



***Design and implementation of a
radiotherapy programme:
Clinical, medical physics, radiation
protection and safety aspects***



INTERNATIONAL ATOMIC ENERGY AGENCY

IAEA

R

29 - 49

The IAEA does not normally maintain stocks of reports in this series.
However, microfiche copies of these reports can be obtained from

INIS Clearinghouse
International Atomic Energy Agency
Wagramerstrasse 5
P.O. Box 100
A-1400 Vienna, Austria

Orders should be accompanied by prepayment of Austrian Schillings 100,—
in the form of a cheque or in the form of IAEA microfiche service coupons
which may be ordered separately from the INIS Clearinghouse.

FOREWORD

The incidence of cancer in the world is increasing, particularly in relation to prolonged life expectancy 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 nine million new cancer cases 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 palliation.

Radiotherapy is a multidisciplinary speciality which uses complex equipment and radiation sources for delivery of treatment. It is estimated that approximately 2500 teletherapy machines are currently installed in developing countries, where the cancer incidence is about 75–150 cases per 100 000 inhabitants. This figure is significantly below the estimated needs of almost 5000 machines, based on a rate of approximately one machine per every 500 new cases of cancer. A conservative estimate points at a need of about 10000 machines by the year 2015. Although this figure might appear difficult to achieve, the number of treatment units in developing countries is increasing considerably. The number of brachytherapy sources and devices is increasing at a similar rate as well. With this in perspective, in addition to the enormous need for qualified professionals (radiation oncologists, medical physicists, radiotherapy technicians, radiation protection officer, maintenance engineers, etc.) capable of operating new radiotherapy equipment, the development of the medical infrastructure for cancer treatment appears to be a substantial undertaking in forthcoming years.

It is widely acknowledged that the clinical aspects (diagnosis, decision, indication for treatment, 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. Whilst it has long been recognized that the physical aspects of quality assurance in radiotherapy are vital to achieve an effective and safe treatment, it has been increasingly acknowledged only recently that a systematic approach is absolutely necessary to all steps within clinical and technical aspects of a radiotherapy programme as well.

The need to establish general guidelines at the IAEA, taking into account clinical, medical physics, radiation protection and safety considerations, for designing and implementing radiotherapy programmes in Member States has been identified through the Member States' increased interest in the efficient and safe application of radiation in health care. Several consultants and advisory group meetings were convened to prepare a report providing a basis for establishing a programme in radiotherapy.

The present TECDOC is addressed to all professionals and administrators involved in the development, implementation and management of a radiotherapy programme in order to establish a common and consistent framework where all steps and procedures in radiotherapy are taken into account. The IAEA staff members responsible for this publication were P. Ortiz-Lopez (NSRW) and P. Andreo (RIHU).

EDITORIAL NOTE

In preparing this publication for press, staff of the IAEA have made up the pages from the original manuscripts as submitted by the authors. The views expressed do not necessarily reflect those of the IAEA, the governments of the nominating Member States or the nominating organizations.

Throughout the text names of Member States are retained as they were when the text was compiled.

The use of particular designations of countries or territories does not imply any judgement by the publisher, the IAEA, as to the legal status of such countries or territories, of their authorities and institutions or of the delimitation of their boundaries.

The mention of names of specific companies or products (whether or not indicated as registered) does not imply any intention to infringe proprietary rights, nor should it be construed as an endorsement or recommendation on the part of the IAEA.

CONTENTS

1.	INTRODUCTION	1
1.1.	Global cancer burden and the need for radiotherapy	1
2.	PROGRAMME DESIGN AND IMPLEMENTATION FLOW	4
2.1.	Programme design.....	4
2.1.1.	Assessment of national needs and countrywide distribution of radiotherapy facilities	4
2.1.2.	Assessment of institution's clinical needs	4
2.1.3.	Assessment of institution's resources	5
2.1.4.	Programme formulation	5
2.2.	Programme implementation	6
2.2.1.	Staff training.....	6
2.2.2.	Equipment specification.....	6
2.2.3.	Facility planning and construction	7
2.2.4.	Equipment delivery	7
2.2.5.	Planning and initiation of the treatment	8
2.3.	Follow-up and assessment	8
3.	STAFF REQUIREMENTS FOR A RADIATION THERAPY PROGRAMME	8
3.1.	Hospital administrators.....	9
3.2.	Radiotherapy staffing	9
3.2.1.	Patient load assessment	9
3.2.2.	Staff	9
4.	RADIOTHERAPY FACILITY DESIGN.....	17
4.1.	External beam therapy	17
4.1.1.	Examination rooms.....	17
4.1.2.	Simulator room.....	17
4.1.3.	Treatment planning room	17
4.1.4.	Mould room.....	18
4.1.5.	Treatment room	18
4.1.6.	Waiting areas.....	18
4.2.	Low dose rate (LDR) brachytherapy	18
4.2.1.	Source storage and preparation room	19
4.2.2.	Operating room.....	19
4.2.3.	Treatment planning room	19
4.2.4.	Patient room	19
4.2.5.	Additional requirements for LDR remote-afterloading.....	19
4.3.	High dose rate (HDR) brachytherapy	20
4.3.1.	Options	20
4.3.2.	Operating room.....	20
4.3.3.	Outpatient surgery room.....	21
4.3.4.	Treatment planning room	21
4.3.5.	Treatment room	21

5.	EQUIPMENT	21
5.1.	Introduction	21
5.2.	Equipment for external beam radiotherapy	22
5.2.1.	Simulator	22
5.2.2.	Treatment planning equipment.....	22
5.2.3.	Teletherapy unit.....	22
5.2.4.	Quality assurance equipment.....	22
5.2.5.	Radiation safety equipment	22
5.3.	Equipment for brachytherapy	22
5.3.1.	Imaging equipment.....	23
5.3.2.	Equipment for treatment planning.....	23
5.3.3.	Treatment delivery equipment.....	23
5.3.4.	Quality assurance equipment.....	24
5.3.5.	Equipment for radiation safety and source handling.....	25
6.	QUALITY ASSURANCE OF THE RADIOTHERAPY PROGRAMME AND PATIENT RADIATION PROTECTION.....	25
6.1.	Clinical aspects of the quality assurance programme.....	26
6.1.1.	Treatment policies	26
6.1.2.	Clinical case conferences for review of proposed/recent patient treatments.....	26
6.1.3.	Clinical follow-up and statistical review	26
6.2.	Physical aspects of the quality control programme.....	26
6.3.	Radiotherapy planning and delivery.....	27
6.3.1.	Initial evaluation.....	27
6.3.2.	Therapeutic decision.....	28
6.3.3.	External beam radiotherapy	28
6.3.4.	Brachytherapy	29
6.4.	Maintenance programme	30
6.4.1.	Preventive maintenance.....	31
6.4.2.	Repair	31
6.4.3.	Spare parts	31
6.5.	Investigation of accidental medical exposures	31
6.6.	Quality audits	31
7.	RADIATION PROTECTION AND SAFETY OF SOURCES	32
7.1.	General	32
7.2.	Organization and managerial measures.....	32
7.2.1.	Management policy	32
7.2.2.	Staffing and training.....	32
7.2.3.	Reassessment of training needs	33
7.3.	Description of equipment and sources	33
7.4.	Facility layout, shielding and interlocks.....	34
7.4.1.	External beam.....	34
7.4.2.	Brachytherapy	35
7.5.	Individual monitoring.....	36
7.6.	Classification of areas	36

7.7. Rules and supervision.....	36
7.7.1. Procedures for external beam therapy	36
7.7.2. Procedures for brachytherapy	36
7.7.3. Supervision.....	38
7.8. Accident prevention	38
7.9. Emergency plans	39
7.9.1. Lost source	39
7.9.2. Stuck source	39
7.9.3. Contamination	39
7.9.4. Patient accidental exposure	39
7.9.5. Staff irradiation.....	39
APPENDIX A: RESPONSIBILITIES OF THE RADIATION ONCOLOGIST AND THE MEDICAL PHYSICIST.....	41
APPENDIX B: SPECIFICATIONS FOR A TREATMENT SIMULATOR	43
APPENDIX C: EQUIPMENT REQUIREMENTS FOR COMPUTERIZED TREATMENT PLANNING SYSTEMS	47
APPENDIX D: SPECIFICATIONS FOR A ⁶⁰ Co TELETHERAPY UNIT AND ITS RADIATION SOURCE.....	51
APPENDIX E: BASIC EQUIPMENT RECOMMENDED FOR DOSIMETRY IN EXTERNAL RADIATION THERAPY	55
APPENDIX F: COMPARISON BETWEEN HIGH-DOSE-RATE (HDR) AND LOW- DOSE-RATE (LDR) BRACHYTHERAPY	57
APPENDIX G: SPECIFICATION OF EQUIPMENT FOR REMOTE LDR AND HDR AFTERLOADING BRACHYTHERAPY	59
APPENDIX H: LICENSING	63
APPENDIX I: CONSIDERATIONS FOR A QUALITY ASSURANCE PROGRAMME IN RADIATION ONCOLOGY	73
APPENDIX J: RADIATION SHIELDING FOR EXTERNAL BEAM FACILITY	87
REFERENCES.....	91
CONTRIBUTORS TO DRAFTING AND REVIEW.....	93
RECENT IAEA PUBLICATIONS ON CLINICAL, MEDICAL PHYSICS, RADIATION PROTECTION AND SAFETY ASPECTS OF RADIOTHERAPY.....	95

1. INTRODUCTION

During the last few years there has been an increased demand from Member States for the International Atomic Energy Agency (IAEA) to provide assistance, including the provision of radiation sources and equipment, in establishing radiotherapy programmes for the treatment of cancer patients. This is usually made through the Technical Co-operation (TC) projects. The provision of this assistance and equipment without a systematic approach to ensure clinical, dosimetric, safety and maintenance aspects could jeopardize the outcome of the treatment of the patient (with either unacceptably high complication or recurrence rates), and might result in an unacceptable risk of accidents. 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 report has been produced so that the IAEA staff, expert consultants, or 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 Radiotherapy" with ^{60}Co teletherapy units 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 (1990 estimate) more than nine million new cancer cases per year world-wide 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 world-wide is fairly even 4.77 million cases occurring in males and 4.55 million cases in females. Since the incidence of cancer increases by age, the majority of new cases occur in the age group 65+ years. The age distribution of cancer is, however, quite different in developed and developing countries; there are significantly more cancer cases in childhood, adolescence and young ages in the developing countries, while cancer in the elderly still dominates in developed countries (Figure 1).

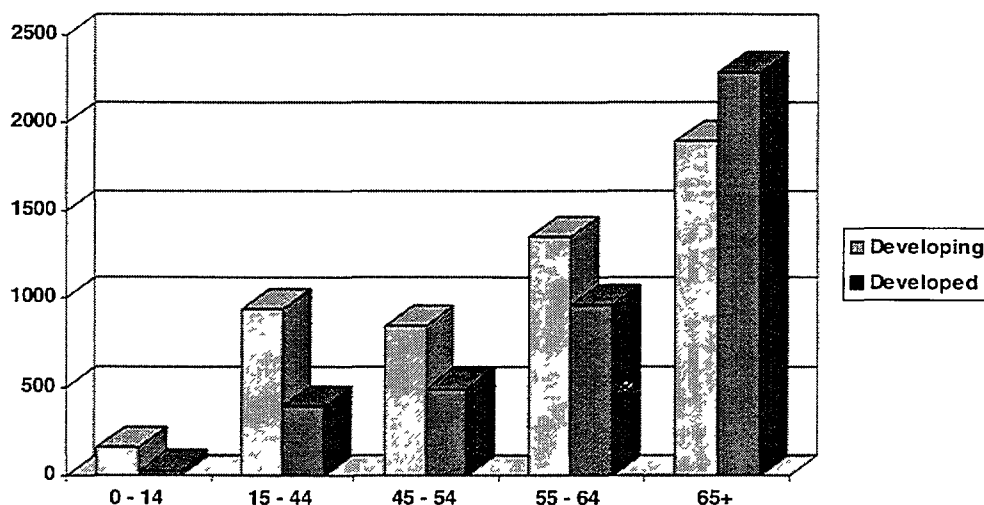


FIG. 1. Age distribution of cancer cases in developed and developing countries 1990. In the age group 0-14 yrs there are 5 times more cases in the developing countries and in the age group 15-45 almost 3 times more (IARC 1990 estimate, by courtesy of D.M. Parkin, IARC, Lyon).

Overall, the most common tumour world-wide is cancer of the lung, with an annual incidence of almost 1.2 million cases, followed by stomach cancer (0.90 million), breast cancer

(0.84 million), colorectal cancer (0.80 million) and cancer of the mouth and pharynx (0.51 million) (Figure 2a). In males the most common tumour is cancer of the lung, followed by stomach (Figure 2b). In females, breast cancer is the most common tumour type, followed by cancer of the cervix (Figure 2c).

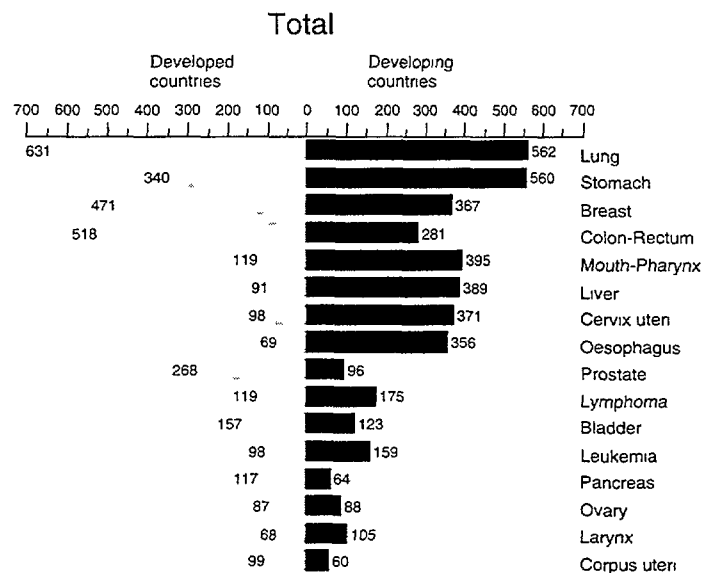


FIG. 2a. World-wide distribution of cancer types 1990, ranked by total number of cases for various diagnoses. (IARC 1990 estimate, by courtesy of D.M. Parkin, IARC, Lyon).

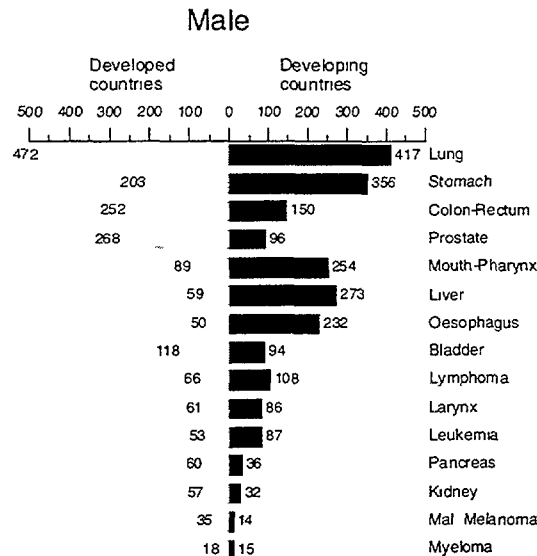


FIG 2b. World-wide distribution of cancer types 1990, ranked by total number of cases for various diagnoses for males. (IARC 1990 estimate, by courtesy of D.M. Parkin, IARC, Lyon).

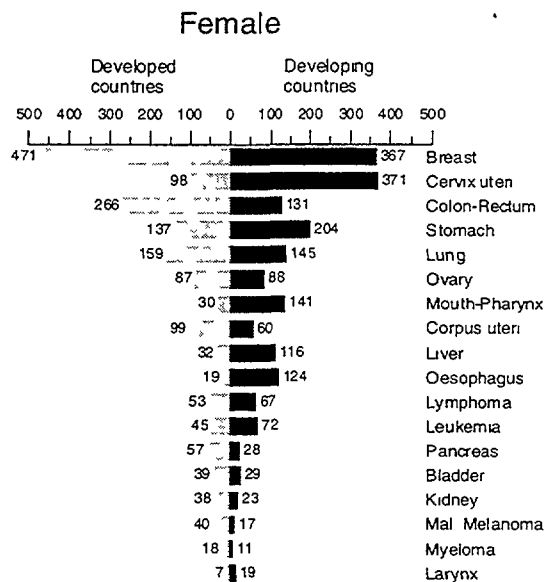


FIG. 2c. World-wide distribution of cancer types 1990, ranked by total number of cases for various diagnoses for female. (IARC 1990 estimate, by courtesy of D.M. Parkin, IARC, Lyon).

The incidence of different cancer types varies considerably among regions, and examples involving the most common tumour types in males and females are given here. Female *breast cancer* reaches high incidence rates in the USA, slightly lower rates in Western Europe, and the lowest rates being reported from Eastern European countries, Asia, and Africa. *Cancer of the cervix* is the leading female cancer in developing countries. In males, *lung cancer* shows the highest rates in the Maoris of New Zealand and black populations of the USA; the lowest rates are seen in India and Africa. A similar pattern is seen for female lung cancer. *Stomach cancer* in males has high rates in the Far East, median rates in eastern Europe, and low rates 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.

It should be recognized that incidence data will change over time due to a number of factors, real or 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. Real factors are also true changes in cancer incidence due to changes of life-style, socio-economic development, and exposure to environmental agents. Among the factors apparently raising incidence figures are the increasing awareness of cancer diseases in the population; availability of diagnostic procedures (this also includes the introduction of screening programs which will increase the incidence, albeit temporarily), and improvement in cancer registration techniques. Due to the interplay of all these factors, the rates of change vary considerably throughout 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 real increase in incidence are observed in breast cancer and melanoma, breast cancer incidence now approaching that of cervical cancer in developing countries. Gastric cancer, the most common type of cancer ten years ago, is decreasing world-wide.

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

An advisory group in 1993 [17] estimated that “approximately 2300 megavoltage teletherapy units are currently installed in developing countries, primarily cobalt-60 units. In these countries, the typical incidence of new cancer patients is 75 to 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 which requiring radiotherapy, and assuming one machine per 500 new cancer cases treated, the current need is for a total of 4,400 machines. By the year 2015, barring a dramatic and unforeseen cure for cancer, a total of 10,000 machines will be needed to provide treatment for an estimated 10 million new cancer cases per year in developing countries.” For comparison, “the number of megavoltage machines per 1 million of population ranges from 8.2 in the USA to 3.4 in the UK, with 70-90% of the machines being electron 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 for designing 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 needing radiation therapy should be assessed as described below. If no national register on cancer is available, this should be extrapolated from country population and age distribution using as much regional hospital data as available. The siting and facilities in individual radiotherapy departments should be compared to the national population distribution.

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 expansion of an existing department.

2.1.2 Assessment of 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 in a comprehensive cancer treatment programme. The projected annual number of patients needing 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 enthusiasm of current and potential referring physicians for enhanced radiation therapy capability 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 a projected 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, sending an appropriately pre-project mission is highly indicated.

