units)	Check four main positions for vertical and horizontal beams	± 0.5°	Yearly
Yoke rotation	Zero position	± 0.2°	Monthly
	Scale	± 0.5°	Yearly
Isocentre	—	± 2 mm	Yearly
Source distance indicators	On a range including points of entry and exit of patients	± 2 mm	Weekly
Beam axis indicators	Cross-hair alignment, *inter alia*	± 2 mm	Monthly
Numerical field indicators	Compared with radiation field at usual treatment distances	± 2 mm	Monthly
Light field indication	Compared with radiation field at usual treatment distances	± 2 mm	Weekly
Collimation system rotation	—	± 0.5°	Yearly
Treatment couches:			
lateral and longitudinal scales		± 2 mm	Yearly
isocentric axis	Compared with gantry isocentre	2 mm	Yearly
vertical scales	Height relative to isocentre	2 mm	Monthly
vertical deflection (with patient load)	—	5 mm	Yearly
Treatment verification systems	Every parameter controlled by system	In accordance with the manufacturer's specification	Monthly
Immobilization devices	Check possible motion of patient	± 2 mm	Monthly or before use for individually adapted devices
Patient alignment devices (e.g., side, ceiling and back pointer laser beams)	—	± 2 mm	Weekly

The tests to be performed on the two types of units are similar, apart from those relating to the isocentre and the couch.

2.3.3 *Teletherapy isotope units*

The advantages of high-energy X-rays as compared to cobalt-60 gamma rays are offset by the much higher capital and annual costs of electron accelerators as compared with cobalt-60 units. Furthermore, accelerators, because of their greater complexity, are more liable to break down and more difficult to repair. The basic treatment unit for radiotherapy in developing countries should therefore be a cobalt-60 unit.

Some isocentric units have a yoke movement whereby the head can be rotated away from the isocentre. The alignment of the beam axis and the isocentre should therefore be checked when the head is returned to the isocentre position. When a locating pin is provided, the accuracy and reproducibility of its positioning should be checked.

Isotope units have been designed for caesium-137 sources. The long half-life of caesium-137 is attractive but these units have sources of low activity and large physical size, giving beams with a wide penumbra. They therefore need to be used at small source–skin distances in order to give reasonable output and penumbra. These units are no longer recommended since they do not provide radiotherapy of adequate quality

2.3.4 *Medical electron accelerators*

Three types of electron accelerators are used in radiotherapy, namely linear electron accelerators, betatrons and microtrons.

Linear electron accelerators, which provide large fields and high X-ray output, constitute the majority of the medical accelerators in use. Most linear accelerators with a maximum energy higher than 8 MeV are "dual-mode" units also providing electron beams at different energies. As betatrons provide smaller field sizes and lower X-ray output, their number is rapidly decreasing. Microtrons are relatively new on the market. Their advantages are similar to those of linear accelerators and they offer the possibility of serving more than one irradiation facility.

The disadvantages of medical accelerators have already been mentioned. In addition, highly trained and experienced technical staff, such as electronic engineers and maintenance technicians, are required to repair and maintain them (6).

The need for a reliable electricity supply, not subject to interruptions or severe reductions in voltage, and for an adequate water supply must also be emphasized.

2.3.5 *Orthovoltage and superficial X-ray units*

Orthovoltage and superficial X-ray units are used to treat primary and secondary malignancies involving the skin and subcutaneous tissues.

They should be considered as supplementary to high-energy machines. They are simple to operate and are very convenient for palliative treatment.

2.3.6 *Treatment simulators*

A treatment simulator is a special radiographic unit that can reproduce the geometrical conditions of the radiotherapy machine with respect to the patient. It is used to localize the tumour and its relations to the normal structures, and to plan and verify the treatment fields.

Treatment simulation may be effected in many cases by taking two radiographs in planes perpendicular to one another with a conventional radiographic unit.

A simulator should be checked for accuracy as carefully as a treatment unit, since any error will be reflected in inaccurate treatment plans.

The movements of a simulator are the same as those of treatment units but it often has a variable source–axis distance. The field wires used to check the field size should be checked for accuracy as collimator systems for all source–axis distances in use. The diaphragm system needs no checking, its function being only to avoid excessive scattered radiation.

Apart from the mechanical and geometrical checks, the simulator should be checked in the same way as a diagnostic radiography unit (*7*).

2.3.7 *Treatment couches*

The couch or patient support system is common to all treatment units and simulators. Couches in the same department should be compatible so that the position of the patient is the same in both simulator and treatment unit as far as possible. To ensure the reproducibility of the patient position, the rigidity of the couch should be checked; it should not be affected by the usual working load.

A couch on an isocentric unit is normally mounted on a turntable rotating about a vertical axis passing through the isocentre of the unit. The position of the rotation axis should be checked. The linear scales corresponding to the lateral, longitudinal and height motions, as well as the rotational scale, should be checked annually.

2.3.8 *Auxiliary equipment*

Some auxiliary equipment is necessary to ensure that the treatment required is properly delivered. Such equipment includes:

—immobilization devices;
—mechanical and optical patient alignment devices;
—source distance read-out devices;
—beam modifiers;
—treatment verification systems.

Immobilization devices include moulds and casts, breast bridges, head supports, arm or leg supports, bite-blocks, etc. They require, as a minimum, visual inspection for mechanical and functional stability and proper labelling.

Mechanical and optical patient alignment devices are used to ensure that the patient is correctly positioned with respect to the beam axis and that the set-up can be reproduced accurately in successive sessions. Such patient alignment is essential to ensure correct irradiation of the target volume and to avoid unnecessary irradiation of organs at risk.

The devices can be mechanical or optical in character. In isocentric units they often include side, ceiling and back pointer lights. Their correct adjustment should be checked, not only at the isocentre, but also at other points at least 20 cm from the isocentre.

Source distance read-out devices are important because incorrect source skin distance or source–axis distance readings result in discrepancies between the delivered and the prescribed dose.

In most modern radiotherapy units or simulators, optical devices are used. They should be checked by comparison with a mechanical indicator whose accuracy has been verified, or by direct measurement from the reference point or from the isocentre, and at least at two different distances along the distance range in use.

Beam modifiers include:

—wedges;
—field-shaping blocks and block trays;
—individual field-shaping blocks;
—compensators;
—beam splitters;
—bolus materials.

They require inspection for mechanical and functional stability, and their alignment accuracy should be verified by radiography with the treatment beam. Their dosimetric properties are considered in section 2.4.6.

