Setting Up a Radiotherapy Programme: Clinical, Medical Physics,

Radiation Protection and Safety Aspects





SETTING UP A RADIOTHERAPY PROGRAMME: CLINICAL, MEDICAL PHYSICS, RADIATION PROTECTION AND SAFETY ASPECTS The following States are Members of the International Atomic Energy Agency:

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INTERNATIONAL ATOMIC ENERGY AGENCY VIENNA, 2008

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FOREWORD

The incidence of cancer is increasing, particularly because of the increase in life expectancy arising from worldwide improvements in standards of living. According to recent estimates of the International Agency for Research on Cancer (IARC) and the World Health Organization (WHO), approximately ten million new cases of cancer are being detected per year worldwide, with slightly more than half of the cases occurring in developing countries. By the year 2015 this number is expected to increase to about 15 million cases, of which two thirds will occur in developing countries. About half of all cancer patients receive radiotherapy, either as part of their primary treatment or in connection with recurrences or palliative treatment.

Radiotherapy is a multidisciplinary specialty which uses complex equipment and radiation sources for the delivery of treatment. It is estimated that approximately 3300 teletherapy machines are currently installed in developing countries. This figure is significantly below the estimated needs, of almost 5000 machines at present and about 10 000 machines by the year 2015. Taking this into account, in addition to the great need for qualified professionals (radiation oncologists, medical radiotherapy physicists, radiotherapy technicians, radiation protection officers, maintenance engineers, etc.), the future development of the medical infrastructure for cancer treatment appears to be a substantial undertaking. While the present publication discusses radiation treatment programmes alone, it is recognized that other components of comprehensive cancer management programmes, such as cancer prevention and diagnosis, also need to be addressed.

It is widely acknowledged that the clinical aspects (diagnosis, treatment decision making, indication for treatment and follow-up), as well as the procedures related to the physical and technical aspects of patient treatment, must be subjected to careful control and planning in order to ensure safe, high quality, radiotherapy. While it has long been recognized that the physical aspects of quality assurance in radiotherapy are vital to achieving effective and safe treatment, it has been increasingly acknowledged that a systematic approach is necessary for all the steps within the clinical and technical aspects of radiotherapy programmes as well.

The need to establish general guidelines at the IAEA, taking into account the clinical, medical physics, radiation protection and safety considerations for designing and implementing radiotherapy programmes in Member States, has been identified through the increased interest of Member States in the efficient and safe application of radiation in health care. To satisfy this need, the IAEA has convened several consultant and advisory group meetings to prepare a publication providing a basis for establishing a programme in radiotherapy. The external expertise has been substantially complemented by the contributions of a large number of IAEA staff members.

The present publication supersedes IAEA-TECDOC-1040 (Design and Implementation of a Radiotherapy Programme: Clinical, Medical Physics, Radiation Protection and Safety Aspects) published in 1998. It is addressed to professionals and administrators involved in the development, implementation and management of a radiotherapy programme, in order to establish a common and consistent framework in which all the steps and procedures in radiotherapy are taken into account. The present publication has been expanded to include orthovoltage X rays and linear accelerators. Major contributors to the present publication have been P. Mayles and V. Levin, whose efforts are gratefully acknowledged. The IAEA officer responsible for this publication was J. Iżewska of the Division of Human Health.

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1. INTRODUCTION

During the last few years there has been an increased demand from Member States for the IAEA to provide assistance, including the provision of radiation sources and equipment, in establishing radiotherapy programmes for the treatment of cancer patients. This assistance is usually made through technical cooperation (TC) projects. The provision of this assistance and equipment without a systematic approach to clinical, dosimetric, safety and maintenance aspects could jeopardize the outcome of the treatment of patients (with either unacceptably high complication or recurrence rates), and might result in an unacceptable risk of accidents. In this context, it must be recognized that both underdosage and overdosage are undesirable, the former leading to a possible increase in recurrences of tumours and the latter to possible complications of treatment. In addition, all projects carried out with the assistance of the IAEA must be in compliance with the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS) [1]. The present publication has been produced so that IAEA staff, expert consultants on missions, and their counterparts from IAEA Member States, will have a consistent and systematic approach to establishing and upgrading a radiotherapy programme. It covers both external beam radiotherapies with ⁶⁰Co teletherapy units or linear accelerators (linacs) and brachytherapy.

1.1. GLOBAL CANCER BURDEN AND THE NEED FOR RADIOTHERAPY

According to estimates made by the International Agency for Research on Cancer (IARC), there are currently (2002 estimate) approximately ten million new cancer cases per year worldwide, with slightly more than half of the cases occurring in developing countries. By the year 2015, this number is expected to increase to about 15 million cases, of which two thirds will occur in developing countries.

The distribution of cancer cases between the sexes worldwide is fairly even, with 5.3 million cases occurring in males and 4.5 million cases in females. Since the incidence of cancer increases with increasing age, the majority of new cases occur in the age group of 65+ years. The age distributions of cancer are, however, quite different between developed and developing countries; there are significantly more cancer cases in childhood, adolescence and young adults in developing countries, while cancer in the elderly dominates in developed countries (Fig. 1).

Overall, the most common tumour worldwide is lung cancer, with an annual incidence of 1.44 million cases, followed by breast cancer (1.22 million), colorectal cancer (1.09 million), stomach cancer (1.00 million) and prostate cancer (0.73 million) (Fig. 2(a)). In males the most common tumour is lung cancer, followed by prostate and stomach (Fig. 2(b)). In females, breast cancer is the most common tumour type, followed by cancer of the cervix (Fig. 2(c)).

The incidence of different cancer types varies considerably between regions. Examples involving the most common tumour types in males and females are given here. For females, a high incidence rate of breast cancer is reported from the United States of America (USA), slightly lower rates from Western Europe, and the lowest rates from Eastern Europe, Asia and Africa. Cancer of the cervix is the second most common female cancer in developing countries. In males, the highest rates of lung cancer are found in the Maoris of New Zealand and the black populations of the USA; and the lowest rates are found in India and Africa. A similar pattern is found for female lung cancer. Rates of stomach cancer in males are high in the Far East, medium in Eastern Europe and low in the USA.

Populations migrating from one country to another with a very different cancer pattern tend to approach the incidence rates of their new home country. This effect has been studied extensively, especially for populations from the Far East moving to California.

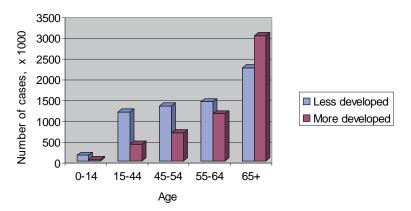


FIG. 1. Estimated age distribution of cancer cases in developed and developing countries in 2005. In the age group 0–14 years there are five times more cases in developing countries and in the age group 15–44 almost three times more. (Globocan 2002, by courtesy of D.M. Parkin, IARC, Lyons)

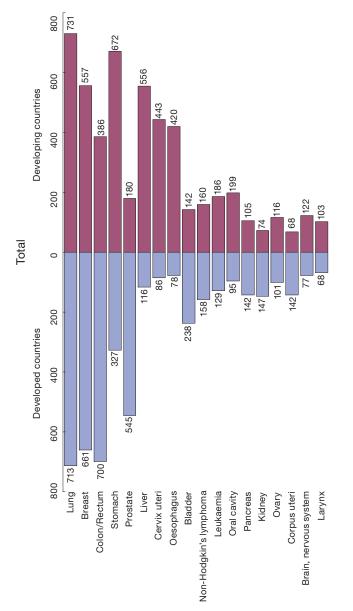


FIG. 2(a). Worldwide distribution of cancer types in 2002, ranked by total number of cases (in thousands) for various diagnoses (Globocan 2002, by courtesy of D.M. Parkin, IARC, Lyons).

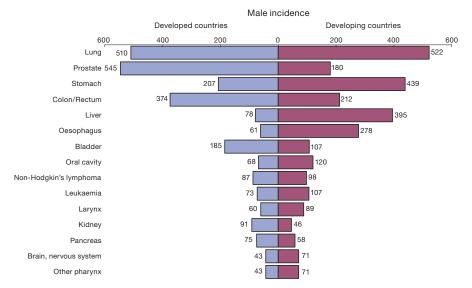


FIG. 2(b). Worldwide distribution of cancer types in 2002, ranked by total number of cases (in thousands) for various diagnoses for males (Globocan 2002, by courtesy of D.M. Parkin, IARC, Lyons).

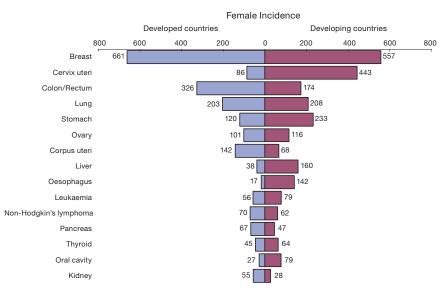


FIG. 2(c). Worldwide distribution of cancer types in 2002, ranked by total number of cases (in thousands) for various diagnoses for females (Globocan 2002, by courtesy of D.M. Parkin, IARC, Lyons).

It should be recognized that incidence data change over time due to a number of factors, real and apparent. The most important real factor is demographic change, in particular, ageing of the population due to elimination of diseases causing early death. This will inevitably lead to an increased number of cancer cases. There are also real changes in cancer incidence due to changes of lifestyle, socioeconomic development and exposure to environmental agents. Among the factors apparently raising incidence figures are the increasing awareness of cancer in the population, the availability of diagnostic procedures (this also includes the introduction of screening programmes, which will increase the incidence figures, albeit temporarily) and improvement in cancer registration techniques. Owing to the interplay of all these factors, the rates of change of cancer incidence vary considerably around the world.

The most obvious example of real change in cancer incidence is the alarming increase of lung cancer, in particular in developing countries, due to the acquisition of smoking habits. Other examples of a real increase in reported incidence are observed in breast cancer and melanoma; in developing countries the incidence of breast cancer now exceeds that of cervical cancer. The incidence of gastric cancer, the second most common type of cancer ten years ago, is decreasing worldwide.

The pattern of cancer in a country has a profound influence on the need for radiotherapy. A high incidence of a certain type of tumour in some populations, such as cancer of the nasopharynx, may also influence the need for specific radiotherapy resources in a region.

The IAEA maintains a computerized international registry of hospitals and clinical institutions that offer radiation therapy, which was given the name DIRAC (Directory of Radiotherapy Centres). DIRAC encompasses data on the teletherapy machines, devices and sources used in brachytherapy, equipment for dosimetry, patient dose calculations and quality assurance. In its current edition, DIRAC includes approximately 6200 radiotherapy centres in 160 countries, which have 8800 radiotherapy machines and 2900 brachytherapy units installed. However, it is still an incomplete description of the present status of radiotherapy in the world, and it is estimated that an additional 1000 machines are not yet accounted for.

In addition to identifying individual institutions with radiotherapy machines, DIRAC provides a global estimate of current and future needs for radiotherapy facilities. Even although developing countries represent about 85% of the world population, the industralized countries (Australasia, Western Europe, Japan and North America) have 60% of the world's radiotherapy facilities: about 80% of all electron accelerators and 25% of all ⁶⁰Co units. Approximately 3300 teletherapy units are currently installed in developing countries, primarily ⁶⁰Co units. An advisory group in 1993 [2] estimated that in

these countries, the typical incidence of new cancer patients is 75–150 per 100 000 population. To serve a current population of 4.4 billion, assuming 4.4 million new cancer cases per year, 50% of whom require radiotherapy, and assuming one machine per 500 new cancer cases treated, the current need is for a total of 4400 machines. By the year 2015, excluding the possibility of a dramatic and unforeseen cure for cancer, a total of 10 000 machines will be needed to provide treatment for an estimated ten million new cancer cases per year in developing countries. For comparison, DIRAC data show that the number of megavoltage machines per million of population in industrialized countries ranges from 8.2 in the USA to 5.5 in Western Europe, with 70–95% of the machines being medical accelerators.

2. PROGRAMME DESIGN AND IMPLEMENTATION FLOW

This section outlines the flow of analysis and activities for initiating a new radiation therapy programme (external beam and/or brachytherapy) or enhancing the capabilities of an existing programme. Emphasis is placed upon developing a comprehensive programme that addresses all elements of such a programme, including adequate professional personnel and essential infrastructure needs, as well as specific equipment and training needs. The institution's clinical and technical needs should be identified.

2.1. PROGRAMME DESIGN

A systematic approach is applied to the design of a radiotherapy programme. All of these steps should be considered in detail.

2.1.1. Assessment of national needs and countrywide distribution of radiotherapy facilities

The projected annual number of patients who require radiation therapy should be assessed as described below. If no national registry on cancer is available, one should be extrapolated from country population and age distributions using as much regional hospital data as are available. The siting of individual radiotherapy departments and their facilities should be compared with the national population distribution. An estimate for each country, with a tumour site breakdown, may also be obtained from the IARC in Lyons.

The benefits to patients of a wider national distribution of radiation oncology facilities at other regional hospitals with adequate diagnostic and surgical infrastructure should be carefully evaluated before embarking on an expansion of an existing department. However, where the transportation infrastructure is good, there are benefits in concentrating resources on a single site.

2.1.2. Assessment of an institution's clinical needs

Surgery, radiation therapy and systemic chemotherapy remain the basis of the management of patients with cancer. A radiotherapy department should be integrated into a comprehensive cancer treatment programme. The projected annual number of patients requiring radiation therapy should be assessed as described in Section 3.2.1. Useful data sources include hospital admission records from previous years, stated patient numbers from the institution's radiation oncologists and other oncology physicians, and demographic data characterizing the hospital's client population. Other relevant information includes the enthusiasm of current and potential referring physicians for enhanced radiation therapy capabilities, and deficiencies in existing referral patterns and treatment policies. The raw patient accrual data should be stratified according to tumour site, stage and other presentation factors required to define the needs for different types of radiation therapy. The result of this analysis should be projected through annualized rates of accrual of patients requiring various types of radiation therapy (external beam and/or brachytherapy) as part of their treatment. If the requirements for radiation therapy are not well known by the institute's counterpart radiation oncologist and physicist, seeking an appropriately composed pre-project mission is highly indicated

2.1.3. Basic clinical essentials

The key to describing the operation of a radiation oncology clinic is the need to consider its essential components: facility layout, equipment, human resources and procedures. It is obvious that in order to start operations, a facility must be equipped with at least basic equipment. No radiotherapy centre should be operated without qualified personnel, radiation oncologists, clinically qualified radiotherapy medical physicists and radiotherapy technologists (RTTs), and other medical and technical staff as required.

The term 'basic' implies that the clinic has the essential equipment and adequate staffing required to treat most tumours, with the intention of

achieving local control of the disease to the extent possible. The clinic operates a cancer registry and has procedures for follow-up of treated patients.

Table 1 lists the requirements for buildings, equipment and staffing that ought to be satisfied by a basic cancer therapy centre that treats approximately 500 new patients per year with teletherapy (about 50% of them with curative intent), and about 200 patients per year with brachytherapy. The work is organized into two shifts. Staff needs should be adjusted to the number of patients treated. The training of staff requires that senior professionals or specialized trainers be available at the clinic.

The basic centre is equipped with a ⁶⁰Co unit or a single energy linac without a multileaf collimator (MLC), portal imaging or networking. With the increasing complexity of radiotherapy treatments, for example, from a simple treatment with ⁶⁰Co using standard blocks to conformal radiotherapy with a multimode linac, the number of staff (especially physics staff) will need to increase.

2.1.4. Assessment of an institution's infrastructure and resources

A radiation oncology service needs to be sited in a comprehensive tertiary hospital or a hospital dedicated to cancer treatment. In a secondary care hospital, these services may be utilized for palliation and routine cancers. Stand-alone radiotherapy centres typically exist in the private sector. The institution's current capability for handling the clinical requirements for appropriate patient evaluation and comprehensive oncological management should be carefully assessed by examining their ability to follow the process set out below:

- (a) The initial referral of a cancer patient is usually directed to the surgical, gynaecological or general medical unit, all of which should be present. These disciplines initiate the investigations leading to a confirmation of a diagnosis of cancer. In general, a referral to oncological services is accepted after a surgical biopsy (which may need to be done under direct vision of the tumour by one or more of bronchoscopy, colonoscopy, cystoscopy, gastroscopy, laparoscopy and oesophagoscopy), histopathological diagnosis involving specialized laboratory facilities and expertise. Commonly, this is accompanied by results, such as blood counts and biochemistry, from a clinical pathology laboratory. Some tumour markers may be included.
- (b) Imaging is a major component of the diagnosis and staging (determining the extent of progression) of cancer. While much can be achieved using

TABLE 1. ESSENTIAL EQUIPMENT AND STAFFING FOR A BASIC RADIOTHERAPY CLINIC

Buildings	 A megavoltage bunker (space for one more is desirable) An X ray bunker for an orthovoltage unit A simulator room A darkroom (for film processing) A dosimetry planning/physicist room (and for equipment storage if necessary) A high dose rate (HDR) bunker (or low dose rate (LDR) room)^a A mould room Ample clinical space (for examination, consulting, changing and waiting rooms)
External beam therapy equipment	A single-photon-energy teletherapy unit An orthovoltage unit Beam measurement and QA + RP ^b physics equipment A simulator, preferably a computed tomography (CT) simulator (otherwise access to a CT is desirable) A computerized treatment planning system (TPS) Film processing equipment Patient immobilization devices and mould room equipment
Brachytherapy HDR or LDR equipment ^a	A brachytherapy afterloader ^a (two or more if LDR) An X ray C-arm A computerized TPS (if LDR, it can be integrated into the external beam TPS) A full range of applicators Quality assurance physics equipment
Personnel	Four or five radiation oncologists ^c Three or four medical physics staff ^d Seven RTTs Three oncology nurses ^c One maintenance technician/engineer

^a HDR versus LDR. An LDR brachytherapy unit can treat only approximately 100 patients per year. Sites with a larger number of cervical cancer cases require HDR brachytherapy.

^b QA + RP: quality assurance and radiation protection.

^c An increase of 50% is required if staff are also responsible for chemotherapy; in that case a chemotherapy suite must be available.

^d This requires at least one, and preferably two, senior clinically qualified radiotherapy medical physicists. Other physics staff required must be clinically qualified radiotherapy medical physicists, resident physicists or dosimetrists.

diagnostic X rays, at times with contrast, CT scans and magnetic resonance imaging (MRI) are desirable adjuncts. In vivo nuclear medicine has an important application in establishing the presence and dissemination of bone metastases, including positron emission tomography (PET) as a cancer monitoring tool.

- (c) Multidisciplinary tumour clinics (combined assessment clinics), jointly staffed by oncological or gynaecological surgeons, radiation oncologists and medical oncologists (chemotherapists), review the patient's details and the relevant medical information. Supplementary investigations may be requested. The primary tumour and stage are determined and a treatment devised for the patient in accordance with established hospital clinical treatment protocols, modified by the individual circumstances of the patient. Multidisciplinary treatment protocols that include components of surgical, radiation and medical oncology are usual.
- (d) The patient is entered into the tumour registry, identifying a number of epidemiological factors in addition to the primary site and stage of the tumour.
- (e) Dedicated radiotherapy wards (inpatient facilities) are required for frail patients, those who live too far away to be outpatients and the occasional patient who has severe reactions to any of the treatments administered. These are needed as radiation therapy almost always comprises a series of administrations of radiation; usually on a daily basis over five to 35 treatment days (one to seven weeks). The majority of patients are well enough to commute on a daily basis if they live near to the department. These wards for radiation oncology are also useful for teaching purposes or when multidisciplinary care is required.
- (f) A surgical suite and anaesthesia may be required for insertion of brachytherapy devices.
- (g) Support services in the fields of nutrition and physiotherapy should be available to both inpatients and outpatients.
- (h) A social worker is an integral part of the oncology patient management team, as the patient will experience at least a disruption of their work schedule (and hence income) and perhaps the trauma of being informed that the cancer is incurable. The selection of a skilled counsellor will add greatly to obtaining patient compliance with what is generally regarded as a long and stressful period of treatment.
- (i) Treatment checks of patients under treatment are a routine weekly activity, with some patients requiring more frequent consultations with the treating radiation oncologist. This continues subsequent to completion of therapy at follow-up clinics at ever-increasing intervals, usually peaking at one year intervals for long term survivors and cured

patients. Patients are rarely completely discharged, as follow-up is required for late morbidity assessment and the rare occurrence of radiation induced tumours. This requires a record keeping system, independent of the main hospital, that usually has a process in place for regular destruction of old records. Evaluation of outcomes should be performed at regular intervals for groups of patients with similar cancers and stages, to assess the efficacy of treatment performed at the institution.

- (j) Support for the radiotherapy activity by the hospital administration, in general by the hospital superintendent or the chief executive officer, should be assured. The budget for upgrading equipment, building suitable accommodation for new pieces of equipment (e.g. a mould room) and ongoing maintenance of associated activities may be under hospital, rather than departmental, control. The licence for any radioactive or X ray source is usually granted to the hospital administrator. As such, the ex officio chairperson of the hospital radiation safety committee is usually the superintendent.
- (k) Library facilities with access to the appropriate clinical and scientific journals are essential in a teaching institution and are desirable in all units.
- (1) Continued medical and technical education of the personnel by attendance at congresses, training courses and interdepartmental training sessions is necessary, to ensure that the qualified personnel in the department constantly update their knowledge.

2.1.5. Formulation of radiotherapy programmes

An initial evaluation should be completed that describes all the resources (personnel, equipment and space renovation) required to realize the clinical needs identified for the resultant programme to conform to acceptable standards of practice. This involves comparing the programme needed to carry out the clinical aims according to accepted practice standards with the existing resources, and identifying additional needs. The options selected will depend on many factors: patient load, clinical training, biases and the institute's interest, and availability of funds. Especially with equipment for technically advanced treatments, a cost–benefit analysis should be prepared that demonstrates that the proposed facility meets the institute's goals in terms of patient workload and clinical capability, and that institutional resources are available to support the programme.

The initial evaluation should include the following elements:

- (a) An overview of the hospital infrastructure to support diagnosis and staging, as well as other oncological facilities.
- (b) A description of the existing radiotherapy programme, including staff, the facilities available and patient utilization in relation to capacity.
- (c) Additional major pieces of equipment, personnel and major space renovation or construction should be briefly described. The division of costs between the institution and its sponsors should be addressed.
- (d) Additional personnel requirements should be described and justified according to the requirements given in Section 3. Emphasis should be placed on having adequate numbers of professional radiation oncology staff (physicians, physicists and RTTs) to support the radiotherapy programme without jeopardizing other programmes.
- (e) Any institutional deficiencies in various areas, such as quality assurance, radiation protection or maintenance, should be described and an action plan outlined for correction of the deficiency.
- (f) Equipment needs (teletherapy machines, simulators, sources, remote afterloaders and planning systems) should be described in sufficient detail that a budget can be prepared. A plan for acquisition and commissioning of equipment should be developed consistent with the training of staff and the pace at which new technology can be integrated into patient care.
- (g) The need for external training of the radiation oncology professional staff (physicians, physicists and technicians) should be described, as well as the need for on-site technical experts for training and helping to manage programme implementation and monitoring its progress. External training of personnel should be identified.
- (h) All major construction and space renovation requirements should be described in detail.
- (i) A plan for clinical implementation, including development of procedures and a quality assurance programme, training of ancillary personnel and programme initiation, should be developed.
- (j) Finally, a master budget should be prepared. The entity (hospital administration or national government) responsible for funding each major item should be identified. The institution's commitment to the project, including funding, must be assured. This budget should include the costs of running and maintaining the equipment over the 10–15 year life expectancy of the equipment.

2.2. PROGRAMME IMPLEMENTATION

This section describes the process of implementing the programme, following acceptance, and includes training, equipment specification, detailed design and construction of the physical facilities, commissioning and initiation of patient treatments.

2.2.1. Staff training

Early in the process, a decision should be made about additional training required for some hospital staff. A plan to train these personnel should be developed, and the training should be completed before installation of the equipment. This plan should include which staff will be trained, the host institution that will provide the training, the material that will be taught and when the training will take place. Resources invested early in training may well pay significant dividends later, improving the efficiency of the later planning and implementation.

It must be realized that a high standard in radiotherapy can only be achieved and maintained by full-time specialists. Radiotherapy involves a team approach and close collaboration with all specialists, including pathology, involved in the diagnosis and treatment of cancer. Refer to Section 3 for a discussion of the training required for the staff physician(s), physicist(s) and RTTs. Note the preference for having the physician and physicist trained in the same host institution and at the same time.

Training may also be necessary for maintenance technicians and support personnel, especially if a linac is to be installed.

2.2.2. Equipment specification

Section 5 and Appendices II–XI give a complete description of the types of equipment needed. The teletherapy machine, simulator, radioactive sources, remote afterloading devices for brachytherapy, applicators, immobilization devices, TPS, dosimetry equipment, quality control equipment and radiation protection instruments will need to be specified and arrangements made for their purchase in a cost effective manner.

2.2.2.1. Contractual considerations

Elements that are important for the life of the equipment and for safety should be addressed early in the planning stage and be included in contractual forms, such as:

- (a) Compliance with quality and safety standards;
- (b) Acceptance tests and conditions to correct deficiencies revealed during acceptance;
- (c) Warranty conditions;
- (d) Enforceable assurances on availability of maintenance support, manufacturer support, manuals and spare parts;
- (e) Possible training of local engineers.

It is suggested that a significant percentage of the contract price be withheld until completion of the installation and acceptance by an expert.

Adequate provision for maintenance in terms of both technical and financial support must be made, especially when a linac is included. For ⁶⁰Co units, provision for regular replacement of the source should be made.

2.2.3. Planning and construction of facilities

The process of finalizing the detailed plan of the facility will involve many steps and will depend upon whether this is a new facility or the remodelling of an existing facility. These steps are outlined here in general terms in a logical sequence, but any actual planning process needs to be flexible and iterative. The planning may involve external experts, but must always involve the local hospital staff who will actually be performing the radiation therapy treatments, as well as representatives of the local funding agency, such as the hospital administration and the equipment manufacturer.

2.2.3.1. Architectural and construction drawings

A description of facility design issues is given in Section 4. The layout of the facility should be planned taking into consideration equipment requirements, water and electrical utilities needed, room shielding required (including dosimetry ports) and climate control. Careful attention must be focused on the flow of patients in the treatment facility. The layout should be planned in accordance with internationally accepted radiation safety standards and in consultation with the radiation oncologist, physicist and equipment manufacturer. Advice on room construction and shielding, including appropriate room drawings, can be obtained from the manufacturers. The responsibility for the drawings remains with the institution, which may refer these to a qualified medical physicist for advice.

2.2.3.2. Licensing

The radiotherapy installation needs to be licensed by the national regulatory authority. As a radiotherapy installation requires major construction work, it is most likely that regulatory authorities in Member States shall provide authorization before construction begins. Therefore, the application for a licence must be prepared at an early stage. It should contain all relevant elements to assure the regulatory authority that the planned facility will be safe. An example of a detailed outline of the elements of a licence is given in Appendix XII.

2.2.3.3. Scheduling

The delivery of equipment should be coordinated with the construction schedule. The teletherapy machine and radioactive sources may not be delivered until the facility is ready to receive them safely. The staff must also have completed their training and be prepared to receive the equipment.

Equipment that is needed to test and commission the teletherapy unit, radioactive sources and afterloading device should arrive early enough to be tested before use.

The arrival of technical expert(s) should be scheduled so that all the necessary equipment is present, the facility prepared and the staff ready to make use of the expertise.

2.2.3.4. Construction

During the construction phase, there must be individual(s) on-site with the knowledge and authority to supervise and inspect the construction. This person must have sufficient training, which may have been received from IAEA experts, to check the specialized requirements of the radiotherapy facility. For example, if concrete is poured with the wrong density, it will be very expensive (or impossible) to rectify this error later.

2.2.4. Delivery of equipment

A number of important steps must be taken before, during and immediately after the equipment arrives. The local staff will typically carry out these steps with the help of an outside expert, if necessary. It is recommended that the expert assist the local staff to develop procedures, equipment tests, etc. Under this expert supervision, the local staff must develop the expertise and confidence to carry on after the departure of the expert.

2.2.4.1. Acceptance testing and commissioning

Radiation sources need to be safely received, registered and stored, the radiation measurement equipment tested and calibrated, the shielding properties of special rooms measured, and the radiation sources tested and calibrated. All major equipment will require commissioning. This includes not only teletherapy machines but also imaging machines (simulators), brachy-therapy units and TPSs. It is best to have specific procedures for all of these steps worked out and in writing in advance. A record keeping system should also be in place. The time required to accomplish all this preparation can be substantial (measured in weeks or months). It may be possible to formulate some of the preparatory procedures in parallel with the training and facility planning steps.

Once the procedures are available in writing and the equipment is on-site, actual testing and commissioning of the facility, equipment and sources can be carried out. This entire process will also be lengthy, again taking several weeks. Refer to Section 6.2 and Appendix XIV for details.

2.2.4.2. Quality control and radiation safety procedures

After the commissioning has been completed, the specific tests needed for ongoing quality control and radiation safety assurance will need to be carried out. Details are given in Section 6 and Appendices XIII and XIV.

2.2.5. Planning and initiation of treatment

2.2.5.1. Clinical treatment protocol design

The radiation oncologist, in conjunction with other specialists of oncological disciplines, will determine the overall clinical treatment protocols. In conjunction with the medical physicist and radiation therapy technologists, the techniques and specific radiotherapy component of treatment procedures (positioning, immobilization, imaging and planning) will be established and documented in a procedure manual. The physicist will need to prepare the technical work instructions associated with each type of treatment, such as procedures for calculation of doses and treatment times, source handling and associated quality control steps. Section 6 has more details on these requirements.

The importance of careful planning for each type of radiotherapy treatment must be well understood by all staff involved, since correct implementation of the treatment is the purpose of the entire programme. Treatment procedures will evolve in time, and these changes need to be reflected in the procedure manual.

2.2.5.2. Training and rehearsal

Before actually treating any patients, staff will need to be trained in the treatment procedures, and each type of treatment should be rehearsed in detail. This becomes increasingly important with more complex techniques such as cranio-spinal irradiation or stereotactic radiotherapy. Any omissions or problems with treatment procedures can then be identified and corrected.

2.3. FOLLOW-UP AND ASSESSMENT MISSION

Some months after treatments have begun, the IAEA may be requested to arrange for a follow-up visit by an expert team to assess the programme and, if required, to recommend changes. The experts will participate in the daily routine, to properly assess the performance of the equipment, the professionals involved in its use and the quality assurance procedures.

3. STAFF REQUIREMENTS FOR A RADIATION THERAPY PROGRAMME

This section covers in detail the various staff required in a radiation therapy programme. The overall purpose is to give the IAEA, the expert on a mission and the institute's counterpart a comprehensive view so that the entire project can be designed and implemented in a manner that best assures that radiation therapy treatments are effective and safe.

A radiotherapy programme generally consists of both external beam and brachytherapy capabilities, and both aspects will be considered together in this section.

3.1. HOSPITAL ADMINISTRATORS

Hospital administrators play a key role in determining the initial and ongoing support provided to the physician and physicist in setting up and maintaining a radiation therapy programme. Issues such as equipment procurement, facility design and staffing levels involve financial considerations that affect the entire institution. Training may need to be provided for these individuals so that the process is approached comprehensively and with foresight. Administrators should be aware that starting or expanding a radiation therapy programme involves much more than acquiring new equipment. It is essential to allocate adequate funds for staff, treatment planning and dosimetry equipment, training, patient follow-up and outcome analysis. Provision must also be made for ongoing needs, such as preventive maintenance and repairs, source replacement and an adequate stock of spare parts.

3.2. RADIOTHERAPY STAFFING

3.2.1. Patient throughput assessment

Before initiating a radiotherapy programme, the number of annual patient treatments shall be estimated. The population within the area from which the institution will draw patients and the annual cancer ratio for that area will yield the approximate number of new cancer patients per year. Approximately 50–60% of these patients should receive radiation therapy, alone or as an alternative or adjuvant treatment to surgery. An estimate of how many of these patients will be seen at the institution should be made and compared with the actual number of patients seen annually. Any unusually high cancer incidence in the area for specific localizations (e.g., lung, oral cavity or nasopharynx) where radiotherapy is more frequently used should be taken into account. Utilization rates must account for possible new uses of radio-therapy as an adjunctive therapy.

For brachytherapy, the number of patients seen annually in the institution with malignancies that are potentially treatable by brachytherapy should be determined. Appropriate categories include intracavitary (particularly cervix, oesophagus, bronchus and nasopharynx cancer) and interstitial (particularly prostate and breast boosts) treatments. The total number of anticipated brachytherapy treatments can be estimated taking into account the stage of the disease sites amenable to the treatment. Care should also be taken in estimating the number of brachytherapy patients, because most will require external beam therapy.

3.2.2. Staff

The clinical use of ionizing radiation is a complex process involving highly trained personnel in a variety of interrelated activities.

The BSS [1] require that:

- (a) No patient be administered therapeutic medical exposure unless the exposure is prescribed by a medical practitioner;
- (b) Medical practitioners be assigned the primary task and obligation of ensuring overall patient protection and safety in the prescription of, and during the delivery of, medical exposure;
- (c) Medical and paramedical personnel be available as needed, and either be health professionals or have appropriate training adequate to discharge assigned tasks in the conduct of the therapeutic procedure that the medical practitioner prescribes;
- (d) For therapeutic uses of radiation (including teletherapy and brachytherapy), the calibration, dosimetry and quality assurance be conducted by or under the supervision of a qualified expert in radiotherapy physics;
- (e) Training criteria be specified or be subject to approval, as appropriate, by the regulatory authority in consultation with relevant professional bodies.

The functions involved in the radiation therapy process are listed in Tables 2 and 3 for external beam therapy and brachytherapy, respectively, whereas the key staff functions in external beam radiation therapy are given in Table 4. These tables refer to industrialized countries and have been adapted from Ref. [3], Radiation Oncology in Integrated Cancer Management, Report of the Inter-Society Council for Radiation Oncology, December 1991. This report is frequently designated 'The Blue Book'. Minimum personnel requirements, based on clinical load, are given in Table 5, also from Ref. [3]. Other recommendations for staffing in medical physics can be found in a joint report by the European Society for Therapeutic Radiation and Oncology (ESTRO) and the European Federation of Organisations for Medical Physics (EFOMP) [4]. These data may require adjustment for developing countries, where the increased ratio of palliative to radical cases and simpler and shorter treatment protocols reduce the duration of professional involvement with each patient. Conversely, the intention to use more elaborate techniques increases the personnel requirements.

It must be emphasized that the most important component of any programme is qualified personnel. It is vital that all the staff dealing with radiation sources and patients have the necessary educational background and

TABLE 2. PROCESS OF RADIATION THERAPY(EXTERNAL BEAMS) [3]

、 /L]	
1. Clinical evaluation	Multidisciplinary evaluation of patient Decision on radiation therapy Assessment of the tumour Staging
2. Therapeutic decision making	Selection of treatment goals: cure or palliation Prescription: determination of dose-time-volume relationship
3. Patient immobilization	Achieving immobilization of treatment region
4. Target volume determination	Definition of tumour extent and potential routes by which it may have spread Identification of sensitive organs and tissues Measurement of patient Construction of patient contours
5a. Planning simulation	Selecting position of simple field arrangements
5b. Treatment planning	Selection of treatment technique Selection of modality and energy Selection of field directions for complex field arrangements Shaping of fields Computation of dose distribution and verification of accuracy Dose volume histogram
6. Fabrication of treatment aids	Construction of custom blocks, compensating filters
7. Simulation of treatment	Radiographic documentation of treatment ports and shielding blocks
8. Treatment	Transfer of treatment data to the treatment machine Initial verification of treatment set-up Verification of accuracy of repeated treatments Continual assessment of equipment performance Periodic checks of dosimetry, record keeping
9. Patient evaluation during treatment	Evaluation of tumour response Assessment of tolerance to treatment
10. Follow-up evaluation	Evaluation of tumour control Assessment of complications

TABLE 3. PROCESS OF RADIATION THERAPY(BRACHYTHERAPY) [3]

1. Clinical evaluation	Initial multidisciplinary evaluation of patient Decision on brachytherapy Assessment of tumour Staging
2. Therapeutic decision making	Selection of treatment goals: cure or palliation Choice of modalities of treatment Prescription: determination of dose-time-volume relationship
3. Target volume determination	Definition of tumour extent and potential routes by which it may have spread Identification of sensitive organs and tissues
4. Treatment planning	Selection of volume to be treated Selection of geometry for application Computation of doses and dose distributions Estimation of tolerance to procedure Check of equipment Arrangement for surgical suite and anaesthesia if required
5. Treatment	Examination of anaesthetized patient Review of initial treatment plan Implantation of applicators and sources
6. Verification of implantation	Orthogonal radiographs or stereoradiographs CT or MRI scans (with dummy sources if required)
7. Post-implant dosimetry	Calculation from actual implantation Establishment of treatment duration Establishment of time of removal
8. Patient evaluation during treatment	Assessment of tolerance to treatment Check of position of applicators and sources
9. Removal of applicators and sources	
10. Follow-up evaluation	Evaluation of tumour control Assessment of complications

TABLE 4. KEY STAFF FUNCTIONS IN CLINICAL RADIATIONTHERAPY [3]

	Key staff	Staff in supportive role
1. Clinical evaluation	Radiation oncologist	
2. Therapeutic decision	Radiation oncologist	
3. Patient immobilization	RTT-MR ^a Dosimetrist	Radiation oncologist Physicist
4. Target volume localization:		
Target volume determination	Radiation oncologist	RTT-Sim Dosimetrist
Sensitive critical organs	Radiation oncologist	RTT-Sim Dosimetrist
Patient contour	RTT-TPS	Physicist RTT-Sim Dosimetrist
5. Treatment planning:		
Beam data computerization	Physicist	
Computation of beams	Physicist	Dosimetrist
Shielding blocks, treatment aids, etc.	Dosimetrist RTT-MR	Radiation oncologist Physicist
Analysis of alternative plans	Radiation oncologist Physicist	Dosimetrist RTT-TPS
Selection of treatment plan	Radiation oncologist/physicist/ dosimetrist	
Dose calculation	Dosimetrist	Physicist
Beam-on time (monitor unit) calculation	RTT-TPS Dosimetrist Physicist	
6. Simulation/verification of treatment plan	Radiation oncologist RTT-Sim	Dosimetrist Physicist

	Key staff	Staff in supportive role
7. Treatment:		
First day set-up	Radiation oncologist Dosimetrist RTT	Dosimetrist Physicist
Localization films	Radiation oncologist RTT	Dosimetrist Physicist
Daily treatment	RTT	
8. Evaluation during treatment	Radiation oncologist RTT	Social worker Dietician
9. Follow-up examinations	Radiation oncologist Nurse	Data manager Social worker Dietician

TABLE 4.KEY STAFF FUNCTIONS IN CLINICAL RADIATIONTHERAPY [3] (cont.)

^a MR: mould room.

specialized training. Investment in equipment without concomitant investment in training is dangerous.

It is also important that training not only include practical details of individual procedures but also details of how to design treatment approaches that are comprehensive, reproducible, of high quality and safe. Successful design and implementation of such treatments requires that the hospital administration, physicians, physicists and other support staff work together towards common goals.

The main categories of the staff required, along with their responsibilities and training requirements, are listed in Tables 4 and 5. Details of additional recommended periods of training for more advanced equipment are given in Appendix XVI.

3.2.2.1. Physicians

Physicians practising radiation therapy must first be qualified as medical practitioners with a postgraduate training in radiation oncology. Radiation oncologists have knowledge, involving special expertise in the therapeutic applications of ionizing radiation, about the causes, prevention and treatment

TABLE	5.	PERSONNEL	REQUIREMENTS	FOR	CLINICAL
RADIATION THERAPY [3]					

Category	Staffing		
Radiation oncologist-in-chief	One per programme		
Staff radiation oncologist	One additional for each 200–250 patients treated annually. No more than 25–30 patients under treatment by a single physician at any one time. Higher numbers of predominantly palliative patients can be managed.		
Radiation physicist	One per centre for up to 400 patients annually. Additional in ratio of 1 per 400 patients treated annually.		
Treatment planning staff:			
Dosimetrist or physics assistant	One per 300 patients treated annually		
RTT-MR	One per 600 patients treated annually		
Radiation therapy technologist:			
Supervisor	One per centre		
RTT	Two per megavoltage unit up to 25 patients treated daily; four per megavoltage unit up to 50 patients treated daily		
RTT-Sim	Two for every 500 patients simulated annually		
RTT-Br	As needed		
Nurse	One per centre for up to 300 patients treated annually and an additional one per 300 patients treated annually		
Social worker	As needed to provide service		
Dietician	As needed to provide service		
Physiotherapist	As needed to provide service		
Maintenance engineer or electronics technician	One per two megavoltage units or one megavoltage unit and a simulator if equipment serviced 'in-house		

Note: If advanced or special techniques such as those described in Appendix VIII are to be undertaken, staff additional to the above will be required.

of cancer and other diseases. They have an understanding of the biology of cancer and of the biological aspects of the interaction of radiation with tissues, as well as of the fundamentals of the physical aspects of radiotherapy. Radiation oncology addresses the therapeutic uses of radiation alone or in conjunction with other treatment modalities such as surgery, chemotherapy and hormonal therapy. A physician may be referred to as a radiation oncologist if they are confined to radiation oncology; however, many countries utilize clinical oncologists trained in both radiation oncology and chemotherapy. These comprise a professional group distinct from surgical, gynaecological or medical oncologists.