2.1.3 Assessment of Institution's Resources

The institution's current capability for handling the clinical need should be carefully assessed including:

- a) Professional and technical personnel, including radiation oncologists, medical physicists and other medical subspecialists (i.e., surgical, medical, pathologists and gynaecologic oncologists) needed. In assessing the adequacy of radiation oncology professional staffing, the total workload of the department for both external beam therapy and brachytherapy should be considered.
- b) Status of existing programme infrastructure, including radiation protection, quality assurance, and clinical peer-review and policy formulation programmes outlined in Section 3. Shortcomings and steps to resolve them should be identified at this time and included as part of the project.
- c) The status and character of any existing radiotherapy programme (external beam and brachytherapy), including patient numbers and procedure types, and quality assurance processes.
- d) Existing capital resources including operating rooms, treatment delivery equipment, treatment planning equipment (planning system and imaging systems), and dosimetry equipment.
- e) Hospital administration commitment and/or government for funding capital and programme operating expenses.
- f) Library facilities with access to the appropriate clinical and scientific journals.

2.1.4 Programme Formulation

A initial evaluation should be developed which describes all resources (personnel, equipment and space renovation) required to realize the identified clinical needs such that the resultant programme conforms to the minimal standards of practice outlined in Section 3. This involves comparing the programme needed to carry out the clinical aims according to the practice standards of Section 3 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 technically advanced treatment equipment, a cost-benefit analysis that demonstrates that the proposed facility meets the institute's goals in terms of patient work load, clinical capability, and institutional resources available to support the programme should be prepared.

The initial evaluation should include the following elements:

- a) A description of the radiotherapy programme, including patient capacity and the facility required.
- b) Major pieces of equipment, additional personnel, and major space renovation or construction should be briefly described. The division of costs, between the institution and its sponsors should be addressed.
- c) Additional personnel needed should be described and justified according to Section 3. Emphasis should be placed on having adequate professional radiation oncology staff (physicians and physicists) to support the radiotherapy programme without jeopardizing other programmes.
- d) Institutional deficiencies (quality assurance, radiation protection, maintenance, etc.) should be described and an action plan outlined for correction of the deficit.
- e) Equipment needs (teletherapy machines, simulators, sources, remote afterloaders, planning systems, etc.) should be described in enough detail that a budget can be prepared.
- f) The need for external training of the radiation oncology professional staff (physicians, physicists and technicians). Describe the need for on-site technical experts for training and helping to manage programme implementation and monitoring its progress. External training of counterpart personnel should be identified.
- g) All major construction and space renovation should be described in detail.
- h) A plan for equipment acquisition and commissioning should be developed consistent with the training of staff.

- i) A plan for clinical implementation including procedure and quality assurance programme development, training of ancillary personnel, and programme initiation should be developed.
- j) An overall work plan or time line, describing the sequence of detailed equipment specification and facility planning, construction, equipment delivery, acceptance and commissioning and clinical implementation should be developed including expert services and training programme. The co-ordination of these activities with expert consultants should be addressed.
- k) Finally, a master budget should be prepared. The entity (hospital administration, country government) responsible for funding each major item should be identified. The institutions commitment to the project, including funding, must be included.

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 the hospital staff. A plan to train these personnel before the equipment installation should be developed. This plan should include who will be trained, the host institution that will provide the training, and when the training will occur. Resources invested early in training may well pay significant dividends later, improving the efficiency of the later planning and implementation. Refer to Section 3 for a discussion of the training required for the staff physician(s) and physicist(s). 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. It must be realized that a high standard in radiotherapy can only be achieved and maintained by full time specialists. It involves team approach and close collaboration with all the specialists, including pathology, involved in the diagnosis and treatment of cancer.

2.2.2 Equipment Specification

Refer to Section 5 and Appendix B - G for a complete description of the types of equipment needed. The teletherapy machine, simulator, radioactive sources, remote afterloading device (if any), applicators, treatment planning system, 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 to the life of the equipment and to safety should be addressed early in the planning stage and be included in contractual form, 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, factory support, manuals and spare parts.
- e) Possible training of local engineers.

It is suggested that at least 50% of the contract price be withheld until completion of the programme has been accepted by an expert.

2.2.3 Facility Planning and Construction

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 are outlined here in general terms in a reasonable 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 be actually 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 Constructional Drawings

Refer to Section 4 for a complete description of facility design issues. The layout of the facility should be planned considering equipment requirements, water and electrical utilities needed, room shielding required 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 the equipment manufacturer.

2.2.3.2 Licensing

The radiotherapy installation needs to be licensed by the National Regulatory Authority. As a radiotherapy installation needs major construction, it is most likely that Regulatory Authorities in Member States shall provide authorization before construction begins. Therefore the application for a license must be prepared at an early stage. It should contain all the relevant elements to assure the Regulatory Authority that the planned facility will be safe. An example of a detailed outline of the elements for a license is given in the Appendix H.

2.2.3.3 Scheduling

The delivery of equipment should be co-ordinated 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 have completed training and be prepared to receive the equipment also.

Equipment that is needed to test and commission the teletherapy unit, the 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 is prepared, and the staff is 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 agency experts, to check the specialized requirements of the radiotherapy facility.

2.2.4 Equipment Delivery

A number of important steps must be taken before, during, and immediately after the equipment arrives. These will typically be done by the local staff with help from an outside expert, if necessary. It is recommended that the expert assists the local staff to develop procedures, equipment test, etc. The expert should not directly do the work, since the local staff must develop the expertise and confidence to carry on after the expert's departure.

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 of special rooms measured, the radiation sources tested and calibrated, and the remote afterloader (if any) and teletherapy unit (if any) commissioned

It is best to have the specific procedures for all of these steps worked out and written in advance. The 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 do some of the preparatory procedure writing in parallel with the training and facility planning steps.

Once the procedures are written and the equipment is on site, actual testing and commissioning of the facility, equipment, sources, etc., can be accomplished. This entire process will be lengthy as well, again taking several weeks. Refer to Section 6.2 for details.

2 2 4 2 Quality Control and Radiation Safety Procedures

After the commissioning has been finished, the specific tests needed for ongoing quality control and radiation safety assurance will need to be carried out. Refer to Section 6 and Appendices I-J for details.

2.2.5 Planning and Initiation of the Treatment

2.2.5 1 Clinical Procedure Design

The radiation oncologist will determine the overall treatment techniques and specific treatment procedures keeping in mind that those procedures evolve in time. 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, associated quality control steps, etc. Section 6 has more details on these requirements.

The importance of careful planning for each type of radiotherapy treatment must be appreciated by all, since the correct execution of the treatment is the purpose of the entire programme.

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. Any omissions or problems with the treatment procedures can then be identified and corrected.

2 3 FOLLOW-UP AND ASSESSMENT

Some months after treatments have begun, the Agency arranges for a follow-up visit by an expert to assess the programme and, if needed, recommend changes. The expert should participate in the daily routine to properly assess the performance of the equipment and the professionals involved in its use.

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 Agency, 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 the radiation therapy treatments are efficacious and safe.

A radiotherapy programme generally consists of both external beam and brachytherapy capabilities and both aspects will be considered together in this section. However where external beam and brachytherapy differ this will be pointed out so that those institutions interested in pursuing only one or the other may readily determine the specific requirements.

3.1 HOSPITAL ADMINISTRATORS

Hospital administrators and/or other officials 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, and training. Provision must also be made for ongoing needs, such as, maintenance, source replacement and an adequate stock of spare parts.

3.2 RADIOTHERAPY STAFFING

3.2.1 Patient Load 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 treatment. An estimate of how many of these patients will be seen at the institution should be made and compared to the actual patients seen annually. Unusually high cancer rate in the area for specific localisation (e.g., lung, oral cavity, nasopharynx, etc.), in which radiotherapy is more frequently used should be taken into account. Utilization rates must account for possible new uses of radiotherapy as 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 and interstitial 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 be taken in estimating the number of brachytherapy patients because many of them will require external beam therapy as well.

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] requires 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 adequately 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 key staff functions in external beam radiation therapy are shown in Table I.A and the functions involved in radiation therapy are listed in Table I.B and I.C for external beam and brachytherapy respectively. These tables have been adapted from reference [2], "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 II, also from reference [2]. Other recommendations for the staffing in medical physics can be found in a joint report by ESTRO-EFOMP [3].

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 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 how to design treatment approaches which 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 toward common goals.

The main categories of the staff required along with their responsibilities and training requirements are listed in Tables I and II .

3.2.2.1 Physician

The physician practicing radiation therapy must first be trained and experienced in oncological practice with post-graduate training in radiation oncology.

The physician will set the overall treatment policy for the radiation therapy programme and should participate in the design of the facility and the procurement of equipment. For individual patients the physician is responsible for the patients care, including the details of the treatment and the patient's follow-up evaluation.

The physician also practicing brachytherapy must first be trained as a radiation oncologist and experienced in oncological practice. The physician 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 this training will depend on many factors, but will usually be measured in months. Such a visit should be undertaken whenever a substantially new form of brachytherapy is introduced into an existing practice, for example when adding high dose rate brachytherapy.

The physician will set the overall treatment policies for the brachytherapy programme and should participate in the design of the brachytherapy facility and 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 the patient's follow-up evaluation.

3.2.2.2 Medical Physicist

The medical physicist's responsibilities cover four major areas: dosimetry, radiation safety, quality control, and equipment selection.

In dosimetry the 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 medical physicist is responsible for the calibration of the output of the treatment machine on a routine basis and assuring 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 medical physicist, and/or the Radiation Protection Officer who may or may not be the same

person. The administrative structure will vary depending on the nation, the facility and the resources, what matters is that the necessary authority is available.

For quality control, the medical physicist will be involved with establishing and running a quality control program for the facility.

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

The medical physicist should have at least an advanced university degree in a physical science or engineering, at least one year of academic and clinical training in radiation oncology physics, and additional training of at least one month in brachytherapy physics at an established centre, preferably the same centre visited by the physician if these treatments are to be done. In this manner a consistent and comprehensive practice can be developed.

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 a suitable medical physicist on staff. It must also be understood that new brachytherapy responsibilities cannot simply be added to the duties of a medical physicist already responsible for teletherapy physics. 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 physics staff required will depend on the number of patients treated, the type of implants performed, and the complexity of the dose calculation required, and whether a treatment planning computer is to be used. However as a minimum each radiotherapy centre shall have one medical physicist on staff.

A high dose rate (HDR) remote afterloading programme requires more technical support than one using low dose rate (LDR) sources. The physician and medical physicist should be present during each treatment, because frequently the degree of complexity of high dose rate planning is greater than low dose rate brachytherapy. The greater potential hazards associated with high activity sources also requires the presence of a physician and a medical physicist.

Large programmes in brachytherapy (300-500 procedures annually) in addition external beam therapy will generally require at least a half-time medical physicist dedicated to brachytherapy and an additional two or three support personnel. If customized treatment planning and/or remote afterloading is practiced, at least one full-time medical physicist devoted to brachytherapy will be needed with an additional two or three support personnel.

The responsibilities of the radiation oncologist and medical physicist are summarized in Appendix A.

3.2.2.3 Ancillary Technical Staff

In addition to the physician and the medical physicist, a radiation therapy programme will require radiation therapy technologists, dosimetrists and radiation oncology nurses. These individuals must have a degree, granted by a university or medical school, for academic studies and clinical training for a period of three or four years.

Although the physician and 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 "treatment planner dosimetrist", or preparation of low dose rate sources for patient treatments and maintenance of the source inventory may be delegated to a "source curator". Such individuals can perform valuable service as technicians, 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 technologists. In some institutions these professionals substitute medical physicists, and treatment planning and delivery procedures are made without the supervision of a qualified medical physicist. Whether this is done for economical or practical reasons, such methodology is not appropriate and might have detrimental consequences for the patient. For example, the lack of education in specialized areas of mathematics and physics restricts the understanding of the algorithms used in modern computerized treatment planning systems; this can easily jeopardize the interpretation of results produced by limitations of the treatment planning system. The role of the dosimetrist is to assist the medical physicist, not to replace him or her.

3.2.2.4 Social worker and Dietician

An appropriately trained social worker is required to help the patient and family with arrangements regarding transport, employment, care of children, etc. This staff member should be well informed on radiation procedures 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, unfamiliar procedures, is pivotal to obtaining cure. A dietician to assist the patients with their nutritional needs during treatment is helpful. Radiation oncology nurses may be able to perform some of the duties of the social worker and dietician.

3.2.2.5 Maintenance Personnel

If there is a large amount of equipment, such as, several external therapy units and simulators, block cutting equipment, treatment planning computers, tissue compensation devices, etc., it might be advisable to ensure the immediate availability of trained engineering maintenance staff.

If remote afterloading devices are used in the brachytherapy programme, then provision must be made for servicing the devices. This may be best accomplished with service agreements with the manufacturer. Alternatively, staff will need to be trained in the repair and preventative maintenance to be given to that equipment as well as in the basics of radiation protection. It will be advisable to have a functional set of manual afterloading devices to allow a continuation of proper treatment of patients when the remote afterloading equipment is out of service.

3.2.2.6 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 its compliance. He/she should prepare the license 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 radiation protection officer functions can be assigned to the medical physicist, but there should be a formal assignment of responsibilities, with clear identification of the line of authority, with respect to radiation protection and safety.

TABLE I.A. KEY STAFF FUNCTIONS IN CLINICAL RADIATION THERAPY [2]

	Key staff	Supportive role
1. Clinical evaluation	Radiation oncologist	
2. Therapeutic decision	Radiation oncologist	
3. Target volume localization		
Tumour volume	Rad. oncologist & physicist	Simulator. technician/ dosimetrist
Sensitive critical organs	Radiation oncologist	Simulator. technician/ dosimetrist
Patient contour	Physicist	Simulator. technician/ dosimetrist
4. Treatment planning		
Beam data-computerization	Physicist	
Computation of beams	Physicist	Dosimetrist
Shielding blocks, treatment aids, etc.	Dosimetrist/ Mould Room technician	Radiation oncologist/ physicist
Analysis of alternate plans	Radiation oncologist/physicist	Dosimetrist
Selection of treatment plan	Radiation oncologist/physicist/ dosimetrist	
Dose calculation	Dosimetrist	Physicist
5. Simulation/verification of treatment plan	Radiation oncologist/ Simulator technician	Dosimetrist/physicist
6. Treatment		
First day set-up	Radiation oncologist/ dosimetrist/ therapy technician	Dosimetrist/physicist
Localization films	Radiation oncologist/ therapy technician	Dosimetrist/physicist
Daily treatment	Radiation therapy technician	
7. Evaluation during treatment	Radiation oncologist/ nurse	Rad. therapy technician/social worker/dietician
8. Follow-up exams	Radiation oncologist/ nurse	Data manager/ social worker/dietician

TABLE I B PROCESS OF RADIATION THERAPY (EXTERNAL BEAM) [2]

1 Clinical evaluation	Initial multidisciplinary evaluation of patient Decision for radiation therapy Assessment of pathobiology of tumour Staging
2 Therapeutic decision-making	Selection of treatment goals-cure/palliation Choice of modalities of treatment
3 Target volume localization	Definition of tumour extent and potential routes of spread Identification of sensitive organs and tissues
4 Treatment planning	Selection of treatment technique Computation of dose distribution and verification of accuracy Determination of dose/time/volume relationship
5 Simulation of treatment	Selection of immobilization devices Radiographic documentation of treatment ports Measurement of patient Construction of patient contours Shaping of fields
6 Fabrication of treatment aids	Construction of custom blocks, compensating filters
7 Treatment	Initial verification of treatment set-up Verification of accuracy of repeated treatments Continual assessment of equipment performance Periodic checks of dosimetry, record keeping
8 Patient evaluation during treatment	Evaluation of tumour response Assessment of tolerance to treatment
9 Follow-up evaluation	Evaluation of tumour control Assessment of complications of treatment

TABLE I C PROCESS OF RADIATION THERAPY (BRACHYTHERAPY) [2]

1 Clinical evaluation	Initial multidisciplinary evaluation of patient Decision for radiation therapy Assessment of pathobiology of tumour Staging
2 Therapeutic decision-making	Selection of treatment goals-cure/palliation Choice of modalities of treatment
3 Target volume localization	Definition of tumour extent and potential routes of 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 off of equipment Arrangement for surgical suite and anaesthesia
5 Treatment	Examination of anaesthetised patient Review of initial treatment plan Implantation
6 Verification of implantation	Orthogonal or stereo radiographs
7 Dosimetry	Calculation from actual implantation Establishment of time for removal
8 Patient evaluation during treatment	Assessment of tolerance Check of position of implant
9 Removal of implant	
10 Follow-up evaluation	Assessment of early and late sequela Evaluation of tumour control

TABLE II MINIMUM PERSONNEL REQUIREMENTS FOR CLINICAL RADIATION THERAPY [2]

Category	Staffing
Radiation Oncologist-in-Chief	One per program
Staff Radiation Oncologist	One additional for each 200-250 patients treated annually No more than 25-30 patients under treatment by a single physician
Radiation Physicist	One per center 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
Physics Technologist (Mould Room)	One per 600 patients treated annually
Radiation Therapy Technologist	
Supervisor	One per center
Staff (Treatment)	2 per megavoltage unit up to 25 patients treated daily per unit, 4 per megavoltage unit up to 50 patients
Staff (Simulation)	2 for every 500 patients simulated annually
Staff (Brachytherapy)	As needed
Treatment Aid Technologist	As needed, usually one per 300-400 patients treated annually
Nurse	One per center 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
Physical Therapist	As needed to provide service
Maintenance Engineer/Electronics Technician	One per 2 megavoltage units or 1 megavoltage unit and a simulator if equipment serviced "in-house"

4. RADIOTHERAPY FACILITY DESIGN

Facilities for radiotherapy fall into three groups: external beam radiotherapy, low dose-rate (LDR) brachytherapy and high dose-rate (HDR) brachytherapy. The same basic considerations apply to all: (i) medical and physical well-being of the patient, (ii) protection of the patient, staff, visitors, and other members of the public from radiation hazards and (iii) geographical and functional integration of the various activities related to the treatment of the patient.

Space common to all three modalities include office space for physicians and physicists, laboratories, dark room, registration area and file room.

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

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

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

4.1 EXTERNAL BEAM THERAPY

An external beam facility requires examination rooms, simulator room, treatment planning room, mould room, treatment room, and waiting areas. Design of the simulator room, treatment planning room and treatment room should be performed in consultation with the manufacturer of the equipment. Power, air conditioning and emergency system requirements must be considered.

4.1.1 Examination Rooms

Examination rooms should be in close proximity to the treatment room. The examination rooms should include a standard and gynaecological examination table, 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 NCRP Report 49¹ [5] paying due regard to 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 of securely mounting patient positioning lasers to the wall at points appropriate to project lines through the isocenter should be included in the plans. 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 and daily quality assurance equipment. If the immobilization devices are to be fabricated in the simulator room, cabinet space to store supplies for their fabrication will be required. A sink should 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 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

¹ At the time of preparation of this document, NCRP Report 49 was in the process of revision. All references to NCRP 49 should be to the revised document when it appears.

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.