Treatment verification systems are offered by many manufacturers of teletherapy units as an optional extra. These systems are used to compare the treatment parameters, e.g., gantry angle, field size, collimator rotation, treatment time or monitor units, beam energy (for linear accelerators), etc., with those entered as input data before treatment or recorded during the first session. A significant difference is signalled as an error which must be corrected before irradiation can commence.

Such systems are likely to improve quality assurance though they add significantly to the cost of a treatment unit. At the present time it is not possible either to recommend or discourage the use of such systems where they are available. Their evaluation will require considerable

effort, but in due course more information is likely to become available on their cost-effectiveness.

2.4 Dosimetry

2.4.1 *Introduction*

It has been demonstrated (*3*) that the success or failure of a radiation treatment depends upon the accuracy with which the dose is delivered to the tumour. The dose delivered at the specified point should be with n $\pm 5\%$ of the prescribed dose.

All the steps in the procedure for determining the absorbed dose must be clearly specified so that they can be followed easily in any part of the world. Numerous codes of practice or protocols have been published in recent years, providing a systematic approach to determination of absorbed dose in a water phantom and recommending factors for calculation of physical quantities (*8–13*). More recently an international code of practice has been prepared, sponsored by IAEA (*14*), which should be used in dose determination and should make possible an acceptable degree of uniformity of dose delivery throughout the world.

It is strongly recommended that the procedures described in the above-mentioned code of practice should be followed as part of any quality assurance programme. The code provides the methodology for the accurate determination of the absorbed dose in water for radiation beams of photons or electrons, including soft X-rays below 100 kV, orthovoltage X-rays, high-energy photon beams, and high-energy electron beams with energies greater than 5 MeV.

In this section, the various items included in published protocols are reviewed, but it should not be used as a substitute for those protocols. Tests on dosimeters and phantoms are summarized in Table 3 and on beam performance in Table 4.

2.4.2 *Dosimeters*

Doses or dose rates in radiotherapy or radiation protection can be measured by means of dosimeters, which are used in acceptance tests and regular performance tests of radiotherapy units and are an essential tool in a quality assurance programme.

Ionization chambers are generally used to determine the absorbed dose in water at several photon and electron beam qualities, but are calibrated in kerma in air. It is then necessary to follow the calibration chain and to consider how the absorbed dose in water may be determined with the various kinds of dosimeters.

Calibration chain. Primary standards have been developed by several primary standard dosimetry laboratories (PSDLs) for absorbed dose in graphite, exposure in air or air kerma. The user has either very limited

Table 3. Tests on dosimeters and phantoms

Test	Remarks	Tolerance level	Frequency
Calibration:			
reference dosimeter	At an SSDL	—	Every three years or after repair
field instrument	In the user's beam	—	Yearly or after repair
Stability check:			
reference dosimeter	—	±2%	Before and after each SSDL calibration; before field instrument calibration
field instrument	—	±2%	Monthly and before each calibration against reference instrument
Checking of dimensions, marks and reproducibility of detector positioning in phantoms and beam data acquisition systems	—	±1 mm	Yearly or before a new series of measurements

Table 4. Tests on beam performance and light-field accuracy

Performance characteristic or item of equipment tested	Remarks	Tolerance level	Frequency
Light field indication	Visual inspection for the four main gantry positions	—	Monthly
	Density measurements	±2 mm	Every 6 months
Central axis dose calibration	At a reference point in a phantom for each set of conditions	—	Yearly[a]
Constancy checks:			
cobalt-60 and caesium-137 units	Under treatment conditions	±2%	Monthly
orthovoltage X-ray units	For each combination of kilovoltage and filter	±2%	Weekly
accelerators	Dose per monitor unit for the most usual energies from 0.1 to 10 Gy	±2%	Daily or at least twice a week
Linearity of monitor	—	±1%	Yearly or after repair
Timer of cobalt-60 unit	—	±0.01 min	Monthly
X-ray beam:			
beam flatness	—	±3%	Twice a month or after repair
beam symmetry	—	±3%	
Cobalt-60 and caesium-137 units:			
beam symmetry	—	±3%	Monthly
Orthovoltage X-ray units:			
beam symmetry	—	±3%	Monthly or after repair
Electron beams:			
flatness and symmetry	For each energy used	±3%	Twice a month or after repair
Transmission factor of wedges and compensators	Any variation is, in general, an indication of a misalignment	±2%	Yearly
Transmission factor of trays	—	±2%	Yearly or after repair

[a] Sufficient only when constancy checks are performed as shown.

or no access to PSDLs, and it is the task of the secondary standard dosimetry laboratories (SSDLs) to transfer the calibration from the PSDL to the user. SSDLs also have the important task of advising the user and helping him to derive the correct factors to be used in determining absorbed dose for his own beam. They also assist the user in performing dose intercomparisons. At present, SSDLs exist in over 50 countries, 40 of which are located in the developing world. Most are members of the IAEA/WHO network established in 1976.

Reference dosimeter. A reference dosimeter consists of an ionization chamber and a measuring assembly satisfying the performance specifications described in dosimetry protocols. Its calibration should be referred to an SSDL, and it should be used only to calibrate other instruments in the department. When a department cannot afford to buy a dosimeter to be used only as a reference dosimeter, it is recommended that at least two ionization chambers should be ordered with the measuring assembly, one being kept as the reference instrument and the other being used as a field instrument.

The validity of any published relation between read-out and dose must be checked carefully for each set of conditions used. The system should be rechecked at least once a year and after any change in the conditions of use.

Field instrument. A field instrument is a dosimeter used either for calibration of radiotherapy units or for dose measurements in the department. It is calibrated by comparison with the reference instrument.

Stability checks. All dosimetry systems should be checked regularly against a stability check source. Strontium-90 and yttrium-90 sources are very suitable for stability checks. When such a source is not available, the dosimeters should be checked in the cobalt-60 beam of a teletherapy unit. The frequency of stability checks should be adapted to the frequency of use of the dosimeter. The stability of the reference dosimeter should be checked before and after each calibration and before its use to calibrate a field instrument. The stability check of the field instrument should be performed at least once a month.

Dosimeter calibrations. Reference dosimeters should be re-calibrated at an SSDL at least every three years and after any repair of the instrument. When a variation larger than ±2% is observed in the stability check, a new calibration should be performed. Field instruments should be calibrated against the reference instrument at least once a year or after any repair or when a variation larger than ±2% is observed in the stability check.

Other dosimetric instruments. Equipment, such as thermoluminescent dosimetry equipment or film densitometers as used for relative dosimetry should be calibrated by relating their read-out to dose. The validity of any published relation between read-out and dose has to be checked

carefully by comparison with the field instrument for each set of conditions used. The system should be rechecked at least once a year and after any change in the conditions of use.

