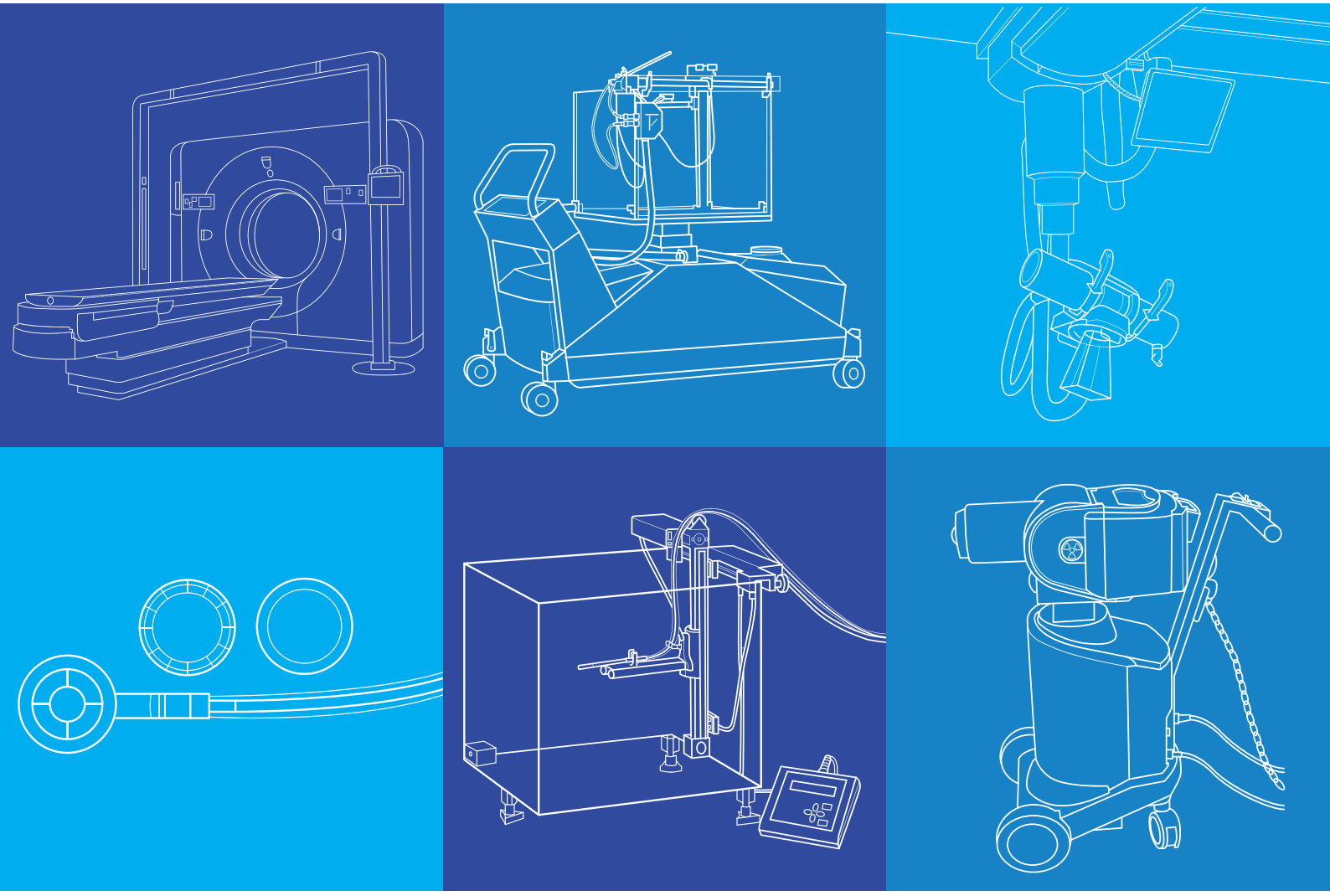
Technical specifications of radiotherapy equipment for cancer treatment



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IAEA
International Atomic Energy Agency

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Abbreviations and acronyms

1D, 2D, 3D	one, two, three dimensional
3D-CRT	three-dimensional conformal radiotherapy
4DCT	four-dimensional computed tomography
BNC	Bayonet Neill-Concelman
CCTV	closed circuit television
CD	compact disc
CE	«Conformité Européenne» or European Conformity
CR	computed radiography
CT	computed tomography
CT-MR	computed tomography-magnetic resonance
CTV	clinical target volume
DICOM	Digital Imaging and Communications in Medicine
DRR	digitally reconstructed radiographs
DVD	digital virtual/visual disc
EBRT	external beam radiotherapy
EPID	electronic portal imaging device
GMDN	Global Medical Device Nomenclature
HDR	high-dose rate
HL7	Health Level Seven International
IAEA	International Atomic Energy Agency
ID	identification
IEC	International Electrotechnical Commission
IGRT	image-guided radiotherapy
IMRT	intensity-modulated radiotherapy
ISO	International Organization for Standardization
IT	information technology
LCD	liquid crystal display
LINAC	medical linear accelerator
LMIC	low- and middle-income country
LMPA	low-melting point alloy
MLC	multileaf collimator
MRI	magnetic resonance imaging

OIS	oncology information system
PACS	picture archiving and communication system
PET	positron emission tomography
PMMA	polymethylmethacrylate
PSDL	primary standards dosimetry laboratory
RVS	record and verify system
SAD	source to axis distance
SPR	scan projection radiograph
SSD	source skin distance
SSDL	secondary standards dosimetry laboratory
TBI	total body irradiation
TNC	Threaded Neill-Concelman
TPS	treatment planning system
UMDNS	Universal Medical Device Nomenclature System
UNSPS	United Nations Standard Products and Services
UPS	uninterruptible power supply
US FDA	United Stated Food and Drug Administration
USA	United States of America
USB	universal serial bus
VMAT	volumetric modulated arc therapy
WHO	World Health Organization

Measurements

cm	centimetre
fA	femto amp
GBq	giga becquerel
Gy	gray
hr	hour
HU	Hounsfield unit
J	joule
keV	kilo electron volt
kg	kilogram
kPa	kilopascal
kV	kilovolt
kVp	peak kilovolt
kW	kilowatt
lp	line pair
m	metre
mA	milliamp
mAs	milliamp second
MeV	mega electron volt
MHz	megahertz
min	minute
mm	millimetre
mm Al HVL	millimetres of aluminium half-value-layer
mm Cu HVL	millimetres of copper half-value-layer
mSv	milli sievert
MU	monitor unit
MV	megavolt
nSv	nano sievert
µSv	micro sievert
Sv	sievert
TB	terabyte
V	volt

Executive summary

Following the adoption of resolutions WHA60.29 on health technologies and WHA70.12 on cancer prevention and control, the World Health Organization (WHO) published the *Lists of priority medical devices for cancer management* in 2017 to assist countries in prioritization and incorporation of medical devices into the health care system *(1)*. The purpose of this joint WHO/International Atomic Energy Agency (IAEA) interagency publication is to provide technical specifications for radiotherapy equipment commonly used in the treatment of cancer and itemized in the WHO *Lists of priority medical devices for cancer management*. This book is intended for a committee involving clinical radiation oncologists, medical physicists and biomedical engineers as well as information technology, financial and planning officers to decide which technologies should be selected. They shall also select the appropriate technology for clinical procedures to be performed safely and securely, and with good quality. The *Technical specifications for radiotherapy equipment in cancer treatment* presents the different options available.

Chapter 1 provides the scope of the major radiotherapy equipment covered in the publication, including treatment equipment, associated imaging equipment, treatment planning software, information management software and various ancillary equipment.

Chapter 2 defines packages of radiotherapy equipment to deliver comprehensive cancer interventions linked to health system capacity. The packages cover the two distinct areas of radiotherapy, namely external beam radiotherapy (EBRT) and brachytherapy.

Chapter 3 covers the equipment needed for an EBRT service within the defined packages and Chapter 4 covers the equipment needed for a brachytherapy service for the same packages. Each subsection of Chapters 3 and 4 follows the same format, namely, a general description of the particular equipment item, a list of relevant International Electrotechnical Commission (IEC) and International Organization for Standardization (ISO) standards, a detailed sample specification, a description of measures required to ensure radiation safety and protection of staff and members of the public, and finally a description of quality assurance recommendations to ensure patient safety and high-quality treatment.

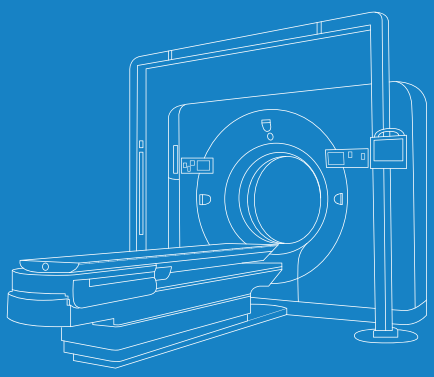
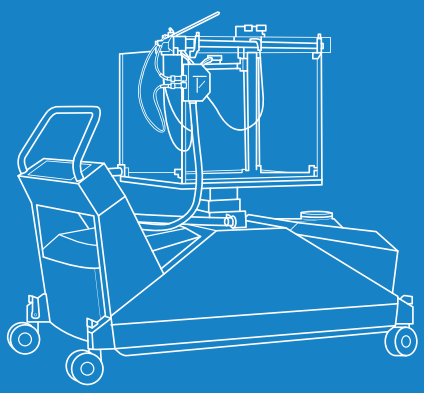
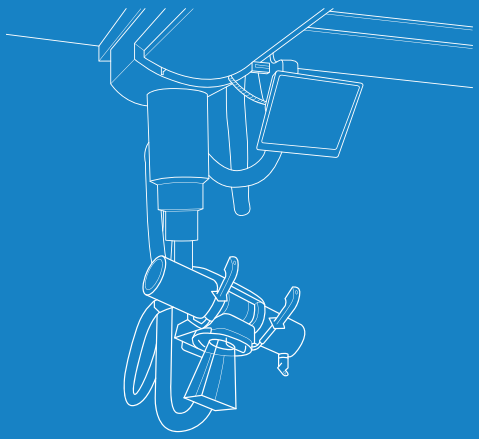
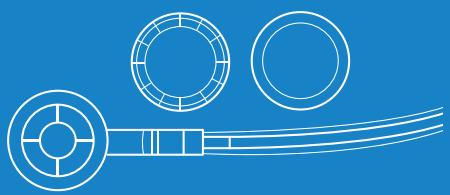
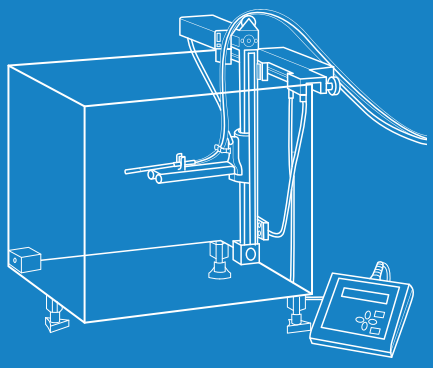
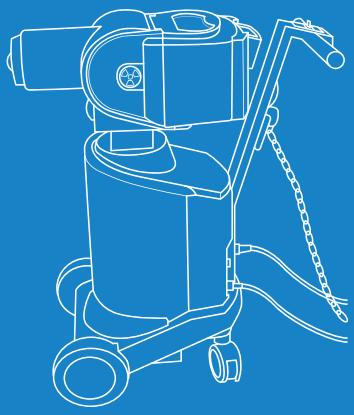
Chapter 5 provides an overview of the establishment of a comprehensive radiotherapy service, including procurement of relevant medical devices. The overview encompasses a range of activities and related personnel, and provides references to comprehensive publications in this area.

In Chapter 6, recent and emerging technology and techniques in radiotherapy are reviewed that may have applicability in limited-resource settings in the future.

The detailed WHO standard template technical specifications tables for major radiotherapy equipment are presented in the annexes of this publication.

Chapter 1.

Introduction

1.1 Background

Following the adoption of the resolutions WHA60.29 on health technologies and WHA70.12 on cancer prevention and control, the World Health Organization (WHO) published the *Lists of priority medical devices for cancer management (1)* to assist countries in prioritization and incorporation of medical devices into the health care system. Radiotherapy plays an important role in cancer management and it is detailed in Chapter 5 of that WHO publication. Radiotherapy is integral in both curative and palliative settings. Radiotherapy has the potential to benefit approximately 50% of cancer patients during the course of their disease *(1)*. In the case of cervical cancer, the population benefit of evidence-based radiotherapy is the greatest with a 5-year overall survival benefit of 18% and 5-year local control of 33% *(2)*.

Improvement of access to radiotherapy is one of the strategic actions in achieving the 90% treatment target of the WHO *Global strategy towards eliminating cervical cancer as a public health problem (3)*.

The practice of radiotherapy relies on the accurate and safe utilization of complex electromechanical devices, radiation sources and multifaceted software applications. Technical specification of such medical devices is required for optimized procurement in establishing or upgrading radiotherapy services.

1.2 Purpose of the publication

The purpose of this joint WHO/International Atomic Energy Agency (IAEA) interagency publication is to provide technical specifications for radiotherapy equipment commonly used in the treatment of cancer and itemized in the WHO publication of the *Lists of priority medical devices for cancer management (1)*. It builds upon a previous IAEA publication of radiotherapy technical specifications from 2008 *(4)*. Further, this publication provides guidance on establishing and implementing the radiotherapy equipment safely and effectively in a clinical setting with reference to relevant publications. This publication covers aspects of health technology management for radiotherapy, including equipment procurement, selection, training and use.

1.3 Scope of the publication

This publication encompasses radiotherapy equipment, including associated imaging equipment, commonly used in cancer management. It follows on from the WHO publication of the *Lists of priority medical devices for cancer management (1)*, which developed medical device lists based on six cancer types, namely breast, cervical, colorectal, leukaemia, lung and prostate. According to that WHO publication, all those cancers can be treated with external beam radiotherapy (EBRT) with or without brachytherapy (and requiring associated imaging and treatment planning services), and with special mention that cervical cancer and prostate cancer as amenable to a high-dose rate (HDR) brachytherapy intervention. This publication supports implementation of the WHO *Global strategy towards elimination of cervical cancer as a public health problem (3)* in developing technical specifications for medical devices required for the radiation treatment approach to cervical cancer management. The major radiotherapy equipment covered in this publication is listed in Table 1. This publication does not include ancillary clinical equipment such as trays, dressings, forceps, anaesthesia units, etc. required for a radiotherapy service. This equipment, including medical furniture, is already listed in the WHO *Lists of priority medical devices for cancer management (1)*.

This publication does not include technical specifications for less frequently used radiotherapy modalities, including neutrons, protons and light ions (e.g. carbon ions). Evidence is emerging of improved organ-at-risk sparing with proton beam therapy for specific cancers, including paediatric cancers, however, evidence supporting cost-effectiveness and potential advantage of this modality over conventional radiotherapy in the low- and middle-income country (LMIC) setting is lacking *(5)*. Chapter 6 of this publication summarizes emerging radiotherapy technology, including proton therapy technology, with a view to their inclusion in a future publication as evidence of their efficacy and cost–benefit emerges.

Cancer treatments involving unsealed radioactive sources (e.g. iodine-131 treatments for thyroid cancer) are not covered in this publication.

Table 1. Major radiotherapy equipment covered in the technical specifications

Category	Item
Major treatment equipment	• LINAC • cobalt-60 teletherapy unit • brachytherapy afterloader (cobalt-60 or iridium-192 based) • superficial/orthovoltage X-ray unit
Associated imaging equipment	• conventional simulator • CT simulator • C-arm fluoroscopic X-ray unit • ultrasound imaging system
Planning software	• TPS
Information management software	• OIS, including RVS
Ancillary equipment	• patient immobilization equipment • mould room equipment • dosimetry and quality control equipment • radiation safety equipment

1.4 Whom this publication is intended for

This publication offers various types of radiotherapy equipment, as listed above, but the final decision of which to select would depend on various factors as:

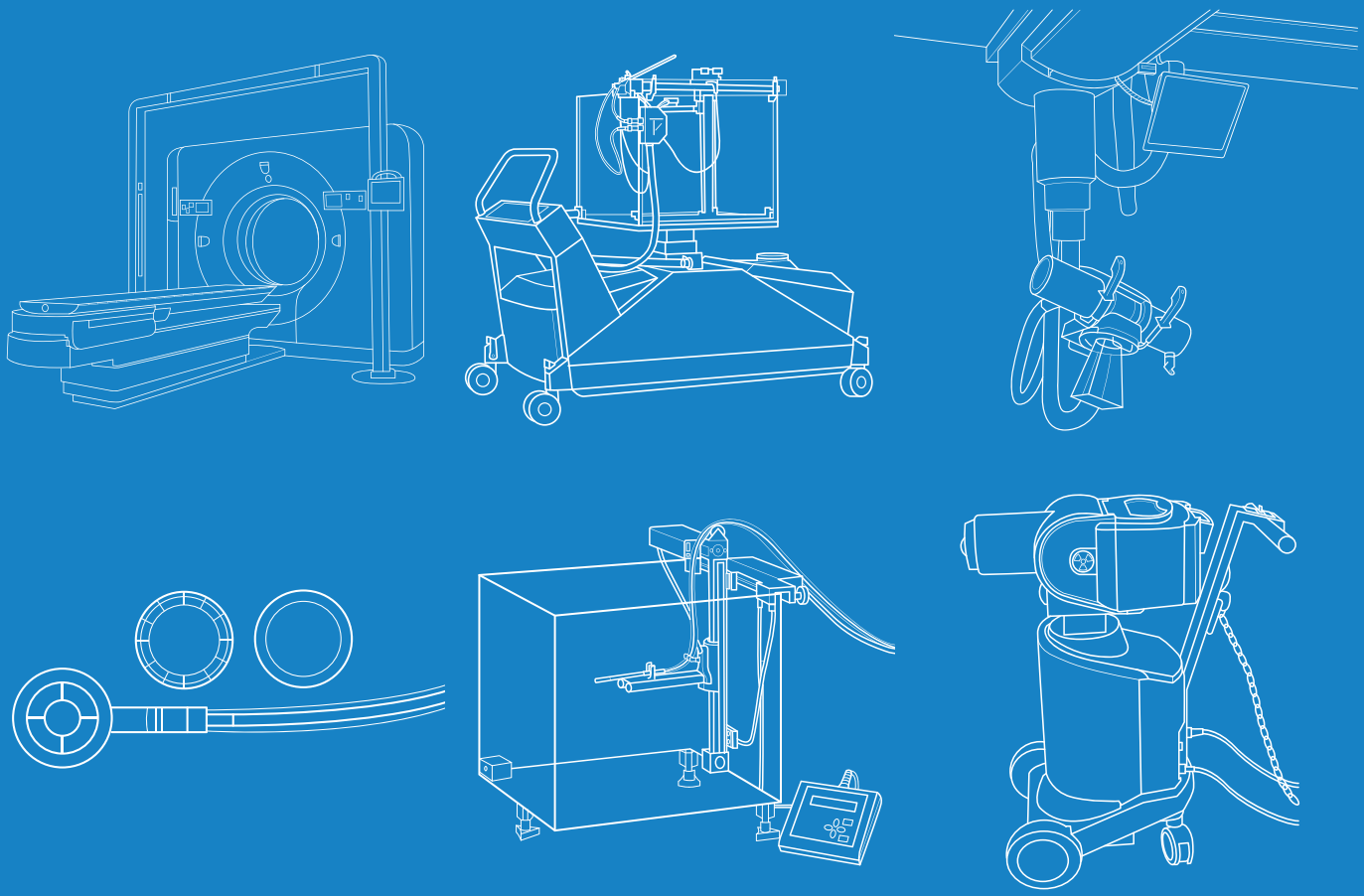
- national cancer control plan and strategies;
- available infrastructure;
- available specialized health workforce, including radiation oncologists, medical physicists, radiation therapists and biomedical/clinical engineers;
- available budgets; and
- in some countries, a decision regarding if radiotherapy would be covered by the national medical insurance plan, or similar.

This publication is intended for radiation oncologists, medical physicists, biomedical/clinical engineers and information technology professionals as well as administrators, including policy-makers, programme managers, hospital personnel, procurement officers and logisticians, in facilities with the responsibility of planning and supplying local, national or international radiotherapy equipment in LMICs.

Global procurement agencies, national health products regulatory authorities and national radiation regulatory authorities may refer to this publication in preparation for the regulatory clearance, procurement, management and effective supply of radiation medicine equipment for cancer management. Manufacturers should comply with these specifications to produce safe, high-quality and affordable radiotherapy equipment that are appropriate for use in LMICs. Others may also benefit from this resource, including health workers, clinical staff, technicians, nongovernmental agencies and academia.

Chapter 2.

Overview of radiotherapy equipment



2.1 Introduction

Radiotherapy has two distinct practices: external beam radiotherapy (EBRT) and brachytherapy; depending on whether the ionizing radiation source is external to the patient (termed external beam radiotherapy/EBRT) or internal/in close proximity to the patient (termed brachytherapy). Separate types of medical equipment are utilized for the practice of EBRT and brachytherapy. The majority of radiotherapy is performed as EBRT, with brachytherapy required for specific disease sites. The ratio of EBRT treatment units to brachytherapy treatment units worldwide is more than 9 to 1 according to the IAEA Directory of Radiotherapy Centres (DIRAC) database *(6)*. Standalone radiotherapy services offering only EBRT are common, with those patients requiring brachytherapy referred elsewhere. However, this publication assumes that a radiotherapy service will provide both EBRT and brachytherapy services. This comprehensive service is essential for the treatment of cervical cancer, where typically a course of EBRT is concurrent with a course of brachytherapy.

2.2 Packages of radiotherapy equipment

This publication defines packages of radiotherapy equipment, as shown in Table 2, inked to health system capacity to deliver a comprehensive package of cancer interventions. It follows the WHO framework for a three-tiered prioritization for selection of cancer interventions *(7)* and principles of classification of radiotherapy techniques according to methodology and tools associated with each step of the procedure, as outlined in a number of IAEA publications *(8–10)*. These packages assist health administrators and radiotherapy health professionals in needs assessment for radiotherapy. WHO defines needs assessment *(11)* as an examination of the availability of service against what should be available given current demand and situation of the catchment area or target group, considering financial and human resources available. WHO categorizes needs assessment (also termed selection) as a component of health technology management along with procurement, training and use, as shown in Figure 1.

The general approach in performing a needs assessment is to examine what is available in the facility, region or country, and to compare it with what should be available, considering the particular demand and situation of the catchment area or target group. In this instance of radiotherapy, the WHO *Lists of priority medical devices for cancer management* can act as the standard in terms of what medical devices and equipment should be available, with reference to any national cancer control plan and strategies *(1)*. The identified gap in currently available devices and equipment compared to the standard determines the overall need. It is necessary subsequently to review the existing financial resources and human resources needed to address the need identified by the gap. If resources are constrained, then priorities will need to be assigned. Prioritization is a strategic process, undertaken by those responsible for the commissioning of services. Those involved in prioritizing should also consider the opinions of service users and service providers regarding how to prioritize needs.

Figure 1. Domains of health technology regulation, assessment and management

Source: WHO 2011 *(12)*.

The technical specifications in this publication cover Packages 1 and 2, which are appropriate in limited-resource settings and include necessary ancillary equipment to support the service such as patient immobilization equipment, mould room equipment, dosimetry and quality control equipment and radiation safety equipment. Specifications for the additional capabilities in Package 3 are not included in this current publication, but could be developed by well-established radiotherapy departments under the framework of the specifications described in Chapters 3 and 4. Note that expansion of the radiotherapy service from Package 1, to Package 2, to Package 3 should occur as resources permit, and a fully resourced comprehensive service can include the equipment in all three packages, as appropriate to the local context. Also note that even within the items of the packages there are options, for example, in Package 2, single-energy or multi-energy linear accelerator, and multileaf collimator (MLC) or not. The following sections on technical specifications cover the advantages and disadvantages of various options to assist health administrators and radiotherapy health professionals in technology selection.

In establishing a new EBRT service, consideration at an early planning stage needs to be given as to whether to include a single external beam treatment unit or two such units. Single machine departments may suffer from being unable to treat patients in the event of machine breakdown and in being unable to meet an increased demand for services in the future. Consideration needs to be given to establishing a new radiotherapy service with two, rather than one, external beam treatment units and planning for future expansion as discussed by IAEA *(13)*. If cobalt-60 teletherapy units are considered, then procuring one unit with 100 cm source to axis distance (SAD) and one unit with 80 cm SAD has advantages in resource sparing (see Section 3.3.1).

Table 2. Equipment packages for radiotherapy services

	Package 1	Package 2	Package 3
Component	**External beam radiotherapy (EBRT)**		
Treatment unit	Cobalt-60 teletherapy unit (preferably at least one with 100 cm SAD) and/or single-photon energy LINAC; orthovoltage X-ray unit as needed	Package 1 and additional single-photon energy unit(s) and/or multiple energy LINAC with electrons	Additional multiple energy LINACs with electrons and IMRT, VMAT, IGRT, SRS, SBRT capabilities
Treatment unit accessories	Laser system for positioning; standard and customized shielding blocks; oncology information system including record and verify system (OIS including RVS); portal imaging	Laser system for positioning; customized blocks with or without MLC; OIS including RVS; EPID	Laser system for positioning; MLC or mini-MLC or cones; EPID; in-room MV or kV-imaging (for IGRT); motion management system (for IGRT); OIS including RVS
Treatment planning	3D TPS (DICOM- compatible)	3D TPS (DICOM- compatible)	3D TPS with additional capabilities (IMRT, VMAT, IGRT, SRS, SBRT)
Simulation imaging	Conventional digital simulator with laser system; access to a CT scanner	Package 1 and dedicated CT simulator with moveable laser system	CT simulator with moveable laser system and with additional 4DCT capability; access to MRI and/or PET/CT; fiducial markers

	Package 1	Package 2	Package 3
Component	**Brachytherapy**		
Treatment unit	HDR remote afterloading unit	HDR remote afterloading unit	HDR remote afterloading unit
Source	Cobalt-60	Cobalt-60 or iridium-192	Cobalt-60 or iridium-192
Applicators	Cervical (ring applicator set; ovoid applicator set; vaginal cylinders set); endometrial applicator set; transfer tubes	Cervical (ring applicator set including interstitial needles; ovoid applicator set; vaginal cylinders set)*; endometrial applicator set; transfer tubes	Additional CT-MR- compatible cervical intracavitary (ring applicator set; ovoid applicator set; vaginal cylinder set); intracavitary-interstitial (Vienna, Utrecht type); endometrial applicator set; prostate (reusable needles set); transfer tubes
Treatment planning	2D TPS	2D or 3D TPS	3D TPS
Imaging	Conventional simulator or C-arm fluoroscopic X-ray unit; ultrasound with convex probe	Conventional simulator or C-arm fluoroscopic X-ray unit or CT simulator; ultrasound with convex probe and endorectal probe	CT simulator; access to MRI; ultrasound with convex probe and endorectal probe

*Applicators that are CT-compatible will need to be procured if treatment planning is 3D CT-based.

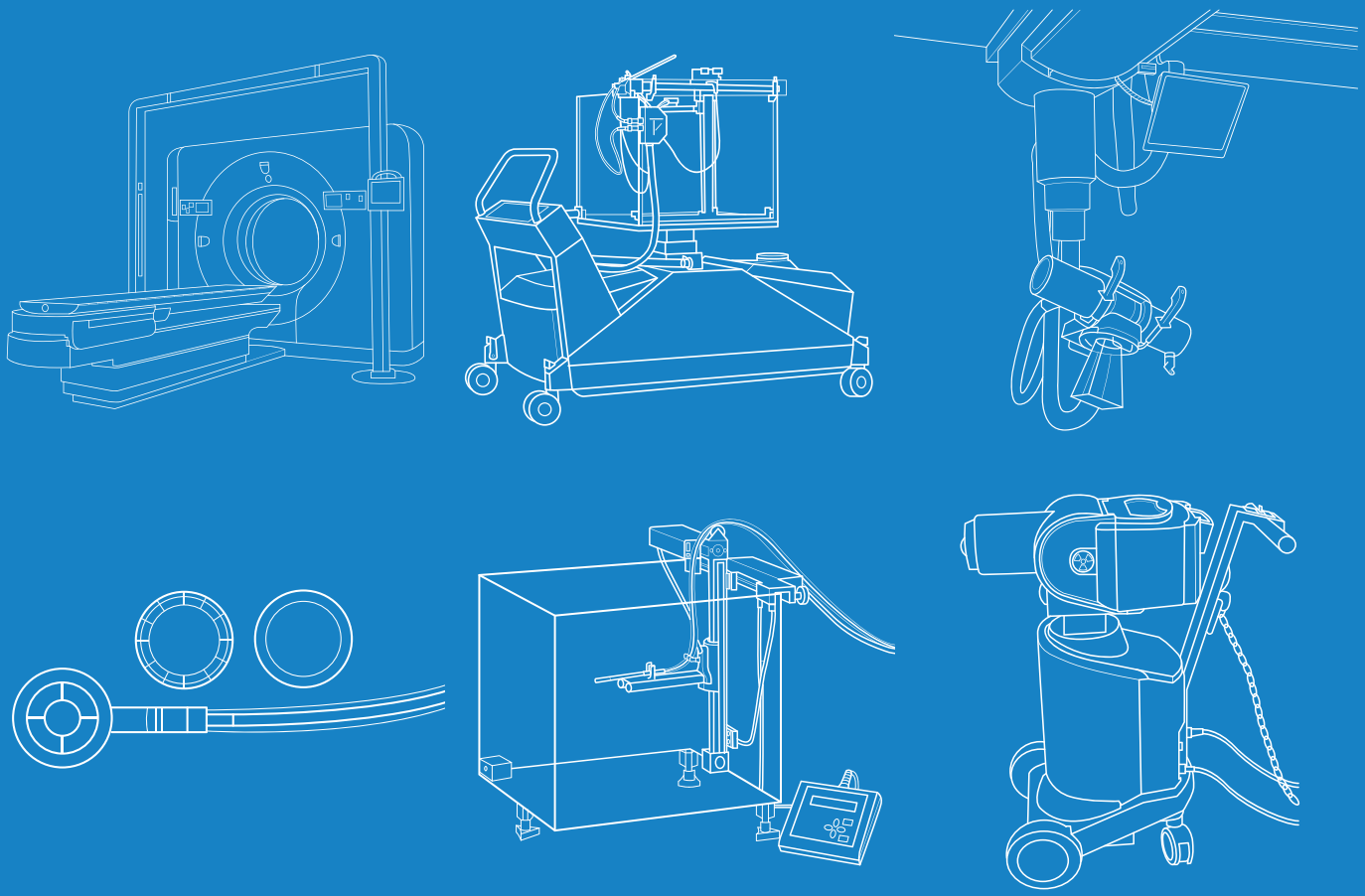
CT=computed tomography; EPID=electronic portal imaging device; HDR=high-dose rate; IGRT=image-guided radiotherapy; IMRT=intensity-modulated radiotherapy; LINAC=medical linear accelerator; MLC=multileaf collimator; MR=magnetic resonance; MRI=magnetic resonance imaging; OIS=oncology information system; PET=positron emission tomography; RVS=record and verify system; SAD=sourceaxis distance; SBRT=stereotactic body radiotherapy; SRS=stereotactic radiosurgery; TPS=treatment planning system; VMAT=volumetric modulated arc therapy

2.3 Summary of next chapters

Chapter 3 covers the equipment needed for an EBRT service covering equipment needed for Packages 1 and 2 from Table 2. Chapter 4 covers the equipment needed for a brachytherapy service for the same packages. Each subsection of Chapters 3 and 4 follows the same format, namely, a general description of the equipment, a list of relevant International Electrotechnical Commission (IEC) and International Organization for Standardization (ISO) standards, a detailed sample specification, a description of measures required to ensure radiation safety and protection of staff and members of the public, and finally a description of quality assurance recommendations to ensure patient safety and high-quality treatment. The detailed WHO standard template for technical specifications *(14)* of the major radiotherapy equipment is presented in the annexes of this publication. Establishing a comprehensive radiotherapy service is not limited to procurement of relevant medical equipment, rather it also encompasses a range of activities and related personnel, including their education and training, which is covered in Chapter 5. Finally, in Chapter 6 recent and emerging technology and techniques in radiotherapy are discussed that may have applicability in limited-resource settings in the future.

Chapter 3.

Technical specifications for external beam radiotherapy (EBRT) equipment



3.1 Description of EBRT

EBRT is a multi-step process once the decision to treat with radiation has been made. The technical aspects of radiotherapy broadly cover three steps: (i) *imaging for treatment planning*, termed simulation; (ii) *treatment planning*; and (iii) *treatment delivery*, including verification imaging. Radiotherapy is most often delivered as fractionated treatments, with the same treatment repeated once per working weekday over a course of treatment that may include up to 40 fractions dependent on the clinical protocol.

Imaging for treatment planning involves X-ray imaging of the patient in the intended treatment position and with the corresponding patient immobilization accessories. The acquired patient images allow the delineation of the treatment volume, the tumour and the nearby organs at risk and are also used to provide reference images to compare against treatment verification images. The imaging is usually accomplished with a dedicated computed tomography (CT) scanner, termed a CT simulator, or a conventional simulator which allows 2D X-ray imaging of the patient in the treatment position. Magnetic resonance imaging (MRI) and positron emission tomography (PET) imaging are used in some cases in conjunction with CT imaging to better delineate the tumour volume and the surrounding healthy tissue. The advantage of CT-based imaging is that it acquires 3D patient geometry and tissue mass density information that allows accurate calculation of radiation absorbed dose in 3D to the patient. For patients where the tumour position within the patient is affected by internal motion, for example, the position of a lung tumour will vary during the phases of the breathing cycle, it is advantageous to acquire CT data sets at different stages of the breathing cycle, a process termed 4DCT. This capability is described in Package 3 in Table 2. Equipment needed to enable 4DCT can include a marker block to be placed on the patient's chest, an imaging camera system for monitoring the position of the marker block and software to sort CT data sets according to the phase of the maker block motion.

Treatment planning is the process of creating a treatment plan for the patient based on the radiation oncologist's[a] dose prescription. Treatment planning is generally nowadays computerized rather than manual and is achieved with a treatment planning system (TPS). This system is a multifaceted software application that receives patient images, allows delineation of the tumour, target volumes and organs at risk from the patient images, creates treatment plans with different levels of user intervention, allows 3D visualization and plan optimization, includes treatment plan review features such as dose statistics and dose-volume-histograms, and includes dose calculation algorithms and treatment beam models that allow accurate radiation dose calculation of the final treatment plan.

Treatment delivery is carried out with a dedicated radiation delivery system such as a medical linear accelerator (LINAC) or a cobalt-60 teletherapy unit. The patient position will have been determined as part of the pre-treatment imaging process in accordance with the particular treatment site protocol and the appropriate immobilization device prepared. In a treatment session, the patient is positioned on the treatment couch by a team of radiation therapists and immobilized using the immobilization equipment together with their individualized immobilization device. The patient is then positioned for treatment using fixed lasers and other optical and mechanical systems, and additionally with dedicated in-room X-ray imaging equipment, if available. When the patient position with respect to the radiation delivery system is correct, the radiation dose is delivered to the patient as per the treatment plan. This involves radiation beams directed to the target volume(s) at various angles with various field sizes, beam modifying devices and, in some cases, modulated beam intensity. An entire treatment session typically lasts 10–15 minutes with radiation beam-on time typically 1–2 minutes depending on the prescribed dose level and the complexity of the delivery technique.

Radiotherapy techniques can be described as two-dimensional (2D), three dimensional conformal (3D-CRT) or intensity–modulated radiotherapy (IMRT) *(8)*. 2D radiotherapy involves the planning of treatments based on two dimensional images such as radiographs and information on patient external anatomical references from physical measurements. Dose calculation can be manual or computerized and the heterogeneity in density of patient tissue is generally ignored. In 3D-CRT, treatment planning is computerized and based on three dimensional CT-based images of the patient. The target is defined in 3D and the beams shaped to conform to the target while avoiding healthy tissues as much as possible. IMRT builds on 3D-CRT to improve the conformality of the dose distribution

[a] In some countries, the radiation oncologist is referred to as a clinical oncologist.

within the target through modulation of the beam intensity, usually by the movement (stepped or continuous) of multiple collimating leaves, for instance, whereas volumetric modulated arc therapy (VMAT) includes gantry rotation during beam delivery as well as leaf motion and dose rate variation. The treatment planning process for IMRT and VMAT is automated through software that determines the optimal intensity modulation based on the desired dose distribution, which is termed inverse planning. In IMRT and VMAT the dose objectives and constraints are used to drive an inverse planning optimization algorithm. In IMRT and VMAT not just a geometrical conformation is achieved, but also a dosimetric conformation characterized by steep dose gradients surrounding the target. The clinical applications of VMAT have previously been reviewed *(15)*.