4.1.4 Mould Room

Space should be planned for a mould room to fabricate custom designed blocks and compensators. Room for 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.

4.1.5 Treatment Room

The treatment room shielding should be designed in accordance with the recommendations of NCRP Report 49 [5] paying due regard to 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 Regulatory Authority. The room should be large enough to accommodate the treatment machine allowing the full range of motion of the treatment table. A door interlock or other suitable means to prevent unauthorized access shall be provided and a power-fail-safe area radiation monitor should be visible on entering the room. 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 isocenter 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 a work space for the treatment 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 information management system, electronic imaging, or treatment time calculation systems.

4.1.6 Waiting Areas

It is desirable to have separate waiting areas for patients attending clinical visits and those awaiting treatment. The clinical 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 stretcher patients. This area should be adjacent to the treatment area but preferably separated from the ambulatory patients. The area should be large enough to accommodate three stretchers.

4.2 LOW DOSE RATE (LDR) BRACHYTHERAPY

For radiation protection purposes, LDR brachytherapy should employ either manual or remote afterloading equipment except for some situations (permanent implants, 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 the patient 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 elevator transport 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 49 [5] paying due regards to 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. 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 aids, 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 room

If anaesthesia is required for placement of applicators or catheters to contain the radiation sources, an operating room facility and recovery room are required. A 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 shift 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

The treatment planning room should be located in proximity to the operating room although the two areas do not have to be adjacent. Other design elements of the treatment planning room may be found in Section 4.1.3.

4.2.4 Patient room

It is preferable to house each LDR brachytherapy patient in a separate room. The room should be shielded according to recommendations in NCRP Report 49 [5] paying due regards to requirements of BSS [1] and Regulatory Authority. A sign should be posted on the door warning of the radiation hazard in accordance with Regulatory Authority. If several rooms are required they should be adjacent to each other. The patient should be attended by nurses with special training in care of radiation therapy patients. Storage for a bed side shield and emergency source container should also be provided.

4.2.5 Additional Requirements for LDR Remote-Afterloading

The major benefit of remote afterloading is reduction of exposure to nursing staff, other personnel, and visitors. Other 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) Door interlock or other suitable means to prevent unauthorized access to the patient's room.
- c) A power-fail-safe area radiation monitor in the patient room.

4.3 HIGH DOSE RATE (HDR) BRACHYTHERAPY

An increased demand to the Agency from developing Member States on HDR brachytherapy equipment is expected in the near future. The reason is that some types of cancer, suitable to be treated with brachytherapy, are very frequent in developing countries and HDR brachytherapy may be the only practical solution to successfully treat a large number of patients. On the other hand, if HDR is introduced without adequate expertise in conventional brachytherapy, training and organizational arrangements, it may lead to an unacceptable risk. In order to reach balanced decisions for the Safety, Clinical-Radiotherapy and Physical-Dosimetry aspects of the projects, a systematic approach has been adopted by the Agency where upon analysis of the benefit/risk ratio, a case by case study will consider if the country satisfies the following criteria:

- a) Demonstrable volume of patient workload justifying the need for the HDR brachytherapy equipment.
- b) Long departmental experience with other forms of brachytherapy, including the ability to plan and calculate brachytherapy treatments and maintain appropriate quality assurance and safety procedures.
- c) At least three radiation oncologists and one medical physicist whom can satisfy requirement (b).
- d) All practitioners (radiation oncologists and medical physicists) must receive training on the specific model of equipment supplied by the Agency, including the Treatment Planning System and safety/emergency procedures for the particular model of equipment.

For reasons of safety and quality, all equipment delivered by the Agency will be accompanied by a document issued by the Agency asking the recipient that all repairs may only be undertaken by factory authorized (namely, trained and certified) personnel.

4.3.1 Options

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 considerations should include the anticipated number of HDR procedures as well as the number of external beam treatments. This report recommends against this strategy in most instances.

An HDR brachytherapy facility requires (i) an operating room or outpatient surgery room, (ii) a radiographic imaging system, (iii) treatment room, and (iv) 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:

- a) Treatment room for the HDR unit, and shared use of existing operating or procedure rooms and imaging systems, such as a simulator. The patient transport (between operating room, imaging room and treatment room) reduces efficiency and hinders immobilization of the applicator system.
- b) A treatment room for both applicator insertion and treatment with imaging performed elsewhere. Conditions for anaesthesia and sterility might require a significant investment. In addition other medical staff, e.g., gynaecologic oncologist and anaesthesiologist, should be committed to supplying medical services outside their usual venue. As above, the patient transport (between operating room, imaging room and treatment room) reduces efficiency and hinders immobilization of the applicator system
- c) Integrated brachytherapy suite. This option adds a dedicated imaging system in the treatment room to approach (b). This option is the most efficient requiring no transport of the patient between the different steps.

4.3.2 Operating Room

For design elements of the operating room, please refer to Section 4.2.2.

4.3.3 Outpatient Surgery Room

If anaesthesia is not required for placement of applicators or catheters to contain the radiation sources, an outpatient surgery room may be used. A X-ray unit, preferably with fluoroscopic capabilities, in this room is desirable because it enables the position of the applicator or catheters to be checked, and if necessary repositioned, before the patient leaves this room. In addition, localization X-rays (orthogonal or stereo shift X-rays) required for dose calculation purposes can be taken with this unit. If no X-ray unit is in this room these functions must be available elsewhere.

4.3.4 Treatment Planning Room

Design elements of the Treatment Planning Room may be found in Section 4.1.3.

4.3.5 Treatment Room

HDR brachytherapy must be performed in a properly shielded and secured area. The room should be shielded according to recommendations in NCRP Report 49 [5] paying due regard to requirements of the BSS [1] and the Regulatory Authority. A door interlock or other suitable means to prevent unauthorized access shall be provided and a power-fail-safe area radiation monitor should be visible on entering the room. A sign should be posted on the door warning of the radiation hazard, in accordance with Regulatory Authority. 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 a work space for the radiographer 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. It is also desirable to provide space for light boxes for viewing CT scans and plane X-ray films.

In contrast to external beam treatment units, the location of the HDR source is not mechanically fixed to a single point in the room and is uncollimated; every wall must serve as a primary barrier. For these reasons in an external beam treatment room used for HDR, existing barriers designed to protect against scattered and leakage radiation may not be adequate.

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. The choice of the equipment that will meet most of the clinical needs in the local situation should be made jointly by the responsible radiation oncologist and the medical physicist. The choice of the kind of treatment delivery system will affect the other equipment needs.

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

- a) conform to applicable standards of the International Electrotechnical Commission (IEC) and the International Standards Organization (ISO) or the equivalent standards
- b) performance specifications and operating and maintenance instructions, including protection and safety instructions, be 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 that this information be translated into local language when appropriate. When equipment manufactured in one country is to be exported into another country with the Agency's assistance, documentary evidence (i.e., a copy) of the National Standards has to be provided

with the quotation (bid) to assess whether the national standards are actually equivalent to IEC and ISO.

5.2 EQUIPMENT FOR EXTERNAL BEAM RADIOTHERAPY

The equipment needs for external beam radiation therapy fall into five main categories: simulation, treatment planning, treatment delivery, quality assurance and radiation safety.

5.2.1 Simulator

The simulator should meet the specifications enumerated in Appendix B, Specifications for a Treatment Simulator. Additional information can be found in the report published by the British Institute of Radiology [6].

5.2.2 Treatment Planning Equipment

The treatment planning system should meet the specifications enumerated in Appendix C and must meet the needs of the external beam radiotherapy treatments as determined by the clinical goals of the department.

A programmable calculator or a personal computer may be used to calculate treatment times, based on either the treatment plan or a central axis depth. If a personal computer is available it should include application programs of a spreadsheet and a word processor. The spreadsheet may be used to develop programs to calculate treatment time, analyze machine data and verify calculations of the treatment planning computer. The word processor may be used for writing reports including results of acceptance testing, commissioning measurements, calibrations and quality assurance tests, and patient in-vivo measurements. The word processor is also useful for writing dosimetry and treatment policies and procedures required by the quality assurance program.

A contouring device should be available for contouring the patient for entry to the treatment planning computer. The contour device could be Plaster of Paris strips, a lead solder wire, or other device expressly designed for patient contouring.

5.2.3 Teletherapy Unit

The ^{60}Co teletherapy unit should meet the specifications enumerated in Appendix D. This report does not consider provisions by the Agency of a clinical accelerator.

5.2.4 Quality Assurance Equipment

Ionometric and film dosimetry systems should be available for quality assurance (commissioning, calibration and quality control) of the teletherapy unit. These systems should meet the specifications enumerated in Appendix E. The ionometric systems should also conform to the specifications in the IAEA TRS-277 [7] or TRS-381 [8] and should have been calibrated at a standards laboratory within the last two years. Supplementary equipment listed in Appendix E should also be available.

5.2.5 Radiation Safety Equipment

This instrumentation should include a power-fail-safe radiation area monitor inside the ^{60}Co treatment room, a Geiger-Mueller survey meter and a large volume ionization chamber.

5.3 EQUIPMENT FOR BRACHYTHERAPY

The equipment needs for brachytherapy fall into five main categories: imaging, treatment planning, treatment delivery (including afterloading equipment, sources, source storage and transportation, and applicators), quality assurance and radiation safety and source handling.

The following distinctions in brachytherapy modalities are made: manually afterloaded low dose rate brachytherapy, remote afterloaded low dose rate brachytherapy and remote afterloaded high dose rate 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 to assess the dose to critical normal structures in all cases. 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. A 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. In addition localization X-rays (orthogonal or stereo shift X-rays) required for dose calculation purposes can be taken with this unit. 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") 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, radio-opaque dummy sources should be inserted in the applicator or in the catheters while taking the localization X-rays.

5.3.2 Equipment for Treatment Planning

For the selection of a treatment planning system it is essential to verify that the system can satisfy the needs of the brachytherapy treatment as set by the clinical goal. Treatment planning systems should meet the recommendations in Appendix C and must meet the needs of the brachytherapy treatments as determined by the clinical goals of the department.

A programmable calculator or a personal computer may be used to calculate treatment times from the prescription based on the treatment plan. If a personal computer is available it should include application programs of a spreadsheet and a word processor. The spreadsheet may be used to develop programs to maintain a database for the source inventory, decay source activities automatically, calculate treatment times, and verify calculations of the treatment planning computer. The word processor may be used for writing reports including results of acceptance testing, commissioning measurements, calibrations and quality assurance tests, and patient in-vivo measurements. The word processor is also useful for writing dosimetry and treatment policies and procedures required by the quality assurance program.

5.3.3 Treatment Delivery Equipment

The decision whether to use a remote afterloading system instead of manual afterloading for LDR brachytherapy should be based on a balance of advantages of a remote afterloader (mainly a reduction of radiation exposure for hospital personnel) against the disadvantages (cost of purchasing and maintenance, increased complexity and possible lack of technical support).

Similarly, the choice between HDR and LDR brachytherapy should be based on a careful consideration of the local clinical situation. This balance will depend strongly both on the local clinical goals of brachytherapy and on the local factors like patient load, available staff and resources, see Section 4.3. Further considerations on these two treatment modalities are given in Appendix F.

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 $\mu\text{Gy h}^{-1}$ at 1 m, c.f. ICRU Report 38).
- 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 clinical preference 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 criterion specified in BSS [1]. A transport container is needed to transport prepared sources to the patient treatment area.

5.3.3.1 Low Dose Rate (LDR) Afterloading

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

Currently, the most common isotopes for LDR brachytherapy are ^{137}Cs , ^{125}I , and ^{192}Ir . ^{137}Cs sources can be obtained as line sources (needles or thin tubes for interstitial applications, spheroidal-shaped pellets or tubes for intracavitary applications). ^{125}I is available as seeds. ^{192}Ir LDR sources can be obtained in many different forms, e.g. 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 ^{137}Cs all brachytherapy sources have a limited period of use, because decay of the sources leads to longer treatment times, and for older sources there is an increased risk of damage to the source integrity.

5.3.3.2 High Dose Rate (HDR) Remote Afterloading Units

The high dose rate remote afterloading units should meet the specifications enumerated in Appendix G.

For HDR brachytherapy, ^{192}Ir sources are used because the sources can be fabricated as thin, flexible wires and ^{192}Ir has a high specific activity permitting the realization of high activity sources. However ^{192}Ir has a rather short half time (approximately 74 days) that necessitates frequent source exchange. The ^{192}Ir source in the HDR afterloader should be exchanged by the manufacturer every three months.

Sources of ^{137}Cs and ^{60}Co are also available for HDR treatments, although their use is not as common as in the case of ^{192}Ir .

5.3.4 Quality Assurance Equipment

Equipment for dosimetry and quality assurance (calibration and quality control) should conform to the recommendations enumerated in Appendix G. Preferably the calibration of the ionometric system should be performed at a standards laboratory every second year. If this is not possible it is recommended that a calibrated brachytherapy source similar in construction to sources used clinically be acquired to calibrate the ionometric system. For verification of high dose rate source calibrations it is desirable to have a specially designed well-type ionization chamber with a calibration traceable to a standards laboratory.

In order to verify the uniformity of a line source, film autoradiography is frequently used. An alternative possibility is using 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 a HDR afterloader with a single stepping source is used, it is mandatory to verify the accuracy of the source cable drive mechanism to position the source. The afterloading machine should be equipped with a device ("source position check ruler") in which the source cable pushes a small marker out to a position measurable along a ruler.

For high dose rate 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 enumerated in Appendix G.

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) 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 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.

Special considerations for HDR source handling in case of a failure of the afterloading unit include:

- a) 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.
- b) A remote manipulator.
- c) A rod mounted GM detector for source localization.

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

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 will 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 WHO [9]. An important aspect of any quality assurance program 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 program 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 program demands a strong commitment from the departmental and institutional leadership to provide the necessary resources of time, personnel and capital.

The objective of patient safety as defined in the BSS (II 18a), 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 patient safety 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 up-dating, 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 (i) list key responsibilities with a statement of who has

overall responsibility for that procedure, (ii) list any documentation that may be required to enable that procedure to be carried out (e.g. work instructions, data sets, etc.), (iii) list the documentation that is generated as part of that procedure, and (iv) 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, nurses, etc.)

It is essential that the management of the installation makes the appropriate arrangements to insure that the radiotherapy equipment is available to the medical physicists to carry out the Quality Control measurements (see Appendix I)

6.1 CLINICAL ASPECTS OF THE QUALITY ASSURANCE PROGRAMME

Prior to embarking on a radiotherapy programme of treatments, the chief radiation oncologist at the centre concerned 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 stage, and presentations.

6.1.2 Clinical Case Conferences for Review of Proposed/Recent Patient Treatments

It is desirable that regular case conferences are 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 mitigate against mistakes arising from incomplete understanding of the clinical problems and of the aims of treatment. Such meetings also provide a forum for continuing resource assessment. 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 CONTROL PROGRAMME

Once the equipment has been shown to meet its specifications and accepted from the manufacturer (see Section 2.2.2.1), it will then be commissioned for clinical use. The results of the commissioning tests serve as reference for subsequent checks. All measurements should be recorded in a logbook. As this logbook serves as the principal archival source for all acceptance tests and commissioning measurements, the logbook should have sequentially numbered pages of high quality paper and these pages should be sewn in, not glued in. Logbooks with inferior paper can quickly degrade. The glue used for attaching the pages in logbooks also deteriorates with time and use and pages can fall out and be lost.

The acceptance tests demonstrate the equipment meets or exceeds the bid specifications. Frequently acceptance tests follow a protocol supplied by the manufacturer, but the purchaser may develop his/her 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 other party.

Acceptance tests protocols specify what tests will be performed, what 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 met the specifications of the bid.

At the completion of acceptance tests, commissioning measurements begin. During commissioning measurements the physicist will measure all the data required to place the unit into clinical service. The physicist must assure that all data needed to perform any anticipated clinical procedure is 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 also serves well for maintaining a set of data to perform hand calculation of treatment times.

Immediately at the conclusion of the commissioning measurements, quality control tests should be established. A good equipment 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, and
- h) 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 the medical physicist, who can delegate the work to persons he/she has trained. Regardless of who performs the tests the physicist remains the responsible party for assuring the correct performance of the equipment.

The physicist must also verify that the data in the treatment planning computer, 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 I, which is mainly based on the reference "Comprehensive QA for radiation oncology. Report of AAPM Radiation Therapy Committee Task Group 40," by Kutcher et al, *Med. Phys.* 21: 581-618, 1994 [4]. Further information can be found in the ESTRO publication "Quality assurance in radiotherapy," *Radiother. Oncol.*, 35, 61-73, 1995 [10].

6.3 RADIOTHERAPY PLANNING AND DELIVERY

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

6.3.1 Initial Evaluation

The overall responsibility for procedures under this heading will lie 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 written. 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 review of all diagnostic studies such as radiographs, 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 sub-clinical 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 Decision

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 in the patient.

6.3.3 External Beam Radiotherapy

6.3.3.1 Tumour Location

Once it is determined that the 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, e.g., radiographic or radionuclide studies, computed tomography, ultrasound, or magnetic resonance imaging. The clinical target volume can then be determined.

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, and the physicist carries out calculation of doses, computation of beams, and isodose distributions. The physician, in consultation with the physicist, will analyze the alternative plans of therapy and select the best for the patient. Dose calculations can also be performed by properly trained staff (technicians, radiographers, or dosimetrists) under the supervision of the physicist.

The need for immobilization and repositioning devices, shielding blocks, masks, and compensating filters must be assessed during the treatment planning procedure. If necessary, these aids will be designed 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 3D conformal therapy and intensity modulated radiation therapy employing non-coplanar beams, the treatment planning process may increasingly include the use of a computed tomography (CT) scanner as a "virtual simulator." 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 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.

6.3.3.3 Treatment Delivery

The *treatment* is carried out by the radiotherapy technician under the supervision of the physician and/or the physicist. Regardless of the degree of participation by the physicist, the physician remains the sole individual responsible for all clinical aspects of the treatment. The participation of the three professionals is always convenient for the first treatment, especially with

complex beam set-ups. Periodically, portal films and verification of doses recorded on the charts are performed.

The physician will evaluate the patient at least weekly during the course of therapy to assess tumour response and tolerance of the patient to the treatment. Examinations may be carried out more often, particularly when there is need for supportive care, such as to improve the nutrition of the patient, prescribe medication to decrease symptoms, treat current 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 co-ordinate 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 tumour response but also to detect recurrences early, should they happen, and to observe the effects of irradiation on the normal tissues.

Table I.B 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 prescriptions will be written prior to insertion of the sources; for others it may be more appropriate to write the prescription after the insertion of sources. In either case the prescription should be written on a prescription sheet which 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 this is achieved safely and efficiently, independently checked, and that the source locations log is appropriately up-dated.

The overall responsibility for the imaging procedure lies with the radiation oncologist. Generally at the time of the brachytherapy procedure, dummy sources (i.e. non radioactive) are inserted into the applicator or catheters. Radiographs of the implant are then obtained for two purposes: i) to see that the position and arrangement of the implant is correct, and ii) 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 or not to continue with the treatment or to modify the application. As described in Section 5, orthogonal or stereo shifted radiographs might be required.

