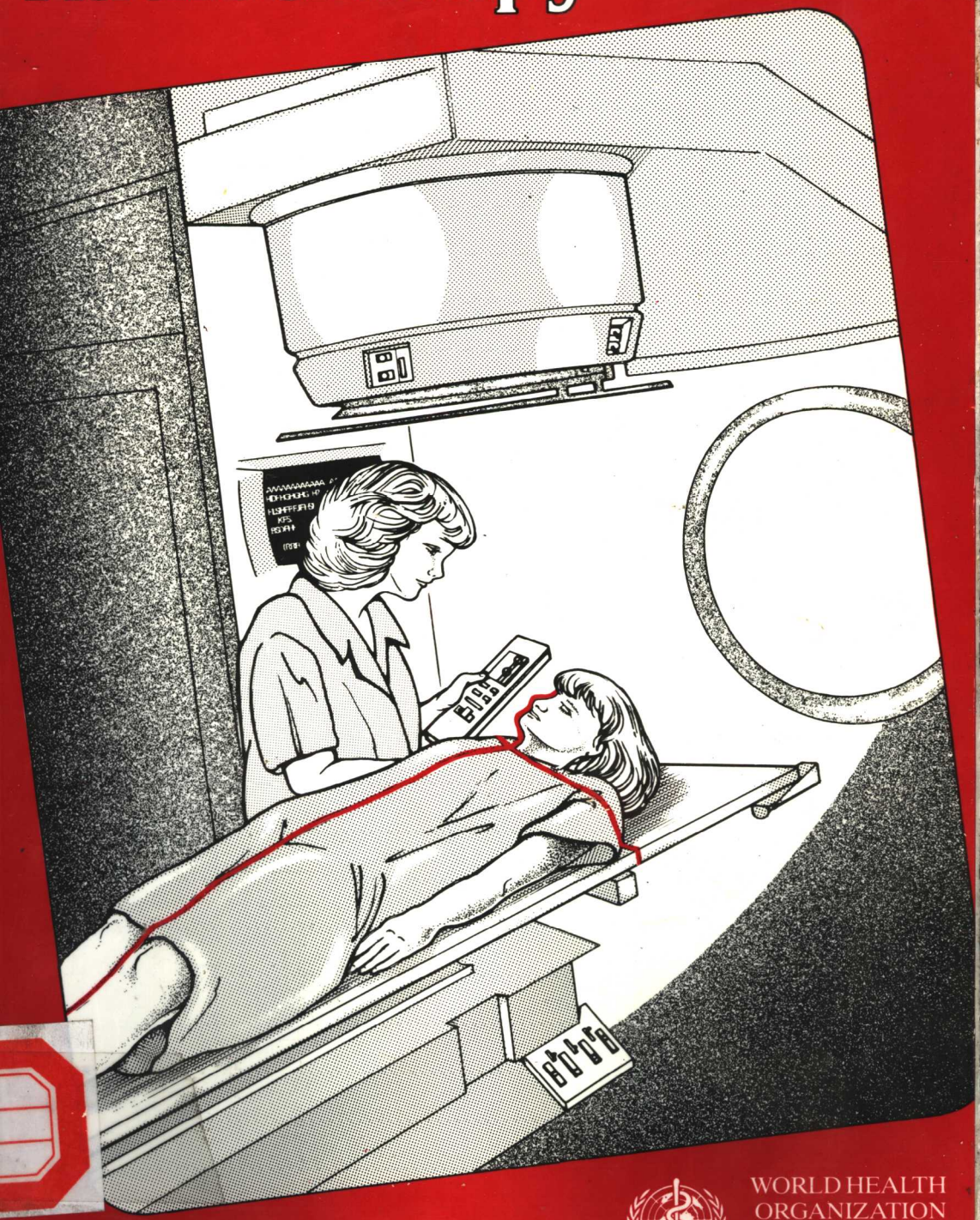
Quality Assurance in Radiotherapy



WORLD HEALTH
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Quality Assurance in Radiotherapy

A guide prepared following a workshop held at
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and organized jointly by

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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.

[b] WORLD HEALTH ORGANIZATION. *Quality assurance in nuclear medicine*. 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