In-room imaging of the patient in the treatment position immediately prior to treatment is becoming increasingly common as digital in-room kV and MV X-ray technology has become integrated in commercial LINACs. This technology has replaced radiographic film-based imaging. The clinical use of in-room imaging technology is termed image-guided radiotherapy (IGRT) *(10)* and is briefly discussed in Chapter 6. Finally, motion management technology is available for tracking of the tumour position during treatment with a number of solutions involving optical, X-ray or ultrasound imaging of the patient during treatment with the goal of eliminating geometric miss of the target.

The WHO publication of the *Lists of priority medical devices for cancer management (1)* specifies leukaemia as one of the cancer types informing the equipment list. Leukaemia treatment can include an EBRT technique called *total body irradiation* (TBI). A whole-body dose of radiation is given to the leukaemia patient to suppress host stem blood cell production prior to transplant from a donor. A LINAC or cobalt-60 teletherapy unit is used for the TBI technique. The standard treatment technique is an extended source skin distance (SSD) technique with a horizontal beam and a distance between the patient and source of approximately 4 metres to allow the divergent radiation beam to fully cover the length of a supine patient. Note that a typical treatment room has a 4.5 metres distance from source to lateral wall *(13)*. It is emphasized that in consideration of TBI implementation, one of the treatment rooms needs to be designed with one wall at least 4 metres from the isocentre (equivalent to 5 metres from source to wall for a horizontal beam). It also needs to be emphasized that risks to the patient are high in whole body irradiation, thus TBI should only be implemented in an environment with strong quality assurance and preferably in consultation with a department already familiar with the technique. Chapter 17A of *The modern technology of radiation oncology (16)* provides a comprehensive review of the technology and techniques of TBI.

3.2 Technical specifications for LINACs

3.2.1 Description

The "conventional" LINAC with open rotating gantry or head, isocentric rotation, bending magnet, flattened photon and electron beams, rotating collimator and rotating couch emerged in the 1970s as the standard design for EBRT applications (Figures 2 and 3). In recent years, a range of distinct "unconventional" designs for LINACs have appeared on the market. It is beyond the scope of this publication to assess the merits of particular linear accelerator designs (such as Accuray Cyberknife™, Accuray Tomotherapy™, Elekta Unity™, ViewRay MRIdian™ and Varian Halcyon™). The specification described in this section is for a conventional LINAC that is capable of delivering radiotherapy for a wide range of treatment sites. In line with Package 2 in Table 2, it describes both photon beam and electron beam modalities, an MLC to allow efficient practice of 3D-CRT, and an electronic portal imaging device (EPID) for digital imaging of the patient in the treatment position. The specification can be adapted to the single-energy LINAC described in Package 1 of Table 2. The 6 MV photon beam is the standard choice for the single-energy LINAC.

Figure 2. Features of a conventional LINAC with gantry stand

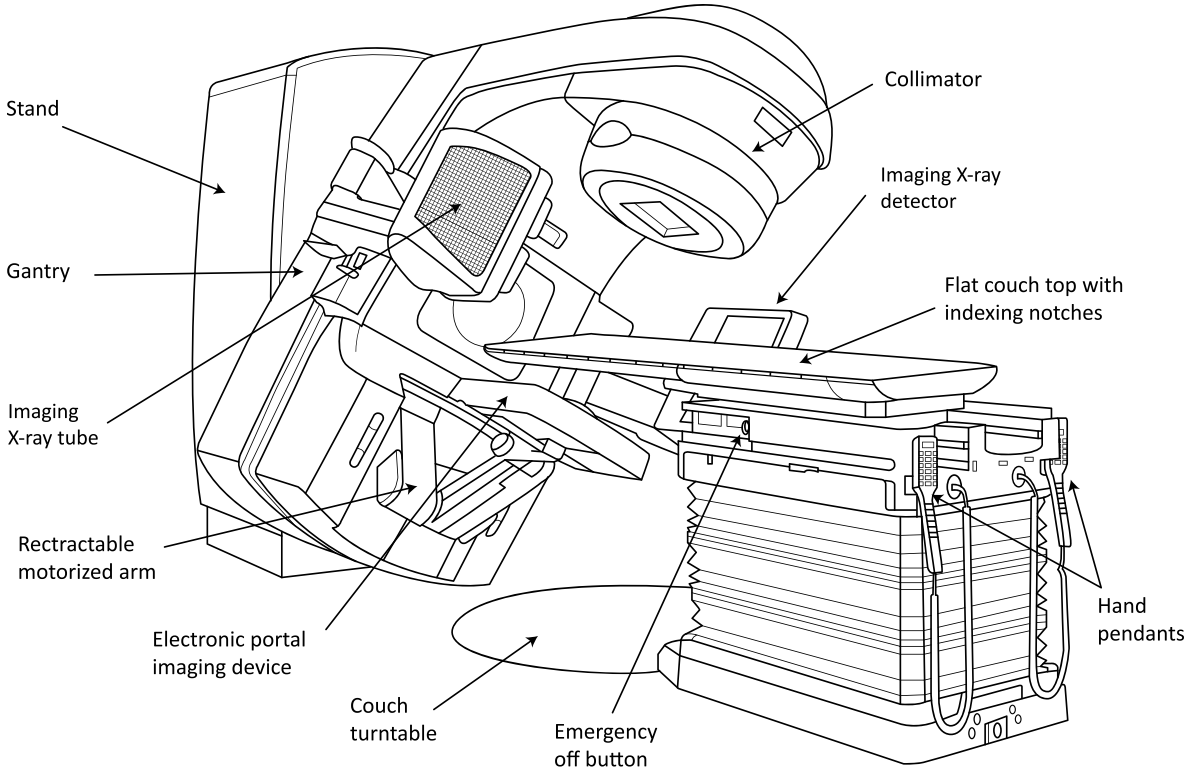
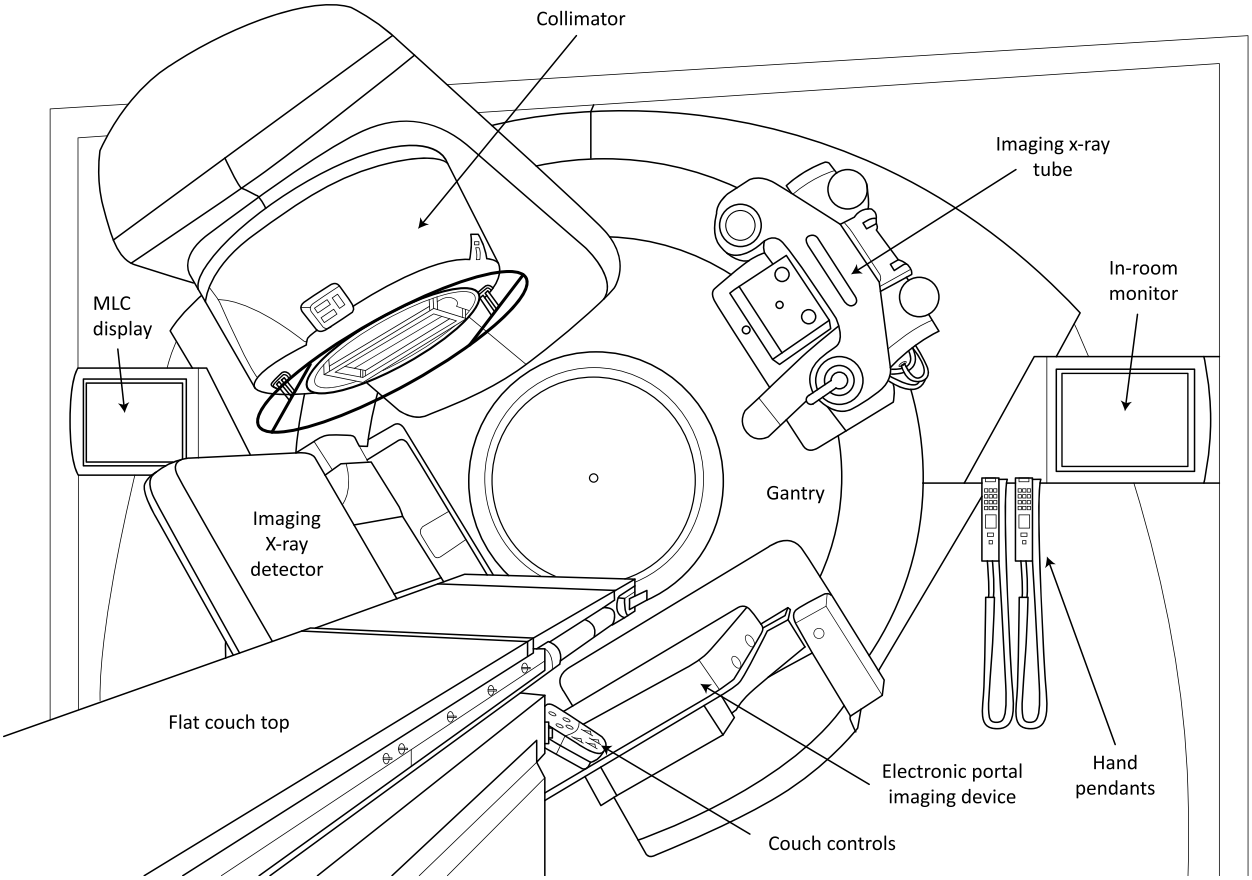


Figure 3. Features of a conventional LINAC with fascia wall



Depending on the vendor, the premises may have to supply the following services to operate the LINAC:

- continuous supply of chilled water;
- access to town water in case of chilled water access failure;
- compressed air supply;
- three phase power, including junction box;
- an UPS, power conditioner, voltage stabilizer; and
- air-conditioning and humidity control in the treatment room with a certain number of air volume replacements per hour.

The vendor's site planning reference guide for the particular model of LINAC to be installed should be consulted for the exact service requirements. It is important in the technical specification and contract to clearly establish the demarcation of the services listed above to be provided by the hospital and those by the vendor.

An important consideration for a new radiotherapy department is deciding on a scale convention for the movements of the various components of the treatment units. There are two IEC scale conventions in clinical use, namely an outdated IEC 60601 scale convention and a more recently released IEC 61217 scale convention *(17)*. While both scale conventions have some similarities, there are differences, for example, in the way negative numbers are handled and in the convention for the rotation of the treatment couch. This publication specifies the extant IEC 61217 scale convention in technical specification of radiotherapy equipment.

In Package 2 described in Table 2, a multi-energy LINAC is given as an option. For this type of LINAC, a 6 MV beam is complemented by a higher photon beam energy, either 10, 15 or 18 MV. Refer to Table 3 for a list of photon beam energies. There are a number of factors in the choice of the second photon energy. The higher energy provides lower entrance dose for the same dose at depth, but one tradeoff is higher exit dose. This higher exit dose makes the higher energies unsuitable where patient separation is small as in head and neck treatments, but more suitable in pelvis treatments where the large patient separation means the high energy reduces entrance dose compared to 6 MV and the exit dose is acceptable. A complicating factor in high-energy beams is the increased neutron production for which radiation protection measures are required (see Section 3.2.4). A radiotherapy department may choose 10 MV as the highest beam energy to minimize any neutron protection measures *(18)*. Another issue with high-energy photon beams is associated neutron dose to the patient and thus an increased secondary cancer risk. McGinley *(19)* showed that the neutron dose equivalent ranged from 0.02 mSv/Gy X-ray for 10 MV to 8.3 mSv/Gy X-ray for 18 MV for Varian linear accelerators and that this neutron dose is 2–10 times higher for IMRT techniques. This is one reason that IMRT and VMAT are generally not practised for photon beams above 10 MV. This specification gives 10 MV for the second photon energy, but the specification can be modified to 15 MV or 18 MV as the local need applies.

Table 3. Photon beam energies and their depth dose in water

	Beam energy						
Parameter	**Cobalt-60 80 cm SSD**	**Cobalt-60 100 cm SSD**	**4 MV 100 cm SSD**	**6 MV 100 cm SSD**	**10 MV 100 cm SSD**	**15 MV 100 cm SSD**	**18 MV 100 cm SSD**
Depth of maximum dose	0.5 cm	0.5 cm	1.0 cm	1.5 cm	2.3 cm	2.9 cm	3.2 cm
Percentage depth dose at 10 cm depth	56.4%	58.7%	63.0%	67.5%	73.0%	77.0%	79.0%

Source: Data from the British Journal of Radiology, Supplement 25 *(20)* for a 10 cm x 10 cm set field size.

The other modality provided with the multi-energy LINAC in Package 2 is megavoltage electrons. Electron beams are typically offered in a range of energies of 4 MeV–22 MeV. Generally, four or five separate electron energies are selected

by the radiotherapy department. As shown in Table 4, electrons are applicable for the treatment of superficial lesions, with the higher energies offering penetration and tumour coverage up to 7 cm depth. Electron energies should be chosen to give a range of evenly spaced penetrations. This specification gives 6, 9, 12 and 15 MeV for the selected electron energies, but the specification can be modified to select different energies, and a different total number of energies, as the local need applies. Electron beams are implemented with a set of applicators proving collimation of the electron beam to within 5 cm of the patient surface. Customized low-melting point alloy (LMPA) cut-outs at the end of the applicator define the treatment field size and these cut-outs need to be prepared individually (see Section 3.9 for a specification of mould room equipment, including equipment to create electron cut-outs).

Table 4. Electron beam energies and their penetration in water

	Electron energy (MeV)										
Parameter	**4**	**6**	**8**	**9**	**10**	**12**	**15**	**16**	**18**	**20**	**22**
Penetration expressed as R90 (cm)	0.9	1.7	2.4	2.7	3.1	3.9	4.7	5.0	5.5	6.3	7.0

Source: Data from the IAEA Handbook *(21)*.

It is noted that for superficial diseases such as skin cancer, a number of radiotherapy technology treatment options are available, including electron beams from LINAC units, superficial X-ray units, or even brachytherapy sources in close proximity to the skin. For radiotherapy departments with only single-energy 6 MV linear accelerators, a superficial X-ray unit is an ideal solution if skin cancer radiotherapy treatments are needed (although it is noted that some vendors can offer a 6 MV linear accelerator with electrons). Section 3.12 provides specific technical details for superficial X-ray units and related orthovoltage X-ray units.

One of the options in Package 2 from Table 2 is an MLC for shaping of photon beams. Customized blocks also shape the photon beam for each patient's treatment fields along with independent jaws (asymmetric collimators), but the blocks must be manufactured for each field for each patient by dedicated staff in a dedicated mould room facility (see Section 3.9). For 2D radiotherapy and 3D-CRT, the MLC can, in almost all cases, replace customized blocks. However, there are some treatment situations such as those requiring central blocks or island blocks where the simultaneous use of both customized blocks and the MLC are still needed. The advantage of the MLC is that it automates the process of shaping the photon beams. Also, patient treatments can be faster with an MLC because the treatment staff do not have to go into the treatment room after each beam delivery to change the block tray. Furthermore, a higher number of beam incidences can be considered in treatment planning, without having the limitation resulting from the need to build a tray for each field incidence.

The MLC is a bank of 40 or more shielding leaf pairs that are incorporated into the head of the linear accelerator above or below the collimating jaws, or even replacing one of the jaw pairs. The leaves are each motorized and can move to the intended beam shape for each patient through computer control. The MLC can also easily facilitate the practice of IMRT or VMAT through controlled movement of the leaves during treatment. Note that a specification for IMRT and VMAT involves not just specifying the performance of the delivery system comprising the MLC, gantry and cumulative dose monitoring, but also an additional specification of the TPS in inverse planning and leaf motion calculation, and an additional specification of the oncology information system (OIS) in transferring IMRT and VMAT delivery instructions from the TPS to the delivery system. The disadvantages of the MLC in a limited-resource setting are in the higher upfront costs in hardware and related software and the complexity of the MLC leading to the need for additional quality control, maintenance and resources.

The LINAC in Package 2 includes an electronic system for portal imaging. The EPID, including hardware and software, is integrated into the LINAC, attaching to the LINAC gantry on a dedicated motorized retractable arm. The EPID replaces portal imaging with a third-party solution such as radiographic film with processor or computed radiography (CR) plates with reader. The advantages of the EPID, and its associated software, are in its automation of the portal imaging process and in allowing confirmation of patient positioning in real time. However, as with the

MLC, the disadvantages of the EPID are in upfront costs and additional maintenance costs. The EPID panel may fail during the lifetime of the LINAC and need to be replaced. If this replacement is not part of a maintenance contract, then the cost of the EPID replacement can be significant.

3.2.2 Standards

The following IEC standards apply to LINACs. Note that IEC 60601-1 is a general standard and it, along with the collateral standard 60601-1-X, apply to medical electrical equipment. IEC 60601-1 is relevant to all radiotherapy equipment and is listed in this section, but not in subsequent sections. Similarly, the International Basic Safety Standards apply to all medical equipment that produce ionizing radiation and is listed in this section, but not in subsequent sections.

It is assumed that manufacturer's compliance with the IEC standards will provide safety features of the equipment. Section 3.2.4, and subsequent similar subsections, outline safety features of the premises to complement the safety features of the equipment.

- IEC, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, IEC 60601-1:2005+AMD1:2012 CSV *(22)*.
- European Commission, Food and Agriculture Organization of the United Nations, International Atomic Energy Agency, International Labour Organization, OECD Nuclear Energy Agency, Pan American Health Organization, United Nations Environment Programme, World Health Organization, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards: General Safety Requirements Part 3, No. GSR Part 3, IAEA, Vienna (2014) *(23)*.
- IEC, *Medical electrical equipment – Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV*, IEC 60601-2-1:2009+AMD1:2014 CSV *(24)*.
- IEC, *Medical electrical equipment – Medical electron accelerators – Functional performance characteristics*, IEC 60976:2007 *(25)*.
- IEC, *Medical electrical equipment – Medical electron accelerators – Guidelines for functional performance characteristics*, IEC TR 60977:2008 *(26)*.
- IEC, *Electrical medical equipment – Part 2–68: Particular requirements for the basic safety and essential performance of X-ray-based image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment*, IEC 60601-2-68:2014 *(27)*.
- IEC, *Medical electrical equipment–- Safety of radiotherapy record and verify systems*, IEC 62274:2005 *(28)*.
- IEC, *Medical electrical system – Guidelines for safe integration and operation of adaptive external-beam radiotherapy systems for real-time adaptive radiotherapy*, IEC TR 62926:2019 *(29)*.
- IEC, *Guidance on error and warning messages for software used in radiotherapy*, IEC TR 63183:2019 *(30)*.
- IEC, *Radiotherapy equipment – Coordinates, movements and scales*, IEC 61217:2011 *(17)*.

3.2.3 Technical specification

The following specification can be used for the single-energy LINAC described in Package 1 or for the multi-energy LINAC described in Package 2. The items that belong to Package 2 are clearly identified.

The LINAC shall include:

- A motorized gantry with isocentric design, 100 cm SAD, isocentre clearance greater than 30 cm, and gantry rotation ±180°. The mechanical isocentre shall have a maximum diameter of less than or equal to 2 mm for all three rotation axes (collimator, gantry and treatment couch).
- A collimating head with motorized rotation of at least ±90°. The maximum photon beam field size shall be 40 cm × 40 cm (50% isodose level) at the isocentre and the minimum field size no more than 4 cm x 4 cm (50% isodose level).
- Asymmetric jaw movements for all jaws, allowing individual jaws to at least cross the central axis.
- A light field to indicate the radiation field aperture and a reticule to indicate the principal axes and collimator axis of rotation. The light/radiation field coincidence shall be less than or equal to 2 mm.
- An optical distance indicator with a range of at least SAD = ±20 cm.
- An optical back pointer.

- Internal, physical or dynamic wedges providing wedge angles up to 60°. Interlocks shall be provided so that the operator has to positively confirm that the correct wedge has been selected.
- (Package 2) An integrated MLC with at least 80 motorized leaves and 1 cm maximum leaf width at the isocentre. The MLC and linear accelerator control shall allow conformal radiotherapy delivery through fixed MLC leaf placement for each treatment beam. The MLC interleaf leakage shall be less than 4% and the leaf position accuracy less than or equal to 1 mm at the isocentre plane.
- A photon beam energy of 6 MV with flattening filter.
- Variable dose rate from 50 MU/min up to at least 400 MU/min for photons.
- (Package 2) A second photon energy of 10 MV with flattening filter.
- (Package 2) Electron energies of 6, 9, 12 and 15 MeV.
- (Package 2) Dose rate at least 400 MU/min for electrons.
- (Package 2) A range of electron applicators up to at least 20 cm x 20 cm with slots to allow placement of individualized LMPA cut-outs. The source to end-of-applicator distance shall be 95 cm to allow 5 cm clearance between the patient and applicator.
- An independent system of dual internal ionization chambers for monitoring dose, dose rate, beam symmetry and beam steering, with associated interlocks. For radiation beams the beam symmetry shall be less than or equal to 2% and the flatness less than or equal to 3%.[b]
- An independent back-up timer to indicate accumulated monitor units (MU) if any power failure occurs.
- A treatment couch with motorized lateral, longitudinal and vertical movements and motorized isocentric table rotation up to ±90°. The tabletop shall be carbon fibre and indexed to allow reproducible placement of immobilization equipment. The lateral range of the couch shall be at least ±20 cm. The longitudinal range of the couch shall be greater than 70 cm. The vertical motion of the couch shall range from the isocentre to at least 60 cm below the isocentre. The sag of the couch top shall be less than 5 mm with a patient of 80 kg weight. The couch shall be able to take a maximum weight of at least 180 kg.
- Hand pendants in the treatment room to allow control of linear accelerator and treatment couch movements.
- An in-room monitor with display of treatment parameters.
- A front pointer to locate the mechanical isocentre.
- A comprehensive set of standard shielding blocks with 100 individually coded block trays and a tray holder that attaches to the collimator head.
- (Package 1) A portal imaging solution, including portable cassette holder, four cassettes optimized for megavoltage imaging, and image processing (radiographic film or CR).
- (Package 2) An integrated amorphous silicon EPID panel mounted on a motorized arm, panel active area at least 30 cm x 30 cm, for digital portal imaging and including software at the treatment control for comparing EPID images with TPS-generated digitally reconstructed radiographs (DRRs). The motorized arm holding the panel shall allow retraction of the panel and allow positioning of the panel at various positions at and below the mechanical isocentre with a range of lateral and longitudinal offsets. The panel shall include an anti-collision system.
- A closed circuit television system (CCTV) system for viewing of the treatment room from the console. There shall be at least two in-room cameras at different locations in the treatment room and the in-room cameras shall have pan and zoom capability.
- A two-way patient intercommunication system.
- Fixed lasers mounted on the treatment room walls: two lateral cross lasers, one ceiling cross laser and one sagittal line laser. Red or green lasers are required.
- A computerized control console outside the treatment room. All the functions and modes of the accelerator shall be controlled via software. The console shall allow activation of the controls so that the accelerator is operational in its various forms. The most important parameters shall be visible in the control console and treatment room. The console shall have a dual login system with various hierarchical modes, including clinical, physics and service modes. The console shall interface with an OIS for record and verification of patient treatments.
- IEC 61217 scale convention as at least one option in clinical mode.

[b] Flatness F is related to maximum Dmax and minimum dose Dmin within the central 80% of beam width as F = (Dmax – Dmin)/(Dmax + Dmin) expressed as a percentage. Flatness is measured in the largest field size at a depth of 10 cm.

3.2.4 Radiation safety and protection

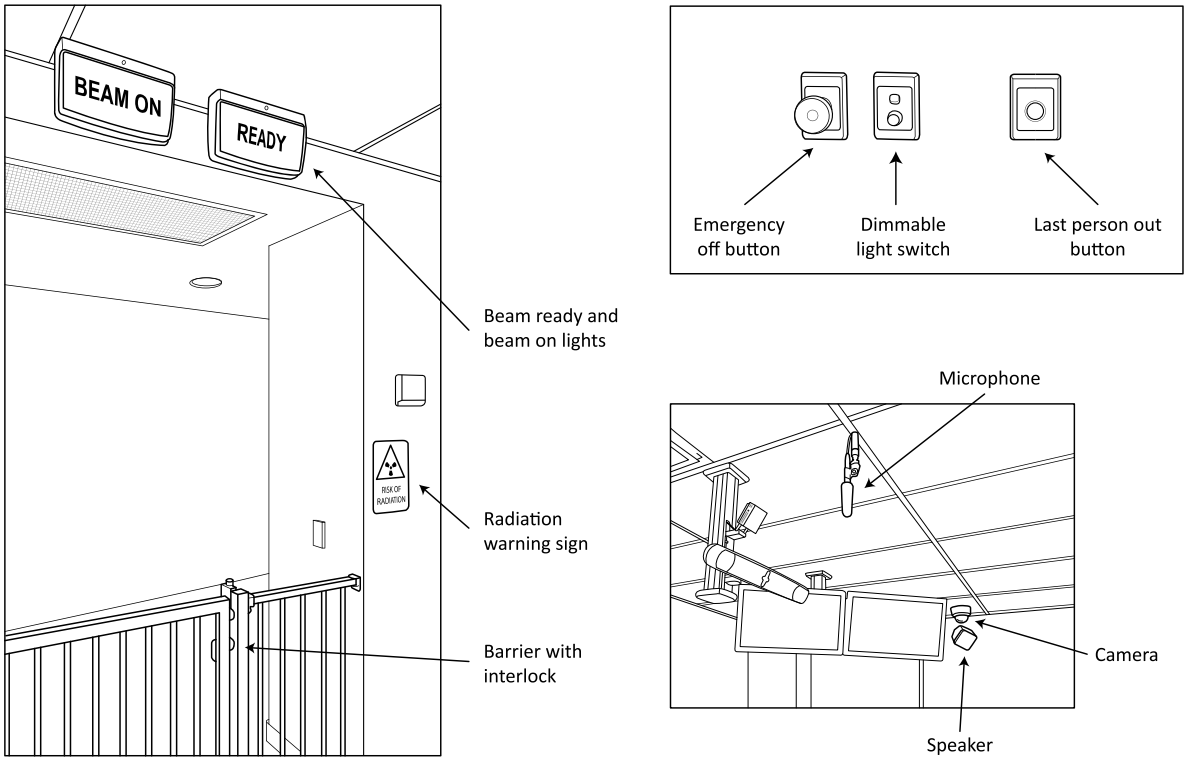
3.2.4.1 Room design

Design and construction of radiotherapy facilities requires special considerations and should be carried out by or in consultation with professionals with appropriate expertise and experience (see Chapter 5). The LINAC is housed in a concrete bunker to ensure radiation protection of staff and members of the public. For calculation of the thickness of concrete shielding required for radiation protection, refer to IAEA Safety Reports Series No. 47 *(18)*, NCRP Report No. 151 *(31)* and ISO-16645:2016 *(32)* along with local requirements for dose constraints and dose limits. Shielding needs to be considered in the floor and ceiling as well as the walls as the gantry can rotate 360°. Where space permits, the treatment room includes a maze to reduce scattered radiation to an adequate level at the entrance without the need for any shielding in an entrance door. If space is a consideration, a maze-less treatment room can be designed, but this has the disadvantage of requiring a heavy shielded motorized door. Refer to IAEA Human Health Reports No. 10 *(13)* for an example of the layout of a teletherapy treatment room, including maze and control room. Under the International Basic Safety Standards classification system, the treatment room will be designated as a *controlled area*. The control room and other areas adjacent to the treatment room, such as any walkway between the treatment room entrance and control room, will also be designated as controlled areas. A comprehensive radiation survey in the vicinity of the bunker shall be conducted after installation to ensure compliance with local regulations for dose limits for staff and members of the public. The survey shall be conducted with calibrated survey meters.

Safety features as part of the premises to prevent accidental exposure of staff and members of the public (Figure 4) include:

- beam-on and beam-ready illuminated signs at the entrance and within the treatment room;
- ionizing radiation trefoil warning sign at the entrance;
- facility access interlock;
- last person out button;
- audio visual communication between the treatment room and control room; and
- emergency-off buttons in the treatment room and control room.

Figure 4. Examples of safety features of premises housing LINACs



3.2.4.2 Neutrons

Of particular importance for LINAC with photon beam energies higher than 8 MV *(32)* is the consideration of neutrons. Neutrons are generated in the head of the linear accelerator during beam-on and also result in neutron capture gamma radiation. The concrete in the walls, floor and ceiling of the bunker designed for protection of the primary beam and scattered radiation should be of sufficient thickness to absorb neutrons and attenuate neutron capture gamma radiation. However, control measures may be necessary at the entrance to the bunker. The methodology in IAEA Safety Reports Series No. 47 *(18)* or NCRP Report No. 151 *(31)* or ISO-16645:2016 *(32)* is used to calculate the neutron dose and neutron capture gamma radiation dose at the entrance as well as the thickness of lead and neutron absorber (typically borated polyethylene) needed to reduce the dose to within the required dose constraint. Careful design of the maze, considering its length, number of turns and cross-sectional area, may also help to reduce neutron dose and neutron capture gamma dose at the entrance, reducing the thickness of shielding required at the entrance. During the radiation survey of the bunker at commissioning, both a neutron meter and an ionizing radiation survey meter are used to confirm the dose level at the entrance to the bunker.

An issue for radiation protection of staff is short-term activation products from neutrons in the head of the linear accelerator immediately after high-energy photon beam irradiation. Aluminium-28 has been identified as a dominant short-term activation product *(33)* in a Varian Clinac™ with a half-life of 2.24 min. A short delay in staff entering the treatment room after high-energy photon beam irradiation is advised and this is usually a major justification for a maze.

Long-term exposure to neutrons over the 10–15-year lifecycle of the LINAC may lead to long-term activation of the head of the LINAC that needs to be addressed at the time of decommissioning. The local radiation regulator shall be consulted in the event of decommissioning of a high-energy LINAC.

3.2.5 Quality assurance

To ensure safety and quality in patient treatment, the LINAC shall be subject to routine quality control testing to maintain its performance. High-quality radiotherapy relies not just on stable and accurate dosimetry, but also accurate and reproducible geometry. Regular testing not only of dosimetry performance, but also of the LINAC's optical, mechanical and imaging systems is recommended. Reference dosimetry shall be carried out with a calibrated dosimeter using an international code of practice based on absorbed dose to water such as the IAEA Technical Reports Series No. 398 *(34)*. International recommendations and standards for quality control tests for LINACs are available:

- IAEA, *Setting up a radiotherapy programme: Clinical, medical physics, radiation protection and safety aspects*, 2008 *(4)*.

The recommendations of various national professional societies are also available:

- AAPM, *Task Group 142 report: Quality assurance of medical accelerators*, Med Phys, 36, 4197–4212, 2009 *(35)*.
- AAPM, *Medical Physics Practice Guideline 8.a.: Linear accelerator performance tests*, J Appl Clin Med Phys, 18, 23–39, 2017 *(36)*.
- Canadian Partnership for Quality Radiotherapy, *Technical quality control guidelines for medical linear accelerators and multileaf collimators*, 2016 *(37)*.
- European Commission, *Criteria for acceptability of medical radiological equipment used in diagnostic radiology, nuclear medicine and radiotherapy*, Radiation Protection No. 162, 2012 *(38)*.

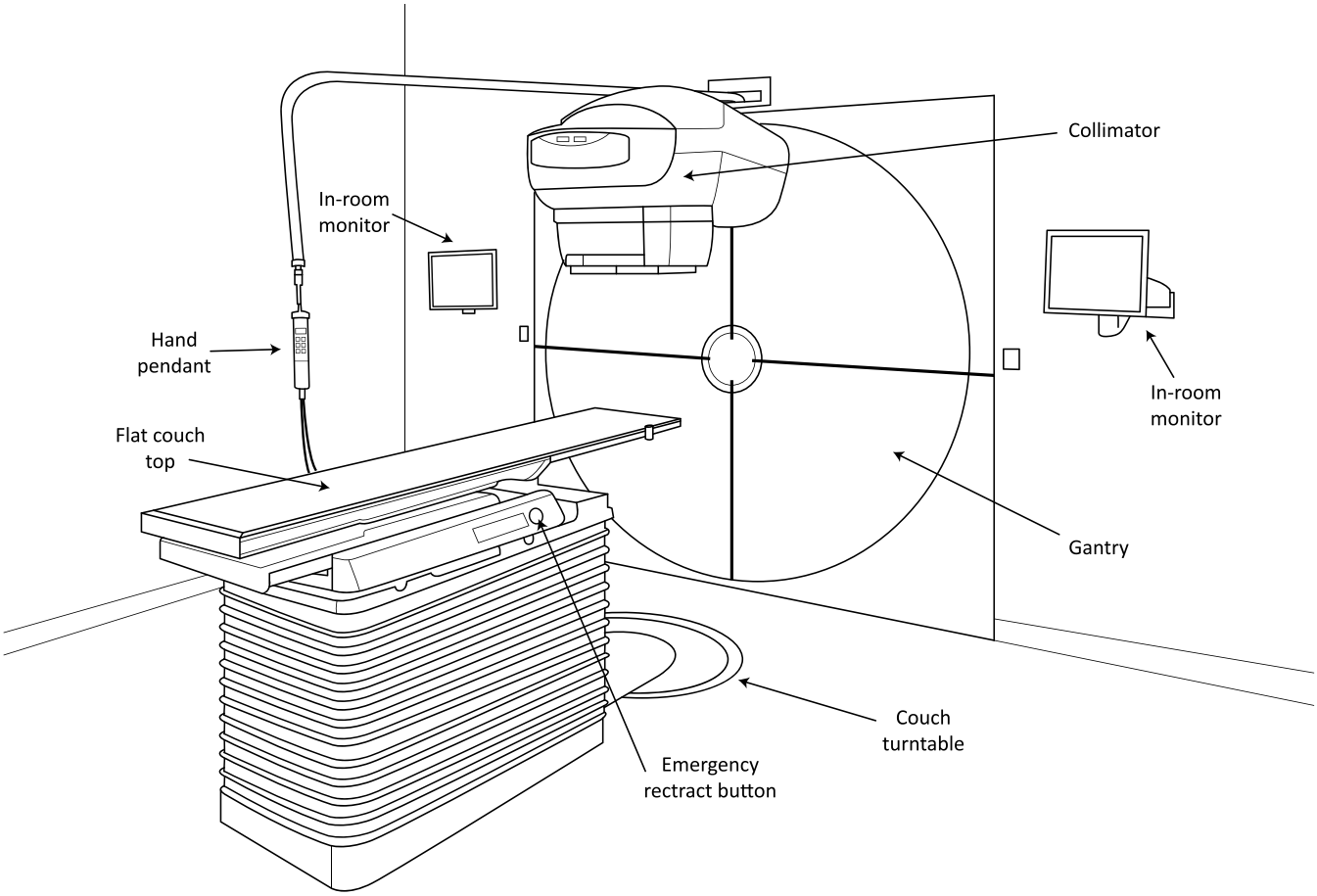
There may also exist local standards and regulations for compliance testing of LINACs that shall be complied with.

3.3 Technical specifications for cobalt-60 teletherapy units

3.3.1 Description

The cobalt-60 teletherapy unit has similar mechanical characteristics to the conventional LINAC in terms of rotating gantry, collimator and couch (Figure 5). The cobalt-60 source essentially replaces the electrical generation of megavoltage photons involving an electron gun, microwave generator, accelerating waveguide, bending magnet, metal target and complex beam monitoring system. The advantages of the cobalt-60 teletherapy unit over the LINAC are the simplicity of design and less infrastructure services needed. This translates to lower purchase cost and lower running and maintenance costs, which are important considerations for LMICs. The disadvantages are the source decay and the additional radiation safety and security considerations needed for the high-activity radioactive cobalt-60 source. Other publications cover the issues of choosing a cobalt-60 teletherapy unit or a LINAC in greater detail *(4,39,40)*.

Figure 5. Features of a cobalt-60 teletherapy unit



It is possible to purchase a cobalt-60 teletherapy unit with either a SAD of 80 cm or of 100 cm. Almost all LINACs have a SAD of 100 cm and this allows the use of isocentric treatment techniques with sufficient clearance between the patient and the collimator head of the treatment unit for all gantry angles. The advantage of the 80 cm SAD cobalt-60 teletherapy unit is the higher dose rate for the same source activity compared to the 100 cm unit due to the fact that the patient is closer to the source. This becomes more important as the dose rate from the radioactive source decays with time, however, with the disadvantage that the reduced clearance between the patient and unit means that isocentric techniques may not be possible in all situations. Fixed SSD treatments are often used instead that are suitable for simple techniques but time consuming in the patient setup for complex techniques. The following technical specification is for a 100 cm SAD unit and can be adapted to specify an 80 cm SAD unit as needed.