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 final treatment parameters must be approved by the prescribing radiation oncologist

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 (i) treatment start-up (for afterloading treatments), (ii) patient and/or applicator monitoring to ensure the continuing integrity of the application, (iii) emergency procedures with clearly stated action criteria, (iv) procedures for unplanned activity or treatment interruption (e g for additional check radiography), and (v) completion procedures including removal of sources and applicators and, where appropriate, the safe return of sources to appropriate storage locations Further technical procedures will cover checking of the returned sources and the up-dating of source location records

6 3 4 5 Periodic Evaluation and Follow-up

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

Table I C 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 (i e , computers, etc) A maintenance strategy determined at the beginning of a project is essential in achieving and maintaining

- a) low down times
- b) high quality treatments
- c) treatment schedules (fractionation)
- d) patient and staff safety and
- e) accident prevention

Three lines of maintenance can be considered

- a) in house service for frequent small repairs
- b) local support by a specialized maintenance company, usually a representative of the supplier
- c) 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 lead to unacceptable and even dangerous consequences The equipment containing large amounts of radioactive material (^{60}Co units and remote afterloader) may require a licensed source handler to carry out the maintenance

Overall management of the maintenance programme should be provided by the medical physicist Since maintenance staff will be working around hazardous radioactive materials and potentially affecting basic safety mechanisms in the devices the help and co-operation of the radiation protection supervisor should be sought The programme should be developed with the co-operation 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 service is performed, and what records are to be kept After each major repair or preventative maintenance, a complete set of quality control measurements should be done

6.4.1 Preventive Maintenance

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

6.4.2 Repair

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 infrequently. There should be a formal procedure for notifying the medical physicist any time there is a repair regardless of its 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 and understandable to the users (i.e. the maintenance engineer) are required by BSS (BSS 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

In accordance with BSS (BSS II.29-30) [1], the following 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.

In most cases the radiation physicist will be the most appropriate person to undertake such an investigation which should include:

- a) a calculation or estimation of the doses received and their distribution within the patient;
- b) corrective measures required to prevent recurrence of such an accident;
- c) 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 this investigation. Unless there is an over-riding 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.

6.6 QUALITY AUDITS

A quality audit is an independent examination and evaluation of the quality assurance activities and results. 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 as well as those from outside the institution. At larger institutions internal audits may include staff members reviewing each others' 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 audit program. In regards 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 packet 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 source calibrations. Organizations offering these services include the IAEA/WHO, ESTRO in Europe and the Radiological Physics Center and Radiation Dosimetry Services in North America.

7. RADIATION PROTECTION AND SAFETY OF SOURCES

7.1 GENERAL

Before initiating construction of the radiotherapy facility, the approval by the Regulatory Authority has to be obtained. Otherwise, if the safety review by the Regulatory Authority is performed after initiating construction, it may occur that the Regulatory Authority requires modifications at a late stage of construction that may be costly or even impracticable in the case of radiotherapy.

The areas which need to be addressed are listed in Appendix H; typically these areas are the description of radiation sources, facility design, managerial and organizational arrangements, personnel, training, operating procedures and resources.

The application needs to include statements on the arrangements and procedures that the licensee will observe during construction and operations. In addition, the user should not make any changes that affect safety without the knowledge of the Regulatory Authority. If the modifications are substantial and affect safety, the Regulatory Authority may require an additional application.

7.2 ORGANIZATION AND MANAGERIAL MEASURES

7.2.1 Management policy

An overall policy on safety culture, defense-in-depth, and source accountability relies primarily on the policy that management introduces and supports.

In some serious accidents², management allowed safety systems to degrade significantly and workers 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 encourage deviation from procedures in order to perform the job more quickly.

The whole radiation protection programme needs its own defense-in-depth mechanism, which can be complemented through independent audits of the programme with formal reports issued to the participants on a periodic basis.

7.2.2 Staffing and training

As discussed in Section 3, sufficient and trained staff has to be assigned and their responsibilities be clearly defined. With regard to medical exposure in radiotherapy, the overall responsibility for patient protection, has to be assigned to medical practitioners and calibration, dosimetry and quality assurance has to be conducted under the supervision of a qualified expert in

² 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 in any place of the world. Periodical reports are planned, the first of them involving radiotherapy is expected in 1998.

radiotherapy physics (usually a medical physicist). The duties of the radiation protection officer (RPO) may be covered by the qualified expert in radiotherapy physics (the medical physicist), depending on the size of the radiotherapy department.

The radiation protection programme cannot rely solely on the above professionals for its operation. Rather, every staff member who comes into contact with the sources must be trained in their role for each procedure and in basic radiation safety. These individuals include:

- a) radiotherapy technologists
- b) source handlers
- c) nurses
- d) patient transporters
- e) maintenance engineers or technicians

Each of these individuals needs to be taught to identify the type of source that they work with and how to 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 his designee. Example syllabus for each category of worker have been given for example by the NCRP [11].

The lines of authority and responsibilities needs to be clearly drawn and documented within the programme.

7.2.3 Reassessment of training needs

The staffing, responsibilities and training needs are to be reassessed any time the radiotherapy department introduces a new equipment, expands activities, incorporates new treatment modalities. The reassessment needs to check both the quantity of the personnel available and the training. A typical example is the purchase of a new machine with the view to increase the number of patients to be treated; the introduction of an accelerator or a brachytherapy HDR machine. Staff needs has to be identified before it becomes insufficient or inadequately trained to operate the department safely, in the case of an expansion. Failure to do so has caused severe accidents involving a large number of patients [see footnote 2].

7.3 DESCRIPTION OF EQUIPMENT AND SOURCES

The most important safety issue with regards to the safety in design is to ensure that equipment meets IEC and sealed sources meet ISO standards and the applicant needs to clearly identify the model and manufacturer, since there will be a generic authorization for each model that is intended to be sold and installed in the country.

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

- a) a safety assessment of the equipment
- b) a quality control test, before the donor decommissions the machine, and submit the test results 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 wrong repair can cause severe injuries or even deaths.

Each sealed source should be purchased with a calibration certificate which details its isotopic activity on a certain date, its encapsulation, and its 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 sources are only used with compatible applicators and with appropriate cleaning techniques.

The recommended working life (RWL) under specified conditions for use need to be observed. When the RWL is exceeded the sources may still be in good use but a safety assessment needs to be made and the frequency of wipe and other test may need to be reconsidered.

7.4 FACILITY LAYOUT, SHIELDING AND INTERLOCKS

7.4.1 External beam

7.4.1.1 Layout

Initial considerations for an external beam treatment unit should give careful consideration to a number of points which will impact 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 room as possible and conversely surround the room with spaces that are not able to be occupied or have very low controlled occupancy (such as a roof which can have access controlled by locks or signs which prevent entry)
- b) Consideration needs to also be given to the ease of access to the room by patients and for the installation and replacement of equipment. A maze is the most practical solution for Co-60 external beam treatment rooms. If well designed, the maze makes a heavy door unnecessary. It should be noted that the staff enters 100 times per day into the room, and heavy doors may become impracticable. Motor driven doors are expensive and slow and are usually not necessary for Co-60 irradiation rooms. The maze also allows easy penetration of the treatment room vault over the maze door for ventilation and electrical conduits and only a minimal amount of scattered radiation will come through the penetration.
- c) Primary barrier widths should be about 0.67 times the distance from source to the barrier, while their thickness is determined by the methods discussed in Appendix J.
- d) It is necessary to supply an open access conduit for equipment cables and test cables near the unit control (Reference to the manufacturer's accompanying documents). This can be done by assuring that the line-of-sight of the conduit does not intercept any surface inside the room which 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 with 4 cm of steel with a 3 cm margin on the sides.

An example calculation spreadsheet for a Cobalt 60 therapy source is shown in Appendix J.

7.4.1.2 Interlocks and signs

In addition to layout and shielding considerations there are safety interlocks and procedures which need to be incorporated into the 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 the treatment. Restart of the irradiation should require both the closing of the door and activation of a switch at the control console.
- b) The door to the room should have a sign which indicates the room is a radiation area and/or contains radioactive materials.
- c) There should be a visible light at the door to the room which 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 scatter radiation detector inside the room which 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 communication from the patient during the treatment.

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 loading unit which 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 one to retract the sources into the safe position whenever anyone, such as a nurse, needs to be around the patient. Therefore staff exposures can be kept to a very low level.

With manually loaded sources there is need of an actual 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.

If the sources are only the LDR type and they 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 source loader to use while identifying and loading the sources into the applicator. Since 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 which house the LDR brachytherapy patients until they are ready for discharge, 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, the sink has led also to loss of sources, for instance, when the patient removed a source and disposed of it through the sink. This can be prevented 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 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 source 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 of 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 which 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 scatter radiation detector inside the room which 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 for the radioactive materials which are within and there should be an indication of how to contact the responsible radiation safety individual in the event of an emergency.

7.4.2.2 Interlocks and signs

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

7.5 INDIVIDUAL MONITORING

Certain staff 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.

Those most likely to require monitoring are the: radiation oncologists, qualified experts in charge of the radiotherapy physics, RPO, source handlers, and any nursing or other staff who must spend unrestricted amounts of time with patients who contain sources.

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 need to be supervised by the authorized personnel and RPO.

7.6 CLASSIFICATION OF AREAS

There are areas in radiotherapy to be classified as **controlled** or **supervised** areas as defined by the BSS.

The controlled areas are the treatment rooms for all external beam and brachytherapy treatments as well as the source storage and preparation rooms. In addition, these areas will require special access restrictions by means of door interlocks and signs when sources are exposed.

The supervised areas are the operating consoles of the external beam treatment unit and the HDR unit as well as any area where calculated exposure rates through shielding barriers are likely to result in exposures of 1 mSv in a year

7.7 RULES AND SUPERVISION

The following procedures need to be prepared:

- a) emergency: teletherapy, HDR
- b) wipe testing
- c) area surveys
- d) inventory of radiation sources

7.7.1 Procedures for external beam therapy

Safe operations of external beam treatment units require procedures in place such as: wipe tests, area surveys, emergency interlock checks, and source status checks; as well as procedures for emergencies such as a source which 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:

- a) a radiation monitor GM-type,
- b) a radiation monitor type ionization chamber, with scales from μSv to 10 Sv/hr,
- c) wipe test capabilities
- d) personal alarm dosimeters, especially for emergency intervention.

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 and 3. turn the monitor on and start reading the radiation dose rate level from outside the room where the source is located.

7.7.2 Procedures for brachytherapy

LDR and HDR sources have certain operating procedures for their safe use in common:

- a) Source inventories should be performed which show the location and current activity of each source at the facility with a unique identifier for each source. This may be either a color coded or letter/number identifier.
- b) Sources should never be left on preparation surfaces. They must be in storage, in transit, or in 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 ensure detect a very low increase above the background radiation. 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 sort 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 responsible radiation safety individual in the event of an emergency.
- f) The storage facilities must be kept locked at all times.
- g) After every temporary brachytherapy treatment, the patient should be monitored with a radiation detection (GM type) survey meter so ensure that no activity remains in the patient.
- h) All source transfers must be done according to the requirements of the Regulatory Authority and must be done with identified persons who receive and sign for the sources.

Procedures which 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) A diagram at the source storage safe which shows exact locations of each source within the safe, aids in reducing the time it takes to locate and identify a source.
- c) Sources should only be handled with long forceps or tongs,
- d) When transporting the sources a mobile shielded container is needed and the shortest route possible should be used.
- e) Sources which 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, chemical attack, and mechanical stresses. Therefore these sources must be inspected after every use.
- f) The work surfaces should be easily cleaned and brightly lighted to make it easy to find any sources which are dropped.
- g) If the source storage and preparation room is also the applicator loading room, there should be a sink for cleaning of the applicators. However, a sink can also lead to a loss of sources to the sewerage when inadvertently a source is left in the applicator or a patient removes a source and throws it through the sink. This can be prevented by a filter in its drain.

Procedures which are unique to HDR sources are:

- h) The HDR afterloader needs to undergo routine QA tests at the beginning of each treatment day. See AAPM Report [22]
- i) The couplings and transfer tubes needs to be checked before each HDR treatment to ensure that there is nothing to prevent the source motion.
- j) Emergency safety precautions require having an emergency container available 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 enough so that it can accept the entire applicator assembly - containing the source - removed from any patient
- k) Manufacturers provide suggested emergency procedures if the source fails to return to the safe. These generally are short single page synopsis, suitable for posting, of the necessary sequential steps involved in the emergency procedure. They assume the physical integrity of the applicator is maintained. These procedures are specific to the actual afterloading unit but generally involve the following sequence:

Each step assumes that if the previous action fails to lead to recovery, then the following action is required. The general sequence is: 1) observation at console of error message and

emergency indicators (audible and visible alarms); 2) recovery at the console (e.g., pressing an emergency off button); 3) entry into the room with a portable radiation survey meter (opening the door activates the interlock that retracts the source); 4) observation of radiation levels in the room (by mounted monitors or portable survey meters); 5) recovery at the afterloading unit (pressing an emergency off button on the remote afterloading unit (RAU)); 6) manual retraction of the source (using a hand crank); 7) patient survey and RAU survey (confirming source is in the safe); 8) applicator removal and placement in the emergency container; 9) patient survey and emergency container survey (to confirm source is not in the patient and is in the emergency container); and 10) removal of patient from the vault (with subsequent redundant survey monitor).

7.7.3 Supervision

Sufficient supervision needs to be exercised in order to avoid a degradation of safety by giving the impression that management tolerates that procedures are not followed. When supervisors failed to make the procedures and rules understood or to take actions when rules are violated, accidents eventually happened. Effective management provides comprehensive safety training to supervisors and holds supervisors accountable for worker observance of rules and procedures.

7.8 ACCIDENT PREVENTION

When developing a project request the following has to be considered:

- a) radiotherapy depends largely on human performance
- b) there are a large number of steps from the prescription of the treatment to the delivery of the radiation dose,
- c) interaction and communication between humans from different professions is present in most of the steps
- d) sophisticated equipment is combined with very manual work

It is not surprising that most accidents are due to:

- a) human mistakes in any of the steps (particularly severe and affecting many patients are errors in commissioning and calibration of the beams and sources).
- b) communication errors (including poorly documented data of the treatment)
- c) misinterpretation of signals
- d) failure to recognize an abnormal situation (training is oriented to deal with normal conditions; when something goes wrong, it is rarely recognized early, before it becomes an accident)
- e) maintenance problems

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

When applying for assistance to develop a radiotherapy programme, a sufficient defence-in-depth needs to be demonstrated and integrated with radiotherapy quality assurance, in order to prevent that a human mistake or equipment failure results 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 accidents case studies to identify and deal with abnormal conditions
- 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 of the manufacturer performs 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 the BSS II.29 and 30, and for deriving and applying preventive and corrective measures, according to the results of the investigation

7.9 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 thought out emergency plans which are concise and easily followed, and these should be developed before the start-up of a radiation treatment programme. The types of situations which need to be planned for include:

7.9.1 Lost source

In this event it is critical that an up-to-date inventory exists so that it can be determined immediately, which source(s) is (are) missing, what is their type and activity, 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 GM type) survey meter.

7.9.2 Stuck source

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 shielding 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 source area and the area must be secured from further entry until the RPO is notified and takes control of the situation.

7.9.3 Contamination

In this situation radioactive material has spread outside of its container or encapsulation. It is very important that the area is closed to further entry and that all who were in the area remain to be surveyed and de-contaminated if necessary. If there are windows or other ventilation present, these should be closed and the RPO should take control of the situation.

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

7.9.4 Patient accidental exposure

The BSS requirements on investigation of accidental medical exposure have been already referred to in section 6, including incident 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 intended.

7.9.5 Staff irradiation

Arrangements and training are needed to recognize an abnormal exposure as well as formal procedures and prompt communication to the RPO.

TABLE III. CLASSIFICATION OF RADIATION AREAS, INTERLOCKS AND CONTROLS

Area	Controlled/ or Supervised	Interlocks		Signs	
		Door interrupt	On/off light	Rad. area	Rad materials
1. Ext. beam treatment rm	controlled	yes	yes	yes	yes
2. Ext. beam control console	supervised	no	at console	on door	on door
3. LDR source storage rm	controlled	no, but door always locked		no	yes
4. Manual LDR pt. Treatment rm	controlled	no	no	no	yes
5. Afterloaded LDR pt. treatment rm	controlled	yes	no	yes	yes
6. HDR treatment rm	controlled	yes	yes	yes	yes

Appendix A

RESPONSIBILITIES OF THE RADIATION ONCOLOGIST AND THE MEDICAL PHYSICIST

Adapted from AAPM TG-40 [4]

The Radiation Oncologist (Physician, Medical Doctor)	The Medical Physicist (Hospital Physicist, Radiation Oncology Physicist)
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:
<ul style="list-style-type: none"> • Consultation and clinical evaluation • Establishment of treatment plan, including dose prescription • Treatment execution, participation on a regular basis • On-treatment evaluations and patient monitoring • Treatment summary • Follow-up and evaluation of the treatment 	<ul style="list-style-type: none"> • Specification of therapy equipment (external beam, brachytherapy, simulators, CT and imaging systems, and treatment planning systems) assuring its radiation safety. • Acceptance testing, commissioning and QA (including calibration) of therapy equipment • Measurement and analysis of beam data; tabulation of beam data for clinical use • Establishment of dose calculation procedures • Establishment of treatment planning technical aspects and treatment procedures • Evaluation and optimization of treatment planning • Establishment of QA procedures in radiotherapy regarding delivery of the treatment, radiation safety, quality control and regulatory compliance • Supervision of therapy equipment maintenance

**NEXT PAGE(S)
left BLANK**

Appendix B

SPECIFICATIONS FOR A TREATMENT SIMULATOR

B.1. TECHNICAL SPECIFICATIONS

All performance specifications and tests shall conform with standards of the International Electrotechnical Commission (IEC) for radiotherapy simulators [12, 13], and of the International Standards Organization (ISO) for radiation sources[14-16].

Gantry

- Gantry motorized with isocentric design
- Gantry rotation: 0-360 deg
- X-ray focus-isocenter distance ± 80 cm
- Isocenter height above floor level ≤ 130 cm
- Isocenter maximal sphere 3.0 mm diameter
- Hand held control of parameters inside treatment room.
- X-ray Housing and Collimator
- X-ray tube and housing, with rotating anode, even in fluoroscopy. Two focii
- X-ray beam collimated by motorized diaphragm with both local and remote control.
- Field defined by wires, independent of the X-ray beam diaphragm, motorized with both local and remote control
- Projection of the wires shall be ≤ 2.5 mm at the isocenter
- Collimator rotation ± 100 deg. Manual and/or motorized rotation.
- Optical distance indication range SAD ± 20 cm
- Maximal field size at isocenter ≥ 30 cm x 30 cm
- Minimal field size at isocenter ≤ 5 cm x 5 cm
- Symmetry better than ± 3 %
- Light/radiation field congruence ≤ 2 mm
- Transparent shadow tray

Couch Table

- X-ray transparent table top
- Isocentric rotation ± 90 deg
- Patient lateral motion range ± 20 cm
- Motorized vertical movement, with minimum height: ≤ 80 cm, and not less than 40 cm below isocenter, and at least up to 3 cm above the isocenter
- Longitudinal range ≥ 70 cm
- Table top sag \leq than 5 mm with a patient of 80 kg

Remote Control Console

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

X-ray Generator

- Fluoro/radiography
- 30 kW high frequency generator; otherwise ≥ 50 kW,
- Radiography 125 kVp and 300 mAs. Fluoroscopy up to 15 mA

Imaging System

- Image intensifier with ≥ 23 cm diameter
- Image intensifier lateral/ longitudinal movements
- Maximum vertical source to input screen distance ≥ 175 cm
- 35 cm x 43 cm cassette film holder, including four cassette

- TV circuit and monitor TV
- Options and Accessories**
- Three lasers for patient centering
- Front pointer
- Interlocks devices against collision

B 2 SAFETY COMPLIANCE

Compliance with safety requirements in the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS) [1] and the International Electrotechnical Commission Standards (IEC), shall be substantiated by providing with the quotation the results of type tests according to IEC [13]

B 3 ACCOMPANYING DOCUMENTS

The accompanying documents shall comply with BSS and IEC standards. 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 are primarily radiographers and maintenance personnel, but also physicists and radiation oncologists may use the equipment.