Physicians will set the overall treatment policy for the radiation therapy programme and should participate in the evaluation of the proposed departmental clinical load, the design of the facility and the procurement of equipment. For individual patients, a physician is responsible for participating in a joint evaluation clinical assessment of optimal therapy for the patient (Section 3.3.1), the patient's care, including the details of the treatment, and the patient's follow-up evaluation.

Many new techniques in radiotherapy treatment are currently being introduced. These require additional training for clinicians. Notably, more conformal radiation therapy will require more attention, skills and time devoted to the localization of tumours and target volumes using modern imaging techniques. Without this additional training, the reduction of margins involved may result in poorer treatment outcomes leading to recurrences because of inaccurately defined volumes.

3.2.2.2. Clinically qualified radiotherapy medical physicists

Medical physicists practising in radiotherapy (or radiation oncology) must be qualified as physicists with academic studies in medical physics (typically at postgraduate level) and clinical training in radiotherapy physics. Medical physicists specialized in radiotherapy physics will be referred to as clinically qualified radiotherapy physicists.

Senior radiotherapy medical physicists are clinically qualified radiotherapy physicists with at least six years of practical experience after qualifying in clinical radiotherapy physics.

A clinically qualified radiotherapy physicist should have at least:

- (a) A university degree in physics, engineering or an equivalent physical science.
- (b) At least one year of academic postgraduate studies leading to a master's degree in medical physics (or an equivalent). This requires studies in

several areas of medicine (e.g., radiodiagnostics, nuclear medicine and radiotherapy).

- (c) The equivalent of at least two years of full-time comprehensive clinical inservice training in radiotherapy physics undertaken in a hospital. This radiotherapy physics residence training will be under the supervision of an experienced or senior radiotherapy physicist. In addition:
 - (i) In the case that the academic studies include a considerable clinical training component, this should be taken into account in the fulfilment of the time requirement.
 - (ii) This training should preferably be approved by a suitable professional body, i.e. a Board that will issue a clinical certification.

It is emphasized that the holder of a university degree in medical physics without the required hospital training cannot be considered to be clinically qualified.

The responsibilities of radiotherapy medical physicists cover five major areas:

- (1) Dosimetry;
- (2) Radiation safety;
- (3) Treatment planning;
- (4) Quality control;
- (5) Equipment selection.

An extensive description of the roles of radiotherapy physics staff has been prepared by the United Kingdom Institute of Physics and Engineering in Medicine [5].

In dosimetry, the radiotherapy medical physicist helps minimize the probability of patient injury and poor treatment outcome by assisting in devising, for each patient, an appropriate treatment regimen, and reviewing all patient treatment plans. The radiotherapy medical physicist is responsible for the calibration of the output of the treatment machine on a routine basis and ensuring that all physical data being used by the facility are accurate and adequate.

Radiation safety requires the establishment and maintenance of a radiation protection programme designed to ensure the safety of staff and the public. There is also a need to design and certify all radiation shielding for the treatment facilities. These duties will be the responsibility of the radiotherapy medical physicist and/or of the radiation protection officer, who may or may not be the same person. The administrative structure will vary depending on

the country, the facility and the resources; what is important is that the necessary authority be available.

For quality control, the radiotherapy medical physicist will be involved in establishing and operating an ongoing quality control programme for the facility.

The radiotherapy medical physicist, in association with the radiation oncologist, determines the treatment equipment needs of the facility. In general, this includes the involvement of the radiotherapy medical physicist in preparing bid specifications and evaluating vendor quotations with respect to both technical requirements and cost effectiveness.

For radiation therapy, the medical physicist is responsible for ensuring that the treatment prescribed by the physician is in fact delivered accurately and safely. Together with the physician, the medical physicist will design and implement all the elements of the radiation therapy programme that are described in this report. These include equipment selection, facility design, quality control of radiation sources and treatment delivery devices, dose calculation and treatment planning, maintenance, training of ancillary staff and radiation protection.

It must be understood that the practice of radiation therapy absolutely requires that the hospital have clinically qualified radiotherapy medical physicists on its staff. It is not sufficient that the physics staff be trained; they must also be available in sufficient numbers to carry out all the required duties.

The specific number of qualified medical physics staff required will depend on the number of patients treated, whether brachytherapy is undertaken and if so the type of implants performed, the complexity of the dose calculation required, whether a treatment planning computer is to be used, and many other factors. For more advanced radiotherapy techniques, such as conformal radiotherapy or intensity modulated radiation therapy (IMRT), an increase in staffing is required if these techniques are to be delivered safely.

When new equipment is installed or new treatment techniques initiated, further training may be required. Such extra training requirements are indicated in Appendix XVI.

The responsibilities of the radiation oncologist and radiotherapy medical physicist are summarized in Appendix I (Table 7).

3.2.2.3. Radiation therapy technologists

This group of professionals working in radiation oncology is referred to differently in different parts of the world. Synonyms used include radiation therapists, radiotherapists (not to be confused with the old name for radiation oncologists), therapist-radiographers (to distinguish them from diagnostic radiographers) and manipulateurs (French usage).

Their tasks are even more varied than their names and may embrace all or some of the following:

- (a) Operating teletherapy machines: linacs, ⁶⁰Co units, and superficial and orthovoltage X ray units;
- (b) Operating simulator and other imaging devices for therapy purposes: CT scanners and simulators (RTT-Sims);
- (c) Providing mould room services: production of immobilization masks, lead blocks, etc. (RTT-MRs);
- (d) Under the supervision of medical physicists, they may also calculate the monitor units for treatment, and operate HDR brachytherapy machines (RTT-Brs) or treatment planning units (RTT-TPSs).

The RTTs, in carrying out these operations, have the responsibility to regularly and meticulously record and check all the parameters needed to repeat or reconstruct the activities undertaken.

Radiation therapy technologists see patients more frequently (daily) during treatment than radiation oncologists do, and therefore a valuable relationship between RTTs and patients develops. This is to be encouraged because early warning of new or unusual symptoms can thereby be received by the radiation oncologist, and often rectified before becoming major problems or before a patient decides to abandon their treatment.

3.2.2.4. Dosimetrists and physics assistants

In addition to physicians, radiotherapy medical physicists and RTTs, a radiation therapy programme may require the services of dosimetrists. These individuals should have a degree, granted by a university, for academic studies followed by clinical training, or they may have been trained as RTTs with additional dosimetry training.

Although the physician and radiotherapy medical physicist may delegate specific duties to these personnel as appropriate, they will retain the responsibility for providing adequate supervision and training. For example, computerized dose calculations may be performed by a dosimetrist, or preparation of LDR sources for patient treatments and maintenance of the source inventory may be delegated to a 'source curator'. Such individuals can perform valuable services, especially where more highly trained persons are rare, but they should not be given responsibilities beyond their professional competence.

A clear delimitation of responsibilities is particularly important in the case of dosimetrists or physics assistants. In some institutions these professionals substitute for medical physicists, and treatment planning and delivery procedures are carried out without the supervision of a clinically qualified radiotherapy medical physicist. Whether this lack of supervision is due to economic or practical reasons, such methodology is not appropriate and might have detrimental consequences for the patient. For example, the lack of an education in specialized areas of mathematics and physics restricts a staff member's understanding of the algorithms used in modern computerized TPSs; this can easily jeopardize their interpretation of results produced by limitations of the TPS. The role of the dosimetrist is to assist the radiotherapy medical physicist, not to replace them.

3.2.2.5. Radiation oncology nurses, social workers and dieticians

Radiation oncology nurses provide supportive care to patients undergoing treatment. Appropriate training in nursing, together with specialist training in oncology, is required. An appropriately trained social worker is required to help the patient and their family with arrangements regarding transport, employment, care of children, etc. This staff member should be well informed about radiation procedures, in order to allay initial fears and clarify misconceptions arising from communications from technical and medical staff. The role of this staff member in ensuring patient compliance with what are repetitive and unfamiliar procedures is pivotal to achieving a cure. It is helpful to have a dietician to assist patients with their nutritional needs during treatment. Radiation oncology nurses may be able to perform some of the duties of the social worker and dietician.

3.2.2.6. Maintenance personnel

If there is a large amount of equipment, such as several external therapy units and simulators, block cutting equipment, treatment planning computers and tissue compensation devices, it might be advisable to ensure the immediate availability of trained engineering maintenance staff. If trained staff are available locally, the time taken to repair simple faults will be considerably reduced compared with the time taken for a manufacturer's service agent to arrive on-site. This will lead to reduced downtime. If linacs are to be installed, it becomes essential to have local staff trained to at least carry out first line maintenance (Appendix VII, Section VII.1.8).

Second line maintenance is usually contracted to the manufacturer. In exceptional cases, manufacturers have trained hospital engineers. Section XVI.2.4

in Appendix XVI provides advice on the training requirements. It must be emphasized that adequate measurements must be performed by a radiotherapy medical physicist, following completion of the maintenance work by the manufacturer's agent or the local engineer.

If remote afterloading devices are used in the brachytherapy programme, then provision must be made for servicing these devices. This may be best accomplished through service agreements with the manufacturer.

3.2.2.7. Radiation protection officer

The radiation protection officer is defined in the BSS [1] as

"An individual technically competent in radiation protection matters relevant for a given type of practice who is designated by the registrant or licensee to oversee the application of the requirements of the Standards."

In a radiotherapy facility, the radiation protection officer should design the radiation protection and safety programme, and oversee compliance with it. They should prepare the licence application, especially the safety assessment for radiotherapy sources, and, as a result, include measures for accident prevention and mitigation. Depending on the size of the department, the functions of the radiation protection officer can be assigned to the radiotherapy medical physicist, but there should be a formal assignment of responsibilities, with a clear identification of the line of authority with respect to radiation protection and safety. Many aspects of radiation protection in radiotherapy require a sound understanding of radiotherapy treatment techniques in addition to an understanding of radiation protection principles.

3.3. INTERNAL STAFF ORGANIZATION

3.3.1. Combined assessment clinic

Non-oncological medical staff usually make the clinical diagnosis of a cancer. Each hospital (or group of hospitals) should have a number of specialized combined assessment clinics, staffed by practitioners experienced in the management of specific cancers. The clinic members are responsible for the preparation of an institutional clinical management protocol in accordance with the resources and skills available.

A typical combined gynaecological assessment clinic would meet weekly and have a gynaecological oncology surgeon, a clinical/radiation oncologist and a medical oncologist. A pathologist with specialization in this field is a useful addition, as is a social worker. The task of the combined clinic is to review all the available clinical, radiological, pathological and biochemical data on a patient, and to determine those further investigations required to stage the patient and consider the suitability of patients for treatment according to established institutional protocols. It may be inappropriate to treat a patient with unassociated illnesses according to a defined protocol; patient specific management deviating from the protocol may then be required, which needs to be endorsed by all the team members. Multidisciplinary treatment protocols that include components of surgical, radiation and medical oncology are usual.

Initially, combined assessment clinics only cover the most common tumours. With time these should be expanded to other, less common sites, to foster greater cooperation between medical professionals (refer also to Section 6.1.2).

3.3.2. Radiation safety

The establishment of a hospital radiation safety committee is a useful adjunct in controlling the use of radiation within a hospital and as a route of communication with the hospital administration and the regulatory authorities. The committee has representatives of all users of radiation within the hospital; diagnostic radiology, nuclear medicine, radiotherapy, and, in instances, chemical and anatomical pathology. It is also usual to include representatives of all professional user groups.

The committee must include the equipment licensee (or their nominee), the radiation safety officer, clinicians, medical physicists, radiographers and maintenance engineers. The purposes of the committee are to continuously monitor the standards of personnel monitoring, equipment and practice to ensure compliance with the BSS [1] Appendix I, Occupational Exposure, and Appendix II, Medical Exposure.

An active hospital radiation safety committee is considered to be a powerful tool in the prevention of radiation accidents in the hospital, as well as ensuring adherence to optimal medical practice.

4. RADIOTHERAPY FACILITY DESIGN

Facilities for radiation therapy fall into three groups:

- (1) External beam radiotherapy;
- (2) Low dose rate brachytherapy (including pulsed dose rate (PDR));
- (3) High dose rate brachytherapy.

The same basic considerations apply to all:

- (a) The medical and physical well-being of the patient;
- (b) Protection of the patient, staff, visitors and other members of the public from radiation hazards;
- (c) Geographical and functional integration of the various activities related to the treatment of the patient.

Such activities in radiotherapy include imaging (simulators and/or CT scanners), immobilization (mould room facilities) and treatment planning.

Spaces common to all activities include office space for physicians and physicists, laboratories, a darkroom, a registration area and a filing room.

A physics laboratory with cabinet space to store phantoms, ionization chambers, electrometers, cables and film should be available. If thermoluminescent dosimetry (TLD) and film dosimetry are available, an area should be designed for these activities. The darkroom should be located conveniently near the simulator, external beam therapy and brachytherapy activity rooms.

An area should be designated for clerical staff to make bookings and register new patients, sign in patients under treatment and retrieve files for follow-up patients. A file storage area should be provided sufficient for long term storage of documentation.

It is preferable to provide air conditioning for the entire facility; however, as a minimum, air conditioning should be provided for the treatment rooms, planning room and the treatment control areas where computers are located.

4.1. EXTERNAL BEAM THERAPY

An external beam facility requires examination rooms, a simulator room, a treatment planning room, a mould room, a treatment room (bunker) and waiting areas. The simulator room, treatment planning room and treatment room should be designed in consultation with the manufacturer of the equipment. The requirements for power, air conditioning, monitoring ports and emergency system must be considered.

4.1.1. Examination rooms

The examination rooms should be in close proximity to the treatment room. The examination rooms should include standard and gynaecological examination tables, a head and neck examination chair, appropriate examination instruments and medical supplies.

4.1.2. Simulator room

The shielding of the simulator room shall be designed according to the recommendations of US National Council on Radiation Protection and Measurements (NCRP) Report No. 151 [6], paying due regard to the requirements of the BSS [1] and the regulatory authority. The room should be large enough to accommodate the simulator, allowing the full range of motion of the treatment table. A means for securely mounting the patient positioning lasers to the wall at points appropriate for projection of lines through the isocentre should be included in the plans. A means for dimming the room lights should be considered in the design of the room. Adequate space should be planned for cabinetry to store treatment devices are to be fabricated in the simulator room, cabinet space to store supplies for their fabrication will be required. A sink should then be provided in this room.

A viewing window should be provided for the control room. Light boxes in the control room and simulator room are useful.

4.1.3. Treatment planning room

The treatment planning room should be located in close proximity to the simulator room, although the two areas do not have to be adjacent. The room should be large enough to house the treatment planning computer with its video monitor, a printer and plotter, a digitizer tablet and other required computer equipment. Space will also be required for supplies of paper and pens or ink for the printer and plotter. An area designed to accommodate an L shaped arrangement of the digitizer tablet and video monitor is frequently more desirable than a linear arrangement with the two devices side by side. It is also desirable to provide space for light boxes and a high intensity light for viewing CT scans and plane X ray films. In larger centres, more than one computer video terminal will be required.

4.1.4. Mould room

Space should be planned for a mould room to fabricate custom designed blocks and compensators. Space for tools, a block cutter and counter-top workspace for pouring and mounting the blocks is required. Storage space for supplies of styrofoam, trays and shielding material for custom blocking is necessary. Adequate ventilation should be provided if shielding materials are melted in this area. If immobilization devices are fabricated in the mould room, space for a patient couch will be required. A sink with a refuse trap is required, as plaster of Paris is frequently utilized. For more detailed information including a suggested floor plan, refer to Ref. [7].

4.1.5. Treatment room

The treatment room shielding should be designed in accordance with the recommendations of NCRP Report No. 151 [6], paying due regard to the requirements of the BSS [1] and the regulatory authority. The room should be large enough to accommodate the treatment machine, allowing the full range of motion of the treatment table. If total body irradiation (TBI) is planned, a larger treatment room is required (Appendix VIII). A door interlock or other suitable means to prevent unauthorized access shall be provided. A sign should be posted at the entrance warning of the radiation hazard, in accordance with regulatory authority requirements. For a ⁶⁰Co unit, an area radiation monitor safe against a power failure should be visible on entering the room.

A means for dimming the room lights should be considered in the design of the room. Adequate space should be planned for cabinetry to store treatment devices, immobilization devices, blocks and daily used quality assurance equipment. A means for secure mounting of patient positioning lasers to the wall at points appropriate for projection of lines through the isocentre should be included in the plans.

It is common practice to have a heavy electrically operated door at the entrance to the room. However, an alternative to this is an appropriately designed extended corridor (called a maze) leading into the room. At the entrance to the maze, a lightweight physical barrier or an optical barrier with appropriate interlocks should be erected. (The design of such a barrier should take into account the need to detect the passage of a child.) This has the advantage of allowing rapid access to the treatment room in the event of a power cut. However, the maze will take up additional space.

Space for a console immediately outside the treatment area overlooking the treatment room door shall be planned. This console area should be large enough to accommodate not only the control console for the unit but also a workspace for the treatment technologist, in addition to space for an intercom and closed circuit television system. The console area should also accommodate any computer equipment associated with the treatment machine. This may include the record and verify (R&V) computer system, an information management system, electronic imaging or treatment time calculation systems. For a modern linac this may involve up to six monitors and their associated computers. An access (dosimetry) port from the control area through the concrete is required to allow the measurement of beam characteristics using an ion chamber in the field while the electrometer and physicist are in the control room, thereby avoiding excessively long extension cables.

For orthovoltage treatments the room requirements are considerably simpler, although an external console area is still required. The shielding required in the room door is much less than that for a 60 Co unit or an accelerator and electrical operation is not required. However, as the X ray machine has more freedom of movement, care must be taken to ensure that the radiation cannot be pointed directly at the door.

4.1.6. Waiting areas

It is desirable to have separate waiting areas for patients attending clinics and those awaiting treatment. The clinic waiting area should have space for approximately eight patients for each physician.

The treatment waiting area should be adjacent to the treatment room, with space for seating of about twelve people for each machine. There should also be an area provided for patients on stretchers, which should be adjacent to the treatment area, but they should preferably be separated from ambulatory patients. The area should be large enough to accommodate three stretchers.

Patients will usually have to remove some of their clothes for treatment. The provision of appropriate changing facilities close to the entrance of the treatment room, and shielded from the view of other patients and visitors, can avoid patients having to undress in the treatment room. This will reduce the time needed for treatment of each patient.

4.2. LOW DOSE RATE BRACHYTHERAPY

It should be noted that from 2002 onwards, LDR brachytherapy equipment, utilizing long half-life isotopes, has received reduced commercial support and is not now readily available. Low dose rate brachytherapy employs either manual or remote afterloading equipment except for some situations (e.g. permanent implants and eye implants). Either modality will require a source storage and preparation room, operating room, treatment planning room and patient room. These facilities should not be too widely separated, in order to reduce distances over which patients and sources have to be transported. The relative proximity of these facilities can significantly influence procedure flow and efficiency. Facility design should incorporate features to avoid transport in elevators of patients containing radioactive sources. Sterilization facilities for applicators will also be required. The sterilization process should be appropriate to prevent damage of the applicators.

4.2.1. Source storage and preparation room

This room should be designed in accordance with the recommendations of NCRP Report No. 151 [6], paying due attention to the requirements of the BSS [1] and the regulatory authority, and be provided with a locked door to control access to the radioactive material. A sign should be posted on the door warning of the radiation hazard, in accordance with regulatory authority requirements. It should contain shielded storage for all sources and have facilities for receiving, preparing, calibrating and returning sources. An area radiation monitor should be visible on entering the room and while preparing the sources. Space for a workbench should be provided. A cabinet for the necessary instruments, equipment, treatment aid and the required documents should also be available. Space for source transportation trolleys should be provided. It may also be necessary to provide storage to allow decay of sources to safe levels.

4.2.2. Operating theatre

If anaesthesia is required for placement of applicators or catheters to contain the radiation sources, an operating room facility and recovery area are required. An X ray unit, preferably with fluoroscopic capabilities, is desirable in the operating room because it enables the position of the applicator or catheters to be checked, and if necessary repositioned, before the patient leaves the operating suite. In addition, localization X rays (orthogonal or stereo-shifted X rays) required for dose calculation purposes can be taken with this unit. If no X ray unit is in the operating room, these functions must be available elsewhere.

4.2.3. Treatment planning room

Treatment planning for LDR brachytherapy is usually performed on a general TPS for teletherapy and brachytherapy using brachytherapy planning

software. Design elements of the treatment planning room may be found in Section 4.1.3.

4.2.4. Patient rooms

It is preferable to house each LDR brachytherapy patient in a separate room. The rooms should be shielded according to the recommendations given in NCRP Report No. 151 [6], paying due attention to the requirements of the BSS [1] and the regulatory authority. A sign should be posted on the door warning of the radiation hazard in accordance with the requirements of the regulatory authority. A list with the maximum duration of daily visits by members of the general public should be posted on the door. If several rooms are required, they should be adjacent to each other. The patient should be attended by nurses with special training in the care of radiation therapy patients. A toilet for each room has added patient convenience but increases the risk of losing sources. A bell connected to the nurses' station is essential as gynaecological patients need to use bedpans and may not use even common toilets. Storage for a bedside shield and emergency source container should also be provided.

4.2.5. Additional requirements for LDR remote afterloading

The major benefit of remote afterloading, compared with manual afterloading, is reduction of exposure to nursing staff, other personnel and visitors. The shielding requirements for uncontrolled areas surrounding the treatment area are unchanged.

Additional requirements for remote afterloading include:

- (a) Additional floor space and required utilities (dedicated compressed air and power sources);
- (b) A door interlock or other suitable means to prevent unauthorized access to the patient rooms;
- (c) An area radiation monitor that is safe against a power failure in the patient rooms.

4.3. HIGH DOSE RATE BRACHYTHERAPY

An increased demand from developing Member States for HDR brachytherapy equipment has resulted from the discontinuation of the limited production of LDR equipment. A secondary reason is that some types of cancer (cervix, oesophagus and nasopharynx), suitable to be treated with brachytherapy, are more frequently found in developing countries, and HDR brachytherapy may be the only practical solution to successfully treat a large number of patients. High dose rates require support from an appropriately qualified physicist, training and proper organizational arrangements. If these criteria are not met, there may be an unacceptable risk. Further details relating to HDR brachytherapy are covered in Ref. [8]. To summarize: in order to make balanced decisions about safety, clinical radiotherapy and physical dosimetry, the following issues should be evaluated prior to the purchase of HDR brachytherapy:

- (a) A demonstrable volume of patient workload justifying the need for HDR brachytherapy equipment;
- (b) A substantial training in general brachytherapy, including selection and insertion of applicators, and the ability to plan and calculate brachy-therapy treatments and maintain appropriate quality assurance and safety procedures;
- (c) At least one radiation oncologist and one medical physicist who can satisfy requirement (b);
- (d) All practitioners (radiation oncologists and medical physicists) must receive training on the specific model of equipment provided, including the dedicated TPS and safety/emergency procedures for the particular model of equipment.

For reasons of safety and quality, all repairs should only be undertaken by manufacturer authorized (namely, trained and certified) personnel.

4.3.1. Options

An HDR brachytherapy facility requires:

- (a) An operating theatre;
- (b) A radiographic imaging system;
- (c) A treatment room;
- (d) A treatment planning area.

The relative proximity of these facilities can significantly influence procedure flow and efficiency. Three major options for the first three of these items, in order of increasing capital cost, are:

- (1) A treatment room for the HDR unit, together with shared use of existing operating or procedure rooms and imaging systems, such as a simulator. Transport of patients (between operating room, imaging room and treatment room) reduces efficiency and hinders immobilization of the applicator system.
- (2) A treatment room for both applicator insertion and treatment, with imaging performed elsewhere. The conditions required for anaesthesia and sterility might require a significant investment. In addition, other medical staff, for example, a gynaecological oncologist and an anaesthesiologist, should be committed to supplying medical services outside their usual venue. As above, transport of patients (between operating room, imaging room and treatment room) reduces efficiency and hinders immobilization of the applicator system.
- (3) An integrated brachytherapy suite. This option adds a dedicated imaging system to the treatment room type of approach (2). This option is the most efficient, requiring no transport of the patient between the different steps.

If the feasibility of sharing a shielded treatment room between an HDR unit and another currently used treatment machine is considered, it should be carefully evaluated. To avoid scheduling problems, the anticipated number of HDR procedures as well as the number of external beam treatments should be taken into account. This report recommends against this strategy in most instances.

4.3.2. Operating theatre/treatment room

For design elements of the integrated operating theatre/treatment room, refer to Ref. [8].

4.3.3. Treatment planning room

Treatment planning for HDR is a separate system from that used for teletherapy and may be housed in a convenient place for usage of the HDR machine.

5. EQUIPMENT

5.1. INTRODUCTION

Before any equipment is selected, the clinical goal of radiation therapy should be clearly defined to ensure that the specifications of the equipment under consideration satisfy the clinical needs of the department. The responsible radiation oncologist and the medical physicist should make the choice of the equipment that will meet most of the clinical needs in the local situation. Furthermore, the capital budget and the budget for sustainability of the equipment with respect to ongoing maintenance and/or service contracts require consultation with the hospital superintendent. The choice of the type of treatment delivery system will affect the other equipment requirements.

The BSS (para. II.13) [1] require that equipment consisting of radiation generators or containing the sealed sources needed for medical exposures (whether imported or manufactured in the country where it is used):

- (a) Conform to the applicable standards of the International Electrotechnical Commission (IEC) and the International Organization for Standardization (ISO) or equivalent standards;
- (b) Conform to performance specifications, operating and maintenance instructions, including protection and safety instructions, provided in a major world language understandable to the users and in compliance with the relevant IEC or ISO standards with regard to accompanying documents, and translated into the local language where appropriate;
- (c) When equipment manufactured in one country is to be exported into another country with the IAEA's assistance, documentary evidence (i.e. a copy) of the national standards of the exporter has to be provided with the quotation (bid) to assess whether the national standards are actually equivalent to the IEC and ISO standards.

5.2. EQUIPMENT FOR EXTERNAL BEAM RADIOTHERAPY

The equipment needed to perform external beam radiation therapy falls into five main categories:

- (1) Imaging;
- (2) Treatment planning;
- (3) Treatment delivery;

- (4) Quality assurance;
- (5) Radiation safety.

5.2.1. Simulator and computed tomography simulators

The simulator should meet the specifications enumerated in Appendix II. Additional information can be found in a report published by the British Institute of Radiology [9].

5.2.2. Treatment planning equipment

The TPS should meet the specifications enumerated in Appendix III and must meet the needs of the external beam radiotherapy treatments as determined by the clinical goals of the radiotherapy department.

A personal computer which includes software programs for calculation spreadsheets may be used to calculate treatment times, based on either the treatment plan or a central axis depth. It is advisable to develop programs to calculate treatment time, analyse machine data and verify calculations of the treatment planning computer, as well as to write reports, including the results of acceptance testing, commissioning measurements, calibrations and quality assurance tests, and patient in vivo measurements. The computer is also useful for writing dosimetry and treatment policies and procedures required by the quality assurance programme.

A contouring device should be available for contouring the patient for entry to the treatment planning computer. The contour device could be a plaster of Paris strip, a lead solder wire, a modern laser system or other device (pantograph) expressly designed for patient contouring.

5.2.3. Teletherapy unit

The teletherapy equipment should meet the specifications enumerated in Appendices IV–VI. The purpose of this publication is not to dictate the type of equipment to be purchased. However, some of the considerations relating to the choice of equipment are included in Appendix VII. While the IAEA is not able to fully fund linacs, assistance can be provided to support their purchase by a hospital. The hospital authorities should, however, consider very carefully whether the required clinical, technological and financial infrastructure is available to support the increased investment and maintenance. Orthovoltage equipment may be found to be a cost effective alternative to the use of electrons for surface and shallow lesions.

5.2.4. Quality assurance equipment

Both ionometric and film dosimetry systems should preferably be available for quality assurance (commissioning, calibration and quality control) of the teletherapy unit. These systems should meet the specifications enumerated in Appendix IX, Table 15. The ionometric systems should also conform to the specifications given by the IAEA in Refs [10–12], and should be calibrated at a standards laboratory every two years or as required by the national regulatory body. Supplementary equipment as referred to in Appendices IX (Tables 16 and 17), V, VI, XIII and XIV should also be available.

5.2.5. Radiation safety equipment

This instrumentation should include an area radiation monitor that is safe against a power failure inside the ⁶⁰Co treatment room, a Geiger–Müller (GM) survey meter and a large volume ionization chamber. For accelerators with energies of 15 MV and above, access to a neutron measuring instrument is required.

5.3. EQUIPMENT FOR BRACHYTHERAPY

The equipment needs for brachytherapy fall into five main categories:

- (1) Imaging;
- (2) Treatment planning;
- (3) Treatment delivery (including afterloading equipment, sources, source storage and transportation, and applicators);
- (4) Quality assurance;
- (5) Radiation safety and source handling.

The following distinctions in brachytherapy modalities are made: manually afterloaded LDR brachytherapy, remote afterloaded LDR brachytherapy and remote afterloaded HDR brachytherapy.

5.3.1. Imaging equipment

Although it is possible to state the delivered tumour dose for some fixed brachytherapy applicators, individual treatment planning is desirable in all cases to assess the dose to critical normal structures. For treatment planning, the applicator and source geometry need to be reconstructed. The most common method is reconstruction by means of a pair of orthogonal radiographs. An X ray unit with fluoroscopic capabilities in the operating room is desirable because it enables the position of the applicator or catheters to be checked, and if necessary repositioned, before the patient leaves the operating suite. If imaging equipment is not available in the operating room, use of an isocentric simulator is preferred. If a simulator is not available, non-isocentric (diagnostic) X ray equipment can be used, but a fixed geometric structure containing fiducial markers (sometimes designated as a 'localization box' or a 'jig box') is often needed to derive or verify the parameters needed for reconstruction (magnification factors and radiography angles).

In order to visualize the positions of sources during treatment, radioopaque dummy sources should be inserted in the applicator or in the catheters while taking the localization X rays. Other markers may be required to designate sensitive structures.

5.3.2. Equipment for treatment planning

Treatment planning systems should meet the recommendations given in Appendix III and must meet the needs of the brachytherapy treatments as determined by the clinical goals of the department.

5.3.3. Treatment delivery equipment

Both LDR and HDR sources should be accompanied by a source certificate, specifying:

- (a) The source strength, preferably in terms of reference air kerma rate (RAKR), i.e. the air kerma rate to air, in air, at a reference distance of 1 m, corrected for air attenuation and scattering (this quantity is expressed in units of μ Gy·h⁻¹ at 1 m);
- (b) The quality control tests applied to the source.

The choice of applicators depends entirely on the treatment protocol and must be compatible with the training and expertise of the physician.

If manually afterloaded LDR sources are used, a source storage container should be located in the source preparation room. The shielding requirements should meet the criteria specified in the BSS [1]. A transport container is needed to transport prepared sources to the patient treatment area.

5.3.3.1. Low dose rate afterloading

Low dose rate brachytherapy may be performed either manually or with a remote afterloading unit. The LDR remote afterloading units should meet the specifications given in Appendix XI.

Currently, the most common isotopes for LDR brachytherapy are ¹³⁷Cs, ¹²⁵I and ¹⁹²Ir. Iodine-125 is available as seeds. Iridium-192 LDR sources can be obtained in many different forms, for example, as flexible wires in coils or sealed in plastic catheters, as ribbons (strands of small cylindrical seeds, usually sealed in plastic catheters) or in a form that may be used directly for interstitial implants (e.g. 'hairpins').

In the decision as to the type of sources to use when starting a brachytherapy programme, the problem of how to dispose of sources after their useful life must be solved. Except for ¹³⁷Cs, all brachytherapy sources have a limited period of use, because decay of the sources leads to unacceptably long treatment times, and there is an increased risk of damage to source integrity for older sources.

5.3.3.2. High dose rate remote afterloading units

The HDR remote afterloading units should meet the specifications given in Appendix XI.

For HDR brachytherapy, ¹⁹²Ir or ⁶⁰Co may be used because they both have high specific activities and can be fabricated into miniature high activity sources.

However, ¹⁹²Ir has a rather short half-life (approximately 74 days) that necessitates frequent source exchange. The ¹⁹²Ir source in the HDR afterloader should be exchanged by the manufacturer every three to four months. Cobalt-60 has a much longer half-life (approximately 5.2 years) and only requires exchanging by the manufacturer every five to seven years. Attention should be paid to the design of the treatment room for ⁶⁰Co HDR brachy-therapy, which requires more shielding than that for ¹⁹²Ir HDR brachytherapy.

5.3.3.3. Pulsed dose rate afterloading units

Pulsed dose rate machines are mechanically similar to ¹⁹²Ir HDR machines. The source control system, however, delivers a series of small dose pulses separated by about an hour to mimic the biological effect of LDR therapy while retaining the use of a small iridium source. Clear indications for this preference have not been demonstrated and will not be considered further in this publication.

5.3.4. Quality assurance equipment

Equipment for dosimetry and quality assurance (calibration and quality control) should conform to the recommendations given in Appendix XI (Tables 18–20). The calibration of the ionometric system should preferably be regularly performed at a standards laboratory [13]. If this is not possible, it is recommended that a calibrated brachytherapy source similar in construction to the sources used clinically be acquired to calibrate the ionometric system. For verification of HDR source calibrations, it is desirable to have a specially designed well-type ionization chamber with a calibration traceable to a standards dosimetry laboratory.

In order to verify the uniformity of a line source, film autoradiography is frequently used. An alternative possibility is to use a detector with a narrow collimator aperture, over which the line source is moved to obtain a relative measurement of the linear source strength. If autoradiography is used, a densitometer should be available in the department. To ensure reproducible placement of line sources parallel to the film, an autoradiography jig can be used.

If an HDR afterloader with a single stepping source is used, it is mandatory to verify the accuracy of the mechanism of the source cable drive to position the source. The afterloading machine should be equipped with a device (a 'source position check ruler') in which the source cable pushes a small marker out to a position measurable along a ruler.

For HDR remote afterloaders, special autoradiography phantoms have been developed to visualize the actual source positions together with fiducial markers caused by scattering at the edges of a number of lead sheets. The use of such a phantom for quality assurance has the advantage that the actual source positions are verified rather than the positions of radio-opaque dummy sources on a radiograph.

5.3.5. Equipment for radiation safety and source handling

Equipment for radiation safety and source handling should be available according to the recommendations given in Appendix XI.

Special considerations for LDR source handling include:

- (a) A workbench in the source preparation room equipped with an L block (workbench shielding) having a lead glass viewing window.
- (b) A magnifying glass and illumination for visual inspection of sources.
- (c) Source manipulators, such as forceps.

- (d) If iridium wires are used, a dedicated source preparation station is needed to cut the wires to the required length and seal them in plastic catheters.
- (e) If iridium wires/seeds are used in a variety of different lengths, several storage containers are needed to allow easy and reliable retrieval of the different line sources in stock.
- (f) For protection of personnel during patient source loading and unloading and during care of the patient, movable lead shields are required.
- (g) Finger dosimeters.
- (h) Special considerations for HDR source handling in the case of a failure of the afterloading unit include:
 - (i) A storage container present in the treatment room, to serve as an emergency source container in case of failure of the afterloader in retracting the source;
 - (ii) A remote manipulator;
 - (iii) A rod mounted GM detector for source localization.

6. QUALITY ASSURANCE OF THE RADIOTHERAPY PROGRAMME AND RADIATION PROTECTION OF THE PATIENT

Quality assurance in radiotherapy consists of procedures that ensure a consistent and safe fulfilment of the dose prescription to the target volume with minimal dose to normal tissues and minimal exposure to personnel and the public. It involves both clinical and physics aspects. The main areas include clinical policies, treatment planning and delivery, a quality control programme for machine and equipment performance, maintenance programmes and investigative procedures for accidental medical exposures. The establishment of such a comprehensive quality assurance programme shall be in accordance with the BSS [1] and the guidelines given by the World Health Organization (WHO) [14]. Publications are also available from ESTRO, giving advice on the setting up of such a system (www.estro.be) [15, 16].

An important aspect of any quality assurance programme is continuous quality improvement (CQI), a commitment of the staff to continuously strive to improve treatment based on new information learned from their quality assurance programme and new techniques developed by the radiation therapy community at large. Continuing medical and medical physics education are essential aspects of CQI. Journal clubs, monthly departmental meetings to review treatment outcomes and unexpected morbidity, visiting lecturers and attendance at professional meetings are strongly encouraged. An effective quality assurance programme demands a strong commitment from the departmental and institutional leaders to provide the necessary resources of time, personnel and capital.

The objective of patient safety as defined in the BSS (para. II 18a) [1], i.e. to ensure that "exposure of normal tissue during radiotherapy be kept as low as reasonably achievable consistent with delivering the required dose to the planning target volume", is part of the objective of the treatment itself. The measures to ensure quality of a radiotherapy treatment inherently provide for patient safety and for the avoidance of accidental exposure. The safety of the patient is integrated, therefore, with the quality assurance of the radiotherapy treatments.

A documented quality assurance programme consists of policy statements, written management procedures, work instructions, data sets and reference documents, prescription sheets, request forms, records, etc. Policy statements commit all staff within an organization to follow a particular policy and are made by persons in senior managerial positions. A management procedure defines how a particular objective is achieved, and should be written by the person with overall responsibility for that procedure. For ease of updating, and for ease of document control and of audit, each written procedure should have limited aims and a limited scope. In addition to stating the aims and scope, each procedure should:

- (a) List key responsibilities with a statement of who has overall responsibility for that procedure;
- (b) List any documentation that may be required to enable that procedure to be carried out (e.g. work instructions and data sets);
- (c) List the documentation that is generated as part of that procedure;
- (d) Contain an outline method indicating who is responsible for different aspects of the work described, and how they interact with, and pass responsibility to, technical and professional staff from other sections (e.g. medical staff, physicists, technicians and nurses).

It is essential that the management of the radiotherapy department make appropriate arrangements to ensure that the radiotherapy equipment is available to the medical physicists to carry out the quality control measurements (Appendix XIII).

6.1. CLINICAL ASPECTS OF THE QUALITY ASSURANCE PROGRAMME

Prior to embarking on a radiotherapy programme of treatments, the chief radiation oncologist at a centre should formulate the centre's policies in respect of the items discussed below. These items constitute the basis of the clinical aspects of quality assurance.

6.1.1. Treatment policies

Treatment policies serve to prevent a mismatch of treatment philosophies, and to allow any non-standard practice to be questioned. Once the treatment policies have been defined by the appropriate physician for the full range of radiotherapy (external and brachytherapy) techniques proposed, they should be implemented in conjunction with the medical physicist. The prescribed doses (or ranges of prescribed doses) and the overall treatment regimens should be defined for different disease sites, tumour stages and presentations.

6.1.2. Clinical case conferences for review of proposed/recent patient treatments

It is desirable that regular case conferences be held involving all technical and professional personnel who may have a part to play in ensuring the quality of the treatment. The purpose is to minimize the risk of mistakes arising from an incomplete understanding of the clinical problems and of the aims of treatment. Such meetings also provide a forum for continuing assessment of resources. Where possible, times, locations and a list of expected attendees should form part of the policy statement.

6.1.3. Clinical follow-up and statistical review

Every effort should be made to assess the outcome of treatments and to compare local results with those published by established practitioners who are following similar treatment policies and regimens. The purpose is to allow controlled and safe introduction of improvements to treatment regimes. If local results are significantly worse then there should be a mechanism to review, and possibly change, local procedures. Statistical methods must follow accepted practice and, where possible, advice should be sought from a professional statistician. The methods of data collection and storage, and the mechanisms for follow-up, review and technique revision, should be documented.

6.2. PHYSICAL ASPECTS OF THE QUALITY ASSURANCE PROGRAMME

Once the equipment has been shown to meet its specifications and has been accepted from the manufacturer (Section 2.2.4.1) it will then be commissioned for clinical use. The results of the commissioning tests serve as a reference for subsequent checks. All measurements should be recorded in a log book. As this log book serves as the principal archival source for all acceptance tests and commissioning measurements, it should have sequentially numbered pages of high quality paper, and these pages should be sewn in, not glued in. Log books with inferior paper can quickly degrade. The glue used for attaching the pages in log books also deteriorates with time and use, which can result in pages falling out and being lost.

The acceptance tests must demonstrate that the equipment meets or exceeds the bid specifications. Frequently, acceptance tests follow a protocol supplied by the manufacturer, but the purchaser may develop their own protocol. In either case, the acceptance test protocol must be part of the purchase order for the equipment, so that both sides agree to what constitutes acceptance of the equipment and both sides are aware of the expectations of the other party.

Acceptance test protocols specify which tests will be performed, which equipment is used to perform these tests and what the results of these tests should be. They constitute a legal document in which the medical physicist confirms that the equipment meets the specifications of the bid.

At the completion of acceptance tests, commissioning measurements begin (Appendix XIII). During commissioning measurements, the physicist will measure all the data required to place the unit into clinical service. The physicist must assure that all the data needed to perform any anticipated clinical procedure are acquired at this time. The data should be acquired in the format required for entry into the treatment planning computer. All data should be compiled into a loose-leaf notebook for archival purposes. The pages of the notebook should be dated and signed by the physicist. This notebook format is also very suitable for maintaining a set of data with which to perform hand calculations of treatment times.

Immediately at the conclusion of the commissioning measurements, quality control tests should be established. A quality control programme should specify:

- (a) The different tests to be performed;
- (b) The equipment, including serial numbers, used to perform the tests;
- (c) The geometry of the tests;

- (d) The frequency of the tests;
- (e) Who performs the tests;
- (f) The expected results;
- (g) Tolerance values;
- (h) The actions required when the tolerance levels are exceeded.