The decrease in dose rate with time for a cobalt-60 teletherapy unit due to radioactive decay means that the cobalt-60 source will have to be replaced at regular intervals over the life of the teletherapy unit. Lower dose rate leads to longer treatment times to deliver the same dose. Longer treatment times are not ideal for the comfort of the patient and allow more possibility for the patient to move during treatment, which can compromise the quality of treatment and thus its outcome. Also, as the source ages, the efficiency of the treatment unit is decreased with fewer patients being able to be treated in a standard working day and with longer treatment times per patient. Radiotherapy departments are encouraged to begin planning for the procurement of a new source in the year before a 5-year lifetime of a cobalt-60 source is reached. This 5-year lifetime may coincide with the manufacturer's recommendation for source drawer inspection or replacement based on the expected number of source position movements.

If the radiotherapy department is considering the procurement of two or more cobalt-60 teletherapy units based on needs, then the selection of both an 80 cm SAD unit and 100 cm SAD unit is recommended to allow optimal long-term usage of the cobalt-60 sources. For example, because of the greater source to treatment distance for the 100 cm SAD unit and consequently lower dose rate for the same source strength, its source will need to be replaced first. However, the used source from the 100 cm unit may still provide adequate dose rate on the 80 cm SAD unit for a number of years. It will be possible to cascade cobalt-60 sources from the 100 cm SAD unit to 80 cm unit, which will be a major resource-sparing initiative for new sources.

The diameter of the cobalt-60 source is an important feature in determining the radiation beam penumbra width as well as the initial dose rate. This specification gives the diameter as 2.5 cm or less, consistent with the IAEA specification *(4)*. A small source diameter can be specified to improve the penumbra width, for example, 1.5 cm or 2.0 cm *(41)*, but it is noted that this will be at the expense of the initial dose rate provided by the source.

3.3.2 Standards

- IEC, *Medical electrical equipment – Part 2–11: Particular requirements for the basic safety and essential performance of gamma beam therapy equipment*, IEC 60601-2-11:2013 *(42)*.
- IEC, *Radiotherapy equipment – Coordinates, movements and scales*, IEC 61217:2011 *(17)*.
- ISO, *Radiological protection – Sealed radioactive sources – General requirements and classification*, ISO-2919:2012 *(43)*.
- IEC, *Guidance on error and warning messages for software used in radiotherapy*, IEC TR 63183:2019 *(30)*.

3.3.3 Technical specification

The cobalt-60 teletherapy unit shall include the following:

- A shielded cobalt-60 source of 2.5 cm diameter or less that provides an initial minimum dose rate of at least 2.0 Gy/min to water at the depth of maximum dose at 100 cm SSD for a field size of 10 cm x 10 cm. The beam symmetry shall be less than or equal to 3% and the flatness less than or equal to 3%.[c]
- A motorized gantry with rotation range ±180° and a SAD of 100 cm. The mechanical isocentre shall have a maximum diameter of less than or equal to 2 mm for all three rotation axes (collimator, gantry and treatment couch). The isocentre clearance shall be greater than or equal to 30 cm with accessories inserted.
- Motorized collimators providing a maximum field size of 40 cm x 40 cm at 100 cm SAD and a minimum field size of 1 cm x 1 cm with asymmetric collimators capable of shielding half the beam and motorized collimator rotation of at least ±90°.
- Secondary collimators (trimmers) to reduce penumbra to less than 10 mm (if needed).
- A light field incorporated in the head of the gantry to indicate the radiation field location. The light/radiation field coincidence shall be less than or equal to 2 mm.
- An optical distance indicator with a range of at least SAD ±20 cm.
- An optical back pointer.
- One universal wedge providing wedging of up to 60° or a set of physical wedge filters of 15°, 30°, 45° and 60°. Interlocks shall be provided so that the operator has to positively confirm that the correct wedge has been selected.

[c] Flatness F is related to maximum Dmax and minimum dose Dmin with in the central 80% of beam width as F = (Dmax – Dmin)/(Dmax + Dmin) expressed as a percentage. Flatness is measured in the largest field size at a depth of 10 cm.

- A patient couch providing motorized vertical movement, longitudinal and lateral motions with isocentric rotation. The tabletop shall be carbon fibre and indexed to allow reproducible placement of patient immobilization devices. The isocentric rotation range of the couch shall be ±90°. The range of lateral motion of the couch top shall be ±20 cm. The longitudinal range of the couch top motion shall be greater than 70 cm. The vertical motion of the couch shall range from the isocentre to at least 60 cm below the isocentre. The sag of the couch top shall be less than 5 mm with a patient of 80 kg weight. The couch shall be able to take a maximum weight of at least 180 kg.
- A hand pendant for control of parameters inside the treatment room.
- An in-room monitor with display of treatment parameters.
- A front pointer to locate the mechanical isocentre.
- A transparent shadow tray for shielding blocks to support blocks up to 20 kg. It shall be possible to use blocks and wedges simultaneously. The block tray shall be interlocked to the console.
- A comprehensive set of standard shielding blocks with 100 individually coded block trays.
- A portal imaging solution, including portable cassette holder, four cassettes optimized for megavoltage imaging, and image processing (radiographic film or CR).
- An area radiation monitor with an acoustic/optical signal of radiation.
- A CCTV system for viewing of the treatment room from the console. There shall be at last two in-room cameras at different locations in the treatment room and the in-room cameras shall have pan and zoom capability.
- A two-way patient intercommunication system.
- A set of four mounted lasers for patient positioning intersecting at the mechanical isocentre (two lateral cross lasers, one ceiling cross laser and one sagittal line laser). Red or green lasers are required.
- An UPS to immediately retract the source and to provide the treatment console information at the time of a power outage.
- T bar for manual source retraction.
- A computerized control console outside the treatment room with an audio visual radiation monitor and display of interlocks, dual channel timer system and display of the treatment parameters. All the functions and modes of the unit shall be controlled via software. The console shall allow activation of the controls so that the unit is operational in its various forms. The most important parameters shall be visible in the control console and treatment room. The control console shall have a removable on/off key and a secondary login system with various hierarchical modes, including clinical, physics and service modes. The console shall interface with an OIS for record and verification of patient treatments.
- IEC 61217 scale convention as at least one option in clinical mode.

3.3.4 Radiation safety and protection, and security of radioactive material

The cobalt-60 teletherapy unit is housed in a concrete bunker to ensure radiation protection of staff and members of the public. For calculation of the thickness of concrete shielding required for radiation protection, refer to IAEA Safety Reports Series No. 47 *(18)* or NCRP Report No. 151 *(31)* along with local requirements for dose constraints and dose limits. Shielding needs to be considered in the floor and ceiling as well as the walls as the gantry can rotate 360°. Typically, the treatment room includes a maze to reduce scattered radiation to an adequate level at the entrance without the need for any shielding at the entrance. If space is a consideration, then a maze-less treatment room can be designed, but this has the disadvantage of requiring a heavy shielded motorized door. In either case, a security door will need to be provided: for the former, a security door must be installed, and for the latter, security components should be added to the shielded door. Refer to IAEA Human Health Reports No. 10 *(13)* for an example of the layout of a teletherapy treatment room, including maze and control room. Under the International Basic Safety Standards classification system, the treatment room will be designated as a *controlled area*. The control room and other areas adjacent to the treatment room, such as any walkway between the treatment room entrance and control room, will also be designated as controlled areas. A comprehensive radiation survey in the vicinity of the bunker shall be conducted after installation to ensure compliance with local regulations for dose limits for staff and members of the public. The survey shall be conducted with a calibrated survey meter.

Safety and security features as part of the premises to prevent accidental exposure of staff and members of the public include:

- beam-on illuminated signs at the entrance and within the treatment room;
- ionizing radiation trefoil warning sign at the entrance;
- facility access interlock;
- last person out button;
- a permanent radiation area monitor in the treatment room that provides a warning if the source is in the open position;
- audio visual communication between the treatment room and control room;
- emergency-retract buttons in the treatment room and control room; and
- security features to prevent unauthorized removal of the radioactive material and sabotage *(44)*.

3.3.5 Quality assurance

To ensure safety and quality in patient treatment, the cobalt-60 teletherapy unit shall be subject to routine quality control testing. Regular measurement of absorbed dose under reference conditions is recommended as well as regular confirmation of relative dosimetry. Of particular importance is routine testing of the position of the cobalt-60 source with respect to the collimator axis of rotation to confirm that the source has moved to the correct open position. Testing of the optical systems, mechanical features and safety features is also required. Reference dosimetry shall be carried out with a calibrated dosimeter using an international code of practice based on absorbed dose to water such as IAEA Technical Reports Series No. 398 *(34)*.

International recommendations and standards for quality control tests for cobalt-60 teletherapy units are available:

- IAEA, *Setting up a radiotherapy programme: Clinical, medical physics, radiation protection and safety aspects*, 2008 *(4)*.

The recommendations of various national professional societies are also available:

- AAPM, *Comprehensive QA for radiation oncology*: *Report of Task Group 40*, 1994 *(45)*.
- European Commission, *Criteria for acceptability of medical radiological equipment used in diagnostic radiology, nuclear medicine and radiotherapy*, Radiation Protection No. 162, 2012 *(38)*.

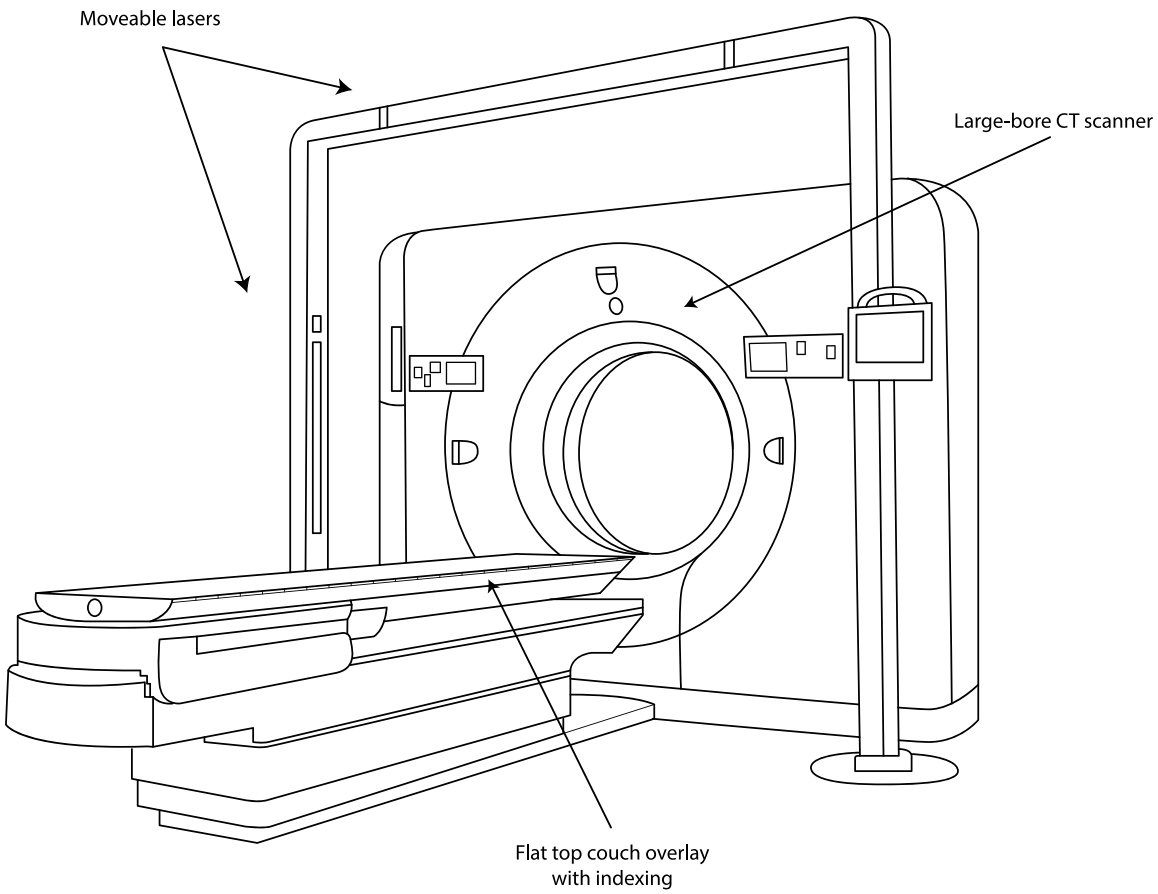
There may also exist local standards and regulations for compliance testing of cobalt-60 teletherapy units which shall be complied with.

3.4 Technical specifications for CT simulators

3.4.1 Description

The CT simulator takes a diagnostic CT scanner and adds a flat top couch and external lasers (Figure 6). Dedicated CT scanners for radiotherapy simulation are available from manufacturers that have a larger bore (at least 80 cm diameter) than the standard 70 cm bore of a diagnostic CT scanner *(46)*. A larger bore is needed in radiotherapy treatment simulation because the patient in the treatment position may be tilted or have arms extended (using an immobilization device such as a breast board) or be placed laterally offset on the couch. It is assumed in this publication that a dedicated large-bore CT scanner will be purchased for radiotherapy simulation. Dedicated CT simulators have little value for diagnostic applications, and they are not usually equipped with radiological image processing features. If there are no resources for a dedicated CT scanner for radiotherapy, then access to a radiology CT scanner should be arranged. The radiology CT scanner will need the flat top couch accessory and an external laser system. It is necessary for a radiation therapist to be present with the patient at the CT scanner to ensure set up parameters are correct. Direct transfer of patient data sets to the 3D TPS will be necessary. This option is highly recommended for centres with Package 1 as it is likely that resources will only permit a small percentage of patients to be prioritized for 3D treatment.

Figure 6. Features of a CT simulator



As well as having internal lasers to locate the centre of the image plane, the CT simulator has an external laser system for patient alignment. The external laser system is set back at a fixed distance from the image plane (typically 600 mm) and consists of lateral and ceiling cross lasers that intersect at the centre of the image plane axis, similar to the arrangement of the lasers in the treatment room. More recently, vendors are integrating these lasers within the CT system.

A carbon fibre flat couch top is required with identical indexing (for all kinds of immobilization systems used in radiotherapy) identical to that of LINACs and/or cobalt-60 teletherapy units in the radiotherapy department.

CT scans of the patient in the treatment position are transferred to the TPS using the Digital Imaging and Communications in Medicine (DICOM) standard.

3.4.2 Standards

IEC standards for diagnostic CT scanners can be applied in the CT simulator setting:

- IEC, *Medical electrical equipment – Part 2–44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography*, IEC 60601-2-44:2009+AMD1:2012+AMD2:2016 CSV *(47)*.
- IEC, *Evaluation and routine testing in medical imaging departments, Part 2–6: Constancy tests – imaging performance of computed tomography X-ray equipment*, IEC 61223-2-6:2006 *(48)*.
- IEC, *Evaluation and routine testing in medical imaging departments, Part 3–5: Acceptance tests and constancy tests – imaging performance of computed tomography X-ray equipment*, IEC 61223-3-5:2019 *(49)*.

3.4.3 Technical specification

The CT simulator shall include the following:

- A CT scanner with whole body spiral and multi-slice (minimum 16 slices per rotation) capabilities with a gantry aperture of at least 80 cm. The scan field of view shall be at least 50 cm and extended field of view a minimum of 70 cm shall be available. The positioning indicators in the gantry shall have a positioning accuracy of ±1 mm or better.
- A couch top constructed of carbon fibre, flat bed type, indexed to allow reproducible placement of immobilization equipment and having horizontal moving range of 170 cm or more. The speed of horizontal movement shall be variable with a maximum speed of at least 100 mm per second. The accuracy of the couch top position shall be better than ±0.25 mm. The scannable range shall be at least 150 cm. The couch shall be able to take a maximum weight of at least 180 kg without any change in stated performance specifications (such as the positioning accuracy). The sag of the couch top shall be less than 5 mm with a patient of 80 kg weight.
- A high-frequency X-ray generator with power rating of at least 60 kW. The kVp range shall be 80 kV–130 kV. The mA range shall be at least 30 mA–400 mA, with step size of 5 mA or better. The peak anode heat dissipation rate shall be at least 1.1 MJ/min or better. The X-ray tube shall have dual focal spots.
- A detector system with high performance, low noise, high data density and active response data acquisition system. The detectors shall be solid state. The detector system shall be free from repeated calibrations. There shall be multiple rows of 650 or more detectors for taking a minimum of 16 slices at a time.
- A computer system for the CT scanner. A high-end main computer system with network capability shall be provided. There shall be two monitors at the console with 19-inch or more flat screen LCD monitors. One of these will be used for acquisition and the other for image review and processing. The hard disk capacity of the main computer system shall be at least 1 TB or more. In the hard disk meant for image storage, the number of uncompressed 512 x 512 images that can be stored should be at least 200 000 or more. The system shall form part of the departmental intranet and should not have access to the internet. Software installation and upgrades/updates should be performed using CD/DVD and all other external data device inputs should be disabled to enhance data protection and minimize virus infection. The system shall be fully DICOM compliant. The system shall support the following: DICOM 3.0 Print service class as a user, DICOM 3.0 Storage class as a user, DICOM 3.0 Storage class as a provider, DICOM 3.0 Send/Receive, DICOM 3.0 Query/Retrieve service class as a user, and DICOM 3.0 Query/Retrieve service class as a provider. A DICOM compliance statement shall be provided.
- An automatic overnight back-up system to an external hard drive for all workstations.
- An external long-term image archive system.
- A dose reporting feature with dose display and the capacity to transfer dose information for recording purposes. DICOM structured dose report shall be available.
- Typical radiotherapy scan protocols for routine adult and paediatric scanning and quality control.
- Automatic mA control software that automatically adjusts mA for patient size, adjusts mA along the z-axis and modulates mA during rotation.
- A metal artefact reduction algorithm incorporated into image processing.
- A pump system capable of injecting contrast media through intravenous cannulas or through peripherally inserted central catheters.
- Software to allow direct transfer of CT data sets to a separate virtual simulation workstation, external beam TPS and OIS.
- A virtual simulation workstation for volume definition (contouring), isocentre localization, field placement and field design (shielding blocks or MLC configuration) of all the EBRT equipment, and the generation of DRRs. It should be possible to seamlessly export patient administrative data, images, volumes and machine parameters to the external beam teletherapy equipment, external beam TPS, laser imager and OIS.
- A bi-directional speaker communication shall be provided between the operator and the patient.
- A CCTV system to view the patient within the gantry bore.
- An external radiotherapy laser system for patient alignment, marking and isocentre localization. The external laser system shall include a moveable ceiling laser and moveable lateral lasers with control of the position of the lasers available within the CT simulator room. Laser projection shall also be at least 50 cm long at the patient plane. Red or green lasers are preferred.
- A networked dry laser imager.

The following performance characteristics shall be met:

- Slice thickness of at least sub-millimetre up to 8 mm.
- Scan time of 0.6 second or less for full 360° rotation.
- Retrospective reconstruction on raw data files with change in parameters such as field of view.
- Starting with a cold tube, the maximum helical scan distance using a 3 mm imaged slice thickness and a pitch of 1.5 of 1500 mm or more.
- The following scanning modes shall be available: scan projection radiograph (SPR), axial and spiral. The SPR length should be more than 1500 mm long and the width shall be at least 500 mm. It shall be possible to obtain the SPR from anterior to posterior (AP) or posterior to anterior (PA) or left to right or right to left directions. The ability of the system to reproduce the scanning protocol from the SPR should be ±3 mm or better. The accuracy of distance measurements in the SPR (taken at isocentre distance) shall be better than twice the pixel dimension
- Pitch selection in the range 0.6–1.5 mm.
- Image quality: the reconstruction matrix shall be 512 x 512 or higher. High-contrast spatial resolution: at least 15 lp/cm maximum at 0% modulation transfer function (MTF). Low-contrast detectability: 5 mm or less at 0.3% using adequate phantom on 10 mm slice thickness. The CT number accuracy shall be better than 0 ±4 HU for water and -1000 ±10 HU for air.

3.4.4 Radiation safety and protection

The X-ray tube of the CT simulator necessitates radiation protection and safety measures. The CT simulator shall be housed in a shielded room, with shielding usually provided by lead, concrete or bricks. The control room should be contiguous with the simulator room and lead glass can be used as part of the control room shielding to facilitate visualization of the patient. The thickness of shielding required for CT scanner rooms can be calculated following the methodologies described by Sutton et al. *(50)* and NCRP Report No. 147 *(51)* along with local requirements for dose constraints and dose limits. Refer to IAEA Human Health Reports No. 10 *(13)* for an example of the layout of a CT simulator room and associated control room. Under the International Basic Safety Standards classification system, the simulator room will be designated as a *controlled area*. The control room and other areas adjacent to the simulator room, such as any walkway between the simulator room entrance and control room, will also be designated as controlled areas. A comprehensive radiation survey in the vicinity of the CT simulator room shall be conducted after installation to ensure compliance with local requirements for dose limits for staff and members of the public. The survey shall be conducted with a calibrated survey meter.

Safety features as part of the premises to prevent accidental exposure of staff and members of the public include:

- X-ray on and X-ray ready illuminated signs at entrances and within the room;
- ionizing radiation trefoil warning signs at entrances;
- audio visual communication between the CT simulator room and control room; and
- emergency-off buttons in the CT simulator room and control room.

3.4.5 Quality assurance

To ensure safety and quality in simulation, the CT simulator shall be subject to routine quality control testing. Regular testing of the X-ray system, image quality, laser systems, mechanical features and safety features is required. The support of a medical physicist clinically qualified in diagnostic radiology is helpful in quality control testing of CT scanners. International recommendations and standards for quality control tests for CT simulators are available:

- IAEA, *Quality assurance programme for computed tomography: Diagnostic and therapy applications*, Human Health Series No. 19, 2012 *(46)*.
- IEC, *Evaluation and routine testing in medical imaging departments, Part 2–6: Constancy tests – Imaging performance of computed tomography X-ray equipment*, IEC 61223-2-6:2006 *(48)*.

The recommendations of various national professional societies are also available:

- AAPM, *Quality assurance for computed-tomography simulators and the computed-tomography-simulation process: Report of the AAPM Radiation Therapy Committee Task Group No. 66*, Med Phys, 30, 2762–2792, 2003 *(52)*.
- Canadian Partnership for Quality Radiotherapy, *Technical quality control guidelines for computed tomography simulators*, 2016 *(53)*.
- European Commission, *Criteria for acceptability of medical radiological equipment used in diagnostic radiology, nuclear medicine and radiotherapy*, Radiation Protection No. 162, 2012 *(38)*.

There may also exist local standards and regulations for compliance testing of CT scanners and simulator equipment which shall be complied with.

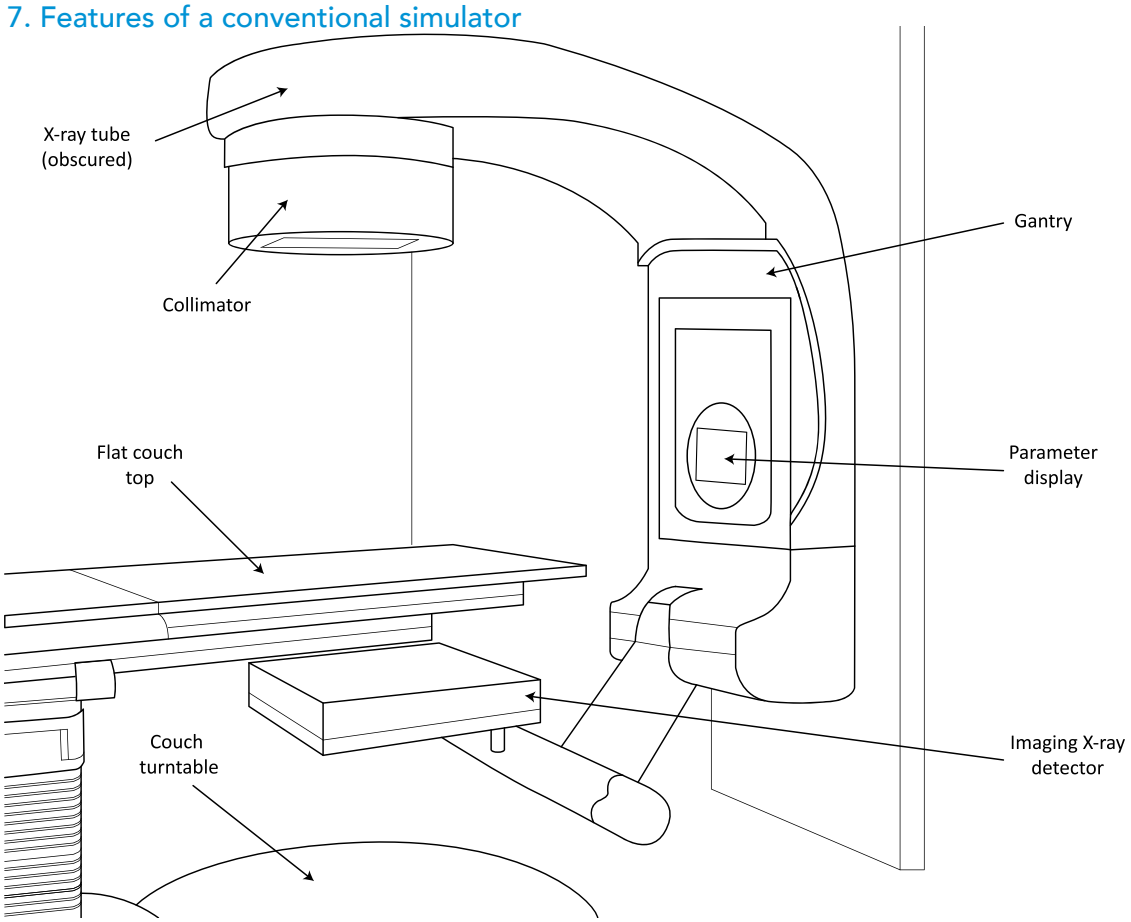
3.5 Technical specifications for conventional simulators

3.5.1 Description

The conventional simulator is intended for radiotherapy treatment planning for treatments on either a LINAC or cobalt-60 teletherapy unit. The conventional simulator can also be used for brachytherapy treatment planning (see Section 4.1). The conventional simulator includes gantry, collimator, X-ray tube and X-ray detector, patient couch and control console (Figure 7).

The conventional simulator has similar mechanical and geometrical characteristics to the conventional LINAC and cobalt-60 teletherapy unit in terms of gantry, collimator and couch. In the conventional simulator, an X-ray tube replaces the high-energy radiation source of the treatment unit, allowing planar X-ray imaging of the intended treatment ports or orthogonal imaging for isocentre verification. The conventional simulator facilitates the practice of 2D EBRT and offline verification and markup of patients for 3D-CRT. The SAD of the simulator needs to able to be adjusted to the SAD of the treatment units in the radiotherapy department.

Figure 7. Features of a conventional simulator



Volumetric imaging is available on conventional simulators as an option and is referred to as sim-CT. This is a cone beam CT mode enabling 3D reconstructed images. However, the image quality of sim-CT is inferior to that of diagnostic CT scanners, which means that the images are of limited applicability in treatment planning. This specification does not include a volumetric imaging option.

3.5.2 Standards

- IEC, *Medical electrical equipment – Part 2–29: Particular requirements for the basic safety and essential performance of radiotherapy simulators*, IEC 60601-2-29:2008 *(54)*.
- IEC, *Radiotherapy simulators – Functional performance characteristics*, IEC 61168:1993 *(55)*.
- IEC, *Radiotherapy simulators – Guidelines for functional performance characteristics*, IEC TS 61170:1993 *(56)*.
- IEC, *Radiotherapy equipment – Coordinates, movements and scales*, IEC 61217:2011 *(17)*.

3.5.3 Technical specification

The conventional simulator shall include the following:

- A motorized gantry of isocentric design and a gantry rotation range ±180° with a maximum mechanical isocentre sphere diameter of 2.0 mm.
- An adjustable X-ray focus-to-isocentre distance at least 80–100 cm.
- An X-ray tube for radiography and fluoroscopy. There shall be two focal spot sizes available.
- An X-ray generator with 30 kW high-frequency capable of fluoroscopy and radiography modes, up to 125 kVp and 300 mAs (radiography) and 4 mA (fluoroscopy).
- A motorized diaphragm to collimate the X-ray beam with both local and remote control. The collimator rotation range shall be at least ±90°. The maximum field size at the isocentre shall be up to 40 cm × 40 cm at 100 cm from the focus.
- Radio-opaque wires to define the intended treatment field, independent of the X-ray beam diaphragm, motorized and with both local and remote control. Asymmetric setting of the wire positions is required.
- A light field shall be incorporated in the head of the gantry to indicate the radiation field location. The light/radiation field coincidence shall be less than 2 mm.
- An optical distance indicator shall be incorporated in the head of the gantry. The optical distance indication range shall be SAD ±20 cm.
- A motorized couch with X-ray transparency of the couch top, isocentric rotation limits of ±90°, lateral motion range of ±20 cm, motorized vertical movement, longitudinal range of greater than or equal to 70 cm, and sag of the couch top less than 5 mm with a patient of 80 kg. The couch shall be able to take a maximum weight of at least 180 kg. The couch shall be indexed to allow reproducible placement of patient immobilization devices and the indexing system should preferably be of the same type as the radiotherapy department's treatment couches.
- A hand pendant for control of parameters inside the simulator room.
- An in-room monitor with display of simulator parameters.
- A front pointer to locate the mechanical isocentre.
- A transparent shadow tray that is positioned at the same source-to-tray distance as the treatment units and a grid tray.
- A digital X-ray imaging system (flat panel) with dimensions greater than or equal to 30 cm x 30 cm. Lateral and longitudinal movements of the imaging system shall be available.
- Anti-collision systems particularly for the imaging system.
- A CCTV system with pan, tilt and zoom capability.
- A patient intercommunication system.
- Four mounted external lasers (two lateral cross lasers, one ceiling cross laser and one sagittal line laser) intersecting at the mechanical isocentre.
- A remote console for control of the X-ray system and control of the gantry, collimator, imaging panel and couch. The console shall include a DICOM 3.0 interface for digital networking of images (transfer of digital images to and from a TPS).
- IEC 61217 scale convention as at least one option in clinical mode.

3.5.4 Radiation safety and protection

The X-ray tube of the conventional simulator necessitates radiation protection and safety measures. The conventional simulator shall be housed in a shielded room, with shielding usually provided by lead, concrete or bricks. The control room should be contiguous with the simulator room and lead glass can be used as part of the control room shielding to facilitate visualization of the patient. The thickness of shielding required can be calculated following the methodology in IAEA Safety Reports Series No. 47 *(18)* along with local requirements for dose constraints and dose limits. Consideration must be given to shielding in the floor, walls and ceiling as the gantry can rotate fully 360°. Refer to IAEA Human Health Reports No. 10 *(13)* for an example of the layout of a simulator room and associated control room. Under the International Basic Safety Standards classification system, the simulator room will be designated as a *controlled area*. The control room and other areas adjacent to the simulator room, such as any walkway between the simulator room entrance and control room, will also be designated as controlled areas. A comprehensive radiation survey in the vicinity of the simulator room shall be conducted after installation to ensure compliance with local requirements for dose limits for staff and members of the public. The survey shall be conducted with a calibrated survey meter.

Safety features as part of the premises to prevent accidental exposure of staff and members of the public include:

- facility access interlock;
- X-ray on and X-ray ready illuminated signs at entrances and within the room;
- ionizing radiation trefoil warning signs at entrances;
- audio visual communication between the simulator room and control room; and
- emergency-off buttons in the simulator room and control room.

3.5.5 Quality assurance

To ensure safety and quality in simulation, the conventional simulator shall be subject to routine quality control testing. Regular testing of the X-ray system, optical systems, mechanical features and safety features is required. International recommendations for quality control tests for conventional simulators are available:

- IAEA, *Setting up a radiotherapy programme: Clinical, medical physics, radiation protection and safety aspects*, 2008, (Appendix XIII, Table 24) *(4)*.

The recommendations of various national professional societies are also available:

- AAPM, *Comprehensive QA for radiation oncology: Report of Task Group 40, 1994 (45)*.
- *Canadian Partnership for Quality Radiotherapy, Technical quality control guidelines for conventional radiotherapy simulators*, 2015 *(57)*.
- European Commission, *Criteria for acceptability of medical radiological equipment used in diagnostic radiology, nuclear medicine and radiotherapy*, Radiation Protection No. 162, 2012 *(38)*.

There may also exist local standards and regulations for compliance testing of radiography, fluoroscopy, and simulator equipment which shall be complied with.

3.6 Technical specifications for external beam treatment planning systems (TPS)

3.6.1 Description

The TPS is a software application used for the planning of radiotherapy treatments based on the radiation oncologist's prescription. The modules of the TPS include:

- image import and registration;
- contouring (also termed segmentation) tools for tumour volumes and organs at risk;
- treatment planning environment, including 3D patient image and dose distribution display;
- plan review module, including dose statistics calculation and tabulation;
- plan preparation and export module; and
- dose calculation algorithm and beam modelling module.

The TPS is supplied with dedicated hardware, including workstations, server (if applicable), monitors and printer.

The number of workstations to be purchased as part of the TPS depends on the patient workload of the radiotherapy department and the number of external beam treatment units. Each full-time staff member dedicated to treatment planning should be allocated a workstation. Departments will also purchase dedicated workstations for radiation oncologists' use in contouring, plan review and plan approval.

3.6.2 Standards

- IEC, *Medical electrical equipment – Requirements for the safety of radiotherapy treatment planning systems*, IEC 62083:2009 *(58)*.
- IEC, *Radiotherapy equipment – Coordinates, movements and scales*, IEC 61217:2011 *(17)*.
- IAEA, *Specification and acceptance testing of radiotherapy treatment planning systems*, TECDOC 1540, 2007 *(59)*.

3.6.3 Technical specification

The TPS shall include:

- Treatment planning workstations, including dual 23-inch monitors, keyboard, mouse and network capability.
- A module to allow import of patient data sets from various imaging modalities that are used to facilitate target definition, using the DICOM standard. Image import may be achieved through direct connectivity to the radiology picture archiving and communication system (PACS) system.
- An image registration module using either rigid and/or deformable registration modes.
- 3D visualization capability for patient data display, beam display and dose distribution display.
- Contouring tools that allow the definition in 3D of structures, including target, organs at risk and patient outline.
- Automated tools to allow the expansion of the clinical target volume (CTV) to a planning target volume (PTV) with non-uniform margins in three dimensions.
- The ability to add bolus structures to the patient data set of various shape and density.
- A comprehensive "forward planning" environment that allows the user to modify beam weights, beam positioning, jaw position, wedges and blocks, or MLC to optimize the treatment plan.
- Photon beam and electron beam algorithms that calculate the dose to the patient considering the 3D nature and heterogeneity of the patient data set. The photon beam algorithm shall use advanced methods (e.g. convolution, Boltzmann transport, Monte Carlo). The electron beam algorithm shall be based on pencil beam or Monte Carlo methods. The dose matrix (calculation grid) should be user adjustable and the accuracy of the dose calculations shall be such that it is possible to meet the tolerance criteria in Table 4 of IAEA TECDOC 1540 *(59)*.
- The ability to calculate MU for all beam models.
- The ability to allow dose prescription to a point, volume or isodose line.
- Advanced plan review and evaluation tools, including dose volume histograms (DVHs), dose statistics, 2D and 3D dose visualization, and plan addition and plan comparison.
- The ability to generate and view DRRs.

- Display of all relevant treatment unit parameters in the IEC 61217 scale convention as at least one option.
- A comprehensive beam modelling module that allows the configuration of complete geometric and dosimetric models for treatment unit photon and electron beams. The module shall have the following features:
  - ability to import measured beam profiles and output factors;
  - ability to model dynamic, fixed and internal wedges;
  - tools to allow the comparison of the beam model and measured data; and
  - security features that protect beam data and beam models from modification.
- A module to allow the creation of CT number to mass density or electron density data for various CT scanners for use by the photon and electron beam algorithms.
- User and password security that allows approval/locking of treatment plans and different levels of access to the functionality of the TPS based on the user's profile, e.g. administrator, planner, medical physicist, physician.
- A printer for A3/4 output of isodose distributions, beam shapes and treatment plan parameters.
- A module to allow export of beam block shapes to a third party block cutting device.
- A module to allow export of approved treatment plans and DRRs to an OIS.