The documentation shall include

- Performance specifications
- Operating instructions
- Installation documents including data to calculate shielding, masses, forces and momentums, ventilation shafts and conduits for cables, pieces to anchor the equipment and couch during construction
- Preventive maintenance instructions and service manual

B 4 ACCEPTANCE TEST

An acceptance test to comply with the present specifications will be performed by an expert provided by the Agency.

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

B 5 WARRANTY AND SERVICE

Hospital administrators typically require warranty and service terms similar to the ones listed here to prevent lengthy downtimes that may adversely impact patient treatments and or lead to accidents.

- Delivery time: no more than four months
- Specify the time needed for manufacturer-installation. This installation shall be included in the price.
- Warranty: one year starting after formal acceptance.
- Maintenance and service (preconditions for the purchase of equipment)
 - + Training for in-house engineers, in the local language, included in the quotation, specify duration, location, programme, etc (first-line service)
 - + Availability of manufacturer service at national or regional level, indicate address of the nearest service location, number and qualification of the maintenance engineers in that location (second-line service)
 - + When the above fails to solve the service request, availability of engineer from the factory in less than one week (third-line service)

- + Permanent service support by immediate specialized response by phone (phone-service) and/or e-mail; consultation for repair and maintenance in a language understandable to the user (BSS)
- + Spare parts kit included. Specify spare parts
- + Service rates and conditions; price per hour, per diem, response time, etc.
- Availability of contracted maintenance: up-time³ ($\geq 95\%$), with acceptance of penalties for late delivery of service, extended installations or periods of initial non performance according to equipment specifications
- Training of staff (physicians, physicists and operators) in the use of the machine

B.6. GENERAL REMARKS

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

³ Up-time is operation without down time (see ref [1])

Appendix C

EQUIPMENT REQUIREMENTS FOR COMPUTERIZED TREATMENT PLANNING SYSTEMS

C.1. HARDWARE

- Computer PC based with :
 - + Screen co-ordinate positioning (joystick, mouse, light pen)
 - + Colour display monitor for high resolution presentation of graphics, (matrix $\geq 256 \times 256$), multi-presentation (text and images).
- Data input/output devices :
 - + Digitizer for image size 40 cm x 50 cm or greater
 - + Resolution better than 0.5 mm
- Printer
- Plotter
 - + DIN A3 format or continuous paper 40 cm wide
 - + Number of colours ≥ 4
 - + Resolution better than 0.5 mm
 - + Reproducibility better than 0.5 mm

C.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.).

External therapy

- 2D calculations for ^{60}Co beams
- Fixed SSD and isocentric calculations.
- Calculation with ≥ 6 simultaneous external beams
- Irregular field calculation
- Obliquity and distance correction
- Tissue inhomogeneity correction
- Wedge calculation
- Ability to modify contour to accommodate bolus

Brachytherapy

- Source position reconstruction from X-ray film.
- Sources : ^{137}Cs , ^{192}Ir , ^{125}I
- Correction for source filtration
- Support most common gynaecological applicators: Henschke, Fletcher-Suit, Manchester and Delouche.
- Calculation for point and line sources and combination of them
- Source rotation display

Data input

- Manually acquired patient contours.
- User radiation beams data (possibility for extracting data tables and plotting distributions)
- Source position and anatomical landmarks for brachytherapy.

Data output

- Real size plots

C.3 OPTIONS

- CT image input
- For high energy photon and electron beam 2.5 D2
- Combination of photon and electron beams.
- Combinations of external beams and brachytherapy
- Arc therapy treatment planning
- Output for customized blocks.
- Output plots at varying scale.
- Selection of bolus density

C 4. COMPLIANCE WITH STANDARDS AND SAFETY

Since IEC standards on TPSs are not yet available, either

- The FDA certification of the US, or
- Documented Quality Assurance procedures (e.g. AAPM TG-40 [4]) verified by a manufacturer-independent quality audit group and published in peer review literature, shall be requested as a substitute

C 5. ACCOMPANYING DOCUMENTS

The accompanying documents shall comply with the International Basic Safety Standards for Radiation Protection and the Safety of Radiation Source (BSS) as well as the IEC. According to the BSS, Appendix II.3, "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, radiotherapists, and engineers

The documentation shall include:

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

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

C.6. ACCEPTANCE TEST

An acceptance test to comply with the present specifications shall be performed by an expert provided by the Agency.

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

C.7. WARRANTY AND SERVICE

Hospital administrators typically require warranty and service terms similar to the ones listed here to prevent lengthy downtimes that may adversely impact patient treatments and or lead to accidents.

- Delivery time: no more than four months.
- Specify the time needed for manufacturer-installation. This installation shall be included in the price.
- Warranty: one year starting after formal definite acceptance
- Maintenance and service (preconditions for the purchase of equipment):
 - + Availability of manufacturer service at national or regional level (indicate address of the nearest service location, number and qualification of the maintenance engineers in that location)
 - + When the above fails to solve the service request, availability of engineer from the factory in less than one week
- Service rates and conditions (price per hour, per diem, response time)
- Upgrades of purchased items of software at no cost for at least for three years
- Training of staff (physicians, physicists and operators) in the use of the system
- Permanent service support by immediate qualified response by phone, fax or e-mail for repair and maintenance.
- Consumables should be available locally
- Spare parts kit included in the price. Specify spare parts

C.8. GENERAL REMARKS

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

**NEXT PAGE(S)
left BLANK**

Appendix D

SPECIFICATIONS FOR A ^{60}Co TELETHERAPY UNIT AND ITS RADIATION SOURCE

D.1. CLINICAL CONSIDERATIONS

The specifications given below are based on clinical requirements (treatment sites, size of target volumes and geometry, treatment time, etc.), as well as on requirements to fulfil treatment fractionation schemes without clinically unacceptable interruptions. The medical requirement considerations are the same as those described in a recent joint report by PAHO/WHO/IAEA/UNIDO on the design of megavoltage x-ray machines for cancer treatment in developing countries [17].

D.2. TECHNICAL SPECIFICATIONS

All performance specifications and tests shall conform with standards of the International Electrotechnical Commission (IEC) for equipment [12, 18], and of the International Standards Organization (ISO) for radiation sources [14-16].

Gantry and treatment head

- Gantry motorized with isocentric design
- Gantry rotation: 0-360 deg
- Source isocenter distance SAD ≥ 80 cm
- Isocenter height above floor level ≤ 130 cm
- Isocenter clearance (with devices inserted) ≥ 15 cm
- Isocenter maximal sphere 3.0 mm diameter
- Hand held control of parameters inside treatment room
- Collimator
 - + Collimator jaw indication: mechanical or electrical with mechanical backup
 - + Collimator rotation ± 100 deg. Manual and/or motorized rotation
- Optical distance indication range: SAD ± 20 cm, with mechanical backup
- Secondary collimators (trimmers) to reduce penumbra
- 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 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.

Radiation field

- Maximal field size at isocenter ≥ 30 cm x 30 cm (50% isodose level)
- Minimal field size at isocenter ≤ 5 cm x 5 cm (50% isodose level)
- Symmetry better than ± 3 %
- Uniformity of ± 3 % over 80 % of the field
- Light/radiation field congruence ≤ 2 mm
- Source diameter ≤ 2.5 cm
- A penumbra ≤ 1 cm should be achievable, either with trimmers or blocks
- Output ≥ 1.5 Gy/min at isocenter (at the depth of d_{max}) for a 10 cm x 10 cm field at acceptance test.
- At least two wedges angles (15 and 45 deg) should be available for 8 cm W x 15 cm. Insertion of

wedges must not restrict use of secondary collimation Max field size covered by wedge specified on the wedge Wedges shall be fixed for collimator and gantry rotation It shall be possible to use blocks and wedges simultaneously

Couch table

- Table top with transparent window up to the maximal field size
- Angle of rotation of the top ± 180 deg
- Isocentric rotation ± 90 deg
- Patient lateral motion range ± 20 cm (necessary for treatment of lateral fields without moving the patient, respective of the couch, from initial positioning This shall be achieved either by moving the table top laterally or by a combination of the isocentric and column rotation)
- Motorized vertical movement, with minimum height ≤ 80 cm, and not less than 40 cm below isocenter, and at least up to 3 cm above the isocenter
- Longitudinal range ≥ 70 cm
- Table top sag ≤ 5 mm with a patient of 80 kg

Control console

- General ON/OFF key

Options and accessories

- Counterweight or beamstopper
- Independent head rotation on arm (range ± 90 deg)
- Couch table with centred spine section
- Area monitor with acoustic/optical signal of radiation
- 3 Lasers for patient centring
- 35 cm x 43 cm cassette holder for portal films, including four cassettes
- TV closed circuit or window
- Immobilization devices for arms, legs and head
- Backpointer
- Inter-communicator with the patient (two stations)

D 3 SAFETY COMPLIANCE

Compliance with safety requirements in the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS) [1] and the International Electrotechnical Commission Standards (IEC), shall be substantiated by providing with the quotation the results of type tests according to IEC-601-2-11 [18]

D 4 ACCOMPANYING DOCUMENTS

The accompanying documents shall comply with BSS, IEC-601-1 and IEC-601-2-11 According to the BSS, Appendix II 3, "performance specifications and operating and maintenance instructions shall be provided in a major world language, understandable to the users " The users are primarily radiographers and maintenance personnel, but also physicists and radiation oncologists may use the equipment

The documentation shall include

- Performance specifications
- Operating instructions
- Installation document including data to calculate shielding, masses, forces and momentums,

- ventilation shafts and conduits for cables, pieces to anchor the equipment and couch during construction
- Preventive maintenance instructions and service manual
- Isodose charts

D 5 ACCEPTANCE TEST

An acceptance test to comply with the present specifications will be performed by an expert provided by the Agency

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

D 6. WARRANTY AND SERVICE

Hospital administrators typically require warranty and service terms similar to the ones listed here to prevent lengthy downtimes that may adversely impact patient treatments and or lead to accidents

- Delivery time no more than four months
- Specify the time needed for manufacturer-installation. This installation shall be included in the price
- Warranty one year starting after formal acceptance
- Maintenance and service (preconditions for the purchase of equipment)
 - + Training for in-house engineers, in the local language, included in the quotation, specify duration, location, programme, etc (first-line service)
 - + Availability of manufacturer service at national or regional level, indicate address of the nearest service location, number and qualification of the maintenance engineers in that location (second-line service)
 - + When the above fails to solve the service request, availability of engineer from the factory in less than one week (third-line service)
 - + Permanent service support by immediate specialized response by phone (phone-service) and/or e-mail, consultation for repair and maintenance in a language understandable to the user (BSS)
 - + Spare parts kit included Specify spare parts
 - + Service rates and conditions, price per hour, per diem, response time, etc
 - + Availability of contracted maintenance up-time⁴ ($\geq 95\%$), with acceptance of penalties for late delivery of service, extended installations or periods of initial non-performance according to equipment specifications
 - + Price for source replacement should include replacement source and cost of removal of old source
 - + The procedure for source exchange shall not require more than 24 h excluding acceptance test and Quality Assurance
- Training of staff (physicians, physicists and operators) in the use of the machine

D 7 GENERAL REMARKS

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

⁴ Up-time is operation without down time (see ref [1])

Appendix E

BASIC EQUIPMENT RECOMMENDED FOR DOSIMETRY IN EXTERNAL RADIATION THERAPY

Although clinical accelerators are not dealt with in this report, recommendations are included here for comparison of the minimum equipment needs in different treatment units

	Basic equipment	Type of installation		
		⁶⁰ Co	LINAC photons only	LINAC with electrons
1	Ionization chamber Farmer-type, 0.6 cm ³ approx, plastic walls (robust), ⁶⁰ Co build-up cap, 10 m cable, 10 m extension cable, extension connectors calibrated at a Standards Laboratory in terms of air kerma (do not include calibration in terms of absorbed dose to water until IAEA CoP is available) The chamber model must be included in IAEA dosimetry publications [7, 8]	X	X	X
2	<u>Highly recommended, in addition</u> Ionization chamber Farmer-type, 0.6 cm ³ approx, graphite walls, ⁶⁰ Co build-up cap, 10 m cable calibrated at a Standards Laboratory in terms of air kerma (do not include calibration in terms of absorbed dose to water until IAEA CoP is available) The chamber model must be included in IAEA dosimetry publications [7, 8]	X	X	X
3	Ionization chamber, 0.1-0.3 cm ³ approx, cylindrical, 10 m cable (max electrode diameter 1 mm)	X	X	X
4	Radioactive source for checking stability of cylindrical ionization chambers	X	X	X
5	Plane-parallel ionization chamber for electrons (min guard ring 4 mm) The chamber model must be included in IAEA dosimetry publications [7, 8]			X
6	Electrometer compatible with chambers above and following specs in IAEA dosimetry publications [7, 8], calibrated or compared at a Standards Laboratory	X	X	X
7	Additional electrometer with varying voltage bias (V1/V2 ratio equal or greater than 3), possibility to reverse the polarity		X	X
8	Water phantom for calibration and checks, 20x20x10 cm ³ approx, PMMA walls, including holder for ionization chambers	X	X	
9	Water phantom for calibration, 30x40x40 cm ³ approx, PMMA walls, including holder for ion chambers with manual steps or automatic system to vary the position of the chamber		X	X
10	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 TLD	X	X	X
11	Barometer (min scale 1 mb or hPa, or 0.5 mm Hg), pref aneroid type or digital, calibrated or compared at a Standards Laboratory	X	X	X

Basic equipment		Type of installation		
		⁶⁰ Co	LINAC photons only	LINAC with electrons
12	Thermometer (min scale 0.25 deg C), calibrated or compared at a Standards Laboratory	X	X	X
13	Densitometer to measure x-ray film optical density, with manual reader and co-ordinate system OD cal. film-strip for check of instrument OD scale. Requires having access to film development	X		
14	Densitometer to measure x-ray film optical density, with automatic register and co-ordinate system. OD cal. film-strip for check of instrument OD scale Requires having access to film development		X	X
15	Radiation field analyser to measure isodose distributions, 50x50x40 cm ³ approx water tank, phantom trolley with vertical movement, water pump		X	X
Supplementary equipment				
1	TLD system (both redundant dosimetry and "in-vivo")		X	X
2	Array of diodes or ion-chambers for Quality Assurance daily checks		X	X
3	Precision water level	X	X	X
4	Calliper, metal ruler	X	X	X
5	Multi-meter (volt, ohm)	X		

ADDITIONAL EQUIPMENT FOR LOW-ENERGY X-RAYS DOSIMETRY

For the range of qualities from 100 to 300 kV items in the previous list 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 following equipment is required.

1. Ionization chamber for kV X-rays, parallel-plate 0.3 cm³, 10 m cable
calibrated at a Standards Laboratory in terms of air kerma for x-rays, at least for three calibration qualities between
10 kV and 100 kV. Both the kV and the HVL should be stated in the calibration certificate
2. Plastic phantom for kV X-rays parallel-plate ion chamber

Appendix F

COMPARISON BETWEEN HIGH-DOSE-RATE (HDR) AND LOW-DOSE-RATE (LDR) BRACHYTHERAPY

The comparison between HDR and LDR brachytherapy is complex and depends upon many variables and the end points chosen from the comparison. If there was a clear clinical advantage of one over the other (e.g. an improved survival rate with comparable or less complications) then the choice, as to which to use, might be easier. As it is no such distinction now exists and the choice must depend upon other factors.

The types of clinical cases most frequently seen at a given institution might help. If a large number of bronchogenic and oesophageal cancers are seen then HDR brachytherapy might be preferred because these cases are difficult if not impossible to treat with LDR.

However it is likely that the clinical cases most frequently seen are gynaecological tumours which can be treated well with either HDR or LDR.

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

- Applicator insertion in the operating room under general anaesthesia (or possibly a spinal block). Radiation Oncologist, anaesthesiologist and support staff need to be present.
- Verification of applicator position using mobile X-ray unit.
- Removal of patient to the Imaging department. Orthogonal X-ray taken. Subsequently patient taken to hospital room.
- Radiation Oncologist, physicist, dosimetrist review the films and decide upon number and strength of sources to be used.
- Treatment planning computer calculation of the isodose distribution around implant. Anticipated source loading could be changed. Length of treatment time calculated.
- Dosimetrist, physicist, or source curator prepares the sources, in the source preparation room, for loading.
- Source loaded (manually) into the applicator in the patient implants in 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
- Patient in the hospital for several days, time for nursing care limited by radiation and visits restricted.
- Sources removed by the trained personnel occasionally some of the sources may be removed earlier or later than planned to obtain a desired dose distribution
- Patient discharged.
- The patient may return in a couple of weeks for a second treatment.

Several such procedures could be done on any given day. Generally the number is restricted by the availability of sources, applicators, operation room and hospital beds.

Modifications of this approach will take place if remote afterloading is used. However the overall approach is the same.

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

- Applicator insertion in the special procedures room under sedation (or local anaesthesia). Radiation Oncologist and support staff present.
- Verification of applicator position and taking of orthogonal films with the special diagnostic radiation equipment (Often a treatment simulator).
- Removal of patient to a holding area to wait for dose calculations
- Dose calculations by the physicist in conjunction with the radiation oncologist on the treatment planning computer using the orthogonal films.
- Patient moved to the treatment room and remote afterloader programmed to deliver the desired treatment.
- Treatment given. This will take several minutes. Physicist will be present during the treatment.
- Patient taken back to the procedures room for the removal of the applicators.

- Patient is allowed to go home.
- Patient returns several times at intervals dependent on the fractionation schedule to complete treatment. The above procedure will be repeated every time.

It is essential to recognize that no more than 3-8 HDR procedures can be performed per day on a single machine, depending on the complexity of treatment planning required. For example, if 200 cases of locally advanced cervix carcinoma are anticipated, and each patient is to receive 4 fractions, an average daily load of 3-4 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. HDR 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 to the cost of amortizing the capital investment required and costs of source replacement and machine maintenance.