It must be emphasised that checks should be performed only by qualified and experienced persons, such as a medical physicist, but who can delegate the work to persons they have trained. Regardless of who performs the tests, the physicist remains the responsible party for ensuring the correct performance of the equipment.

The physicist must also verify that the data in the treatment planning computer, in any computer used to calculate treatment times and in the loose-leaf notebooks are correct and consistent.

The details of a quality control and safety programme are given in Appendix XIII, which is mainly based on a report of the American Association of Physicists in Medicine (AAPM) [17]. Further information can be found in a report of the Institute of Physics and Engineering in Medicine (IPEM) [18].

6.3. RADIOTHERAPY PLANNING AND DELIVERY

This section discusses procedures that occur between the consultation, or examination, at which the decision is taken to treat a patient with radiotherapy, and the completion of that treatment.

6.3.1. Initial evaluation

The overall responsibility for procedures under this heading lies with the radiation oncologist. The aim will be to ensure that appropriate clinical management decisions are taken for the particular site, stage, extent, etc., of the disease, and that an unambiguous prescription is formulated. Methods for examination procedures should state the nature of the examinations required, give reference to staging protocols, treatment protocols, etc., and state where the results of the examinations, and any consequent clinical management decisions, are recorded.

A very critical step is the initial evaluation of the patient and the extent and nature of the tumour. This includes a complete physical examination of the patient and a review of all diagnostic studies such as radiographs, CT, MRI, PET and radionuclide scans, ultrasound, laboratory data, pathology slides and reports. It is important for the radiation oncologist to be aware of the biological and pathological characteristics of the tumour, as well as clinical manifestations, so that probable subclinical extensions of the tumour can be included in the treated volume. The full extent of the lesions should be determined and staged accordingly.

6.3.2. Therapeutic decisions

The therapeutic decision includes a determination of the goal of therapy (cure or palliation), evaluation of the alternative therapeutic approaches and a choice of the therapeutic modalities to be used for the patient.

6.3.3. External beam radiotherapy

6.3.3.1. Definition of target volume

Once it has been determined that radiation therapy is to be administered, it is critical to assess the extent and location of the tumour volume and the surrounding normal structures. This can be accomplished by physical examination and appropriate imaging modalities, for example, radiographic or radionuclide studies, CT, ultrasound or MRI. The clinical target volume can then be determined. Considerations relating to the definition of target volumes and organs at risk are given in two ICRU reports [19, 20].

6.3.3.2. Treatment planning

Treatment planning involves several steps, including localization and/or simulation, procedures carried out using a special radiographic unit (simulator) that can reproduce the geometric conditions of the patient on the radiation therapy machines. The tumour and normal structures must be localized in a geometry identical to that used during the delivery of the treatment; the planning target volume is determined at this time. Depending on the complexity of the treatment, portals can be designed directly in the simulator, or their size, orientation, weight, etc., may be determined with the aid of a treatment planning computer system.

The physician prescribes the dose to the tumour and any organs at risk; the physicist carries out calculations of doses, and computation of beams and isodose distributions. The physician, in consultation with the physicist, will analyse the alternative plans of therapy and select that which is best for the patient. Dose calculations can also be performed by properly trained staff (technicians, RTTs or dosimetrists) under the supervision of the physicist. The need for immobilization and positioning devices, shielding blocks, masks and compensating filters must be assessed during the treatment planning procedure. If necessary, these aids will be specified by the physician and constructed by the treatment planning team.

At the completion of the treatment planning process, it may be advisable to use the simulator again to simulate the patient with the final treatment portals, including the immobilization devices and shielding blocks in position prior to the initial treatment.

With the emergence of three dimensional (3-D) conformal radiation therapy and IMRT employing non-coplanar beams, the treatment planning process may increasingly include the use of a CT scanner with a 'virtual simulator' function. An important aspect in the use of a CT scanner for treatment planning is that the patient support assembly (PSA) of the scanner must be flat to match the treatment machine PSA (treatment couch), rather than the more usual concave PSA of CT scanners. An insert with a flat top and curved bottom that fits the curvature of the CT support assembly is an easy method to achieve this goal. As treatment margins are reduced with the advent of these new techniques, so the accuracy of the delineation of the target volume must increase. This requires that all members of the multidisciplinary team be trained to a high level of expertise. The accuracy of treatment delivery must be carefully assessed and corresponding treatment margins applied. Radiation therapy with tight margins and poor quality control will reduce the possibility of cure rather than increase it. These issues are discussed further in Appendix VIII.

6.3.3.3. Treatment delivery

The treatment is carried out by the RTT under the clinical supervision of the physician and the scientific supervision of the physicist. Regardless of the degree of participation by the physicist or the level of skill of the radiotherapy technician, the physician remains the sole individual responsible for all clinical aspects of the treatment. The participation of the three professionals is very important during the first treatment, especially with complex beam set-ups. Periodically, portal films are taken and the doses recorded on charts are verified to ensure treatments are consistent.

The physician will evaluate the patient at least weekly during the course of therapy, to assess tumour response and the tolerance of the patient to the treatment. Examinations may be carried out more often, particularly when there is a need for supportive care, such as to improve the nutrition of the patient, prescribe medication to reduce symptoms, treat concomitant diseases, and provide instructions and medication to treat the side effects of therapy. The radiation oncologist will work closely and communicate with the referring physician to coordinate the overall care of the patient and to integrate the radiation therapy with other therapeutic modalities.

6.3.3.4. Periodic evaluation and follow-up

Periodic follow-up examinations after treatment are critical, not only to evaluate the general condition of the patient and the tumour response but also to detect recurrences early, should they occur, and to observe the effects of irradiation on the normal tissues.

Table 2 in Section 3 outlines the above steps for external beam radiotherapy.

6.3.4. Brachytherapy

6.3.4.1. Examination and prescription

For some brachytherapy treatment techniques the prescription will be written prior to insertion of the sources; for others it may be more appropriate to write the prescription after insertion of the sources. In either case, the prescription should be written on a prescription sheet that has been designed for that purpose, and signed by the responsible clinician. There should be a procedure whereby the prescription is independently checked (e.g. by a different calculation method) for compatibility with the departmental policy, and a record should be made of that check.

6.3.4.2. Insertion of the applicator or catheter and source preparation

The overall responsibility for the insertion procedures themselves will again lie with the radiation oncologist. Procedures for preparation of sources and the calibration of instruments should be carefully defined. Critical procedures (e.g. source preparation) should incorporate an independent check and authorization signature. Following a manual application, there may be unused sources that must be returned to an appropriate storage location. There should be a procedure to ensure that this is achieved safely and efficiently, independently checked, and that the source locations log book is appropriately updated.

Generally at the time of the brachytherapy procedure, dummy sources (i.e. non-radioactive ones) are inserted into the applicator or catheters. Radiographs of the implant are then obtained for two purposes:

- (1) To check that the position and arrangement of the implant are correct;
- (2) To determine the location of the sources (shown by the dummy sources) in order to calculate the dose distribution and to select the appropriate activity of the sources required to deliver the dose.

At this time the clinician can make an immediate decision on whether to continue with the treatment as it is or to modify the application. As described in Section 5.3.1, orthogonal or stereo-shifted radiographs might also be required. The overall responsibility for these procedures lies with the radiation oncologist.

6.3.4.3. Treatment planning

The overall responsibility for calculation of dose and dose distribution to determine the duration of the implant will lie with the medical physicist. The planning procedures must be compatible with the chosen clinical practice and must include a method of independent verification. These procedures will define how the specific treatment parameters are passed to the person controlling treatment delivery. The prescribing radiation oncologist must approve the final treatment parameters.

6.3.4.4. Treatment delivery

The overall responsibility for treatment delivery and particularly for the termination of treatment will lie with the radiation oncologist. The main procedures will cover:

- (a) Treatment startup (for afterloading treatments);
- (b) Patient and/or applicator monitoring to ensure the continuing integrity of the application;
- (c) Emergency procedures with clearly stated action criteria;
- (d) Procedures for unplanned activity or treatment interruption (e.g., for an additional radiography check);
- (e) Completion procedures, including removal of sources and applicators;
- (f) Where appropriate, the safe return of sources to proper storage locations.

Further technical procedures will cover checking of the returned sources and updating of source location records.

6.3.4.5. Periodic evaluation and follow-up

Periodic follow-up examinations after treatment are critical, not only to evaluate the general condition of the patient and tumour response but also to detect recurrences early, should they occur, and to observe the effects of irradiation on the normal tissues.

Table 3 in Section 3 outlines the procedures listed above.

6.4. MAINTENANCE PROGRAMME

Any radiotherapy programme requires ongoing maintenance for the teletherapy units, remote afterloading devices and any other major pieces of equipment (e.g. computers). A maintenance strategy determined at the beginning of the project is essential to achieving and maintaining:

- (a) Acceptable out-of-service interruptions;
- (b) High quality treatments;
- (c) Planned treatment schedules (fractionation);
- (d) Patient and staff safety;
- (e) Accident prevention.

Three lines of maintenance can be considered:

- (1) In-house service for routine small repairs;
- (2) Local support by a specialized maintenance company, usually a representative of the supplier;
- (3) Prompt support by the manufacturer for major repairs.

The approach generally taken is a combination of the above. The scope and limitations of each should be clearly established in writing, and the necessary training and certification by the manufacturer should be arranged. No option is inexpensive, but neglect of maintenance is even more expensive as it can have unacceptable and even dangerous consequences. Equipment containing large amounts of radioactive material (⁶⁰Co units and remote afterloaders) may require a licensed source handler to carry out particular maintenance tasks.

Overall, the medical physicist should provide management for the maintenance programme. When maintenance staff will be working around hazardous radioactive materials and potentially affecting basic safety mechanisms in the devices, the help and cooperation of the radiation protection officer should be sought. The programme should be developed with the cooperation and assistance of the manufacturer of the equipment, and the level of on-site support will depend partially on the availability of timely support from the manufacturer.

Each of the procedures developed as part of this programme should clearly establish who is authorized to perform the service, who must be notified before and after a service has been performed, and what records are to be kept. After each major repair or preventive maintenance has been carried out, a complete set of quality control measurements must be taken.

6.4.1. Preventive maintenance

Procedures should include provision of preventive maintenance services. These procedures should identify the frequency of service and items to be checked following the manufacturer's recommendations. A service contract including preventive maintenance may be preferred, since the manufacturer may provide both spare parts and expertise.

6.4.2. Repairs

Written procedures should establish who is authorized to work on various components of the system, recognizing the hazards and potential consequences associated with different subsystems and radioactive sources. Specific repair procedures should use the manufacturer's documentation and training materials. Again, a service contract may be the preferred route, since in practice it is difficult for local staff to maintain the expertise required to repair the equipment when problems occur only infrequently. There should be a formal procedure for notifying the medical physicist every time there is a repair, regardless of its apparent importance. For safety reasons, the medical physicist will decide the extent of quality control required.

6.4.3. Spare parts

Funds must be allocated for the purchase of an adequate supply of spare parts to be maintained on-site. A kit of spare parts and sources for parts not included in the kit are necessary. Maintenance manuals in a major world language, understandable to the users (i.e. maintenance engineers), are required by the BSS (para. II.13) [1]. Particular attention should be paid to the possibility and advisability of substituting components obtained from local vendors. It may be cost effective to do so, but only if the substitutes are of sufficient quality and compatibility.

6.5. INVESTIGATION OF ACCIDENTAL MEDICAL EXPOSURES

Pre-established procedures should be set up for the investigation of significantly incorrect treatments. In accordance with the BSS (paras II.29 and II.30) [1], the following questions shall be promptly investigated:

- (a) Any therapeutic treatment delivered to either the wrong patient or the wrong tissue, or using the wrong radioisotope, or with a dose or dose fractionation differing substantially from the values prescribed by the radiation oncologist or that may lead to undue acute secondary effects.
- (b) Any equipment failure, accident, error, mishap, miscalculation or other unusual occurrence with the potential for causing a patient dose significantly different from that intended.
- (c) In most cases the radiation physicist will be the most appropriate person to undertake such an investigation, which should include:
 - (i) A calculation or estimation of the doses received and their distribution within the patient;
 - (ii) Corrective measures required to prevent recurrence of such an accident;
 - (iii) A method to implement any corrective measures.

Following the investigation, a report of the incident should be made to the appropriate hospital safety committee. This report should contain the findings of the investigation. Unless there is an overriding medical reason not to, the radiation oncologist, after consultation with the patient's referring physician, shall inform the patient about the incident in a timely manner. Depending upon national regulations, it may also be necessary to report to an external regulatory authority.

6.6. QUALITY AUDITS

A quality audit is an independent examination and evaluation of the quality assurance activities and results of a particular cancer centre. Individuals performing these audits must not be directly responsible for the activities that are audited. Ideally, quality audits review the entire quality assurance process. Quality audits may be conducted by personnel within the institution (internal audits), as well as those from outside the institution (external audits). At larger institutions, internal audits may include staff members reviewing each other's treatment plans and outcomes on a scheduled periodic basis. However, even at larger institutions, an external review by qualified experts is an important

aspect of any quality assurance programme. With regard to an external quality audit, the best results are achieved with site visits by outside, qualified, experts; however, this is an expensive process. A less expensive alternative may include a 'self-study'. This approach involves the outside review team forwarding a package of questions to which the reviewed organization responds. The reviewers then evaluate these responses. Other examples of quality audits of a more limited nature are the postal TLD services that audit radiation beam calibrations. Organizations offering these services include the IAEA and WHO operating worldwide [21], ESTRO in the European Union and the Radiological Physics Center and Radiation Dosimetry Services in North America.

In addition to providing a TLD service to hospitals, the IAEA supports its Member States in developing national programmes for TLD audits and, whenever possible, establishes links between national programmes and the IAEA's dosimetry laboratory, assuring at the same time traceability to primary dosimetry standards. Several countries in Africa, Asia, Eastern Europe and Latin America have established TLD programmes to audit their own radiotherapy beams with the assistance of the IAEA.

7. RADIATION PROTECTION AND SAFETY OF SOURCES

7.1. AUTHORIZATION

The BSS [1] require that legal persons apply to the regulatory authority for an authorization, which in the case of radiotherapy usually takes the form of a licence. A radiotherapy department involves the construction of facilities, which are difficult to modify later. In some countries, regulatory authorities require a two stage process of authorization, i.e. an initial application before construction begins and a second stage before clinical use starts. A practical way to implement the two stage process is for the regulatory authority to receive the initial application containing information about the design of the facility and a description of its equipment [22, 23]. The areas that need to be addressed in the licensing and inspection process are summarized in Appendix XII; these areas are typically the description of radiation sources, facility design, managerial and organizational arrangements, personnel, training, operating procedures and resources required.

After authorization, substantial modifications to the radiotherapy facilities, sources and procedures may have safety implications, and regulatory

authorities may also require a specific application for any modifications. The same is true for partial or total decommissioning of a radiotherapy facility.

Radioactive sources and associated equipment for radiotherapy that have not been used for a long time while awaiting disposal have been involved in severe accidents when not properly secured or when security has lapsed over time [24–27]. A means of preventing such accidents may be a requirement to notify the regulatory authority of the planned date for resuming operation or of the decommissioning and disposal of the sources and the security conditions for interim storage. Three months is the advisable period. The longer the period, the higher the risk that the sources become orphaned, but too short a period may increase the bureaucracy involved without having a significant impact on safety.

7.2. ORGANIZATION AND MANAGERIAL MEASURES

7.2.1. Management policy

An overall policy on safety culture, defence in depth and accountability for sources relies primarily on the policy that management introduces and supports.

In some serious accidents [28, 29]¹, management allowed safety systems to degrade significantly and staff to improvise procedures or continue operations when a safety system failed, or to operate without sufficient training, quality assurance programme or documented and rehearsed procedures. Workers may have perceived that management encouraged deviation from procedures in order to perform the job more quickly.

7.2.2. Organization and responsibilities

Paragraphs 1.6 and 1.7 of the BSS [1] establish that

"The principal parties having the main responsibilities for the application of the Standards shall be:

(a) registrants or licensees; and

¹ The IAEA has developed a repository of information on incidents and accidents with the purpose of disseminating the lessons to be learned in order to prevent similar events from occurring anywhere in the world.

(b) employers.

"1.7. Other parties shall have subsidiary responsibilities for the application of the Standards. These parties may include, as appropriate:

- (a) suppliers;
- (b) workers;
- (c) radiation protection officers;
- (d) medical practitioners;
- (e) health professionals;
- (f) qualified experts;
- (g) Ethical Review Committees; and
- (h) any other party to whom a principal party has delegated specific responsibilities."

The licensee should assign clear subsidiary responsibilities to personnel (e.g., medical practitioners, qualified experts in radiotherapy physics, radiotherapy technologists, radiation protection officers and other health professionals) so that adequate radiation protection of patients, workers and the public is ensured. The broad responsibilities of medical practitioners and qualified experts in radiotherapy physics with regard to the BSS [1] requirements on medical exposure are dealt with in Section 7.6 on medical exposure.

According to the BSS [1], para. 1.9, it is also the responsibility of the licensee to "develop, implement and document a protection and safety programme commensurate with the nature and extent of the risks associated with the practices", in this case radiotherapy. For the programme to be effective the licensee needs to provide for its implementation, including the necessary resources to comply with this programme and the arrangements to facilitate cooperation between all relevant parties.

An effective means to ensure compliance with the programme is the appointment of a committee for radiation protection², with the function of

 $^{^2}$ The radiation protection committee — which includes occupational, public and medical exposure — and the quality assurance committee — which includes ensuring consistency of the medical prescription and the safe fulfilment of that prescription — have overlapping functions, especially with regard to the BSS requirements on radiation protection for medical exposure. Members of both committees may also be the same: an administrator representing the management, the chief radiation oncologist, a qualified expert (medical physicist), a radiotherapy technologist, and possibly a brachytherapy nurse and a maintenance engineer. Provisions for harmonizing the work of both committees are needed.

supervising safe operation and compliance with regulatory requirements. Since a representative of the management is usually a member of the radiation protection committee, communication to this person may be the most appropriate. The members of the committee typically include an administrator representing the management, the chief radiation oncologist, a qualified expert in radiotherapy physics (medical physicist), the radiation protection officer, a radiotherapy technologist, possibly a brachytherapy nurse and a maintenance engineer. A suggested list of items for the programme is given in Appendix XII.

For the day-to-day oversight of the radiation protection programme, a radiation protection officer is necessary, who should report to the committee. The licensee should provide them with the time and resources required to supervise the programme, and with the authority to communicate not only periodically with the committee but in case of breaches of compliance that may compromise safety, they should have the authority to communicate directly with the licensee.

7.2.3. Staffing and training

A sufficient number of trained staff have to be assigned and their responsibilities clearly defined. With regard to medical exposure in radiotherapy, the overall responsibility for patient protection has to be assigned to medical practitioners [1], and calibration, dosimetry and quality assurance have to be conducted by or be done under the supervision of a qualified expert in radiotherapy physics (usually a medical physicist). The duties of the radiation protection officer (RPO) may be covered by the qualified expert in radiotherapy physics, depending on the size of the radiotherapy department.

In addition, every staff member who uses or maintains radioactive sources or X ray generators must be trained in their respective role for each procedure as well as in basic radiation safety. These individuals include:

- Radiotherapy technologists;
- Source handlers;
- Nurses;
- Patient transporters;
- Maintenance engineers or technicians.

Each of these individuals needs to be taught to identify the type of source that they work with and how they will know if the source is in a safe or non-safe condition. They must also know what immediate steps to take during an emergency and especially how to contact the RPO or their designee. The lines of authority and responsibility need to be clearly drawn and documented within the programme.

7.2.4. Reassessment of training needs

Staffing, responsibilities and training needs are to be reassessed every time a radiotherapy department introduces new equipment, expands activities and incorporates new treatment modalities. Both the number of the personnel available and their training need to be checked at such a reassessment. A typical example is the purchase of a new machine with a view to increasing the number of patients to be treated, for example, the introduction of an accelerator or a brachytherapy HDR machine. The staffing needs have to be identified before the point is reached when the number of staff is insufficient or when they are inadequately trained to operate the equipment safely. Failure to do so has been the cause of severe accidents involving a large number of patients [27].

7.3. SAFETY IN EQUIPMENT AND SOURCES

It is important at the design stage to ensure that equipment meets IEC standards and that sealed sources meet ISO standards [30–38]. Applicants for licences need to clearly identify the model and manufacturer of the equipment, since there will be a generic authorization for each model to be sold and installed in each country.

It may well be, especially in a developing country, that the equipment is donated after having been used in another country. If the equipment is old, it may not meet current safety standards and could become a problem for the recipient rather than a benefit. In this case, recipients, before accepting a donation, should ensure that equipment meets current safety standards and is likely to work safely and reliably. For this purpose, the recipient needs to prepare:

- (a) A safety assessment of the equipment;
- (b) A quality control test before the donor decommissions the machine, the results of which are to be submitted to the regulatory authority in the recipient country;
- (c) A full, safe and workable maintenance strategy.

The full maintenance strategy is especially critical in the case of accelerators, since a faulty repair can cause severe injuries or even death, and an unreliable machine will compromise the potential success of patient treatments.

Each sealed source should be purchased with a calibration certificate, which provides details of its isotopic activity on a certain date, its encapsulation, and the manufacturer's model and serial number. The exact source type and size, including encapsulation, is very important information; not only for source calibration, but also to ensure that the source is only used with compatible applicators and with appropriate cleaning techniques.

The recommended working life under the conditions specified for use needs to be observed. When this period has been exceeded, a source may still be in good condition, but a safety assessment needs to be made and the frequency of wipes and other tests may need to be reconsidered.

7.4. FACILITY LAYOUT, SHIELDING AND INTERLOCKS

7.4.1. External beams

7.4.1.1. Layout

Initial considerations for an external beam treatment unit should include careful consideration of a number of points which will have an impact on the radiation aspects of the programme:

- (a) The types of use and proximity of the work and public access spaces beyond the treatment room will play a major role in the amount of shielding required in each of the barriers. It is best to keep highly occupied areas as far away from the treatment room as possible, and conversely to surround that room with spaces that cannot be occupied or have very low and controlled occupancy (such as a roof, which can have access controlled by locks or signs to prevent entry).
- (b) Ease of access to the treatment room by patients and for the installation and replacement of equipment is also an important factor. A maze is the most practical solution for ⁶⁰Co external beam treatment rooms. If well designed, a maze makes a heavy door unnecessary. It should be noted that staff may enter the room a 100 times per day, and heavy doors may become impractical. Motor driven doors are expensive and slow, and are usually not necessary for ⁶⁰Co irradiation rooms. For ventilation and electrical conduits, the maze also allows easy installation of ducts into the treatment room vault over the maze door, and only a minimal amount of scattered radiation will come through the ducts.

- (c) Primary barrier widths should be about 0.67 times the distance from the source to the barrier, while their thickness is determined by the methods discussed in Appendix XV.
- (d) It is necessary to supply an open access conduit for equipment cables and test cables near the unit control (as specified in the manufacturer's accompanying documents). This can be done by ensuring that the line of sight of the conduit does not intercept any surface inside the room that can be struck by the primary beam.
- (e) Care should be taken to ensure that there are no voids, including conduits, in any of the primary barriers.
- (f) Any junction boxes in the secondary walls should be backed by 4 cm of steel with a 3 cm margin at the sides.

An example of a calculation spreadsheet for a 60 Co therapy source is given in Appendix XV.

7.4.1.2. Interlocks and signs

In addition to layout and shielding considerations, there are safety interlocks and procedures that need to be incorporated into the radiotherapy programme:

- (a) The door to the treatment room should have a fail-safe interlock to switch off the radiation beam (i.e. return the source to the shielded position) if the door is opened during a treatment. Restarting irradiation should require both closing of the door and activation of a switch at the control console. This is intended as a reminder to record the irradiation time given prior to opening the door.
- (b) The door to the room should have a sign which indicates that the room contains radiation sources or radioactive materials.
- (c) There should be a visible light at the door to the room that shows if the source is on. Typically, this will be red when the source is on and green when it is off.
- (d) There should be a battery operated detector of scattered radiation inside the room that shows when the source is on.
- (e) There should be emergency buttons located inside the room to shut off the radiation, and these should be reachable without passing through the radiation beam.
- (f) There should be audio intercommunication with the patient.

7.4.2. Brachytherapy

7.4.2.1. Layout and shielding

Low dose rate brachytherapy can be performed by manually loading the sources into the applicators, which have been placed into the patient, or by using a remote afterloading unit that stores the sources until they are needed and then drives them into position in the applicator.

The remote afterloader acts as its own storage safe and allows the sources to be retracted into the safe position whenever anyone, such as a nurse, needs to be near the patient. Therefore, staff exposures can be kept to a very low level.

With manually loaded sources there is a need for a shielded and locked container, which is usually kept in a locked room. Security for the sources is of the utmost importance. This room can also serve for loading the sources into the applicators.

For LDR type sources that are always stored in a locked shielded safe within the room, except while loading and unloading the applicators, the room itself does not need to be shielded. It will usually have a work area with an L block shield for the person loading the source to use while identifying and loading the sources into the applicator. Since the sources and their identifying marks are very small, it is useful to have a leaded glass viewing window on the L block along with a magnifying lens mounted to a light assembly.

The patient rooms used to house the LDR brachytherapy patients until they are ready to be discharged may not need to have shielding in their walls if mobile lead shields around the patient's bed are made available.

A sink in this room can aid in the cleaning of the applicators. However, sinks have also led to loss of sources; for instance, when a patient has removed a source and disposed of it down the sink. This can be avoided by placing a filter to prevent any source from falling down the drain.

High dose rate remote afterloading units require some special considerations in their layout and shielding. Each of the walls, the ceiling and the floor of an HDR room is a primary barrier and shall be of adequate thickness to protect the staff and public, who must remain outside the room during the treatments. If the HDR source may be positioned anywhere inside the room, the resulting calculated barrier thickness can be very large since distance cannot be assumed to aid in the protection beyond any barrier. Thus, it is advisable to require the HDR unit to be located within a defined area of the room and to use a chain or electrical interlock to ensure that it cannot be turned on (i.e. the source driven outside its protective housing) unless the HDR unit is in that prescribed area. The room should be designed so that:

- (a) There is an interlock on the door that will cause the source to be retracted into its shielded housing if the door is opened during the time the source is on.
- (b) There is an indicator at the door to the room as well as at the treatment console of the source 'on/off' status.
- (c) There is a battery operated detector of scattered radiation inside the room that shows when the source is on.
- (d) There are emergency procedures for safely removing the source from the patient and quickly storing it in a safe location in the event that it does not retract all the way into its source housing when expected. This requires that a wire cutter sufficient to cut the source cable and a shielded storage container be located inside the treatment room.
- (e) The door to the room should be marked to indicate the radioactive materials that are within, and there should be an indication of how to contact the person responsible for radiation safety in the event of an emergency.

Detailed information relating to HDR and LDR brachytherapy can additionally be found in Refs [8, 13].

7.4.2.2. Interlocks and signs

The doors to the source storage rooms need to be locked and have a sign indicating that there are radioactive materials stored within. There should also be an indication of the responsible person to contact in the event that entry is needed, for example, for fire safety purposes.

7.5. OCCUPATIONAL PROTECTION

Detailed requirements for protection against occupational exposure are given in the BSS [1], and recommendations on how to meet these requirements are given in the safety guidance provided by the IAEA on occupational radiation protection. References [39, 40] apply to radiotherapy practice. In this section, a very brief summary of the safety guidance most relevant to radiotherapy is given.

The principal parties responsible for occupational exposure are not only licensees but also employers. In some cases, the employer, registrant and licensee is the same legal person, but in other cases they may be different. For example, the employer of a maintenance engineer for radiotherapy equipment (an 'itinerant worker') may be the maintenance company, while maintenance engineers work in many radiotherapy departments, each one under a different licensee.

Licensees and the employers of workers are responsible for ensuring that exposures are limited, that protection and safety are optimized, and that appropriate radiological protection programmes are set up and implemented. Workers have the subsidiary responsibility for following the procedures, using proper monitoring devices and protective tools, cooperating with the licensee and the employer in protection, safety and health surveillance, and dose assessment, as well as providing feedback of any circumstance that may adversely affect safety.

7.5.1. Investigation levels for staff exposure in radiotherapy

The establishment of investigation levels is a tool used to provide a 'warning' on the need to review procedures and performance, to investigate what is not working as expected and to take timely corrective action. In radio-therapy, a suitable quantity for use as the investigation level is the monthly effective dose itself, but the dose to the hands can be used as a quantity to establish the investigation level for staff in manual brachytherapy.

The following are examples of levels and their related tasks that are rarely exceeded and, therefore, could be suitable as investigation levels:

- (a) For persons working only with accelerators or remote control brachytherapy, a monthly investigation level of 0.4 mSv effective dose;
- (b) For staff working with ⁶⁰Co external beam therapy, brachytherapy nurses, and persons inserting and removing manual brachytherapy sources, a monthly investigation level of 0.5 mSv effective dose.

7.5.2. Pregnant workers

The BSS [1] establishes that "A female worker should, on becoming aware that she is pregnant, notify the employer in order that her working conditions may be modified if necessary." The notification of pregnancy shall not be considered a reason to exclude a female worker from work; however, the employer shall adapt the working conditions in respect of occupational exposure so as to ensure that the embryo or foetus is afforded the same broad level of protection as required for members of the public. The limitation of the dose to the conceptus does not mean that it is necessary for pregnant women to avoid work with radiation, but it does imply that it is necessary for the employer to carefully review the exposure conditions with regard to both normal exposure and potential exposure.

7.5.3. Classification of areas

Relevant areas of a practice can be classified as controlled or supervised (BSS requirements I.21–25) (Table 6) [1]. A controlled area is defined as an area in which specific protection measures and safety provisions are needed to control normal exposure and to prevent potential exposure.

In radiotherapy practice, areas requiring specific protection measures (controlled areas) include, at least, all the irradiation rooms for external beam therapy and remote afterloading brachytherapy, operating rooms during brachytherapy procedures using real sources, brachytherapy patient rooms, and radioactive source storage and handling areas. It is preferable to define controlled areas by physical boundaries such as walls or other physical barriers marked or identified with 'radiation area' signs. The area of the control panel could be considered a controlled area, not because of normal exposure, which can be reduced by shielding, but rather for reasons of preventing accidental exposure of patients, by restriction of access to non-related persons, to prevent distraction of the operator of a radiotherapy machine (Table 6).

A supervised area is any area not already designated as a controlled area but where occupational exposure conditions need to be kept under review even although specific protection measures and safety provisions are not normally needed. Supervised areas may involve areas surrounding brachytherapy patients' rooms or around radioactive source storage and handling areas.

All areas not designated as controlled or supervised areas should be such that persons in them are afforded the same level of protection as members of the public.

7.5.4. Individual monitoring and exposure assessment

The purpose of monitoring and dose assessment is, inter alia, to provide information about the actual exposure of workers and confirmation of good working practices. They contribute to reassurance and motivation. Certain staff members need to be monitored with individual dosimeters, while others, because of the defined procedures, have their exposures restricted by limiting their access to the radiation sources.

The BSS [1] require individual monitoring for any worker who is normally employed in a controlled area and may receive significant occupational exposure. Those most likely to require individual monitoring are: radiation oncologists, qualified experts in radiotherapy physics, a radiation protection officer, radiotherapy technologists, source handlers, maintenance staff and any nursing or other staff who must spend time with patients under treatment with brachytherapy.

A 100	Controlled or	Interlocks	ocks		Signs
7154	supervised	Door interrupt On/off light	On/off light	Radiation area	Radiation area Radioactive materials
External beam treatment room	Controlled	Yes	Yes	Yes	Yes
External beam control console	Controlled	No	At console	On door	On door
LDR source storage room	Controlled	No, but door always locked	ways locked	No	Yes
Manual LDR patient treatment room	Controlled	No	No	No	Yes
Remote controlled LDR patient treatment room	Controlled	Yes	No	Yes	Yes
HDR treatment room	Controlled	Yes	Yes	Yes	Yes

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Staff whose access to the sources can be restricted may not need to be monitored directly, but they will still need to be trained so that they recognize the radiation sources and can comply with their restricted access.

Visitors and other members of the public have to be supervised by the authorized personnel and the RPO.

Monitoring includes more than just measuring. It includes interpretation and assessment. Individual external doses can be assessed by using individual monitoring devices such as thermoluminescent dosimeters or film badges, which are usually worn on the front of the upper torso (in most radiotherapy procedures, the whole body is assumed to be fairly uniformly exposed). The operational dosimetric quantity required in the BSS [1] and in IAEA Safety Guide RS-G-1.3 is the personal dose equivalent $H_p(d)$ [40].

For weakly and strongly penetrating radiation the recommended depths are 0.07 and 10 mm, respectively. The radiation used in radiotherapy is usually strongly penetrating, and therefore d = 10 mm, except in the case of use of sources of beta radiation for brachytherapy. Other depths may be appropriate in particular cases, for example, 3 mm for the lens of the eye, in cases that the dose to the eye is higher than that for the rest of the body and requires, therefore, specific assessment. This is, generally, not the case in radiotherapy, in which the handling of the sources for preparation and insertion should be done with the face protected by a workbench, provided with an L block shielding with a lead glass viewing window. When there is the possibility of substantial exposure to the hands, such as in the handling of brachytherapy sources, extremity dosimeters may need to be worn (if compatible with clinical practice).

The interval of exchange of dosimeters in a radiotherapy department and receipt of the dose reports should typically not exceed a period of one month. Delays in the evaluation of a dosimeter can result in the fading of the stored information. If an individual's dosimeter is lost, it is necessary to perform and document an assessment on the dose the individual is likely to have received and add it to the worker's dose record. Often, the most reliable method for estimating an individual's dose is to use their recent dose history, provided that nothing unusual occurred in the period.

The use of additional operational dosimeters such as electronic dosimeters is also recommendable for use in radiotherapy, as these devices can give workers an instant indication of both accumulative dose and dose rate, allowing presetting of an alarm.

7.5.5. Monitoring of the workplace

Initial monitoring is to be conducted immediately after the installation of new radiotherapy equipment and after the replacement of teletherapy sources and remote controlled brachytherapy sources. Initial monitoring includes measurements of radiation leakage from equipment during acceptance tests and area monitoring of occupying space around irradiation rooms³.

Monitoring is to be conducted in association with brachytherapy procedures. Soon after implantation of the sources, a survey of exposure rates in the vicinity of the patient is necessary. After removal of brachytherapy sources from a patient, a survey is to be performed to confirm removal from the patient and return to shielding of all sources. The transport container should be surveyed before and after brachytherapy procedures. Monitoring of packages containing radioactive sources, upon receipt by the licensee, is to be performed.

All survey meters used for workplace monitoring need to be calibrated, and this calibration needs to be traceable to a standards dosimetry laboratory. For more detailed guidance, see Ref. [40].

7.5.6. Rules and supervision

Procedures for the following tasks need to be prepared:

- (a) Specific procedures for external beam therapy and brachytherapy;
- (b) Emergency external beam therapy and HDR therapy;
- (c) Wipe testing;
- (d) Area surveys;
- (e) Making an inventory of radiation sources.

7.5.7. Procedures for external beam therapy

Safe operation of external beam treatment units requires procedures to be in place such as wipe tests, area surveys, emergency interlock checks and source status checks. In addition, procedures are needed for emergencies such as when a source becomes stuck in the 'on' or 'partially on' position.

Such procedures require that the necessary equipment be available, calibrated and in good working order. These include:

³ Ambient dose equivalent $H^*(10)$ can be used to estimate the personal dose equivalent $H_p(10)$ that would correspond to an individual staying in the same radiation field. $H_p(10)$ provides an estimate of the effective dose.

- (a) A radiation monitor of the GM type;
- (b) A radiation monitor type ionization chamber, with scales from μ Sv to 10 Sv/h;
- (c) Wipe test capabilities;
- (d) Personal alarm dosimeters, especially for emergency interventions.

The procedures for the use of this equipment should recognize that some instruments will lock up in a very high radiation field and read erroneously. Hence the procedure should require a three step process:

- (1) Check the battery;
- (2) Check the monitor response with a check source;
- (3) Turn the monitor on and start reading the radiation dose rate level from outside the room where the source is located.

7.5.8. Procedures for brachytherapy

Low dose rate and HDR sources have in common several operating procedures for their safe use:

- (a) Source inventories should be maintained that show the location and current activity of each source at the facility with a unique identifier for each source. This may be either a colour coded or letter/number identifier.
- (b) Sources should never be left on preparation surfaces. They must be in storage, in transit or in use with the patient.
- (c) Leak tests (using moist wipes) must be performed and documented on a periodic basis, and these must have a sensitivity sufficient to detect a very low increase above the background radiation level. For the HDR unit, the wipe tests are only performed on the afterloading drive assembly and transport containers, since the source itself has too high a dose rate to allow this type of test.
- (d) Area surveys should be performed periodically around the source storage facilities for LDR and HDR sources.
- (e) The storage facilities must be marked to indicate that they contain radioactive materials and how to contact the individual responsible for radiation safety in the event of an emergency.
- (f) The storage facilities must be kept locked at all times.
- (g) After every brachytherapy treatment, the patient should be monitored with a radiation detection (GM type) survey meter to ensure that no radioactive source remains in the patient.

(h) All source transfers must be done according to the requirements of the regulatory authority by identified persons who receive and sign for the sources.

Procedures that are unique to LDR sources are:

- (a) The sources should be inspected visually for possible damage after each use, by means of magnifying viewers and a leaded viewing window in a shielded work area.
- (b) There should be a diagram at the source storage safe that shows the exact location of each source within the safe, thus reducing the time taken to locate and identify a source.
- (c) Sources should only be handled with long forceps or tongs.
- (d) When transporting sources, a mobile shielded container is needed and the shortest route possible should be used.
- (e) Sources that come into direct contact with body tissues will require cleaning and possible sterilization after each use. This can subject the sources to possible damage from heat, abrasion, chemicals and mechanical stresses. Therefore, these sources must be inspected after every use.
- (f) Work surfaces should be easy to clean and brightly lit to make it easy to find any sources that have been dropped.
- (g) If the source storage and preparation room is also the applicator loading room, there should be a sink for cleaning the applicators. However, a sink can also lead to a loss of sources to the sewage system when a source is left in the applicator or a patient removes a source and puts it in the sink, situations that are preventable by placing a filter in its drain.

Procedures that are unique to HDR sources are:

- (a) The HDR afterloader needs to undergo routine quality assurance tests at the beginning of each treatment day [41].
- (b) The couplings and transfer tubes need to be checked before each HDR treatment, to ensure that there are no obstacles to prevent motion of the source.
- (c) Emergency safety precautions require the availability of an emergency container in the treatment room, as well as an emergency kit containing surgical clamps and long handled forceps for manipulation of the source guide tubes and applicators if the source fails to return to the safe, or for other source retrieval actions. The emergency container should be placed close to the patient and should be sufficiently large that it can accept the

entire applicator assembly containing the source removed from any patient.

- (d) Manufacturers provide suggested emergency procedures if the source fails to return to the safe. These generally consist of a short single page synopsis, suitable for posting, of the necessary sequential steps involved in the emergency procedure. They assume that the physical integrity of the applicator is maintained. These procedures are specific to the actual afterloading unit, but, in general, each step assumes that if the previous action fails to lead to recovery, then the following actions are required. The general sequence is:
 - (i) Observation at the console of an error message and emergency indicators (audible and visible alarms);
 - (ii) Recovery at the console (e.g. pressing an emergency 'off' button);
 - (iii) Entry into the room with a portable radiation survey meter (opening the door activates the interlock that retracts the source);
 - (iv) Observation of radiation levels in the room (by mounted monitors or portable survey meters);
 - (v) Recovery at the afterloading unit (pressing an emergency 'off' button on the remote afterloading unit);
 - (vi) Manual retraction of the source (using a hand crank);
 - (vii) Patient survey and the afterloader survey (confirming that the source is in the safe);
 - (viii) Applicator removal and placement in the emergency container;
 - (ix) Patient survey and emergency container survey (to confirm that the source is not in the patient and that it is in the emergency container);
 - (x) Removal of the patient from the vault with subsequent redundant survey monitoring.

7.5.9. Supervision

Sufficient supervision needs to be exercised in order to avoid the degradation of safety that occurs if the impression forms that the management tolerates a situation in which procedures are not followed. When supervisors fail to make procedures and rules understood or take no actions when rules are violated, accidents will eventually occur. Effective management provides comprehensive safety training to supervisors and holds supervisors accountable for worker observance of rules and procedures.

7.5.10. Health surveillance

The BSS, in para. I.41 [1], state that "Employers and licensees shall make arrangements for appropriate health surveillance in accordance with the rules established by the Regulatory Authority." The primary purpose of health surveillance is to assess the initial and continuing fitness of employees for their intended tasks. Health surveillance programmes should be based on the general principles of occupational health. It should be rare for the radiation component of the working environment to significantly influence the decision about the fitness of a worker to undertake work with radiation, or to influence the general conditions of service (Ref. [39], para. 7.6). No specific health surveillance related to exposure to ionizing radiation is necessary for staff involved in the operation of a radiotherapy practice. Special investigations involving biological dosimetry and further extended diagnosis and medical treatment would only be necessary in the case of overexposed workers at doses much higher than the dose limits (e.g. 0.2–0.5 Sv or higher) (Ref. [39], para. 7.18).

Counselling should be available to workers such as women who are or may be pregnant, individual workers who have or may have been exposed substantially in excess of dose limits, and workers who may be worried about their radiation exposure. This is particularly necessary for women who are or may be pregnant, such as, for example, female technologists working in radiotherapy units and nurses working in brachytherapy wards.