3.6.4 Quality assurance

Quality assurance of the TPS is required to ensure stability of performance. Regular tests of features and results of algorithms are recommended. Particular importance needs to be paid to software upgrades. Any upgrades should be planned in advance and only occur outside normal patient treatment hours to allow sufficient time for testing of the performance of the upgraded software. Any new features of the TPS software included in the upgrade will need to be thoroughly commissioned. The availability of a test environment independent of the clinical software for testing of the upgraded software in advance of clinical release is particularly useful. International recommendations for quality assurance of TPSs are available:

- IAEA, *Commissioning and quality assurance of computerized planning systems for radiation treatment of cancer*, Technical Reports Series No. 430, 2004 *(60)*.
- IAEA, *Commissioning of radiotherapy treatment planning systems: Testing for typical external beam treatment techniques*, TECDOC 1583, 2008 *(61)*.
- The recommendations of various national professional societies are also available:
- AAPM, *Medical Physics Practice Guideline 5.a.: Commissioning and QA of Treatment Planning Dose Calculations – Megavoltage Photon and Electron Beams,* Journal of Applied Clinical Medical Physics, 2016 *(62)*.
- Canadian Partnership for Quality Radiotherapy, *Technical quality control guidelines for treatment planning systems*, 2015 *(63)*.
- Netherlands Commission on Radiation Dosimetry, *Quality assurance of 3D treatment planning systems for external photon and electron beams*, 2005 *(64)*.

A strong international recommendation for the clinical use of a TPS is to perform an independent calculation of the MU or treatment time for each treatment beam for every patient treatment plan as a safety and quality measure. This check should occur before first patient treatment, or if this is not possible (e.g. in an emergency treatment), then before 10% of the prescribed dose is delivered *(65)*. For simple 2D and 3D treatment techniques, this independent MU or time calculation can be performed manually or in a semi-automated fashion with spreadsheets or in-house developed functions. In the long term, a more efficient solution is to purchase, commission and maintain independent calculation software of which there are several commercially available. This publication does not include a technical specification for such software; however, it urges radiotherapy departments to adopt independent calculations and decide whether to develop an in-house solution or purchase commercial software.

Along a similar line as the recommendation for independent MU calculation is the international recommendation for patient-specific dosimetry measurement prior to first patient treatment for modulated techniques such as IMRT and VMAT or complex non-routine treatment techniques. This measurement directly confirms the TPS dosimetry and also confirms the correct transfer of information from the TPS to the treatment unit. The dosimetry measurement can be achieved with radiochromic film in a phantom (with film dosimetry software), or with a 2D electronic detector array (see Section 3.10.3) or with the linear accelerator's EPID if it is properly commissioned and calibrated (see Section 3.10.1).

3.7 Technical specifications for oncology information systems (OIS), including a record and verify system (RVS)

3.7.1 Description

The OIS is a software application that manages the flow and storage of electronic information, including patient data, in the radiotherapy department. It evolved out of the RVS *(66)*, which is a software application at the treatment console that confirms that the treatment parameters set on the treatment unit match those of the treatment plan and provides an electronic record of treatment. Nowadays, the OIS performs not only the functions of the RVS, but can also transfer treatment plan information and reference images from the TPS to the treatment unit, record detailed dose delivery information and images for each treatment session, include an image review module, manage the patient care pathway, include an electronic patient record and manage staff workflow through defined tasks, treatment unit schedules and appointments. The OIS needs to be compatible with the treatment units and TPS used in the radiotherapy department. The OIS uses the DICOM RT standard *(67)* for transfer of radiotherapy specific electronic information. The OIS may also connect to the hospitals information system using the Health Level Seven International (HL7) standard or equivalent and connect to a radiology PACS system for image transfer.

The implementation of an OIS will lead to large amounts of electronic data storage of patient information, including images, treatment plans and records of treatment delivery. The risks of electronic information loss are high in the event of server and computer failures if redundancy and back-up procedures are not in place. The radiotherapy department needs to engage information technology professionals to maintain the security and integrity of electronic data to prevent its unauthorized disclosure or modification that may compromise the radiotherapy process, prevent its loss from hacking and data corruption, and have in place strategies for backup, archive and retrieval.

3.7.2 Standard

- IEC, *Medical electrical equipment – Safety of radiotherapy record and verify systems*, IEC 62274:2005 *(28)*.

3.7.3 Technical specification

The OIS shall include:

- A secure, remote server and workstations, at least 19-inch monitors, keyboard, mouse and network capability.
- An UPS, including an automated daily back-up system to an external hard drive (or equivalent) with auto-detect and auto-shutdown after 20 minutes in the event of a power failure.
- A gateway that is HL7-compliant to a hospital information system (HIS) for patient administrative fields only (retrieve only). Mandatory fields shall be used to ensure and internally validate unique patient ID, e.g. first name, surname, gender, date of birth and national ID number.
- Workstations located in the treatment planning room that shall be capable of:
  - manual data entry of 2D cases, clinical markups and emergencies;
  - approval and entry of prescriptions and free text setup instructions;
  - upload of photographic images;
  - electronic chart checks;
  - image review of DRRs and treatment images (portal and setup); and
  - networking to the TPS to allow import of the patient administration data, beam delivery parameters and DRRs of graphically planned patients; the importation of data should be customized to correctly download and translate the TPS information to the scales and graduations of the department treatment units.
- A fully integrated workstation shall be provided for each of the treatment units, including all interfaces to fully operationalize the system for automated download and verification of the treatment parameters as well as capture and storage of portal and setup images. The workstations should include an in-room alternative monitor to facilitate patient identification and viewing of the setup instructions, including digital images. The system should be supported by a local UPS such that there is no loss of data in the event of a power failure to the treatment unit.

- Software features including:
  - digital photos of patient (ID and/or setup photos);
  - automated logging of cumulative dose;
  - free text entry of setup instructions or alerts based on cumulative dose;
  - hierarchical security features, including requirement for authorized approval of the dose prescription and field parameters prior to treatment;
  - complete log of activities and users;
  - generation of statistical data according to user-defined fields, e.g. diagnosis and managing consultant;
  - library of diagnoses according to the WHO *International classification of diseases*, 11th revision (ICD-11);
  - ability to correctly log cumulative dose in the event of a treatment interruption or termination; and
  - patient appointment scheduling.

3.7.4 Quality assurance

The OIS, including its RVS functions, requires routine checks to ensure stability of performance. Of particular importance are checks of uncorrupted flow of information between the TPS and treatment units. Upgrades and updates of the OIS software need to be managed to ensure no loss of patient data, no compromise of information and computer security and no loss of expected performance.

International recommendations for quality assurance of the OIS, including RVS are available:

- IAEA, *Record and verify systems for radiation treatment of cancer: Acceptance testing, commissioning and quality control*, Human Health Reports No. 7, 2013 *(66)*.

The recommendations of various national professional societies are also available:

- *ACPSEM ROSG Oncology-PACS and OIS working group recommendations for quality assurance*, Australas Phys Eng Sci Med, 37, 3–13, 2014 *(68)*.
- IPEM, *Guidance for the commissioning and quality assurance of a networked radiotherapy department*, Report 93, 2006 *(69)*.

3.8 Technical specifications for patient immobilization equipment

3.8.1 Description

Patient immobilization is needed to provide reproducible, stable and as comfortable as possible patient positioning during radiotherapy. Immobilization equipment crucially prevents/limits movement of the patient during treatment delivery. The type of immobilization equipment needed in the radiotherapy department depends on the range of treatments offered. Generally, different types of immobilization equipment are needed for different treatment sites, including the brain, head and neck, thorax, breast, pelvis and limbs. Specific immobilization equipment is needed for paediatric oncology. Most immobilization equipment is reusable, however, thermoplastic masks are single use and an ongoing supply is needed.

The immobilization equipment must be compatible with the department's type of treatment couch, including its type of indexing. Generally, lock bars provide the interface between the immobilization equipment and the treatment and simulator couches; the lock bars are fitted to the immobilization equipment with slots and the lock bar then locks to the treatment/simulator couch at the indexing points.

It is noted that sufficient storage shelving is required for immobilization equipment in the treatment room and simulator room and this needs to be considered in the design and fit-out of these rooms (see Section 5.1).

Currently, a few vendors are supplying couch tops with complete (all in one) sets of immobilization equipment. These may be explored to fit to the requirement of individual departments.

It is noted that the list of immobilization equipment in Table 5 is for the patient supine position, which is the most common setup. There are some treatment sites where a prone position is possible, for example brain, whole spine, breast and pelvis. However, such prone techniques, which require suitable immobilization equipment, should only be embarked upon after consultation with an experienced radiotherapy department and considering patient comfort as well as reproducibility of setup.

3.8.2 Technical specification

Table 5 lists the various immobilization equipment and accessories available for EBRT. Multiple sets of the base frame equipment (neck base frame, head and neck base frame, breast board, wing board) will be needed, one set for each simulator room and one set for each treatment room. The quantity of thermoplastic masks and vacuum bags depends on the workload of the radiotherapy department.

Table 5. Description of patient immobilization equipment

Item	Description
Brain	
Three-point thermoplastic masks	Perforated thermoplastic material suitable for three-point head base frame
Base frame	Base plate (low density) for head, three-point fixation, CT-compatible
Head support	Set of high-density head rests
Head and neck	
Five-point thermoplastic masks	Perforated thermoplastic material suitable for five-point head base frame
Base frame	Base plate (low density) for head and neck, five-point fixation, CT-compatible
Head support	Set of head rests
Breast	
Breast board	Breast board for supine patient support, capable of angling up to 25°, including arm and wrist support, CT-compatible
Thorax	
Wing board	Wing board with hand grips, CT-compatible
Pelvis	
Vacuum bags (10 per treatment unit)	Vacuum bag with skin of durable plastic, 70 cm x 100 cm (polyurethane casts are more durable and can be used instead)
Paediatric	
Three-point thermoplastic masks	Perforated thermoplastic material suitable for three-point head base frame
Five-point thermoplastic masks	Perforated thermoplastic material suitable for five-point head base frame
Paediatric headrests	Supine and prone paediatric headrests
Vacuum bags	Vacuum bag with skin of durable plastic, 70 cm x 70 cm (polyurethane casts are more durable and can be used instead)

Item	Description
Ancillary equipment	
Knee support	Contoured knee support
Feet support	Contoured feet support
Water bath*	Water bath for heating thermoplastic material, digital temperature display
Compressor	Compressor for vacuum bags capable of both inflate and deflate cycles, including connector
Radio-opaque skin markers	Radio-opaque point and wire markers for CT and kV planar imaging applications
Locking bars (multiple)	Lock bars compatible with the indexing system of the treatment couches and with immobilization equipment bases
Bolus	A range of thicknesses of 0.3 cm–2.0 cm (depending on photon energies and electron energies), skinless, 30 cm x 30 cm
Gonad shield	Lead shielded, a range of sizes, with holding stand
Eye shield	Rounded metal shields for eye coverage, coated, suitable for shielding orthovoltage or megavoltage electron beams

*A hot-air oven is an alternative to a water bath for heating thermoplastic material.

3.9 Technical specifications for mould room equipment

3.9.1 Description

Mould room equipment will be required for a cobalt-60 teletherapy practice, if electron beams are to be used clinically or if the LINAC does not include an MLC. Also, even if the linear accelerator has an MLC there may be treatment cases that require in addition a customized block. In these cases, customized cut-outs (electrons) or customized blocks (photons) will need to be manufactured for patients in a mould room facility. For transfer of block shapes from the TPS, there should be provided a link to the TPS, either electronically in DICOM format or through the printouts of the blocks or cut-outs at a given distance to the source of radiation (usually at the isocentre plane).

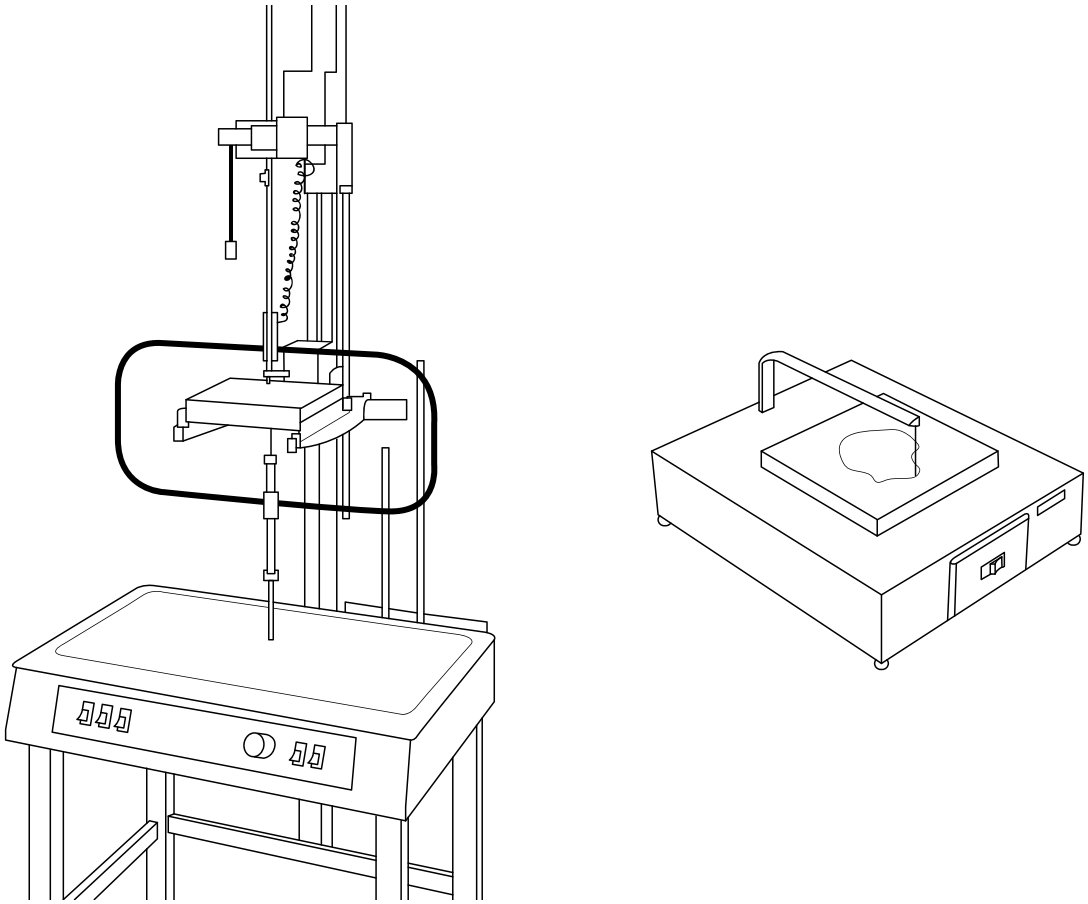
3.9.2 Technical specification

Table 6 lists the various mould room equipment for EBRT. Personal protective equipment (gloves, eyewear, gown) and hand wash will also be required.

Table 6. Description of mould room equipment for EBRT

Item	Description
Fume cupboard	Cabinet with work bench, sink, floor mat and integrated air cleaning system
Melting pot (alloy dispenser)	Alloy dispenser for alloy melting, temperature control up to 120 °C with digital readout, alloy capacity at least 50 kg
Stock of LMPA	LMPA, 70 °C melting point (alloy of bismuth, lead, tin and cadmium)
Cooling plate	Aluminium cooling plate, at least 30 cm x 30 cm, levelling adjustment
Foam blocks (consumable)	Styrofoam blocks 2 cm thick (electrons) and 7 cm thick (photons)
Hot-wire cutter for electron cut-outs (Figure 8)	Foam cutter for perpendicular cutting, heated metal cutting wire, able to handle foam blocks up to 25 cm x 25 cm, stock of cutting wire
Hot-wire cutter for photon beam blocks (Figure 8)	Manual or automated foam cutter for divergent cutting, adjustable height of block arm and source point, able to handle foam blocks up to 7 cm x 30 cm x 30 cm, stock of cutting wire
Tools	Block grip tool, metal file, clamps, alloy pourer

Figure 8. Hot wire cutters for photon beam blocks (left) and electron cut-outs (right)



3.9.3 Quality assurance

On an individual patient basis, the block shape or cut-out shape shall be compared with a template shape generated by the TPS from the approved treatment plan or simulator image.

3.10 Technical specifications for dosimetry and quality control equipment

3.10.1 Description

Dosimetry equipment is required to fully characterize the radiotherapy beams from LINAC and cobalt-60 teletherapy units. *Reference dosimetry equipment* establishes and maintains the beam dosimetry under reference conditions. *Relative dosimetry equipment* characterizes the radiation beams under non-reference conditions and in three dimensions. Radiochromic film is a useful 2D relative dosimeter in radiotherapy to complement point detector dosimeters. Additionally, an electronic 2D detector array will assist in the commissioning of a dynamic wedge system and, if available, the commissioning, and ongoing quality assurance of, an IMRT service. 1D detector arrays are also commercially available and can be used for commissioning dynamic wedges, but are not suitable for the IMRT application.

Separate to dose measuring equipment, *quality control equipment* comprises various tools to test the performance of the various imaging, optical and mechanical components of the treatment equipment and simulation equipment.

In vivo dosimetry equipment is required to confirm the dose to the patient during treatment and verify doses to various relevant organs at risk, including for example, the lens of the eye, testes and skin.

Separate to the radiation oncologist's prescribed dose to the patient is the significantly lower radiation dose received by the patient from simulation X-ray imaging and in-room verification X-ray imaging. This imaging dose should be quantified with *radiology dosimetry equipment*. It is noted that a clinical qualified medical physicist trained only in radiation oncology dosimetry may not have the necessary skills to use and interpret the results of radiology dosimetry equipment and kV image quality phantoms. In this case, the radiotherapy department should consult with a clinically qualified medical physicist in diagnostic radiology.

The concept of end-to-end testing has become common in radiotherapy dosimetry as a part of overall quality assurance. It is recognized that it is not sufficient from a quality and safety perspective to commission only the individual components of the treatment process: the simulator, the TPS and the treatment unit, but in addition to perform an end-to-end test. In this test, an anthropomorphic patient-like phantom is taken through the whole process of radiotherapy from simulation to treatment planning to treatment delivery. Dose delivered to the phantom is measured with dosimetry equipment embedded in the phantom. The measured dose delivered should match the expected dose from the treatment plan. IAEA has published a methodology for end-to-end testing of 3D-CRT *(61)* and also a similar methodology for testing of IMRT *(70,71)*. End-to-end testing relies on the availability of suitable anthropomorphic phantoms with detector cavities and holders matched to the department's detectors. Such phantoms are available for different treatment regions: head and neck phantoms, thorax phantoms, pelvis phantoms and paediatric phantoms. Radiotherapy departments are strongly encouraged to perform end-to-end tests with anthropomorphic phantoms during commissioning of new equipment and at the introduction of new techniques. Given the high cost of these phantoms and the low frequency of their use, radiotherapy departments are encouraged to consider sharing such phantoms at a national level.

A recent trend in dosimetry and quality control of LINACs is to use the EPID as a tool for quality control tests. The EPID has been used, for example, in patient-specific IMRT quality assurance, MLC performance tests and radiation field size tests *(72–74)*. The advantages of using the EPID are in its efficiency in performing quality control tests and in replacing the use of consumable radiochromic film. Careful commissioning of the EPID as a dosimeter is required. If the radiotherapy department is considering using the EPID for quality control, then licences, calibrations and image access are required.

3.10.2 Standards

- IEC, *Medical electrical equipment – Dosimeters with ionization chambers as used in radiotherapy*, IEC 60731:2011+AMD1:2016 CSV *(75)*.
- IEC, *Medical electrical equipment – Dosimeters with ionization chambers and/or semiconductor detectors as used in X-ray diagnostic imaging*, IEC 61674:2012 *(76)*.

3.10.3 Technical specification

Tables 7–11 describe the dosimetry and quality control equipment needed for the practice of EBRT. Figures 9–11 illustrate various examples of dosimetry and quality control equipment.

Table 7. Reference dosimetry equipment

Item	Description	Comments
Farmer type ionization chamber (one reference per department and one field per treatment unit)	Waterproof Farmer type ionization chamber for reference dosimetry with graphite wall material. Active volume approximately 0.6 cm^3. TNC or BNC connector. SSDL or PSDL calibration in terms of absorbed dose to water in conjunction with an electrometer. Cobalt-60 build-up included.	Calibration at PSDL or SSDL required every two years.
Plane parallel ionization chamber (one per department, only required for electron beams)	Plane parallel chamber volume with approximately 0.4 cm^3 for electron beam reference dosimetry with BNC or TNC connector.	Calibration at PSDL or SSDL required every two years or alternatively cross-calibrated against reference Farmer type chamber in the radiotherapy department.
Triaxial cables (one per electrometer plus one spare)	Triaxial 20 metre extension cables with BNC or TNC connector.	Purchase of a spare cable is recommended as these cables often fail through multiple handling or mishandling.
Reference class electrometer (one per department)	Single channel electrometer for radiotherapy dosimetry, reference class according to IEC 60731, BNC or TNC connector, including carry case.	Internal desiccator needs replacement at intervals depending on humidity levels. Calibration at PSDL or SSDL required every two years.
Field class electrometer (one per treatment unit)	Single channel electrometer for radiotherapy dosimetry, field class according to IEC 60731, BNC or TNC connector.	As above.
Thermometer (one per treatment unit)	Glass thermometer (spirit type) 0 °C–50 °C with scale resolution 0.2 °C or less. Include a calibration certificate.	The use of mercury type rather than spirit type should not be allowed.
Barometer (one or two per department)	Digital or aneroid barometer with 0.01 kPa resolution, calibration certificate, with a pressure reading range suitable to the elevation of the radiotherapy department's location.	The pressure range of the barometer is important for radiotherapy departments at high elevations. Atmospheric pressure reduction is of the order of 1% per 80 m elevation.
Strontium-90 check source for Farmer type chamber (one per department)	Strontium-90 check device for Farmer type chamber, including holder for Farmer type chamber.	Inclusion of radioactive material requires following requirements of the local radiation regulator.

Item	Description	Comments
Strontium-90 check source for plane parallel chamber (one per department)	Strontium-90 check device for plane parallel chamber, including holder for plane parallel chamber.	As above.
Constancy meter (one per treatment unit)	System for automated measurement on a daily basis of LINAC beams or a cobalt-60 teletherapy unit beam. Multiple detectors (at least five) for measurements of beam symmetry as well as beam output are required. The meter shall include software for control and calibration of the system, as well as long-term display and storage of readings. It should be possible to set tolerance limits for daily readings and for the associated software to notify of out-of-tolerance readings.	
Water phantom (one per department)	Water phantom for reference dose measurements according to IAEA Technical Reports Series No. 398 dosimetry protocol. The measurement depth to be adjusted manually or with a motorized system up to a depth of at least 20 cm. Measurement depth to be adjustable in 0.1 mm steps or finer. Holder for Farmer type chamber and plane parallel chamber to be included.	

Table 8. Relative dosimetry equipment

Item	Description	Comments
Radiation beam data acquisition system	3D scanning water tank for linear accelerator commissioning, including scanning water tank, lift table, water reservoir, electrometer/controller, laptop computer, software, two approximately 0.13 cm^3 waterproof ionization chambers and associated cables. Water tank scanning dimensions up to 480 x 480 x 400 mm^3. Detector position accuracy of ±0.1 mm and position reproducibility of ±0.1 mm. Water tank with motorized scanning capability in the X, Y and Z planes for ionization chambers or diode detectors. A lift table with vertical travel range of 500 mm and rotation in the XY plane of ±5 degrees. A dual electrometer system and control unit with bias range of 50–400 V, minimum resolution of 10 fA, and leakage current <250 fA. A control unit to control movement of moving mechanisms and interface with electrometer. A water reservoir with bi-directional water transport to and from the water tank and volume capacity more than 200 litres. One portable laptop computer with Windows operating system with connectivity to the control unit. Software for data acquisition with scan optimization, data handling and analysis and TPS transfer environment. A software feature to allow export of beam profile data or depth dose data in text format to Microsoft Notepad or Excel is desirable. Software modules should allow transfer of beam data to commercial TPS. Two waterproof thimble chambers of active volume approximately 0.13 cm^3. Holders for Farmer, thimble, plane parallel and diode detectors. Connector cables between the computer, controller and water tank. Two TNC or BNC triaxial cables compatible with ionization chamber detectors, diode detectors and dual electrometer system and one spare triaxial cable equivalent to above.	Specification will need to include which particular commercial TPS the beam data are to be exported to. The laptop computer for the control software may be purchased locally and separately.
Plane parallel ionization chamber	Small volume (approximately 0.05 cm^3) plane parallel chamber for electron beam relative dosimetry with BNC or TNC connector.	
Scanning diode set	Waterproof shielded diode, unshielded diode and reference diode with active diameter less than or equal to 2 mm.	
Radiochromic film	Self-developing radiochromic film with sensitivity up to 10 Gy for radiotherapy dosimetry applications.	Consumable
Film scanner	Flatbed transmission scanner (A4 or A3 size) with separate red, green and blue channels.	
Film analysis software	Software to manage radiochromic film dosimetry, including calibration feature, image display and ability to compare film dose planes with TPS generated dose planes. At least one perpetual licence.	
Build-up caps	PMMA or brass build-up caps for Farmer type chamber and thimble chamber suitable for photon beam energies 6 MV and 10 (15 or 18) MV.	
ESTRO mini-phantom	ESTRO mini-phantom according to ESTRO Booklet No. 3 *(77)* for in air measurements, including a cavity for a Farmer type chamber mounted parallel to the beam axis (only required if using ESTRO Booklet No. 3 formalism for independent MU checks).	

Item	Description	Comments
Solid water block set	Set of plates manufactured of water equivalent material consisting of at least one plate of 0.1 cm thickness, two plates of 0.2 cm thickness, one plate of 0.5 cm thickness and 29 plates of 10 mm thickness. Plate outer dimensions: 30 cm x 30 cm. Adapter plates for Farmer type chamber, 0.13 cm^3 thimble chamber, 0.4 cm^3 plane parallel chamber and 0.05 cm^3 plane parallel chamber to be included.	
Two-dimensional detector array (for dynamic wedge or IMRT)	A detector array for radiotherapy dosimetry with more than 700 individual detectors, with centre-to-centre spacing less than or equal to 1 cm and covering at least 20 cm x 20 cm in a 2D array, with an appropriate phantom. Software shall be provided that controls the data collection from the detector array, allows import of dose planes from commercial TPS and provides tools for comparison of the measured and TPS dose planes. A universal gantry mount shall be included to allow the detector array to be attached to the LINAC head.	1D detector arrays are also commercially available and can be used for commissioning dynamic wedges, but are not suitable for the IMRT application.

Table 9. Quality control equipment

Item	Description	Comments
Digital level	Digital level with 0.1° display resolution.	
LINAC alignment phantom	Cube phantom or rotating test plate that allows checking the position of LINAC cross-hairs, lasers and light field size at gantry angles 0°, 90° and 270°.	
Laser alignment phantom (CT simulator)	PMMA phantom with 2 mm wide notches for alignment to lateral, ceiling and sagittal lasers.	
Electron density calibration phantom	Phantom for CT number to electron density calibration of CT scanner for radiotherapy treatment planning. The phantom shall have plugs of a range of electron densities from lung to bone. The body of the phantom shall be made of water equivalent material. The electron densities of the various plugs and phantom body shall be given in the user manual.	
EPID image quality phantom	Phantom and software for EPID image quality tests, including high-contrast resolution and low-contrast resolution.	
Image quality phantom for kV planar imaging	Phantom for image quality tests of general radiography X-ray units, including low-contrast resolution, high-contrast detectability, line pair resolution, and sensitometric analysis.	
Image quality phantom for kV volumetric imaging	A volumetric phantom suitable for CT image quality tests, including CT number, uniformity, noise, slice thickness, high-contrast resolution and low-contrast resolution.	
Graph paper	A3 and A4 graph paper, 1 mm grid.	
Metal rulers 1 m and 30 cm	Metal rulers 1 m and 30 cm with at least 1 mm resolution.	

There are competing detector technologies for in vivo dosimetry, including MOSFET, diode, thermoluminescence dosimeter (TLD), radiophotoluminescence dosimeter (RPLD), optically stimulated luminescent dosimeter (OSLD) and film *(78)*. The specification in Table 10 is for the widely used diode system, however, the specification could be modified to incorporate other technologies. Diodes for in vivo dosimetry have the advantage of instantaneous readout and reusability.

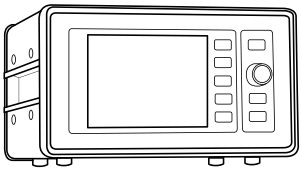
Table 10. In vivo dosimetry equipment

Item	Description	Comments
Photon entrance dose detector	Diode detectors of construction with flat surface and build-up material sufficient for photon energies in the range of 6 MV–15 MV.	Temperature, dose rate and energy dependence of diodes should be considered in calibration and clinical use.
Electron entrance dose detectors	Diode detectors of construction with flat surface and build-up material sufficient for electron energies in the range of 6 MeV–18 MeV.	
Surface entrance detector	Diode detector of construction with flat surface and minimal build-up.	
Out-of-field detector	Diode detector with 5 mm surrounding build-up material for out-of-field dosimetry.	
Controller and electrometer	Multi-channel controller and electrometer allowing calibration and reading of diode signals.	

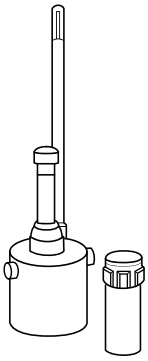
Table 11. Radiology dosimetry equipment

Item	Description	Comments
Ionization chamber	Ionization chamber with approximate active volume 6 cm^3, X-ray beam calibration, energy dependence less than ±2% in kV energy range.	
kVp meter	Solid state kVp meter for radiography in the range of 50–150 kVp, resolution 0.1 kVp.	
Controller	Combined electrometer and display, capable of displaying dose, dose rate, exposure time in milliseconds and separately kVp (with kVp meter).	
Aluminium filter set	High purity (99%) aluminium filter set 100 mm x 100 mm, total thickness at least 7.5 mm, minimum thickness 0.05 mm.	
Pencil ionization chamber (for CT dosimetry)	Pencil ionization chamber, 10 cm active length, X-ray beam calibration, energy dependence less than ±3% in kV energy range.	
CT phantom	Nested PMMA phantom for CTDI measurements, 32 cm diameter, 15 cm length, central and peripheral inserts for pencil chamber.	

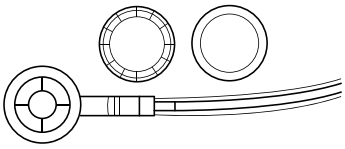
Figure 9. Examples of dosimetry equipment



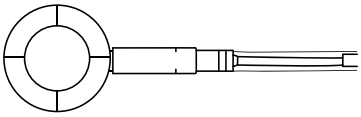
Single channel electrometer



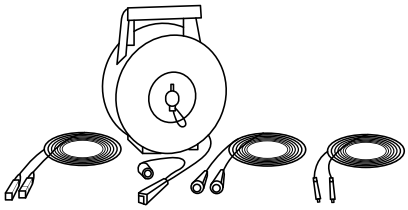
Strontium-90 check source



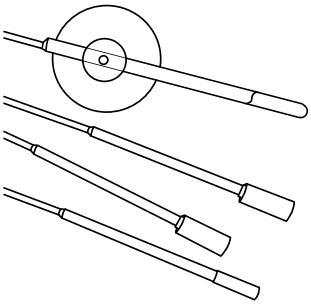
Small volume plane parallel chamber



Plane parallel chamber

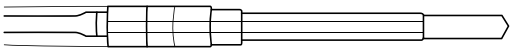


Triaxial cables



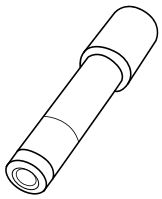
Scanning diode set

Water proof thimble chamber

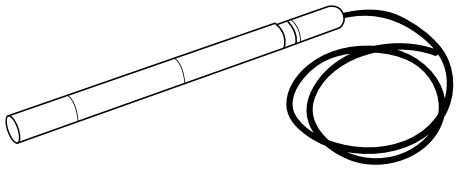


Farmer type chamber

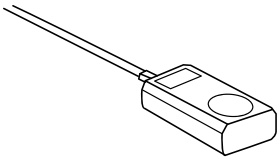
Figure 10. Examples of dosimetry equipment



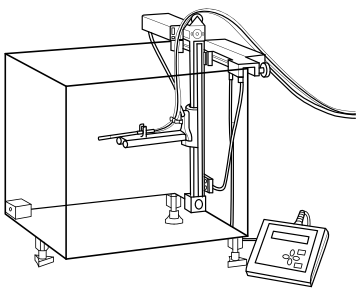
Diagnostic X-ray chamber



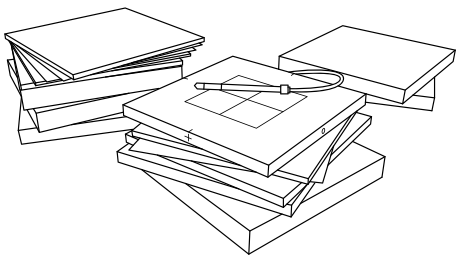
CT pencil chamber



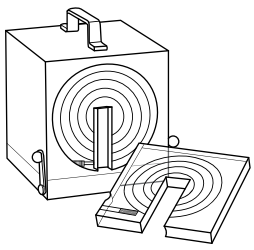
Superficial X-ray chamber



1D water phantom

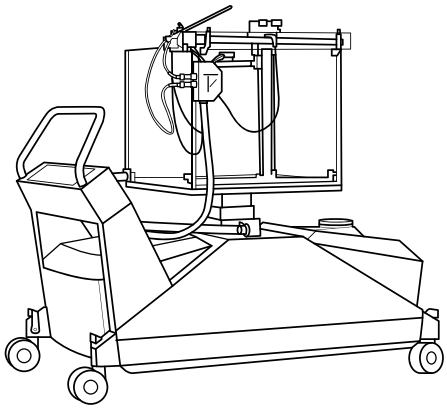


Solid water plates

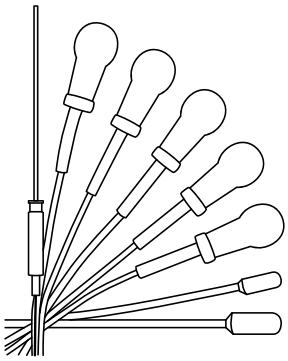


PMMA block set for superficial X-rays

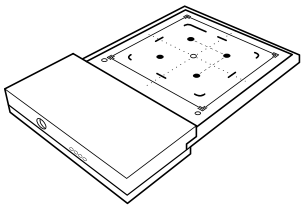
Figure 11. Examples of dosimetry equipment



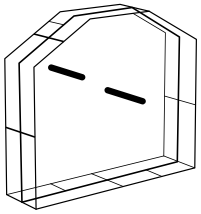
Radiation beam data acquisition system



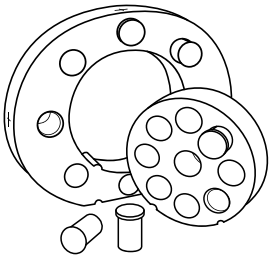
Diode in vivo dosimeters



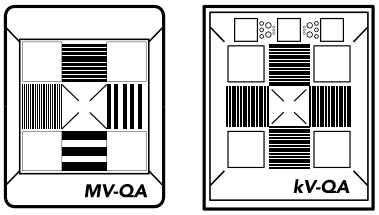
Constancy meter



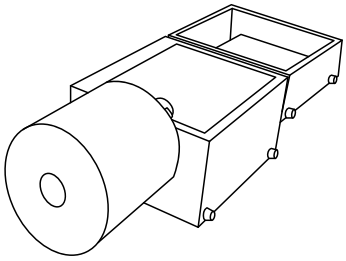
CT laser QA phantom



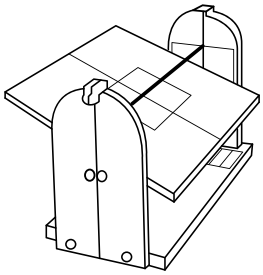
CT electron density phantom



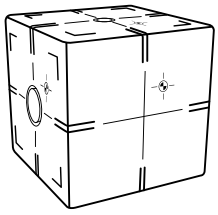
kV and MV planar image quality test phantoms



kV volumetric image quality test phantom



Linac rotating test plate



Linac cube phantom

QA=quality assurance

3.10.4 Radiation safety and protection

The only radiation emitting device among the dosimetry equipment is the strontium-90 check source. This low activity beta source is permanently housed in a lead container. The source shall only be used by clinically qualified medical physicists. Secure storage of the source in its container is required. Local standards and regulations for transport, use and storage of radioactive material shall be followed.