Appendix G

SPECIFICATION OF EQUIPMENT FOR REMOTE LDR AND HDR AFTERLOADING BRACHYTHERAPY

G 1 EQUIPMENT FOR LOW-DOSE-RATE (LDR) AFTERLOADING BRACHYTHERAPY

G.1.1 Technical Specifications

All performance specifications and tests shall conform with standards of the International Electrotechnical Commission (IEC) for equipment, and of the International Standards Organization (ISO) for radiation sources. It is required

- Source positioning reproducibility ± 1 mm
- Automatic power-failure source retraction
- Intermediate source storage container
- Minimum of 3 source channels for intracavitary and endoluminal treatments, 4 source channels highly desirable
- Remote nurse alarm station

G.1.2. Safety compliance

Shall comply with the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS) [1] and the relevant IEC standards [19]

G.1.3. Accompanying documents

- Shall comply with the BSS as well as the relevant IEC standards
- Performance specifications
- Operating instructions
- Installation documents including requirements on shielding, power, ventilation, compressed air or any other items
- Preventive maintenance and service manuals
- Source exchange instructions

G.1.4. Acceptance test

An acceptance test to show compliance with agreed upon specifications will be performed by an expert provided by the Agency

A satisfactory result is a precondition for payment

G.1.5. Warranty and service

- Delivery within four months, specify installation time
- One year warranty starting on acceptance date
- Maintenance and service training for hospital engineer, present availability of manufacturer service at national or regional level (give address and number of qualified engineers)
- Training of staff (physicians, physicists and operators) in the use of the equipment
- Prices shall include transportation and installation
- Price for source exchange, including rates for disposal of old sources and including transportation

G.1.6. general remarks

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

G 2 MINIMUM EQUIPMENT RECOMMENDED FOR LOW-DOSE-RATE (LDR) BRACHYTHERAPY

		Manual LDR	Remote LDR
1	¹⁹² Ir source loading and cutting devices	X	X
2	Source storage and transport containers (for Remote LDR this should be part of the equipment) within the department	X	X
3	Source handling instruments and accessories (in source preparation room and patient loading room)	X	X
4	Area radiation monitor in treatment room with light signal outside the entrance door, power-fail-safe	X	X
5	Portable radiation monitor instrument	X	X
6	Highly recommended Area radiation monitor with audio signal at the entrance to the treatment room	X	X
7	Emergency container and emergency source handling instruments at the treatment room	X	X
8	Radioactive waste storage	X	X
9	Equipment for source/applicator localization and identification (e g X-ray)	X	X
10	Dummy sources for applicator localization in patient	X	X
11	Patient couch adapted for LDR brachytherapy applications gyn , H&N, bronch (leg rests, film cassette holders, anaesthesia requirements, etc)	X	X
12	Device for fixation of connector between transportation tube-applicator tubes to patient		X
13	Set of applicators for intracavitary (e g Henschke, Fletcher-Suit, Manchester or Delouche type) and interstitial treatments	X	X
14	Radiation protection barrier for source loading in patients and for patient care	X	
15	Portable radiation protection barriers in case of insufficient protection in patient ward walls and door	X	X

G.3. EQUIPMENT FOR REMOTE HIGH-DOSE-RATE (HDR) AFTERLOADING BRACHYTHERAPY

G.3.1. Technical Specifications

All performance specifications and tests shall conform with the relevant standards of the IEC (as no IEC standard exists for HDR equipment at the time of writing, relevant parts of that for low dose rate equipment shall be used) and the International Standards Organization (ISO). Alternatively the AAPM report No 41 [20] and AAPM recommendations by TG-43 and TG-56 [21, 22] should be used.

- Manual emergency source retraction
- Automatic power-failure source retraction
- Source positioning reproducibility ± 1 mm
- Minimum of 3 source channels for intracavitary and endoluminal treatments; 4 source channels, highly desirable
- TPS including optimization, treatment parameter transfer to treatment unit
- Automatic correction for source decay in case of ^{192}Ir
- Dummy source simulation before treatment

G.3.2. Safety Compliance

Shall comply with the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS) [1] and the relevant IEC standards [12, 19].

G.3.3. Accompanying Documents

Shall comply with the BSS as well as the relevant IEC standards

- Performance specifications
- Operating instructions
- Installation documents including requirements on shielding, power, ventilation, compressed air or any other items
- Preventive maintenance and service manuals
- Source exchange instructions

G.3.4. Acceptance Test

An acceptance test to show compliance with agreed upon specifications will be performed by an expert provided by the Agency.

A satisfactory result is a precondition for payment.

G.3.5. Warranty and Service

- Delivery within four months; specify installation time
- One year warranty starting on acceptance date
- Maintenance and service: training for hospital engineer, present availability of manufacturer service at national or regional level (give address and number of qualified engineers)
- Prices shall include transportation and installation
- Price for source exchange, including rates for disposal of old sources and including transportation

G.3.6. General Remarks

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

G 4 MINIMUM EQUIPMENT RECOMMENDED FOR HIGH DOSE RATE (HDR) BRACHYTHERAPY

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

- 1 Area radiation monitor in treatment room connected to the door interlock with power-fail-safe audio signal independent of treatment equipment
- 2 Portable radiation monitor instrument at the entrance of the treatment room door
- 3 Highly recommended Area radiation monitor with audio signal at the entrance to the treatment room
- 4 Emergency container and emergency source handling devices at the entrance of the treatment room door
- 5 Equipment for applicator localization and identification (e.g. X-ray unit)
- 6 Dummy sources for applicator localization
- 7 Treatment couch adapted for HDR brachytherapy gyn, bronch (leg rests, film cassette holders, anaesthesia requirements, etc)
- 8 Set of applicators for intracavitary (e.g. Henschke, Fletcher-Suit, Manchester or Delouche type) and endoluminal treatments
- 9 Device for applicator fixation to treatment couch

G 5 MINIMUM EQUIPMENT RECOMMENDED FOR IMPLEMENTING QUALITY ASSURANCE PROGRAMMES IN BRACHYTHERAPY

Items	Type of installation		
	Manual LDR	Remote LDR	Remote HDR
Well-type ionization chamber or Isotope Calibrator with source holding inserts, calibrated at a Standards Laboratory for the clinical sources available	X	X	X
If ^{137}Cs sources are not available a long-lived reference source for checking well chamber stability	X	X	X
Facility to verify source homogeneity and source position Requires having access to film development	X	X	X
Barometer (min scale) 1 mb or 0.5 mm Hg), pref aneroid type or digital, calibrated or compared at a Standards Laboratory (if not available in external radiotherapy)	X	X	X
Thermometer (min scale 0.25 deg C), calibrated or compared at Standard Laboratory (if not available in external radiotherapy)	X	X	X
Caliper, metal ruler	X	X	X

Appendix H LICENSING

H.1. APPLICATION FOR AUTHORIZATION AND SAFETY REVIEW PLAN FOR RADIOTHERAPY

TYPE OF AUTHORIZATION

- ☐ New Application
☐ Amendment to existing authorization number: _____
☐ Renewal of Authorization number: _____

PURPOSE OF APPLICATION

- ☐ Construction (Complete Sections I through III)
☐ Import/Purchase (Complete Sections I and II)
☐ Use/Begin operation (Complete Sections I through V)

You may refer to previous submissions by date and application or authorization number(s).

The legal person who will be responsible for using any sealed source or radiation generator must, unless the source is exempted, submit the following information to the regulatory authority.

GENERAL INFORMATION

Name and Address of organisation:

Main address	Mailing address (if different)	Address of use (if different)
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

Name and information about qualified experts:

Expertise: Radiation Protection Officer

Name: _____
 Degree: _____
 Certification: _____
 Experience: _____

Telephone number: _____

Expertise: Radiation Oncology

Name: _____
 Degree: _____
 Certification: _____
 Experience: _____

Expertise: Radiotherapy Physics

Name: _____
 Degree: _____
 Certification: _____
 Experience: _____

Expertise: _____

Name: _____
 Degree: _____
 Certification: _____
 Experience: _____

The responsible representative of the legal person:

Name: _____ Telephone number _____
Title: _____ Facsimile number _____
e-mail address _____

Proposed date of installation and/or commissioning of facilities and equipment:

SIGNATURE AND CERTIFICATION

Signature of the authorised representative of the legal person

Printed name: _____

Title: _____

Date: _____

Notes:

- 1. The Regulatory Authority may require additional information to fully consider this application prior to issuing an authorization.*
- 2. In the event that all the above information is not available at the time of application, the Regulatory Authority may issue an authorization limiting the applicant to import, acquire, or store radiation sources, or construct facilities. Complete information will be required from the applicant prior to authorising use of the radiation sources.*
- 3. Medical exposure may be under the jurisdiction of a regulatory authority other than the regulatory authority responsible for occupational and public exposure. However, the authorised user should address the items in Section V for referral to any appropriate authority.*

H.2. SOURCES AND EQUIPMENT

For external beam therapy specify the following:

Type: (Accelerator, x-ray generator, or gamma)

Name of manufacturer: _____

Address: _____

Model No. and Name: _____

Country of manufacture: _____

Year of manufacture: _____

Type of gantry: (Stationary or rotary)

Output Gy/min at isocenter: _____

Describe the movement of the treatment table:

a. For Gamma external beam units:

- i) Radionuclide:
- ii) Model No. of the source:
- iii) Initial activity of sources:
- iv) Number of units installed:
- v) Maximum design activity of the associated equipment:
- vi) Total activity installed:
- vii) Types of source carrier or shutter (exposure mechanism):

b. For Accelerators:

- i) Maximum energy (MeV) or nominal accelerating potential (kV, MV):
- ii) Maximum current (mA):

For External beam therapy, describe the features that will be available, including:

- a. External Beam Therapy Electrical Indicators/ Interlocks (treatment room door, head lock, off shield, hand control, treatment mode - Fixed / Arc / Skip / Rotation, treatment angle, source drawer or shutter, emergency stop buttons to interrupt the irradiation, head collision switch, fixed area radiation monitor).
- b. External Beam Source Head Displays (Beam "OFF" indicator, beam "ON" indicator, head lock indicator, collimator rotation indicator, off shield indicator, light field displays).
 - i) performance specifications and operating and maintenance instructions, including protection and safety instructions, be 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 that this information be translated into local languages when appropriate;
- ii) where practicable, the operating terminology (or its abbreviations) and operating values be displayed on operating consoles in a major world language acceptable to the user.
- c. Teletherapy Control Console Displays (beam "OFF" indicator, beam "ON" indicator, head lock indicator, off shield indicator, arm position indicator, door position indicator).
 - d. Teletherapy Control Console Functions
 - i) power switch
 - ii) reset switch
 - iii) beam "ON" switch
 - iv) beam "OFF" switch
 - v) timer switch (with treatment & elapsed time displays)
 - vi) treatment mode selection switch - Fixed/ Arc/ Skip
 - vii) rotation selection switch for clockwise & anti-clockwise rotation)

For brachytherapy, specify:

Devices:

Manufacturer:	Model No:	Radionuclide:	Type of loading: Manual (M) Remote (R)	Dose Rate: High (H) Low (L)	Number of Channels: (Remote)	Maximum Activity
			M R	H L		
			M R	H L		
			M R	H L		
			M R	H L		

Sources:

Manufacturer:	Model No:	Radionuclide:	Physical type: Ribbon (R) Wire (W) Individual (I)	Physical dimensions and shape	Total Activity (per cm for wires and ribbons)	Number of sources: (total activity for wire)
			R W I			
			R W I			
			R W I			
			R W I			
			R W I			
			R W I			
			R W I			

Standards

Indicate to which IEC and ISO standards does the equipment and sources used for medical exposure conform:

For remotely loaded brachytherapy sources, describe the equipment features including:

- a. Door to treatment room electrically interlocked with source movement mechanism, and
- b. Fixed area radiation monitor.

For manual brachytherapy, describe source handling devices that will be available including:

- a. Source storage and transport container,
- b. Source handling devices and accessories (such as tongs, lead containers, etc.), and
- c. Radiation protection barrier during manual source loading in patient.

Servicing of equipment

Identify who will be authorised to perform service and maintenance on the equipment and their authorization number:

H.3. FACILITIES

Approval should be obtained from the Regulatory Authority before starting construction of the treatment rooms.

In an attachment to this application, describe the facilities, including:

Location of the facility

Provide a detailed description of the location of the radiotherapy facilities including surrounding structures or rooms and activities.

Layout of facilities

Describe factors such as the layout of the facility and its safety systems, including:

- a. building materials,
- b. alarms,
- c. shielding,
- d. engineering controls (mechanical interlocks, warning safety devices, emergency stop buttons inside/outside enclosure, prevention of unauthorised personnel entering area, and means of escape or communication from within enclosure).

Sketch or drawing

Attach a detailed sketch or drawing of the facility showing the above details. Include on the drawings any penetrations or openings in the shielding materials such as conduits or ventilation ducts.

Dose rate calculations

Taking into account existing shielding, provide calculations of the maximum dose rates expected in all areas outside the treatment room(s) which could be occupied. For these calculations, assume any radiation beam is oriented in the position that would result in the highest directional exposures. Include a statement of all assumptions used in the calculations.

H.4. RADIATION PROTECTION AND SAFETY PROGRAMME

In an attachment to this application, describe the radiation protection programme, including:

Organisational structure

- a. Describe your organisation and management control systems including assignment of responsibilities related to radiation safety. In particular include: staffing levels, equipment selection, other assignments of the Radiation Protection Officer, authority of the Radiation Protection Officer to stop unsafe operations, personnel training, and maintenance of records.

- b. Identify the authorised users, radiation physicist, and Radiation Protection Officer by name and include their training, qualifications, and experience. (Note: the authorised user, radiation physicist, and/or Radiation Protection Officer may be the same individual).
- c. Confirm that training will include: explanation of written procedures, use of equipment (radiation source and instrumentation), meanings of warning signals, and a method to confirm adequacy of training (testing or demonstrations).

Individual monitoring and classification and monitoring of areas

- a. Describe your programme for monitoring the workplace (BSS, I.37-I.40), including: the quantities to be measured, where and when the measurements are to be made, the measurement methods and procedures, and reference levels and the actions to be taken if they are exceeded.
- b. Describe your policies and procedures for classification of controlled and supervised areas. (BSS, I.21-I.25).
- c. Describe personal dosimeters provided to workers and your policies for assigning dosimetry to individual workers (BSS, I.32-I.36).

Denote type:

- i) Film
- ii) ThermoLuminescent Dosimeter (TLD)
- iii) Direct Reading Dosimeter (DRD)
- iv) other: _____

Local rules and supervision

- a. Describe your local rules and procedures regarding: investigation or authorised levels, protective measures and safety provisions, providing adequate supervision, providing workers information regarding health risks due to occupational exposure, and emergency planning instruction (BSS, I.26-I.27).
- b. Provide copies of your operating and safety procedures including: area access control, entry procedures, source inventory and leak testing , etc.
- c. Describe your training program to ensure all appropriate personnel are adequately trained in the operating procedures (BSS, I.27).
- d. Describe your policies regarding notification by female workers of pregnancy and the instructions you will provide to female workers (BSS, I.16-I.17 and I.27).
- e. Describe your programme of health surveillance based on general principles of occupational health and designed to assess the initial and continuing fitness of workers for their intended tasks (BSS, I.41-I.43).

Quality assurance

- a. Describe your program to periodically review procedures, maintain procedures current and available, and your procedure modification process.
- b. Describe your program for optimising occupational and public exposures to levels as low as reasonably achievable.

Transportation of radioactive material

If you will be transporting or shipping new or used sources, describe your arrangements for preparation and transport of packages containing radioactive sources (IAEA Safety Series 6). These procedures should address: documentation of package certification, package surveys, transfer / receipt documents, and details of shipments preparation.

Emergency procedures

Provide your emergency procedures to address potential emergencies such as potential damage to the source, loss of source shielding, or stuck sources, and misadministration to patients. If other emergencies are envisaged, please provide additional appropriate emergency procedures.

Transfer or disposal of radioactive sources

Describe arrangements for transfer or disposal of spent radioactive sources.

System of Records (BSS; 2.40, I.44-I.49, II.31-II.32), including:

- a. Disposal of spent sources
- b. Personnel exposure
 - i) current records
 - ii) prior work history
- c. Area surveys
 - i) dose or dose rate
 - ii) contamination
- d. Instrument tests and calibrations
- e. Tests for radioactive sealed source leakage.
- f. Inventory of sources and accountability
- g. Audits and reviews of radiation safety program
- h. Incident and accident investigation reports
- i. Maintenance and repair work
- j. Facility modifications
- k. Training provided
- l. Evidence of health surveillance of workers
- m. Transportation
- n. Patient discharge surveys
- o. Clinical dosimetry records

H.5. MEDICAL EXPOSURE

If appropriate for the purposes of the Regulatory Authority, in an attachment to this application, describe the programme to control medical exposure, including:

(BSS requirements related to this section may be found in Appendix II "Medical Exposure.")

Responsibilities for medical exposure

- a. Describe your arrangements to assure that patient treatment will only be prescribed by medical practitioners.
- b. Describe your arrangements to assure that calibration, dosimetry and quality assurance requirements for therapy are conducted by or under the supervision of a qualified expert in radiotherapy physics.
- c. Describe criteria and arrangements to ensure an adequate number of trained medical and paramedical personnel to discharge assigned tasks.

Justification of medical exposures

- a. Describe your arrangements to ensure that the therapeutic benefits will be weighted against the radiation detriment they might cause, taking into account the benefits and risks of available alternative techniques that do not involve medical exposure.
- b. Confirm that exposure of humans for medical research will always be in accordance with the Helsinki Declaration and will follow the guidelines for its application prepared by the Council for International Organizations of Medical Sciences and the World Health Organisation.

- c Confirm that each exposure of humans for medical research is subject to the advice of an Ethical Review Committee or other similar institutional body

Optimisation of patient protection

- a Describe your arrangements to ensure that with regard to equipment consisting of radiation generators or containing sealed sources for medical exposures
- b the equipment conforms to applicable standards of the International Electrotechnical Commission (IEC) and the ISO or to equivalent national standards (whether imported into or manufactured in the country where it is used),
- c performance specifications and operating and maintenance instructions, including protection and safety instructions, will be 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 that this information be translated into local languages when appropriate,
- d where practicable, the operating terminology (or its abbreviations) and operating values will be displayed on operating consoles, in a major world language acceptable to the user

Calibration

- a Describe your systems to ensure the calibration of sources used for medical is exposure traceable to a Standards dosimetry laboratory
- b Describe radiotherapy equipment calibration in terms of radiation quality or energy and either absorbed dose or absorbed dose rate at a predefined distance under specified conditions (IAEA Technical Report Series No 277)
- c Describe procedures for calibration of sealed sources as of a reference date, for activity or at a specific distance in terms of reference air kerma in air or absorbed dose rate in a specific medium
- d Describe your programme of calibration to be carried out at commissioning of a unit, after maintenance that could affect dosimetry and at periodic intervals

Clinical dosimetry

Describe your arrangements to ensure determination and documentation of

- a in radiological examinations, representative values for typical sized adult patients of entrance surface doses, dose-area products, dose rates and exposure times, or organ doses,
- 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,
- d in diagnosis or treatment with unsealed sources, representative absorbed doses to patients, and
- e in all radiotherapeutic treatments, the absorbed doses to relevant organs

Quality assurance for medical exposure

Describe your quality assurance programme (BSS II 22) which should include the items listed below. The programme must include arrangements made to insure that the radiotherapy equipment be available during enough time to carry out the Quality Control measurements

- a Verification of the appropriate physical and clinical factors used in treatment including measurements of physical parameters at the time of commissioning and periodically thereafter
- b Written records of relevant procedures and results

- c. Verification of the appropriate calibration and conditions of operation of dosimetry and monitoring equipment.
- d. Verification of patient identity.
- e. Regular and independent quality audit reviews.