Other instruments. Instruments for measuring the atmospheric conditions—temperature, pressure and humidity—are needed for ionization dosimetry. Barometers and thermometers must be checked carefully by comparison with high-precision devices both for linearity and accuracy at least once a year. When the pressure is compared with the figure given by a local meteorological office (e.g., at an airport) it is necessary to verify that the latter has not been corrected to sea level.

2.4.3 *Phantoms and beam data acquisition systems*

Beam data acquisition equipment is needed for obtaining data either for treatment planning systems or for the construction of isodose charts. Such equipment usually consists of one or more detectors in a solid or liquid phantom. In liquid phantoms, the position of the detectors may be changed by hand, or by remote control, or such changes may be fully automated by means of a computer. In such a system, detector position and dosimetric information are automatically acquired.

When solid phantoms are used, the tissue-equivalence of the material employed must be taken into account. Solid phantoms often consist of sheets of material, and the thickness of each sheet must then be measured individually and the constancy of the thickness over the whole area checked. All dimensions should be checked at least once a year or before a new series of measurements is made.

In most protocols, the reference material for dose distribution is water. In addition, water is the most readily available phantom material for homogeneous liquid phantoms. Water phantoms should therefore be used for beam data measurement whenever possible.

Both plastic containers for water and solid phantoms should be marked so that they can be aligned in the beam. The marks should be checked once a year or before a new series of measurements.

If semi-automatic or fully automatic systems are used, a manual containing a detailed description of the measuring procedure must be available. This must include a full description of the method recommended for alignment in the beam and a summary of the main sources of error. A number of copies should be made for use in the training of the users. Whenever it is proposed to use the system, the coincidence of the detector position with the scales or read-outs must first be checked.

2.4.4 *Beam light localizer and scales*

The light source or its virtual image must be adjusted and maintained so that it remains on the axis of collimator rotation and at the same distance from the collimator jaws as the radiation source; the light field will then always define the geometrical boundaries of the radiation field. Experiments should be conducted to show that the geometrical field corresponds to the 50 % isodose curve with an accuracy of ±2 mm, whatever the beam quality. It is recommended that the agreement between the light and radiation fields should be checked with X-ray film. A prepacked film is positioned and marked to show the light field limits and cross-hair. It is then exposed with a build-up layer thick enough to provide electronic equilibrium and scanned to check the coincidence between the radiation beam and the light beam.

A visual inspection may be sufficient for purposes of constancy checks, which should be carried out at least monthly for the four main gantry positions. Density measurements should be performed every six months.

Other field positioning aids, such as field size scales, lasers or mechanical pointers, should be checked at least monthly.

2.4.5 *Beam performance*

Central axis dose calibration. This consists of the measurement of the absorbed dose at a reference point in a phantom in relation to the monitor reading. Such a calibration must be performed by a trained physicist at least once a year for every type of radiation unit and set of treatment conditions. It should follow the recommendations given in the protocol adopted by the user.

An annual calibration is sufficient provided that constancy checks of the dose rate or of the dose per monitor unit are performed at a higher frequency. Such checks are essential to ensure treatments of good quality. They may be performed with simple devices and do not require the use of sophisticated data acquisition systems.

For cobalt-60 and caesium-137 units, the rate of decay of the radionuclide is known with high accuracy and the dose rate variation with time can easily be calculated. The dose rate must be corrected for decay at least monthly for cobalt-60 sources and twice a year for caesium-137 sources. However it is recommended that the dose rate should be checked monthly. When the measured dose rate differs from the calculated dose by more than ±2 %, careful measurements must be made to determine the cause of the difference, which may be either a change in the dosimeter or a failure in the treatment unit. The first step should be a careful check of the field dosimeter against the reference dosimeter.

In orthovoltage X-ray units, the constancy of the dose rate must be checked for each combination of operating voltage and filtration used. As the dose rate is strongly dependent on the added filtration, a mistake in the filter used may result in a severe overdosage or underdosage of the patient. It is then recommended that the number of combinations of voltage and filtration used should be kept to a minimum. Weekly checks of the dose rate are recommended.

Accelerators are more liable than other units to failures that cause modifications in output. Any change in the accelerating energy, in the

direction of the accelerated electron beam on the target or in the position of the flattening filter, results in a change in the dose per monitor unit. A frequent check of the dose per monitor unit is therefore the best way of detecting a failure, and constancy checks should be performed daily or at least twice a week.

Dose distributions. These should be measured carefully for each treatment condition. However, when convenient data acquisition systems are not available, published data for the same type of radiation unit may be used, provided depth doses and beam profiles are checked for two or three typical beams.

It is not, in general, necessary to recheck periodically the full dose distributions provided the checks for uniformity, flatness, symmetry and beam energy are performed as recommended below.

Beam uniformity, flatness and symmetry. These terms have been defined in the various published protocols as well as by the International Electrotechnical Commission (IEC).

When a treatment is planned, it is assumed that the beam is uniform, reasonably flat and symmetrical. However, there are many sources of malfunction which can affect beam profiles, e.g., asymmetry in the collimator jaws, misalignment of the target or the flattening filter in high-energy X-ray machines, or malfunction of the source holder in a cobalt-60 unit.

Variations in beam flatness and beam symmetry should not be more than $\pm 3\,\%$. For high-energy X-ray beams, these parameters should be checked at least every two weeks and, for cobalt-60 beams, beam symmetry should be checked monthly. For orthovoltage X-ray units, these parameters should be checked carefully when a new X-ray tube is installed and rechecked monthly.

For electron beams, beam uniformity is strongly dependent upon the collimation and scattering system used and varies with the energy of the electrons.

Flatness and symmetry should be checked for each energy used at least every two weeks. The acceptable tolerance is the same as for photon beams.

Beam quality. The penetration of the radiation beam is an essential feature in the determination of absorbed dose at the depth of the tumour; depth doses should therefore be accurately known for all the irradiation conditions: beam energy, field size and source–skin distance (SSD).

Depth doses are strongly dependent on beam energy; the energy stability of the machine must therefore be checked frequently. For high-energy X-ray beams, a quality index has been recommended as a quantity to be determined in constancy checks. For high-energy photon beams, the quality index I is the ratio of the dosimeter readings J_{20} and J_{10} at 20 cm and 10 cm depth, respectively, in a 10 cm × 10 cm beam measured at a constant source–detector distance:

$$I = J_{20}/J_{10}$$

This ratio should be checked monthly, and should vary by less than $\pm 2\,\%$.