3.10.5 Quality assurance

Stability of the performance of dosimetry equipment is crucial in radiotherapy. Reference dosimetry equipment shall be calibrated every two years at a secondary standards dosimetry laboratory (SSDL) or a primary standards dosimetry laboratory (PSDL). International recommendations for quality control tests for radiotherapy dosimetry equipment are available:

- IAEA, *Setting up a radiotherapy programme: Clinical, medical physics, radiation protection and safety aspects*, 2008 (Appendix XIII, Table 25) *(4)*.
- IAEA, *Development of procedures for in vivo dosimetry in radiotherapy*, Human Health Reports No. 8, 2013 *(78)*.

The recommendations of various national professional societies for quality assurance of dosimetry equipment are also available:

- AAPM, *Comprehensive QA for radiation oncology*: *Report of Task Group 40*, 1994 *(45)*.
- AAPM, *Diode in vivo dosimetry for patients receiving external beam radiation therapy: Report of Task Group 62*, 2005 *(79)*.
- Canadian Partnership for Quality Radiotherapy, *Technical quality control guidelines for major dosimetry equipment*, 2015 *(80)*.

3.11 Technical specifications for radiation safety equipment

3.11.1 Description

The survey meter is a portable ionizing radiation detector capable of protection level detection in a LINAC or cobalt-60 teletherapy facility. The survey meter is used for comprehensive surveys upon the installation of treatment equipment and simulation equipment and periodically thereafter.

Access to a neutron meter is required for LINAC with photon beam energy 10 MV or higher. In that case, neutron dose measurements are required at the entrance to the treatment room at commissioning and periodically thereafter.

Radiotherapy staff are radiation monitored in the workplace through implementation of a personal radiation monitoring service. Staff wear passive radiation detector badges during work hours. The badges are exchanged every one to three months and the service provider reads the badges and provides a dose report for all staff members.

In addition to the passive radiation detector service, the availability of direct readout electronic monitors is recommended for various situations that may involve exposure, including handling of radioactive material or source exchanges.

3.11.2 Standards:

- IEC, *Radiation protection instrumentation – Dosimetry systems with integrating passive detectors for individual, workplace and environmental monitoring of photon and beta radiation*, IEC 62387:2020 *(81)*.
- IEC, *Radiation protection instrumentation – Alpha, beta and alpha/beta (beta energy >60 keV) contamination meters and monitors*, IEC 60325:2002 *(82)*.
- IEC, *Radiation protection instrumentation – Neutron ambient dose equivalent (rate) meters*, IEC 61005:2014 *(83)*.
- IEC, *Radiation protection instrumentation – Transportable, mobile or installed equipment to measure photon radiation for environmental monitoring*, IEC 61017:2016 *(84)*.

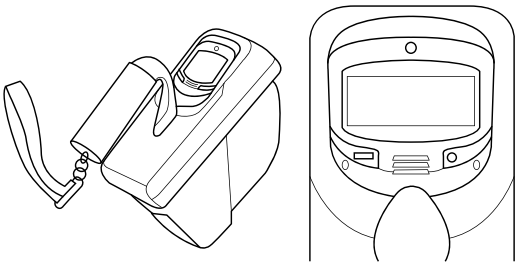
3.11.3 Technical specification

Table 12 provides a description of radiation safety equipment needed for EBRT. Figure 12 illustrates examples of radiation safety equipment.

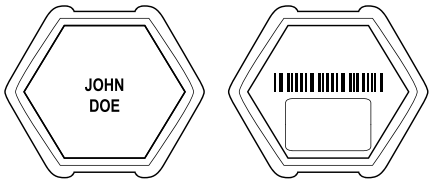
Table 12. Radiation safety equipment

Item	Description	Comments
Survey meter	A portable ionization chamber-based survey meter capable of detecting X-ray and gamma radiation above 25 keV, integrated display, dose rate and integrated dose modes, dose rate range of 0.5 μSv/hr–50 mSv/hr, energy dependence less than 20% in the range of 50 keV–1 MeV, calibration certificate included.	Protection level calibration with caesium-137 required every two years.
Neutron meter (if photon energies 10 MV or higher in clinical use)	A spherical rem-counter probe that can be used for measurement of ambient dose equivalent rate (Sv/hr) for neutrons according to the International Commission on Radiological Protection (ICRP) Publication 60. Measuring range of 30 nSv/hr–80 mSv/hr shall be covered and the energy dependence shall be around ±30% of 50 keV–10 MeV. The sensitivity shall be less than 3 counts per nSv. The probe shall have a calibration that is traceable to primary standards.	Given the expense, infrequent use and difficulty in accessing calibrations, radiotherapy departments are encouraged to borrow or share a neutron survey meter rather than purchase their own.
Personal radiation monitoring service	A service is required to provide radiation monitoring of staff with passive radiation badges sensitive to X-ray, gamma and beta radiation. The radiation badges shall be exchanged every three months. Reports of radiation dose received by the badges shall be provided promptly after the wearing period. The report shall identify any dose readings above national dose limits.	Dose reports may have to be forwarded to the radiation regulator. The monitoring period specified by regulatory bodies is typically one to three months.
Electronic personal dosimeter	A direct readout personal radiation monitor, audible dose rate indication, energy range of 45 keV–1.2 MeV, display of accumulated dose in Sv, with reset function.	

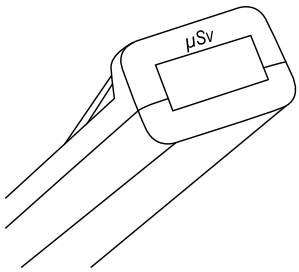
Figure 12. Examples of radiation safety equipment



Survey meter



Personal radiation badge



Electronic personal monitor

3.11.4 Quality assurance

Recalibration of radiation safety equipment is required at regular intervals. The services of an SSDL or PSDL with protection level calibration services should be used.

3.12 Technical specifications for orthovoltage X-ray units

3.12.1 Introduction

Orthovoltage X-ray units are often intended as an alternative to electron beams from LINACs. The application of low-energy superficial X-ray units can be extended to deeper treatments with the procurement of an orthovoltage X-ray unit. Both superficial X-ray units and combined superficial/orthovoltage units are covered in this section.

3.12.2 Description

Superficial X-ray units generally operate in the range of 50–100 kVp. Short SSDs are implemented in the range of 5–15 cm to maximize the dose fall-off with depth in water. The radiation field is defined by applicators of various sizes and customized shapes can be created with lead cut-outs. The unit comes with various aluminium filter sets, which with different kV settings, create radiation beams of different energies. Typical beam energies and their depth dose in water are shown in Table 13 from compiled data from the British Journal of Radiology, Supplement 25 *(20)*. Beam-on duration is usually controlled with a timer system.

Table 13. Depth dose of superficial X-rays in water

	Beam energy (mm Al HVL)					
Parameter	**0.7**	**1**	**2**	**3**	**4**	**8**
Percentage depth dose at surface	100%	100%	100%	100%	100%	100%
Percentage depth dose at 0.5 cm depth	65.0%	77.1%	82.2%	85.4%	86.7%	89.0%
Percentage depth dose at 2.0 cm depth	26.6%	35.2%	46.0%	51.0%	53.7%	59.5%

Note: The data are for a field size of 5.0 cm diameter and SSD of 10 cm. The beam energy is expressed as half-value-layer of aluminium (Al HVL).

Source: Data from the British Journal of Radiology, Supplement 25 *(20)*.

Orthovoltage X-ray units (Figure 13) include the capability of superficial X-ray therapy, but by extending the potential up to 300 kV, they allow the possibility of treating deeper tumours than the superficial X-ray unit. The combined superficial/orthovoltage unit will typically operate in the range of 50 kV–300 kV. As well as applicators at short SSDs for superficial therapy, the unit will include applicators for use at SSDs of 25 cm–50 cm for higher energies from approximately 100 kV–300 kV. The unit comes with various aluminium and copper filter sets, which with different kV settings, create radiation beams of different energies. Typical orthovoltage beam energies and their depth dose in water are shown in Table 14 from compiled data from the British Journal of Radiology, Supplement 25 *(20)*. Beam-on duration is usually controlled by an internal monitor chamber that must be calibrated for each beam energy.

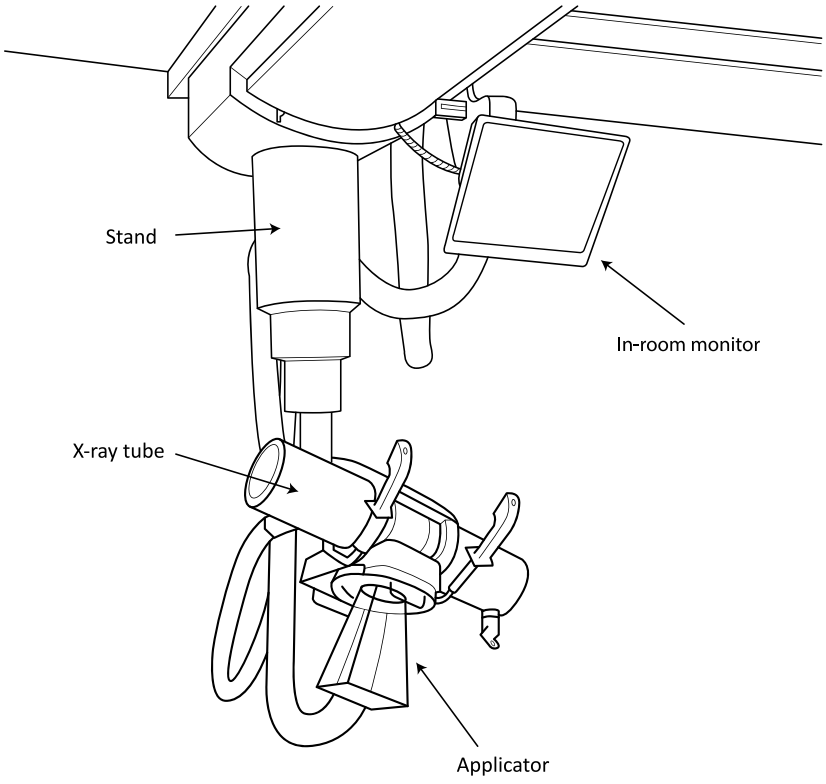
Table 14. Depth dose of orthovoltage X-rays in water

	Beam energy (mm Cu HVL)				
Parameter	**0.5**	**1.0**	**2.0**	**3.0**	**4.0**
Percentage depth dose at surface	100%	100%	100%	100%	100%
Percentage depth dose at 2 cm depth	77.1%	80.5%	81.8%	81.9%	83.0%
Percentage depth dose at 5 cm depth	44.8%	49.5%	52.3%	53.6%	55.3%

Note: The data are for a field size of 5.0 cm x 5.0 cm and SSD of 50 cm with closed applicators. The beam energy is expressed as half-value-layer of copper (Cu HVL).

Source: Data from the British Journal of Radiology, Supplement 25 *(20)*.

Figure 13. Features of an orthovoltage X-ray unit



3.12.3 Standard

- IEC, *Medical electrical equipment – Part 2–8: Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV*, IEC 60601-2-8:2010+AMD1:2015 CSV *(85)*.

3.12.4 Technical specification

The superficial/orthovoltage unit shall include:

- An X-ray tube capable of producing X-ray energies up to 300 kV with a cooling system. A minimum of three X-ray energies, one low energy of 1.0–3.0 mm Al HVL, and two medium energies of 1–3 mm Cu HVL are required.
- An X-ray generator with a voltage regulator to operate at a range of potentials up to 300 kV.
- A filter for each therapeutic X-ray beam and one additional filter that blocks the entire beam for warm-up of the tube.
- A range of X-ray tube current settings so that a constant therapeutic dose-rate can be achieved for each energy from the X-ray unit.
- An internal monitor ionization chamber whose response is corrected for ambient conditions such as temperature and pressure or a timer. Dual systems (chamber or timer) are required. It shall be possible to set the output of the machine such that standard reference dosimetry can be maintained within +/-2%.
- Movement of the X-ray tube relative to the floor in the following directions: vertically, horizontally, as well as rotation around the column or tube stand, including vertical and axial inclination of the tube by rotation.
- A locking mechanism with a brake so that the X-ray unit will not move during treatment even in the event of a failure of power. It shall be possible to release the vertical brake in the event of power failure to remove the patient.
- A computerized control console with an alternative display inside the treatment room. The control console shall have an on/off removable key, allow selectable kilovoltage settings interlocked to filter interlocks on the treatment head and have operation modes controlled by passwords. The control console shall have a feature for back-up of system and patient data. The control software shall have the following features:
  - a check that the correct filter and applicator is selected before the start of treatment;
  - inhibition of radiation if kV or mA exceeds 3% from the selected value;
  - inhibition of radiation if planned treatment time exceeded or stop caused by the secondary timer/monitor chamber;
  - display of digital photos of patient (ID and/or setup photos);
  - complete log of activities and users;
  - patient appointments;
  - ability to correctly log cumulative dose in the event of a treatment interruption or termination;
  - password protection of data; and
  - import/export of data to an RVS using DICOM RT protocols.
- An internal battery or UPS to retrieve patients' treatment data and to control shutdown of the system in the event of mains power failure.
- A removable patient support table with wheels and brakes, and the table surface should have a flat top.
- Two colour CCTV systems for viewing of the patient from the console (one with pan, tilt and zoom) and a bi-directional audio intercom system.
- A set of open ended applicators for operation at a fixed focus to source distance (FSD) less than or equal to 30 cm, for circular field sizes of a diameter 2 cm–8 cm.
- A set of closed applicators for an FSD of at least 50 cm, for rectangular field sizes ranging from 6 cm x 6 cm to 20 cm x 20 cm, but must include a 10 cm x 10 cm and 20 cm x 20 cm square applicator.
- A supply of metal sheets for creating customized cut-out shapes at the end of the applicator.

Along with the superficial/orthovoltage X-ray unit, the radiotherapy department will require dosimetry, quality control and radiation safety equipment. The equipment described in Sections 3.10 and 3.11, including water phantom, electrometer, film and survey meter, can be used for the X-ray unit, however, specialized dosimetry equipment is also required, as shown in Table 15.

Table 15. Additional dosimetry equipment for superficial/orthovoltage X-ray dosimetry

Item	Description
Farmer type chamber	Farmer type chamber, approximate active volume 0.6 cm^3, calibration certificate in terms of air kerma in the range of 80–300 kV, TNC or BNC connector, holder for in-air measurements.
Plane parallel chamber	Plane parallel chamber consistent with IAEA Technical Reports Series No. 398 Table 5, 0.2 cm^3 active volume, calibration certificate in terms of air kerma in the range 30–80 kV, TNC or BNC connector.
PMMA block set	Set of PMMA blocks, minimum thickness 1 mm, including holder for plane parallel chamber.
Aluminium plates	Set of aluminium plates, greater than 99% purity, 100 mm x 100 mm in size, total thickness 20 mm, smallest thickness 0.05 mm, including holder.
Copper plates	Set of copper plates, greater than 99% purity, 100 mm x 100 mm in size, total thickness 10 mm, smallest thickness 0.1 mm, including holder.
Pinhole applicator	Pinhole applicator for determining the focal spot size.

3.12.5 Radiation safety and protection

The X-ray tube of the superficial/orthovoltage unit requires radiation safety and protection measures. The unit will be housed in a lead-lined room. A control room housing the control console will be in a neighbouring contiguous room. The thickness of lead shielding required can be calculated using the methodology in IAEA Safety Reports Series No. 47 *(18)*. Consideration must be given to shielding in the floor, walls and ceiling as the beam can be pointed in various directions. Under the International Basic Safety Standards classification system, the treatment room will be designated as a *controlled area*. The control room and other areas adjacent to the treatment room, such as any walkway between the treatment room entrance and control room, will also be designated as controlled areas. A comprehensive radiation survey in the vicinity of the treatment room shall be conducted after installation to ensure compliance with local regulations for dose limits for staff and members of the public. The survey shall be conducted with a calibrated survey meter.

Safety features as part of the premises to prevent accidental exposure of staff and members of the public include:

- facility access interlock;
- X-ray on and X-ray ready illuminated signs at entrances and within the room;
- ionizing radiation trefoil warning signs at entrances;
- audio visual communication between the treatment room and control room; and
- emergency-off buttons in the treatment room and control room.

3.12.6 Quality assurance

To ensure safety and quality in patient treatment, the superficial/orthovoltage X-ray unit shall be subject to routine quality control measures. Regular testing of beam dosimetry is required. Reference dosimetry shall be carried out with calibrated dosimeters using a code of practice based on dose to water such as IAEA Technical Reports Series No. 398 *(34)* or a code of practice based on air kerma such as those of IPEM *(86,87)* and AAPM *(88)*. International recommendations for quality control tests for superficial/orthovoltage X-ray units are available:

- IAEA, *Setting up a radiotherapy programme: Clinical, medical physics, radiation protection and safety aspects*, 2008 *(4)*.

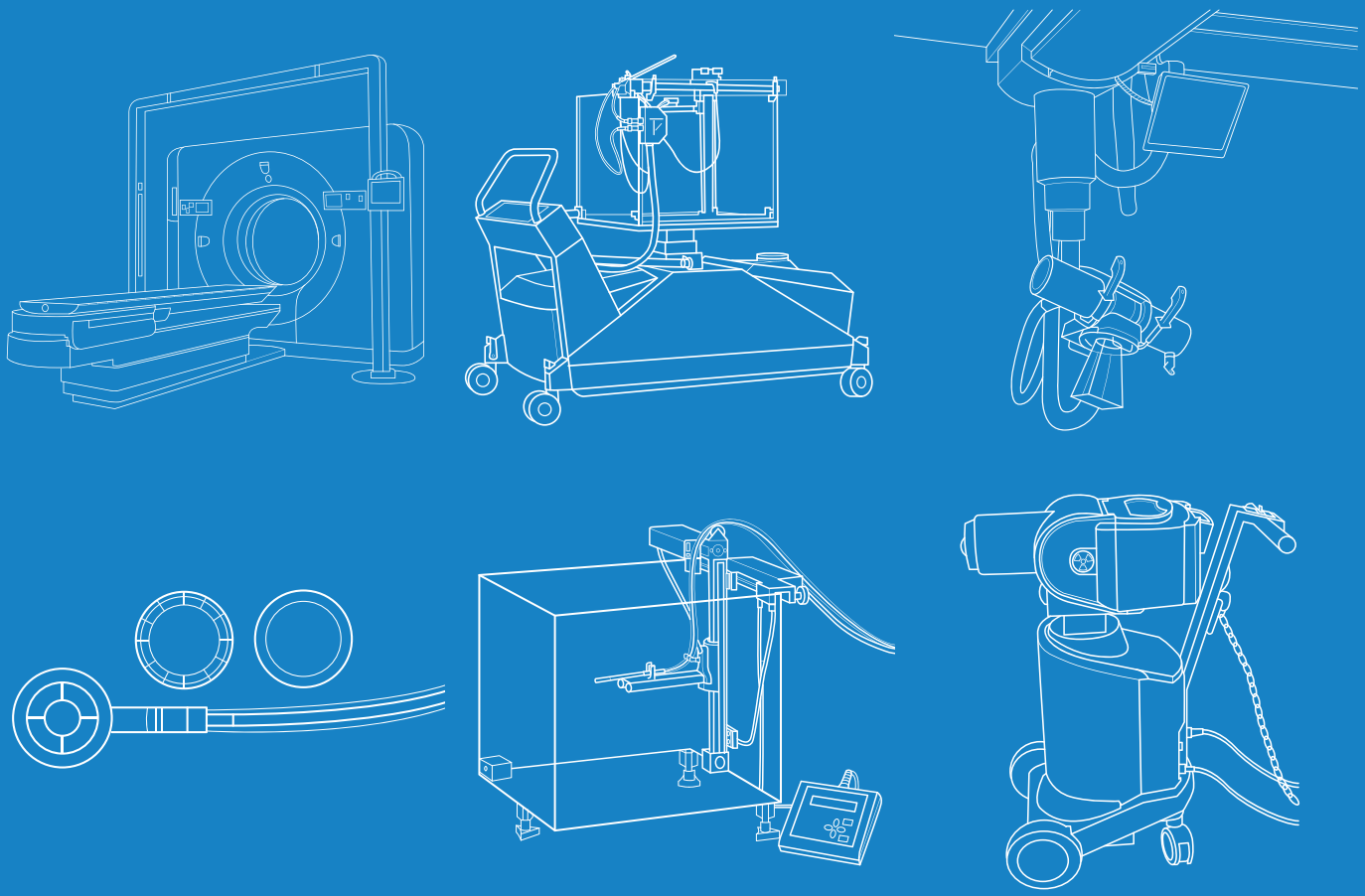
The recommendations of various national professional societies are also available:

- Canadian Partnership for Quality Radiotherapy, *Technical quality control guidelines for kilovoltage xray radiotherapy machines*, 2015 *(89)*.

There may also exist local standards and regulations for compliance testing of X-ray equipment that shall be complied with.

Chapter 4.

Technical specifications for brachytherapy equipment



4.1 Description of brachytherapy

Brachytherapy involves the process of delivering a radiation dose to the cancer patient with sealed radioactive sources placed into, or in close proximity to, the tumour. Over the years, various sealed radioactive sources have been used in various configurations to treat a range of cancer sites, including skin, eye, prostate, breast, cervix, oesophagus, bronchus and sarcoma. This publication focusses on HDR brachytherapy with a sealed cobalt-60 source situated in a dedicated afterloader and used to treat gynaecological cancers with customized applicators.

In HDR brachytherapy, an applicator is placed in proximity to the tumour and a single sealed radioactive source attached to a guide wire is electromechanically moved to different positions within the applicator to create a dose distribution covering the tumour. The position of the source within the applicator and the dwell time at each position are varied to create the desired dose distribution covering the tumour.

The HDR brachytherapy steps are applicator placement and imaging, treatment planning and treatment delivery. The applicator placement, planning and treatment are carried out on a single day over approximately two hours. Typically, two to four fractions are delivered for cervix cancer treatment.

HDR brachytherapy can be performed with an iridium-192 source or a cobalt-60 source. The advantage of cobalt-60 is the longer half-life (5.27 years compared to 73.8 days for iridium-192) requiring fewer source exchanges over the lifecycle of the afterloader. Dosimetric differences between cobalt-60 and iridium-192-based brachytherapy are minimal *(90)*. The higher energy of the cobalt-60 radiation (1.25 MeV versus 0.38 MeV average photon energy) means thicker barriers are needed to ensure radiation protection (see Section 4.2.4 for radiation protection measures). The specification in Section 4.2.3 is for a cobalt-60 source, but it could be modified for iridium-192-based brachytherapy.

For cobalt-60 brachytherapy, the source exchange should be after a 3-year lifetime. The manufacturer may recommend a shorter lifetime of each source based on the expected number of source movements. Iridium-192-based brachytherapy units will require source exchange every three to four months to ensure continuity of service.

In this publication, it is assumed that a C-arm fluoroscopic X-ray unit or the simulator procured for EBRT will be used in the imaging for brachytherapy. The advantage of the C-arm fluoroscopic X-ray unit is that it is dedicated for brachytherapy, with the disadvantage that it allows only 2D planning. A reconstruction box is needed for the C-arm fluoroscopic X-ray unit to be used for planning purposes. The specification for a CT simulator is described in Section 3.4 and that of a conventional simulator in Section 3.5. An ultrasound imaging system is used in brachytherapy procedures to guide and confirm the placement of intracavitary applicators.

4.2 Technical specification for HDR brachytherapy afterloaders, including accessories

4.2.1 Description

The HDR brachytherapy system (Figure 14) consists of the following items:

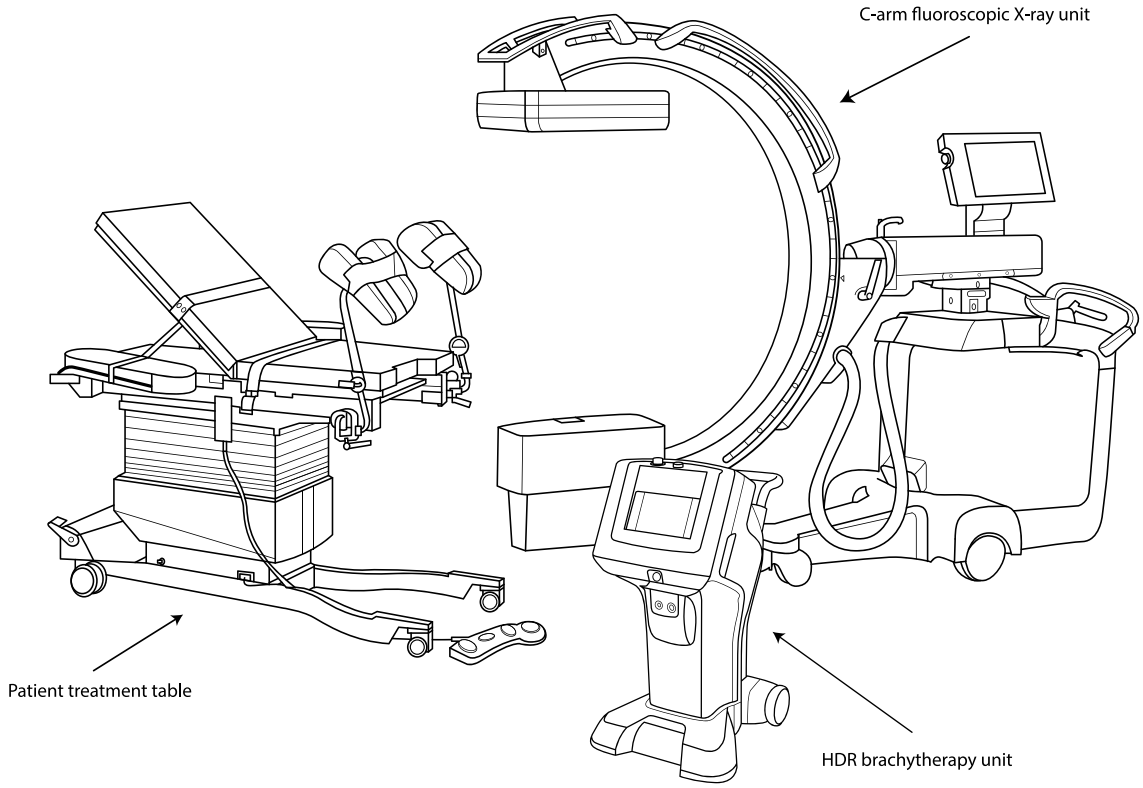
- an afterloader unit for source storage and delivery of the source to defined positions within treatment applicators;
- a sealed cobalt-60 radioactive source;
- applicators specific to the treatment site;
- a treatment couch; and
- control console.

It should be noted that the specification includes applicators specific to gynaecological treatment sites. If applicators are required for other treatment sites, then they should be included in the specification. The number of each type of applicator required will depend on expected patient workload.

This publication specifies computed tomography-magnetic resonance (CT-MR)[d]-compatible applicators for CT-based treatment planning. If 2D planning with a conventional simulator or C-arm fluoroscopic X-ray unit is envisaged, then metallic applicators are also suitable, and these have the advantages of robustness and durability over CT-MR-compatible applicators.

An important point in specifying an HDR afterloader is the number of channels since gynaecological applications may only require three channels. The specification gives an afterloader with at least 20 channels on the basis that more complex techniques may be utilized during the lifetime of the afterloader. However, the number of channels in the specification can be modified as the local need applies.

Figure 14. Examples of brachytherapy equipment



4.2.2 Standards

- IEC, *Medical Electrical Equipment, Part 2–17: Particular requirements for the basic safety and essential performance of automatically controlled brachytherapy afterloading equipment*, Rep. IEC 60601-2-17:2013 *(91)*.
- ISO, *Radiological protection – Sealed radioactive sources – General requirements and classification*, ISO-2919:2012 *(43)*.
- ISO, *Radiation protection – Sealed radioactive sources – Leakage test methods*, ISO-9978:1992 *(92)*.
- IEC, *Guidance on error and warning messages for software used in radiotherapy*, IEC TR 63183:2019 *(30)*.

[d] Strictly speaking, only CT-compatible applicators are required, however, currently vendors only refer to either metallic or CT-MR-compatible applicators.

4.2.3 Technical specification

- The brachytherapy afterloader system shall include the following:
- A remote controlled afterloading system with at least 20 channels for intracavitary HDR brachytherapy with a cobalt-60 source of activity 74 GBq ±10% on delivery. The treatment afterloader unit shall automatically verify all unique applicator connections and be easily manoeuvrable within the treatment room.
- Precise double drives in the afterloader for a miniaturized cobalt-60 source and a dummy source with continuous digital positioning, including pre-exposure routine dummy test run for safety and catheter length check.
- A control unit, which facilitates operation, controlling and monitoring functions including:
  - a connection to the dedicated TPS via a network;
  - password-defined access for all users with restricted access to data of high security, e.g. source strength;
  - a log of user activities and the number of source transfers;
  - database of uniquely defined standard treatment plans for rigid applicator sets and line sources with automatic update of source dwell times; access to the database for plan editing purposes should be password-controlled and restricted;
  - unique patient identification and treatment plan preparation;
  - display of status information, including during a power interruption;
  - online recording of treatment with visual graphic display of treatment progress; and
  - hardcopy output of the entire treatment protocol after treatment.
- An internal battery or UPS to ensure safe source or dummy retraction in the event of a power failure, including a crank for manual source retraction, long-handle forceps and an emergency container thick enough for storage of up to 81 GBq cobalt-60 and large enough to fit the largest possible applicator.
- A radiation area monitoring system with audible and visible signal for treatment room and control panel monitoring, warning lights, facility access interlock, patient intercommunication device, two complete CCTV systems with pan, zoom and tilt facility.
- A patient treatment table, including head plate, removable leg plates, stirrups, seat plate extension and backrest manoeuvrability in order to treat a patient in the seated position. The tabletop shall be radiolucent to enable X-ray imaging.
- Applicators and accessories (usually several quantities of each of the following sets are required depending on the workload and case mix) including:
  - CT-MR Fletcher applicator set;
  - interstitial CT-MR ring applicator set (ring angle 60° from horizontal), e.g. Vienna type;
  - CT-MR ring applicator set (at least a ring angle 60° from horizontal);
  - CT-MR vaginal/rectal applicator set;
  - intrauterine tubes, diameter 3.5 mm, titanium;
  - intrauterine tubes, diameter 5.0 mm, titanium;
  - CT-MR vaginal applicator set with intrauterine tube and additional concentric channels;
  - CT-MR endometrium set diameter 3.5 mm;
  - CT-MR endometrium set diameter 5.0 mm;
  - required accessories for the above applicator sets (e.g. transfer tubes, markers and sterilization box);
  - universal clamping device; and
  - reconstruction box for use in gynaecological applications.

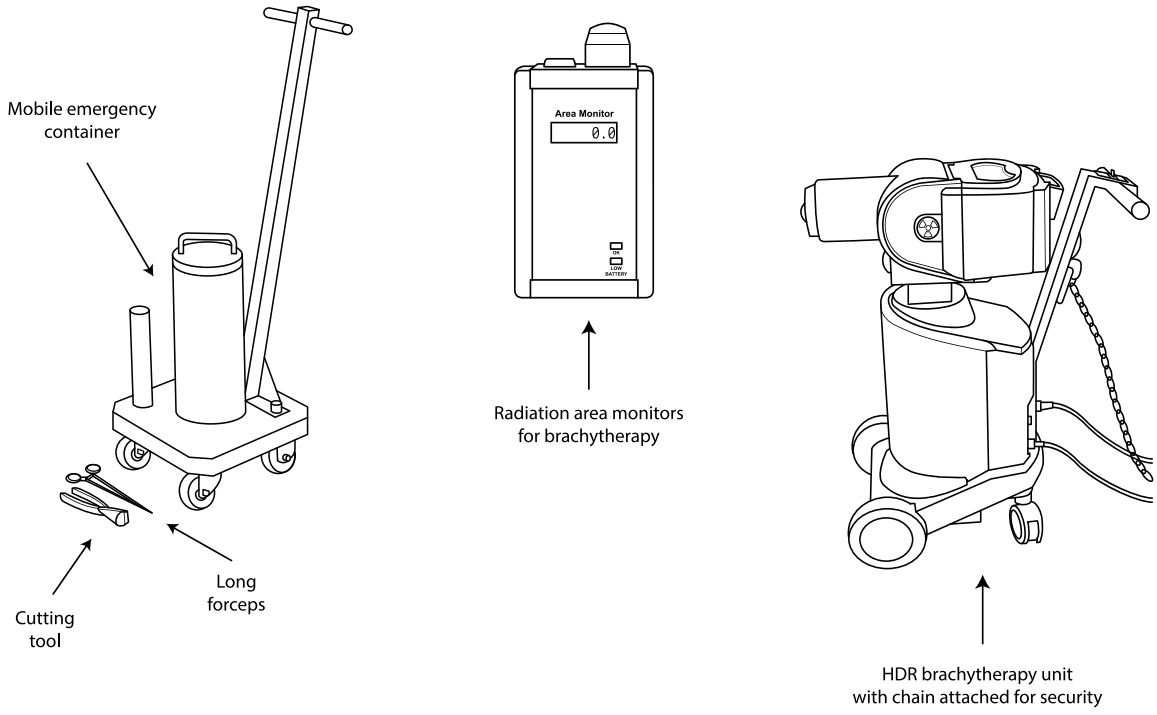
4.2.4 Radiation safety and protection, and security of radioactive material

The afterloader, including source, shall be stored and operated in a concrete bunker. The methodology described in the IAEA Safety Reports Series No. 47 *(18)* can be used to calculate the concrete thickness required to ensure radiation protection for staff and members of the public along with local requirements for dose constraints and dose limits. Consideration needs to be given to shielding in the floor, ceiling and walls. Refer to IAEA Human Health Reports No. 10 *(13)* for a typical layout of a brachytherapy suite, including treatment room, control room, and preparation and recovery rooms. Under the International Basic Safety Standards classification system, the brachytherapy suite will be designated as a *controlled area*. Security measures for the radioactive source shall be implemented according to local regulations, including measures such as securing the afterloader with locks when not in use, implementing secure door access and implementing out-of-hours security of the radiotherapy department. A comprehensive radiation survey in the vicinity of the brachytherapy treatment room shall be conducted after installation to ensure compliance with local requirements for dose limits for staff and members of the public. The survey shall be conducted with a calibrated survey meter.

The treatment room shall include the following features to ensure safety, protection and source security (Figure 15):

- area radiation monitor;
- facility access interlock;
- emergency storage container and forceps;
- beam-on illuminated signs at the entrance and within the room;
- ionizing radiation trefoil warning signs at the entrance;
- audio visual communication between the treatment room and control room;
- emergency-retract buttons in the treatment room and control room; and
- security features to prevent unauthorized removal of the radioactive material and sabotage *(44)*.

Figure 15. Examples of brachytherapy safety and security equipment



4.2.5 Quality assurance

Quality assurance of the brachytherapy afterloader and its accessories is required to ensure patient safety and stability of performance. Of particular importance is checking the integrity of applicators and guide tubes that may degrade with repeated use and checking source positioning reproducibility. Furthermore, a critical component of a brachytherapy quality assurance programme is ensuring that the correct applicator and guide tube is used for each treatment. Dosimetry of new sources is also vital and will involve update of the TPS with details of the new source.

International recommendations for quality control tests for brachytherapy equipment are available:

- IAEA, *Setting up a radiotherapy programme: Clinical, medical physics, radiation protection and safety aspects*, 2008 *(4)*.

The recommendations of various national professional societies are also available:

- AAPM, *Code of practice for brachytherapy physics: Report of the AAPM Radiation Therapy Committee Task Group No. 56*, Med Phys, 24, 1557–1598, 1997 *(93)*.
- Canadian Partnership for Quality Radiotherapy, *Technical quality control guidelines for brachytherapy remote afterloaders*, 2015 *(94)*.
- ESTRO, *A practical guide to quality control of brachytherapy equipment*, Booklet No. 8, 2004 *(95)*.
- Netherlands Commission on Radiation Dosimetry, *Code of practice for quality assurance of brachytherapy with Ir-192 afterloaders*, 2018 *(96)*.

There may also exist local standards and regulations for compliance testing of brachytherapy equipment that shall be complied with.

4.3 Technical specification for C-arm fluoroscopic X-ray units

4.3.1 Description

The C-arm fluoroscopic X-ray unit is a mobile X-ray source and imaging system mounted on a rotating C-arm. It allows planar X-ray imaging of the brachytherapy patient in the treatment room with the applicator already inserted. The unit will be mobile and designed to allow easy motion of the unit around the patient in the treatment position. The unit shall provide digital X-ray planar images that can be exported to a brachytherapy TPS.