Investigation of accidental medical exposure

Describe the procedures to 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 fractionation differing substantially from the values prescribed by the medical practitioner or which may lead to undue acute secondary effects;
- b. any diagnostic exposure substantially greater than intended or resulting in doses repeatedly and substantially exceeding the established guidance levels; and
- c. any equipment failure, accident, error, mishap or other unusual occurrence with the potential for causing a patient exposure significantly different from that intended.

With respect to any investigation:

- 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.

Dose constraints to comforters and visitors to patients

Describe your procedures to ensure that the dose of any comforter or visitor of patients be unlikely to exceed 5 mSv during the patient's treatment.

**NEXT PAGE(S)
left BLANK**

Appendix I

CONSIDERATIONS FOR A QUALITY ASSURANCE PROGRAMME IN RADIATION ONCOLOGY

I.1. INTRODUCTION

The role of quality assurance in radiation oncology has received increasing attention in the last few years and its importance is now fully recognized in maintaining consistent accuracy of the absorbed dose delivered to patients undergoing radiation therapy [4, 9, 10, 23]. Sources of error can derive from deficiencies in tumour localization, patient immobilization, field placement, daily patient set-up, dose calibration and calculation as well as from equipment related problems.

As already introduced in Section 6, the quality assurance program in radiation therapy, therefore, covers a wide range of areas, often involving several medical disciplines and the medical institution's management. Co-ordination, therefore, is critical among medical physicists, dosimetrists, maintenance engineers, radiation oncologists, radiotherapy technologists (radiographers), other medical disciplines and management. In many institutions the medical physicist is best placed to oversee such a program.

The aim of a physics quality control (QC) program 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 accuracy of the applied dose. There are two main parts of such a program: (i) periodic QC measurements and evaluation and (ii) regular preventative maintenance. The medical physicist should be responsible for making sure that both parts of the program are carried out.

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

- a) Physical dosimetry, i.e., the commissioning and calibration of treatment machines and sources.
- b) Treatment planning, i.e., the delineation of the target volume and critical structures, acquisition of patient specific factors and dose distribution calculations.
- c) 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 QC program 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 similar machines until verified. Most manufacturers provide in written form, their acceptance test procedures which list the mechanical and radiation parameters that will provide the benchmark for the equipment. Commissioning provides the detailed information about the equipment, e.g., tables of beam data. This data obtained for each piece of equipment adds to the benchmark data. Once the acceptance tests, commissioning and calibrations have been completed a QC program must commence to insure that the accuracy of the treatments is maintained, i.e., the goal of such a program is to assure that the performance characteristics established during commissioning shows no serious deviations. A QC programme also provides data and techniques to be used following any machine repairs. It is essential that the management of the installation makes the appropriate arrangements to insure that the 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," by Kutcher et al, *Med. Phys.* 21:581-618, 1994 [4]. This publication will subsequently be referred to as AAPM TG-40. Detailed QC procedures can also be found in various other publications [24, 25].

I 2 THE QC PROGRAM IN RADIATION THERAPY

QC 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

- a) External Beam Treatments
- b) Brachytherapy Treatments
- c) Measurement Equipment
- d) Clinical Aspects of the Treatments

In developing a QC program 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

I.3 THE QC OF ^{60}Co UNITS

Recommended QC tests for ^{60}Co units are given in Table I I. It should be noted that in many countries the specification, performance and quality control of ^{60}Co teletherapy units may be mandated by governmental regulations. If this is the case then these governmental regulations must be adhered to.

I 4 THE QC 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 guidelines for diagnostic radiography units [26, 27]. Table I II summarizes the QC tests for simulators.

I 5 THE QC OF EXTERNAL BEAM MEASUREMENT EQUIPMENT

The measurement equipment is equally important as the radiation treatment equipment and should be part of the QC program. The recommended QC tests, frequency, and tolerance limits are given in Table I III.

Redundancy is an important part of any QC programme. The IAEA/WHO TLD postal system provides a redundant dose measuring system. Redundancy in dose calibration equipment is necessary to assure that instruments are maintaining their calibration. Although ^{90}Sr does not provide a truly redundant system it does provide a means of assuring the constancy of the calibration system. A ^{60}Co 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 intercomparisons, if possible.

TABLE I I. QC OF ^{60}Co UNITS^a
Adapted from AAPM TG-40.

Frequency	Procedure	Tolerance ^b
Daily	Safety	
	Door interlock	Functional
	Radiation room monitor	Functional
	Audio-visual monitor	Functional
	Mechanical	
	Lasers	2 mm
	Distance indicator (ODI)	2 mm
Weekly	Check of source positioning	3 mm
Monthly	Dosimetry	
	Output constancy	2%
	Mechanical checks	
	Light/radiation field coincidence	3 mm
	Field size indicator (collimator setting)	2 mm
	Gantry and collimator angle indicator	1 deg
	Cross-hair centring	2 mm
	Latching of wedges, trays	Functional
	Safety interlocks	
	Emergency off	Functional
	Wedge interlocks	Functional
Annual	Dosimetry	
	Output constancy	2%
	Field size dependence of output constancy	2%
	Central axis dosimetry parameter constancy (PDD/TAR)	2%
	Transmission factor constancy for all standard accessories	2%
	Wedge transmission factor constancy	2%
	Timer linearity and error	1%
	Output constancy vs gantry angle	2%
	Beam uniformity vs gantry angle	3%
	Off axis points measurements with and without wedges	3%
	Safety Interlocks	Functional
	Follow test procedures of manufacturers	
	Mechanical Checks	
	Collimator rotation isocenter	2 mm diameter
	Gantry rotation isocenter	3 mm diameter
	Couch rotation isocenter	2 mm diameter
	Coincidence of collim , gantry, couch axis with isocenter	2 mm diameter
	Coincidence of radiation and mechanical isocenter	2 mm diameter
	Table top sag with 80 kg mass evenly distributed	5 mm
	Vertical travel of table	2 mm
	Field-light intensity	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 tolerance listed in the tables should be interpreted to mean that if a parameter either (1) exceeds the tabulated value (e.g., the measured isocenter under gantry rotation exceeds 2 mm diameter), or (2) that 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, percent values are plus/minus the deviation of the parameter with respect to its nominal value. Distances are referenced to the isocenter or nominal SSD (3).

TABLE I II QUALITY CONTROL OF SIMULATORS

Adapted from AAPM TG-40

Frequency	Procedure	Tolerance ^a
Daily	Localizing lasers	2 mm
	Distance indicator (ODI)	2 mm
Monthly	Field size indicator	2 mm
	Gantry/collimator angle indicators	1 deg
	Cross-hair centering	2 mm
	Focal spot-axis indicator	2 mm
	Fluoroscopic image quality	Baseline
	Emergency/collision avoidance	Functional
	Light/radiation field coincidence	2 mm or 1%
Annual	Film processor sensitometry	Baseline
	Mechanical Checks	
	Collimator rotation isocenter	2 mm diameter
	Gantry rotation isocenter	3 mm diameter
	Couch rotation isocenter	2 mm diameter
	Coincidence of collimator, gantry, couch axes and isocenter	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 resolution	Baseline

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

TABLE I.III. QC OF MEASUREMENT EQUIPMENT

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 appropriate energy (dosimeter element position should also be considered); D, documented and correction applied or noted in report of measurement; M, monthly. Adapted from AAPM TG-40.

Instrument type	Test	Frequency	Tolerance ^a
Local standard ^b	SSDL calibration	2y ^c	D
	Linearity	2y ^c	0.5%
	Venting	2y ^c	D
	Extra-cameral signal	I	0.5%
	(stem effect)	E	0.1%
	Leakage	E	2%
	Redundancy check ^d	I	D
	Recombination	E	D
	Collecting potential		
Field instruments	Local std. comparison	2y	1%
	Linearity	2y	D
	Venting	2y	D
	Extra-cameral signal	2y	D
	Leakage	E	0.1%
	Recombination	I	D
	Collecting potential	E	D
Output check	Local std. comparison	M	1%
Relative dose			
Ion chamber	Linearity	1y	D
	Extra-cameral signal	I	1%
Film	Dose response	B	D
	Densitometer linearity	1y	D
	Processor	E	D
TLD	Uniformity/reproducibility		
	Calibration	E	D
	Linearity	I	D
Accessories	Thermometer calibration	I	0.1 deg/C
	Barometer calibration	3 mo	1mm/Hg
	Linear rule calibration	I	0.3%

^a Percent values are plus/minus the deviation of the parameter with respect to the nominal, and distances are referred to the isocenter or nominal SSD

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

^c Without a redundancy program, this may be inadequate

^d With a radionuclide (e.g., ⁹⁰Sr) or chamber intercomparison

I.6. THE QC OF TREATMENT PLANNING COMPUTERS

The treatment planning computer is a critical component of the entire treatment process. Computers may be used to calculate patient dose distributions and treatment time or monitor units for a given prescribed dose and fixed point dose calculations for irregular fields, etc. All such systems should undergo acceptance testing and commissioning. Following acceptance testing and commissioning a QC programme 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. QC tests should be performed after program modifications and as part of an ongoing QC program. Table I.IV. lists the recommended QC for treatment planning systems and treatment time calculations.

TABLE I.IV. QC FOR TREATMENT PLANNING SYSTEMS AND TREATMENT TIME CALCULATIONS

Reproduced with permission of AAPM TG-40.

Frequency	Test	Tolerance ^a
Commissioning and following software update	Understand algorithm	Functional ^b
	Single field or source isodose distributions	2% ^a or 2 mm ^b
	Treatment time calculations	2%
	Test cases	2% or 2 mm
	I/O system	1 mm
Daily	I/O devices	1 mm
Monthly	Checksum	No change ^c
	Subset of reference Quality Assurance test set (when checksums not available)	2% or 2 mm ^c
	I/O system	1 mm
Annual	Treatment time calculations	2%
	Reference Quality Assurance test set	2% or 2 mm ^d
	I/O system	1 mm

^a % difference between calculation of the computer treatment planning system and measurement (or independent calculation)

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

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

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

I 7 THE QC OF EXTERNAL BEAM TREATMENT PLANNING

In this section, QC for the treatment planning process is discussed, followed by a discussion of QC for individual patients. QC 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 percent depth dose, tissue phantom ratios or tissue maximum ratios, and beam output calibration tables. Furthermore, the field apertures, which define the treatment volume, are usually designed on radiographs obtained during localization/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 either obtained using a mechanical device (e.g., lead solder wire) or from CT. The field arrangements are designed and dose distributions calculated on one or a limited number of axial cross sections using a computerized treatment planning system. The radiation oncologist prescribes the dose and fractionation schedule.

I.7.1. The QC of the Treatment Planning Process

Treatment planning is a process that begins with patient data acquisition 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 treatment planning system. Each step of the complex treatment planning process involves a number of issues relevant to quality assurance. The process is represented schematically in Table I V.

TABLE I V TREATMENT PLANNING PROCESS

Reproduced with permission of AAPM TG-40

Process	Related QC Procedures
Positioning and immobilization	Port films. Laser alignment
Localization (simulation)	Simulator QC including image quality and mechanical integrity
Patient data acquisition (CT, MRI, manual contouring)	CT, MRI QC including image quality and mechanical integrity (Accuracy of mechanical contouring)
Data transfer to treatment planning system	QC of the entire data transfer process, including digitizers, digital data transfer, etc
Definitions of target volumes	Peer review, e.g., new patient planning conference, 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 QC of treatment machines. Accuracy and QC of treatment planning system
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	Treatment planning system QC. Independent check within 48 hours
Production of blocks, beam modifiers	QC for block cutting and compensator systems. Port film review
Plan implementation	Review of set-up by treatment planning team. Chart review
Patient Quality Assurance	Treatment plan review. Chart review after new or modified field, weekly chart review, port film review. In-vivo dosimetry for unusual fields, critical organ doses (e.g., gonadal dose). Status check, follow-up

I.7.2 The QC of the Individual Treatment Planning Process

All 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 assure that all beam modifying devices (blocks, wedges, compensators) are correctly positioned. Although errors in block fabrication and mounting are often discovered during the review 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 be undetected due to misunderstanding of the physical concepts. Details of QC recommendations for individual patients are given in Table I VI.

TABLE I VI SUMMARY OF QC RECOMMENDATIONS FOR INDIVIDUAL PATIENTS
Adapted from AAPM TG-40

Procedure	Recommendations
Treatment time calculation	Reviewed prior to treatment by an authorized individual who did not perform initial calculation, or when not possible (e.g., emergency treatment), then prior to 3rd fraction or before 10% of the dose has been delivered, whichever occurs first
Graphical treatment plan review	<ol style="list-style-type: none"> 1 Reviewed prior to treatment, or when not possible, then prior to 3rd fraction or before 10% of the dose has been delivered, whichever occurs first 2 Reviewed by a medical physicist who did not formulate treatment plan. Where only one physicist and that person performed 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 dose 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 treatment. In addition, ongoing patients	Initial films reviewed by radiation oncologist prior to first risk 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	<ol style="list-style-type: none"> 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, gonads) 3 May be used to record dose for unusual treatment conditions

I.8. USE OF IN-VIVO DOSIMETRY IN A QC PROGRAMME

In-vivo dosimetry can be used to identify major deviations in the delivery of treatment and to verify and document the dose to critical structures. Thermoluminescent dosimetry (TLD) is often used because the device is small and relatively easy to calibrate, while diodes have the advantage of instantaneous readout. These in-vivo systems can have relatively large uncertainties which should be assessed before using them. In-vivo systems are useful for individual patient measurements and should be considered as part of a comprehensive QC programme.

I.9. CHART REVIEW

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

I.9.1. Review of New or Modified Treatment Fields

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

- a) Treatment Prescription
- b) Treatment Parameters
- c) Isodose Distribution, Special Dose Calculation
- d) Treatment Time
- e) In-Vivo Measurements
- f) Daily Record
- g) Previous Radiation Treatments

I.9.2. Weekly Chart Review

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

- a) Review of Treatments for Previous Week
- b) Cumulative Dose

I.9.3. Review at Completion of Treatment

As a final review before the chart is placed in a file, the following items should be checked:

- a) Prescribed dose delivered
- b) Chart properly documented according to department policy
- c) Treatment summary included

I 10 THE QC PROGRAMME FOR BRACHYTHERAPY

The following lists the elements that should be in a quality control programme for brachytherapy. Further details can be found in the references listed at the end of this appendix.

I.10.1. Sources

Recommended QC tests for brachytherapy sources are given in Table I VII

TABLE I VII QC TESTS FOR BRACHYTHERAPY SOURCES

I, Initial purchase, D, Documented, and E, at every use. Reproduced with permission of AAPM TG-40

Type of source	Test	Frequency	Tolerance
Long half-life description	Physical/chemical form	I	D
	Source encapsulation	I	D
	Radionuclide distribution and source uniformity	I	D
	Location of Radionuclide	I	1 mm
Long half-life calibration	Means of batch	I	3%
	Deviation from mean	I	5%, D
	Calibration verification	E	^a
short half-life description	Physical/chemical form	I	D
	Source encapsulation	I	D
Short half-life calibration	Mean of batch	E	3%
	Deviation from mean ^b		5%
	Radionuclide distribution and source uniformity	E	V ^c

^a Visual check of source color 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

I 10 1 1 Identification

For sealed sources large enough to carry identification numbers or coloured, labelled tapes, check that the accompanying certificate detailing the serial number and the different characteristics of the source are in agreement with the number engraved on the source.

For small sources that cannot be identified individually (examples ¹⁹²Ir wires or seed ribbons), check separately in a well ionization chamber and store in special containers. Every time the source is cut, it should be identified again and stored in another compartment.

I 10 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 logbook or record of all sources present in the department and their location should be available at any time.

I.10.1.3. Contamination

The manufacturer should provide a certificate detailing 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). Results should be recorded in a logbook.

I.10.1.4. Uniformity of linear activity

Autoradiography may be used to verify 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 distances between sources should be verified. A linear activimeter is an alternate method of verifying uniformity of linear activity.

I.10.1.5. 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 air kerma rate. Total reference air kerma rate can be measured by placing the radioactive source in the iso-response region of a well-type chamber previously calibrated by a Standards Laboratory with a source of the same geometrical characteristics. Particular attention should be taken when measuring HDR sources to assure that the measurement range of the instrument is appropriate and the collection voltage is high enough to prevent significant recombination.

I.10.2. The QC of Applicators

QC tests should be performed before initial use, after repairs and periodically according to Table I.VIII.

TABLE I.VIII. QC TESTS FOR BRACHYTHERAPY APPLICATORS

I, initial use or following malfunction and repairs; D, documented and correction applied or noted in report of measurement, when appropriate; and E, as a minimum, a visual inspection to verify that the dummy sources fairly represent the active source distribution.

Reproduced with permission of AAPM TG-40.

Type of applicator	Test	Frequency	Tolerance
Intracavitary	Source location	I, yearly	D
	Coincidence of dummy and active sources	I	1 mm
	Location of shields	I ^b	D
Interstitial	Coincidence of dummy and active sources	I,E	1 mm

^a To reduce personnel exposure, the dummy source location may be checked in place of the active source, if it is established that the dummy and active source locations are coincident

^b Location of shields should be verified by radiograph before the first use. Before every use, the applicator may be shaken to listen for loose parts

TABLE I IX QC OF REMOTE AFTERLOADING BRACHYTHERAPY UNITS
Reproduced with permission of AAPM TG-40

Frequency	Test	Tolerance
Each treatment day	Room safety door interlocks, lights, and alarms	Functional
	Console functions, switches, batteries, 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 change or quarterly	Calibration ^a	3%
	Timer function	1%
	Check accuracy of source guides and connectors	1 mm
	Mechanical integrity of applicators (by X-ray if appropriate)	Functional
Annual	Dose calculation algorithm (at least one standard source configuration for each isotope)	3%, 1 mm
	Simulate emergency conditions	
	Verify source inventory	

^a It is worthwhile at source change to calibrate both new and old sources to establish and document reproducibility of calibration method

TABLE I X QC TESTS FOR BRACHYTHERAPY SOURCE CALIBRATOR

I, initial use or following malfunction and repairs^a, S, isotope/source specific, D, documented and correction applied or noted in report of measurement, when appropriate, and E, each use (measurement sequence) or ongoing evaluation. Reproduced with permission of AAPM TG-40

Instrument type	Test	Frequency	Tolerance
Well ionization chamber	Standards Laboratory calibration	I,S ^a	D
	Precision	I	2%
	Linearity	I, 2 year	1%
	Collection Efficiency	I	1%
	Geometrical/length dependence	I	D
	Energy dependence	I	D
	Source wall dependence	I	D
	Venting	I	D
	Redundant check	E	2%
	Leakage	E	D
In-air calibration chamber and external source holder	SSDL calibration	I,S ^a	D
	Accuracy of source chamber distance	1 yr, S	1%, D
	Redundancy	E	D
	See Table I III for other tests		

^a Instruments or sources must have a calibration directly traceable to a Standards Laboratory

I.10.3. QC of Remote Afterloading Devices

Recommended QC tests for remote afterloading devices are given in Table I.IX.