7.5.11. Records

The BSS (para. I.44) indicate that [1] employers and licensees "shall maintain exposure records for each worker". The exposure records shall include information on the general nature of the work involving occupational exposure, information on doses, and the data upon which the dose assessments have been based; when a worker is or has been occupationally exposed while in the employment of more than one employer, information on the dates of employment with each employer and the doses, exposures and intakes in each such employment, and records of any doses due to emergency interventions or accidents, which shall be distinguished from doses during normal work.

Employers and licensees are to provide for access by workers to information in their own exposure records, and to give due care and attention to the maintenance of appropriate confidentiality of records.

7.6. PROTECTION AGAINST MEDICAL EXPOSURE

The detailed requirements given in Appendix II of the BSS [1] are applicable, in particular, to radiotherapy. In addition, IAEA Safety Guide RS-G-1.5 [42] describes strategies to involve organizations outside the regulatory framework, such as professional bodies, whose cooperation is essential to ensure compliance with the BSS [1] requirements for medical exposures. As an overall remark, it is important to note that the principles of justification and optimization of protection requirements also apply to medical exposure but not to dose limitation.

7.6.1. Responsibilities

With regard to responsibilities of registrants and licensees for medical exposure, the BSS [1] require that:

"II.1. Registrants and licensees shall ensure that:

- (a) No patient be administered a diagnostic or therapeutic medical exposure unless the exposure is prescribed by a medical practitioner;
- (b) Medical practitioners be assigned the primary task and obligation of ensuring overall patient protection and safety in the prescription of, and during the delivery of, medical exposure;
- (c) Medical and paramedical personnel be available as needed, and either be health professionals or have appropriate training adequately to discharge assigned tasks in the conduct of the diagnostic or therapeutic procedure that the medical practitioner prescribes;
- (d) For therapeutic uses of radiation (including teletherapy and brachytherapy), the calibration, dosimetry and quality assurance requirements of the Standards be conducted by or under the supervision of a qualified expert in radiotherapy physics."

7.6.2. Justification

Pursuant to para. II.4 of the BSS [1], justification of medical exposure is required:

"Medical exposures should be justified by weighting the diagnostic or therapeutic benefits they produce against the radiation detriment they might cause, taking into account the benefits and risks of available alternative techniques that do not involve medical exposure."

7.6.3. Optimization

Licensees of radiotherapy practices shall ensure that [1]:

- "(a) Exposure of normal tissue during radiotherapy be kept as low as reasonably achievable consistent with delivering the required dose to the planning target volume, and organ shielding be used when feasible and appropriate; (BSS para. II.18(a)).
- (b) Radiotherapeutic procedures causing exposure of the abdomen or pelvis of women who are pregnant or likely to be pregnant be avoided unless there are strong clinical indications; (BSS para. II.18(b)).
- (d) Any therapeutic procedure for pregnant women be planned to deliver the minimum dose to any embryo or foetus; (BSS para. II.18(d)).
- (e) The patient be informed of possible risks (BSS para. II.18 (e))".

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7.6.4. Calibration

Paragraph II.19 of the BSS [1] requires that:

"Registrants and licensees shall ensure that:

- (a) The calibration of sources used for medical exposure be traceable to a Standards dosimetry laboratory;
- (b) Radiotherapy equipment be calibrated in terms of radiation quality or energy and either absorbed dose or absorbed dose rate at a predefined distance under specified conditions, e.g. following the recommendations given in IAEA Technical Reports Series No. 277²⁰; ⁴

⁴ At the time of publication of the BSS, the IAEA code of practice based on air kerma in air was included in the requirements given in Technical Reports Series No. 277 [11]. More recent codes of practice based on standards of absorbed dose to water, such as those given in Technical Reports Series No. 398, were not available at that time. It is, however, obvious to extend the application of this BSS requirement to the up to date codes of practice.

(c) Sealed sources used for brachytherapy be calibrated in terms of activity, reference air kerma rate in air or absorbed dose rate in a specified medium, at a specified distance, for a specified reference date;

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(e) The calibrations be carried out at the time of commissioning a unit, after any maintenance procedure that may have an effect on the dosimetry and at intervals approved by the Regulatory Authority.

²⁰INTERNATIONAL ATOMIC ENERGY AGENCY, Absorbed Dose Determination for Photon and Electron Beams, Technical Reports Series No. 277, IAEA, Vienna (1987)."

7.6.5. Clinical dosimetry

Paragraph II.20 of the BSS [1] states that:

"Registrants and licensees shall ensure that the following items be determined and documented:

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- (b) For each patient treated with external beam radiotherapy equipment, the maximum and minimum absorbed doses to the planning target volume together with the absorbed dose to a relevant point such as the centre of the planning target volume, plus the dose to other relevant points selected by the medical practitioner prescribing the treatment;
- (c) In brachytherapeutic treatments performed with sealed sources, the absorbed doses at selected relevant points in each patient;

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(e) In all radiotherapeutic treatments, the absorbed doses to relevant organs."

7.6.6. Quality assurance for medical exposures

Paragraph II.22 of the BSS [1] requires that:

"Registrants and licensees, in addition to applying the relevant requirements for quality assurance specified elsewhere in the Standards, shall establish a comprehensive quality assurance programme for medical exposures with the participation of appropriately qualified experts in the relevant fields, such as radiophysics."

7.6.7. Investigation of accidental medical exposures

Paragraphs II.29 and II.30 of the BSS [1] state that:

"II.29. Registrants and licensees shall promptly investigate any of the following incidents:

- (a) Any therapeutic treatment delivered to either the wrong patient or the wrong tissue, or using the wrong pharmaceutical, or with a dose or dose fractionation differing substantially from the values prescribed by the medical practitioner or which may lead to undue acute secondary effects;
- (c) Any equipment failure, accident, error, mishap or other unusual occurrence with the potential for causing a patient exposure significantly different from that intended."

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"II.30. Registrants and licensees shall, with respect to any investigation required under para. II.29:

- (a) Calculate or estimate the doses received and their distribution within the patient;
- (b) Indicate the corrective measures required to prevent recurrence of such an incident;
- (c) Implement all the corrective measures that are under their own responsibility;
- (d) Submit to the Regulatory Authority, as soon as possible after the investigation or as otherwise specified by the Regulatory Authority, a written report which states the cause of the incident and includes

the information specified in (a) to (c), as relevant, and any other information required by the regulatory authority; and

(e) Inform the patient and his or her doctor about the incident."

7.7. PREVENTION OF ACCIDENTAL MEDICAL EXPOSURES

When developing a project for radiotherapy, the following issues have to be considered:

- (a) The great dependence of radiotherapy on human performance;
- (b) The large number of steps from prescription of a treatment to delivery of the radiation dose;
- (c) The fact that interaction and communication between staff from different professions are necessary in most of the steps;
- (d) The combination of sophisticated equipment with manual work.

IAEA Safety Report No. 17 [28] provides an overview of radiotherapy accidents. They are mostly caused by [28]:

- (a) Human mistakes at any of the radiotherapy steps (particularly severe and affecting many patients are errors in commissioning and calibration of beams and sources);
- (b) Communication errors (including poorly documented data regarding the treatment);
- (c) Misinterpretation of signals;
- (d) Failure to recognize an abnormal situation (training is oriented towards dealing with normal conditions when an abnormal situation occurs, it is rarely recognized early, before it becomes an accident);
- (e) Maintenance problems.

Human factors leading to accidents do not apply only to radiation emitting devices and sources, but also to TPSs.

When applying for assistance to develop a radiotherapy programme, sufficient defence in depth needs to be demonstrated and integrated into the radiotherapy quality assurance, in order to prevent human errors or equipment failures resulting in an accident. This implies:

(a) Redundant, independent procedures for safety critical steps (for example for calibration of beams, two independent persons should determine the absorbed dose);

- (b) Training on accident case studies to identify and deal with abnormal conditions (Ref. [28] provides a useful basis for such training);
- (c) Written and rehearsed procedures, including communication procedures and protocols;
- (d) A thorough maintenance strategy, with provisions to ensure that only personnel with training and certification from the manufacturer perform repairs;
- (e) Emergency planning to mitigate the consequences of a human error or equipment fault;
- (f) Arrangements for investigating and reporting accidental exposures as defined in paras II.29 and II.30 of the BSS [1], and for deriving and applying preventive and corrective measures, according to the results of the investigation.

7.8. PUBLIC EXPOSURES

The licensee is responsible for controlling public exposures resulting from a radiotherapy practice. Public exposure is controlled by proper design of shielding and, in large part, by ensuring that radiation sources are shielded and secured (e.g. located in a locked area), and that keys to the control panel are secured to prevent unauthorized access or use. Presence of members of the public in and near the radiotherapy department should be taken into account when designing the shielding of storage and treatment facilities.

7.9. SAFETY IN THE TRANSPORT OF RADIOACTIVE MATERIALS

It is a common arrangement that suppliers transport external beam sources and remote control brachytherapy sources under their own responsibility (under their own licence) until the source change has been completed and the transfer of ownership has been accomplished with the acceptance tests, while sources for manual brachytherapy are usually delivered directly to hospitals. In other cases, it is the licensee or a radiotherapy department who makes all the transport arrangements. The term 'licensee' in this section refers to the person responsible for the transport of the sources.

The licensee has to comply with the requirements of the IAEA Regulations for the Safe Transport of Radioactive Material [43] and/or any existing equivalent national legislation for all activities involving transport of radioactive sources. In the case of radiotherapy, this requirement applies to external beam radioactive sources and to brachytherapy sources.

7.10. EMERGENCY PLANS

The greatest hazard to staff, public and patients occurs when events do not follow accepted procedures. For such situations, there need to be well prepared emergency plans that are concise and easily followed, and these should be developed before the startup of a radiation treatment programme. The types of situations that need to be planned for are discussed below.

7.10.1. Lost sources

In the case of a lost source, it is critical that an up to date inventory exist so that it can be determined immediately which source(s) is (are) missing, what their type and activity are, when and where they were last known to be, and who last took possession of them.

The area where the sources were last known to be should be closed to entry and exit until a survey has been performed. This search needs to be performed with the most sensitive radiation detection (usually of the GM type) survey meter available.

7.10.2. Stuck sources

There should be emergency procedures posted at the treatment unit for this event. In general, the first steps are to use the source driving mechanism to return the source to the shielded position (external beam or HDR unit). If this is not immediately successful and there is a patient present, the patient must be removed from the radiation field and the area must be secured from further entry until the RPO is notified and takes control of the situation.

7.10.3. Contamination

Contamination may occur if radioactive material has spread outside its container or encapsulation. It is very important that the area be closed to further entry and that all those persons who were in the area remain to be surveyed and decontaminated if necessary. If there are windows or ventilation shafts, these should be closed and the RPO should take control of the situation.

Emergency procedures should be posted at the control console in the event that the radiation unit does not turn off. These procedures should deal with the safe evacuation of the patient from the room and securing the room from further entry until the appropriate experts have arrived. There should also be information on how to contact the responsible radiation safety individual in the event of an emergency.

7.10.4. Accidental exposures of patients

The BSS [1] requirements on investigation of accidental medical exposures have already been referred to above, including the reporting and corrective measures to be taken. Formal procedures need to be developed to report and deal with the situation upon detection of an exposure different than that intended.

	Appendix I
RESPONSIBILITI AND	RESPONSIBILITIES OF RADIATION ONCOLOGISTS AND MEDICAL PHYSICISTS
The responsibilities of radiation oncologists and medical physicists are set out in Table 7.	nd medical physicists are set out in Table 7.
TABLE 7. RESPONSIBILITIES OF RADIATIO (adapted from Ref. [17])	TABLE 7. RESPONSIBILITIES OF RADIATION ONCOLOGISTS AND MEDICAL PHYSICISTS (adapted from Ref. [17])
Radiation oncologists (physicians and medical doctors)	Radiotherapy medical physicists (clinical physicists and radiation oncology physicists)
The director of the radiation oncology department is responsible for the overall care of the patient.	To provide a high standard of clinical physics service and supervision.
	Responsibilities:
Responsibilities:	
 Consultation and clinical evaluation 	 Specification of therapy equipment (external beams, brachytherapy, simulators CT and imaging systems and TPSs) assuring its radiation safety
• Establishment of treatment plan, including dose	Facility design
prescription	Acceptance testing, commissioning and quality assurance (including
• Treatment execution, participation on a regular	calibration) of therapy equipment
basis	Measurement and analysis of beam data, and tabulation of beam data for
 On-treatment evaluations and patient monitoring 	clinical use
Treatment summary	Establishment of dose calculation procedures
• Follow-up and evaluation of the treatment	• Establishment of technical aspects of treatment planning and treatment
	procedures
	Supervision, evaluation and optimization of treatment planning

(adapted from Ref. [17]) (cont.)	
Radiation oncologists (physicians and medical doctors)	Radiotherapy medical physicists (clinical physicists and radiation oncology physicists)
•	• Establishment and supervision of quality assurance procedures in radio-
	therapy regarding delivery of the treatment, radiation safety, quality
	control and regulatory compliance
•	 Supervision of maintenance of therapy equipment

TABLE 7. RESPONSIBILITIES OF RADIATION ONCOLOGISTS AND MEDICAL PHYSICISTS

Appendix II

SPECIFICATIONS FOR TREATMENT SIMULATORS

II.1. TECHNICAL SPECIFICATIONS

All performance specifications and tests shall conform with the standards of the IEC for radiotherapy simulators [30–32], and of the ISO for radiation sources [33–35]. The specifications given are the minimum acceptable. For more advanced radiotherapy techniques, higher performance specifications may be desirable, and recommendations for these are given in brackets. It is an essential requirement that a simulator can simulate all the set-ups possible on the treatment machines. Where the rest of the equipment in a department has already been identified, specifications (e.g. the focus isocentre distance) can be tailored to the corresponding therapy equipment.

II.1.1. Gantries

The gantry should have the following characteristics:

- (a) Motorization of gantry with isocentric design;
- (b) A gantry rotation of $0-360^{\circ}$;
- (c) An X ray focus to isocentre distance of 80–120 cm (depending on the local equipment);
- (d) An isocentre height above floor level ≤ 130 cm;
- (e) An isocentre maximum sphere diameter of 3.0 mm (2.0 mm preferred);
- (f) Control of parameters inside the treatment room.

II.1.2. X ray housings and collimators

The X ray housing and collimator should meet the following requirements:

- (a) The X ray tube and housing should be with a rotating anode, even in fluoroscopy. There should be two foci.
- (b) The X ray beam should be collimated by a motorized diaphragm with both local and remote control.
- (c) The field should be defined by wires, independent of the X ray beam diaphragm, motorized and with both local and remote control.
- (d) The projection of the wires should be ≤ 2.5 mm at the isocentre.

- (e) The collimator rotation limits should be $\pm 100^{\circ}$ (manual and/or motorized rotation).
- (f) The optical distance indication range source-axis distance (SAD) should be SAD \pm 20 cm.
- (g) The maximum field size at the isocentre should be $\geq 30 \text{ cm} \times 30 \text{ cm}$ at 100 cm from the focus (40 cm × 40 cm preferred).
- (h) The minimum field size at the isocentre should be $\leq 5 \text{ cm} \times 5 \text{ cm} (3 \text{ cm} \times 3 \text{ cm preferred}).$
- (i) An asymmetric setting of the jaw positions is desirable.
- (j) The light/radiation field congruence should be ≤ 2 mm.
- (k) There should be a transparent shadow tray⁵.

II.1.3. Couch tables

Couch tables should meet the following requirements:

- (a) X ray transparency of the table top;
- (b) Isocentric rotation limits of $\pm 90^{\circ}$;
- (c) A patient lateral motion range of ± 20 cm;
- (d) Motorized vertical movement, with a minimum height of ≤ 80 cm and not less than 40 cm below the isocentre, and up to at least 3 cm above the isocentre;
- (e) A longitudinal range of \geq 70 cm;
- (f) Sag of table top of ≤ 5 mm with a patient of 80 kg.

II.1.4. Remote control consoles

Movement and light controls should be provided together with the appropriate X ray control switches: gantry, collimator, image intensifier and couch.

II.1.5. X ray generators

X ray generators should include:

- (a) Fluoro/radiography;
- (b) A 30 kW high frequency generator; otherwise \geq 50 kW;

⁵ The shadow tray should duplicate the geometry of the treatment machine and be able to bear the weight of the lead blocks used for shielding during treatment without distorting the isocentric stability.

(c) Radiography: 125 kVp and 300 mAs. Fluoroscopy: up to 15 mA.

II.1.6. Imaging systems

Imaging systems should include:

- (a) An image intensifier with a diameter of ≥ 23 cm;
- (b) Lateral and longitudinal movements of the image intensifier;
- (c) A maximum vertical source to input screen distance of \geq 175 cm;
- (d) A 35 cm \times 43 cm cassette film holder, including four cassettes;
- (e) A TV circuit and monitor TV.

II.1.7. Options and accessories

Options and accessories include:

- (a) Three lasers for patient centring;
- (b) A front pointer;
- (c) Anticollision devices.

II.2. SAFETY COMPLIANCE

Compliance with the safety requirements given in the BSS [1] and the standards of the IEC shall be substantiated by providing the purchaser of the equipment with a quotation of the results of type tests according to the IEC [32].

II.3. ACCOMPANYING DOCUMENTS

The accompanying documents shall comply with the BSS [1] and IEC standards. According to the BSS, Appendix II.1.3, performance specifications and operating and maintenance instructions shall be provided in a major world language, understandable to the users. The users are primarily RTTs and maintenance personnel, but also physicists and radiation oncologists may use the equipment.

The documentation shall include:

- (a) Performance specifications;
- (b) Operating instructions;

- (c) Installation documents, including data to calculate shielding, masses, forces and momenta, ventilation shafts and conduits for cables, and fittings to anchor the equipment and couch during construction;
- (d) Preventive maintenance instructions and a service manual.

II.4. ACCEPTANCE TESTS

An acceptance test to comply with the present specifications will be performed by an expert in medical radiation physics.

A satisfactory result of the acceptance test is a precondition for payment.

II.5. WARRANTY AND SERVICE

Hospital administrators typically require warranty and service terms similar to those listed here, to prevent lengthy downtimes that may have an adverse impact on patient treatments and/or lead to accidents:

- (a) The delivery time should not be longer than four months.
- (b) The time needed for installation by the manufacturer should be specified. This installation shall be included in the price.
- (c) The warranty should be one year, starting after formal acceptance.
- (d) The maintenance and service conditions (preconditions for the purchase of equipment) include:
 - (i) Training for in-house engineers, in the local language, should be included in the quotation; the duration, location, programme, etc., should be specified (first line service).
 - (ii) Service by the manufacturer at national or regional level should be available; the address of the nearest service location, and the number and qualifications of the maintenance engineers at that location should be indicated (second line service).
 - (iii) When the above fails to solve the service request, an engineer should be available from the factory in less than one week (third line service).
 - (iv) Permanent service support should be available, with an immediate specialized response by telephone (a telephone service) and/or email; consultation for repair and maintenance should be in a language understandable to the user (BSS) [1].
 - (v) A spare parts kit should be included. Specify which spare parts are needed.

- (vi) Service rates and conditions should be specified: price per hour, per diem, response time, etc.
- (vii) Maintenance contracts should be availabile: up-time⁶ (≥95%), with acceptance of penalties for late delivery of service, extended installations or periods of initial non-performance according to equipment specifications.
- (viii) Training of staff (physicians, physicists and operators) in the use of the machine should be available.

II.6. GENERAL REMARKS

The equipment quoted in the bid will be supplied with all the interconnection devices necessary for a correct and total functioning in the country of destination.

II.7. ADDITIONAL REQUIREMENTS FOR MULTILEAF COLLIMATORS

If a department is equipped with MLCs on its accelerators, it is important that the simulator should be equipped to plan for these devices. Some method of displaying the intended leaf positions superimposed on the radiographic image should be provided. (This can be through computer generated graphics on the image monitor.) It will also be necessary to have a method of transmitting these data electronically to the treatment machine.

⁶ Up-time is operation without operational breaks for equipment failures and repair (downtime) [1].

Appendix III

EQUIPMENT REQUIREMENTS FOR COMPUTERIZED TREATMENT PLANNING SYSTEMS

III.1. HARDWARE

The personal computer (PC) should be equipped with:

- (a) Screen coordinated positioning (joystick, mouse and a light pen);
- (b) A colour display monitor for high resolution presentation of graphics (matrix $\ge 256 \times 256$) and multipresentation (text and images).

The data input/output (I/O) devices require:

- (a) A digitizer for image size $40 \text{ cm} \times 50 \text{ cm}$ or greater;
- (b) A resolution better than 0.5 mm;
- (c) A printer.

A plotter should:

- (a) Be of DIN A3 format or have continuous paper 40 cm wide;
- (b) Be at least four colour;
- (c) Have a resolution better than 0.5 mm;
- (d) Have a repeoducibility better than 0.5 mm.

III.2. SOFTWARE

If absolute dose calculations (time) are performed, the system shall provide a detailed list of all corrections (wedges, tray, decay, etc.) and physical constants (gamma factors, half-life, etc.). The minimum requirements are:

(a) For external therapy:
 (i) 2.5-D⁷ calculations for ⁶⁰Co beams;

⁷ As opposed to 3-D, 2.5-D means that calculations are performed in 2-D, ignoring scattering from adjacent structures/CT slices, whereas the display can still be done in 3-D.

- (ii) Fixed source-skin distance (SSD) and isocentric calculations;
- (iii) Calculation with at least six simultaneous external beams;
- (iv) Irregular field calculations;
- (v) Corrections for obliquity and distance;
- (vi) Correction for tissue inhomogeneity;
- (vii) Wedge calculation;
- (viii) Ability to modify contours to accommodate boluses.
- (b) For brachytherapy:
 - (i) Source position reconstruction from X ray film;
 - (ii) Cs-137, 192 Ir and 125 I sources;
 - (iii) Correction for source filtration;
 - (iv) Support for the most common gynaecological applicators (Henschke, Fletcher–Suit, Manchester and Delouche, depending on equipment available in the hospital);
 - (v) Calculation for point and line sources, as well as combinations of these;
 - (vi) Source rotation display.
- (c) For data input:
 - (i) Manually acquired patient contours;
 - (ii) User radiation beam data (possibility for extracting data tables and plotting distributions);
 - (iii) Source position and anatomical landmarks for brachytherapy.
- (d) For data output:
 - (i) Real size plots.

III.3. ADDITIONAL REQUIREMENTS FOR LINEAR ACCELERATORS AND 3-D PLANNING

Linear accelerators and 3-D planning need:

- (a) Computer tomography image input (e.g. via DICOM3);
- (b) Three dimensional dose calculations and display algorithms (or at least 2.5-D) for high energy photon and electron beams;
- (c) Combination of photon and electron beams;
- (d) Combinations of external beams and brachytherapy;
- (e) Arc therapy treatment planning;
- (f) Output for customized blocks;
- (g) Output plots at varying scales;
- (h) Selection of bolus density;
- (i) Support for dynamic and automatic wedges (depending on the linacs in use);

(j) Support for MLC planning (if available in the hospital).

III.4. COMPLIANCE WITH STANDARDS AND SAFETY

Compliance with IEC standards on TPSs [44] is required, as well as:

- (a) Certification by the Food and Drug Administration (FDA) in the USA; or
- (b) Documented quality assurance procedures (e.g. those given in Refs [17, 45]) verified by a quality audit group independent of manufacturer and published in peer review literature.

III.5. ACCOMPANYING DOCUMENTS

The accompanying documents shall comply with the BSS [1] as well as the IEC. According to the BSS, Appendix II.13(b), "performance specifications and operating and maintenance instructions ... shall be provided in a major world language understandable to the users". Potential users of TPSs are medical physicists, radiation oncologists, dosimetrists and engineers.

The documentation shall include:

- (a) Performance specifications;
- (b) Operating instructions;
- (c) Details on the algorithms used for calculations;
- (d) Trouble shooting procedures;
- (e) Preventive maintenance and service manuals;
- (f) Commitment by the supplier that any changes in software or hardware will be reflected in a simultaneously updated manual.

III.6. ACCEPTANCE TEST

A medical physics expert shall perform an acceptance test following Ref. [45] verifying compliance with the present specifications, and a satisfactory result of the acceptance test shall be a precondition for payment.

III.7. WARRANTY AND SERVICE

Hospital administrators typically require warranty and service terms similar to those listed here, to prevent lengthy downtimes that may have an adverse impact on patient treatments and/or lead to accidents:

- (a) The delivery time should not be longer than four months.
- (b) The time needed for installation by the manufacturer should be specified. This installation time shall be included in the price.
- (c) The warranty should be for a period of one year, starting after formal definite acceptance.
- (d) Maintenance and service (preconditions for the purchase of equipment):
 - (i) Service by the manufacturer should be available at national or regional level (the address of the nearest service location, and the number and qualifications of maintenance engineers at that location should be indicated).
 - (ii) When the above fails to solve the service request, availability of an engineer from the factory in less than one week is necessary.
- (e) Service rates and conditions (price per hour, per diem and response time) should be specified.
- (f) Upgrades of purchased items of software should be at no cost for at least three years.
- (g) Training of staff (physicians, physicists and operators) in the use of the system should be available.
- (h) There should be permanent service support by immediate qualified response by phone, fax or email for repair and maintenance.
- (i) Consumables should be available locally.
- (j) A spare parts kit should be included in the price. Specify which spare parts are needed.

III.8. GENERAL REMARKS

The equipment quoted in the bid will be supplied with all interconnection devices necessary for correct and total functioning in the country of destination.

III.9. CONSIDERATIONS IN INTERPRETING THE SPECIFICATIONS

Reference is made to 3-D and 2-D dose calculations. A 2-D dose calculation allows a dose to be calculated on one transverse slice with no ability to consider other transverse slices in the same data set. Even for the simplest radiotherapy this limitation can be restrictive. It is therefore recommended that, as a minimum, a 2.5-D system be purchased. Such systems are able to load a full 3-D data set, allowing the user to display the dose distribution on multiple parallel slices. However, the effects of inhomogeneities and missing tissue on neighbouring slices are not considered. A fully 3-D calculation takes into account the effect of scattering from adjacent transverse slices.

Appendix IV

SPECIFICATIONS FOR ORTHOVOLTAGE UNITS

IV.1. TECHNICAL SPECIFICATIONS

All performance specifications and tests shall conform with the standards of the IEC for therapy X ray generators [36] and of the ISO for radiation sources [33–35].

IV.1.1. Support systems

The ceiling or floor mounted support system for the X ray tube assembly should permit movement in all three orthogonal planes, together with rotation about two orthogonal horizontal axes. If the movements are motorized, provision shall be made for a motion inactuator.

IV.1.2. Couch tables

There should be a wheeled patient support table (preferably with height adjustment), and the table surface should be non-absorbent.

IV.1.3. Control consoles

The control console should include:

- (a) A dual timer and a timer/ionization chamber or dual ionization chamber dose control system;
- (b) Selectable kilovoltage settings interlocked to filter interlocks on the treatment head.

IV.1.4. X ray generators

The X ray generator system should include:

- (a) A three phase X ray generator with a voltage regulator;
- (b) A generator to operate at a range of kilovoltages up to about 300 kV.

IV.1.5. Options and accessories

Options and accessories include (Section IV.7):

- (a) A range of filters appropriate to the available kilovoltages;
- (b) A range of applicators.

IV.2. SAFETY COMPLIANCE

Compliance with the safety requirements in the BSS [1] and the standards of the IEC shall be substantiated by providing the results of type tests according to the IEC [36].

IV.3. ACCOMPANYING DOCUMENTS

The accompanying documents shall comply with the BSS and IEC standards. According to the BSS [1], Appendix II.13, "performance specifications and operating and maintenance instructions ... shall be provided in a major world language understandable to the users." The users are primarily RTTs and maintenance personnel, but physicists and radiation oncologists may also use the equipment.

The documentation shall include:

- (a) Performance specifications;
- (b) Operating instructions;
- (c) Installation documents, including data to calculate shielding, masses, forces and momenta, ventilation shafts and conduits for cables, and fittings to anchor the equipment and couch during construction;
- (d) Preventive maintenance instructions and a service manual.

IV.4. ACCEPTANCE TESTS

A medical physics expert shall perform an acceptance test verifying compliance with the present specifications, and a satisfactory result of the acceptance test is a precondition for payment.

IV.5. WARRANTY AND SERVICE

Hospital administrators typically require warranty and service terms similar to those listed here, to prevent lengthy downtimes that may have an adverse impact on patient treatments and or lead to accidents.

- (a) The delivery time should be no longer than four months.
- (b) The time needed for installation by the manufacturer should be specified. Installation shall be included in the price.
- (c) The warranty should be for one year starting after formal acceptance.
- (d) Maintenance and service (preconditions for the purchase of equipment):
 - (i) Training for in-house engineers, in the local language, should be included in the quotation, with, for example, the location, duration and programme (first line service) being specified.
 - (ii) Service by the manufacturer at national or regional level should be available; the address of the nearest service location, as well as the number and qualifications of the maintenance engineers at that location (second line service), should be indicated.
 - (iii) When the above fails to solve the service request, an engineer from the factory should be available in less than one week (third line service).
 - (iv) Permanent service support by an immediate specialized response by telephone and/or by email; consultation for repair and maintenance in a language understandable to the user (BSS) [1] should be available.
 - (v) A spare parts kit should be included. Specify which spare parts are needed.
 - (vi) Service rates and conditions, the cost per hour and per diem, the response time, etc., should be specified.
- (e) Maintenance contracts should be available: up-time (≥95%), with acceptance of penalties for late delivery of service, extended installations or periods of initial non-performance according to equipment specifications.
- (f) Training of staff (physicians, physicists and operators) in the use of the machine should be available.

IV.6. GENERAL REMARKS

The equipment quoted in the bid will be supplied with all interconnection devices necessary for a correct and total functioning in the country of destination.

IV.7. CONSIDERATIONS IN INTERPRETATION OF SPECIFICATIONS

IV.7.1. Generating potential and filters

The depth dose of an orthovoltage machine depends on both the generating potential used and the filtration. The penetration is specified in terms of the half-value layer (HVL) of aluminium or copper, depending on the energy. For a given kilovoltage setting, it is possible to have more than one filter yielding more than one HVL. Generators up to 150 kV will provide HVLs of up to 8 mm of aluminium, while generators up to 300 kV can provide HVLs up to 3 mm of copper. Because a generator operating with the wrong combination of filter and kilovoltage can deliver a dose rate differing widely from that intended, it is essential that the filter/generating potential combinations be interlocked to each other. Machines will usually be supplied with a wide range of filters associated with a wide range of generating potentials. It is advisable to select a small subset from these (e.g. 50, 90, 140 and 250 kV) and to place the other filters where they cannot be used in error.

IV.7.2. Applicators

A range of applicators is usually provided as standard. These are often at two different source–skin distances: a choice of two from 15, 25 and 30 cm, which are common treating distances for generating kilovoltages up to 150 kV, and 50 cm for higher energies. The dose rate from a low kilovoltage machine will be less than that from a high kilovoltage machine, and, for this reason, shorter applicators are usually used for lower kilovoltages. It is recommended that applicators of the same size but with different treating distances are not used on the same machine. This is because it is easy to confuse applicators, and treating at 15 cm distance with a dose rate measured at 25 cm will result in a 278% overdose. It is not necessary to have a different applicator for every field size required, as it is possible to use lead cut-outs to reduce the area treated by a particular applicator. Typical applicator requirements are shown in Table 8.

TABLE 8. TYPICAL APPLICATORS WITH THEIR CLINICAL USES

SSD of 50 cm	
8 cm × 20 cm	Spinal and long bone metastases
$20 \text{ cm} \times 20 \text{ cm}$	Brain metastases
$20 \text{ cm} \times 10 \text{ cm}$	Fungating breast lesions
$10 \text{ cm} \times 10 \text{ cm}$	General use
$6 \text{ cm} \times 6 \text{ cm}$	General use
Short SSDs	
2 cm diameter	Skin
4 cm diameter	Skin
$4 \text{ cm} \times 10 \text{ cm}$	Keloids, lip

Appendix V

SPECIFICATIONS FOR ⁶⁰Co TELETHERAPY UNITS AND THEIR RADIATION SOURCES

V.1. TECHNICAL SPECIFICATIONS

All performance specifications and tests shall conform with the standards of the IEC for equipment [30, 37] and those of the ISO for radiation sources [33–35].

V.1.1. Gantries and treatment heads

Gantries and treatment heads should have the following characteristics:

- (a) A gantry motorized with isocentric design;
- (b) A gantry rotation of $0-360^{\circ}$;
- (c) A source isocentre distance $SAD \ge 80$ cm;
- (d) An isocentre height above floor level ≤ 130 cm;
- (e) An isocentre clearance (with devices inserted) \geq 15 cm;
- (f) An isocentre maximum sphere ≤ 3.0 mm diameter;
- (g) Hand-held control of parameters inside the treatment room;
- (h) Collimator:
 - (i) Collimator jaw indication, either mechanical or electrical;
 - (ii) Collimator rotation at least ±100°, with manual and/or motorized rotation;
- (i) An optical distance indication range SAD ± 20 cm, with mechanical backup;
- (j) Secondary collimators (trimmers) to reduce penumbra;
- (k) A transparent shadow tray for secondary collimation (blocks) to support blocks up to 20 kg. To allow treatment at any angle with blocks, it shall be possible to fix the blocking tray to the collimator without the use of hand tools. A standard set of blocks shall be supplied. It shall be possible to use blocks and wedges simultaneously. The block tray should be interlocked to the console.

V.1.2. Radiation field

The radiation field should have the following characteristics:

- (a) Maximum field size at isocentre ≥ 30 cm × 30 cm (50% isodose level) (Section V.7.4);
- (b) Minimum field size at isocentre $\leq 5 \text{ cm} \times 5 \text{ cm} (50\% \text{ isodose level});$
- (c) Symmetry better than $\pm 3\%$;
- (d) Uniformity of $\pm 3\%$ over 80% of the field;
- (e) Light/radiation field congruence ≤ 2 mm;
- (f) Source diameter ≤ 2.5 cm;
- (g) Achievable penumbra ≤ 1 cm, either with trimmers or blocks;
- (h) Output ≥ 1.5 Gy/min at isocentre (at a depth of d_{max}) for a 10 cm \times 10 cm field during the acceptance test;
- (i) Four wedge angles (15, 30, 45 and 60°) available for 15 cm in the wedged direction and 18 cm in the perpendicular direction. Insertion of wedges must not restrict the use of secondary collimation. The maximum field size covered by the wedge should be specified on the wedge. Wedges shall be fixed for collimator and gantry rotation. It shall be possible to use blocks and wedges simultaneously. Interlocks must be provided so that the operator has to positively select the correct wedge.

V.1.3. Couch tables

Couch tables should have the following characteristics:

- (a) The table top should have a transparent window exceeding the maximum field size.
- (b) The limits of the angle of rotation of the top should be $\pm 180^{\circ}$.
- (c) The isocentric rotation limits should be $\pm 90^{\circ}$.
- (d) The range of patient lateral motion should be ± 20 cm (necessary for treatment of lateral fields without moving the patient, irrespective of the couch, from the initial position). This shall be achieved either by moving the table top laterally or by a combination of isocentric and column rotation.
- (e) Vertical movement should be motorized, with a minimum height ≤80 cm; not less than 40 cm below the isocentre and at least up to 3 cm above the isocentre.
- (f) The longitudinal range should be ≥ 70 cm.
- (g) The sag of the table top should be ≤ 5 mm with a patient of 80 kg weight.

V.1.4. Control console

The control console should have a general on/off key.

V.1.5. Options and accessories

Options and accessories include:

- (a) A counterweight (or beamstopper only if the room design is inadequate);
- (b) Independent head rotation on arm (range: $\pm 90^{\circ}$) (Section V.7.5);
- (c) A couch table with centred spine section;
- (d) An area monitor with an acoustic/optical signal of radiation;
- (e) Three lasers for patient centring (two cross and one sagittal);
- (f) A 35 cm \times 43 cm cassette holder for portal films, including four cassettes;
- (g) A closed circuit TV^8 or window;
- (h) Immobilization devices for arms, legs and head;
- (i) A backpointer;
- (j) Intercommunication with the patient (two stations).

V.2. SAFETY COMPLIANCE

Compliance with the BSS safety requirements [1] and the IEC standards shall be substantiated by providing the results of type tests according to Ref. [37].

V.3. ACCOMPANYING DOCUMENTS

The accompanying documents shall comply with the BSS [1] and IEC standards [30, 37]. According to the BSS, Appendix II.13, "performance specifications and operating and maintenance instructions ... shall be provided in a major world language understandable to the users." The users of equipment are primarily RTTs and maintenance personnel, but also physicists and radiation oncologists.

The documentation shall include:

- (a) Performance specifications;
- (b) Operating instructions;

⁸ Two cameras, one of which has a pan, tilt and zoom capability.

- (c) Installation documents, including data to calculate shielding, masses, forces and momenta, ventilation shafts and conduits for cables, and fittings to anchor the equipment and couch during construction;
- (d) Preventive maintenance instructions and a service manual;
- (e) Isodose charts.

V.4. ACCEPTANCE TESTS

A medical physics expert shall perform an acceptance test verifying compliance with the present specifications, and a satisfactory result of the acceptance test is a precondition for payment.

V.5. WARRANTY AND SERVICE

Hospital administrators typically require warranty and service terms similar to those listed here, to prevent lengthy downtimes that may have an adverse impact on patient treatments and/or lead to accidents:

- (a) The delivery time should not be longer than four months.
- (b) The time needed for installation by the manufacturer should be specified. Installation shall be included in the price.
- (c) The warranty should be for one year starting after formal acceptance.
- (d) Maintenance and service (preconditions for the purchase of equipment):
 - (i) Training for in-house engineers, in the local language, should be included in the quotation; the duration, location and programme, etc., should be specified (first line service).
 - (ii) Service by the manufacturer should be available at national or regional level; the address of the nearest service location, and the number and qualifications of the maintenance engineers at that location, should be indicated (second line service).
 - (iii) When the above fails to solve a request for service, an engineer should be available from the factory in less than one week (third line service).
 - (iv) There should be permanent service support by an immediate specialized response by telephone and/or email; consultation for repair and maintenance should be in a language understandable to the user (BSS) [1].
 - (v) A spare parts kit should be included. Specify which spare parts are needed.

- (vi) Service rates and conditions, including cost per hour and per diem, and response time, should be specified.
- (vii) Maintenance contracts should be available with an up-time $\ge 95\%$ and acceptance of penalties for late delivery of service, extended installation periods or periods of initial non-performance, according to the specifications of the equipment.
- (viii) The cost of source replacement should include source replacement and the cost of removal of the old source.
 - (ix) The procedure for source exchange shall not require more than 24 hours, excluding the acceptance test and quality assurance.
 - (x) Training of staff (physicians, physicists and operators) in the use of the machine should be included.

V.6. GENERAL REMARKS

The equipment quoted in the bid will be supplied with all interconnection devices necessary for a correct and total functioning in the country of destination.

V.7. CONSIDERATIONS IN INTERPRETING THE SPECIFICATIONS

V.7.1. Infrastucture requirements

Cobalt-60 units require minimal infrastructure. The electrical supply requirements are minimal and the units can be operated using an uninterruptible power supply for up to 30 min.

V.7.2. Source-axis distance and isocentre clearance

Source–axis distances of 80 and 100 cm are commonly available. A distance of 80 cm has the advantage that for a given source the dose rate will be about 1.5 times greater. On the other hand, a distance of 100 cm has the advantage that the distance between the front of the machine and the isocentre will be greater, allowing easier access to the patient, and the beam will be less divergent. Further discussion of this topic can be found in Appendix VII.1.

V.7.3. Penumbra trimmers

Penumbra trimmers can be used to reduce the penumbra. There are, however, drawbacks to their use in terms of the conflict with accessory mounts. Customized blocks also have the effect of reducing the penumbra and are an excellent alternative. In addition, it is important that careful quality control be carried out of the alignment of the trimmers with the principal collimators, for otherwise they may cause a less satisfactory penumbra.

V.7.4. Maximum and minimum field sizes

A limit of 30 cm \times 30 cm can prove restrictive in clinical use. Where a 100 cm SSD machine is specified, it will be possible to specify 40 cm \times 40 cm as for a linac. Fields smaller than 5 cm \times 5 cm may also be required; however, it is not advisable to use fields smaller than 4 cm \times 4 cm with a ⁶⁰Co unit. If necessary, small field sizes can be achieved with blocks. Large fields are especially necessary for spinal fields for cranio-spinal irradiation, and for mantle and inverted Y treatments.

V.7.5. Independent head rotation

Independent head rotation on the gantry (swivel) is of little clinical use. For example, it may be used for breast tangential fields, but a central beam block or asymmetric jaws are alternatives. However, it may be required for the service mode and source exchange. In this case, it is essential that there be a mechanical stopper at the zero position, to ensure that isocentric accuracy is maintained. Head tilt now has no clinical indications.

V.7.6. Wedges

The dimensions specified above (i.e. $15 \text{ cm} \times 18 \text{ cm}$) are required for breast treatments. Ideally, the unwedged dimension should cover the entire field. The maximum field size and the wedge angle should be clearly marked on the wedge. Because a wedge reduces the dose rate, it is common practice with ⁶⁰Co units to have multiple wedges for different field sizes, so that for small fields the reduction in dose rate is minimized. Facilities should be provided to interlock the wedge system to the field size, so that for a given field size only one wedge can be used and the maximum field size is not exceeded. Another technique is to lock the wedge to one of the jaws so that as the field size is increased the minimum thickness of wedge is used. In this event, output will

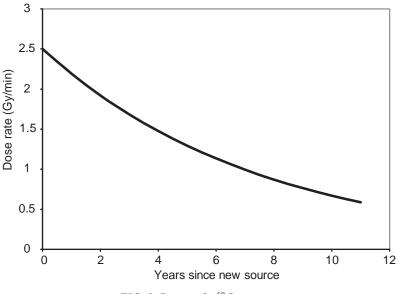


FIG. 3. Decay of a ⁶⁰Co source.

change rapidly with field size, and care must be taken that this is properly accounted for in dose calculations.