For cobalt-60 beams, the depth dose is slightly dependent on the source size and the collimation device; however, it cannot vary with time for a given cobalt unit so that its stability does not need to be checked.

For conventional X-ray units, the half-value layer (HVL) (i.e., the thickness of a given filter material that reduces the intensity of the X-ray beam to $50\,\%$ of its initial value) is a convenient measure of beam quality. It is strongly dependent on the voltage applied to the tube and on the nature and thickness of the filter used. When no safety device is included to guarantee that the correct filter is used, it is necessary to check carefully, before each measurement and each patient irradiation, that the correct filter is present. The HVL should be measured when a new X-ray tube is installed and rechecked at least twice a year.

For electron beams, the target volume is in general positioned so that the dose at the deeper edge is at least $85\,\%$ of the maximum dose. The depth of the $85\,\%$ isodose is known as the therapeutic range (R85). The value of R85 for a 10 cm × 10 cm field at the usual skin source distance must be checked monthly and should not vary by more than ±2 mm.

2.4.6 *Treatment accessories*

The dose distribution in the patient can be markedly improved by the insertion of shielding blocks, compensators and wedges in the beam. However, misalignment of compensators and wedges not only decreases the dose homogeneity throughout the target but also directly affects the central axis dose rate due to the variation in beam attenuation. It is necessary, therefore, to ensure that the positioning of all blocks, compensators and wedges is reproducible.

The transmission factor of standard wedges and compensators must be carefully measured and rechecked annually. Any variation in the transmission factor is, in general, an indication of misalignment.

The trays used to support shielding blocks or compensators attenuate the photon beam. The transmission factor of such trays must be rechecked annually or after any repair or modification.

2.4.7 *Dose intercomparisons*

Dose intercomparison is a useful method of checking dose measurements and the radiation output of teletherapy machines.

Since 1969, as already mentioned, IAEA and WHO have carried out a TLD postal dose intercomparison for the dose output of radiotherapy machines, covering approximately 600 radiotherapy facilities in 85 countries.

Similar dose intercomparisons, but in more restricted areas, are performed by some SSDLs as well as by national and regional scientific and professional organizations (American Association of Physicists in Medicine, Nordic Association of Clinical Physics, European Organization for Research on Therapy of Cancer, etc.).
Dose intercomparisons make it possible to:

(i) evaluate the correctness of dosimetry in each of the participating facilities;
(ii) specify the magnitude of errors in dose output measurements so that appropriate corrections can be made;
(iii) provide reliable technical support for medical physicists working in isolation in small radiotherapy facilities.

The need for a wider role for the SSDL network in dose intercomparison and for a more elaborated process of intercomparison in radiotherapy procedures was recognized and emphasized in the recommendations of an Advisory Group of the SSDL network held at IAEA, Vienna, in 1984.

2.4.8 In vivo *dosimetry (dosimetry on patients)*

An effective way of checking the quality of the entire dosimetric procedure, from the performance of the treatment machine to the accurate positioning of the patient, is to make absorbed dose measurements on the patient and, when possible, in body cavities. Such measurements have revealed human and technical failures that would have caused significant errors in the treatment dose.

Diodes, condenser chambers or thermoluminescent dosimeters can be used for such measurements, depending on the local situation. Large numbers of measurements with diodes can be made without any great need for additional manpower, and the results are known immediately. Measurements with thermoluminescent dosimeters and condenser chambers are more difficult to evaluate. It might, however, be preferable for this evaluation to be conducted by a person not involved in the treatment procedure. Whichever dosimeter is chosen, it should be calibrated regularly against the local standard and care should be taken to avoid damage arising from daily use.

Entrance dose measurements have been found very useful as an overall check of the procedures involved, not least the accurate positioning of the patient and the correct calculation of treatment time. If several dosimeters are used, deviations from acceptable field flatness and symmetry may be revealed. For measurements on high-energy photons, a suitable build-up cap must be used.

Exit dose measurements can be used to check the calculated dose distribution in the patient, especially when large corrections are made for body inhomogeneities and compensating filters applied. They can also detect changes in patient size during the course of the treatment, but these can be difficult to evaluate.

Intracavitary measurements are preferably carried out with small solid thermoluminescent dosimeters. They are very useful for checking and correcting treatment plans in complicated cases, such as treatment of the oesophagus.

Dose measurements on the patient may also be performed when the dose to sensitive organs, such as the lens of the eye and the gonads, is critical. In the measurement of doses in steep dose gradients, the size and orientation of the sensitive volume of the dosimeter must be taken into account.

Another important field for *in vivo* dosimetry is in the measurement of dose rate in the rectum and bladder during the intracavitary treatment of gynaecological malignancies. High-sensitivity scintillation counters can also be used with advantage for this purpose.

When new and/or complicated treatment methods are initiated, with irregularly shaped fields, for example, *in vivo* dose measurements are of great value.

2.5 Brachytherapy

2.5.1 *General*

Brachytherapy may be performed by inserting sources either into the tissues (interstitial therapy) or into a natural body cavity (intracavitary therapy). In both cases the active sources may either be inserted directly or by using afterloading methods.

The quality of the application can be assured more easily when afterloading methods are used since the position of the inactive guides or applicators can be checked by radiography. If, in addition, dummy sources are used, irradiation of the staff can be avoided. Afterloading methods are therefore strongly recommended. Manual afterloading methods are as accurate and safe as remote afterloading methods for low dose-rate applications and are also inexpensive. However, remote afterloading methods are obligatory in high dose-rate applications.

2.5.2 *Sources*

Radium and its daughter product radon were the radionuclides mainly used in the development of brachytherapy. Vast experience in the use of these sources has thus been accumulated, but the disadvantages are such that their use is now strongly discouraged. These disadvantages include:

—the radiation hazards associated with contamination by highly toxic daughter products. One of these daughter products, radon, is gaseous, so that hermetic sealing is required and frequent tests to detect leakage are necessary;
—the low specific activity and consequent large size of the sources, which makes the use of afterloading techniques difficult;
—the high-energy components of the gamma spectrum produced make very heavy and cumbersome protective equipment necessary;
—the increasing difficulty in disposing of old radium sources.

Since the cost of manual afterloading equipment and sources is low compared with that of external beam therapy, the radium sources in use should be replaced as soon as possible by modern radioactive sources. Out-dated radium sources should never be accepted by a radiotherapy department even as a gift.