It should be noted that in many countries the specification, performance and quality control of afterloading devices may be mandated by government regulations. If this is the case then these regulations must be adhered to. If they are different from the recommendations given in Table I.IX then the table should be modified to reflect the appropriate regulations.

I.10.4. Measurement Equipment for Brachytherapy

I.10.4.1. Well-Type Ionization Chambers

QC procedures for well-type ionization chambers are given in Table I.X.

I.10.5. The QC of Brachytherapy Treatment Planning System

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, detailing the methods used and the results. General aspects of the quality control of treatment planning systems are given in table I.IV.

I.10.5.1. QC 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 then 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 then a detailed record should be made of the method of conversion and of all conversion factors used in the process.

Some tests of dose and dose rate computation and display algorithms that should be performed include:

- a) Dose rates at points around a single source should be calculated at defined points relative to the source and the results should then be compared to reference values and/or hand calculations. The exact co-ordinates 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 to 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 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, say, an intracavitary cervix application then there should be a test using sources in a geometry typical of local practice, and the results compared to dose rates determine by hand calculations.
- d) Correction for source decay, when included in the software, should be compared to hand calculations.
- e) The co-ordinate 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 the clinical practice.

I.10.6. QC of Patient Treatment Plan

Computer generated treatment planning for each individual patient should be checked with hand calculations of dose at selected points. Various graphs and tables from pertinent 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 the ones 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 J

RADIATION SHIELDING FOR EXTERNAL BEAM FACILITY

Figure J.1 shows the plan and elevation views of a Cobalt 60 radiation therapy vault. Note that the use of a maze allows for a rather standard door with only 3.2 mm of lead in the door. The figure also shows that the room requires primary thick barriers on the walls and ceiling wherever the Cobalt 60 beam may aim since there is no beamstop attached to this unit. If there were space below the floor, then the floor would also be a very thick primary barrier. However, because of the weight of the treatment unit and its shielding it is always best to put such a facility on unexcavated ground.

The method described in NCRP [5], for calculating the necessary shielding is based on three steps:

- establishing a dose value P at a given, occupied area,
- estimating the dose, D, that would be received if no shielding were to be provided, and
- obtaining the attenuation factor that is necessary to reduce D to P, e.g., finding the ratio D/P.

In [5], the dose value P was the regulatory individual dose limit. International recommendation has recently 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, 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 [5] methodology can be applied, with the only difference of replacing the individual dose limit by the individual dose constraint.

The ratio of 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 tenth-value-layer thickness, TVL (in cm), then the wall thickness can be determined from the equation:

$$(P/D) = 10^{-(\text{thickness}/\text{TVL})}$$

J.1 DETERMINATION OF P

The constraint could be assumed to be $\frac{1}{2}$ of the individual dose limit related to the source (the teletherapy unit). Since the dose 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.

J.2 DETERMINATION OF D

Direct beam (calculation of primary barrier):

The weekly workload (W) is obtained: the dose delivered to a patient at the isocenter (usually 80 cm) is multiplied by $(80/100)^2$ and by the number treatments per week, i.e., number of patients/day, multiplied by 5 days/week.

Therefore, as an example, if 40 patients/day are to be treated with 2 Gy/patient, 5 days/week, thus the workload at the isocenter is $W=400$ Gy/week. There are actually three components to the dose value D

This dose value can be modified by the Use Factor (U) for the barrier (the fraction of the 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 might someone be present. The modified dose is WUT.

The dose rate of the beam at one meter from the source, is converted to the dose at the position in question by using the inverse of the square of the distance from the isocenter of the treatment unit, e.g., the primary dose

$$D = WUT / d^2 \quad (1)$$

Leakage radiation:

There is the leakage radiation from the head of the unit (D_l) which is given as the percent of the primary dose rate (%l). Since leakage radiation is not a beam but a radiation field, the use factor is $U=1$

The leakage dose is

$$D_l = WT (\%l / 100) / d^2 \quad (2)$$

Scattered radiation:

There is the radiation which is scattered to the position, mainly from the patient (D_s) which is given by the scatter fraction (a).

The scatter dose is

$$D_s = WT (a) / d^2 \quad (3)$$

Note that both the leakage and the scatter components are also decreased by the square of the distance from the isocenter.

Combination of the three types of radiation:

If there can be a primary beam directed to the position then that will be the greatest thickness by far and that should be the design thickness for the barrier. If there is no primary beam at the barrier, then use the bigger of the leakage or scatter thickness if one is bigger than the other by at least one TVL, otherwise use the bigger value and add 0.333 TVL.

The use factor can only be less than 1 for the primary barriers since the barriers always have leakage and scatter striking them when the beam is on.

J.3 EXAMPLE OF CALCULATION OF PRIMARY BARRIER

From figure J.1, if the point A is taken as the control console for the machine, the dose constraint would be $P=0.1$ mSv/wk. Since this is a primary barrier the use factor U may be less than 1; assuming $U=0.25$, i.e., the beam strikes the barrier only $1/4$ of the "beam on" time. The operator is always at the console when the beam is on so the occupancy $T = 1$. The unattenuated dose per week at A is given by decreasing W by the square of the distance from the isocenter and by the use and occupancy factors: U and T .

$$D_p = WUT / (d_A)^2 = 400 * 0.25 * 80^2 / (120 + 160 + 80)^2 = 5 \text{ Gy/week}$$

Therefore, the primary barrier must attenuate the fraction $5 / 0.0001 = 50,000$

$$\log (50,000) = 4.69 \text{ TVL}$$

If the TVL of concrete is 20.6 cm for concrete with 2.35 gm/cc. Therefore a thickness of 96.6 cm. A barrier of 100 cm would be used

J.4 EXAMPLE OF SECONDARY BARRIER

J.4.1 Leakage radiation

$P = 0.01$ mSv/wk as a dose constraint for members of the public (the ambient dose equivalent of 1 Sv corresponds numerically to 1 Gy absorbed dose for Co-60 at the dose maximum)

$W = 400$ Gy/week

$U = 1$ for all secondary barriers

$T = 0.1$ for an area occupied all the time

$d_i = 200+60$ cm

% leakage = 0.05 % for the cobalt head

$a = 0.0009$ for scatter

The barrier required by leakage is then given by eq (2)

$$D_l = (400 \cdot 0.05 / 100) / 2.6^2 = 0.03 \text{ Gy/wk}$$

$$\text{and } D_l/P = 0.03 / 0.00001 = 3,000$$

Therefore we need 3.4 TVL's or about 72 cm of concrete.

J.4.2 Example of secondary barrier for scatter radiation

$$D_s = 400 \cdot 0.0009 / (2.6)^2 = 0.052 \text{ Gy/week}$$

$$\text{and } D_s/P = 0.052 / 0.00001 = 5,200$$

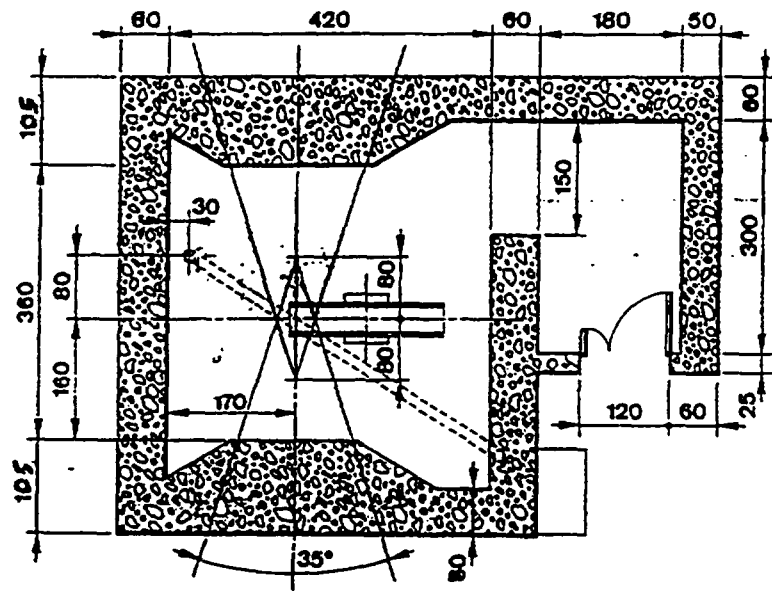
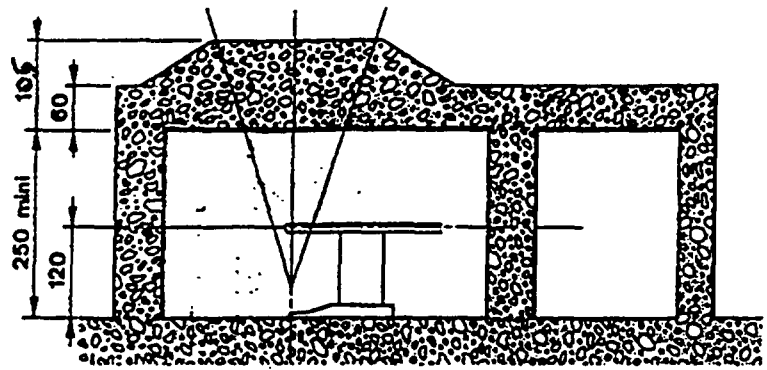
J.4.3 Combination of leakage and scatter radiation

This indicates the need for 3.72 TVL's 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 3.72 TVL's is 43.5 cm of concrete. Since this is more than one TVL smaller than the leakage requirement one can just use the thickness required for leakage radiation, i.e., 72 cm.

Remark:

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 made in combination with conservative factors, such as W , U , T , which provided a safety margin leading to actual doses that were well below the limits, often 1/10 of the dose limit. The use of dose constraints is a step toward 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 rather than overestimated factors. 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 keeping conservative factors, thus ignoring that the actual doses were 1/10 of the calculated ones or even lower, e.g., ignoring existing safety margins. The result may be an increased barrier thickness, that is not necessary, nor it is optimized and can not be considered as a good practice of protection.



REFERENCES

- [1] INTERNATIONAL ATOMIC ENERGY AGENCY, International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, Safety Series No. 115, IAEA, Vienna (1996).
- [2] INTER-SOCIETY COUNCIL FOR RADIATION ONCOLOGY, Radiation Oncology in Integrated Cancer Management (Blue Book), Report of the ISCRO (1991).
- [3] EUROPEAN SOCIETY FOR THERAPEUTIC RADIOLOGY AND ONCOLOGY, Quality assurance in radiotherapy: the importance of medical physics staffing levels. Recommendations from an ESTRO/EFOMP joint task group, Radiother. Oncol. 41 (1996) 89-94.
- [4] AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE, Comprehensive QA for radiation oncology: Report of AAPM Radiation Therapy Committee Task Group-40, Med. Phys. 21 (1994) 581-618.
- [5] NATIONAL COMMITTEE ON RADIATION PROTECTION AND MEASUREMENTS, Structural shielding design and evaluation for medical use of X-rays and gamma rays of energies up to 10 MeV, NCRP 49, NCRP, Washington, DC (1976).
- [6] BRITISH JOURNAL OF RADIOLOGY, Treatment simulators, BJR Supplement 23, British Institute of Radiology, London (1989).
- [7] INTERNATIONAL ATOMIC ENERGY AGENCY, Absorbed Dose Determination in Photon and Electron Beams: An International Code of Practice, Technical Reports Series No. 277, IAEA, Vienna (1987).
- [8] INTERNATIONAL ATOMIC ENERGY AGENCY, The use of plane-parallel ionization chambers in high energy electron and photon beams. An International Code of Practice for Dosimetry, Technical Reports Series No. 381, IAEA, Vienna (1997).
- [9] WORLD HEALTH ORGANIZATION, "Quality Assurance in Radiotherapy", WHO, Geneva (1988).
- [10] EUROPEAN SOCIETY FOR THERAPEUTIC RADIOLOGY AND ONCOLOGY, Quality assurance in radiotherapy, Radiother. Oncol. 35 (1995) 61-73.
- [11] NATIONAL COMMITTEE ON RADIATION PROTECTION AND MEASUREMENTS, Radiation Protection for Medical and Allied Health Personnel, NCRP 105, NCRP, Bethesda, MD (1989).
- [12] INTERNATIONAL ELECTROTECHNICAL COMMISSION, Medical Electrical Equipment. Part 1: General requirements for safety, Publ. IEC-601-1, IEC, Geneva, Geneva (1988).
- [13] INTERNATIONAL ELECTROTECHNICAL COMMISSION, Medical Electrical Equipment. Part 2: Particular requirements for the safety of radiotherapy simulators, Publ. IEC-60601-2-29, IEC, Geneva, Geneva (1993).
- [14] INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, Sealed radioactive sources - General, ISO-1677-1977, ISO, Geneva, (1977).
- [15] INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, Sealed radioactive sources - Leakage test methods, ISO/TR 4826, ISO, Geneva, (1979).
- [16] INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, Sealed radioactive sources - Classification, ISO-2919-1980, ISO, Geneva, (1980).
- [17] PAHO/WHO/IAEA/UNIDO, Design requirements for megavoltage x-ray machines for cancer treatment in developing countries. Report of an Advisory Group Consultation, Washington D.C December 1993, Report LA-UR-95-4528, Los Alamos National Laboratory, Los Alamos, NM (1995).

- [18] INTERNATIONAL ELECTROTECHNICAL COMMISSION, Medical Electrical Equipment. Part 2: Particular requirements for the safety of gamma beam therapy equipment, Publ. IEC-60601-2-11, IEC, Geneva, Geneva (1997).
- [19] INTERNATIONAL ELECTROTECHNICAL COMMISSION, Medical Electrical Equipment. Part 2: Particular requirements for the safety of remote-controlled automatically-driven gamma-ray afterloading equipment, Publ. IEC-60601-2-17, IEC, Geneva, Geneva (1989).
- [20] AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE, Remote afterloading technology, AAPM Report No. 41, American Institute of Physics, New York, New York (1993).
- [21] AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE, Dosimetry of interstitial brachytherapy sources: Recommendations of the AAPM Radiation Therapy Committee Task Group No. 43, Med. Phys. 22 (1995) 209-234.
- [22] AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE, Code of Practice for brachytherapy physics: Report of the AAPM Radiation Therapy Committee Task Group No. 56, Med. Phys. 24 (1997) 1557-1598.
- [23] AMERICAN COLLEGE OF MEDICAL PHYSICS, "Quality assurance in radiotherapy physics. Proceedings of an American College of Medical Physics Symposium", ed. Starkschall, G., Horton, J., Medical Physics Publishing, Madison, (1991).
- [24] HORTON, J.L., "Handbook of Radiation Therapy Physics", Prentice Hall Inc, New Jersey (1987).
- [25] WILLIAMS, J.R., THWAITES, D.I., eds., "Radiotherapy Physics in Practice", Oxford University Press, Oxford (1993).
- [26] AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE, Physical aspects of quality assurance in radiation therapy, AAPM Report Series No. 13, American Institute of Physics, New York, New York (1984).
- [27] AMERICAN COLLEGE OF MEDICAL PHYSICS, Radiation Control and Quality Assurance in Radiation Oncology: a suggested protocol, Report No. 2, ACMP, Washington, D.C. (1986).

CONTRIBUTORS TO DRAFTING AND REVIEW

Aguilar, V.	International Atomic Energy Agency
Almond, P.	James Graham. Brown Cancer Center, USA
Andreo, P.	International Atomic Energy Agency
Baeza, M.	Instituto de Radiomedicina, Chile
Ezzell, G. A.	Harper Hospital and Wayne State University, USA
Habjouqa, A.	International Atomic Energy Agency
Horton, J.	M.D. Anderson Cancer Center, USA
Hudson, A.	National Radiation Protection Board, UK
Izewska, J.	International Atomic Energy Agency
Kamel, R.	International Atomic Energy Agency
Levin, V.	International Atomic Energy Agency
Llamas, A.	International Atomic Energy Agency
Liniecki, J.	Medical University of Lodz, Poland
Marinello, G.	Hopital Henri Mendor, France
Matscheko, G.	International Atomic Energy Agency
Mattsson, O.	Shalgren University Hospital, Sweden
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
Shanta, A.	International Atomic Energy Agency
Stovall, M.	M.D. Anderson Cancer Center, USA
Tölli, H.	International Atomic Energy Agency
Viser, A.	Academic Hospital Rotterdam, The Netherlands
Volodin, V.	World Health Organization
Wilkinson, J.	Christie Hospital, UK
Williamson, J. F.	Mallinckrodt Institute of Radiology, USA

Consultants Meetings

Vienna, 22-24 May 1995, 11-15 December 1995, 3-7 June 1996,
20-25 October 1997, 8-12 December 1997, 4-8 May 1998

Advisory Group Meeting

Vienna, 9-12 December 1996

RECENT IAEA PUBLICATIONS ON CLINICAL, MEDICAL PHYSICS, RADIATION PROTECTION AND SAFETY ASPECTS OF RADIOTHERAPY

- 1994 Measurement Assurance in Dosimetry (Proceeding Series – STI/PUB/930)
- 1994 Radiation Dose in Radiotherapy from Prescription to Delivery,
Proceedings of an IAEA Seminar in Leuven (IAEA-TECDOC-734)
- 1995 Calibration of Dosimeters Used in Radiotherapy (Technical Reports Series No. 374)
- 1996 Radiation Dose in Radiotherapy from Prescription to Delivery,
Proceedings of an IAEA Seminar in Rio de Janeiro (IAEA-TECDOC-896)
- 1996 Review of Data and Methods Recommended in the International Code of Practice,
Technical Reports Series No. 277 for Absorbed Dose Determination in Photon and
Electron Beams. (IAEA-TECDOC-897)
- 1996 FAO/IAEA/ILO/OECD(NEA)/PAHO/WHO, International Basic Safety Standards for
Protection against Ionizing Radiation and for the Safety of Radiation Sources, Safety
Series No. 115
- 1997 The Use of Plane-Parallel Ionization Chambers in High-Energy Electron and Photon
Beams. An International Code of Practice for Dosimetry. (Technical Reports Series
No. 381)
- 1997 Absorbed Dose Determination in Photon and Electron Beams: An International Code of
Practice (Technical Reports Series No. 277, 2nd edition)
- 1997 Quality Assurance in Radiotherapy (IAEA-TECDOC-989)
- 1997 IAEA/ESTRO Monitor Unit Calculation for High-Energy Photon Beams.
ESTRO Physics for Clinical Radiotherapy, Booklet No. 3 (Garant Publ., Leuven)
- 1998 The Accidental Overexposure of Radiotherapy Patients in San José, Costa Rica (Special
Publication Series, STI/PUB/1027)