V.7.7. Source size and activity

There are various source sizes available: 15, 17, 18, 20 and 22 mm in diameter. Smaller sources with the same activity are more expensive but provide a smaller penumbra. To achieve higher activities, larger sources will be required.

A 60 Co source decays with a half-life of 5.26 years. The effect of this is shown in Fig. 3, where the reference dose rate is shown starting from a reference dose rate of 2.5 Gy/min.

It is important to realize that there are different ways to specify source activity. Source strength of the treatment machine may be specified in TBq (or Ci)⁹. The important specification is the output of the source in the equipment head at 1 m, expressed as the exposure rate at 1 m, RMM. The exposure rate may also be measured free in air in a test cell, and also expressed in RMM. All three figures should be stated by the manufacturer. The dose rate free in air at

⁹ Note that 1 TBq = 27 Ci.

TABLE 9. EXAMPLE OF RELATIONSHIP OF ACTIVITY AND DOSERATE MEASUREMENTS FOR A Co-60 UNIT

Quantity		
Quoted activity	355.2 TBq (9601 Ci)	
Quoted exposure rate at 1 m	Free in air: 152.5 RMM	In head: 176.6 RMM
Measured output for a 10×10 cm ² field and depth of dose maximum	At 80 cm SSD: 257.6 cGy/min (measured)	At 100 cm SSD: 167.0 cGy/min (calculated)

1 m (specified in cGy/min at 1 m) will be approximately 15% higher, which corresponds to one year's decay.

The maximum activity in TBq will be limited by the design of the ⁶⁰Co unit head, and it is possible to obtain sources with higher outputs for the same activity.

Reference [37] stipulates a dose rate at the isocentre > 1.5 Gy/min for a $10 \text{ cm} \times 10 \text{ cm}$ field size.

Table 9 gives an example of the relationship between activity measurements and dose rate measurements for a particular 80 cm SAD 60 Co unit. (The data should not be used in place of dose measurements, but may be a useful guide to what might be expected.)

V.7.8. Source replacement costs

When a 60 Co machine is purchased, provisions should be made for source replacement and disposal of the old source at regular intervals. It is recommended that the minimum reference dose rate for a 60 Co beam should never be allowed to fall below 0.4 Gy/min for a 10 cm × 10 cm field at the depth of dose maximum with the phantom surface at the isocentre. Safe practice requires inspection and servicing of the parts of the machine close to the source at, at most, five year intervals, so there will probably be a requirement to inspect the source before this dose rate is reached, for safety reasons. The five year service requires removal of the source into a suitable source container. A licensed source handler must perform this procedure. This may be an appropriate moment to change the source. Disposal of the source to an approved storage site must be arranged as part of the source change procedure. Significant overexposures leading to death of members of the public have resulted from inappropriate disposal arrangements [26]. The source change

procedure, including the required service to the head and recommissioning of the ⁶⁰Co unit, will take approximately one week. From one country to another, it is striking that the costs of ⁶⁰Co sources can vary by a factor of more than ten. Low costs are found in countries that supply locally produced sources or reprocessed ones, but high costs are difficult to explain. An international supplier of ⁶⁰Co sources provided current (2005) list prices. These varied from US \$250 to over US \$300 per TBq, dependent on source activity and source diameter.

V.7.9. Decommissioning

Decommissioning is a special problem for ⁶⁰Co units, in respect of both the radioactive source and any depleted uranium used in the construction of the head. The licensee is responsible for safe decommissioning of machines according to the national safety regulations. The component of the purchase contract relating to the source shall include source removal and disposal. In the case of future bankruptcy of a company, a bank warranty can be a safety measure, which means that a bank account is opened at purchase for the decommissioning could involve substantial costs (i.e. at least US \$20 000–30 000), depending on the local situation. The company and the carriers selected for the decommissioning and source removal/disposal must be licensed for handling nuclear materials.

Appendix VI

SPECIFICATIONS FOR LINEAR ACCELERATORS

VI.1. TECHNICAL SPECIFICATIONS

All performance specifications and tests shall conform with the standards for equipment of the IEC [30, 38]. The specifications given are the minimum acceptable. For more advanced radiotherapy, higher performance specifications are desirable and recommendations for these are given in the following in brackets.

VI.1.1. Gantries and treatment heads

The gantry and treatment head should have the following characteristics:

- (a) A gantry motorized with isocentric design;
- (b) A gantry rotation of $\pm 190^{\circ}$;
- (c) A source–isocentre distance (SAD) of 100 cm;
- (d) An isocentre height above floor level of ≤ 135 cm;
- (e) Isocentre clearance (with devices inserted) \ge 30 cm;
- (f) Isocentre maximum sphere ≤ 2.0 mm in diameter;
- (g) Hand-held control of parameters inside the treatment room;
- (h) A collimator with:
 - (i) Collimator jaw indication either mechanical or electrical with mechanical backup;
 - (ii) Collimator rotation at least $\pm 100^{\circ}$ with motorized rotation;
- (i) Optical distance indication range: $SAD \pm 20$ cm, with mechanical backup;
- (j) A transparent shadow tray for secondary collimation (blocks) to support blocks up to 20 kg. To allow treatment at any angle with blocks, it shall be possible to fix the blocking tray to the collimator without use of hand tools. A standard set of blocks shall be supplied. It shall be possible to use blocks and wedges simultaneously.

VI.1.2. Photon radiation field

The photon radiation field should have the following characteristics:

(a) The single photon energy should be equivalent to 6 MV (Section VI.8).

- (b) The maximum field size at the isocentre should be $\ge 40 \text{ cm} \times 40 \text{ cm} (50\% \text{ isodose level}).$
- (c) The minimum field size at the isocentre should be ≤ 4 cm × 4 cm (50% isodose level) (3 cm × 3 cm is preferred).
- (d) Symmetry should be to better than $\pm 3\%$.
- (e) The uniformity should be to $\pm 3\%$ over 80% of the field.
- (f) The light/radiation field congruence should be ≤ 2 mm.
- (g) A penumbra ≤ 8 mm should be achievable.
- (h) The output should be variable from 0.5 Gy/min to more than 3 Gy/min at the isocentre (at a depth of d_{max}) for a 10 cm × 10 cm field.
- (i) Nominal wedge angles of 15, 30, 45 and 60° must be available. An extended set of wedge angles (achievable as a single beam) would be preferred. The wedged field size should be at least 20 cm (w) × 30 cm. (Coverage of the full field size in the unwedged direction is preferred.) Insertion of wedges must not restrict the use of secondary collimation. The maximum field size covered by the wedge must be interlocked to the machine. Wedges shall be fixed for rotation of collimator and gantry. It shall be possible to use blocks and wedges simultaneously. Ideally, wedges should be selectable from outside the treatment room either using a motorized wedge or a 'dynamic wedge' created by jaw movements.

VI.1.3. Dose monitoring

The dose monitoring equipment should include the following:

- (a) A dual ionization chamber system with independently monitored high voltage supply;
- (b) Interlocks to detect dose rate differences between the two channels;
- (c) A high dose rate interlock to prevent an excess dose rate;
- (d) An independent backup timer.

VI.1.4. Couch tables

For the couch table:

- (a) The table top should have a transparent window up to the maximum field size.
- (b) The angular rotation limits of the table top should be $\pm 180^{\circ}$.
- (c) The isocentric rotation limits should be $\pm 90^{\circ}$.
- (d) The lateral motion range of the patient should be ±20 cm (necessary for treatment of lateral fields without moving the patient, from initial

positioning with respect to the couch). This shall be achieved either by moving the table top laterally or by a combination of isocentric and column rotations.

- (e) Vertical movement should be motorized, with a minimum height of ≤ 80 cm but not less than 40 cm below the isocentre, and at least up to 3 cm above the isocentre.
- (f) The longitudinal range should be ≥ 70 cm.
- (g) Table top sag should be ≤ 5 mm with a patient of 80 kg (≤ 3 mm is preferred).

VI.1.5. Control consoles

Control consoles should have a general on/off key.

VI.1.6. Options and accessories

Options and accessories should include:

- (a) A counterweight or a beamstopper;
- (b) A couch table with a centred spine section;
- (c) An acoustic or optical signal for the radiation dose rate;
- (d) Three lasers for patient centring;
- (e) A 35 cm \times 43 cm cassette holder for portal films, including four cassettes;
- (f) A closed circuit TV;
- (g) Immobilization devices for arms, legs and head;
- (h) A backpointer preferably optical;
- (i) An intercommunication device with the patient (two stations);
- (j) Connectivity to an R&V system;
- (k) The accelerator should have protection to avoid collisions with the patient where this could be hazardous to the patient, and collisions with other parts of the accelerator where this could lead to damage or interruption of dynamic treatments.

VI.2. SAFETY COMPLIANCE

Compliance with the safety requirements in the BSS [1] and the standards of the IEC shall be substantiated by providing the results of type tests according to Ref. [38] along with the quotation.

VI.3. ACCOMPANYING DOCUMENTS

The accompanying documents shall comply with the BSS [1] and the appropriate IEC standards [30, 38]. According to the BSS [1], Appendix II.13, "performance specifications and operating and maintenance instructions ... shall be provided in a major world language understandable to the users". The users are primarily RTTs and maintenance personnel, but physicists and radiation oncologists may also use this equipment.

The documentation shall include:

- (a) Performance specifications;
- (b) Operating instructions;
- (c) Installation documentation including data to calculate shielding, masses, forces and momenta, ventilation shafts and conduits for cables, and fittings to anchor the equipment and couch during construction;
- (d) Preventive maintenance instructions and service manual;
- (e) Isodose charts.

VI.4. ACCEPTANCE TESTS

A medical physics expert shall perform acceptance tests verifying compliance with the present specifications, and a satisfactory result of the acceptance test is a precondition for payment.

VI.5. WARRANTY AND SERVICE

Hospital administrators typically require warranty and service terms similar to those listed here, to prevent lengthy downtimes that may have an adverse impact on patient treatments and/or lead to accidents:

- (a) The delivery time should be no longer than four months;
- (b) The time needed for installation by the manufacturer should be specified. This installation shall be included in the price.
- (c) The warranty should be one year, starting after formal acceptance.
- (d) Maintenance and service (preconditions for the purchase of equipment):
 - (i) Training for in-house engineers, in the local language, should be included in the quotation; the duration, location, programme, etc., should be specified (first line service).

- (ii) Service by the manufacturer at national or regional level should be available; the address of the nearest service location, and the number and qualifications of the maintenance engineers at that location, should be indicated (second line service).
- (iii) When the above fails to solve a request for service, an engineer from the factory should be available in less than one week (third line service).
- (iv) Permanent service support by immediate specialized response by telephone and/or email should be available; and consultations for repair and maintenance should be in a language understandable to the user (BSS) [1].
- (v) A spare parts kit should be included. Specify which spare parts are needed.
- (v) Service rates and conditions should be specified: cost per hour and per diem, response time, etc.
- (vi) Maintenance contracts should be available: up-time (≥95%), with acceptance of penalties for late delivery of service, extended installation times or periods of initial non-performance, according to equipment specifications.
- (e) Training of staff (physicians, physicists and operators) in the use of the machine should be available.

VI.6. GENERAL REMARKS

The equipment quoted in the bid will be supplied with all interconnection devices necessary for a correct and total functioning in the country of destination.

VI.7. ADDITIONAL ITEMS

The following additional features and capabilities may also be required:

- (a) Additional photon energies (see Appendix VII.2 for a discussion of the relevant factors).
- (b) Electron treatment (see Appendix VII.3 for a discussion of the requirement for electrons):
 - (i) Electron applicators should range from 6 cm \times 6 cm to 20 cm \times 20 cm (minimum) with a capability for customized inserts.

- (ii) There should be an electronic indication of the energy and applicator selected.
- (iii) There should be interlocks to prevent the use of an electron beam with photon beam currents.
- (iv) There should be an HDR interlock to terminate the treatment if dose rates exceed 10 Gy/min. Treatment cessation must be activated before 5 Gy has been delivered.
- (c) Multileaf collimators (Appendix VIII).
- (d) An extended warranty period (Section VI.8.2).
- (e) An R&V system (Section VI.8.4).
- (f) A plotting tank system (Section VI.8.5).

VI.8. CONSIDERATIONS IN INTERPRETING THE SPECIFICATIONS

VI.8.1. Isocentre height

The isocentre height will depend on the design of the accelerator. Accelerators with no bending magnet or with a 270° bending magnet will have a higher isocentre height than those of other designs. A low isocentre is advantageous for RTTs when setting up patients, and if the isocentre is higher than 127 cm the RTTs may require a stool to stand on. Note, however, that for low energy machines a 'straight through' linac (without bending magnets) is simpler and can eliminate problems with beam steering.

VI.8.2. Service support

It cannot be overemphasized that linacs require adequate service support. An interruption in treatment of even a few days will compromise the success of that treatment. The availability of service support from the manufacturer should be a major factor in selecting the equipment. Before a linac is purchased (or a donation accepted), arrangements for ongoing service support must be finalized. There are a number of possible service models, ranging from reliance on local trained engineers to a long term service agreement with the manufacturer. If reliance is to be placed on local engineers, the provision for training these must be appropriate. A fully trained linac engineer from one manufacturer may require a period of about six weeks' training to become competent to service equipment supplied by another manufacturer. For manufacturers to train their service representatives from the beginning will take up to three years, depending on the baseline level of their training. In addition, service engineers will require easy access to spare parts, some of which may be

Item ^a	Expected life	Cost (US \$)		
Klystron	5 years	60 000-170 000		
Magnetron	2 years	10 000-15 000		
Waveguide ^b	5–15 years, depending on the accelerator design	70 000		
Replaceable electron gun ^b	1 year	2000		
Flight tube (if fitted) ^b	3 years	20 000		

TABLE 10. MAJOR COMPONENTS OF A LINAC THAT MAY NEED REGULAR REPLACEMENT

^a The replacement of some of these parts may require a visit from a manufacturer's representative. It should be noted that quotations for spare parts in developing countries are often higher than in industrialized countries.

^b Replacement of parts within the evacuated waveguide will require vacuum pumping equipment (cost: approximately US \$8000). Vacuum components have a shelf life, and it is not recommended that such components should be stored for long periods of time.

extremely expensive (Table 10). A better solution may be to take out a fully comprehensive parts and labour contract with the manufacturer with guarantees about the maximum time delay before an engineer is available onsite. Such a contract may cost in the region of 15% of the cost of the linac. It may be possible to negotiate a payment made at the time of purchase to cover a substantial period of the life of the machine. However, most manufacturers will be reluctant to enter into such a service agreement without there being some trained local first line engineers available, who can assist the visiting engineer and identify simple problems such as blown fuses, as well as replace bulbs.

VI.8.3. Infrastructure requirements

Linear accelerators require appropriate servicing, depending on the requirements of the individual manufacturer. Typical requirements are:

- (a) For the electricity supply:
 - Appropriate voltage and frequency;
 - Voltage stability $\pm 10\%$;
 - Voltage regulators if the fluctuation is >7%;
 - A continuous and permanent power supply, which may require a standby generator;

- Possibly power for 24 h a day for some parts of the linac (e.g. ion pumps);

- Appropriate control of temperature, dust and humidity.
- (b) For the water supply:
 - Some form of water cooling;
 - Possibly deionized water;
 - Appropriate pressure, flow rate and purity for the supply of water;
 - Preferably, a closed water system with a refrigeration plant.

VI.8.4. Record and verify systems

An R&V system (see also Section XIII.9) may be a useful addition to the safety of radiotherapy treatment, although it is not a substitute for careful checking of the treatments, especially before the first fraction. The supplier should be asked to demonstrate that data transfer between the particular TPS, the verification system and the linac is possible. Errors in such transfers are not uncommon and are likely to occur in a systematic way. If careful systematic checking is not carried out, more errors may occur than would have occurred without the electronic system. For simple treatments it is possible to work without an R&V system.

VI.8.5. Dosimetry equipment

In addition to the standard dosimetry equipment required (Appendix IX), an essential requirement for a linac is a dose plotting tank (radiation field analyser). A full 3-D system will be required for at least one month for machine acceptance and commissioning. A number of solutions to this requirement exist:

- (a) Purchase (cost about US \$50 000–80 000). This is the ideal solution as there are likely to be further requirements for dose measurements when alterations or repairs are carried out to the accelerator.
- (b) Rental.
- (c) A plotting tank shared between different centres.
- (d) A plotting tank kept at a secondary standards dosimetry laboratory (SSDL). This approach has the advantage over general sharing that one person can be made responsible for maintaining the system.

The local staff should be appropriately trained to use such equipment. A period of up to one month, including practical training, will be required.

VI.8.6. Machine commissioning

Two linacs of the same type and with the same nominal energy may have significantly different dose distribution parameters, and there is therefore a requirement for a significant series of measurements to be made in order that the TPS may accurately calculate patient doses (Appendix XIV).

The quality control in production of modern linacs has improved considerably in recent years, and some manufacturers are now able to offer linacs matched to each other. This has the potential to reduce the commissioning time by a significant amount, especially if beam data appropriate to the TPS are available from a trusted source. However, the constraints of beam matching need to be well understood. In order to achieve satisfactory matching, the reference machine must have been set up to be in the middle of the range of parameters for that machine. It is therefore considerably easier for a manufacturer to match two machines prospectively, and it has been found possible to match all parameters of a machine to within 1% (or experimental error). However, matching to previous machines or to machines of a different type is likely to be much less successful, particularly if the original machine is several years old. Attempts to match such pairs of machines may be more time consuming than measuring the beam data ab initio.

It must be emphasized that verification of the beam data and of the use that is made of such data is the responsibility of the local medical physicist, and this responsibility cannot be transferred to some other person or organization.

Appendix VII

FACTORS TO BE CONSIDERED WHEN CHOOSING TELETHERAPY EQUIPMENT

VII.1. ACCELERATOR OR ⁶⁰Co UNIT

In this section, the decision as to whether to purchase a linac rather than a 60 Co unit is considered. A comparison is presented with a 6 MV linac. The possibility of higher energies is only relevant once the decision has been made to purchase a linac.

VII.1.1. Clinical considerations

Decisions regarding the choice of teletherapy equipment should be made on the basis of the anticipated clinical benefit. Unfortunately, with regard to the question of megavoltage beam energy, there have been few clinical studies directly addressing this issue. Therefore, the decision has often to be made on the basis of other considerations such as costs (initial and operational) and downtime. In developing countries, the costs of treatment per patient are generally much lower with ⁶⁰Co teletherapy than with linac teletherapy (Table 11). Furthermore, experience in developing countries has shown that the downtime of a linac is considerably longer than that of a ⁶⁰Co unit. Therefore, by choosing a ⁶⁰Co unit, it may be possible to offer more reliable

TABLE 11. COSTS OF RADIOTHERAPY PER TREATMENT COURSE (*The costs incorporate local labour costs and are based on an IAEA study [47]. Costs are in US dollars at 2002 prices, and are intended for comparison purposes only.*)

		radiotherapy fraction)	Radical radiotherapy (30 fractions)			
Country	⁶⁰ Co unit	6 MV linac	⁶⁰ Co unit	6 MV linac		
India	3	11	90	330		
Indonesia	10	17	300	510		
Netherlands	34	32	1020	960		

radiotherapy treatment to more people. Any interruptions to treatment due to equipment breakdowns adversely affect the outcomes of patients. The longer or more frequent the interruptions, the worse the impact. There have been many instances where even after acquiring a linac, no patients could be treated because the proper support arrangements had not been made.

VII.1.2. Buildup

With orthovoltage beams the maximum dose is on the surface of the skin. This is undesirable unless the skin is directly involved in the cancer. Megavoltage photon beams, on the other hand, deliver a higher dose below the skin surface. This phenomenon is due to the range of secondary electrons that deliver the dose and is called the 'buildup effect'. For ⁶⁰Co beams the depth of the dose maximum is 5 mm, whereas for a 6 MV linac it is 16 mm. A greater depth of dose maximum is usually an advantage, except where the target volume includes or is close to the skin surface. However, in the event that one wishes to include treatment of the skin, it is possible to put some artificial buildup material on the skin to remove the effect. (Note, however, that the use of buildup material to reduce the depth of the dose maximum for a high energy beam is not equivalent to the use of a lower megavoltage energy, because the rate of increase of dose in the first few millimetres is substantially higher than it is closer to the point of the dose maximum.)

VII.1.3. Penumbra

The penumbra for megavoltage photon beams is defined as the lateral distance between the 20 and 80% isodoses at 10 cm depth. The size of the penumbra depends on the effective source size and the distance between source, collimator and patient. A smaller effective source size and a shorter distance between the collimator and the patient result in a smaller penumbra. A small penumbra is needed to spare critical structures, but, to benefit from this, accurate localization of the critical structures and reliable fixation of the patient are required.

In general, the penumbra for high energy photon beams is smaller than that for the 60 Co gamma beam. For modern linacs, it should be of the order of 6 mm for small fields. For machines fitted with an MLC, the effective penumbra width may be up to 9 mm. The penumbra may increase slightly with increasing photon beam energy, especially above 10 MV. For 60 Co beams, the penumbra is typically two times larger.

The penumbra width can be minimized in a ⁶⁰Co unit by choosing a smaller source diameter (at the expense of limiting the maximum dose rate

obtainable), by choosing an 80 cm SSD unit and by using additional trimmers (Section V.7.3).

VII.1.4. Penetration

The higher energy of a linac secures greater penetration, which reduces the integral dose to the patient when treating a deep seated tumour. Table 12 compares the penetrative quality of a 60 Co unit with that of a 6 MV linac for a 10 cm² field. With parallel opposed fields (such as are used in breast treatments), the poorer penetration is offset, to some extent, by the reduced exit dose. In Table 12 the doses are normalized to the dose at the depth of dose maximum below the skin. It should be noted, however, that poorer penetration can in many cases be ameliorated by an increased number of fields.

VII.1.5. Dose rate

Unlike a linac a ⁶⁰Co source decays and the treatment times will therefore become progressively longer (1.1% per month), and it is necessary therefore to make arrangements to replace the source at regular intervals (Section VII.7.9). This is illustrated in Fig. 4.

The dose rate from a megavoltage unit depends on the field size and the depth at which the measurement takes place. The reference dose rate is usually stated at the depth of dose maximum with the isocentre at the surface of the measurement phantom. The reference dose rate from a linac is typically between 3 and 4 Gy/min but can be as high as 6 Gy/min, whereas the highest

		Single field		Parallel opposed				
Depth				(separ	ration = twice	depth)		
(mm)	⁶⁰ Co ⁶⁰ Co 6 M		6 MV linac	⁶⁰ Co	⁶⁰ Co	6 MV linac		
	80 cm SSD	$100 \mathrm{~cm~SSD}$	$100 \mathrm{~cm~SSD}$	80 cm SSD	$100 \mathrm{ cm} \mathrm{ SSD}$	$100 \mathrm{ cm} \mathrm{ SSD}$		
5	100	100	≈80	100	100			
16	95.5	96.0	100	_	_	100		
50	78.8	80.4	86.9	99.5	100.1	102.7		
100	56.4	58.7	67.5	87.8	90.0	96.2		
150	39.4	41.6	51.7	69.2	72.3	83.8		

TABLE 12. COMPARISON OF PENETRATIONS (%) OF 60Co ANDACCELERATOR BEAMS(data from Br. J. Radiol. [48])

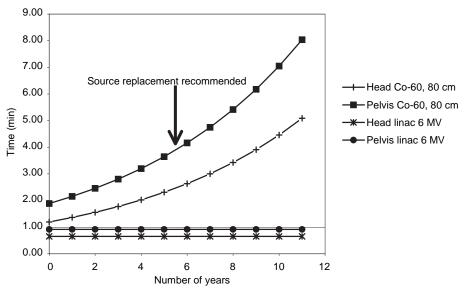


FIG. 4. Effect of dose rate on treatment time.

dose rate for a ⁶⁰Co unit is about 2.5 Gy/min, depending on the source strength and the design of the treatment head.

For an accelerator, the dose rate can vary by small amounts from day to day and must be checked each day before treatment starts. These variations should be less than 2%. For a ⁶⁰Co unit the dose rate decays in a predictable way over time. This reduces the frequency of necessary checks to monthly. (Note that problems with source manufacture [49] have led to the source activity changing unpredictably so that regular checks remain essential.)

The dose rate (and to a lesser extent the penetrative quality) will affect the duration of a patient's treatment. In Fig. 4, the effect of decay is shown in terms of the treatment time required to give 2 Gy to a typical pelvic tumour (at a depth of 14 cm) and to a typical head and neck tumour (at a depth of 7.5 cm) using different equipment. The increased treatment time will have an impact on the immobilization of the patient, with a concomitant increase in the uncertainty of dose delivery. It will be noted that the treatment time for the linac is constant. In Fig. 5 this is translated into the number of patients that can be treated in an eight hour day, assuming a 10 min set-up time for each patient.

VII.1.6. Versatility

Linear accelerators are in general more versatile than ⁶⁰Co units, but with this extra versatility come additional costs in terms of quality control, training

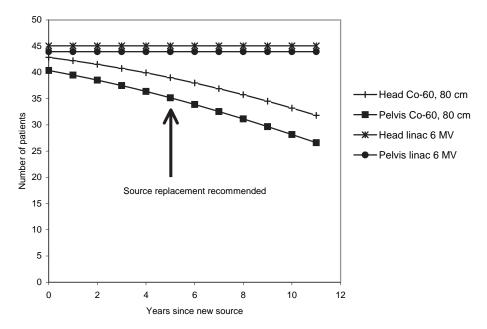


FIG. 5. Effect of dose rate on number of patients treated in eight hours for the same source as in Fig. 4.

and maintenance. Asymmetric collimators are at present available on most accelerators and have only recently been made an option for a ⁶⁰Co unit. These can be useful in many ways, such as in providing a non-diverging junction and in shrinking field techniques, where it is possible to keep the same isocentre throughout the treatment.

Accelerators usually have some type of automatic wedge system, either as a motorized wedge or as a 'dynamic wedge' in which the wedged dose distribution is created by moving the jaws across the beam. The dynamic wedge solution requires more dosimetry and verification. With older designs of ⁶⁰Co unit, the wedge has to be inserted manually into the wedge holder. Motorized wedges and dynamic wedges have the advantage of allowing automatic set-up. Some manufacturers of ⁶⁰Co machines have recently included these features as options.

For an 80 cm SAD 60 Co unit the distance between the front of the machine and the patient is reduced, and this can cause difficulties with some head and neck treatments in which the couch must be angled. Thus, 100 cm SAD 60 Co units have advantages in this area, but the cost of the higher activity source is substantial. All linacs have an SAD of 100 cm.

Multileaf collimators (Appendix VIII) are typically available on linacs. However, individually shaped blocks provide a satisfactory alternative in most situations and the inherently greater resolution of the block may even be an advantage in some circumstances. Machines with MLCs can treat more patients in a given time than those that require the use of blocks because of the time taken to install the blocks.

VII.1.7. Beam profile

Because of the use of a beam flattening filter, the beam uniformity is better for linacs than for ⁶⁰Co units for both large and small fields, provided that it is properly maintained.

VII.1.8. Maintenance

VII.1.8.1. Technological infrastructure

The requirements for a well regulated power supply and for appropriate air conditioning are critical for a linac, whereas a ⁶⁰Co unit is more tolerant of environmental variability. It is essential that a local engineer be trained to carry out first line maintenance on either a ⁶⁰Co unit or a linac. The level of skill necessary to repair and maintain an accelerator is significantly higher (Appendix VI). The linac engineer will require an understanding of electronics and electrical engineering as well as mechanical engineering. Local hospital maintenance personnel will require considerable training before they will be able to cope with the technology associated with linacs.

VII.1.8.2. Repair and maintenance

As discussed in Section VII.1.1, it can be expected that the downtime of a linac will be greater than that of a ⁶⁰Co unit. If there is only one facility in the region, then a ⁶⁰Co machine should be selected. An isocentric ⁶⁰Co unit having a dose rate of 2.0 Gy/min can optimally treat 500 patients per year; however, it might be possible to treat up to 1000 patients per year if the majority of the treatments are palliative.

If there is adequate backup to ensure that there would be no gap in the treatment schedule then a linac may be considered. When evaluating the adequacy of the backup, the factors to be considered are:

- (a) Training of the staff on the backup facility;
- (b) The availability of spare time;
- (c) Transportation logistics if the backup facility is at a different site.

The further a machine is from the nearest support base of the manufacturer, the more problems there will be with support. As breakdowns are more probable with linacs, this is likely to be more of a problem.

VII.1.8.3. Support costs

A linac is likely to break down more frequently than a 60 Co unit. The annual cost of a long term service contract (without 'glassware') may be up to 15% of the purchase price for a linac, and up to 8% for a 60 Co unit. Many of the spare parts associated with a linac are expensive (Appendix VI), and it is essential that provision be made from the outset for the urgent funding of these in the event of need.

VII.1.8.4. Source changes

Cobalt-60 sources require to be changed approximately every five years (Appendix V). In addition to the capital cost, with the support of an external contractor, the procedure for source change will involve a downtime of approximately one week. This is not an issue for linacs.

VII.1.9. Computer control

Computer control is widely available for linacs, but is now also becoming available for ⁶⁰Co units. The issues relating to R&V systems are discussed in Appendix VIII.

VII.1.10. Decommissioning

For both ⁶⁰Co units and accelerators there is a potential problem with depleted uranium if used for head shielding or beam collimation. A radio-therapy machine typically contains 1.5–4 kg depleted uranium, which is a registered material (for all Member States of the IAEA) that must be disposed of by a company licensed to handle nuclear materials. Before disposal of parts from high energy linacs (>10 MV), these should be checked for induced contamination. Decommissioning of the ⁶⁰Co source must be included in the cost of purchase of the source.

VII.1.11. Safety and security issues

It is generally assumed that a linac is safer because once the power has been switched off there is no further hazard. However, consideration of the risks given in Table 13 leads to the conclusion that both ⁶⁰Co and accelerator teletherapy equipment are inherently dangerous, with a potential for mechanical, electrical and radiation accidents. Great care must be given to establishing infrastructure, properly designed procedures and well trained staff.

VII.2. CHOICE OF ACCELERATOR ENERGY

In this section the choice of energy, given that it has been decided to purchase a linac, is discussed. Several manufacturers offer two different accelerators, for low energies and for high energies. Some manufacturers offer electrons with their low energy accelerator while others offer photons only. The issue of the clinical benefit of electrons is discussed in Section VII.3. Multienergy and multimodality accelerators are inherently more complex and therefore more difficult to maintain. They are also inherently more dangerous because of the possibility for confusion between energies. It is therefore recommended that unless experience with accelerators already exists within a country that a single energy, single modality machine be purchased (or even a ⁶⁰Co unit as already discussed).

The properties of high energy photons, better depth penetration and generally lower surface dose are advantageous for deep seated tumours and skin sparing. However, the penumbra is broader, absorption in bone is higher and dose interface problems between air cavities and tissues can occur. In addition, the cost of the treatment room increases above 10 MV because of the need to make provision for shielding of neutrons. These factors lead to the conclusion that the considerably increased expense for accelerators above 15 MV is not justified and that higher energies may provide reduced clinical benefits for the majority of patients [50–52]. A combination of 6 and 10 MV is an appropriate choice [53].

These issues are discussed in Sections VII.2.1-VII.2.7.

VII.2.1. Depth dose

Higher energy beams are more penetrating and therefore are better for treating deep seated tumours. However, with the increasing sophistication of IMRT this advantage may become less significant, although the integral dose will always be greater with a low energy beam and a deep seated tumour. Figure 6 shows the variation of the percentage dose on the midline for a parallel opposed pair of beams applied to a 30 cm thick patient. It will be seen for energies below 10 MV that the midline dose is over 10% less than the maximum dose. However, in this case, it is often possible to use additional

An issue for:	Co-60	Linac
Safety of staff		
Equipment related		
Co-60 source sticking	Yes	No
Electric shocks	Slight	Yes
Faulty tray resulting in falling blocks	Yes	Yes
Back injuries from lifting blocks and heavy applicators	Yes	Yes
		(not MLC
Inadequate or poorly implemented procedures		
Accidental irradiation if staff left in a bunker	Yes	Yes
Danger to staff from door open/closed (if fitted)	Yes	Yes
Accidents during replacement of heavy equipment items during maintenance or repair work	Yes	Yes
Accidental irradiation during Co-60 source replacement	Yes	No
Safety of patients		
Equipment related		
Co-60 source sticking	Yes	No
Patient overexposure due to incorrect radiation mode	No	Yes
Malfunction of machine interlocks causing incorrect delivery of radiation dose, for example, incorrect beam flatness or poorly positioned wedge	Yes	Yes
Malfunction of control software	Slight	Yes
Malfunction of a treatment table	Yes	Yes
Incorrect electronic transfer of data	Slight	Yes
Inadequate or poorly implemented procedures		
Incorrect beam calibration	Yes	Yes
Incorrect calculation for monitor units or of treatment time	Yes	Yes
Inadequate quality control procedures	Yes	Yes
Inversion of wedge and open monitor units	Slight	Yes
Incorrect data transfer to and from the TPS	Yes	Yes
Incorrect understanding of treatment planning data	Yes	Yes
Incorrect understanding of irradiation geometry (SAD/SSD)	Yes	Yes

TABLE 13. SAFETY ISSUES RELATING TO Co-60 AND ACCELERATOR UNITS

TABLE 13. SAFETY ISSUES RELATING TO Co-60 AND ACCELERATOR UNITS (cont.)

An issue for:	Co-60	Linac
Dropping blocks or wedges	Yes	Yes
Overriding interlocks	Yes	Yes
Interrupted treatment	Slight	Yes
Miscommunication	Yes	Yes
Incorrect identification of patient, treatment site or positioning	Yes	Yes
Misinterpretation of prescription or treatment protocol	Yes	Yes
Inadequate training of staff	Yes	Yes
Unauthorized modifications of treatment machines	Yes	Yes
Safety of general public		
Equipment related		
Probably none		
Inadequate or poorly implemented procedures		
Incorrect decommissioning, including Co-60 source disposal	Yes	No
Accidental irradiation due to poorly designed bunker	Yes	Yes

beams, although parallel opposed beams may be the ideal choice for midline thoracic tumours. For smaller patient separations 6 MV will be satisfactory, and it has been found in centres that have a choice of energy that 6 MV is in fact the most widely used energy [51]. With limited resources, a 6 MV machine may provide a satisfactory solution.

VII.2.2. Buildup

The depth of maximum dose increases with energy, as shown in Table 14. Where a tumour is located within the buildup region, it is advisable to use a lower energy. The result of applying a bolus to reduce the depth of dose maximum (as opposed to bringing the maximum to the surface) is not satisfactory (Section VII.1.2).

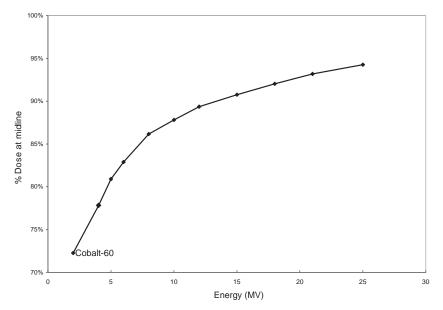


FIG. 6. Percentage midline doses for parallel opposed fields and 30 cm thickness with different photon energies (data from Br. J. Radiol. [48]).

TABLE 14. DEPTH OF MAXIMUM DOSE FOR DIFFERENT ACCELERATION ENERGIES (data from Br. I. Radiol. [48])

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Energy (MV)	4	5	6	8	10	12	15	18	21	25
Depth of d_{\max} (mm)	10	12.5	15	20	23	26	29	32	35	38

VII.2.3. Penumbra and buildup at interfaces

As the energy increases, the width of the beam penumbra increases because of the transport of secondary electrons. This means that for very high energies a significantly wider beam may be required to achieve a dose up to the beam edge [50, 52]. This loss of electron equilibrium also results in a dose reduction at the interface between lung and tissue. This is a similar effect to that observed at the skin surface. For this reason, some authors [54] recommend the use of lower energy linac beams, for example 6 MV, for lung cancer therapy. However, for central tumours where parallel opposed fields are appropriate, it has been argued that there may be some benefit in using higher energies [55]. Some practitioners also argue that the outer layers of such tumours may be oedematous and therefore do not need to be irradiated to the central dose. One factor to take into consideration is that many TPSs do not model this interface effect well, and the dose distributions shown may therefore be misleading.

VII.2.4. Absorbed dose to bone

Above 10 MV pair production takes place, and therefore there will be differential absorption in bone leading to a higher dose being delivered to trabecular bone. This is similar to the effect of orthovoltage irradiation (although less marked). This enhanced dose may be desirable in some cases (such as in TBI for leukaemia [56]), but in most instances it is an undesired effect.

VII.2.5. Radiation protection

As the photon beam energy increases, more shielding is required in the facility walls. In addition, the thresholds for many (γ , n) reactions are in the range 6–8 MeV for many isotopes in the materials used in the construction of linac treatment head components, including photon targets, flattening filters and collimators. The cross-sections for these (γ , n) reactions increase from their threshold energies to reach maxima at approximately 25 MeV.

Neutrons are produced by clinical photon beams above approximately 10 MV as a result of these (γ , n) reactions with treatment head components, and the number of neutrons increases as the photon energy increases. This neutron production requires an increase in complexity in the shielding design of the facility to protect the general public and staff. In most instances the principal area of concern is the treatment room door, as walls designed to shield the primary and scattered photons are usually adequate for the additional neutrons. Treatment room doors for high energy treatment units (>10 MV) are typically of a composite construction with borated polyethylene and lead sandwiched between outer surfaces of wood.

A bunker for a high energy machine will cost significantly more than a bunker for a 6 MV machine.

VII.2.6. Machine costs

Machine costs for higher energy machines are likely to be greater depending on the accelerator manufacturer. A multienergy machine may cost significantly more than a comparably equipped single energy machine.

VII.2.7. Electron energies

The choice of photon energies does not necessarily have an impact on the choice of electron energies. Maximum use is from energies between 6 and 12 MeV. There is little benefit from energies above 15 MeV (apart from the occasional head and neck tumour that may need 18 MeV) because the rate of decrease of dose with depth beyond the 80% depth is much slower, which negates the benefit of the electron beam. Care must be taken with the use of high energy electrons in areas of low tissue density. The electron range in such low density tissues will increase significantly. An inappropriate choice of electron energy for a breast boost treatment can result in an excess dose being given to a substantial part of a lung. It is also important to use an appropriate electron dose calculation algorithm, as dense areas of tissue may also cause unexpectedly high doses. For any curative treatment, the advice of a physicist must be sought for any individual patient treatment using electrons, especially for energies above 12 MeV. An advantage of a mixed modality machine is that, in the case of combined electron-photon treatments, patients do not have to be moved between machines.

VII.3. ELECTRONS OR ORTHOVOLTAGE X RAYS

The principal use of electron beams is to treat superficial lesions. These may also be treated with orthovoltage radiation. An orthovoltage unit is relatively cheap and can be expected to work for many years. There may therefore be situations in which the preferred choice is to purchase an orthovoltage machine rather than a high energy electron machine. Even in the most advanced centres, electrons are used in 10–15% of treatments at most.

VII.3.1. Clinical considerations

Particular indications for the use of electrons are superficial and subcutaneous tumours overlying bone and cartilage, breast cancer, and head and neck tumours. Electrons are either used alone or in combination with photons. The advantages of using electrons in these treatments are inherent from the limited range of electrons.

If electron beams are not available, they can in many cases be substituted by orthovoltage X rays, brachytherapy or by tangential or oblique megavoltage photon beams. For treatments of lesions close to the eye, it is necessary to use eye shields and, in this case, the unwanted dose to the critical structures of the eye will be higher if electrons are used compared with the use of orthovoltage [57]. When using electrons with eye shields, dose measurements behind the shield should be made before use. The real clinical needs for electron beams in the department should be balanced against the increased complexity of the machine. Apart from this consideration, there are problems due to dose inhomogeneities at interfaces between air cavities and soft tissue or between bone and soft tissue, which indicates that electrons in these cases may not be the modality of choice. Furthermore, in order to predict the dose distributions in these situations, an advanced dose algorithm is required for the TPS. This further increases the costs.

VII.3.2. Variation of dose with depth

Electron beam doses have a very steep fall-off with depth, and the dose beyond the treatment depth is always lower than that for orthovoltage beams. A comparison of the doses over a range of depths for two roughly equivalent X ray and electron beams is shown in Fig. 7.

VII.3.3. Surface dose

As can be seen from Fig. 7, electrons allow some skin sparing. This may be an advantage or a disadvantage, depending on the clinical situation. However, it is always possible to use bolus materials to increase the skin dose. The actual skin dose is strongly dependent on machine and applicator, and careful measurements are required.

VII.3.4. Dosimetry

Dose measurements with both electrons and orthovoltage X rays are not straightforward. With orthovoltage beams, it is important to realize that the relative biological effectiveness (RBE) is likely to be greater than with electron and megavoltage photon beams [58].