At the present time, the most commonly used sources are:

1. miniaturized caesium-137 or cobalt-60 sources for intracavitary procedures using afterloading methods;
2. cobalt-60 for high-intensity sources in remote afterloading devices used in so-called "high dose-rate" brachytherapy techniques;
3. iridium-192 in wires or seeds for removable interstitial implants;
4. iodine-125 seeds for permanent interstitial implants.

Calibration of sources. Discrete sources with long half-life (^{60}Co, ^{137}Cs) should be clearly marked and a calibration certificate should accompany each new source purchased. When sources without a calibration certificate are in use in a hospital, their apparent activity should be determined by comparison with a calibrated source of the same radionuclide and similar geometry.

Iridium wires or seeds in nylon tubes should preferably be calibrated individually and the homogeneity of the source activity along the length of each source should be checked on receipt and before any clinical use.

The exact geometry of a source or of a train of miniaturized sources may be checked by means of an X-ray radiograph of the source; an autoradiograph of the source is a simple and cheap means of checking the homogeneity of the activity to a first approximation. In some sophisticated remote afterloading devices, the sources cannot be identified and the user must rely on the manufacturer to guarantee that in no case does the activity of the sources differ by more than 5% from the stated activity. When purchasing such equipment, the user should request a certificate of the homogeneity of the source activities from the manufacturer.

Source inventory. This should be carried out in association with each brachytherapy procedure and a general source inventory should be carried out at least every month.

During such periodic inventory, a correction for decay should be applied to the long half-life sources when necessary; the frequency recommended is every month for cobalt-60 sources and twice a year for caesium-137 sources.

For iridium-192 and iodine-125 sources, the correction for radioactive decay, both up to the time of intended use and during treatment, should be part of the treatment planning.

Contamination hazards. If radium sources are used, they must be tested for leakage with a frequency depending upon their use but at least once a year. Since radium needles are encapsulated in a very thin platinum sheath (0.5 mm thick), they can easily be damaged and should be replaced by less hazardous sources as soon as possible.

Contamination hazards associated with the other radionuclides have been considerably reduced. Contamination tests are, in general, performed by the manufacturers for cobalt-60 and caesium-137 sources. The results should be included in the calibration certificate. Leakage tests should be repeated at least every two years.

The tools used to prepare iridium sources (cutters, forceps, etc.) should be tested for contamination twice a year.

2.5.3 *Tests on remote afterloading devices*

A detailed document on afterloading equipment is in course of preparation by IEC.

Source positioning in the applicator. The accuracy and the reproducibility of source positioning with respect to the applicator used should be checked periodically with dummy sources under various conditions of use. The frequency of checking will depend on the frequency of use of the device but should not be less than every month.

Safety position of the sources. When in the "off" position, the sources should be inside the shielded part of the device (the safe) and the radiation hazard should be within the limits required by the local legislation. The correct positioning of the sources in the safe should be checked periodically and at least twice a year.

Timers. Depending upon the design of the device, either one or a number of timers will be available. They are intended to record the time during which the active sources are positioned within the applicator and to ensure that the duration of the treatment is as prescribed. They should be checked periodically and at least every month.

2.5.4 *Quality control of treatment*

Before the active sources are positioned, dummy sources should be used to check the source position within the inactive guides or applicators with respect to the anatomical structures concerned.

A pair of radiographs, generally in the anteroposterior and lateral planes, perpendicular to one another and taken under well defined conditions, is necessary in order to reconstruct the source geometry so as to be able to compute the dose distribution and compare it with the planned treatment. For this purpose, rigid film holders are required in order to ensure orthogonality. The distances (X-ray tube–source–film) must also be known so that the magnification can be calculated.

When the above conditions cannot be met, a pair of radiographs taken in the anteroposterior and lateral planes is the minimum required to check whether the source positions are acceptable.

2.6 Treatment planning system

The introduction of computer technology should help to improve both the quality of the treatment plan (by permitting more sophisticated plans) and the dosimetric accuracy of the treatment.

However, manual procedures are in use in all parts of the world and are capable of giving good standard radiotherapy. The introduction of computer technology in radiotherapy planning should therefore not be regarded as implying that such procedures are obsolete. Rather, it is strongly recommended that the ability to perform manual procedures should be maintained and that such procedures should continue to be practised in radiotherapy departments for the following reasons:

1. they are useful for educational or training purposes;
2. the computer system may be temporarily unavailable because of technical breakdown, renovation or system modification;
3. someone experienced in manual procedures will more easily detect any errors that may have occurred in the use of a computerized dose planning system;
4. in unusual clinical situations, or in the implementation of new treatment techniques, the range of applicability of the computer algorithms may be exceeded.

The use of computers will introduce new risks of error because of both hardware failures and software mistakes. Although hardware failures leading to errors in calculation are unusual, their importance is too often underestimated. Software mistakes are more frequent, and initial and systematic checks should be performed to detect and correct them.

An experimental check of the computer calculation must therefore involve measurements by the same instrument both at the point of interest and at the reference or normalization point.

According to ICRU Report No. 42 (*15*), a computerized dose distribution can be considered as sufficiently accurate if calculated and measured doses differ by less than 2% *at points of relevance for the treatment*. In regions involving very steep dose gradients, the observed position of a given isodose curve should differ from its calculated position by less than 0.2 cm. These requirements can be considered as an *optimum*; however, larger uncertainties may be accepted under certain conditions.

2.6.1 *Programme and system documentation*

At the most basic level of quality assurance, the user of a computer system must be provided with documents explaining the procedures necessary for the operation of the system software and hardware. Detailed information must therefore be available on the following system components:

(1) *Beam library*. The user must have access to the beam library. In some situations, however, accepted tables may be used (such as those for cobalt-60 beams) (*16*), provided that the computed values can be verified on the treatment unit at several depths.

(2) *Beam model*. The documentation must include a description of the physical model on which the calculations are based as well as the values of the parameters used. It must also include detailed information on the possible range of applications, the limitations and the accuracy of the results, as well as on the applications for which the model is not suitable.

(3) *Dose distribution calculations*. The documentation must include a complete description of the procedure for entering patient data and treatment parameters. The method used to obtain the dose distribution and to interpret the results must also be described.

2.6.2 *Test programme*

Initial checks. Before a computer system is brought into clinical use, it must be carefully checked with respect both to its various functions and to its accuracy. Such initial checks can reasonably cover only a representative set of the applications used in the various institutions, but should consist of at least:

- the reproduction of input information, e.g., in radiotherapy planning, the computation of the absorbed dose in radiation beams for which the radiation dose was entered;
- the calculation of a set of selected examples of treatment plans, either produced manually or taken from the literature (see section 2.6.1).