4.3.2 Standards

- IEC, *Medical electrical equipment – Part 1–3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment*, IEC 60601-1-3:2008+AMD1:2013 CSV *(97)*.
- IEC, *Medical electrical equipment – Part 2–28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis*, IEC 60601-2-28:2017 *(98)*.
- IEC, *Medical electrical equipment – Part 2–54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy*, IEC 60601-2-54:2009+AMD1:2015+AMD2:2018 CSV *(99)*.

4.3.3 Technical specification

The C-arm fluoroscopic X-ray unit shall include the following:

- a high-frequency X-ray generator with potential in the range of 40–110 kV and X-ray tube with dual focal spots;
- a fluoroscopic mode, including foot switch and last image hold capability as well as a radiographic mode;
- a flat panel imaging detector with dimensions at least 21 cm x 21 cm;
- dual high-resolution flat display screens of at least 18-inch diameter with last image hold capability;
- a C-arm gantry with orbital movement of at least 120° (– 30° to + 90°);
- motor-driven vertical travel greater than or equal to 40 cm;
- horizontal travel greater than or equal to 20 cm;
- focus-image receptor distance greater than or equal to 90 cm;
- free space greater than or equal to 76 cm;
- a braking system for gantry control;
- a DICOM 3.0 interface for digital networking of images (transfer of digital images to a brachytherapy TPS or hospital PACS); and
- hard disk image storage capability as well as external storage capability.

4.3.4 Radiation safety and protection

The X-ray source of the C-arm fluoroscopic X-ray unit requires radiation safety and protection measures. The C-arm fluoroscopic X-ray unit will only be used in the brachytherapy treatment room that already has concrete shielding for the brachytherapy source. The shielding for the brachytherapy source will be sufficient to provide protection for operation of the C-arm fluoroscopic X-ray unit. However, the operator of the mobile C-arm fluoroscopic X-ray unit and treatment staff will require protection in the form of a lead gown with thyroid collar during exposure. Alternatively, other staff apart from the operator shall be outside the treatment room when the C-arm fluoroscopic X-ray unit is operated.

4.3.5 Quality assurance

To ensure safety and quality in imaging, the C-arm fluoroscopic X-ray unit shall be subject to routine quality control testing. Regular testing of the X-ray system, mechanical features and safety features is required. International recommendations for quality control tests for C-arm fluoroscopic X-ray units are available from IAEA Human Health Series No. 28 *(100)* and references therein.

4.4 Technical specification for ultrasound imaging systems

4.4.1 Description

The ultrasound imaging system is used in brachytherapy procedures to guide and confirm the placement of intracavitary applicators. Transducers are needed for the specific application, namely abdominal transducers for applicator placement guidance.

4.4.2 Standards

- IEC, *Medical electrical equipment – Part 2–37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment*, IEC 60601-2-37:2007+AMD1:2015 CSV *(101)*.
- IEC, *Ultrasonics - Pulse-echo scanners – Part 1: Techniques for calibrating spatial measurement systems and measurement of point-spread function response*, IEC 61391-1:2006+AMD1:2017 CSV *(102)*.
- IEC, *Ultrasonics - Pulse-echo scanners – Part 2: Measurement of maximum depth of penetration and local dynamic range*, IEC 61391-2:2010 *(103)*.
- IEC, *Ultrasonics - Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields*, IEC 62359:2010+AMD1:2017 CSV *(104)*.

4.4.3 Technical specification

The ultrasound imaging system shall include the following:

- a mobile clinical ultrasound imaging unit capable of operating in the following modes: 2D mode and M-mode (motion mode);
- two active transducer ports;
- two high-frequency convex transducers for trans-abdominal gynaecological examinations covering a frequency range of 2.0–5.0 MHz;
- (Package 2) two biplane transrectal transducers for sagittal and transverse imaging covering a frequency range of 3.0–12.0 MHz;
- a single high-resolution monitor, at least 18-inch, for image display and image processing; the displayed image shall contain not less than 256 grey levels in 2D mode;
- keyboard with one button control;
- a USB port, video output, onboard thermal printer and A4 laser printer;
- image processing measurements: length, height, width, angle, area and volume calculations;
- image storage in a clinically useful format and resolution on a hard drive and with capability to transfer images to external media with the DICOM standard; and
- a supply of water soluble and hypoallergenic ultrasound gel.

4.4.4 Quality assurance

Quality assurance of the ultrasound unit and its accessories is required to ensure stability of performance. Of particular importance is stability of image quality for each transducer and the system overall.

The recommendations of various national professional societies for ultrasound quality control tests are available:

- *Real-time B-mode ultrasound quality control test procedures: Report of AAPM Ultrasound Task Group No. 1*, Med Phys, 25, 1385–1406, 1998 *(105)*.
- *Guideline for Technical Quality Assurance (TQA) of ultrasound devices (B-Mode): EFSUMB Technical Quality Assurance Group–US-TQA/B*, Ultraschall Med, 33, 544–549, 2012 *(106)*.

There may also exist local standards and regulations for compliance testing of ultrasound equipment which shall be complied with.

4.5 Technical specification for brachytherapy TPS

4.5.1 Description

The brachytherapy TPS is a software application for creating brachytherapy treatment plans based on the source dosimetric characteristics, applicator dimensions, patient images and allowable source positions and dwell times.

4.5.2 Standard

- IEC, *Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems*, IEC 62083:2009 *(58)*.

4.5.3 Technical specification

The brachytherapy TPS shall include the following:

- a networked workstation with 23-inch monitor and significant storage capacity;
- software for dose optimization based on points, planes or volumes based on catheter and source dwell positions obtained by reconstruction from isocentric, orthogonal and semi-orthogonal images;
- hardware, software and licenses that allow DICOM-compliant image transfer from a CT scanner, MRI scanner and conventional simulator or a C-arm fluoroscopic X-ray unit;
- a flatbed film scanner (or equivalent) to allow the manual input of films or digitized images;
- reference data sets for the source all applicators offered (library) and for the source;
- hierarchical password-controlled security access to source calibration, modelling parameters, library of standard treatment plans and synchronization of source data with the treatment control panel;
- system manager software for database maintenance and archiving;
- a printer for A3/4 output of isodose distributions and treatment plan parameters; and
- software for automatic online transfer of patient and authorized treatment plan data to the treatment afterloader control panel.

4.5.4 Quality assurance

Quality assurance of the brachytherapy TPS is required to ensure stability of performance. Regular tests of features and results of algorithms are recommended. Particular importance needs to be paid to software upgrades as discussed in Section 3.6.4. Also of importance is confirming that the current source strength is reflected in the TPS. International recommendations for quality assurance of brachytherapy TPSs are available:

- IAEA, *Commissioning and quality assurance of computerized planning systems for radiation treatment of cancer*, Technical Reports Series No. 430, 2004 *(60)*.

The recommendations of various national professional societies are also available:

- AAPM, *Code of practice for brachytherapy physics: Report of the AAPM Radiation Therapy Committee Task Group No. 56*, Med Phys, 24, 1557–1598, 1997 *(93)*.
- ESTRO, *A practical guide to quality control of brachytherapy equipment*, Booklet No. 8, 2004 *(95)*.

4.6 Technical specifications for dosimetry and quality control equipment

4.6.1 Description

The basis for dosimetry in brachytherapy is the establishment of the reference air kerma rate (RAKR) of the radioactive source. The well-type ionization chamber has become the preferred detector for this application.

4.6.2 Technical specification

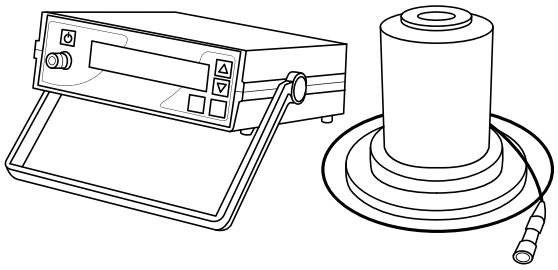
Table 16 describes the dosimetry and quality control equipment specific to HDR brachytherapy. It includes an image quality phantom for ultrasound units. The radiology dosimetry equipment and image quality phantom described in Section 3.10.3 can be used for quality control of the C-arm fluoroscopic X-ray unit. Figure 16 illustrates examples of dosimetry and quality control equipment.

Table 16. Dosimetry and quality control equipment for HDR brachytherapy

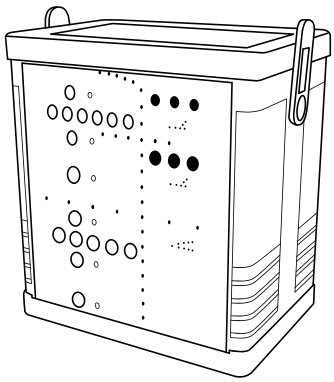
Item	Description	Comments
Well-type ionization chamber	Well-type ionization chamber for measuring source strength of HDR afterloader cobalt-60 or iridium-192 brachytherapy source, TNC or BNC connector, including calibration certificate, adapter required specific to afterloader manufacturer and model.	Recalibration at an SSDL or PSDL is recommended every two years.
Triaxial cable	Triaxial extension cable at least 10 m in length, TNC or BNC connectors.	Purchase of a spare cable is recommended as these cables often fail through multiple handling or mishandling.
Electrometer	Reference class single channel electrometer compatible with well-type chamber, TNC or BNC connector.	Internal desiccator needs replacement at intervals depending on humidity levels. It is preferable to calibrate the electrometer together with the well-type ionization chamber.
Thermometer	Glass thermometer (spirit type) 0 °C–50 °C with scale resolution 0.2° or less, including calibration certificate.	The use of mercury type rather than spirit type should not be allowed.
Barometer	Digital or aneroid barometer with 0.01 kPa resolution, calibration certificate, with a pressure reading range suitable to the elevation of the radiotherapy department's location.	The pressure range of the barometer is important for radiotherapy departments at high elevations. Pressure reduction is of the order of 1% per 80 m elevation.
Check source	Caesium-137 check device for well-type chamber, including adapter/holder.	Inclusion of radioactive material requires following the requirements of the local radiation regulator.
Film	Self-developing radiochromic film for brachytherapy dosimetry.	Consumable
Source position check tool	A source position check tool with cavity for source, length scale in millimetres and ability to incorporate radiochromic film for autoradiography.	This device is supplied by the afterloader vendor.

Item	Description	Comments
Ultrasound image quality phantom	An image quality phantom for ultrasound imaging capable of performing tests of uniformity, geometric scale, contrast, resolution, elasticity sensitivity and dead zone. Rubber based, tissue mimicking long lasting material; includes a combination of monofilament line targets and tissue mimicking volumetric targets of various sizes; minimum line target diameter of approximately 0.1 mm; optimized for image display at the abdominal probe frequency range (2–5 MHz).	
Ultrasound quality assurance phantom for transrectal imaging	A phantom of tissue equivalent material consisting of combinations of complex shapes to check the alignment of the electronic grid that appears on the screen for correct horizontal and vertical distance measurements; the ability to confirm the axial and lateral resolution of the system. A minimum of three (3) different calibration objects to be visualized when turning the probe 60 degrees to the right or left; capability to test for the depth of penetration, resolution, distance, area and volume measurements; and capability to test for geometric consistency.	This phantom should be considered when using transrectal ultrasound imaging for interstitial implants (Package 2).

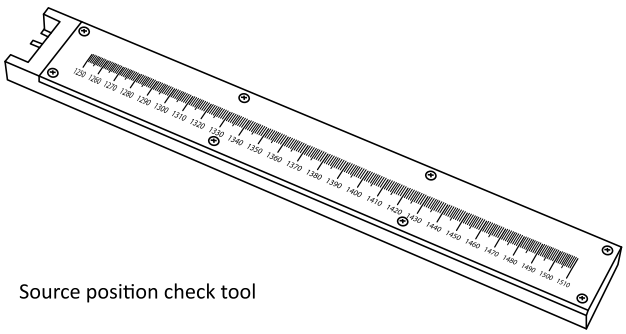
Figure 16. Examples of brachytherapy dosimetry and quality control equipment



Well type chamber measuring brachytherapy source strength



Ultrasound QA phantom



Source position check tool

QA=quality assurance

4.6.3 Radiation safety and protection

The only radiation emitting device among the brachytherapy dosimetry equipment is the check source. The source shall only be used by clinically qualified medical physicists. Secure storage of the source in its container is required. Local standards and regulations for transport, use and storage of radioactive material shall be followed.

4.6.4 Quality assurance

The well-type chamber requires recalibration every two years by an SSDL or PSDL. Between calibrations, checks of the stability of the well-type chamber sensitivity can be performed with the check source.

4.7 Technical specifications for radiation safety equipment

4.7.1 Description

The survey meter is a portable radiation detector capable of protection level detection in an HDR brachytherapy facility. The survey meter is used in comprehensive surveys upon the installation of treatment and imaging equipment and periodically thereafter, including at the time of source exchange.

Radiotherapy staff are radiation monitored in the workplace through implementation of personal radiation monitoring service. Staff wear passive radiation detector badges during work hours. The badges are exchanged every one to three months and the service provider reads the badges and provides a dose report for all staff members.

In addition to the passive radiation detector service, the availability of direct readout electronic monitors is recommended for various situations that may involve exposure, including handling of radioactive material or source exchanges.

Usually supplied with the HDR brachytherapy afterloader are a room area radiation monitor and an emergency source storage container. The area monitor shall be sensitive to gamma radiation at protection level and indicate if the source is outside the afterloader. The emergency storage container will store the source in an emergency situation if the source cannot be returned to the afterloader.

4.7.2 Technical specification

Table 17 describes the radiation safety equipment for HDR brachytherapy.

Table 17. Radiation safety equipment

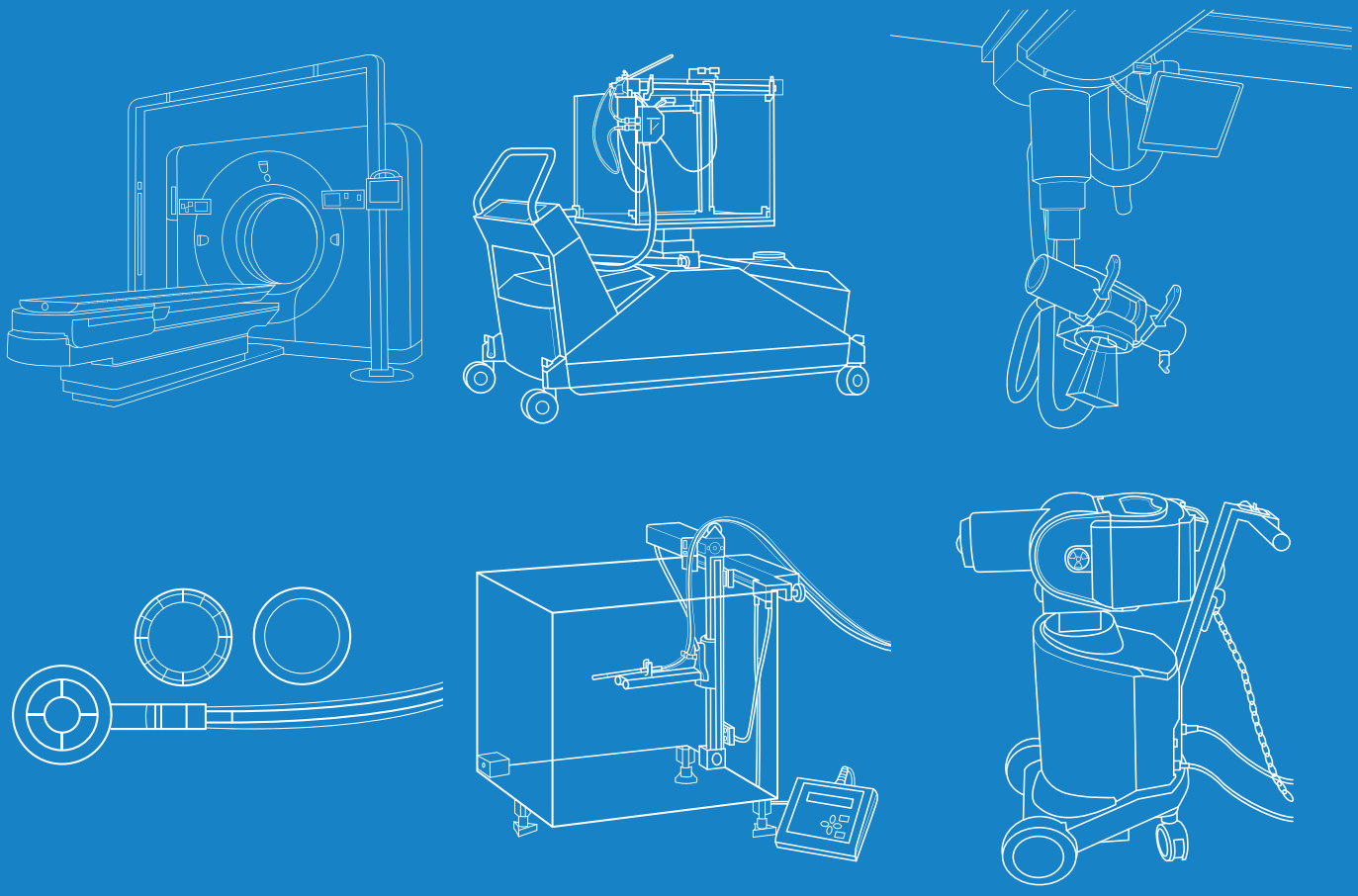
Item	Description	Comments
Survey meter	A portable ionization chamber-based survey meter capable of detecting X-ray and gamma radiation above 25 keV, integrated display, integrated dose and dose rate modes, dose rate range of 0.5 uSv/hr–50 mSv/hr, energy dependence less than 20% in the range of 50 keV–1 MeV, calibration certificate included.	Protection level calibration with caesium-137 required every two years at an SSDL or PSDL.
Personal radiation monitoring service	A service is required to provide radiation monitoring of staff with passive radiation badges sensitive to X-ray, gamma and beta radiation. The radiation badges shall be exchanged every three months. Reports of radiation dose received by the badges shall be provided promptly after the wearing period. The report shall identify any dose readings above national dose limits.	Dose reports may have to be forwarded to the radiation regulator. The monitoring period specified by regulatory bodies is typically one to three months.
Electronic personal monitor	Direct readout personal radiation monitor, audible dose rate indication, energy range of 45 keV–1.2 MeV, display of accumulated dose in Sv, reset function.	
Radiation area monitor	Radiation area monitoring system with audible and visible signal for treatment room and control panel monitoring.	Usually included with the supply of the afterloader.
Emergency storage container	Portable emergency container for HDR brachytherapy source, with handle incorporating lead shielding and an emergency source handling tool.	Usually included with the supply of the afterloader.
Lead gown (C-arm fluoroscopic X-ray unit operation only)	Full apron with equivalent 0.5 mm lead protection, including thyroid collar and/or lead glass screen for operator console.	

4.7.3 Quality assurance

Recalibration of radiation safety equipment is required at regular intervals. The services of an SSDL or PSDL with protection level calibration capability should be used.

Chapter 5.

Establishing a radiotherapy service



5.1 Project management and implementation

Establishing a radiotherapy service requires a multidisciplinary approach. Broadly there are clinical, technical and radiation safety matters to address covering the medical devices, infrastructure and human resources *(1,4,107)*. The implementation will depend on whether it will be a new service or an upgrade to an existing service, and its relationship within an existing hospital infrastructure. Table 18 provides an outline of suggested teams and tasks to establish a radiotherapy service. In this scheme, overall responsibility for the project lies with a project management team, which will delegate responsibilities to a clinical implementation team, a technology implementation team and a radiation safety implementation team.

Table 18. Tasks in establishing a radiotherapy service

Team	Members	Tasks
Project management team	Administration, clinical, technical, governance	Engage a health architect for design of the radiotherapy department considering patient care-path, staff workflow, equipment requirements and future expansion. Seek relevant government approvals for building construction.
		Conduct needs assessment (technology selection) for major radiotherapy equipment, including treatment equipment (teletherapy and brachytherapy) and related imaging equipment.
		Engage a radiation protection specialist for design of treatment and simulation room shielding for radiation protection and seek approval of the design by the radiation regulator.
		Engage building and engineering contractors (including a structural engineer) for construction of the radiotherapy department.
		Establish links to other services, including surgery, medical imaging, pathology, medical oncology, anaesthesiology, sterilization and pharmacy.
		Raise awareness with potential referrers of the capabilities of the new radiotherapy service.
		Oversee the building construction, including holding regular meetings with the contractor for updates, timelines and handover.
		Engage procurement services for tender of radiotherapy equipment, including award of contract.
		Engage information technology services to ensure support of the radiotherapy department's IT needs, including workstations and network, and information and computer security.
		Recruit clinical and technical staff with appropriate qualifications, certification and registration. Staffing levels are to be according to international recommendations *(108)*. If staff are to be educated as part of the project, then significant lead time will be needed, e.g. it takes from four to five years to train a physician in the speciality of radiation oncology, the same for a clinically qualified medical physicist and two to four years for radiation therapists.
		Appoint and manage clinical, technical and radiation safety implementation teams.
		Appoint a radiation protection officer.

Team	Members	Tasks
Clinical implementation team	RO, MP, nursing, RTT, administrative staff, IT, BE	Establish clinical protocols for major disease sites.
		Establish role in multidisciplinary tumour boards.
		Establish an electronic or paper-based library of reference material and journals.
		Prepare patient areas (treatment rooms, simulation room, consultation rooms, etc.) with necessary ancillary equipment and resources.
Technology implementation team	RO, MP, RTT, IT, BE, hospital engineering	Prepare specifications of radiotherapy equipment.
		Undertake technical evaluation of radiotherapy equipment bids.
		Oversee the installation of equipment with suppliers, including pre-installation meetings and inspections, and review of vendors pre-installation requirements for power, ventilation and other services.
		Conduct acceptance and commissioning of radiotherapy equipment, including calibration of treatment units.
		Commission dosimetry equipment, quality control test equipment, and radiation safety and protection equipment.
		Arrange for independent dosimetric audit of treatment equipment.
		Undertake applications training for major radiotherapy equipment.
		Establish written policies and procedures for all staff practices.
		Establish quality control procedures based on risk assessment *(109)* and checklists for equipment and processes, including preparing quality control baselines in preparation for the ongoing quality assurance.
		Establish an ongoing quality management committee, including defining its terms of reference.
		Prepare the treatment rooms and simulation room with necessary ancillary equipment for patient management.
Radiation safety implementation team	MP, RSO, RTT	Develop a comprehensive departmental radiation management plan.
		Prepare all relevant radiation licence applications for users and equipment, and submit to the radiation regulator. Radiation therapists will need licences to operate treatment equipment and imaging equipment in clinical mode. Medical physicists will need licences to perform commissioning, quality control and safety tasks.
		Establish a radiation monitoring service for staff.
		Establish a radiation incident reporting and learning system.
		Establish procedures for managing possible and confirmed patient and staff pregnancy.
		Conduct training of staff in radiation safety.
		Conduct radiation surveys of treatment and simulation rooms and submit reports of the surveys to the radiation regulator.
		Test the radiation safety features of premises and submit reports of the tests to the radiation regulator.
		Establish emergency procedures for potential incidents involving radioactive sources.
		Establish an ongoing radiation safety. Committee, including defining its terms of reference.

BE=biomedical engineer; IT=information technology professional; MP=medical physicist, RO=radiation oncologist; RSO=radiation safety office; RTT=radiation therapist

The list of tasks in Table 18 are broad in nature and the detailing of more specific subtasks are beyond the scope of this publication. More details on establishing radiotherapy services can be found in the following publications:

- IAEA, *Setting up a radiotherapy programme: Clinical, medical physics, radiation protection and Safety Aspects*, 2008 *(4)*.
- IAEA, *Radiotherapy facilities: Master planning and concept design considerations*, Human Health Reports No. 10, 2014 *(13)*.
- IAEA, *Planning national radiotherapy services: a practical tool*, Human Health Series No. 14, 2011 *(110)*.
- IAEA, *Radiotherapy in palliative cancer care: Development and implementation*, Human Health Reports No. 2, 2012 *(111)*.
- IAEA, *Implementation of high-dose rate brachytherapy in limited-resource settings*, Human Health Series No. 30, 2015 *(112)*.
- IAEA, *Radiation protection and safety in medical uses of ionizing radiation*, Specific Safety Guide No. SSG-46, 2018 *(113)*.
- WHO, Chapter 5 of WHO *Lists of priority medical devices for cancer management*, 2017 *(1)*.
- IAEA and WHO, *Roadmap towards a national cancer control programme: Milestones for establishing nuclear medicine, diagnostic imaging and radiotherapy services*, 2019 *(107)*.

In terms of timeline, establishing a radiotherapy department, including construction of the facility, can take from 18 to 24 months before the first patient is treated. Major timelines include construction (12 months), phased installation of services and equipment (four to six months), major equipment acceptance and commissioning, including LINAC, brachytherapy afterloader, simulator, TPS and OIS (four to six months, dependent on type and numbers of equipment as well as availability of qualified staff).

5.2 Equipment procurement, maintenance and lifecycle

5.2.1 Procurement guidance

There are a number of medical devices for radiotherapy on the market, therefore, the development of technical specifications and the procurement process should appropriately match the identified need. Thus, key specifications that can be included in a tender in order to help managers and procurement personnel to purchase the correct product are described in each corresponding chapter of this publication; however, care should be taken to adapt contents to suit the needs of the end-users if necessary.

In addition to outlining specifications, a request for supplemental information is also useful to include in a tender/request for quotation to aid in the decision-making. Such information includes, but is not limited to, the following:

- site layout drawings;
- technical evaluation criteria;
- lead-time from receipt of contract/purchase order;
- method of shipment;
- shipping route;
- incoterms;
- shipment/delivery costs, if applicable;
- weight and dimension of shipment;
- validity of quotation;
- payment terms;
- general and any special terms and conditions that will appear on the contract and/or the purchase order;
- evidence of ISO/IEC compliance when applicable;
- copy of regulatory approvals/clearances (e.g. US FDA, CE, or other acceptable stringent regulatory authority [SRA]);
- copy of proof of registration in the country of import;
- warranty period and scope;

- applications training included, detailed by personnel and location; and
- letter of availability of parts for a minimum period of 10 years.

Once a tender is awarded, it is important for the purchaser to obtain necessary documents in order to facilitate the movement of commodities or devices and to clear customs in an expeditious manner as possible. The following information and documentation should be obtained, as a minimum, in advance:

- delivery date
- copy of the certificate of origin
- copy of the certificate of conformity
- commercial invoice
- final transportation documents (waybill).

It is also important to note that countries that have not historically regulated medical devices are moving in this direction. It is becoming increasingly common for aspects of regulation to be in place, and very likely that both the device manufacturer and the make and model of specific devices must be registered in order for importation to take place.

In the absence of a registered product/manufacturer, an importer can often work with the Ministry of Health to apply for an import waiver. However, import waivers are usually only issued on a *per shipment* basis, thus it is important to also work with manufacturers to ensure that they apply to the local regulatory authority (or body responsible) in order to become registered for future procurements. In some countries, the registration process can take from one to three years; the earlier the manufacturer applies, the better.

Warranties should always be requested during the procurement process. The procurer defines the time of the warranty and it is recommended that the warranty should be at least one year. Warranty shall include preventative maintenance, updates and upgrades, spare parts and labour. The warranty period starts at the end of acceptance testing. It is also useful to seek from bidders the terms and conditions of maintenance contracts (see Section 5.2.2) that would apply after the warranty period so that lifecycle costing can be considered at the evaluation phase.

The technical specification shall include the language for user manuals, maintenance manuals, operation and safety markings. The technical specification for major equipment shall define acceptance as the testing of the equipment by the contractor and end-user (medical physicist) that the performance meets the manufacturer's performance specifications and the items of the specification. The results of the acceptance testing shall be documented and signed by the end-user.

Manufacturers must demonstrate compliance with ISO standards for good manufacturing practice and ISO quality assurance standards or equivalent.

The technical specification for major equipment shall include provision of applications training for users, principally radiation therapists, medical physicists, radiation oncologists and any in-house maintenance engineers. Training for radiation therapists would typically be onsite during the period near the first clinical operation, while options for comprehensive offsite training at dedicated training centres would normally be included. This applications training, however, is not an alternative to appropriate education programmes and should be considered complementary.

For procurement involving sealed radioactive sources, the supplier should be asked to confirm that they will take back and dispose of the source at the end of its useful life. As mentioned in Section 3.2.1, major medical equipment such as LINACs, CT scanners, etc. will require specific services, including electric power, lighting and air-conditioning. Depending on the equipment and manufacturer, special services such as chilled water or compressed air may be required. Also, special requirements are needed to ensure radiation safety and protection, for example, facility access interlocks, lead glass windows and radiation beam-on lighting. The contract with the supplier needs to be clear in stating the responsibilities of both the hospital and the supplier in having the premises ready for the installation of the equipment with all services in place. Once the successful bidder is known, consultation of the manufacturer's relevant site planning guide is essential. Regular meetings between the hospital's implementation team and the supplier and a pre-installation inspection of the premises are highly recommended.

Further guidance on the procurement process for medical devices can be found in a WHO publication *(114)*.

5.2.2 Maintenance and life cycle of radiotherapy equipment

After the warranty period of major equipment expires, maintenance provisions must be in place to ensure continuity of service over the expected lifetime of the major radiotherapy equipment. Maintenance can be provided by contracts with suppliers or through an in-house engineering service or through a mixture of both.

In negotiating a maintenance contract with suppliers, the following should be considered:

- inclusion of spare parts;
- inclusion of all safety, hardware and software updates and upgrades during the lifetime of the equipment;
- inclusion of a regular service schedule specifying the numbers of days of service per year and whether the service is performed during work hours or out of hours;
- access to help desk and remote diagnostics;
- whether major parts (e.g. X-ray tube for CT scanner or waveguide system for a linear accelerator) are included or excluded in the contract;
- whether maintenance contracts for any local sourced parts (e.g. UPS, chiller) are included;
- whether front-line maintenance by trained in-house maintenance engineers is included or excluded;
- penalties for not meeting pre-agreed levels of uptime, e.g. 95% uptime (defined as time available for clinical service as a percentage of normal operating hours) could be stipulated with a penalty of reduced maintenance contract cost in the following year; and
- penalties for not meeting pre-agreed response time in the corrective maintenance (e.g. 24 hours) could be stipulated with a penalty of 5% per day of delay of the annual cost.

Maintenance contracts should also be considered for the department's operational software, including the TPS and OIS. Maintenance contracts are advantageous in including all software updates and upgrades, access to a help desk and repair of hardware faults.

Funding of a radiotherapy department includes recognition of the need for ongoing replenishment of consumables. Examples of consumables include thermoplastic masks, dressings and sheets of radiochromic film. Provision for ongoing radiation safety services such as calibrations, renewal of radiation licences and personal dosimetry services should also be included.

Consideration for funding of replacement of equipment needs to be considered based on the expected lifecycle of equipment as shown in Table 19. The durations listed in the table can only be approximate and indicative. Well-maintained equipment may operate safely and effectively for longer periods or for shorter periods dependent on usage and environmental conditions. Evidence of need for replacement includes the equipment becoming unreliable and needing excessive maintenance time, unstable performance and major damage. Importantly, any lack of ongoing support from the vendors in terms of access to spare parts and support service may dictate the end of life of some of the equipment.

For equipment that includes a sealed radioactive source, hospitals need to budget for source exchanges at regular intervals. The cost of replacement of the cobalt-60 source for a teletherapy unit can be substantial. As part of the contract for source exchange, the contractor shall agree to remove and dispose of the old source.

For equipment that includes a sealed radioactive source, such as the cobalt-60 teletherapy unit and brachytherapy afterloader, decommissioning at end of life includes consideration of the safe disposal of the radioactive material. As discussed in Section 3.2.4, a high-energy LINAC may have head activation at its end of life. The local radiation regulator shall be consulted on decommissioning and the cost of decommissioning sources and equipment shall be considered.

In the context of the radiotherapy department, inventory management of medical devices *(115)* and medical equipment is essential for continuous service delivery. An up-to-date inventory also aids in developing budgets, determining relevant staffing levels, managing service contracts and planning for spare parts and consumables orders. Inventories of ionizing radiation sources are required by the radiation regulator.

Table 19. Expected lifecycle of radiotherapy equipment

Item	Indicative lifecycle	Comments
LINAC	10–15 years	
Cobalt-60 teletherapy unit	minimum 15 years	Including three cobalt-60 source exchanges
CT simulator	5–10 years	
Conventional simulator	10 years	
TPS	5 years	Regular hardware and software updates and upgrades can extend the lifecycle
OIS	5 years	Regular hardware and software updates and upgrades can extend the lifecycle
Patient immobilization equipment	5–10 years	Dependent on usage
Mould room equipment	minimum 10 years	
Dosimetry, quality assurance (QA) and radiation safety equipment	10 years	Calibration of radiation detectors at regular intervals is required
Superficial/orthovoltage X-ray unit	minimum 15 years	Lifetime could be limited to 10 years depending on the availability of spare parts
Brachytherapy afterloader	10–15 years	Including three cobalt-60 source exchanges
Brachytherapy applicators	3 years	Dependent on usage
C-arm fluoroscopic X-ray unit	10 years	
Ultrasound unit	5–10 years	

5.3 Patient safety and quality management

Patient safety is of paramount importance in the delivery of therapeutic levels of radiation dose. The International Basic Safety Standards *(23)*, taking account of the latest finding of UNSCEAR and the latest recommendations of the ICRP *(116)*, provide the framework for patient safety and form the basis of radiation safety and protection legislation and regulations in many countries along with the other IAEA General Safety Requirements (Parts 1 to 7) publications. Complementing the International Basic Safety Standards is an IAEA safety guide for radiation protection and safety in medical uses, which provides specific guidelines to the practitioner for safe practice *(113)*. A key principle of the International Basic Safety Standards as it applies to therapeutic radiation medicine practice is justification whereby the medical practitioner shall weigh up the benefits and detriment of medical exposure. The country's legal and regulatory framework for ionizing radiation is managed and implemented by a governmental radiation regulatory body that is the contact point for the radiotherapy department in radiation safety and protection.

The radiotherapy department appoints a radiation protection officer who advises the department on radiation safety matters and carries out radiation safety duties. The radiation protection officer has a key role in the department's radiation safety committee, which represents all staff groups. The duties of the radiation safety committee and radiation protection officer as they apply to establishing a radiotherapy department are described in Section 5.1. Once the radiotherapy department is operational, the tasks for the committee and the radiation protection officer include, but are not limited to:

- manage the department's radiation incident reporting and learning system;
- ensure radiation licences for equipment, premises and staff are up to date;
- operate the staff personal monitoring programme;
- conduct regular staff training in radiation safety, including emergency procedures and induction for new staff;
- ensure the department's radiation management plan is up to date;
- ensure a process of handover is followed after repair and service to treatment and simulation equipment, whereby medical physicists perform appropriate checks on the equipment before it is returned to clinical service; and
- ensure thorough commissioning, safety and risk assessment are followed in the introduction of any new techniques or technology.

The radiation incident and learning system is used to report and learn from deviations from the intended treatment plan and dose prescription in practice, as well as a quality, safety and education tool. Radiation incidents in radiotherapy involve not just overdose, but also underdose as well as any geometric miss (the right dose in the wrong place). A no-blame culture is encouraged in the reporting of incidents and near-misses. A nomenclature for incident reporting needs to be adopted along with a framework for reporting incidents. Learning from incidents often involves changes to staff practice. Refer to the IAEA SAFRON incident reporting and learning system *(117)* or the ESTRO ROSEIS platform (https://roseis.estro.org/) for more information.

Proactive risk assessment is expected with the introduction of new techniques and technology (including establishing a new radiotherapy service), such guidelines are available *(109,118,119)*.

Safety in radiotherapy is strengthened by the implementation of a quality management programme, which would ensure high-quality patient care and in doing so ensure patient safety. Quality management in radiotherapy will also be aligned with the hospital's overall commitment for delivering quality health services *(120)*. Quality is also emphasized in the WHO framework for health systems, with one of the building blocks for a health system being "equitable access to essential medical products, vaccines and technologies of assured quality, safety, efficacy and cost-effectiveness, and their scientifically sound and cost-effective use" *(121)*. International standards and recommendations are available for quality management in radiotherapy and are listed at the end of this section. Elements of a quality management programme for radiotherapy include:

- performing process checks with checklists during treatment planning and during treatment (chart check);
- internal peer review of treatment plans and prescriptions (chart round);
- double checks by different staff groups;

- performing quality assurance on major equipment, including establishing baselines and action levels and performing routine quality control tests (as outlined in Chapters 3 and 4);
- through the quality management committee, implement continuous quality improvement through, e.g. process optimization; and
- based on risk assessment, devising and implementing a quality assurance framework for new techniques and technology.