Dosimetry with electrons is particularly difficult in the case of inhomogeneities or where there are sharp steps at the entry surface of the beam. In situations where there are air cavities within the patient, electron ranges can be

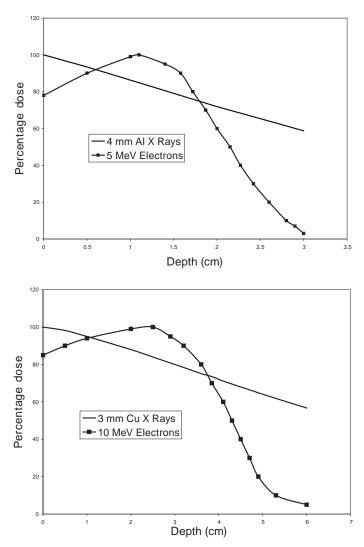


FIG. 7. Comparison of doses over a range of depths for orthovoltage X rays and electrons.

substantially increased. In such situations, orthovoltage X rays are much simpler as they do not exhibit these effects.

VII.3.5. Penumbra

Typically the electron penumbra at normal SSD does not exceed 1 cm at the depth of dose maximum. A small penumbra can be achieved by using

applicators. The size of the penumbra varies with energy, field size and the distance between the end of the applicator and the patient's skin. Where adjacent fields need to be treated the penumbra can create difficulties. Again, these situations are easier to deal with using orthovoltage X rays.

For both orthovoltage beams and electrons, manufacturers provide a standard set of applicators for rectangular fields, but for other field shapes and sizes, customized apertures have to be manufactured by users. For this purpose, a mould room is necessary, which involves additional costs, especially for materials and equipment.

VII.3.6. Large field irradiations

Irradiating large surface lesions is often easier using electrons. However, for really large fields where the surface is not flat, matching of electron beams demands highly accurate dose calculation algorithms, while matching orthovoltage beams may require less physics support. It is normal to use short SSDs for low energy orthovoltage beams and 50 cm for higher energy ones. If there is a frequent need for large fields with orthovoltage beams, then applicators at 50 cm SSD may be used. It is not advisable to allow two different distance applicators to be used with the same filter combination. In addition, the machine should be interlocked to prevent use of the wrong SSD.

VII.3.7. Small field treatments

With electron beams the loss of lateral scattering results in a severe modification to the isodose curves and the depth of dose maximum moves towards the skin surface. For such treatments it is better to use orthovoltage beams.

VII.4. SINGLE VERSUS MULTIPLE VENDORS

There is often a dilemma as to whether to choose to have only one vendor or to have multiple vendors within an institution. There are many advantages to the single vendor solution with regard to similar equipment such as linacs. Fewer spares need to be kept and the training burden is reduced. On the other hand, being committed to only one vendor may create problems if that vendor perceives a monopoly situation, or if the vendor ceases to develop equipment of that type.

Connectivity is also an issue between different types of equipment such as simulators and TPSs. With the development of DICOM RT (a communication

standard for radiotherapy parameters) this problem is becoming less severe, although DICOM conformity does not guarantee connectivity or accurate transfer of information. Correct operation of an interface should be made a condition of the purchase contract.

Appendix VIII

ADVANCED AND SPECIAL TECHNIQUES IN PHOTON RADIOTHERAPY

VIII.1. CONFORMAL RADIOTHERAPY

VIII.1.1. Introduction

It has always been tried in radiation oncology to make the radiation fields conform to the tumour volume, in order to give the dose required for a cure to the tumour and to reduce the dose to normal tissue. Traditionally, this has been done by blocking the radiation fields. During the last ten years, new tools have become available for this type of treatment. An MLC makes it possible to irradiate patients with irregular fields without the use of external blocks. This has simplified the use of multiple beams directed towards the tumour volume.

If better conformation to the target volume is achieved, it may be possible to increase the dose delivered to the tumour while keeping the side effects to normal tissue constant. Such dose escalation is usually only possible if the dose to normal tissue can be kept at its original level. Alternatively, the increased sparing of normal tissues can be applied to reducing the morbidity associated with radiotherapy.

Further improved diagnostic tools have made it possible to outline tumours (gross tumour volume) in 3-D geometry. Three dimensional dose planning systems have improved the possibility to compute the dose distribution. Advanced computing also makes it possible to find parameters to define the quality of the dose distribution, such as dose volume histograms (DVHs). In order to make use of these improvements, it is important to use good quality immobilization and portal imaging. Even in advanced radiotherapy departments, new procedures are under continuous development. However, it should be stressed that if even a small part of a tumour is not irradiated, the chances of a cure will be impaired. It is thus important that margins are adjusted to the level of sophistication reached in the department.

Accurate radiotherapy requires accurate immobilization as well as 3-D visualization, and this is particularly true for treatments of the brain and the head and neck, where sensitive normal tissues are often very close to the tumour volume. The rigid nature of the skull allows very precise fixation using a variety of stereotactic fixation devices. Stereotaxy is a method of setting up the patient to conform to a rigid coordinate system. The term is often misused

in being associated with arc therapy using circular collimators. This approach to fixation may be used for any treatment of lesions in the brain or brainstem.

The most recent development towards more conformal radiotherapy is IMRT. This uses a deliberately non-uniform beam in order to be able to shape the high dose region more precisely to the target volume. With shaped fields it is not possible to produce concavities in the dose distribution, which are particularly relevant when an organ at risk is surrounded by a tumour.

These advanced procedures require both expensive equipment and staff who are highly trained in diagnostic radiology, medical physics and radiation oncology. This implies high costs of treatment, two to three times as high as those for conventional radiotherapy.

VIII.1.2. Simple approaches to conformal radiotherapy

The minimum requirement to perform conformal radiotherapy is a three dimensional planning system, a CT scanner and a method of preparing individually shaped blocks. The target is outlined on each CT slice. The planning system must provide a facility for showing the geometric relationship between the radiation beam and the target volume. This is called a beam's eye view (BEV). Appropriate margins must be applied to the defined target volume, as described in Refs [19, 20]. These margins should be created using software to 'grow' the volume in three dimensions. The margins applied on a slice by slice basis will not accurately represent the intended 3-D target volume. In the absence of an appropriate volume growing algorithm, satisfactory results can nevertheless be obtained by applying the margin in the BEV, which is almost exactly equivalent.

Blocks can be made using expanded polystyrene foam and an alloy with a low melting point. A number of devices are available that use a hot wire to cut shapes out of the polystyrene foam, allowing for the divergence of the radiation beam. Tin–lead alloys are available that melt at less than 100°C and have densities about 80% that of lead. The alloy blocks can then be mounted on trays that fit onto the head of the radiotherapy unit. As supplied, these trays often do not have sufficiently tight tolerances for this purpose, and the availability of skilled staff to ensure that the trays are accurately aligned to the accelerator is essential.

It must be emphasized that, while the technology required to deliver conformal radiotherapy with shaped blocks is not at a high level, the requirements for reproducible patient fixation and for accurate definition of the target volume are in no way reduced. The margins of set-up uncertainty must be established for each individual centre so that appropriate margins can be applied. Poorly implemented conformal radiation therapy may result in poorer treatment results because of undertreatment of part of the tumour volume.

VIII.1.3. Multileaf collimators

Multileaf collimators use multiple thin blades of tungsten driven by individual motors to shape the field automatically rather than using alloy blocks fixed to a tray. It is usual for the leaf width projected at the isocentre to be 10 mm, although higher resolution collimator systems are available. Although this appears to produce a field with very jagged edges, in practice, at the 90% level, scattered radiation results in a smoother edge to the dose distribution. The standard 10 mm resolution collimator may be inadequate for shielding close to the spinal cord or the eye, and for very small fields it may limit the amount of shielding of normal tissue that can be achieved. In these circumstances, it is useful to have a few lead blocks available [59], but at least 90% of blocking can be achieved with such an MLC. Higher resolution collimators are available, either as an add-on device or as part of the standard MLC. The MLC fields are set up more quickly on the treatment machine and do not require a facility for casting customized blocks. In a busy department with high labour costs, the use of an MLC can be shown to be cost effective [61], but the added initial cost and complexity may limit the benefit in parts of the world where labour costs are lower.

Two types of MLC exist: those in which the MLC is an integral part of the collimation system and those in which the MLC is an add-on feature. The latter have theoretical advantages where service personnel are not readily available, because the MLC can be disabled and treatment can proceed with open fields. However, in practice this advantage is not significant. The use of an MLC does require more quality control checks, and a machine with an MLC can be expected to have more downtime than a machine with a traditional collimator. A downtime of the order of 1% of the lost treatment time associated with MLC problems can be expected, even where service personnel are readily available.

VIII.1.4. Stereotactic radiotherapy

As pointed out in Section VIII.1.1, the term stereotactic simply describes a method of fixation and target localization valuable for precision radiotherapy of very small targets. The techniques were originally developed for neurosurgery. However, the increased precision achievable (about 1 mm for brain treatments) requires significantly increased quality control if it is to be maintained. The basic requirements for fixation during stereotactic radiotherapy of the brain include:

- (a) A stereotactic fixation device (relocateable or skull based);
- (b) A system for attachment to the linac couch;
- (c) A fiducial system;
- (d) A marking system;
- (e) A compatible planning system.

Treatments may be delivered either using multiple arcs with circular collimators or with multiple fixed fields. For the former, it is necessary to have a set of these collimators from about 10 mm diameter up to 50 mm diameter. For the latter, alloy blocks can be cast or a high resolution MLC can be used.

For the treatment of small targets, the quality control requirements are increased, including the use of special techniques for small field dosimetry. A small ionization chamber or other detector will be required as well as a device to check the radiation isocentre, such as the Winston–Lutz test [61]. Stereo-tactic procedures require both expensive equipment (with increased isocentre specifications for the gantry and treatment table, and preferably an HDR) and more staff who are highly trained in medical physics, neurosurgery, diagnostic radiology including CT, MRI and/or angiography, and radiation oncology. A set of dedicated instrumentation is required. Linear accelerators have the advantage of a higher dose rate, but it is also possible to use ⁶⁰Co units with a 100 cm SAD at the expense of increased treatment time. The irradiation time will be two to three times longer for ⁶⁰Co units, whereas the patient set-up times are comparable for ⁶⁰Co and linacs.

A specialized multisourced ⁶⁰Co unit called a gamma knife is also available for brain treatments. The cost of this equipment can only be justified if a large number of patients are likely to be treated in a single centre because, unlike linacs, they cannot be used for treatment of other tumour sites.

Stereotactic treatments can be delivered either as single fractions (usually called stereotactic radiosurgery) or as fractionated stereotactic radiotherapy.

VIII.1.5. Intensity modulated radiation therapy

Intensity modulated radiation therapy is a relatively new treatment modality. It requires all the facilities for conformal radiation therapy and in addition some means of creating non-uniform beams. This may be achieved by using either MLCs or custom designed tissue compensators. The latter are simpler to implement, but the fabrication of the compensator is time consuming and error prone.

Intensity modulation can bring a number of treatment benefits. As well as enabling the delivery of concave dose distributions, it is also possible to treat different parts of the target volume to different doses. This may be either a 'simultaneous boost' to part of the target volume or a deliberate reduction in dose to part of the volume that is particularly close to a sensitive structure. These techniques are likely to be of benefit when the target dose limits the chances of a cure.

Intensity modulated MLC treatments may be delivered either in 'step and shoot' mode or in dynamic mode. In the former, the beams are made up of a number of 'segments' covering part of the field. Between the segments, the beam is turned off and the shape of the MLC adjusted. When added together these multiple segments make up a non-uniform beam. This approach is easier to conceptualize, and the requirements for accuracy in setting up the geometry of the MLC are less critical. In dynamic mode, the radiation remains on throughout the field delivery and the MLC leaves are scanned across the field. Since in this mode the dose is determined in part by the separation of the MLC leaves, it becomes more important to ensure that these are very accurately calibrated.

Planning for IMRT can be carried out either by inverse planning, where the dose distribution required is specified and the computer then determines the fluence maps required for individual beams, or by forward planning. In the latter case, beam segment shapes may be defined geometrically and then an optimization of the segment weights is carried out. This is a simpler form of IMRT, which requires correspondingly less quality control.

Considerable prior experience with conformal radiotherapy is essential before embarking on a programme of IMRT. It must be emphasized that the requirements for quality control for IMRT are substantially higher than those for conventional radiotherapy even with conformal blocking. Because the beams are deliberately non-uniform it is more difficult to make measurements, owing to the requirement for very precise positioning of the radiation detectors.

The lower dose rate for ⁶⁰Co units becomes a limiting factor, which in practice means that accelerators should be used. The costs involved are comparable to the costs of stereotactic treatments.

The treatment planning and quality control requirements for IMRT reduce the number of patients who can be treated, although, to some extent, the better conformation to the target volume can allow some compensation for this by treatment with fewer fractions. There is a particular requirement for more quality control and planning staff.

For IMRT, accurate localization of the target volume and methods to ensure that the target volume is fixed during treatment become even more vital. This has led to the concepts of gated therapy (where the beam is turned on and off to account for motion of the target) for lung treatments and of image guided radiotherapy (where diagnostic quality imaging equipment is attached to the linac at an angle to the treatment beam).

VIII.1.6. Treatment planning requirements

Radiotherapy treatment planning is a complex process beginning with the diagnosis of patients, including clinical data, medical tests, histopathology and imaging data (e.g. X ray, CT, MRI and PET). This involves multidisciplinary teams of professionals (e.g., radiologists, pathologists, surgeons, radiation oncologists and medical physicists). The target volume based on this medical information will be developed into the radiation beam geometry and physical calculations, which may include a graphical isodose distribution. The availability of these medical data determines the level of dose planning and treatment facilities needed. Simulation has an important role in this process. Basic diagnostic data have to be of good quality, otherwise the rest of dose planning may not be meaningful. In many situations, a simple non-graphical (p. 595 of Ref. [17]) treatment dose calculation can be performed for single or parallel opposed fields, but computerized treatment planning is needed for more complex beam arrangements. It is important to check that the proposed system can cope with all the treatment techniques intended for use at the centre

VIII.1.7. Infrastructure requirements

For advanced radiotherapy, there are significant infrastructure requirements. In order to enable accurate target definition, adequate imaging facilities are required. Computed tomography scanning is essential not only to ensure geometric accuracy of treatment but also to enable estimation of the effect of tissue density variations on the delivered dose. However, many tumours are not well delineated by CT and, in these circumstances, other imaging modalities, such as MRI and nuclear medicine, become important. In addition to this, the radiological skills necessary to interpret the images are required.

Quality control of treatment delivery requires good immobilization systems (with or without fixation) and a means of determining the accuracy of the set-up. Although electronic portal imaging devices provide real time verification, adequate verification can also be achieved with film. Economizing on this aspect of the requirements is not an option.

The increased complexity of treatments requires increased maintenance of the equipment. Local technical support is essential to conducting advanced radiotherapy.

VIII.2. TOTAL BODY IRRADIATION

VIII.2.1. Introduction

Total body irradiation is a treatment for leukaemia that involves destroying the patient's bone marrow by irradiating the whole patient to a potentially lethal dose followed by bone marrow transplantation, to restore the bone marrow function. Total body irradiation has two functions: to destroy the tumour cells and to suppress the immune system, thus preventing rejection of the bone marrow transplant. The doses delivered are toxic not only to the bone marrow but also to the lungs, and it is the lung toxicity that is the dose limiting factor. It has been shown that small increases in dose can have a significant impact on life threatening lung complications, and it is therefore essential that dosimetry be carried out to an extremely high standard.

VIII.2.2. Requirements for radiotherapy

In order to be able to treat the whole of the patient in a single field, a large SSD is required. Where this is not possible, various techniques involving moving the patient or the gantry have been developed [49], but the simplest solution is to use a horizontal beam with a supine patient at an SSD of at least 3.5 m. For this set-up, the radiation energy should be as high as possible [50], with the skin sparing effect of the high energy beam being removed by the use of a sheet of perspex placed close to the patient. However, it is not essential to have a high energy linac, and much successful work with TBI has been carried out using ⁶⁰Co units. In this case, however, it will be necessary to turn the patients on their side so that a uniform dose is delivered.

VIII.2.3. Dosimetry of total body irradiation

As already stated, a failure in the dosimetry of TBI treatment can be life threatening. The situation with TBI is fundamentally different from standard radiotherapy, with a very much extended treatment distance and a field that is always larger than the patient. In these circumstances, the amount of scattered radiation is more significant and measurements made at the standard treatment distance cannot simply be extrapolated. It is advisable to make in vivo dose measurements to check the accuracy of any calculation based dosimetry. This may be done either with diodes or with thermoluminescent dosimeters. These dosimeters should be calibrated under conditions approximating to those used in the treatment. Guidance on dosimetry can be found in Refs [62–66].

VIII.2.4. Infrastructure requirements

The infrastructure required for TBI is primarily that needed for bone marrow transplantation, which requires the nursing of patients with suppressed immune systems. Unless patients can be kept free of infection, treatments will not be successful.

In addition, it must be understood that once the process of TBI has been started, it is essential that the treatment be completed. This means that there is a requirement for a backup facility that will allow treatment to continue even if in a non-ideal way. The reliability of ⁶⁰Co units is an advantage in this respect.

VIII.3. HADRON THERAPY

Protons, neutrons and other particles are sometimes used for therapy. Protons have the benefit of a very steep fall-off in dose at the end of their range. Their principal use has been for treating ocular tumours, but a number of higher energy proton facilities have been built. Neutrons are said to be good for treating anoxic tumours, but unless very small fields are used neutron irradiation can be very toxic to normal tissues.

Hadron therapy must be regarded as still being at the experimental stage. The equipment used to generate the beams is of a highly specialized nature and requires a considerable technical infrastructure to support it. It is recommended that only in areas where there is considerable experience and corresponding technical support should treatments with these other particles be considered.

Appendix IX

BASIC EQUIPMENT RECOMMENDED FOR DOSIMETRY IN EXTERNAL RADIATION THERAPY

The basic, supplementary and additional items of equipment that are recommended for dosimetry in external radiation therapy are given in Tables 15, 16 and 17, respectively.

TABLE 15. BASIC EQUIPMENT RECOMMENDED FOR DOSIMETRYIN EXTERNAL RADIATION THERAPY

	Type of installation		
Basic equipment		Linac, photons only	Linac with electrons
An ionization chamber of Farmer type, of 0.6 cm ³ volume approximately, with plastic walls (robust), a Co-60 buildup cap, a 10 m long cable and a 10 m long extension cable with connectors calibrated at a standards laboratory. The chamber model must be included in IAEA dosimetry publications [10–12].	×	×	×
An ionization chamber of Farmer type, of 0.6 cm ³ volume approximately, with graphite walls, a Co-60 buildup cap and a 10 m long cable, calibrated at a standards laboratory in terms of absorbed dose to water. The chamber model must be included in IAEA dosimetry publications [10–12].	×	×	×
A cylindrical ionization chamber, of $0.1-0.3 \text{ cm}^3$ volume approximately, with a 10 m long cable (maximum electrode diameter: 1 mm)	×	×	×
A radioactive source for checking the stability of the cylindrical ionization chamber	×	×	×
A plane-parallel ionization chamber for electrons (minimum width of guard ring: 4 mm). The chamber model must be included in IAEA dosimetry publications [10–12].			×
An electrometer compatible with the chambers above and following the specifications in IAEA dosimetry publications [10–12], calibrated or compared at a standards laboratory	×	×	×

Basic equipment		Type of installation		
		Linac, photons only	Linac with electrons	
An additional electrometer with varying voltage bias (V1/V2 ratio equal to or greater than 3), and the possibility to reverse the polarity		×	×	
A water phantom for calibration and checks, of volume $20 \times 20 \times 10 \text{ cm}^3$ approximately, with PMMA ^a walls, including a holder for ionization chambers	×	×		
A water phantom for calibration, of $30 \times 40 \times 40$ cm ³ volume approximately, with PMMA walls, including a holder for ion chambers with manual steps or an automatic system to vary the position of the chamber	×	×	×	
A plastic slab phantom for verification of field size and coincidence of radiation and light field. Used also for output verification, with holes for the chambers, and preferably TLD	×	×	×	
A barometer (minimum scale 1 mbar or hPa, or 0.5 mmHg), preferably of aneroid type or digital, calibrated or compared at a standards laboratory	×	×	×	
A thermometer (minimum scale: 0.25°C), calibrated or compared at a standards laboratory	×	×	×	
A densitometer to measure the optical density (OD) of X ray films, with an automatic reader and coordinate system. An OD calibration film strip for checking of the instrument OD scale. Requires having access to film development	×	×	×	
A radiation field analyser to measure isodose distributions, of $50 \times 50 \times 40$ cm ³ volume approximately, with a water tank, a phantom trolley with vertical movement and a water pump		×	×	

TABLE 15. BASIC EQUIPMENT RECOMMENDED FOR DOSIMETRYIN EXTERNAL RADIATION THERAPY (cont.)

^a PMMA: polymethylmethacrylate.

Supplementary equipment	Co-60	Linac, photons only	Linac with electrons
A TLD system (both relative dosimetry and in vivo)	×	×	×
An array of diodes or ion chambers for daily quality assurance checks		×	×
A precision water level	×	×	×
Calipers and a metal ruler	×	×	×
A multimeter (volt, ohm)	×	×	×

TABLE 16.SUPPLEMENTARY EQUIPMENT FOR EXTERNALRADIOTHERAPY

For very low energy therapy (50 kV or less) a Grenz ray chamber will be needed. For the range of beam qualities from 100–300 kV, the items of equipment given in Table 15 can be used if the ionization chamber is calibrated at a standards laboratory over the range of qualities in clinical use. Below 100 kV the equipment listed in Table 17 is required.

These ionization chambers should be calibrated at a standards laboratory in terms of air kerma for X rays for at least three calibration qualities between 10 and 100 kV. Both the kV and the HVL values should be stated on the calibration certificate.

TABLE 17. ADDITIONAL EQUIPMENT FORLOW ENERGY X RAY DOSIMETRY

Equipment	50 kV or less	50–100 kV
Grenz ray chamber	×	
Ionization chamber		×
Plastic phantom		×

APPENDIX X

COMPARISON BETWEEN HDR AND LDR BRACHYTHERAPIES¹⁰

The decision regarding LDR versus HDR brachytherapy should be relatively straightforward. High dose rate brachytherapy eliminates most of the radiation safety problems associated with LDR. There is enough evidence to state that for most, if not all, clinical indications, the clinical outcomes with HDR are at least as good as those with LDR. Furthermore, many more patients can be treated with HDR in one day (often as outpatients) than with LDR in one week (and LDR patients also require hospitalization). The decision is, unfortunately, complicated by the fact that HDR is costlier to install and to maintain. Improperly maintained HDR units can be very dangerous.

If LDR brachytherapy is performed then the treatment may proceed along the following lines:

- (a) In the operating room, an applicator is inserted under general anaesthesia (or possibly a spinal block) with a radiation oncologist, anaesthesiologist and support staff present.
- (b) The applicator position is verified using a mobile X ray unit.
- (c) The patient is removed to the imaging department, an orthogonal X ray taken and the patient subsequently moved to a hospital room.
- (d) The radiation oncologist, physicist and dosimetrist review the films and decide upon the number and strength of sources to be used.
- (e) A calculation of the isodose distribution around the implant is made on the treatment planning computer. The anticipated source loading may be refined. The length of the treatment time is calculated.
- (f) A dosimetrist, physicist or source curator prepares the sources, in the source preparation room, for loading.
- (g) The source is loaded (manually) into the applicator in the patient in the hospital room by trained personnel. Although this room should ideally be shielded, bedside shields, distance and reduced occupancy in adjacent rooms can be used as a substitute.
- (h) The patient remains in the hospital for several days. Time for nursing care is limited by the radiation emitted, and visits are restricted.

¹⁰ It should be noted that, from 2002, LDR brachytherapy equipment, utilizing long half-life isotopes, has received reduced commercial support and is no longer widely available.

- (i) The sources are removed by trained personnel; occasionally some of the sources may be removed earlier or later than planned, to obtain the desired dose distribution.
- (j) The patient is discharged.
- (k) The patient may return in one or two weeks for a second treatment.

Several such procedures can be performed on any given day. In general, the number of procedures is restricted by the availability of sources, applicators, the operating room and hospital beds.

Modifications to this approach will be made if remote afterloading is used. However, the overall approach is the same.

For HDR remote afterloading, the procedure may be as follows:

- (a) The applicator is inserted in the special procedures room under sedation (or local anaesthesia) with a radiation oncologist and support staff present.
- (b) The applicator position is verified and orthogonal films taken with special diagnostic radiation equipment (often a C-arm or CT).
- (c) The patient is moved to a holding area to wait until the dose calculations are ready.
- (d) The dose calculations are made by a physicist in conjunction with a radiation oncologist on the treatment planning computer using the orthogonal films.
- (e) The patient is moved to the treatment room and a remote afterloader programmed to deliver the desired treatment.
- (f) The treatment is given. This will take several minutes. The physicist will be present during the treatment.
- (g) The patient is taken back to the procedures room for the removal of the applicators.
- (h) The patient is allowed to go home.
- (i) The patient returns several times at intervals dependent on the fractionation schedule to complete their treatment. The above procedure will be repeated on each occasion.

It is essential to recognize that no more than three to eight HDR procedures can be performed per day on a single machine, depending on the complexity of treatment planning required. For example, if 200 cases per annum of locally advanced cervix carcinoma are anticipated, and each patient is to receive four fractions, an average daily load of three to four procedures per day will be expected. Since the primary advantages of HDR over LDR are potential cost savings and patient convenience, institutions should weigh

carefully the advantages and disadvantages of HDR. High dose rate treatments dramatically increase the physician and physicist resources that must be allocated to brachytherapy while reducing the need for inpatient beds. The relative cost and availability of these resources should be compared, and the cost savings, if any, compared with the cost of amortizing the capital investment required and the costs of source replacement and machine maintenance.

Appendix XI

SPECIFICATION OF EQUIPMENT FOR REMOTE LDR AND HDR AFTERLOADING BRACHYTHERAPIES

XI.1. EQUIPMENT FOR LOW DOSE RATE AFTERLOADING BRACHYTHERAPY

XI.1.1. Technical specifications

All performance specifications and tests shall conform with the standards of the IEC for brachytherapy equipment [67] and of the International Standards Organization (ISO) for radiation sources [33–35]. The following features are required:

- (a) A source positioning reproducibility to ± 1 mm;
- (b) Automatic source retraction in the case of a power failure;
- (c) An intermediate source storage container;
- (d) A minimum of three source channels for intracavitary and endoluminal treatments (but four source channels are highly desirable);
- (e) A remote nurse alarm station.

XI.1.2. Safety compliance

Compliance with safety requirements is necessary as described in the BSS [1] and the relevant IEC standard [67].

XI.1.3. Accompanying documents

The accompanying documents shall comply with the BSS [1] as well as the relevant IEC standards concerning:

- (a) Performance specifications;
- (b) Operating instructions;
- (c) Installation documents, including requirements on shielding, power, ventilation, compressed air and any other items;
- (d) Preventive maintenance and service manuals;
- (e) Source exchange instructions.

XI.1.4. Acceptance test

An acceptance test to show compliance with agreed upon specifications will be performed by a medical physics expert, and a satisfactory result is a precondition for payment.

XI.1.5. Warranty and service

The terms of the warranty and service contract should include:

- (a) Delivery should be within four months and the installation time should be specified.
- (b) The warranty should be for one year, starting on the acceptance date.
- (c) Maintenance and service: Training for the hospital engineer should be provided, and service by the manufacturer at national or regional level should be available (give address and number of qualified engineers).
- (d) Training of staff (physicians, physicists and operators) in the use of the equipment should be included.
- (e) Prices shall include transportation and installation.
- (f) The cost of source exchange should be stated, including the rates for disposal of old sources inclusive of transportation.

XI.1.6. General remarks

The equipment quoted in the bid will be supplied with all interconnection devices necessary for a correct and total functioning in the country of destination. The minimum level of equipment recommended for LDR brachytherapy is given in Table 18.

TABLE 18. MINIMUM EQUIPMENT RECOMMENDED FOR LOWDOSE RATE BRACHYTHERAPY

	Type of installation		
Items of equipment	Manual LDR	Remote LDR	
Ir-192 source loading and cutting devices	×	×	
Source storage and transport containers (for remote LDR this should be part of the equipment) within the department	×	×	
Source handling instruments and accessories (in source preparation room and patient loading room)	×	×	
An area radiation monitor in treatment room with a light signal outside the entrance door, safe against power failure	×	×	
A portable radiation monitor	×	×	
Highly recommended: an area radiation monitor with an audio signal at the entrance to the treatment room	×	×	
An emergency container and emergency source handling instruments in the treatment room	×	×	
Radioactive waste storage	×	×	
Equipment for source/applicator localization and identification (e.g. X ray equipment)	×	×	
Dummy sources for applicator localization in patients	×	×	
A patient couch adapted for LDR brachytherapy applications: gynaecological, head and neck, bronchial (leg rests, film cassette holders, anaesthesia requirements, etc.)	×	×	
A device for fixation of a connector between the transportation applicator tubes to the patient		×	
A set of applicators for intracavitary (e.g. Henschke, Fletcher–Suit, Manchester or Delouche type) and interstitial treatments	×	×	
A radiation protection barrier for source loading in patients and for patient care	×		
Portable radiation protection barriers in the case of insufficient protection in patient ward walls and doors	×	×	

XI.2. EQUIPMENT FOR REMOTE HIGH DOSE RATE AFTERLOADING BRACHYTHERAPY

XI.2.1. Technical specifications

All performance specifications and tests shall conform to the relevant standards of the IEC [30, 67] and the ISO [33–35]. Alternatively, the following recommendations made by the AAPM [68–70] should be used:

- (a) Manual emergency source retraction;
- (b) Automatic source retraction in the event of a power failure;
- (c) Source positioning accuracy and reproducibility of ±1 mm;
- (d) A minimum of three source channels for intracavitary and endoluminal treatments with more source channels being highly desirable for breast, prostate, rectal and sarcoma implants;
- (e) A TPS including optimization and treatment parameter transfer to a treatment unit;
- (f) Automatic correction for source decay in the case of 192 Ir;
- (g) Dummy source simulation before treatment.

XI.2.2. Safety compliance

Compliance with safety requirements is necessary, as described in the BSS [1] and the relevant IEC standards [30, 67].

XI.2.3. Accompanying documents

The accompanying documents have to comply with the BSS [1] as well as the relevant IEC standards [30, 67]:

- (a) Performance specifications;
- (b) Operating instructions;
- (c) Installation documents including requirements on shielding, power, ventilation, compressed air or any other items;
- (d) Preventive maintenance and service manuals;
- (e) Source exchange instructions.

XI.2.4. Acceptance tests

Acceptance tests to show compliance with agreed upon specifications will be performed by a medical physics expert, and a satisfactory result is a precondition for payment.

XI.2.5. Warranty and service

The terms of the warranty and service contract should include:

- (a) Delivery should be within four months and the installation time should be specified.
- (b) There should be a one year warranty, starting on the acceptance date.
- (c) Maintenance and service: Training should be provided for the hospital engineer, and service by the manufacturer at national or regional level (give the addresses and number of qualified engineers) should be available.
- (d) Prices shall include transportation and installation.
- (e) The cost of source exchange should be stated, including rates for disposal of old sources inclusive of transportation.

XI.2.6. General remarks

The equipment quoted in the bid will be supplied with all interconnection devices necessary for a correct and total functioning in the country of destination.

The minimum level of equipment recommended for HDR bachytherapy¹¹ is as follows:

(a) An area radiation monitor in the treatment room, connected to the door interlock with an audio signal safe against power failure and independent of treatment equipment;

¹¹ High dose rate brachytherapy is potentially a high risk technique, and extreme accuracy and care are essential. Adequate and well trained staff (radiation oncologists, physicists, nurses, etc.) are required. In addition, the expected increase in the number of patients compared with LDR should be accompanied by a corresponding increase in the number of staff members. The short response time required for emergency actions (on the scale of minutes) imposes a requirement for the presence of both a physician and a physicist trained in emergency procedures during all applications.

- (b) A portable radiation monitor instrument at the entrance of the treatment room;
- (c) Highly recommended: an area radiation monitor with an audio signal at the entrance to the treatment room;
- (d) Emergency container and emergency source handling devices at the entrance of the treatment room door;
- (e) Equipment for applicator localization and identification (e.g. an X ray unit);
- (f) Dummy sources for applicator localization;
- (g) A treatment couch adapted for HDR brachytherapy: gynaecological and bronchial equipment (leg rests, film cassette holders, anaesthesia requirements, etc.);
- (h) A set of applicators for intracavitary (e.g. Henschke, Fletcher–Suit, Manchester or Delouche type) and endoluminal treatments;
- (i) A device for applicator fixation to the treatment couch.

The minimum level of equipment recommended for quality assurance programmes in brachytherapy is given in Table 19.

TABLE 19. MINIMUM EQUIPMENT RECOMMENDED FOR IMPLEMENTING QUALITY ASSURANCE PROGRAMMES IN BRACHYTHERAPY

	Type of installation			
Item of equipment	Manual LDR	Remote LDR	Remote HDR	
A well type ionization chamber or an isotope calibrator with source holding inserts, calibrated at a standards laboratory for the clinical sources available	×	×	×	
If Cs-137 sources are not available, a long lived reference source for checking the stability of the well chamber	×	×	×	
A facility to verify source homogeneity and source position (requires access to film development)	×	×	×	
A barometer (minimum scale: 1 mbar or 0.5 mmHg), preferably of aneroid type or digital, calibrated or compared at a standards laboratory (if not available in external radiotherapy)	×	×	×	
Calipers and a metal ruler	×	×	×	

Appendix XII

SUMMARY OF ITEMS FOR REVIEWS OF RADIATION PROTECTION AND SAFETY IN RADIOTHERAPY, INCLUDING LICENSING AND INSPECTION REVIEWS

This appendix contains lists of major items to assist in appraisals of radiation protection and safety in radiotherapy. The relative complexity of each facility should be taken into account when assessing compliance. These lists are intended only to provide the basis of a systematic appraisal, to ensure the consistency in these appraisals and to avoid omission of major items. They should not be construed as replacing professional judgement and knowledge of how safety features fit into the operation of a radiotherapy practice and of how to avoid interfering with medical care. These lists can be used as guidance for self-assessment by the licensee, by peers when performing an appraisal and by regulators, when checking compliance with the BSS [1].

XII.1. GENERAL INFORMATION ABOUT THE FACILITY AND ADMINISTRATIVE REQUIREMENTS

The following factors should be considered:

- (a) The patient workload (the number of new cancer patients per year treated with radiotherapy):
 - (i) For external beams,
 - (ii) For brachytherapy;
- (b) Treatment machines (number and type);
- (c) The number of brachytherapy sources (specify type and number);
- (d) Availability of an authorization granted by the regulatory authority to build the facility, to import the source and to operate the radiotherapy practice;
- (e) Specific conditions in the authorization;
- (f) Previous reviews and inspections performed;
- (g) Safety concerns identified in previous appraisals.

XII.2. SECURITY OF SOURCES

With respect to security of sources, there should be the following measures in place:

- (a) Provision to keep an inventory of all sources in the radiotherapy department;
- (b) Clear assignment of responsibility for keeping and updating the inventory;
- (c) A log book to record all movements of sources, with responsibility for keeping the log book assigned to a specific individual;
- (d) Provisions for dealing with spent sources in a safe manner (return to manufacturer or disposal, with a description included);
- (e) A mechanism for prompt reporting of any missing sources, both internally to the management and to the regulatory authority;
- (f) A means to prevent unauthorized access to sources.

XII.3. RADIATION PROTECTION AND SAFETY PROGRAMME

For the radiation protection and safety programme, there should be:

- (a) A programme in place and endorsed by the licensee;
- (b) A radiation protection committee or equivalent mechanism;
- (c) Approriate membership of the committee (usually comprising the chief radiation oncologist, a qualified expert in radiotherapy physics, a radiotherapy technologist, the radiation protection officer, a person responsible for coordinating the maintenance of equipment, and an administrator (representing the hospital management) for decision making and provision of resources);
- (d) A clear definition of responsibilities in the radiotherapy department;
- (e) An understanding of these responsibilities by the responsible staff and an acknowledgement by them of these responsibilities;
- (f) Provisions to ensure that only qualified staff assume the above responsibilities.

XII.4. RULES AND PROCEDURES

Procedures are required for the following tasks:

- (a) Purchase of radiation sources and radiotherapy equipment: questions of which staff members are involved in preparation of technical specifications before purchase and of which staff member provides internal clearance;
- (b) Receipt, storage and disposal of radioactive sources;
- (c) Use of radiotherapy equipment, including safety devices;

- (d) Individual exposure monitoring (Section L.5);
- (e) Workplace monitoring (Section L.5);
- (f) Leak testing;
- (g) Communication of issues critical to safety;
- (h) Maintenance and repair of radiotherapy equipment, including obligatory notification to the qualified expert in radiotherapy physics before resumption of use (for a decision about whether beam measurements are necessary before resumption of treatments);
- (i) Movement of radiation sources and patients with sources inside the hospital.

XII.5. PROTECTION AGAINST OCCUPATIONAL EXPOSURE

The provisions given in this section should be made to inform workers about their obligations and responsibilities both for their own protection and for the protection of others against radiation, as well as for the safety of sources.

XII.5.1. Conditions of service

There should be provisions to encourage pregnant workers to notify pregnancies and to adapt their working conditions so as to ensure that the embryo or foetus is protected and afforded the same broad level of protection as is required for members of the public, without excluding a female worker from work.

XII.5.2. Classification of areas

The following spaces should be controlled areas: all irradiation rooms for external beam therapy and remote afterloading brachytherapy, operating rooms during brachytherapy procedures using real sources, brachytherapy patient rooms, and radioactive source storage and handling areas.

XII.5.3. Local rules and supervision

Local rules should cover the following:

(a) Procedures for ensuring adequate levels of protection and safety of workers;

- (b) Provisions to ensure that these procedures, protective measures and safety provisions are known to those workers to whom they apply and to other persons who may be affected by them;
- (c) Supervision to ensure observance of procedures;
- (d) The investigation levels in place;
- (e) In the case in which some workers are employed in other facilities using radiation, cooperation between workers, employers and licensees of both facilities. A full description of these provisions should be given.

XII.5.4. Personal protective equipment

Tools and devices for protection of workers (interlocks, tools for handling brachytherapy sources, mobile shielding, etc.) should be readily available. A full description should be provided.

XII.5.5. Monitoring and assessment

For individual monitoring and exposure assessment, and workplace monitoring, there should be:

- (a) Arrangements to provide individual monitoring by an accredited and authorized service;
- (b) Identification of those staff members requiring individual monitoring;
- (c) Establishment of monitoring period, frequency of readings, system for recording accumulated doses, and rules for returning and changing dosimeters;
- (d) Arrangements to ensure that dose readings are made available to the staff;
- (e) Rules for estimating the staff member's dose if a personal dosimeter is lost or damaged.

XII.5.6. Monitoring of the workplace

There should be provisions for keeping the workplace under supervision and for monitoring at a frequency that enables assessment in controlled areas and in supervised areas.

XII.5.7. Health surveillance

For health surveillance, there should be:

- (a) Arrangements based on the general principles of occupational health;
- (b) Counselling available for pregnant women.

XII.5.8. Records

There should be provisions for keeping records for each worker for whom assessment of occupational exposure is required.

XII.6. PROTECTION FROM MEDICAL EXPOSURES

XII.6.1. Responsibilities and training

Responsibilities and training should include the following:

- (a) Assignment of the overall responsibility for patient protection and safety to a medical practitioner. Specify the responsible person (department head, radiation oncologist, chief medical officer, etc.).
- (b) Assignment of responsibility for conducting or supervising calibration of beam and sources, clinical dosimetry and quality assurance to a qualified expert on radiotherapy physics. Specify the type of expert (a medical physicist who has specialized in radiotherapy or a hospital physicist).
- (c) Provision to review the number of staff when workload increases, new equipment is purchased or new techniques are introduced. Specify the provisions made.
- (d) Documented education and training given to all staff.
- (e) Inclusion in the training given of lessons learned from accidents and their prevention.
- (f) Provisions for additional training when needed (e.g. when new equipment is brought into operation or when new techniques are introduced).

XII.6.2. Justification of medical exposures

The justification of medical exposures should include the following:

- (a) The procedure to ensure and provide evidence that the decision to apply a therapeutic medical exposure is made by a radiation oncologist;
- (b) Provisions for a formal justification before performing research that involves application of radiation on humans, according to the declaration of Helsinki (June 1964).

XII.6.3. Optimization: Design and testing

The optimization of design and testing should include:

- (a) An acceptance test carried out according to international (such as IEC) or equivalent national standards for radiotherapy equipment. A description of this should be provided.
- (b) A commissioning programme, including commissioning of treatment equipment as well as commissioning of TPSs, simulators and other ancillary equipment. A description of this should be provided.

XII.6.4. Optimization: Operational considerations

There should be provision for optimization (see BSS [1]: exposure of normal tissue during radiotherapy should be kept as low as reasonably achievable consistent with delivering the required dose to the planning target volume, and organ shielding should be used when feasible and appropriate), for example:

- (a) Fixation devices used to reproduce treatments;
- (b) Checks that the position of the patient at the radiotherapy unit agrees with that in the dose planning;
- (c) Portal films taken to verify the treatment;
- (d) Participation of the radiation oncologist and qualified expert in radiotherapy physics in the first patient set-up.

XII.6.5. Optimization: Calibration

For optimization of calibration there should be:

- (a) Provisions for calibration of radiation beams and brachytherapy sources;
- (b) Redundant independent verification as part of the provisions;
- (c) An internationally accepted protocol or code of practice for calibration (absorbed dose determination to reference point) in place;
- (d) A programme for follow-up calibration in place (with a description of this);
- (e) Participation in a dose quality audit programme;
- (f) Provisions for source activity verification and identification of brachytherapy sources before use;
- (g) A calibrations programme:
 - (i) At the time of commissioning a unit,

- (ii) After any maintenance procedure that may have an effect on the dosimetry,
- (iii) At intervals approved by the regulatory authority.