Periodic checks. These should be carried out at regular intervals and at least once a month. Checks should be made on examples taken from the typical range of irradiation techniques used in the radiotherapy department. The results of repeated runs of such standard problems can be compared with those of the initial checks.

Checks should be carried out, in particular, after each modification of the beam library and/or after each programme update or modification of the hardware.

Spot checks should be carried out at shorter intervals, e.g., every week or every day if the system is used intensively. They are useful in detecting inadvertent or accidental modifications of either hardware or software. They can be performed by computing a typical treatment for a typical patient as a computation sample, often referred to as a "quality control tool". This "tool" must be carefully designed so as to cover a wide spectrum of practical conditions. A permanent record of the results of such tests must be kept and referred to if any error is suspected. Such tests may also prove to be useful in comparing the accuracy of different treatment planning systems.

2.7 Safety

Ensuring the safety of both patient and personnel is a part of quality assurance. Safety requirements, including radiological protection, are basically the same as in other clinical situations. However, vigilance is necessary at all times if hazards are to be avoided.

2.7.1 *Mechanical and electrical safety*

Mechanical and electrical safety is a basic prerequisite in such technologically advanced machines as radiotherapy units. It is strongly recommended that the units should be installed and serviced by qualified personnel and that the operators should be well trained.

The following items may need consideration:

—the shutter and timer in cobalt-60 and caesium-137 teletherapy units;
—the brakes on the treatment couch;
—safety circuits to prevent persons from being accidentally squeezed in the door of the treatment room;
—the safe holding of collimation blocks;
—safety circuits to prevent either machine or patient colliding with the collimator;
—adequate earthing of the treatment unit to prevent electric shocks;
—the arrangements for audio and visual communication with the patient;
—emergency stop switches.

Faults must be repaired immediately and the equipment checked carefully afterwards.

All the items mentioned above must be checked monthly. However, when one particular system fails frequently, it may be necessary to check it weekly or more often.

2.7.2 *Radiological safety*

Measures must be taken to ensure that the dose received by staff during the treatment of patients is within the limits recommended by ICRP (*17*, *18*). Recommendations on radiation protection in treatment rooms and in work with radiotherapy units have been published by ICRP (*19*).

The treatment room should be planned in the light of the procedures to be undertaken and should not be too small.

The structural shielding of the walls must be designed to avoid irradiation of personnel in adjacent areas and must satisfy the requirements of local regulations. If no such regulations exist, it is recommended that the maximum possible exposure of personnel should not exceed the limits laid down by ICRP (*17*). The entrance to the treatment room must be interlocked to prevent inadvertent staff entry and must provide adequate protection.

The housing of radioisotope teletherapy units should be such that, with the beam control mechanism in the "off" position, the air kerma rate from the leakage radiation measured at a distance of 1 m from the source does not exceed 10 μGy per hour. At any readily accessible position 5 cm from the surface of the housing, the air kerma rate from the leakage radiation should not exceed 200 μGy per hour.

In treatment rooms containing a high-energy accelerator, the ventilation provided must be sufficient to minimize irradiation by activation products in the air; this, however, is a minor hazard.

The short-lived activation products in the collimator of an accelerator are a problem only when the treatment head of the machine has to be repaired; it may then be necessary to wait for a few hours before dismantling it.

Parts of some collimators are made of uranium. Contamination checks should then be carried out when there is a risk of flaking. Repair or modification of these parts should be strictly forbidden except by suitably qualified personnel in surroundings such that any hazard is minimized.

Radiation transmission by walls and doors must be monitored for every possible position of the gantry and for the maximum field size. The transmission of the primary barrier should be measured without a phantom in the beam but that of the secondary barriers should be measured with a water or tissue-equivalent phantom under the usual treatment conditions.

It is not, in general, necessary to recheck periodically the transmission of the walls. This should, however, be rechecked after any repair or modification or after the installation of a new treatment unit or a new cobalt or caesium source.

For high-energy equipment producing neutrons, it should be noted that the wall transmission of neutrons may increase with decreasing water content of the walls.

It is necessary to check the transmission of the door and of the frame annually and the integrity of the door interlocks monthly.

3. Clinical aspects

3.1 Methodology

A general methodology exists for the assessment of quality in medicine based on the work of Donabedian (*20*) and consisting of the following four steps. Firstly, standards of performance in the delivery of medical care are established by consensus. Secondly, the actual performance of medical practitioners is assessed for compliance with these agreed standards. Thirdly, when important deviations from these established standards are seen, procedures must be designed and instituted to improve compliance with the established standards to an acceptable level. Finally, the quality of medical practice must again be reviewed in order to determine whether the deviation from the established standards has been eliminated.

For quality assurance in radiation oncology, these steps take the following form:

(1) Development of a consensus view of "best current management". For a particular cancer, this can only be done within an area or country in which practice is similar, and where the facilities available for treatment are not too widely different.
(2) Development of a survey mechanism with a minimum "check-list" of pertinent questions based on the consensus "best current management". This can be used to assess how closely individual treatment facilities and indeed individual practitioners actually conform to the "best current management" benchmark of their own peers.
(3) Identification of important variations from "best current management" among individual treatment facilities and practitioners, and development of a programme to correct such deficiencies.
(4) A further survey of treatment carried out in individual facilities by individual practitioners to determine whether there has been improvement in conformity with the consensus "best current management".

If a programme for quality assurance in radiotherapy and oncology is to be successful, a consensus on "best current management" must be developed logically and only after the widest possible discussion among

radiotherapists, oncologists, and other specialists, including surgeons and medical oncologists, widely distributed geographically within the area or country. Only for treatment of cancers in a few selected sites will it be possible to establish such a consensus internationally. The improvement of standards of medical care in the future in many countries may permit such a consensus to be attained internationally for the treatment of cancer in additional sites. When a consensus is developed for a specific site, it should include a detailed statement of the minimum appropriate pretreatment evaluation, details of the treatment, and the requirements for assessment and follow-up. For those sites for which consensus cannot be reached, clinical research is necessary to establish a clear-cut "best" method of treatment.

The committee that drafts such consensus views must justify its conclusions as fully as possible by reference to the scientific literature. Such a carefully developed consensus can then form the basis of a process survey mechanism, with a "check-list" of questions to be asked in assessing the degree of conformity with the agreed "best" practice in individual facilities and by individual practitioners. Decision-trees may be constructed for particular disease sites and may be helpful in the development of the survey questionnaires. The check-list is then used to examine individual records of patient treatment, selected at random in individual treatment facilities.