One important element of a robust quality management programme is regular independent peer review or audit of practice. IAEA has established a framework for audit covering both clinical and technical aspects *(122)* and practice standards that are useful to audit performance against *(110,123–125)*.

For consistency of national practice of radiotherapy, common guidelines for nomenclature *(126)* and reporting of radiotherapy should be followed. The International Commission on Radiation Units & Measurements (ICRU) reports on radiotherapy provide a common approach to prescribing, recording and reporting radiotherapy *(127–131)*.

Also in the interests of quality, radiotherapy clinical protocols shall be evidence-based taking into account the available radiotherapy technology in the radiotherapy department. Clinical protocols from national and international clinical trials involving radiotherapy are an excellent source of protocols *(132,133)*. Also pertinent are the QUANTEC recommendations *(134)* for dose limits for organs at risk in radiotherapy.

Selected bibliography of international standards and recommendations on patient safety and quality management in radiotherapy:

- AAPM, *Report of Task Group 100 of the AAPM: Application of risk analysis methods to radiation therapy quality management*, Med Phys, 43, 4209–4262, 2016 *(118)*.
- ESTRO, *Recommendations for a quality assurance programme in external radiotherapy*, Booklet No. 2, 1995 *(135)*.
- IAEA, *Lessons learned from accidental exposures in radiotherapy*, Safety Reports Series No. 17, 2000 *(136)*.
- IAEA, *Setting up a radiotherapy programme: Clinical, medical physics, radiation protection and safety aspects*, 2008 *(4)*.
- IAEA, *Comprehensive audits of radiotherapy practices: A tool for quality improvement*, 2007 *(122)*.
- IAEA, *Accuracy requirements and uncertainties in radiotherapy*, Human Health Series No. 31, 2016 *(137)*.
- IAEA, *Radiation protection and safety in medical uses of ionizing radiation – specific safety guide*, IAEA Safety Standards Series No. SSG-46, 2018 *(113)*.
- ICRP, *Prevention of accidental exposures to patients undergoing radiation therapy*, ICRP Publication 86, Ann ICRP, 30 (3), 2000 *(138)*.
- ICRP, *Preventing accidental exposures from new external beam radiation therapy technologies*, ICRP Publication 112, Ann ICRP, 39 (4), 2009 *(139)*.
- WHO, *Radiotherapy risk profile*, 2008 *(109)*.
- *Quality and safety in radiotherapy*, CRC Press, 2010 *(140)*.

5.4 Education and training of radiotherapy health professionals

Safe practice in radiotherapy requires not only applications training in safe use of radiotherapy equipment for relevant health professionals; prior to independent practice in radiotherapy, health professionals must achieve comprehensive academic education and clinical training, leading to qualification and certification. Table 20 describes the principal health professionals required for the safe and effective practice of radiotherapy, their roles as described by IAEA and WHO *(109)*, and their recommended education and training requirements as published by IAEA.

Table 20. Principal health professionals in the practice of radiotherapy

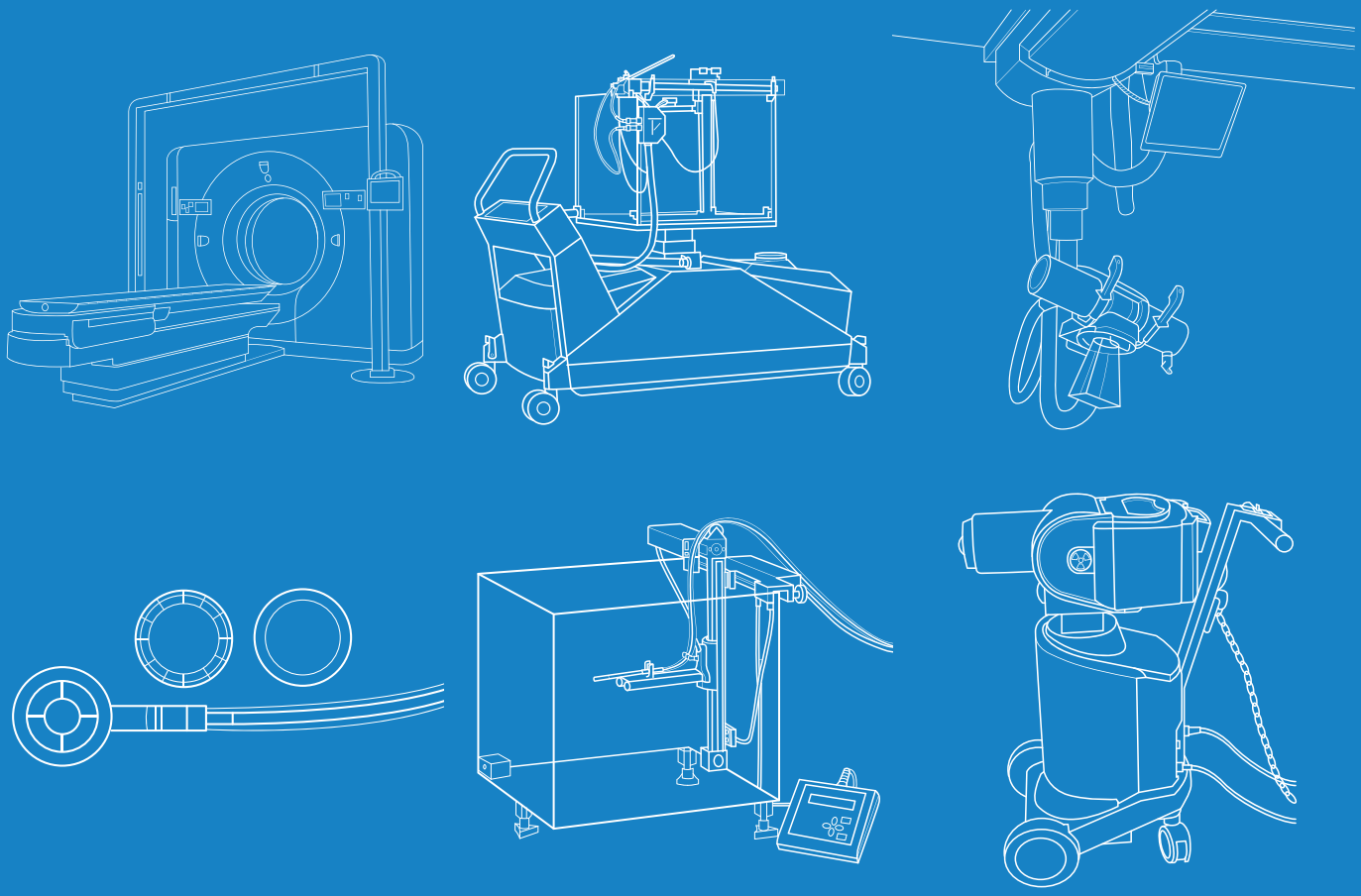
Health professional	Definition and role	Education and training	Relevant IAEA publications
Radiation oncologist	A clinical physician with knowledge concerning the causes, prevention and treatment of cancer and other diseases involving special expertise in the therapeutic applications of ionizing radiation.	Degree in medicine. At least three years specialty training in radiation oncology.	Syllabus for the education and training of radiation oncologists, Training Course Series No. 36, 2012 *(141)*.
Medical physicist	A health professional with specialist education and training in the concepts and techniques of applying physics in medicine and competent to practise independently in radiotherapy medical physics. Responsibilities in equipment commissioning, radiation safety and protection, radiation dosimetry, dose optimization and quality management.	Degree in physical sciences or engineering. Postgraduate academic degree in medical physics. Two to three years of structured clinical training in a radiotherapy department under the clinical supervision of a clinically qualified medical physicist.	*Roles and responsibilities, and education and training requirements for clinically qualified medical physicists*, Human Health Series No. 25, 2013 *(142)*. *Postgraduate medical physics academic programmes*, Training Course Series No. 56, 2013 *(143)*. *Clinical training of medical physicists specializing in radiation oncology*, Training Course Series No. 37, 2009 *(144)*.
Radiation therapist (RTT)	A technologist with direct responsibility for the daily administration of radiotherapy to cancer patients.	Degree in radiation therapy, including at least one year of clinical training.	*A handbook for the education of radiation therapists (RTTs)*, Training Course Series No. 58, 2014 *(145)*.
Radiation oncology nurse	A registered professional nurse with responsibilities in care support to patients receiving radiotherapy.	Degree in nursing. Subsequent clinical training in radiation oncology of at least 12–16 weeks duration under the direct supervision of a coordinator.	A syllabus for the education and training of radiation oncology nurses, Training Course Series No. 28, 2009 *(146)*.

Along with education and training comes national registration for each health professional specialty. Registration implies adherence to a professional code of conduct and the maintenance of registration is contingent upon achieving agreed upon levels of professional development activities.

Supporting professions include, but are not limited to, biomedical engineers, maintenance engineers, information technology professionals, social workers, dieticians, physiotherapists, dental surgeons, speech therapists and administrative staff.

Chapter 6.

Emerging technology and techniques in radiotherapy



6.1 Introduction

New medical equipment and techniques are consistently emerging in the field of radiotherapy, which need assessment as to their appropriate deployment in the health sector *(147,148)*. WHO has developed the health technology assessment framework *(12)* to assist its Member States. Health technology assessment is defined as "the systematic evaluation of properties, effects, and/or impacts of health care technology. It may address the direct, intended consequences of technologies as well as their indirect, unintended consequences. Its main purpose is to inform technology-related policy-making in health care. HTA is conducted by interdisciplinary groups using explicit analytical frameworks drawing from a variety of methods" *(12)*. Health technology assessment is inclusive of, but not limited to:

- cost–benefit analysis
- review of evidence of efficacy and performance
- review of the implementation process
- review of patient safety.

The sections of this chapter highlight emerging technologies and techniques in radiotherapy that warrant assessment for future deployment in limited-resource settings.

6.2 Electronic brachytherapy

In the field of brachytherapy, the replacement of sealed radioactive sources such as cobalt-60 and iridium-192 with miniature X-ray tubes for brachytherapy applications has emerged *(149)*. Early studies have shown promise in cervical cancer applications *(150)*. The advantages are in not needing to replace radioactive sources at regular intervals and in not having to deal with regulatory issues of safety and security of radioactive sources. More studies are needed to confirm the efficacy of electronic brachytherapy treatments and confirm its applicability for various treatment sites. Also, the reliability of the miniature X-ray tubes must be demonstrated; if tube replacement is required at only short intervals, then the cost-effectiveness of electronic brachytherapy in limited-resource settings may be questionable.

6.3 Image guided and adaptive radiotherapy

Imaging has always been a part of radiotherapy, however, in the last 10–15 years the advent of digital imaging and computer control has seen the introduction of more imaging options in radiotherapy, both in simulation and at the time of treatment. Dedicated imaging for treatment planning such as MRI for cervix and prostate and PET-CT for lung and head and neck cancers allows better delineation of the target. Dedicated in-room imaging at the time of treatment ensures the target is being covered by the treatment beams and coincidently is also an additional safety measure in ensuring the patient is in the correct treatment position. Real-time rapid imaging of the patient in the treatment position immediately prior to treatment also allows the possibility of adaptive treatment whereby the treatment plan is modified based on the images of the day. Table 21 lists many of the options for imaging in radiotherapy. Some of these imaging modalities are already in widespread use; however, any additional imaging in simulation and treatment guidance requires investigation in terms of health technology assessment.

Table 21. Imaging modalities in radiotherapy and their applications

Modality	Technique
MRI (simulation)	MRI imaging for treatment planning with both EBRT and brachytherapy applications.
MRI (in-room)	In-room MRI imaging integrated with the treatment unit for tumour and organs at risk visualization prior to treatment.
PET-CT (simulation)	PET-CT scanning for treatment planning. The CT scans act as the planning images. The PET images are registered to the CT images and assist in the identification of tumours and active nodes.
Ultrasound (in-room)	Ultrasound images assist in the correct applicator placement for brachytherapy and in tumour motion tracking during treatment in EBRT.
kV planar imaging (in-room)	Planar X-ray imaging at the time of treatment either with a kV source and detector panel integrated into the treatment unit or with a pair of kV systems located in fixed positions in the treatment room. Applications in pre-treatment imaging and potentially during treatment imaging.
kV cone beam CT (in-room)	Cone beam CT images at the time of treatment with a kV source and detector panel integrated into the treatment unit. Applications in pre-treatment imaging and adaptive radiotherapy.
MV imaging (in-room)	Digital portal imaging with an EPID for pre-treatment imaging and post-treatment verification, including MV cone beam CT. Dedicated imaging beams, e.g. a 2.5 MV photon beam, improve the image quality.
Active and inert fiducial markers (in-room)	Radio-opaque fiducial markers inserted surgically to aid in the visualization of the tumour. Gold seeds are typically used. Markers can also emit a radiofrequency (RF) signal for real-time tumour tracking during treatment with a dedicated detector.
4DCT (simulation)	Acquisition of CT data sets at different phases of the breathing cycle. Requires a transducer to monitor the breathing cycle and linked to the CT data acquisition.
Optical imaging (in-room)	Tracking of breathing cycle during treatment with the possibility to gate the treatment based on the phase of the breathing cycle. Optical surface imaging may also aid in confirming patient setup.

6.4 Hypofractionated radiotherapy and stereotactic radiotherapy

A recent trend, aligned with improved localization, imaging and dosimetry on LINACs, is implementation of hypofractionated radiotherapy for disease sites where conventional fractionation (around 2 Gy per fraction) was previously the norm or curative radiotherapy was not attempted. The same LINACs are now also used for stereotactic radiotherapy. Conventional LINACs were previously commissioned only down to a field size of 4 cm x 4 cm. Treatment of smaller lesions was left to dedicated units, such as those LINACs incorporating a frame-based immobilization system with dedicated conical collimators or a dedicated cranial unit such as the Gammaknife™. These dedicated units were also utilized in radiosurgery (single fraction delivery).

More recently, the prevalence of in-room imaging, motion management technology and MLCs with a resolution of 5 mm or less has allowed the possibility of hypofractionated radiotherapy and stereotactic radiotherapy on conventional LINACs. Additionally, the availability of flattening-filter-free (FFF) photon beams with HDRs above 10 Gy/min reduces the overall treatment time and a six degrees of freedom treatment couch, with the addition of pitch and roll to the standard couch, allows improved patient setup. Applications in hypofractionated radiotherapy or stereotactic radiotherapy are under investigation for prostate *(151)*, lung *(152)*, liver *(153)* and metastatic disease *(154)*. Smaller targets, multiple targets and higher dose per fraction require careful dosimetry and geometrical placement. An international code of practice *(155)* supports accurate small-field dosimetry and recommendations

for use and commissioning of imaging and motion management technology are emerging *(156,157)*. If efficacy and safety are assured, then the reduced number of fractions for courses of radiotherapy has obvious advantages for patients in reducing the overall length of time of treatment and for the radiotherapy department in allowing more patients to be treated with the same number of equipment and staff.

6.5 Specialized linear accelerators

As mentioned in Section 3.2.1, various "unconventional" LINAC designs have emerged in recent years, Table 22 lists various designs and their features, some of which are already in widespread clinical use and have been for many years. Thorough needs assessment is required in adoption of these designs in any radiotherapy setting.

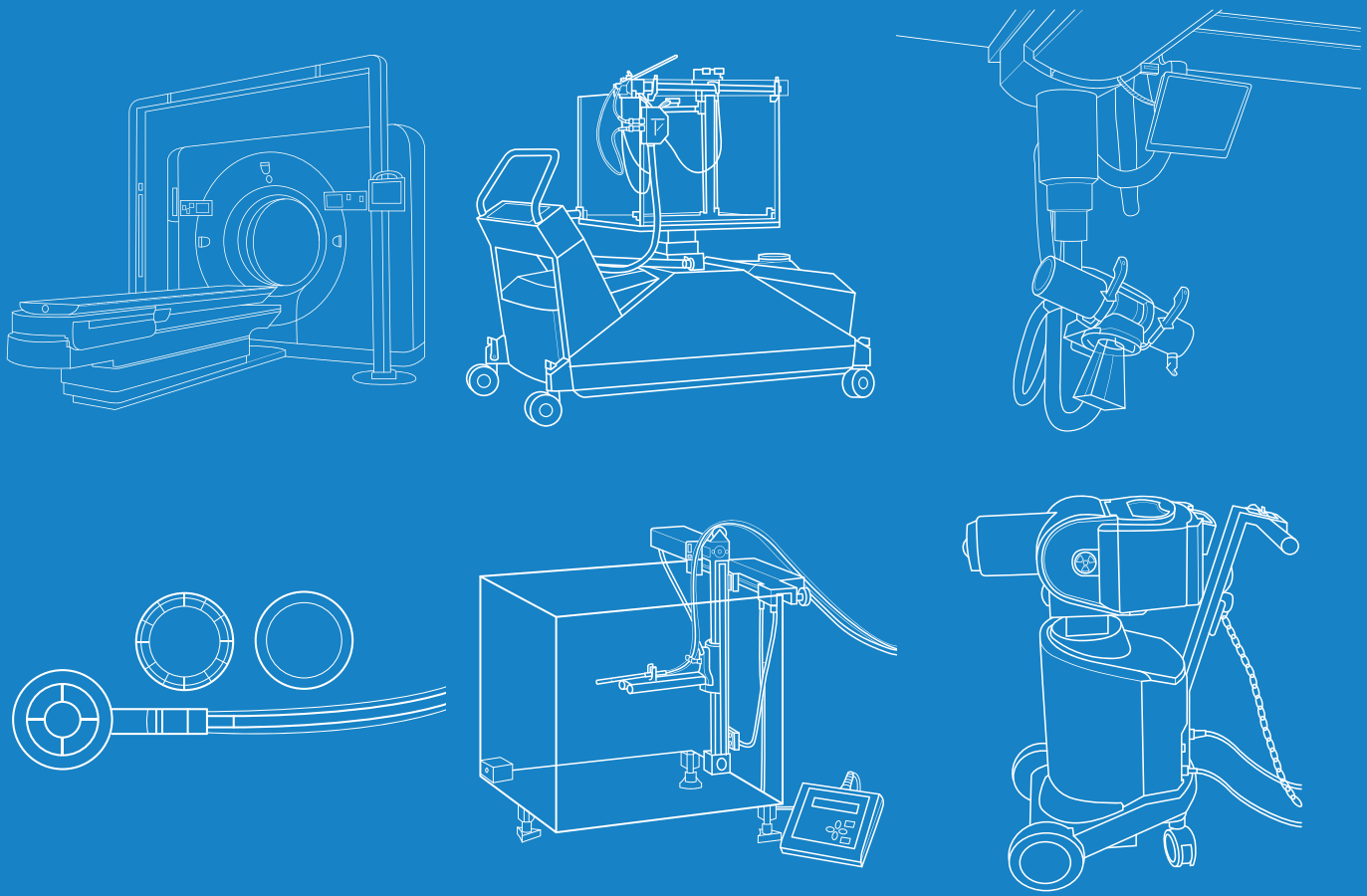
Table 22 Various linear accelerator designs

Design	Description
Robotic arm mounted LINAC	Single energy LINAC with various small-field collimators mounted on a robotic arm.
Gimbal mounted LINAC	Single energy LINAC mounted on gimbals allowing pan and tilt movements.
Enclosed gantry LINAC	Single energy LINAC with enclosed gantry allowing faster gantry rotation speeds.
LINAC with MRI	Multi-energy or single energy LINAC coupled with an MRI scanner. The static magnetic field axis can be either perpendicular to or in line with the LINAC beam.
Fan beam LINAC	Single energy LINAC with fan beam collimation. Treatment of a volume is achieved with continuous gantry rotation coupled with linear couch movement as in CT scanners.
LINAC with gyroscopic motion	Dedicated self-shielded LINAC for brain and head and neck applications.
LINAC with PET	LINAC coupled with a PET imaging system.

6.6 Proton and light ion therapy

Radiotherapy with proton beams and light ion beams has emerged in high-income countries in recent years. There are currently 79 operational proton therapy centres throughout the world *(158)*, concentrated mainly in China, Japan, the United States and Europe. There are 13 carbon ion beam facilities in China, Japan and Europe *(158)*. Prior to the advent of high-energy proton facilities, there were developments in the application of lower-energy proton beams in treating ocular disease and there are four low-energy proton therapy centres in Europe and North America *(158)*. The advantage of proton and light ion therapy is in the reduction of dose to surrounding healthy tissue and thus also in the potential for dose escalation *(159,160)*. The reduction in dose to healthy tissue with proton therapy is often highlighted in the treatment of paediatric cancers *(161)*. The resources needed in establishing and maintaining a proton or light ion therapy centre are significantly higher than for a LINAC facility with the same patient throughput. These modalities are currently not cost-effective in LMICs, however, this situation may change in the future with technology development and scale of use *(5,162)*.

Annexes



Annex 1. WHO template for medical linear accelerator (LINAC) technical specifications

Medical device specifications		
i	Version No.	1
ii	Date of initial version	10 October 2019
iii	Date of last modification	13 November 2020
iv	Date of publication	13 November 2020
v	Completed/ submitted by	Working group (WHO/IAEA)
Name, category and coding		
1	WHO category/ code	(under development)
2	Generic name	Medical linear accelerator
3	Specific type or variation (optional)	Not applicable
4	GMDN name	(to be completed if final user owns valid license or permission)
5	GMDN code	(to be completed if final user owns valid license or permission)
6	GMDN category	(to be completed if final user owns valid license or permission)
7	UMDNS name	(to be completed if final user owns valid license or permission)
8	UMDNS code	(to be completed if final user owns valid license or permission)
9	UNSPS code (optional)	42203003; 42202702
10	Alternative name/s (optional)	Not applicable
11	Alternative code/s (optional)	Not applicable
12	Keywords (optional)	External beam radiotherapy

Medical device specifications		
13	GMDN/UMDNS definition (optional)	(to be completed if final user owns valid license or permission)
Purpose of use		
14	Clinical or other purpose	Delivery of megavoltage X-ray and electron beams for external beam radiotherapy (EBRT).
15	Level of use (if relevant)	Hospital
16	Clinical department/ ward (if relevant)	Radiation Oncology Department
17	Overview of functional requirements	A medical linear accelerator (LINAC) producing collimated megavoltage X-ray and electron beams for EBRT. The LINAC shall include gantry, collimator and treatment couch to allow a range of treatment techniques. The LINAC shall interface with a record and verify system (RVS).
Technical characteristics		
18	Detailed requirements	• A motorized gantry with isocentric design, 100 cm source axis distance (SAD), isocentre clearance greater than 30 cm, and gantry rotation ±180°. The mechanical isocentre shall have a maximum diameter of less than or equal to 2 mm for all three rotation axes (collimator, gantry and treatment couch). • A collimating head with motorized rotation of at least ±90°. The maximum photon beam field size shall be 40 cm × 40 cm (50% isodose level) at the isocentre and the minimum field size no more than 4 cm x 4 cm (50% isodose level). • Asymmetric jaw movements for all jaws, allowing individual jaws to at least cross the central axis. • A light field to indicate the radiation field aperture and a reticule to indicate the principal axes and collimator axis of rotation. The light/radiation field coincidence shall be less than or equal to 2 mm. • An optical distance indicator with range of at least SAD = ±20 cm. • An optical back pointer. • Internal, physical or dynamic wedges providing wedge angles up to 60°. Interlocks shall be provided so that the operator has to positively confirm that the correct wedge has been selected. • (Package 2) An integrated multileaf collimator (MLC) with at least 80 motorized leaves and 1 cm maximum leaf width at the isocentre. The MLC and linear accelerator control shall allow conformal radiotherapy delivery through fixed MLC leaf placement for each treatment beam. The MLC interleaf leakage shall be less than 4% and the leaf position accuracy less than or equal to 1 mm at the isocentre plane. • A photon beam energy of 6 MV with flattening filter. • Variable dose rate from 50 MU/min up to at least 400 MU/min for photons. • (Package 2) A second photon energy of 10 MV with flattening filter. • (Package 2) Electron energies of 6, 9, 12 and 15 MeV. • (Package 2) Dose rate at least 400 MU/min for electrons. • (Package 2) A range of electron applicators up to at least 20 cm x 20 cm with slots to allow placement of individualized low-melting point alloy (LMPA) cut-outs. The source to end-of-applicator distance shall be 95 cm to allow 5 cm clearance between the patient and applicator. • An independent system of dual internal ionization chambers for monitoring dose, dose rate, beam symmetry and beam steering, with associated interlocks. For radiation beams the beam symmetry shall be less than or equal to 2% and the flatness less than or equal to 3%.

Medical device specifications		
18	...Detailed requirements	• An independent back-up timer to indicate accumulated monitor units (MU) if any power failure occurs. • A treatment couch with motorized lateral, longitudinal and vertical movements and motorized isocentric table rotation up to ±90°. The tabletop shall be carbon fibre and indexed to allow reproducible placement of immobilization equipment. The lateral range of the couch shall be at least ±20 cm. The longitudinal range of the couch shall be greater than 70 cm. The vertical motion of the couch shall range from the isocentre to at least 60 cm below the isocentre. The sag of the couch top shall be less than 5 mm with a patient of 80 kg weight. The couch shall be able to take a maximum weight of at least 180 kg. Hand pendants in the treatment room to allow control of linear accelerator and treatment couch movements. An in-room monitor with display of treatment parameters. A front pointer to locate the mechanical isocentre. A comprehensive set of standard shielding blocks with 100 individually coded block trays and a tray holder that attaches to the collimator head. (Package 1) A portal imaging solution, including portable cassette holder, four cassettes optimized for megavoltage imaging, and image processing (radiographic film or computed radiography [CR]). (Package 2) An integrated amorphous silicon electronic portal imaging device (EPID) panel mounted on a motorized arm, panel active area at least 30 cm x 30 cm, for digital portal imaging and, including software at the treatment control for comparing EPID images with treatment planning system (TPS)-generated digitally reconstructed radiographs (DRRs). The motorized arm holding the panel shall allow retraction of the panel and allow positioning of the panel at various positions at and below the mechanical isocentre with a range of lateral and longitudinal offsets. The panel shall include an anti-collision system. A CCTV system for viewing of the treatment room from the console. There shall be at least two in-room cameras at different locations in the treatment room and the in-room cameras shall have pan and zoom capability. A two-way patient intercommunication system. Fixed lasers mounted on the treatment room walls: Two lateral cross lasers, one ceiling cross laser and one sagittal line laser. Red or green lasers are required. A computerized control console outside the treatment room. All the functions and modes of the accelerator shall be controlled via software. The console shall allow activation of the controls so that the accelerator is operational in its various forms. The most important parameters shall be visible in the control console and treatment room. The console shall have a dual login system with various hierarchical modes, including clinical, physics and service modes. The console shall interface with an oncology information system (OIS) for record and verification of patient treatments. IEC 61217 scale convention as at least one option in clinical mode.
19	Displayed parameters	Comprehensive parameters at control console and on in-room monitors.
20	User adjustable settings	At control console, couch and hand pendants.

Medical device specifications		
Physical/chemical characteristics		
21	Components (if relevant)	Major components of the LINAC include microwave generator, accelerating waveguide, beam generation system, collimators, treatment couch, imaging equipment and control console.
22	Mobility, portability (if relevant)	Fixed, not mobile
23	Raw materials (if relevant)	Not applicable
Utility requirements		
24	Electrical, water and/or gas supply (if relevant)	Three phase electrical power, chilled water, compressed air (as needed), SF6 gas (supplied by manufacturer) and air-conditioning capable of six air exchanges per hour.
Accessories, consumable, spare parts and other components		
25	Accessories (if relevant)	Simulator, TPS, OIS, patient immobilization equipment, mould room equipment, dosimetry and quality control equipment, radiation safety equipment.
26	Sterilization process for accessories (if relevant)	Not applicable
27	Consumables/ reagents (if relevant)	Not applicable
28	Spare parts (if relevant)	Onsite spare parts kit is recommended.
29	Other components (if relevant)	Room laser system, audio visual communication system.
Packaging		
30	Sterility status on delivery (if relevant)	Not applicable
31	Shelf life (if relevant)	Not applicable
32	Transportation and storage (if relevant)	If storage is required prior to installation, the storage area should be secure, clean and dust-free, dry, cool, well-lit, ventilated and vermin-proof.
33	Labelling (if relevant)	Symbols used according to ISO-15233 standards.

Medical device specifications

Environmental requirements		
34	Context-dependent requirements	LINACs are housed in a concrete bunker to provide radiation protection for staff and members of the public. Special attention is needed for the maze entrance where door shielding may be required. Refer to IAEA publications Safety Reports Series No. 47 and Human Health Reports No. 10. It is the responsibility of the hospital to ensure that the manufacturer's recommended operation and storage conditions, as given in their site planning guide, are respected. If the device requires that the operating and/or storage environment be climate-controlled, appropriate temperature and humidity control systems, including monitoring, should be applied to avoid premature material disintegration and/or device failure.
Training, installation and utilization		
35	Pre-installation requirements (if relevant)	Radiation regulatory approval of room shielding and approval to acquire radiation source. It is the responsibility of the hospital to comply with requirements in the manufacturer's site planning guide and ensure services are ready for installation of the equipment. Pre-installation inspection of the site by the installer may be required.
36	Requirements for commissioning (if relevant)	Acceptance testing, commissioning of radiation beams, reference dosimetry, dosimetry audit, baselines for quality control, comprehensive radiation survey.
37	Training of user/s (if relevant)	Applications training in configuration, clinical operation, safety features and service mode.
38	User care (if relevant)	The equipment shall only be used in accordance with departmental policies, procedures and work instructions, and consistent with manufacturer's use instructions, to ensure safety and protection.
Warranty and maintenance		
39	Warranty	At least 12 months
40	Maintenance tasks	4–8 service days per year. Tasks as per manufacturer's preventative maintenance schedule.
41	Type of service contract	Full service contract, including parts, service and repair or in-house maintenance engineering service.
42	Spare parts availability post-warranty	10 years minimum
43	Software/ hardware upgrade availability	To be specified by manufacturer.
Documentation		
44	Documentation requirements	Comprehensive user manual, including emergency procedures.
Decommissioning		
45	Estimated lifespan	10–15 years

Medical device specifications		
Safety and standards		
46	Risk classification	US FDA: Device Class 2
47	Regulatory approval/ certification	Radiation regulatory approval for equipment possession, use and premises. FDA approval (USA) or CE Mark (EU).
48	International standards	IEC, Medical Electrical Equipment, Part 1: General Requirements for Safety, Rep. IEC 60601-1:2005+AMD1:2012. Radiation Protection and Safety of Radiation Sources, International Basic Safety Standards, No. GSR Part 3, IAEA, Vienna, 2014 *(23)*. IEC, Medical Electrical Equipment, Part 60601-2-1: Particular Requirements for the Basic Safety and Essential Performance of Electron Accelerators in the Range 1 MeV to 50 MeV, Rep. IEC 60601-2-1:2009+AMD1:2014. IEC, Medical electrical equipment – Medical electron accelerators – Functional performance characteristics, IEC 60976, 2007. IEC, Medical electrical equipment – Medical electron accelerators – Guidelines for functional performance characteristics, IEC TR 60977:2008. IEC, Electrical medical equipment – Part 2–68: Particular requirements for the basic safety and essential performance of X-ray-based image-guided radiotherapy (IGRT) equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment, IEC 60601-2-68:2014. IEC, Medical electrical equipment – Safety of radiotherapy record and verify systems, IEC 62274:2005. IEC, Medical electrical system – Guidelines for safe integration and operation of adaptive external-beam radiotherapy systems for real-time adaptive radiotherapy, IEC TR 62926:2019. IEC, Guidance on error and warning messages for software used in radiotherapy, IEC TR 63183:2019. IEC, Radiotherapy equipment – Coordinates, movements and scales, IEC 61217, 2011.
49	Regional/local standards	Country-specific and regional standards may apply.
50	Regulations	USA: 21CFR892.5050 Medical charged-particle radiation therapy system. Local radiation safety regulations may apply.

Annex 2.
WHO template for cobalt-60 teletherapy unit technical specifications

Medical device specifications		
i	Version No.	1
ii	Date of initial version	10 October 2019
iii	Date of last modification	13 November 2020
iv	Date of publication	13 November 2020
v	Completed/ submitted by	Working group (WHO/IAEA)
Name, category and coding		
1	WHO category/ code	(under development)
2	Generic name	Cobalt-60 teletherapy unit
3	Specific type or variation (optional)	Not applicable
4	GMDN name	(to be completed if final user owns valid license or permission)
5	GMDN code	(to be completed if final user owns valid license or permission)
6	GMDN category	(to be completed if final user owns valid license or permission)
7	UMDNS name	(to be completed if final user owns valid license or permission)
8	UMDNS code	(to be completed if final user owns valid license or permission)
9	UNSPS code (optional)	42202701
10	Alternative name/s (optional)	Not applicable
11	Alternative code/s (optional)	Not applicable
12	Keywords (optional)	External beam radiotherapy

Medical device specifications		
13	GMDN/UMDNS definition (optional)	(to be completed if final user owns valid license or permission)
Purpose of use		
14	Clinical or other purpose	Delivery of gamma ray beams for external beam radiotherapy (EBRT).
15	Level of use (if relevant)	Hospital
16	Clinical department/ward (if relevant)	Radiation Oncology Department
17	Overview of functional requirements	A unit delivering collimated cobalt-60 gamma rays for EBRT. The unit shall include gantry, collimator and treatment couch to allow a range of treatment techniques. The unit shall interface with a record and verify system (RVS).
Technical characteristics		
18	Detailed requirements	• A shielded cobalt-60 source of 2.5 cm diameter or less that provides an initial minimum dose rate of at least 2.0 Gy/min to water at the depth of maximum dose at 100 cm source skin distance (SSD) for a field size of 10 cm x 10 cm. The beam symmetry shall be less than or equal to 3% and the flatness less than or equal to 3%. • A motorized gantry with rotation range ±180° and a source to axis distance (SAD) of 100 cm. The mechanical isocentre shall have a maximum diameter of less than or equal to 2 mm for all three rotation axes (collimator, gantry and treatment couch). The isocentre clearance shall be greater than or equal to 30 cm with accessories inserted. • Motorized collimators providing a maximum field size of 40 cm x 40 cm at 100 cm SAD and a minimum field size of 1 cm x 1 cm with asymmetric collimators capable of shielding half the beam and motorized collimator rotation of at least ±90°. • Secondary collimators (trimmers) to reduce penumbra to less than 10 mm (if needed). • A light field incorporated in the head of the gantry to indicate the radiation field location. The light/radiation field coincidence shall be less than or equal to 2 mm. • An optical distance indicator with a range of at least SAD ±20 cm. • An optical back pointer. • One universal wedge providing wedging of up to 60o or a set of physical wedge filters of 15°, 30°, 45° and 60°. Interlocks shall be provided so that the operator has to positively confirm that the correct wedge has been selected. • A patient couch providing motorized vertical movement, longitudinal and lateral motions with isocentric rotation. The tabletop shall be carbon fibre and indexed to allow reproducible placement of patient immobilization devices. The isocentric rotation range of the couch shall be ±90°. The range of lateral motion of the couch top shall be ±20 cm. The longitudinal range of the couch top motion shall be greater than 70 cm. The vertical motion of the couch shall range from the isocentre to at least 60 cm below the isocentre. The sag of the couch top shall be less than 5 mm with a patient of 80 kg weight. The couch shall be able to take a maximum weight of at least 180 kg.