XII.6.6. Optimization: Clinical dosimetry

For optimization of clinical dosimetry there should be:

- (a) A procedure in place for specifying the doses absorbed by the target and the relevant organs (with a description of this);
- (b) Provisions for cross-checks of dose calculations.

XII.6.7. Optimization: Quality assurance

For optimization of quality assurance there should be:

- (a) A quality assurance programme, based on widely accepted and proven protocols (with a description of these);
- (b) Assignment of all tasks of the programme to qualified persons;
- (c) Availability of the necessary instruments, quality control equipment and other ancillary equipment, as described in the programme¹²;
- (d) Provisions for external audits as part of the programme;
- (e) A programme of maintenance, including follow-up of any safety related equipment fault detected by quality control or by other means;
- (f) Provisions to ensure that brachytherapy sources do not remain in the patient, including monitoring of patients and their clothes.

XII.6.8. Investigation of accidental medical exposures

For accidental medical exposures, there should be:

- (a) Provisions in place to investigate and report:
 - (i) Any treatment delivered to the wrong patient, the wrong tissue, or with a dose or dose fractionation differing substantially from the values prescribed by the medical practitioner or which may lead to undue secondary effects;

¹² It is advisable to consider the feasibility of implementing in vivo dosimetry.

- (ii) Any equipment failure, accident, error, mishap or other unusual occurrence with the potential to cause a patient exposure significantly different from that intended.
- (b) Provisions to estimate the doses received, indicate corrective measures to prevent recurrence, implement the corrective measures, submit a report to the regulatory authority and inform the patient.

XII.7. PROTECTION FOR THE PUBLIC

For protection of the public there should be:

- (a) Provisions for protection of the public in normal operating conditions through shielding and control of access and visitors;
- (b) Provisions to reduce the likelihood of accidents involving the public, through:
 - (i) Warning signals,
 - (ii) Provisions to ensure that control of sources is never relinquished,
 - (iii) Ensuring safe transport,
 - (iv) Dealing with disused sources safely (Section XII.2).

XII.8. EMERGENCY PREPAREDNESS AND RESPONSE

For emergency preparedness and response, there should be:

- (a) A list of predictable incidents and accidents, as well as measures to deal with them;
- (b) The persons responsible to take action, with complete relevant information about them, including their telephone numbers;
- (c) Definition in the procedures of the responsibilities of persons in an emergency (for radiation oncologists, medical physicists, radiation technologists, etc.);
- (d) A set of concise instructions posted in a visible area;
- (e) Availability of, or quick access to, the persons responsible for carrying out emergency response actions;
- (f) The equipment and tools necessary to carry out the appropriate procedures;
- (g) Training and periodic rehearsals;
- (h) A recording and reporting system;

- (i) Immediate measures to avoid unnecessary radiation doses to patients, staff and the public (such as removal of patients from a teletherapy unit, removal of implants, and return of sources to the shielded position in remote control brachytherapy and teletherapy);
- Measures to prevent access of persons to the affected area during the time that the sources are exposed and before normal conditions are restored;
- (k) In the case of leaking sources, measures to prevent dispersion of contamination and access of persons to the contaminated area.

XII.9. TRANSPORT OF RADIOACTIVE SOURCES

Provisions should be made to ensure that transport outside the hospital (e.g., for returning sources) follows the IAEA transport regulations [43].

APPENDIX XIII

CONSIDERATIONS FOR A QUALITY ASSURANCE PROGRAMME IN RADIATION ONCOLOGY

XIII.1. INTRODUCTION

The role of quality assurance in radiation oncology has received increasing attention, and its importance is now fully recognized in maintaining consistent accuracy of the absorbed doses delivered to patients undergoing radiation therapy [14–18, 71, 72]. Sources of error can arise from deficiencies in tumour localization, patient immobilization, field placement, daily patient set-up, dose calibration and calculation, as well as equipment related problems.

As already mentioned in Section 6, quality assurance programmes in radiation therapy cover a wide range of areas, often involving several medical disciplines and the medical institution's management. Coordination, therefore, is critical among medical physicists, dosimetrists, maintenance engineers, radiation oncologists, RTTs, other medical disciplines and management. In many institutions, the medical physicist is best placed to oversee such a programme.

The aim of a physics quality control programme for radiation therapy is an ongoing evaluation of the functional performance characteristics of the associated equipment and calculations, because these characteristics influence both the geometrical and dosimetric accuracies of the applied doses. There are two main parts of such a programme:

- (1) Periodic quality control measurements and evaluation;
- (2) Regular preventive maintenance.

The medical physicist should be responsible for making sure that both parts of the programme are carried out.

The three main areas for sources of inaccuracy in dose delivery can be identified as:

- (1) Physical dosimetry, i.e. the commissioning and calibration of treatment machines and sources;
- (2) Treatment planning, i.e. the delineation of target volume and critical structures, acquisition of patient specific factors and dose distribution calculations;

(3) Patient treatment, i.e. the set-up of the patient and the recording of the treatment and final verification of the accuracy of the delivered dose.

Any equipment quality control programme will be based upon a complete determination of baseline values at the time of acceptance and commissioning of the equipment. Data for any machine should not be assumed to be identical to those of similar machines until verified. Most manufacturers provide, in written form, their acceptance test procedures that list the mechanical and radiation parameters that will provide the benchmark for the equipment. Commissioning provides the detailed information about the equipment, for example, the tables of beam data. These data obtained for each piece of equipment add to the benchmark data. Once the acceptance tests, commissioning and calibrations have been completed, a quality control programme must commence to ensure that the accuracy of the treatments is maintained, i.e. that the goal of such a programme is to assure that there are no serious deviations from the performance characteristics established during commissioning. A quality control programme also provides data and techniques to be used following any machine repairs. It is essential that the management of the radiotherapy department make the appropriate arrangements to ensure that necessary radiotherapy equipment is available to the medical physicists to carry out the quality control measurements.

Many references in this appendix are made to the publication "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group 40" [17]. This publication will subsequently be referred to as AAPM TG-40. Additional items not covered in AAPM TG-40 are taken from IPEM Rep. 81 [18]. Detailed quality control procedures can also be found in various other publications [73–75].

XIII.2. THE QUALITY CONTROL PROGRAMME IN RADIATION THERAPY

Quality control in a radiation therapy department covers a wide range of activities, and the treatment process can be viewed in many different ways. For the purposes of this discussion, four main areas have been identified. They are:

- (1) External beam treatments;
- (2) Brachytherapy treatments;
- (3) Measurement equipment;
- (4) Clinical aspects of the treatments.

In developing a quality control programme, it is important to use measurement techniques that are simple and rapid (to minimize the test time) and reproducible at a level adequate to determine parameter changes smaller than the tolerance or action level.

It should be noted that in many countries the specification, performance and quality control of teletherapy units may be subject to government regulations. If this is the case, these government regulations must be adhered to.

XIII.3. QUALITY CONTROL OF ORTHOVOLTAGE UNITS

Table 20 summarizes the quality control tests for orthovoltage units.

Frequency	Procedure	Tolerance
Daily	Output constancy	±5%
•	Interlocks and warnings	Functional
	Mechanical fixtures	Functional
	Filter interlock	Functional
Monthly	Output measurement	±3%
-	Timer end error	±0.01 min
	Timer accuracy	±2% or ±0.02
	Backup timer	Functional
	Timer response to power failure	Functional
	Filter interlocks	Functional
	Mechanical fixtures	Functional
	Monitor chamber linearity	±2%
	Coincidence of light beam and X ray beam	±5 mm
	HVL constancy	±5%
Annually	Field uniformity	±5%
	Half-value layer	±10%
	Applicator factors	±3%

TABLE 20. QUALITY CONTROL OF ORTHOVOLTAGE UNITS(adapted from IPEM Rep. 81 [18])

XIII.4. QUALITY CONTROL OF ⁶⁰Co UNITS

The recommended quality control tests for $^{60}\mathrm{Co}$ units are given in Table 21.

Frequency	Procedure	Tolerance ^b
Daily	Safety Door interlock Radiation room monitor Audiovisual monitor	Functional Functional Functional
	Mechanical Localizing lasers Optical distance indicator (ODI)	2 mm 2 mm
Weekly	Check of source positioning	3 mm
Monthly	Dosimetry Output constancy Mechanical checks	2%
	Coincidence of light and radiation fields Field size indicator (collimator setting) Gantry and collimator angle indicator Cross-hair centring Latching of wedges and trays	3 mm 2 mm 1° 2 mm Functional
	Safety interlocks Emergency off switches Wedge interlocks	Functional Functional
Annually	DosimetryOutput constancy traceable to SSDLField size dependence of output constancyCentral axis dosimetry parameter constancy (PDD/TAR) ^c Transmission factor constancy for all standard accessoriesWedge transmission factor constancyTimer linearity and errorOutput constancy versus gantry angleBeam uniformity versus gantry angleOff-axis point measurements with and without wedgesSafety interlocksFollow test procedures of manufacturer	2% 2% 2% 2% 2% 1% 2% 3% 3% Functional

TABLE 21. QUALITY CONTROL OF 60 Co UNITSa(adapted from AAPM TG-40 [17])

TABLE 21. QUALITY CONTROL OF 60 Co UNITS^a (cont.)(adapted from AAPM TG-40 [17])

Frequency	Procedure	Tolerance ^b	
	Mechanical checks	2 mm	
	Collimator rotation isocentre	diameter	
		3 mm	
	Gantry rotation isocentre	diameter	
		2 mm	
	Couch rotation isocentre	diameter	
	Coincidence of collimator, gantry and couch axes with	2 mm	
	isocentre	diameter	
	Coincidence of radiation and mechanical isocentres	2 mm	
		diameter	
	Table top sag with 80 kg mass evenly distributed	5 mm	
	Vertical travel of table	2 mm	
	Field intensity of light	Functional	

^a All these procedures should be carried out during commissioning. Appropriate tests should be performed following any repair of the teletherapy unit.

^b The tolerances listed should be interpreted to mean that if a parameter either exceeds the tabulated value (e.g., the measured isocentre under gantry rotation exceeds 2 mm diameter) or the change in the parameter exceeds the nominal value (e.g., the output changes by more than 2%), then an action is required. The distinction is emphasized by the use of the term 'constancy' for the latter case. Moreover, for constancy, per cent values are plus/minus the deviation of the parameter with respect to its nominal value; distances are referenced to the isocentre or nominal SSD.

^c PDD/TAR: percentage depth dose/tissue air ratio.

XIII.5. QUALITY CONTROL OF LINEAR ACCELERATORS

The recommended quality control tests for linacs are given in Tables 22 and 23.

XIII.6. QUALITY CONTROL OF SIMULATORS

Since simulators are designed to reproduce the geometric conditions of the radiation therapy equipment, they are subject to the same mechanical checks as the treatment unit. In addition, the simulator should be checked for image quality according to the guidelines for diagnostic radiography units [76, 77]. Table 24 summarizes the quality control tests for simulators.

TABLE 22.QUALITY CONTROL OF LINEAR ACCELERATORSWITHOUT ELECTRON BEAMS^a

(adapted from AAPM TG-40 [17])

Frequency	Procedure	Tolerance ^b
Daily	Dosimetry Output constancy	3%
	Safety	
	Door interlock	Functional
	Audiovisual monitor	Functional
		Functional
	Mechanical	
	Localizing lasers	2 mm
	ODI	2 mm
Monthly	Dosimetry	
	Output constancy with field instrument, with appropriate corrections	2%
	Backup monitor constancy	2%
	Central axis dosimetry parameter constancy (e.g. PDD and TAR)	2%
	Beam flatness constancy	3%
	Beam symmetry	3%
	Mechanical checks	
	Coincidence of light and radiation fields	2 mm or 1% on a side ^c
	Field size indicator (collimator setting)	2 mm
	Field light intensity	Functional
	Jaw symmetry ^d	2 mm
	Gantry and collimator angle indicator	1°
	Cross-hair centring	2 mm diameter
	Wedge position	2 mm or 2% change in transmission
		factor
	Tray position	2 mm
	Treatment couch position indicators Latching of wedges and blocking tray	$2 \text{ mm}/1^{\circ}$
		Functional
	Safety interlocks	
	Emergency off switches	Functional
	Wedge interlocks	Functional
	For foo	tnotes see p. 172

TABLE 22. QUALITY CONTROL OF LINEAR ACCELERATORS WITHOUT ELECTRON BEAMS^a (cont.)

(adapted from AAPM TG-40 [17])

Frequency	Procedure	Tolerance ^b
Annually	Dosimetry	
-	Output calibration traceable to SSDL	2%
	Field size dependence of output constancy	2%
	Transmission factor constancy for all standard accessories	2%
	Off-axis factor constancy	2%
	Wedge transmission factor constancy (including depth and field size dependence)	2%
	Monitor chamber linearity	1%
	Output constancy versus gantry angle	2%
	Beam uniformity constancy versus gantry angle	2%
	Arc mode	As specified
	Off-axis point measurements with and without wedges	3%
	Safety interlocks	
	Follow test procedures of manufacturer	Functional
	Mechanical checks	
	Collimator rotation isocentre	2 mm diameter
	Gantry rotation isocentre	2 mm diameter
	Couch rotation isocentre	2 mm diameter
	Coincidence of collimator, gantry and couch axes with isocentre	2 mm diameter
	Coincidence of radiation and mechanical isocentres	2 mm diameter
	Table top sag with 80 kg mass evenly distributed	2 mm
	Vertical travel of table	2 mm

^a All these procedures should be carried out during commissioning. Appropriate tests should be performed following any repair of the teletherapy unit.

^b The tolerances listed should be interpreted to mean that if a parameter either exceeds the tabulated value (e.g., the measured isocentre under gantry rotation exceeds 2 mm diameter) or the change in the parameter exceeds the nominal value (e.g., the output changes by more than 2%), then an action is required. The distinction is emphasized by the use of the term 'constancy' for the latter case. Moreover, for constancy, per cent values are plus/minus the deviation of the parameter with respect to its nominal value; distances are referenced to the isocentre or nominal SSD.

^c Whichever is greater. Should also be checked after a change in light field source.

^d Jaw symmetry is defined as the difference in distance of each jaw from the isocentre.

TABLE 23. QUALITY CONTROL OF LINEAR ACCELERATORELECTRON BEAMS^a(adapted from AAPM TG-40 [17])

Frequency	Procedure	Tolerance ^b
Daily	Dosimetry	
-	Output constancy with constancy meter	3%
Monthly	Dosimetry	
-	Output constancy with field instrument, with appropriate corrections	2%
	Central axis dosimetry parameter constancy (PDD) ^c	2 mm at therapeutic depth
	Beam flatness constancy	3%
	Beam symmetry	3%
	Mechanical checks	
	Applicator position	2 mm
	Safety interlocks	
	Electron cone interlocks	Functional
Annually	Dosimetry	
-	Output calibration traceable to SSDL	2%
	Applicator output factor constancy	2%
	Output constancy versus gantry angle	2%

^a These tests are those that are additional to those given in Table 22, for accelerators equipped with an electron beam. All these procedures should be carried out during commissioning. Appropriate tests should be performed following any repair of the teletherapy unit.

^b The tolerances listed should be interpreted to mean that if a parameter either exceeds the tabulated value (e.g., the measured isocentre under gantry rotation exceeds 2 mm diameter) or the change in the parameter exceeds the nominal value (e.g., the output changes by more than 2%), then an action is required. The distinction is emphasized by the use of the term 'constancy' for the latter case. Moreover, for constancy, per cent values are plus/minus the deviation of the parameter with respect to its nominal value; distances are referenced to the isocentre or nominal SSD.

^c PDD: percentage depth dose.

XIII.7. QUALITY CONTROL OF EXTERNAL BEAM MEASUREMENT EQUIPMENT

Measurement equipment is equally important as radiation treatment equipment and should be part of the quality control programme. The recommended quality control tests, frequency and tolerance limits are given in Table 25.

TABLE 24. QUALITY CONTROL OF SIMULATORS	
(adapted from AAPM TG-40 [17])	

Frequency	Procedure	Tolerance ^a
Daily	Localizing lasers	2 mm
	ODI	2 mm
Monthly	Field size indicator	2 mm
	Gantry/collimator angle indicators	1°
	Cross-hair centring	2 mm
	Focal spot-axis indicator	2 mm
	Fluoroscopic image quality	Baseline
	Emergency/collision avoidance	Functional
	Coincidence of light and radiation fields	2 mm or 1%
	Film processor sensitometry	Baseline
Annually	Mechanical checks	
-	Collimator rotation isocentre	2 mm diameter
	Gantry rotation isocentre	3 mm diameter
	Couch rotation isocentre	2 mm diameter
	Coincidence of collimator, gantry, couch axes and isocentre	2 mm diameter
	Table top sag with 80 kg mass evenly distributed	5 mm
	Vertical travel of couch	2 mm
	Radiographic checks	
	Exposure rate	Baseline
	Table top exposure with fluoroscopy	Baseline
	kVp and mAs calibration	Baseline
	High and low contrast resolutions	Baseline

^a The tolerances mean that the parameter exceeds the tabulated value (e.g., the measured isocentre under gantry rotation exceeds 2 mm diameter).

Redundancy is an important part of any quality control programme. The IAEA/WHO TLD postal audit service [78] provides a redundant dose measuring system. Redundancy in dose calibration equipment is necessary to ensure that instruments are maintaining their calibration. Although the use of ⁹⁰Sr reference sources does not provide a truly redundant system, it does provide a means of ensuring the constancy of the calibration system. A ⁶⁰Co teletherapy machine can be used as part of a constancy system. If only one dosimetry system is available, a redundant system should be formed with a dosimetry system at another institution with annual comparisons, if possible.

TABLE 25. OUALITY CONTROL OF MEASUREMENT EOUIPMENT

(Key: I, initial use for each mode used or following malfunction and repairs; *E*, each use (measurement sequence) or ongoing evaluation; *B*, each batch or box at the appropriate energy (the position of the dosimeter element should also be considered); D, documented and correction applied or noted in report of measurement; M, monthly; a, annually; 2a, once every two years. Adapted from AAPM TG-40 [17])

Instrument type	Test	Frequency	Tolerance ^a
Local standard ^b	SSDL calibration	2a ^c	D
	Linearity	2a ^c	0.5%
	Venting	2a ^c	D
	Extra-cameral signal (stem effect)	Ι	0.5%
	Leakage	E	0.1%
	Redundancy check ^d	E	2%
	Recombination	Ι	D
	Collecting potential	E	D
Field instruments	Local standard comparison	2a	1%
	Linearity	2a	D
	Venting	2a	D
	Extra-cameral signal	2a	D
	Leakage	E	0.1%
	Recombination	Ι	D
	Collecting potential	E	D
Output check	Local standard comparison	М	1%
Relative dose			
Ion chamber	Linearity	1a	D
Film	Extra-cameral signal	I	1%
	Dose response	В	D
	Densitometer linearity	1a	D
	Processor uniformity/reproducbility	Е	D
	Calibration	E	D
TLD	Linearity	Ι	D
Accessories	Thermometer calibration	T	0.1°C
	Barometer calibration	3 months	1 mmHg
	Linear rule calibration	I	0.3
		-	0.0

^a Per cent values are plus/minus the deviation of the parameter with respect to the nominal value, and distances are referred to the isocentre or nominal SSD.

^b A local standard instrument has a calibration directly traceable to an SSDL and should be reserved for calibration of radiation beams, field instruments and comparisons.

^c Without a redundancy programme, this may be inadequate. ^d With a radionuclide (e.g. ⁹⁰Sr) or chamber comparison.

XIII.8. QUALITY CONTROL OF TREATMENT PLANNING COMPUTERS

The treatment planning computer is a critical component of the entire treatment process. Computers may be used to calculate, for example, patient dose distributions and treatment time or monitor units for a given prescribed dose and fixed point dose calculations for irregular fields. All such systems should undergo acceptance testing and commissioning. Following acceptance testing and commissioning should be implemented.

Complete documentation by the manufacturer should include the methods for obtaining the beam data and other data necessary to implement the system. The manufacturer should provide a complete description of the physical models for dose calculations with expected accuracy and limitations along with complete input–output and operating instructions. Quality control tests should be performed after any programme modifications and as part of an ongoing quality control programme. Table 26 lists the recommended quality control measures for TPSs and treatment time calculations.

XIII.9. QUALITY CONTROL OF EXTERNAL BEAM TREATMENT PLANNING

In this section, quality control for the treatment planning process is discussed, followed by a discussion of quality control for individual patients. Quality control in treatment planning may refer to two distinct processes:

- (1) Non-graphical planning, in which the treatment time for the prescribed dose to a point on the central axis is calculated using central axis per cent depth dose, tissue phantom ratios or tissue maximum ratios (TMRs), and beam output calibration tables. Furthermore, the field apertures, which define the treatment volume, are usually designed on radiographs obtained during localization and simulation.
- (2) Graphical planning is used for many patients. In this method, a target volume is defined from CT or orthogonal simulation films, and the patient's contour is obtained either using a mechanical device (e.g. lead solder wire) or from the CT. The field arrangements are designed and the dose distributions calculated on one or a limited number of axial cross-sections using a computerized TPS. The radiation oncologist prescribes the dose and fractionation schedule.

TABLE 26. QUALITY CONTROL FOR TREATMENT PLANNING SYSTEMS AND TREATMENT TIME CALCULATIONS (reproduced with permission of the AAPM (AAPM TG-40 [17]))

Frequency	Test	Tolerance ^a
Commissioning	Understand algorithm	Functional
and following	Single field or source isodose distributions	$2\%^{a}$ or 2 mm^{b}
software updates	Treatment time calculations including	2% or 5%
	inhomogeneity corrections where	if including
	appropriate	inhomogeneities
	Test cases	2% or 2 mm
	I/O system	1 mm
Daily	I/O devices	1 mm
Monthly	Check sum	No change
-	Subset of reference quality assurance test set (when check sums not available)	2% or 2 mm ^c
	I/O system	1 mm
Annually	Treatment time calculations	2%
-	Reference quality assurance test set	2% or 2 mm ^d
	I/O system	1 mm

^a Per cent differences between calculations of the computer TPS and measurements (or independent calculations).

^b In the region of high dose gradients, the distance between isodose lines is more appropriate than the percentage difference. In addition, less accuracy may be obtained near the end of single sources.

^c These limits refer to a comparison of dose calculations at commissioning with the same calculations subsequently.

^d These limits refer to a comparison of calculations with measurements in a water tank.

XIII.9.1. Quality control of the treatment planning process

Treatment planning is a process that begins with acquisition of patient data and continues through graphical planning, plan implementation and treatment verification. It entails interactions among the entire radiation oncology treatment team, and the use of a computerized TPS. Each step of the complex treatment planning process involves a number of procedures relevant to quality assurance. The process is represented schematically in Table 27.

TABLE 27. TREATMENT PLANNING PROCESS(reproduced with permission of the AAPM (AAPM TG-40 [17]))

Process	Related quality procedures
Positioning and immobilization	Port films. Laser alignment
Localization (simulation)	Simulator quality control, including image quality and mechanical integrity
Patient data acquisition (CT, MRI and manual contouring)	Computed tomography and MRI quality control, including image quality and mechanical integrity (accuracy of mechanical contouring)
Data transfer to TPS	Quality control of the entire data transfer process, including digitizers and digital data transfer
Definitions of target volumes	Peer review, e.g., a new patient planning conference and chart rounds
Design of beam portals	Independent check of delivery (e.g. port films) and peer review
Computation of dose distributions	Machine data from commissioning and quality control of treatment machines. Accuracy and quality control of the TPS
Plan evaluation	Peer review of plan, e.g., during chart rounds. Independent check by a medical physicist
Prescription	Written, signed and dated
Computation of monitor units	Quality control of the treatment planning system. Independent check made within 48 hours
Production of blocks and beam modifiers	Quality control for block cutting and compensator systems. Review of port films
Plan implementation	Review of set-up by the treatment planning team. Chart review
Patient quality assurance	Treatment plan review. Chart review after introduction of a new or modified field, weekly chart review and port film review. In vivo dosimetry for unusual fields, critical organ doses (e.g. gonadal doses). Status check and follow-up.

XIII.9.2. Quality control of the individual treatment planning process

All the parameters in the treatment plan should be verified during the first set-up so that any ambiguities or problems can be corrected immediately. Special care should be taken to ensure that all beam modifying devices (blocks, wedges and compensators) are correctly positioned. Although errors in block fabrication and mounting are often discovered during reviews of port films, wedge or compensator misalignment is much more insidious, and may remain throughout the course of treatment if not discovered during initial patient set-up. A check of the initial set-up by the physicist will minimize errors that may go undetected due to misunderstanding of physical concepts. Details of the quality control recommendations for individual patients are given in Table 28.

XIII.10. USE OF IN VIVO DOSIMETRY IN A QUALITY CONTROL PROGRAMME

In vivo dosimetry can be used to identify major deviations in the delivery of treatment as well as to verify and document the dose to critical structures. Thermoluminescent dosimetry is often used because TLD detectors are small and relatively easy to calibrate, while diodes have the advantage of instantaneous readout. These in vivo systems can have relatively large uncertainties that should be assessed before using them. However, with care, accurate dose measurements can be made. In vivo systems are useful for individual patient measurements and should be considered as part of a comprehensive quality control programme.

XIII.11. RECORD AND VERIFY SYSTEMS

Record and verify systems (Appendix VI.8.4) can improve the safety of treatment considerably and are essential where a multileaf collimator is in use. Most linacs and some ⁶⁰Co units have R&V systems as standard. However, the potential exists for such systems to cause a false sense of security, and it remains essential to ensure that the prescription is thoroughly checked before treatment commences. Direct transfer of treatment data from the treatment planning computer is also beneficial, but users should be aware of the possibility of data corruption during transfer. It is essential that all such systems be carefully checked as part of the commissioning process.

TABLE 28. SUMMARY OF QUALITY CONTROL RECOMMENDATIONS FOR INDIVIDUAL PATIENTS (*adapted from AAPM TG-40* [17])

Procedure	Recommendations
Treatment time calculation	Reviewed prior to treatment by an authorized individual who did not perform the initial calculation, or, when that is not possible (e.g. emergency treatments), prior to the third fraction or before 10% of the dose has been delivered, whichever occurs first
Graphical treatment plan review	1. Reviewed prior to treatment, or, when that is not possible, then prior to the third fraction or before 10% of the dose has been delivered, whichever occurs first
	2. Reviewed by a medical physicist who did not formulate the treatment plan. Where there is only one physicist and that person implemented the plan, then reviewed by another authorized individual
	3. Review includes calculated treatment time, input–output and plan quality
	4. Independent calculation of dose at a point: Compare for each field, with an independent calculation of dose to a point using the calculated monitor units: the prescribed and calculated doses
	5. If these differ by more than 5%, then the discrepancy should be resolved before continuing treatment
Plan set-up	Radiation oncologist present at first set-up for major changes in treatment
Beam (portal) films, curative and high morbidity palliative treatments. In addition, ongoing patients	Initial films reviewed by radiation oncologist prior to first treatment. Portal films (the standard is weekly) also reviewed by the radiation oncologist
Beam (portal) films: palliative patients	Films reviewed prior to second fraction
In vivo dosimetry	1. All institutions should have access to TLD or other in vivo dosimetry systems.
	2. Should be used to measure dose to critical structures (e.g., lens of the eye and gonads).
	3. May be used to record doses for unusual treatment conditions.

XIII.12. CHART REVIEWS

A procedure for checking patient charts for the technical parameters of treatment should be developed. An outline of the parameters to be checked and verified is given below.

XIII.12.1. Review of new or modified treatment fields

The first task of chart reviews is to find any errors. The following specific areas of the chart should be reviewed:

- (a) Treatment prescription;
- (b) Treatment parameters;
- (c) Isodose distribution and special dose calculation;
- (d) Treatment time;
- (e) In vivo measurements;
- (f) Daily records;
- (g) Previous radiation treatments.

XIII.12.2. Weekly chart reviews

In addition to the initial chart check, a weekly review should take place and should include:

- (a) A review of treatments in the previous week;
- (b) Determination of the cumulative dose.

XIII.12.3. Reviews at completion of treatment

As a final review before the chart is filed, the following checks should be made:

- (a) That the prescribed dose has been delivered;
- (b) That there is proper documentation of the chart according to departmental policy;
- (c) That a treatment summary has been included.

XIII.13. A QUALITY CONTROL PROGRAMME FOR BRACHYTHERAPY

The following elements should be included in a quality control programme for brachytherapy.

XIII.13.1. Sources

Recommended quality control tests for brachytherapy sources are given in Table 29.

TABLE 29. QUALITY CONTROL TESTS FOR BRACHYTHERAPY SOURCES

(Key: I, initial purchase; D, documented; E	, at e	every	use.	Reproduced	with
permission of the AAPM (AAPM TG-40 [17]))				

Type of source	Test	Frequency	Tolerance
Long half-life:	Physical/chemical form	Ι	D
description	Source encapsulation	Ι	D
	Radionuclide distribution and source uniformity	Ι	D
	Location of radionuclide in encapsulation	Ι	1 mm
Long half-life:	Mean of batch	Ι	3%
calibration	Deviation from mean	Ι	5%, D
	Verification of calibration	Е	а
Short half-life:	Physical/chemical form	Ι	D
description	Source encapsulation	Ι	D
Short half-life:	Mean of batch	Е	3%
calibration	Deviation from mean ^b		5%
	Radionuclide distribution and source uniformity	Е	\mathbf{V}^{c}

^a Visual check of source colour code or measurement in a calibrator.

^b For short half-life sources, this may not always be practical.

^c V, visual check, autoradiograph or ionometric check.

XIII.13.1.1. Identification

For sealed sources large enough to carry identification numbers or coloured, labelled tapes, a check should be made that the accompanying certificate giving the serial number and details of the various characteristics of the source is in agreement with the number engraved on the source.

For sources that cannot be identified individually (e.g. ¹⁹²Ir wires or seed ribbons), a separate check should be made in a well ionization chamber and the sources stored in special containers. Every time the source is cut, it should be identified again and stored in another compartment.

XIII.13.1.2. Inventory

This should be carried out with each new delivery of sources and updated every time a change occurs; in particular when sources are used for patient loading, it should be checked that they are returned after patient treatment. Moreover, a general source inventory should be carried out at least every month. A log book or record of all the sources present in the department and their location should be available at all times.

XIII.13.1.3. Contamination

The manufacturer should provide a certificate giving details of the tests used to check the level of contamination of each source. Periodic tests should be performed to ensure that no degradation of the sources has occurred (swab test). The results should be recorded in a log book.

XIII.13.1.4. Uniformity of linear activity

Autoradiography may be used to verify the uniformity of linear activity. To obtain an acceptable precision, a low sensitivity film must be used and read out with a densitometer. For ribbon sources, the distances between the sources should be verified. A linear activimeter is an alternative instrument for verifying the uniformity of linear activity.

XIII.13.1.5. Calibration

The use of the International System (SI) of units has been obligatory since 1985, and it is recommended that the intensity of a source be specified in terms of reference air kerma rate. This can be measured with a well type chamber previously calibrated by a standards dosimetry laboratory with a source of the same geometrical characteristics. Particular attention should be paid when measuring HDR sources, to ensure that the measurement range of the instrument is appropriate and that the collection voltage is high enough to prevent significant recombination.

XIII.13.2. Quality control of applicators

Quality control tests should be performed before initial use, after repairs and periodically according to Table 30.

XIII.13.3. Quality control of remote afterloading devices

The quality control tests recommended for remote afterloading devices are given in Table 31.

It should be noted that in many countries, the specifications, performance and quality control of afterloading devices may be mandated by government regulations. If this is the case, these regulations must be adhered to. If they are different from the recommendations given in Table 31, the table should be modified to reflect the appropriate regulations.

TABLE 30. QUALITY CONTROL TESTS FOR BRACHYTHERAPY APPLICATORS

(Key: I, initial use or following malfunction and repairs; D, documented and correction applied or noted in report of measurement, when appropriate; E, as a minimum, a visual inspection to verify that the dummy sources fairly represent the active source distribution. Reproduced with permission of the AAPM (AAPM TG-40 [17]))

Type of applicator	Test	Frequency	Tolerance
Intracavitary	Source location	I, yearly	D
	Coincidence of dummy and active sources	\mathbf{I}^{a}	1 mm
	Location of shields	I^{b}	D
Interstitial	Coincidence of dummy and active sources	I, E	1 mm

^a To reduce exposure of personnel, the dummy source location may be checked instead of the active source if it is established that the dummy and active source locations are coincident.

^b The location of shields should be verified by radiograph before first use. Before every use, the applicator may be shaken to listen for loose parts.

TABLE 31. QUALITY CONTROL OF REMOTE AFTERLOADING BRACHYTHERAPY UNITS

Frequency	Test	Tolerance
Each treatment day	Room safety door interlocks, lights and alarms	Functional
	Console functions, switches, batteries and printer	Functional
	Visual inspection of source guides	Free of kinks and firmly attached
	Verify accuracy of ribbon preparation	Autoradiograph
Weekly	Accuracy of source and dummy loading (dummies used for spacing and/or simulation/verification)	1 mm
	Source positioning	1 mm
At each source	Calibration ^a	3%
change or quarterly	Timer function	1%
	Check accuracy of source guides and connectors	1 mm
	Mechanical integrity of applicators (by X ray if appropriate)	Functional
Annually	Dose calculation algorithm (at least one standard source configuration for each isotope)	3%, 1 mm
	Simulate emergency conditions	
	Verify source inventory	

(reproduced with permission of the AAPM (AAPM TG-40 [17]))

^a It is worthwhile on changing a source to calibrate both the new and the old sources to establish and document the reproducibility of the calibration method.

XIII.13.4. Measurement equipment for brachytherapy

The quality control procedures for well type ionization chambers are given in Table 32.

TABLE 32. QUALITY CONTROL TESTS FOR BRACHYTHERAPY SOURCE CALIBRATORS

(Key: I, initial use or following malfunction and repairs^a; S, isotope/source specification; D, documented and correction applied or noted in report of measurement, when appropriate; E, at each use (measurement sequence) or ongoing evaluation. Reproduced with permission of the AAPM (AAPM TG-40 [17]))

Instrument type	Test	Frequency	Tolerance
Well type ionization	Standards laboratory calibration	I, S ^a	D
chamber	Precision	Ι	2%
	Linearity	I, every two years	1%
	Collection efficiency	Ι	1%
	Geometrical/length dependence	Ι	D
	Energy dependence	Ι	D
	Source wall dependence	Ι	D
	Venting	Ι	D
	Redundancy check	Е	2%
	Leakage	E	D
In-air calibration	SSDL calibration	I, S ^a	D
chamber and external source holder	Accuracy of source chamber distance	Annually, S	1%, D
	Redundancy See Table 25 for other tests	E	D

^a Instruments or sources must have a calibration directly traceable to a standards laboratory.

XIII.13.5. Quality control of brachytherapy treatment planning systems

A systematic validation of both software and hardware is required, both before first use and after any major revision. In any event, full commissioning should be repeated annually to ensure that no unintentional modifications have been introduced. A log should be kept of all tests, giving details of the methods used and the results. General aspects of the quality control of TPSs are given in Table 26.

XIII.13.5.1. Quality control tests of computer software

Prior to data entry, peer reviewed literature relating to the method of calculation should be identified and studied carefully, together with the system documentation. Where a commercial software supplier offers a training course, a physicist from the local department should attend. If the source specification quantity required by the computer system is different from that used for source calibration, a detailed record should be made of the method of conversion and of all the conversion factors used in the process.

Some tests of dose and dose rate computation and display algorithms that should be performed include the following:

- (a) Dose rates at points at short distances (i.e. 1–2 cm) from a single source should be calculated at defined points relative to the source, and the results should be compared with reference values and/or hand calculations. The exact coordinates of the calculation points should be entered, and the results should not be interpolated from a display grid or isodose display.
- (b) Isodose displays around a single source should be generated and compared with reference data.
- (c) Dose rate computations with multiple sources should also be performed. Multiple source testing for linear sources should include a test with sources in different orientations: one possibility would be to calculate the dose rate at the centre of a cube with sources arranged along the twelve edges. It is recommended that a test case with multiple sources should be run monthly as a part of ongoing quality control, together with a check sum test if this is available. The software should be tested over the limits of its expected clinical usage and must not be used outside these limits without further testing. If the software is to be used for dose calculations following, for example, an intracavitary cervix application, there should be a test using sources in a geometry that is typical of local practice, and the results compared with dose rates determined by manual calculations.
- (d) Correction for source decay, when included in the software, should be compared with hand calculations.
- (e) The coordinate transformations and scaling involved in calculating doses and dose rates in arbitrary planes with magnification should be tested.

The above tests should be considered as examples. Other tests may be necessary at each institution, depending on their clinical practice.

XIII.13.6. Quality control of patient treatment plans

Computer generated treatment planning for each individual patient should be checked with hand calculations of dose at selected points. Various graphs and tables from the relevant literature can be used for this purpose. This verification process can be facilitated with computerized spreadsheets. The data used for the verification should be for sources identical to those being used clinically and pertain to sources specified in the same units. In particular, confusion between various source specifications can lead to large errors in dose rate calculations.

Appendix XIV

CONSIDERATIONS FOR COMMISSIONING OF RADIOTHERAPY EQUIPMENT

XIV.1. INTRODUCTION

Commissioning of radiotherapy equipment is the responsibility of the local physicist, although the IAEA may be able to provide support from a visiting consultant. In any case, it is important that the local physicist should be fully aware of the measurements being made and should take responsibility for their accuracy. A detailed summary of the measurements should be made, with cross-references to computer files and notebook entries. All measurement records should be signed and dated.

Guidance is given below on the principal requirements of commissioning. Further guidance can be obtained in the report of AAPM Task Group 40 [17] and IPEM Report 54 [79] for accelerators, in addition to the report of AAPM Task Group 53 [80] for TPSs. These publications are principally directed at ongoing quality assurance. Guidance on the commissioning of TPSs is also contained in IPEM Report 68 [81]. IPEM Report 81 [18] on quality control of radiotherapy equipment can also be used. Thorough reviews of TPS commissioning and quality assurance are given by Van Dyk et al. [82] and an IAEA report [45].

Estimates are given below of the time required for each stage of commissioning. It is important to realize that making measurements on the equipment is only part of the process. The data collected have to be collated into beam data manuals for treatment dose calculations and relevant data entered into the treatment planning computer. The latter process can be very time consuming as most modern TPSs use models that enable the computer to calculate doses under non-standard conditions. The parameters used in these models have to be carefully adjusted to match the measured beam data under standard conditions and then tested with a sample of data measured under non-standard conditions. The amount of time taken to complete this part of the process is dependent on the planning system being commissioned and on the complexity of the treatments likely to be carried out. Timescales can be shortened if several identical machines are in use within the department, provided that the manufacturer is required to ensure that the beams from the machines are well matched. Matching of beams also simplifies operational use of the equipment. The times given assume that there are no problems with measurements. It is very unlikely that there will be no delays, and an overhead of 50% of the time

specified should be allowed for unforeseen circumstances, breakdowns and adjustments that have to be made as a result of the measurements. Newly released equipment is likely to have more such problems, and in this case an overhead of 100% should be allowed.

Before putting equipment into use, appropriate procedures for daily calibrations and instructions for use of the equipment should be prepared. A multidisciplinary review meeting should be held before the equipment is handed over for clinical use, to review the commissioning process and to ensure that the treatment staff are fully briefed on any limitations of the equipment.

XIV.2. COMMISSIONING OF ORTHOVOLTAGE UNITS

Before any measurements are made, it is important to check that the kilovoltage and the radiation protection are adequate. For an orthovoltage unit, the beams are characterized on the basis of the HVL of the beam. Clinical characteristics depend on these parameters, including the factors to be used for calibration, it is wise to start with measurement of the HVL and to ensure that the desired beam qualities have been properly characterized. Surface measurements at these energies can be difficult, and compilations of backscattering factors and depth doses such as those contained in British Journal of Radiology Supplement 25 can be used [48]. The output factors for each applicator must, however, be independently measured, as they will not be exactly predicted by the ratio of backscattering factors, which can nevertheless be used as a check. Table 33 summarizes the measurements required and provides a suggested order for the measurements to be taken in.

XIV.3. COMMISSIONING OF ⁶⁰Co UNITS

Before any measurements are made, it is important to check that the radiation protection is adequate. A measurement of the source transit time should be made at an early stage, as this can be an important indicator of problems with the source transit mechanism. It is important that staff be given appropriate training on procedures to be carried out in the event of a failure of the source transfer mechanism. Table 34 lists the tests and measurements that should be carried out, and their suggested order. For a ⁶⁰Co unit, published depth dose data may be used, but measurements should also be made to check these. However, for treatment planning isodose calculations it will be necessary to measure the beam profiles, and it is convenient to measure the depth doses at the same time. Checks should be made that the measured data are close to

TABLE 33. ORTHOVOLTAGE COMMISSIONING MEASUREMENTS AND CHECKS

Test or measurement	Time needed	Equipment required
Mechanical checks	2 h	None: visual inspection
Electrical safety checks	2 h	Safety test equipment
Protection measurements	3 h per filter	Protection level dosimeter
HVL measurements	1 h per filter	Pure Al, Cu and ion chamber system
Films to check uniformity for all applicators	30 min per applicator	Film and densitometer
Focal spot films	1 h	Pinhole and film
Output measurements for principal applicator	2 h per filter	Calibrated ionization chamber system and calibration protocol
Timer linearity	30 min	Stop watch
Dosimeter linearity	1 h	Ionization chamber system
Applicator factors	1 h per filter per applicator	Ionization chamber
Depth dose measurement checks	1 h per filter per applicator	Ionization chamber
Verification of source distance	1 h	Ionization chamber, stand and ruler
Preparation of data for clinical use	16 h per filter	

the published data. The calibration of the equipment is especially important and must be carried out by a suitably qualified physicist. Ideally, the calibration should be checked by a second physicist using independent measurement equipment. If this is not possible, it is important to reconcile the dose rate measurement with that predicted from the source calibration certificate. On the basis of the times given in Table 34, a ⁶⁰Co unit with wedges would take four to five weeks to commission after the completion of installation.