When differences in conformity are observed, as between treatment facilities or individual practitioners, a value judgement must be made as to how important these differences are. This judgement is often best made by the committee that originally established the consensus "best current management". Important differences, such as inadequate pretreatment evaluation, staging, or inadequate radiation dose, will require the development of a corrective programme designed to increase conformity with the agreed "best" management. This corrective programme should then be introduced prospectively into the management of the particular tumour by the treatment centres concerned. Finally, at an appropriate later date, a second survey should be conducted to determine whether there has actually been an increase in conformity with the consensus "best current management". If so, quality of treatment has been assured by a change in the behaviour of individual treatment centres and individual practitioners. If no improvement is seen, further corrective programmes must be introduced and clinical practice resurveyed until satisfactory conformity with the agreed "best current management" is achieved. If this cannot be achieved, the cessation of treatment of that particular cancer by the individual facility or practitioner should be considered.

3.2 Patient registration

3.2.1 *Patient identification*

The name, date of birth of the patient, and a hospital number are generally used as means of identification. However, with common

surnames, the possibility of confusion in patients' records exists. Some countries have a system in which each person has a unique reference number for social security or other reasons and where possible, it is recommended that such a number be used for health records.

3.2.2 *The medical record*

The basic patient data required for cancer registration must include patient identification, i.e., at least name, address, date of birth where possible, some identifying number, ethnic origin, and diagnosis (preferably according to the International Classification of Diseases (*21*)). In addition to this basic information, the hospital medical record must include details of the patient's history, including previous treatments, physical examination, pretreatment evaluation of the extent of disease, and details of treatment and follow-up. When the patient is discharged from hospital, a summary of the course of the disease and its treatment to date should be included in the record. This will facilitate the transfer of clinical information if the patient is subsequently admitted to another facility.

3.2.3 *Cancer registry*

The results of cancer treatment vary widely, both nationally and from one country to another, depending upon disease site, stage and, in part, upon the facilities and manpower available. The effective planning of cancer services requires a knowledge of the pattern of disease in any country and its various regions, and this in turn requires the establishment of cancer registries in which tumour incidence and the results of treatment can be recorded. Guidance on standardized formats for the recording of both diagnostic information and the results of cancer treatment has been given by WHO (*5*, *22*). Where economically possible, such recording can best be achieved with the aid of modern computer systems, but where manpower costs are low, manual registry systems are perfectly satisfactory. Only population-based cancer registries can give information on cancer incidence, but these are costly to establish. As a first step, hospital-based cancer registries can give useful information on the pattern of referral of cancer patients for hospital treatment, and can serve as a basis for subsequent expansion to cover the population of the area served by the hospital concerned. Quality assessment in radiotherapy can best be achieved by measurement of treatment outcome, and cancer registries are a cost-effective means of collecting this information.

3.3 Pathological diagnosis

Before patients undergo radiotherapy for malignant disease, it is first necessary to confirm the clinical diagnosis by cytological or histopathological examination of surgically removed or needle biopsy material obtained from the tumour. Where possible, this should include clinical staging (tumour size) (*23*), pathological staging, grading (*24*), and relevant special studies, such as those for hormone receptors, surface markers, etc. The pathology report should include information on the involvement of adjoining normal structures (pT) and lymph nodes (pN), if these are included in the excised material, as well as comments on the completeness of excision of the tumour.

It is recognized that, for certain life-threatening conditions, radiotherapy may need to be given without prior histological confirmation of the diagnosis, but this requires justification *in every individual case*.

3.4 Pretreatment evaluation

3.4.1 *History and physical examination*

A full history of the patient's illness must be taken and information collected on as many etiological factors as are recognized. The patient's performance status must also be assessed by means of a recognized method (e.g, with the Karnofsky, Zubrod, or other scale). A complete physical examination should be performed, with special emphasis on the examination of sites to which the particular primary tumour commonly spreads. The clinical extent of disease should be recorded in anatomical diagrams on which the dimensions are indicated. Where surgical procedures have been undertaken, the procedure used and the findings, in terms of tumour extent and the involvement of neighbouring structures, should be described in full.

3.4.2 *Diagnostic work-up*

Additional diagnostic studies should be directed towards establishing the extent of distant disease and should include laboratory tests, suitable imaging investigations and, where indicated, endoscopic investigation or surgical procedures. The extent of such investigations will reflect the availability of these technologies in the institution concerned; they should be as non-invasive as possible.

3.4.3 *Staging*

Imaging and laboratory investigation technologies are changing rapidly, but the goal should always be a full pretreatment staging of the development of the primary tumour, and the extent of nodal and distant metastatic spread, in accordance with an internationally agreed classification or staging system (*23*).

3.5 Treatment alternatives

Cancer is commonly treated by surgery, radiotherapy, or medical intervention, which includes the use of cytotoxic drugs and/or hormones. These modalities may also be used in combination, either simultaneously or in sequence. The choice of treatment for the individual patient should take into account the particular skills of local surgical and medical personnel, as well as the site, type and extent of disease in the patient. Where possible, the choice should also depend on the preference of the patient, who should be fully informed of the available treatment alternatives giving similar long-term survival. (For example, in early carcinoma of the breast, long-term survival is of comparable duration whether the treatment selected is local excision and radiotherapy or radical mastectomy.) Ideally, a recommended treatment plan should be drawn up by a multidisciplinary tumour board. The treatment objectives must be clearly stated (radical treatment with curative intent, adjuvant treatment or symptomatic palliation) and the reasons for the choice recorded.

3.5.1 *Objectives of radiotherapy*

Curative radiotherapy involves exposing the target volume containing the tumour to a radiation dose which often closely approaches the normal tissue tolerance, and is limited by the acceptable levels of damage to normal tissues. By contrast, adjuvant treatment less frequently approaches the normal tissue tolerance; palliative treatment should be planned to avoid symptomatic injury to normal tissues. When therapy is started, its objectives should be clearly stated. For the majority of curative radiotherapy applications, teletherapy isotope units or medical accelerators producing megavoltage X-ray beams will most commonly be used because of their ability to achieve suitable patterns of dose distribution. Orthovoltage X-ray units will be used mainly for the curative treatment of skin and other superficial tumours. However, orthovoltage machines may have a very useful role in palliation. Where possible, all curative treatment should be simulated using suitable diagnostic X-ray equipment to ensure that the appropriate target volume is being irradiated and that sensitive normal tissues are not unduly exposed. The complexity of the irradiation field should be the minimum compatible with a suitable dose distribution within the patient. This will depend upon the facilities available in the individual treatment centre; the ability to deliver accurately parallel opposed radiation fields, which may give a less than ideal dose distribution, may outweigh the risk of "geographical miss" of the tumour if a complex treatment field arrangement is used without verification. However, except for the treatment of skin and other superficial malignancies, single applied radiation fields should virtually never be used in curative treatment.