XIV.4. COMMISSIONING OF LINEAR ACCELERATORS

Before any measurements are made, it is important to check that the radiation protection is adequate. Table 35 lists the tests and measurements that

TABLE 34. COBALT-60 UNIT COMMISSIONING: MEASUREMENTS AND CHECKS

Test or measurement	Time needed	Equipment required
Protection measurements	3 h	Protection level dosimeter
Mechanical checks	2 h	None: visual inspection
Electrical safety checks	2 h	Safety test equipment
Mechanical alignment checks	4 h	Pointers and graph paper
Source activity verification	1 h	Ionization chamber and phantom
Beam uniformity checks	1 h	Film or scanner
Verification of radiation isocentre	1 h	Star film apparatus or other test device
Depth dose and profile measurements for open fields	10 h	Plotting tank
Depth dose and profile measurements for wedged fields	8 h per wedge	Plotting tank
Output variation with field size in water	4 h	Ionization chamber
Output variation with field size in air	4 h	Ionization chamber
Additional measurements for penumbra trimmers (if fitted)	10 h	Ionization chamber and plotting tank
Measurements in non-standard conditions to test planning system calculation	8 h	Plotting tank
Wedge factor and variation with field size	6 h per wedge	Ionization chamber
Verification of source distance	2 h	Ionization chamber
Final source calibration	3 h	Ionization chamber and phantom
Timer linearity	30 min	Stop watch
Preparation of data for clinical use	>40 h plus 10 h per wedge	PC

should be carried out for photon beams, and their suggested order. Additional tests for electron beams are given in Table 36. It is important that, before beam data are collected for treatment planning, all the necessary adjustments are carried out that might affect the radiation beam or the field size. The characteristics of different accelerators of the same manufacturer and type are becoming

Test or measurement	Time needed	Equipment required
Protection measurements	3 h*	Protection level dosimeter
Mechanical checks	2 h	None: visual inspection
Electrical safety checks	3 h	Safety test equipment
Mechanical alignment checks	4 h	Pointers and graph paper
Beam energy checks	1 h*	Plotting tank
Beam uniformity checks	1 h*	Plotting tank
Radiation and light field coincidence and field size calibration	3 h*	Plotting tank and film
Verification of radiation isocentre	1 h*	Star film apparatus or other test device
Depth dose and profile measurements for open fields	10 h*	Plotting tank
Depth dose and profile measurements for wedged fields	8 h per wedge*	Plotting tank
Additional measurements for multileaf collimator (if fitted)	12 h*	Ionization chamber and plotting tank
Output variation with field size in water	4 h*	Ionization chamber
Output variation with field size in air	4 h*	Ionization chamber
Measurements in non-standard conditions to test planning system calculation including asymmetric fields	16 h*	Plotting tank
Wedge factor and variation with field size	4 h per wedge*	Ionization chamber
Verification of source distance	2 h	Ionization chamber
Final calibration	3 h*	Ionization chamber and phantom
Dosimeter linearity	30 min	Stop watch
Preparation of data for clinical use, first energy	>80 h plus 10 h per wedge	PC
Preparation of data for clinical use, second energy	>60 h plus 10 h per wedge	РС

TABLE 35. LINAC COMMISSIONING: MEASUREMENTS AND CHECKS

* Indicates that measurements must be carried out independently for each energy. The times shown are for one energy only.

Test or measurement	Time needed	Equipment required
Mechanical checks	2 h	None: visual inspection
Energy measurements	2 h*	Plotting tank
Backup jaw position checks	1 h per applicator*	Plotting tank
Depth dose and profile measurements	1 h per applicator*	Plotting tank
Output measurements for principal applicator	2 h*	Calibrated ionization chamber system, calibration protocol
Applicator factors	30 min per applicator*	Ionization chamber
Corrections for non-standard distances	8 h*	Ionization chamber and phantom
Preparation of data for clinical use	24 h + 2 h per applicator*	PC

TABLE 36. ADDITIONAL MEASUREMENTS FOR ELECTRON BEAMS

* Indicates that measurements must be carried out independently for each energy. The times shown are for one energy only.

increasingly similar. If requested, manufacturers are often able to match another machine of the same type, and if this is done, it should be possible to share beam data. However, it is unlikely that matching will be perfect and it will still be necessary to check that the data used are relevant to each machine. Commissioning of a simple single energy linac should not take much longer than the time for a ⁶⁰Co unit. However, with a multimode/multienergy linac, each energy must be treated independently. Published data such as those in British Journal of Radiology Supplement 25 [48] are useful to provide a check of the measurements, but should not be used for calculation of patient doses. The calibration of the equipment is especially important and must be carried out by a suitably qualified medical physicist. Ideally, the calibration should be checked by a second physicist using independent measurement equipment. It is important to realize that the control values for different energies are different, and it is therefore essential to make independent measurements of all the factors, including the beam geometry, at all the energies. In Tables 35 and 36, an asterisk indicates that that the measurements must be separately carried out for all the energies. The tables do not include the time required to commission special techniques such as TBI or stereotactic arc radiotherapy. Application of the times shown in Tables 35 and 36 shows that a simple single energy linac should take about the same amount of time as a ⁶⁰Co unit to commission, but that a linac with two photon energies and five electron energies will take about 16 weeks to commission.

XIV.5. COMMISSIONING OF SIMULATORS

Table 37 lists the checks and measurements required to commission a simulator. These will take a little over a week. It is particularly important to establish a baseline for assessment of the imaging performance, to act as a reference for future testing. Evidently the mechanical alignment of the simulator is of paramount importance, as otherwise information derived from it will be misleading. Computed tomography simulation is gradually being introduced either as simulator CT or as an add-on to CT scanners. It is important to check that both the geometry of the scanning and the measurement of density are accurate. Such checks will take an additional two days.

XIV.6. COMMISSIONING OF TREATMENT PLANNING SYSTEMS

It is difficult to be prescriptive about what should be done to test a planning system. Report 68 of the IPEM [81] provides the minimum basis for such testing, but considerable additional testing is required [45, 82] if advanced features of modern TPSs are to be used. It will never be possible to test every

Test or measurement	Time needed	Equipment required
Protection measurements	3 h	Protection level dosimeter
Mechanical checks	2 h	None: visual inspection
Electrical safety checks	3 h	Safety test equipment
Mechanical alignment checks	4 h	Pointers and graph paper
Radiation and light field coincidence and field size calibration	3 h	Film
Verification of radiation isocentre	1 h	Star film apparatus or other test device
Radiation measurements	8 h	kVp meter, dosimeter and timer
Imaging measurements	4 h	Test objects
Data transfer checks	8 h	PC
Preparation of instructions for clinical use	>10 h	PC

TABLE 37. SIMULATOR COMMISSIONING: MEASUREMENTS AND CHECKS

feature under every condition, and it is imperative that an ongoing system for checking individual plans be established. Testing may take three weeks for a basic planning system and up to six months or more for a more advanced system. A balance is needed between requiring exact matches to measured data in every situation and being overly restrictive of treatment techniques that are allowed to be used. This judgement should be made after discussions between physicists and clinicians.

XIV.7. COMMISSIONING OF BRACHYTHERAPY EQUIPMENT

XIV.7.1. Commissioning of a remote brachytherapy afterloading unit

Before beginning the commissioning of a remote brachytherapy afterloading unit, the physicist must be trained by the vendor's representative in its operation. After the physicist has become thoroughly familiar with the unit, its commissioning will begin with a radiation survey around the source storage safe. Measurements should be made at the surface of the source storage safe and at monthly intervals. The physicist will then place an emergency source storage container in the room and perform a room survey with the source(s) out of the storage safe in a treatment applicator. After successful completion of the room survey, the physicist will verify that all interlocks are functional. These interlocks include ensuring that treatment cannot be initiated with the door open and that the source will automatically retract in the cases of power failure, opening the treatment room door, and activating the treatment interrupt and emergency off buttons. Other interlocks include those that prevent the treatment from being initiated if no source guides or defective source guides are attached to the remote afterloading unit, or if the source guides are not correctly attached to the unit. After verifying the functionality of all the interlocks, the physicist should verify that all alarms, area radiation monitors, closed circuit TVs and intercoms are functional.

The physicist will then proceed with the source calibration or verification of the manufacturer's source specification. Any variance between the manufacturer's specification and the in-house measurement greater than 5% is highly unusual. The physicist should investigate a difference this large and determine the correct values of the source strength for entry into the computerized treatment planning unit and the treatment control station of the remote after-loading unit. The physicist should verify that the values in the computerized treatment planning unit and the treatment control station are identical, and that the decays of the source strengths agree for both systems.

After determining the source strength, the physicist should verify that the source positioning accuracy and reproducibility are in accordance with the specification (± 1 mm). Then, the physicist should verify the accuracy of the treatment timer.

Because the physicist is the first line of defence in an emergency, they should be intimately familiar with all emergency procedures required for the remote afterloading unit. The physicist must be able to respond correctly and without hesitation to any emergency resulting from a malfunction of the unit.

Before starting treatments, the physicist, in consultation with the physician, should develop policies and procedures for each type of treatment to be administered.

XIV.7.2. Commissioning of manually afterloaded sources

The physicist will calibrate manually afterloaded sources or verify the manufacturer's source specification. Any variance between the manufacturer's specification and the in-house measurement greater than 5% is highly unusual. The physicist should investigate any variance greater than 5% and determine the correct value of the source strength for entry into the computerized treatment planning system. The physicist must also perform autoradiographs of each of the brachytherapy sources to ensure that the radioactive material is correctly distributed within the source capsule. Additional information on brachytherapy quality control is provided in Appendix XIII.

XIV.7.3. Commissioning of brachytherapy applicators

The physicist must ensure that the brachytherapy sources will be correctly positioned in the brachytherapy applicators, whether the applicators are for a remote afterloading unit or for manually afterloaded systems. This may be accomplished by taking orthogonal radiographs of the applicators with dummy sources in place. If the applicators are equipped with internal shields, the physicist must verify correct placement of these shields. This verification may also be accomplished with orthogonal radiographs. Additional information on brachytherapy quality control is given in Appendix XIII.

XIV.7.4. Commissioning of brachytherapy treatment planning systems

As with commissioning of computerized treatment planning systems for teletherapy, it is difficult to be prescriptive in the commissioning of computerized treatment planning systems for brachytherapy. However, as a minimum, the radiation distribution around all clinical sources must be entered into the system. The format for entry of these data is highly dependent on the computerized TPS. The radiation distributions produced by the computerized TPS should be compared with published data for the identical (manufacturer and model number) brachytherapy sources. Additional information regarding quality control of brachytherapy TPSs is given in Appendix XIII. The tests discussed in this appendix should also be performed as part of the commissioning of the TPS.

The physicist must verify the accuracy of any digitization equipment to be used to enter source data from source localization films. The physicist should also verify all source reconstruction algorithms used. A phantom designed to place dummy sources at known positions can be imaged, and the dummy source positions can be entered from these images into the treatment planning computer. The coordinates determined by the computerized TPS can be compared with the known source coordinates.

Useful references for brachytherapy commissioning and practice include Refs [8, 13, 18, 41, 68, 70].

XIV.7.5. Summary of requirements

A summary of the requirements is given in Table 38.

TABLE 38. BRACHYTHERAPY COMMISSIONING: MEASUREMENTS AND CHECKS

Test or measurement	Time needed	Equipment required
Remote afterloading unit	8 h ^a	Well type ion chamber, GM counter, survey meter, film, diagnostic X ray source and stop watch
Manual sources	8 h	Dummy sources, film and diagnostic X ray source
Brachytherapy applicators	2 h per applicator	Film and diagnostic X ray source

^a This time is for commissioning of the unit and does not include the time required for the vendor's training of the physicist or development of policies and procedures.

Appendix XV

RADIATION SHIELDING FOR EXTERNAL BEAM FACILITIES

Figure 8 shows the plan and elevation views of a ⁶⁰Co radiation therapy vault. Note that the use of a maze allows for a rather standard door with a thickness of only 3.2 mm of lead in it. The figure also shows that the room requires primary thick barriers on the walls and ceiling wherever the ⁶⁰Co beam may aim since there is no beamstopper attached to this unit. If there was space below the floor, the floor would also be a thick primary barrier. However, because of the weight of the treatment unit and its shielding, it is always best to locate such a facility on unexcavated ground.

The method described in NCRP Report 151 [6] for calculating the necessary shielding is based on three steps:

- (1) Establishing a dose value P in a given occupied area;¹³
- (2) Estimating the dose D that would be received if no shielding were to be provided;¹³
- (3) Obtaining the attenuation factor that is necessary to reduce D to P; for example, finding the ratio D/P.

In Ref. [6], the dose value P was the regulatory individual dose limit. International recommendation has shifted from the traditional method of accepting P as the regulatory individual dose limit to the optimization of protection by using a collective dose.

However, as optimization of protection based on the collective dose is complex and subject to a number of uncertainties, an accepted, more practical, method is the constrained optimization method, based on establishing a (source related) individual dose constraint, which is set to be below the regulatory dose limit.

The advantage of using individual rather than collective dose values is that the method is simple and robust and that the NCRP methodology can be applied, with the only difference being to replace the individual dose limit by the individual dose constraint.

The ratio P/D is then the fractional attenuation, which must be supplied by the barrier wall. If the barrier material such as concrete has a known

¹³ Doses are given in terms of effective dose, which is approximated by the personal dose equivalent $H_p(10)$.

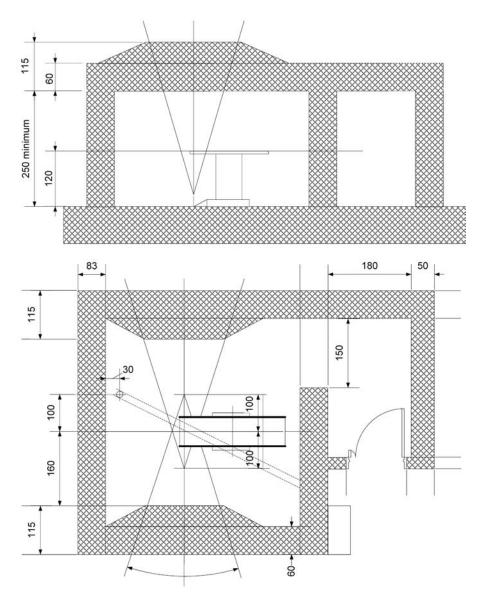


FIG. 8. The diagram used to calculate shielding thickness (dimensions in cm).

tenth-value-layer thickness (TVL) (in cm), the wall thickness can be determined from the following equation:

$$P/D = e^{(-2.3 \times \text{thickness/TVL})} = 10^{-\text{thickness/TVL}}$$

or

thickness required = $\text{TVL} \times \log_{10}(D/P)$.

XV.1. DETERMINATION OF P

The constraint could be assumed to be a half of the individual dose limit related to the source (the teletherapy unit). Since the exposure of persons is uniformly distributed throughout the year, the weekly dose constraint for occupational exposure could be 10/50 = 0.2 mSv, corresponding to an ambient dose equivalent of $H^*(d) = 0.2$ mSv/week.

For members of the public, the dose constraint would be

 $1/50 \times 2 = 0.01$ mSv/week.

XV.2. DETERMINATION OF D

XV.2.1. Direct beam (calculation of primary barrier)

The first step in determining D is to determine the radiation dose delivered in a week at the isocentre. This quantity is referred to as the workload W.

Example: To determine the workload assume that a facility's records indicated that on average 40 patients per day are treated to a dose of 2 Gy/ patient for five days per week. Also assume an average TMR to the prescription point of 0.67 and an isocentre distance d_{iso} of 100 cm. Then the workload is:

W = 40 patients/day × 2 Gy/patient × 5 days/(week × 0.67) = 600 Gy/week

at 1 m from the source.

This dose value can be modified by the use factor U for the barrier (the fraction of work performed with the beam directed to the barrier in question)

and by the occupancy factor T for the position in question, which represents how much time during the treatment week someone might be present. The modified dose is WUT.

The dose rate of the beam at 1 m from the source is converted to the dose at the position in question by using the inverse square law. For a point on the axis of the beam this relates to the attenuation of the primary beam so that the inverse square correction is to the distance in metres from the source d_{pri} :

$$D = \frac{WUTd_{\rm iso}^2}{d_{\rm pri}^2} \tag{1}$$

XV.2.2. Leakage radiation

There is leakage radiation from the head of a 60 Co unit, D_L , which is given as the percentage of the primary dose rate (% D_{pri}) in the beam-on position. The appropriate IEC standard [37] puts a limit of 0.1% of the dose rate at the isocentre in a plane perpendicular to the beam axis at 1 m distance from the source outside the beam area. At the same time, leakage should not exceed 0.5% of the dose rate at the isocentre on a sphere of 1 m radius centred at the source. The use factor is U = 1 for the leakage radiation.

The leakage dose at the distance d_{leakage} is:

$$D_{\rm L} = WT(\% \ D_{\rm pri}/100) d_{\rm iso}^2 / d_{\rm leakage}^2$$
(2)

At the same time, the aforementioned IEC standard [37] requires that the absorbed dose rate due to stray radiation in the beam-off condition at 1 m from the radiation source should not exceed 0.02 mGy/h, so that staff working with ⁶⁰Co units can safely approach them as required.

For some commercially available 60 Co units, the leakage through the radiation head is less than 0.02 mGy/h at 1 m in both the beam-off and beam-on conditions, and the leakage may be ignored in the shielding calculations. However, for other 60 Co units the leakage must be considered, because it constitutes a significant component of the shielding requirements.

XV.2.3. Scattered radiation

Barriers must also shield against scattered radiation. To determine the dose, D_s , from scattering at the point of interest, the NCRP provides tables of scattering factors indicating the fraction of dose scattered from an object at a particular angle. This scattering factor is denoted by a, and is stated for a 20 cm

 \times 20 cm field size. If the average field size differs from 20 cm \times 20 cm, then *a* must be increased by a factor equal to the ratio of the areas of the fields. For instance, if the average field size is 30 cm \times 30 cm, then the factor *a* is multiplied by 900/400. The use factor is U = 1 for scattered radiation. It should be noted that the energy of the scattered radiation varies with angle, but in all cases is less than that of the primary beam.

The equation for the dose from scattered radiation is:

$$D_{\rm s} = \frac{aWTFd_{\rm iso}^2}{d_{\rm sca}^2 d_{\rm sec}^2} \tag{3}$$

where

- $D_{\rm s}$ is the dose from scattered radiation at the point of interest;
- *a* is the scattering factor;
- W is the workload;
- *T* is the occupancy factor;
- *F* is the field size factor;
- d_{iso} is the distance in metres from the source to the isocentre;
- $d_{\rm sca}$ is the distance in metres from the source to the scatterer; and
- d_{sec} is the distance in metres from the scatterer to the barrier.

For radiation that is scattered to the position, mainly from the patient (D_s) the inverse square law is applied from the isocentre rather than from the source.

Note that both the leakage and scattered components are reduced by the square of the distance from the isocentre.

XV.2.4. Combination of the three types of radiation

If there can be a primary beam directed to the point of interest, this will be the greatest thickness by far and should be the design thickness for the barrier. If there is no primary beam at the barrier, use the larger of the leakage or scattering thickness if one is larger than the other by at least one TVL, otherwise use the larger value and add 0.333TVL.

The use factor can only be less than 1 for the primary barriers, since the barriers always have leakage and scattered radiation striking them when the beam is on.

XV.3. EXAMPLE OF CALCULATION OF A PRIMARY BARRIER

From Fig. 8, if the point A is taken as the control console for a 60 Co machine with 100 cm SAD, the dose constraint would be P = 0.1 mSv/week. Since this is a primary barrier, the use factor U may be less than 1. We assume that U = 0.25, i.e. that the beam strikes the barrier only for a quarter of the 'beam-on' time. The operator is always at the console when the beam is on, so the occupancy T is 1. The unattenuated dose per week at A is given by reducing W by the square of the distance from the isocentre and by the use and occupancy factors, U and T, respectively:

$$D = \frac{WUTd_{\rm iso}^2}{d_{\rm pri}^2} \tag{4}$$

where

$$\begin{split} D &= 600 \times 0.25 \times 1 \times 1^2 / (1.6 + 1.0 + 1.15 + 0.15)^2 \\ W &= 600 \text{ Gy/week at 1 m} \\ U &= 0.25 \\ T &= 1 \\ d_{\text{iso}} &= 1 \text{ m} \\ d_{\text{pri}} &= 1.6 \text{ m} + 1.0 \text{ m} + 1.15 \text{ m} + 0.15 \text{ m} = 3.9 \text{ m} \\ \text{ (i.e. } 1.6 \text{ m from the isocentre to the shielding wall,} \\ 1.0 \text{ m from the source to the isocentre,} \\ 1.15 \text{ m thickness of the shielding wall,} \\ 0.15 \text{ m width of the control console, distance from the wall to where } \\ \text{ personnel will stand} \end{split} \\ D &= 600 \times 0.25 \times 1 / (3.9)^2 = 9.9 \text{ Gy/week} \Rightarrow \text{ round to 10 Gy/week} \end{split}$$

The primary barrier must attenuate by a factor of $10/0.0001 = 100\ 000$ and $\log(100\ 000) = 5.0$ TVL.

If the TVL of concrete with a density of 2.35 g/cm^3 is 23 cm, the thickness of the barrier required is 115 cm.

XV.4. EXAMPLE OF A SECONDARY BARRIER

XV.4.1. Leakage radiation

Typical parameters involved in leakage radiation for a secondary barrier are:

P = 0.01 mSv/week as a dose constraint for members of the public (the ambient dose equivalent of 1 Sv corresponds numerically to an absorbed dose of 1 Gy for ⁶⁰Co at the dose maximum);

W = 600 Gy/week

U = 1 for all secondary barriers T = 1 for an area occupied all the time

 $D_{\rm L} = 200 + 60 \, {\rm cm}$

and the percentage leakage is 0.05% for a 60 Co head.

The barrier required by leakage is then given by Eq. (1):

$$D_{\rm L} = (600 \times 0.05/100)/2.6^2 = 0.044 \text{ Gy/week}$$

and

 $D_{\rm L}/P = 0.03/0.00001 = 4400$

Therefore, 3.6TVL is needed, or about 83 cm of concrete, as the TVL for the leakage radiation is the same as that for the primary beam.

XV.4.2. Example of a secondary barrier for scattered radiation

Typical values involved in scattered radiation for a secondary barrier are:

$$D_{\rm s} = \frac{aWTFd_{\rm iso}^2}{d_{\rm sca}^2 d_{\rm sec}^2}$$

where

a = 0.0009 W = 600 Gy/week at 1 m T = 1 $d_{iso} = 1$ m $d_{sca} = 1$ m $d_{sec} = 2.6 \text{ m}$ F = 1, i.e. the average field size is 20 cm × 20 cm

$$D_{\rm s} = \frac{0.0009 \times 600 \times 1 \times 1 \times 1^2}{(1)^2 \times (2.6)^2} = 0.08 \text{ Gy/week}$$

The secondary barrier factor is:

$$D_{\rm s}/P = 0.08/0.00001 = 8000$$

log(8000) = 3.9TVL.

XV.4.3. Combination of leakage and scattered radiation

The example above indicates the need for 3.9TVL, but one must remember that the energy of scattered radiation is greatly reduced from the primary beam energy and is usually about 0.5 MeV, which has a TVL of 11.7 cm of concrete so that 3.9TVL is 45.6 cm of concrete. Since this is more than one TVL smaller than the leakage requirement, one can simply use the thickness required for leakage radiation, i.e. 83 cm.

XV.4.4. Remarks

It should be noted that there is a conceptual difference between using the dose limits for P and using dose constraints. The use of dose limits for P was done in combination with conservative factors, such as W, U and T, which provided a safety margin leading to actual doses that were well below the limits: often a tenth of the dose limit. The use of dose constraints is a step towards optimization (constrained optimization). Therefore, the safety margins should be reduced, since a safety margin is already incorporated in the constraint. Conceptually, optimization should be used with realistic factors rather than overestimated ones. Using conservative factors together with constraints goes beyond optimization, i.e. it is 'not optimized'.

A typical conceptual error is to re-evaluate existing shielding using dose constraints but retaining conservative factors. This ignores the fact that the actual doses were a tenth of the calculated ones or even lower, i.e. ignoring existing safety margins. The result may be an increased barrier thickness, which is neither necessary nor optimized, and cannot be considered as good protection practice.

XV.5. EFFECT OF ENERGY ON BARRIER THICKNESS

If linacs are to be installed, it is necessary to increase the thickness of the barrier according to the maximum energy of the beam. Table 39 shows the variation in TVL and the resulting typical primary barrier thicknesses for a range of energies. For energies above 10 MV, it is necessary to consider the requirements for neutron shielding. In respect of the primary barrier this will not be a problem, as neutrons will be sufficiently attenuated by the barrier designed to attenuate photons. However, there is an implication for maze design as neutrons are not attenuated by scattering in the same way as photons. The issue of maze design is considered in NCRP Report 79 [83] and IPEM Report 75 [84]. Lining the maze with wood could be helpful.

An additional consideration with accelerators above 10 MV is induced activity. The neutrons induce activity both in the walls of the room and more especially in the materials in the head of the accelerator. It is important when servicing such equipment to check the activity of the materials in the head before working on them. If a high energy beam is used for the majority of treatments, it will be necessary to allow short half-life isotopes to decay to a safe level.

XV.6. ERGONOMIC CONSIDERATIONS

XV.6.1. Treatment room design considerations

The treatment room shielding should be designed in accordance with the recommendations of IPEM Report 75 [84] and NCRP Report 151 [6], as well as guides provided by manufacturers (especially for conduits), paying due regard

Beam	TVL (cm)	Typical wall thickness (m)
Co-60	23	1.38
4 MV	27	1.64
6 MV	34	2.03
10 MV	38	2.32
20 MV	47	2.74

TABLE 39. THICKNESSES OF PRIMARYBARRIERS FOR DIFFERENT ENERGIES

to the requirements of the BSS [1] and any additional requirements imposed by the regulatory authority. A sign should be posted on the door warning of the radiation hazard, in accordance with the requirements of the regulatory authority. The room should be large enough to accommodate the treatment machine, allowing the full range of motion of the treatment table, and also for assembly and disassembly of the machine. A door interlock or other suitable means to prevent unauthorized access shall be provided, and an area radiation monitor safe against a power failure should be visible on entering the room. A means for dimming the room lights should be considered in the design of the room. Adequate space should be planned for cabinetry to store treatment devices, immobilization devices, blocks and daily quality assurance equipment. A means of securely mounting patient positioning lasers to the wall at points appropriate to project lines through the isocentre should be included in the plans.

Space for a console immediately outside the treatment area overlooking the treatment room door shall be planned. This console area should be large enough to accommodate not only the control console for the unit but also a work space for the radiotherapy technologist and space for an intercom and closed circuit television system (if there is no viewing window). The console area should also accommodate any computer equipment associated with the treatment machine. This may include an R&V system, electronic imaging, treatment time calculation systems or in vivo dosimetry systems.

XV.6.2. Treatment room size

The benefits of a larger treatment room are:

- (a) Easier setting up of the patient;
- (b) The possibility to accommodate a larger machine later;
- (c) Adequate space for accessories as well as patient-specific immobilization equipment and blocks;
- (d) Space for stretcher patients.

However, it must be borne in mind that accessories are likely to be kept adjacent to the walls of the room, so that too large a room can be a disadvantage.

If TBI is planned, a 3.5 m distance from the source to the wall would be convenient.

XV.6.3. Wall materials

Normal concrete (with a density of 2.35 g/cm^3) may be cheaper to pour even though it requires thicker walls and therefore more space than high density concrete (with a density of 3.8 g/cm^3).

A boron enriched plaster (in the form of polyethylene sheets or bricks 5 cm thick) for accelerators with photon energies higher than 15 MV may be required. An alternative is a longer maze, which takes more space and may involve higher costs.

Conduits through the wall are needed for dosimetry items, intercom, airconditioning and heating, etc. The conduits through the wall for dosimetry items need to be of minimum diameter 150 mm and to pass through the wall obliquely. Permanent wiring for dosimetry is desirable.

XV.6.4. Roof

A roof simply to shield from the rain and sun is only possible if the vault is far from other higher buildings; this constitutes a hazard, as access is difficult to prevent. Most governments have passed legislation for some minimal roof shielding. If vertical or adjacent development is expected, higher specifications are required for the roof slab.

XV.6.5. Doors and mazes

The entrance to the treatment room has to permit access to patients on stretchers. It is also wise to allow sufficient size for easy installation and removal of the treatment machine. Doors have the advantage of providing absolute control of entry. They also allow the maze to be shorter. It is essential that doors can be opened (but not closed) from inside. The disadvantages are that the mechanism can break, requiring a relatively slow manual override, and that patient/staff entry and exit is made slower. Injuries have been caused by malfunctions of doors. In the absence of a door, the barrier can take the form of a boom fixed to interlocks or of a light beam. The former has the advantage of being quick to open and visible without being claustrophobic. The latter is even more aesthetically pleasing but does not provide as satisfactory prevention of access. In any case, the activation of the 'door' interlock should give rise to a low level audible warning.

XV.6.6. Beam stoppers

Beam stoppers are available for some machines. These are mounted on the treatment gantry opposite to the radiation head and are intended to allow thinner primary barriers. While this objective is achieved, beam stoppers can be cumbersome and may limit patient access.

XV.6.7. Waiting and changing areas

In some countries, changing cubicles are legislated for with regard to size and position. Provision of changing cubicles may make patient changeover more rapid.

Appendix XVI

TRAINING REQUIREMENTS FOR RADIOTHERAPY

XVI.1. INTRODUCTION

Although the largest capital outlay in a radiotherapy facility may be for the equipment and buildings, the most valuable asset of a facility is its well trained personnel. Accordingly, sufficient resources should be invested in their initial training and in their ongoing training. Regular in-service training on at least an annual basis should be provided for all personnel. Continuing medical and medical physics education for at least one radiation oncologist and one medical physicist in the team should be expected annually. It is the responsibility of senior personnel to establish an ongoing formalized training programme in their institution as part of the initiation of new radiotherapy facilities. This stratagem is required in order to build and maintain the radiotherapy infrastructure.

When any new equipment is purchased or any new special procedures are implemented, additional training will be required for all staff. Alternative methods for this training could be:

- (a) Radiation oncologists and radiotherapy medical physicists spending a period of time in a host institution whose staff have considerable experience in the new techniques or equipment;
- (b) A visit from an IAEA expert to the institution.

The former has the advantage of observing the procedure in an established setting; an advantage of the latter is that the whole team will benefit from the time of implementation. Ideally a combination of both should be provided.

XVI.2. TYPICAL TRAINING REQUIREMENTS FOR TELETHERAPY

XVI.2.1. Radiation therapists/therapy radiographers

The members of this profession have disparate tasks in different countries (Section 3.2.2.3). Requirements for training and, where enforced, registration vary widely. In the European Union, a standardized curriculum has been established [85, 86], and in the USA the training is overseen by the Joint

TABLE 40. TRAINING REQUIRED FOR NEW EQUIPMENT IN ADDITION TO BASIC TRAINING (RTTs)

Change of equipment	Additional training required
Modern Co-60 machine with wedges and blocks, etc.	Two weeks
80 cm SSD to 100 cm SAD Co-60 machine conversion (using SAD techniques)	Two days
Upgrade to computer controlled Co-60 machine (assuming computer literacy as part of basic training)	Two weeks
Simple Co-60 machine to single energy computer controlled linac (assuming computer literacy as part of basic training)	Four weeks
Computer controlled Co-60 to single energy linac controlled by a computer	Three weeks
Single energy linac to multienergy linac with electrons	One week

Review Committee on Education in Radiologic Technology (JRCERT). Other national standards and syllabi exist. Typical training is of the order of two to three years.

It is assumed in Table 40 that the staff have been trained to this acceptable standard in basic radiography practice. However, for particular new equipment, further training will be required.

XVI.2.2. Clinically qualified radiotherapy medical physicists

It is assumed that the staff have been trained to an acceptable standard in radiotherapy physics (Section 3.2.2.2), following a curriculum such as ESTRO-EFOMP [87]. However, for particular new equipment, further training will be required as shown in Table 41.

XVI.2.3. Clinicians

It is assumed that the clinical staff have been trained following a curriculum such as ESTRO [88] and are already practicing as radiation oncologists. However, for particular new equipment, further training will be required as shown in Table 42.

TABLE 41. ADDITIONAL TRAINING REQUIRED FOR NEWEQUIPMENT (RADIOTHERAPY PHYSICISTS)

Change of equipment	Additional training required
Modern Co-60 machine with wedges and blocks, etc.	Two weeks
Upgrade to computer controlled Co-60 machine (assuming computer literacy as part of basic training)	Two weeks
Simple Co-60 machine to single energy linac controlled by a computer (assuming computer literacy as part of basic training)	Two months +
Single energy linac to multienergy linac with electrons	Two months +

TABLE 42.ADDITIONAL TRAINING REQUIRED FOR NEWEQUIPMENT (CLINICIANS)

Change of equipment	Additional training required
Simple Co-60 to modern Co-60 machine with wedges and blocks, etc.	One month +
80 cm SSD to 100 cm SAD Co-60 machine conversion (using SAD techniques)	Two weeks
Upgrade to computer controlled Co-60 machine (assuming computer literacy as part of basic training)	n.a.
Simple Co-60 machine to single energy computer controlled linac (assuming computer literacy as part of basic training)	One month +
Computer controlled Co-60 to single energy computer controlled linac	Two days
Single energy linac to multienergy linac with electrons	One month +

XVI.2.4. Maintenance personnel

It is assumed that the staff have a basic electronics background and some experience with therapy equipment. However, for particular new equipment, further training will be required that will need to be provided by the manufacturer (Section 3.2.2.6). The training required for an upgrade is shown in Table 43. In principle, it would be possible to minimize the impact of the requirement for maintenance personnel by taking out a service contract with

TABLE 43.ADDITIONAL TRAINING REQUIRED FOR NEWEQUIPMENT (MAINTENANCE STAFF)

Change of equipment	Additional training required
Simple Co-60 to modern Co-60 machine with wedges and blocks, etc.	One week
80 cm SSD to 100 cm SAD Co-60 machine conversion (using SAD techniques)	Nil
Upgrade to computer controlled Co-60 machine (assuming computer literacy as part of basic training)	Two days
Simple Co-60 machine to single energy computer controlled linac (assuming computer literacy as part of basic training)	Four weeks
Computer controlled Co-60 to single energy computer controlled linac	Three weeks
Single energy linac to multienergy linac with electrons	Two weeks

the manufacturer of the equipment. However, problems with equipment are often not difficult to cure and it is wise to have trained staff on-site.

XVI.3. TRAINING REQUIREMENTS FOR BRACHYTHERAPY

Physicians practicing brachytherapy must first be trained as radiation oncologists. They should also have specific training in brachytherapy at an institution with an established practice, so that the indications for patient selection, applicator insertion, catheter placement and dose prescription can be learned under the supervision of experienced mentors. The length of the training will usually be measured in months. Such training should be undertaken whenever a substantially new form of brachytherapy is introduced into an existing practice, for example, when adding HDR brachytherapy.

The physician will set the overall treatment policies for the brachytherapy programme and should participate in the planning of the brachytherapy facility and in the procurement of equipment. For individual patients, the physician is responsible for selecting and inserting the applicator or placing catheters, prescribing the dose, reviewing and approving the dose calculations, overseeing the dose delivery, removing the applicator or catheters, and for the patient's follow-up evaluation.

Like the physician, the radiotherapy medical physicist practicing brachytherapy must first be trained in radiation oncology physics. They should also have specific training of one to two months in brachytherapy at an institution with an established practice, to ensure accuracy and safety in brachytherapy treatment planning and delivery. The training should preferably be at the same centre where the radiation oncologist is receiving training. In this manner, a consistent and comprehensive practice can be developed.

It must be understood that new brachytherapy responsibilities cannot simply be added to the duties of a medical physicist already responsible for teletherapy physics. Large programmes in brachytherapy (300–500 procedures annually), in addition to external beam therapy, will generally require at least a half-time medical physicist dedicated to brachytherapy and an additional two or three RTTs. If customized treatment planning and/or remote afterloading are practiced, at least one full-time medical physicist devoted to brachytherapy will be needed.

An HDR remote afterloading programme requires more technical support than one using LDR sources. The radiation oncologist and the radiation oncology physicist should be present during each treatment, because frequently the degree of complexity of HDR planning is greater than that for LDR brachytherapy. The greater potential hazards associated with high activity sources also require the presence of a physician and a medical physicist.

All practitioners (radiation oncologists and radiotherapy medical physicists) must receive training on the specific model of equipment provided, including the dedicated TPS (if included) and safety/emergency procedures for the particular model of equipment. This training would be expected to take at least a week and may be provided on-site by specialist factory trainers or at the factory.

ABBREVIATIONS

The following abbreviations have been used in the text and are collected here for easy reference:

- **BSS.** Basic Safety Standards [1], an IAEA publication giving requirements for radiation safety.
- **CT.** Computed tomography
- **HDR.** High dose rate; a term used to distinguish brachytherapy at HDRs in a short period of time from brachytherapy given over an extended period of time (the latter denoted as LDR brachytherapy).
- **IMRT.** Intensity modulated radiotherapy; a method of patient treatment which involves the use of non-uniform beams to provide the required dose distribution, allowing conformation to various targets.
- **LDR.** Low dose rate; a term used to distinguish the brachytherapy given over an extended period of time from brachytherapy given in a short time (the latter denoted as HDR brachytherapy).
- MRI. Magnetic resonance imaging
- NMR. Nuclear magnetic resonance
- **PET.** Positron emission tomography
- **PDR.** Pulsed dose rate; a brachytherapy system in which a patient is connected to a brachytherapy treatment unit for an extended period of time and given short bursts of radiation at regular intervals.
- **RAKR.** Reference air kerma rate; the recommended quantity for specifying the activity of brachytherapy sources.
- **RPO.** Radiation protection officer; a hospital staff member responsible for radiation safety.
- **RTT.** Radiation therapy technologist; see Section 3.2.2.3 for an explanation.

- **RWL.** Recommended working life; used particularly for brachytherapy sources, which may become damaged through use.
- **R&V.** Record and verify system.
- **SAD.** Source–axis distance; the distance between the radiation source and the axis of rotation of an isocentric treatment unit.
- **SSD.** Source–skin distance; the distance between the radiation source and the patient's skin.
- **TBI.** Total body irradiation; a treatment, usually for leukaemia, in which the whole patient is irradiated.

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CONTRIBUTORS TO DRAFTING AND REVIEW

Aguilar, V.	International Atomic Energy Agency
Almond, P.	James Graham Brown Cancer Center, United States of America
Andreo, P.	International Atomic Energy Agency
Baeza, M.	Instituto de Radiomedicina, Chile
Drew, J.	International Atomic Energy Agency
Ezzell, G.A.	Harper University Hospital/Wayne State University School of Medicine, United States of America
Habjouqa, A.	International Atomic Energy Agency
Horton, J.	MD Anderson Cancer Center, United States of America
Hudson, A.	National Radiological Protection Board, United Kingdom
Iżewska, J.	International Atomic Energy Agency
Kamel, R.	International Atomic Energy Agency
Levin, V.	International Atomic Energy Agency
Liniecki, J.	Medical University of Łódź, Poland
Llamas, A.	International Atomic Energy Agency
Marinello, G.	Hôpital Henri Mondor, France
Matscheko, G.	International Atomic Energy Agency
Mattsson, O.	Sahlgren University Hospital, Sweden
Mayles, P.	Clatterbridge Centre for Oncology, United Kingdom

Meghzifene, A.	International Atomic Energy Agency
Möller, T.	Southern Swedish Regional Tumour Registry, Sweden
Mukuna, B.	International Atomic Energy Agency
Oresegun, M.	International Atomic Energy Agency
Ortiz Lopez, P.	International Atomic Energy Agency
Rodriguez, P.	MedTec Galicia, Spain
Rosenblatt, E.	International Atomic Energy Agency
Shanta, A.	International Atomic Energy Agency
Shortt, K.R.	International Atomic Energy Agency
Stovall, M.	MD Anderson Cancer Center, United States of America
Tölli, H.	International Atomic Energy Agency
Vatnitskiy, S.	International Atomic Energy Agency
Vikram, B.	International Atomic Energy Agency
Viser, A.	Academic Hospital Rotterdam, Netherlands
Volodin, V.	World Health Organization
Wilkinson, J.	Christie Hospital, United Kingdom
Williamson, J.F.	Mallinckrodt Institute of Radiology, United States of America
Zubizarreta, E.	International Atomic Energy Agency

Consultants Meetings

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This publication provides guidance for designing and implementing radiotherapy programmes, taking into account clinical, medical physics, radiation protection and safety aspects. It reflects the up-todate requirements for radiotherapy infrastructure in resource limited settings. It is addressed to professionals and administrators involved in the development, implementation and management of radiotherapy programmes.

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