3.5.2 *Treatment prescription*

The treatment prescription should be based on all available clinical information on the biology, natural history and histology of the tumour concerned; it consists of the definition of the target volume(s), the target absorbed dose, and the dose fractionation scheme. The *target volume* contains the tumour volume as well as the surrounding normal tissues, which may be involved and which must be irradiated to the prescribed dose level (*target absorbed dose*). The target volume(s) should be defined in anatomical terms, the dimensions given and wherever possible, related to easily identifiable external body landmarks. Definition of the target volume implies identification of normal tissues (*organs at risk*) whose presence in the vicinity of the target volume may influence the treatment prescription. The target absorbed dose should be defined in accordance with the ICRU recommendations (*25*). The decision as to the *fractionation scheme* or *time factor* (number of fractions, dose per fraction, overall time) forms part of the treatment prescription. In a multifield treatment plan, it is normally good clinical practice to treat *every* field at each treatment session. For each site and stage of malignant disease, optimum treatment prescription implies a consensus among radiotherapists, at the appropriate local, regional, or national levels, as to the minimum and maximum acceptable radiation dose. This is usually achieved through agreed radiotherapy protocols.

3.5.3 *Planning*

Treatment planning comprises the procedures that take place between the prescription of treatment and its execution. It consists mainly of the choice of the best arrangement of radiation treatment fields (number, size, orientation), for which additional information concerning the patient (*patient data*) may be required; external contour, localization of target volume with respect to anatomical reference points, and localization of organs at risk; and information on the characteristics of the available radiation beams (*beam data*). The beam position is checked by means of a treatment simulator, i.e., a diagnostic X-ray machine designed to mimic the movements of the radiotherapy unit. The final selection of beam arrangement is generally based on the calculated *dose distribution*; this is now being obtained with increasing frequency by the use of computers (see section 2.6). Speed of calculation is important in order to facilitate the rapid comparison of different treatment plans (treatment optimization).

3.5.4 *Positioning*

Patients should be positioned as comfortably as possible for treatment so that they can maintain their position during treatment and reproduce

it at subsequent treatment sessions. Where possible, when treatment is to be given with an isocentrically mounted machine, the patient should not have to be turned over, as this can give rise to large changes in the position of internal organs. Certain patients, such as those with tumours in the head or neck will require immobilization devices, such as casts (masks) or bite-blocks, to enable them to produce identical positioning during the course of fractionated treatments. This is particularly important when limiting normal structures may be close to the target volume. Children may require special equipment and procedures to allow them to be positioned accurately for treatment. This may include sedation or even general anaesthesia.

3.5.5 *Specification of dose, time and volume*

For the treatment of tumours at different sites, the required dose is a function of the goal of radiotherapy (curative, adjuvant, or palliative) and of the planned dose fractionation and overall time. The volume treated is a function of the biology of the tumour and its natural history. For any particular anatomical site, the combination of these factors that is defined as "best current management" can only be determined by consensus among radiotherapists at the appropriate local, regional or national level after detailed consideration of the international radiotherapy literature and their own clinical experience.

3.6 Responsibility of the radiation oncologist

The management of the patient with cancer and, in particular, the administration of radiotherapy require a multidisciplinary team effort in which, in addition to the doctor, the skills of the medical physicist and the radiographer are used extensively. The ability to carry out high-quality radiotherapy depends on the availability of a sufficiently large staff of well-trained and highly motivated individuals. Recommendations as to suitable staffing levels for departments of radiation oncology were made at a WHO Meeting of Investigators (*6*). Ultimately, however, the radiation oncologist must accept sole responsibility for the care of the cancer patient. This means that the radiation oncologist must be present at the initial planning of treatment, personally involved in confirmation of the treatment volume, present at set-up for the first treatment, and must see the patient at regular intervals during the course of treatment to observe both the response of the tumour and any adverse reactions in normal tissues so that the latter can be dealt with properly.

3.7 Brachytherapy

Sealed radionuclide sources are used in intracavitary, interstitial and surface treatment of accessible tumours, and in some clinical situations are preferable to external beam irradiation techniques. However,

brachytherapy poses special hazards for both patients and staff, and the use of brachytherapy techniques in radiotherapy requires, as a minimum, special training for the radiotherapists and sufficient continuing experience to ensure their safe performance. For many interstitial and intracavitary treatments, the services of an anaesthetist will be required to provide general anaesthesia while the sources or suitable inactive guides are inserted in the patient.

In addition to the clinical skills required for the practice of brachytherapy, certain technical facilities are necessary, including those needed for the radiographic localization of the position of the implanted sources, while medical physicists must be available to calculate the dose distribution around these sources in each individual patient. Special care is needed before techniques employed at conventional low dose rates are used with high-dose-rate afterloading methods, where excessive damage to normal tissues can be easily produced through inexperience.

3.8 Psychosocial aspects

The diagnosis of any life-threatening disease, in particular cancer, is a highly stressful experience for the patient. In addition, treatment may be associated with temporary or permanent disability, whether or not the tumour is cured. Every department of radiation oncology should therefore have a programme of cancer counselling, covering the largest possible number of patients, so as to deal with their psychosocial problems and prevent avoidable morbidity.

3.9 Follow-up and outcome

All patients treated by radiotherapy must be followed up to assess the extent to which local tumour control has been achieved and to note the presence or absence of unwanted sequelae of treatment or of distant metastases. The appropriate interval for such follow-up will depend upon the disease and form of treatment. Although the responsibility for follow-up lies with the radiotherapist, it may be delegated to other medical facilities or physicians who have been involved in the prior care of the patient or who are in closer geographical proximity.

The follow-up programme should include, in addition to the examination of the patient, such diagnostic tests at appropriate intervals as are required to assess the presence or absence of local disease or metastases, and of the complications of treatment. As a minimum, freedom from local disease, freedom from metastases and the presence or absence of complications must be recorded in the hospital record at each attendance.

From the above-mentioned data, the radiotherapist should periodically evaluate the results of treatment and compare them with those obtained

in patients with similar disease treated in other facilities, whether locally, nationally or internationally. Only by such comparison can the quality of treatment be assessed, and the assessment of quality is a prerequisite for quality assurance.

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Annex 1

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Annex 2

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