Medical device specifications		
18	...Detailed requirements	• A hand pendant for control of parameters inside the treatment room. • An in-room monitor with display of treatment parameters. • A front pointer to locate the mechanical isocentre. • A transparent shadow tray for shielding blocks to support blocks up to 20 kg. It shall be possible to use blocks and wedges simultaneously. The block tray shall be interlocked to the console. • A comprehensive set of standard shielding blocks with 100 individually coded block trays. • A portal imaging solution, including portable cassette holder, four cassettes optimized for megavoltage imaging, and image processing (radiographic film or computed radiography/[CR]). • An area radiation monitor with an acoustic/optical signal of radiation. • A CCTV system for viewing of the treatment room from the console. There shall be at last two in-room cameras at different locations in the treatment room and the in-room cameras shall have pan and zoom capability. • A two-way patient intercommunication system. • A set of four mounted lasers for patient positioning intersecting at the mechanical isocentre (two lateral cross lasers, one ceiling cross laser and one sagittal line laser). Red or green lasers are required. • An uninterruptable power supply (UPS) to immediately retract the source and to provide the treatment console information at the time of a power outage. • T bar for manual source retraction. • A computerized control console outside the treatment room with an audio visual radiation monitor and display of interlocks, dual channel timer system and display of the treatment parameters. All the functions and modes of the unit shall be controlled via software. The console shall allow activation of the controls so that the unit is operational in its various forms. The most important parameters shall be visible in the control console and treatment room. The control console shall have a removable on/off key and a secondary login system with various hierarchical modes, including clinical, physics and service modes. The console shall interface with an oncology information system (OIS) for record and verification of patient treatments. • IEC 61217 scale convention as at least one option in clinical mode.
19	Displayed parameters	Comprehensive parameters at control console and on in-room monitors.
20	User adjustable settings	At control console, couch and hand pendants.
Physical/chemical characteristics		
21	Components (if relevant)	Major components of the cobalt-60 teletherapy unit include the cobalt-60 source, source housing, source movement mechanism, gantry, collimator head, treatment couch, imaging equipment, and control console.
22	Mobility, portability (if relevant)	Fixed, not mobile
23	Raw materials (if relevant)	Not applicable
Utility requirements		
24	Electrical, water and/or gas supply (if relevant)	Single-phase electrical power, compressed air (as needed), and air-conditioning.

Medical device specifications

Accessories, consumable, spare parts and other components

25	Accessories (if relevant)	Simulator, treatment planning system (TPS), OIS, patient immobilization equipment, mould room equipment, dosimetry and quality control equipment, radiation safety equipment.
26	Sterilization process for accessories (if relevant)	Not applicable
27	Consumables/ reagents (if relevant)	Not applicable
28	Spare parts (if relevant)	Onsite spare parts kit is recommended.
29	Other components (if relevant)	Room laser system, audio visual communication system.
Packaging		
30	Sterility status on delivery (if relevant)	Not applicable
31	Shelf life (if relevant)	Not applicable
32	Transportation and storage (if relevant)	If storage is required prior to installation, the storage area should be secure, clean and dust-free, dry, cool, well-lit, ventilated and vermin-proof.
33	Labelling (if relevant)	Symbols used according to ISO-15233 standards.

Environmental requirements

34	Context-dependent requirements	Cobalt-60 teletherapy units are housed in a concrete bunker to provide radiation protection for staff and members of the public. Special attention is needed for the maze entrance where door shielding may be required. Refer to IAEA publications Safety Reports Series No. 47 and Human Heath Reports No. 10. It is the responsibility of the hospital to ensure that the manufacturer's recommended operation and storage conditions, as given in their site planning guide, are respected. If the device requires that the operating and/or storage environment be climate-controlled, appropriate temperature and humidity control systems, including monitoring, should be applied to avoid premature material disintegration and/or device failure.

Training, installation and utilization

35	Pre-installation requirements (if relevant)	Radiation regulatory approval of room shielding and approval to acquire radiation source. It is the responsibility of the hospital to comply with requirements in the manufacturer's site planning guide and ensure services are ready for installation of the equipment. Pre-installation inspection of the site by the installer may be required.
36	Requirements for commissioning (if relevant)	Acceptance testing, commissioning of radiation beam, reference dosimetry, dosimetry audit, baselines for quality control, comprehensive radiation survey.

Medical device specifications		
37	Training of user/s (if relevant)	Applications training in configuration, clinical operation, safety features and service mode.
38	User care (if relevant)	The equipment shall only be used in accordance with departmental policies, procedures and work instructions, and consistent with manufacturer's use instructions, to ensure safety and protection.
Warranty and maintenance		
39	Warranty	At least 12 months
40	Maintenance tasks	Approximately 4 service days per year. Tasks as per manufacturer's preventative maintenance schedule.
41	Type of service contract	Full-service contract, including parts, service and repair or in-house maintenance engineering service.
42	Spare parts availability post-warranty	10 years minimum
43	Software/hardware upgrade availability	To be specified by manufacturer.
Documentation		
44	Documentation requirements	Comprehensive user manual, including emergency procedures.
Decommissioning		
45	Estimated lifespan	10–15 years with cobalt-60 source exchange every 5 years.
Safety and standards		
46	Risk classification	US FDA: Device Class 2
47	Regulatory approval/ certification	Radiation regulatory approval for equipment possession, use and premises.
48	International standards	IEC, Medical Electrical Equipment, Part 1: General Requirements for Safety, Rep. IEC 60601-1:2005+AMD1:2012. Radiation Protection and Safety of Radiation Sources, International Basic Safety Standards, No. GSR Part 3, IAEA, Vienna, 2014 *(23)*. IEC, Medical electrical equipment – Part 2-11: Particular requirements for the basic safety and essential performance of gamma beam therapy equipment, IEC 60601-2-11:2013. IEC, Radiotherapy equipment – Coordinates, movements and scales, IEC 61217, 2011. ISO, Radiological protection – Sealed radioactive sources – General requirements and classification, ISO-2919:2012. IEC, Guidance on error and warning messages for software used in radiotherapy, IEC TR 63183:2019.
49	Regional/local standards	Country-specific and regional standards may apply.
50	Regulations	USA: 21CFR892.5750 Radionuclide radiation therapy system Local radiation safety regulations may apply.

Annex 3.
WHO template for CT simulator technical specifications

Medical device specifications		
i	Version No.	1
ii	Date of initial version	10 October 2019
iii	Date of last modification	13 November 2020
iv	Date of publication	13 November 2020
v	Completed/ submitted by	Working group (WHO/IAEA)
Name, category and coding		
1	WHO category/ code	(under development)
2	Generic name	CT simulator
3	Specific type or variation (optional)	Not applicable
4	GMDN name	(to be completed if final user owns valid license or permission)
5	GMDN code	(to be completed if final user owns valid license or permission)
6	GMDN category	(to be completed if final user owns valid license or permission)
7	UMDNS name	(to be completed if final user owns valid license or permission)
8	UMDNS code	(to be completed if final user owns valid license or permission)
9	UNSPS code (optional)	42203202
10	Alternative name/s (optional)	Not applicable
11	Alternative code/s (optional)	Not applicable
12	Keywords (optional)	External beam radiotherapy

Medical device specifications		
13	GMDN/UMDNS definition (optional)	(to be completed if final user owns valid license or permission)
Purpose of use		
14	Clinical or other purpose	Volumetric imaging of patients for radiotherapy treatment planning.
15	Level of use (if relevant)	Hospital
16	Clinical department/ ward (if relevant)	Radiation Oncology Department
17	Overview of functional requirements	A unit providing CT X-ray imaging of patients for radiotherapy treatment planning. The unit shall include a flat top couch insert and external laser system for positioning of the patient. The unit shall be Digital Imaging and Communications in Medicine (DICOM) compatible for transfer of images to a treatment planning system (TPS).
Technical characteristics		
18	Detailed requirements	• A CT scanner with whole body spiral and multi-slice (minimum 16 slices per rotation) capabilities with a gantry aperture of at least 80 cm. The scan field of view (FOV) shall be at least 50 cm and extended FOV of minimum 70 cm shall be available. The positioning indicators in the gantry shall have a positioning accuracy of ±1 mm or better. • A couch top constructed of carbon fibre, flat bed type, indexed to allow reproducible placement of immobilization equipment and having horizontal moving range of 170 cm or more. The speed of horizontal movement shall be variable with a maximum speed of at least 100 mm per second. The accuracy of the couch top position shall be better than ±0.25 mm. The scannable range shall be at least 150 cm. The couch shall be able to take a maximum weight of at least 180 kg without any change in stated performance specifications (such as the positioning accuracy). The sag of the couch top shall be less than 5 mm with a patient of 80 kg weight. • A high-frequency X-ray generator with power rating of at least 60 kW. The kVp range shall be 80 kV–130 kV. The mA range shall be at least 30 mA–400 mA, with step size of 5 mA or better. The peak anode heat dissipation rate shall be at least 1.1 MJ/min or better. The X-ray tube shall have dual focal spots. • A detector system with high performance, low noise, high data density, active response data acquisition system. The detectors shall be solid state. The detector system shall be free from repeated calibrations. There shall be multiple rows of 650 or more detectors for taking a minimum of 16 slices at a time. • A computer system for the CT scanner. A high-end main computer system with network capability shall be provided. There shall be two monitors at the console and they shall be 19-inch or more flat screen LCD monitors. One of these will be used for acquisition and the other will be used for image review and processing. The hard disk capacity of the main computer system shall be at least 1 TB or more. In the hard disk meant for image storage, the number of uncompressed 512 x 512 images that can be stored should be at least 200 000 or more. The system shall form part of the departmental intranet and should not have access to the internet. Software installation and upgrades/updates should be performed using CD/DVD and all other external data device inputs should be disabled to enhance data protection and minimize virus infection.

Medical device specifications		
18	...Detailed requirements	• The system shall be fully DICOM-compliant. The system shall support the following: DICOM 3.0 Print service class as a user, DICOM 3.0 Storage class as a user, DICOM 3.0 Storage class as a provider, DICOM 3.0 Send/Receive, DICOM 3.0 Query/Retrieve service class as a user, and DICOM 3.0 Query/Retrieve service class as a provider. A DICOM compliance statement shall be provided. • An automatic overnight back-up system to an external hard drive for all workstations. • An external long-term image archive system. • A dose reporting feature with dose display and the capacity to transfer dose information for recording purposes. DICOM structured dose report shall be available. • Typical radiotherapy scan protocols for routine adult and paediatric scanning and quality control. • Automatic mA control software that automatically adjusts mA for patient size, adjusts mA along the z-axis, and modulates mA during rotation. • A metal artefact reduction algorithm incorporated into image processing. • A pump system capable of injecting contrast media through intravenous cannulas or through peripherally inserted central catheters. • Software to allow direct transfer of CT data sets to a separate virtual simulation workstation, external beam TPS (model to be decided) and oncology information system (OIS) (model to be decided). • A virtual simulation workstation for volume definition (contouring), isocentre localization, field placement and field design (shielding blocks or multileaf collimater [MLC] configuration) of all the external beam radiotherapy (EBRT) equipment, and the generation of digitally reconstructed radiographs (DRRs). It should be possible to seamlessly export patient administrative data, images, volumes and machine parameters to the external beam teletherapy equipment, external beam TPS, laser imager and the OIS. • A bi-directional speaker communication shall be provided between the operator and the patient. • A CCTV system to view the patient within the gantry bore. • An external radiotherapy laser system for patient alignment, marking and isocentre localization. The external laser system shall include a moveable ceiling laser and moveable lateral lasers with control of the position of the lasers available within the CT simulator room. Laser projection shall also be at least 50 cm long at the patient plane. Red or green lasers are preferred. • A networked dry laser imager. The following performance characteristics shall be met: • Slice thickness of at least sub-millimetre up to 8 mm. • Scan time of 0.6 second or less for full 360° rotation. • Retrospective reconstruction on raw data files with change in parameters such as field of view (FOV). • Starting with a cold tube, the maximum helical scan distance using a 3 mm imaged slice thickness and a pitch of 1.5 of 1500 mm or more. • The following scanning modes shall be available: scan projection radiograph (SPR), axial, and spiral. The SPR length should be more than 1500 mm long and the width shall be at least 500 mm. It shall be possible to obtain the SPR from anterior to posterior (AP) or posterior to anterior (PA) or left to right or right to left directions. The ability of the system to reproduce the scanning protocol from the SPR should be ±3 mm or better. The accuracy of distance measurements in the SPR (taken at isocentre distance) shall be better than twice the pixel dimension. • Pitch selection in the range from 0.6 to 1.5 mm. • Image Quality: The reconstruction matrix shall be 512 x 512 or higher. High-contrast spatial resolution: at least 15 lp/cm maximum at 0% modulation transfer function (MTF). Low-contrast detectability: 5 mm or less at 0.3% using adequate phantom on 10 mm slice thickness. The CT number accuracy shall be better than 0 ± 4HU for water and – 1000 ±10 HU for air.

Medical device specifications		
19	Displayed parameters	Comprehensive parameters at control console.
20	User adjustable settings	At control console and gantry.
Physical/chemical characteristics		
21	Components (if relevant)	Major components of the CT simulator include CT scanner with wide bore, patient couch, including flat top overlay and external laser system.
22	Mobility, portability (if relevant)	Fixed, not mobile
23	Raw materials (if relevant)	Not applicable
Utility requirements		
24	Electrical, water and/or gas supply (if relevant)	Three phase electrical power, chilled water (as needed) and air-conditioning.
Accessories, consumable, spare parts and other components		
25	Accessories (if relevant)	Patient immobilization equipment, dosimetry and quality control equipment, radiation safety equipment.
26	Sterilization process for accessories (if relevant)	Not applicable
27	Consumables/ reagents (if relevant)	Not applicable
28	Spare parts (if relevant)	Access to spare parts is required.
29	Other components (if relevant)	Not applicable
Packaging		
30	Sterility status on delivery (if relevant)	Not applicable
31	Shelf life (if relevant)	Not applicable
32	Transportation and storage (if relevant)	If storage is required prior to installation, the storage area should be secure, clean and dust-free, dry, cool, well-lit, ventilated and vermin-proof.
33	Labelling (if relevant)	Symbols used according to ISO-15233 standards.

Medical device specifications		
Environmental requirements		
34	Context-dependent requirements	CT simulators are housed in a shielded room to provide radiation protection for staff and members of the public. Refer to Sutton et al. 2012 (50) and IAEA Human Health Reports No. 10. It is the responsibility of the hospital to ensure that the manufacturer's recommended operation and storage conditions, as given in their site planning guide, are respected. If the device requires that the operating and/or storage environment be climate-controlled, appropriate temperature and humidity control systems, including monitoring, should be applied to avoid premature material disintegration and/or device failure.
Training, installation and utilization		
35	Pre-installation requirements (if relevant)	Radiation regulatory approval of room shielding and approval to acquire radiation source. It is the responsibility of the hospital to comply with requirements in the manufacturer's site planning guide and ensure services are ready for installation of the equipment. Pre-installation inspection of the site by the installer may be required.
36	Requirements for commissioning (if relevant)	Acceptance testing, commissioning of imaging system, electron density calibration, baselines for quality control, comprehensive radiation survey.
37	Training of user/s (if relevant)	Applications training in clinical operation, safety features and service mode.
38	User care (if relevant)	The equipment shall only be used in accordance with departmental policies, procedures and work instructions, and consistent with manufacturer's use instructions, to ensure safety and protection.
Warranty and maintenance		
39	Warranty	At least 12 months
40	Maintenance tasks	Approximately 4 service days per year. Tasks as per manufacturer's preventative maintenance schedule.
41	Type of service contract	Full-service contract, including parts, service and repair (inclusive or exclusive of X-ray tube).
42	Spare parts availability post-warranty	10 years
43	Software/ hardware upgrade availability	To be specified by manufacturer.
Documentation		
44	Documentation requirements	Comprehensive user manual, including emergency procedures.
Decommissioning		
45	Estimated lifespan	5–10 years

Medical device specifications		
Safety and standards		
46	Risk classification	US FDA: Device Class 2
47	Regulatory approval/ certification	Radiation regulatory approval for equipment possession, use and premises.
48	International standards	IEC, Medical Electrical Equipment, Part 1: General Requirements for Safety, Rep. IEC 60601-1:2005+AMD1:2012. Radiation Protection and Safety of Radiation Sources, International Basic Safety Standards, No. GSR Part 3, IAEA, Vienna, 2014 *(23)*. IEC, Medical electrical equipment – Part 2–44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography, IEC 60601-2-44:2009+AMD1:2012+AMD2:2016 CSV. IEC, Evaluation and routine testing in medical imaging departments – Part 2–6: Constancy tests Imaging performance of computed tomography X-ray equipment, IEC 61223-2-6:2006. IEC, Evaluation and routine testing in medical imaging departments – Part 3–5: Acceptance tests and constancy tests – Imaging performance of computed tomography X-ray equipment, IEC 61223-3-5:2019.
49	Regional/local standards	Country-specific and regional standards may apply.
50	Regulations	Local radiation safety regulations may apply.

Annex 4.
WHO template for conventional simulator technical specifications

Medical device specifications		
i	Version No.	1
ii	Date of initial version	10 October 2019
iii	Date of last modification	13 November 2020
iv	Date of publication	13 November 2020
v	Completed/ submitted by	Working group (WHO/IAEA)
Name, category and coding		
1	WHO category/ code	(under development)
2	Generic name	Conventional simulator
3	Specific type or variation (optional)	Not applicable
4	GMDN name	(to be completed if final user owns valid license or permission)
5	GMDN code	(to be completed if final user owns valid license or permission)
6	GMDN category	(to be completed if final user owns valid license or permission)
7	UMDNS name	(to be completed if final user owns valid license or permission)
8	UMDNS code	(to be completed if final user owns valid license or permission)
9	UNSPS code (optional)	42203200; 42203201
10	Alternative name/s (optional)	Not applicable
11	Alternative code/s (optional)	Not applicable
12	Keywords (optional)	External beam radiotherapy, brachytherapy

Medical device specifications		
13	GMDN/UMDNS definition (optional)	(to be completed if final user owns valid license or permission)
Purpose of use		
14	Clinical or other purpose	X-ray imaging of patients for radiotherapy treatment planning.
15	Level of use (if relevant)	Hospital
16	Clinical department/ ward (if relevant)	Radiation Oncology Department
17	Overview of functional requirements	A unit providing planar X-ray imaging of patients for radiotherapy treatment planning. The unit shall include a gantry, collimator and couch to allow simulation of the treatment position on a treatment unit. The unit shall be Digital Imaging and Communications in Medicine (DICOM) compatible for transfer of images to a treatment planning system (TPS).
Technical characteristics		
18	Detailed requirements	• A motorized gantry of isocentric design and a gantry rotation range ±180° with a maximum mechanical isocentre sphere diameter of 2.0 mm. • An adjustable X-ray focus-to-isocentre distance at least 80–100 cm. • An X-ray tube for radiography and fluoroscopy. There shall be two focal spot sizes available. • An X-ray generator with 30 kW high-frequency capable of fluoroscopy and radiography modes, up to 125 kVp and 300 mAs (radiography) and 4 mA (fluoroscopy). • A motorized diaphragm to collimate the X-ray beam with both local and remote control. The collimator rotation range shall be at least ±90°. The maximum field size at the isocentre shall be up to 40 cm × 40 cm at 100 cm from the focus. • Radio-opaque wires to define the intended treatment field, independent of the X-ray beam diaphragm, motorized and with both local and remote control. Asymmetric setting of the wire positions is required. • A light field shall be incorporated in the head of the gantry to indicate the radiation field location. The light/radiation field coincidence shall be less than 2 mm. • An optical distance indicator shall be incorporated in the head of the gantry. The optical distance indication range shall be SAD ±20 cm. • A motorized couch with X-ray transparency of the couch top, isocentric rotation limits of ±90°, lateral motion range of ±20 cm, motorized vertical movement, longitudinal range of greater than or equal to 70 cm, and sag of the couch top less than 5 mm with a patient of 80 kg. The couch shall be able to take a maximum weight of at least 180 kg. The couch shall be indexed to allow reproducible placement of patient immobilization devices and the indexing system should preferably be of the same type as the radiotherapy department's treatment couches. • A hand pendant for control of parameters inside the simulator room. • An in-room monitor with display of simulator parameters. • A front pointer to locate the mechanical isocentre.

Medical device specifications		
18	...Detailed requirements	• A transparent shadow tray that is positioned at the same source-to-tray distance as the treatment units and a grid tray. • A digital X-ray imaging system (flat panel) with dimensions greater than or equal to 30 cm x 30 cm. Lateral and longitudinal movements of the imaging system shall be available. • Anti-collision systems particularly for the imaging system. • A CCTV system with pan, tilt and zoom capability. • A patient intercommunication system. • Four mounted external lasers (two lateral cross lasers, one ceiling cross laser and one sagittal line laser) intersecting at the mechanical isocentre. • A remote console for control of the X-ray system and control of the gantry, collimator, imaging panel and couch. The console shall include a DICOM 3.0 interface for digital networking of images (transfer of digital images to and from a TPS). • IEC 61217 scale convention as at least one option in clinical mode.
19	Displayed parameters	Comprehensive parameters at control console and on in-room monitors.
20	User adjustable settings	At control console, couch and hand pendants.
Physical/chemical characteristics		
21	Components (if relevant)	Major components of the conventional simulator include X-ray tube, housing and generator, X-ray detector system, gantry, collimator, patient couch, and control console.
22	Mobility, portability (if relevant)	Fixed, not mobile
23	Raw materials (if relevant)	Not applicable
Utility requirements		
24	Electrical, water and/or gas supply (if relevant)	Three phase electrical power and air-conditioning.
Accessories, consumable, spare parts and other components		
25	Accessories (if relevant)	Patient immobilization equipment, mould room equipment, dosimetry and quality control equipment, radiation safety equipment.
26	Sterilization process for accessories (if relevant)	Not applicable
27	Consumables/ reagents (if relevant)	Not applicable
28	Spare parts (if relevant)	Onsite spare parts kit is recommended.
29	Other components (if relevant)	Room laser system, audio visual communication system.

Medical device specifications

Packaging		
30	Sterility status on delivery (if relevant)	Not applicable
31	Shelf life (if relevant)	Not applicable
32	Transportation and storage (if relevant)	If storage is required prior to installation, the storage area should be secure, clean and dust-free, dry, cool, well-lit, ventilated and vermin-proof.
33	Labelling (if relevant)	Symbols used according to ISO-15233 standards.
Environmental requirements		
34	Context-dependent requirements	Conventional simulators are housed in shielded rooms to provide radiation protection for staff and members of the public. Refer to IAEA publications Safety Reports Series No. 47 and Human Health Reports No. 10. It is the responsibility of the hospital to ensure that the manufacturer's recommended operation and storage conditions, as given in their site planning guide, are respected. If the device requires that the operating and/or storage environment be climate-controlled, appropriate temperature and humidity control systems, including monitoring, should be applied to avoid premature material disintegration and/or device failure.
Training, installation and utilization		
35	Pre-installation requirements (if relevant)	Radiation regulatory approval of room shielding and approval to acquire radiation source. It is the responsibility of the hospital to comply with requirements in the manufacturer's site planning guide and ensure services are ready for installation of the equipment. Pre-installation inspection of the site by the installer may be required.
36	Requirements for commissioning (if relevant)	Acceptance testing, commissioning of imaging system, baselines for quality control, comprehensive radiation survey.
37	Training of user/s (if relevant)	Applications training in configuration, clinical operation, safety features and service mode.
38	User care (if relevant)	The equipment shall only be used in accordance with departmental policies, procedures and work instructions, and consistent with manufacturer's use instructions, to ensure safety and protection.
Warranty and maintenance		
39	Warranty	At least 12 months
40	Maintenance tasks	Approximately 4 service days per year. Tasks as per manufacturer's preventative maintenance schedule.
41	Type of service contract	Full-service contract, including parts, service and repair or in-house maintenance engineering service.
42	Spare parts availability post-warranty	9 years minimum

Medical device specifications		
43	Software/ hardware upgrade availability	To be specified by manufacturer.
Documentation		
44	Documentation requirements	Comprehensive user manual, including emergency procedures.
Decommissioning		
45	Estimated lifespan	10 years
Safety and standards		
46	Risk classification	US FDA: Device Class 2
47	Regulatory Approval/ certification	Radiation regulatory approval for equipment possession, use and premises.
48	International standards	IEC, Medical Electrical Equipment, Part 1: General Requirements for Safety, Rep. IEC 60601-1:2005+AMD1:2012. Radiation Protection and Safety of Radiation Sources, International Basic Safety Standards, No. GSR Part 3, IAEA, Vienna, 2014 *(23)*. IEC, Medical electrical equipment – Part 2–29: Particular requirements for the basic safety and essential performance of radiotherapy simulators, IEC 60601-2-29:2008. IEC, Radiotherapy simulators – Functional performance characteristics, IEC 61168:1993. IEC, Radiotherapy simulators – Guidelines for functional performance characteristics, IEC TS 61170:1993. IEC, Radiotherapy equipment – Coordinates, movements and scales, IEC 61217.
49	Regional/local standards	Country-specific and regional standards may apply.
50	Regulations	Local radiation safety regulations may apply.

Annex 5.
WHO template for external beam treatment planning system (TPS) technical specifications

Medical device specifications		
i	Version No.	1
ii	Date of initial version	10 October 2019
iii	Date of last modification	13 November 2020
iv	Date of publication	13 November 2020
v	Completed/ submitted by	Working group (WHO/IAEA)
Name, category and coding		
1	WHO category/ code	(under development)
2	Generic name	Treatment planning system
3	Specific type or variation (optional)	Not applicable
4	GMDN name	(to be completed if final user owns valid license or permission)
5	GMDN code	(to be completed if final user owns valid license or permission)
6	GMDN category	(to be completed if final user owns valid license or permission)
7	UMDNS name	(to be completed if final user owns valid license or permission)
8	UMDNS code	(to be completed if final user owns valid license or permission)
9	UNSPS code (optional)	Not applicable
10	Alternative name/s (optional)	Not applicable
11	Alternative code/s (optional)	Not applicable
12	Keywords (optional)	External beam radiotherapy

Medical device specifications		
13	GMDN/UMDNS definition (optional)	(to be completed if final user owns valid license or permission)
Purpose of use		
14	Clinical or other purpose	Preparation of patient treatment plans for external beam radiotherapy (EBRT).
15	Level of use (if relevant)	Hospital
16	Clinical department/ ward (if relevant)	Radiation Oncology Department
17	Overview of functional requirements	Software to generate treatment plans for EBRT. The software shall include modules for image import and registration, contouring of target volumes and organ at risk, planning of treatment beams, dose calculation, plan review and export, and beam modelling.
Technical characteristics		
18	Detailed requirements	• Treatment planning workstations, including dual 23-inch monitors, keyboard, mouse and network capability. • A module to allow import of patient data sets from various imaging modalities that are used to facilitate target definition, using the Digital Imaging and Communications in Medicine (DICOM) standard. Image import may be achieved through direct connectivity to the radiology PACS system. • An image registration module using either rigid and/or deformable registration modes. • 3D visualization capability for patient data display, beam display and dose distribution display. • Contouring tools that allow the definition in 3D of structures, including target, organs at risk and patient outline. • Automated tools to allow the expansion of the clinical target volume (CTV) to a planning target volume (PTV) with non-uniform margins in three dimensions. • The ability to add bolus structures to the patient data set of various shape and density. • A comprehensive "forward planning" environment which allows the user to modify beam weights, beam positioning, jaw position, wedges and blocks or multileaf collimator (MLC) to optimize the treatment plan. • Photon beam and electron beam algorithms which calculate the dose to the patient considering the 3D nature and heterogeneity of the patient data set. The photon beam algorithm shall use advanced methods (e.g. convolution, Boltzmann transport, Monte Carlo). The electron beam algorithm shall be based on pencil beam or Monte Carlo methods. The dose matrix (calculation grid) should be user adjustable and the accuracy of the dose calculations shall be such that it is possible to meet the tolerance criteria in Table 4 of IAEA TECDOC 1540. • The ability to calculate MU for all beam models. • The ability to allow dose prescription to a point, volume or isodose line. • Advanced plan review and evaluation tools, including dose volume histograms (DVHs), dose statistics, 2D and 3D dose visualization, and plan addition and plan comparison. • The ability to generate and view digitally reconstructed radiographs (DRRs). • Display of all relevant treatment unit parameters in the IEC 61217 scale convention as at least one option.

Medical device specifications		
18	...Detailed requirements	• A comprehensive beam modelling module that allows the configuration of complete geometric and dosimetric models for treatment unit photon and electron beams. The module shall have the following features: » ability to import measured beam profiles and output factors; » ability to model dynamic, fixed and internal wedges; » tools to allow the comparison of the beam model and measured data; and » security features which protect beam data and beam models from modification. • A module to allow the creation of CT number to mass density or electron density data for various CT scanners for use by the photon and electron beam algorithms. • User and password security that allows approval/locking of treatment plans and different levels of access to the functionality of the TPS based on the user's profile e.g. administrator, planner, medical physicist, physician. • A printer for A3/4 output of isodose distributions, beam shapes and treatment plan parameters. • A module to allow export of beam block shapes to a third party block cutting device. • A module to allow export of approved treatment plans and DRRs to an oncology information system (OIS).
19	Displayed parameters	Not applicable
20	User adjustable settings	Not applicable
Physical/chemical characteristics		
21	Components (if relevant)	Major components of the TPS are networked computer workstations, server (if applicable), printer and software.
22	Mobility, portability (if relevant)	Fixed, not mobile
23	Raw materials (if relevant)	Not applicable
Utility requirements		
24	Electrical, water and/or gas supply (if relevant)	Single-phase electrical power and air-conditioning.
Accessories, consumable, spare parts and other components		
25	Accessories (if relevant)	Not applicable
26	Sterilization process for accessories (if relevant)	Not applicable
27	Consumables/ reagents (if relevant)	Not applicable
28	Spare parts (if relevant)	Not applicable

Medical device specifications		
29	Other components (if relevant)	Not applicable
Packaging		
30	Sterility status on delivery (if relevant)	Not applicable
31	Shelf life (if relevant)	Not applicable
32	Transportation and storage (if relevant)	If storage is required prior to installation, the storage area should be secure, clean and dust-free, dry, cool, well-lit, ventilated and vermin-proof.
33	Labelling (if relevant)	Not applicable
Environmental requirements		
34	Context-dependent requirements	It is the responsibility of the hospital to ensure that the manufacturer's recommended operation and storage conditions, as given in their site planning guide, are respected. If the device requires that the operating and/or storage environment be climate-controlled, appropriate temperature and humidity control systems, including monitoring, should be applied to avoid premature material disintegration and/or device failure.
Training, installation and utilization		
35	Pre-installation requirements (if relevant)	Network availability
36	Requirements for commissioning (if relevant)	Acceptance testing, commissioning of radiation beam models and dose calculation algorithms, baselines for quality control.
37	Training of user/s (if relevant)	Applications training in configuration and clinical operation.
38	User care (if relevant)	The equipment shall only be used in accordance with departmental policies, procedures and work instructions, and consistent with manufacturer's use instructions, to ensure safety and protection.
Warranty and maintenance		
39	Warranty	At least 12 months
40	Maintenance tasks	Software updates as required
41	Type of service contract	Service contract, including software upgrades and access to helpdesk.
42	Spare parts availability post-warranty	4 years minimum

Medical device specifications		
43	Software/ hardware upgrade availability	To be specified by manufacturer.
Documentation		
44	Documentation requirements	Comprehensive user manual, including emergency procedures.
Decommissioning		
45	Estimated lifespan	5 years
Safety and standards		
46	Risk classification	US FDA: Device Class 2
47	Regulatory approval/ certification	Radiation regulatory approval for equipment possession, use and premises.
48	International standards	IEC, Medical Electrical Equipment, Part 1: General Requirements for Safety, Rep. IEC 60601-1:2005+AMD1:2012. Radiation Protection and Safety of Radiation Sources, International Basic Safety Standards, No. GSR Part 3, IAEA, Vienna, 2014 *(23)*. IEC, Medical electrical equipment – Requirements for the safety of radiotherapy treatment planning systems, IEC 62083:2009. IEC, Radiotherapy equipment – Coordinates, movements and scales, IEC 61217, 2011. IAEA, Specification and acceptance testing of radiotherapy treatment planning systems, TECDOC 1540, 2007.
49	Regional/local standards	Country-specific and regional standards may apply.
50	Regulations	USA: 21CFR892.5050 Medical charged-particle radiation therapy system.

Annex 6.
WHO template for oncology information system (OIS) technical specifications

Medical device specifications		
i	Version No.	1
ii	Date of initial version	10 October 2019
iii	Date of last modification	13 November 2020
iv	Date of publication	13 November 2020
v	Completed/ submitted by	Working group (WHO/IAEA)
Name, category and coding		
1	WHO category/ code	(under development)
2	Generic name	Oncology information system
3	Specific type or variation (optional)	Not applicable
4	GMDN name	(to be completed if final user owns valid license or permission)
5	GMDN code	(to be completed if final user owns valid license or permission)
6	GMDN category	(to be completed if final user owns valid license or permission)
7	UMDNS name	(to be completed if final user owns valid license or permission)
8	UMDNS code	(to be completed if final user owns valid license or permission)
9	UNSPS code (optional)	Not applicable
10	Alternative name/s (optional)	Not applicable
11	Alternative code/s (optional)	Not applicable
12	Keywords (optional)	External beam radiotherapy

Medical device specifications		
13	GMDN/UMDNS definition (optional)	(to be completed if final user owns valid license or permission)
Purpose of use		
14	Clinical or other purpose	Management of electronic data in external beam radiotherapy (EBRT).
15	Level of use (if relevant)	Hospital
16	Clinical department/ ward (if relevant)	Radiation Oncology Department
17	Overview of functional requirements	Software to manage the flow and storage of information in radiotherapy. The software shall include modules for input of patient details, transfer of treatment plans to treatment units, and record and verification of treatments.
Technical characteristics		
18	Detailed requirements	• A secure, remote server and workstations, at least 19-inch monitors, keyboard, mouse, and network capability. • An uninterrupted power supply (UPS), including an automated daily back-up system to an external hard drive (or equivalent) with auto-detect and auto-shutdown after 20 minutes in the event of a power failure. • A gateway that is Health Level 7 (HL7)-compliant to a hospital information system (HIS) for patient administrative fields only (retrieve only). Mandatory fields shall be used to ensure and internally validate unique patient ID, e.g. first name, surname, gender, date of birth and national ID number. • Workstations located in the treatment planning room that shall be capable of: » manual data entry of 2D cases, clinical markups and emergencies; » approval and entry of prescriptions and free text setup instructions; » upload of photographic images; » electronic chart checks; » image review of digitally reconstructed radiographs (DRRs) and treatment images (portal and set-up); and » networking to the treatment planning system (TPS) to allow import of the patient administration data, beam delivery parameters and DRRs of graphically planned patients; the importation of data should be customized to correctly download and translate the TPS information to the scales and graduations of the department treatment units. • A fully integrated workstation shall be provided for each of the treatment units, including all interfaces to fully operationalize the system for automated download and verification of the treatment parameters as well as capture and storage of portal and set-up images. The workstations should include an in-room alternative monitor to facilitate patient identification and viewing of the setup instructions, including digital images. The system should be supported by a local UPS such that there is no loss of data in the event of a power failure to the treatment unit.

Medical device specifications		
18	...Detailed requirements	• Software features including: » digital photos of patient (ID and/or setup photos); » automated logging of cumulative dose; » free text entry of setup instructions or alerts based on cumulative dose; » hierarchical security features, including requirement for authorized approval of the dose prescription and field parameters prior to treatment; » complete log of activities and users; » generation of statistical data according to user-defined fields, e.g. diagnosis and managing consultant; » library of diagnoses according to WHO ICD-11; » ability to correctly log cumulative dose in the event of a treatment interruption or termination; and » patient appointment scheduling.
19	Displayed parameters	Not applicable
20	User adjustable settings	Not applicable
Physical/chemical characteristics		
21	Components (if relevant)	Major components of the OIS include networked computer workstations, server and software.
22	Mobility, portability (if relevant)	Fixed, not mobile
23	Raw materials (if relevant)	Not applicable
Utility requirements		
24	Electrical, water and/or gas supply (if relevant)	Single-phase electrical power and air-conditioning.
Accessories, consumable, spare parts and other components		
25	Accessories (if relevant)	Not applicable
26	Sterilization process for accessories (if relevant)	Not applicable
27	Consumables/ reagents (if relevant)	Not applicable

Medical device specifications		
28	Spare parts (if relevant)	Not applicable
29	Other components (if relevant)	Not applicable
Packaging		
30	Sterility status on delivery (if relevant)	Not applicable
31	Shelf life (if relevant)	Not applicable
32	Transportation and storage (if relevant)	If storage is required prior to installation, the storage area should be secure, clean and dust-free, dry, cool, well-lit, ventilated and vermin-proof.
33	Labelling (if relevant)	Not applicable
Environmental requirements		
34	Context-dependent requirements	It is the responsibility of the hospital to ensure that the manufacturer's recommended operation and storage conditions, as given in their site planning guide, are respected. If the device requires that the operating and/or storage environment be climate-controlled, appropriate temperature and humidity control systems, including monitoring, should be applied to avoid premature material disintegration and/or device failure.
Training, installation and utilization		
35	Pre-installation requirements (if relevant)	Network availability
36	Requirements for commissioning (if relevant)	Acceptance testing, commissioning of treatment unit configurations, baselines for quality control.
37	Training of user/s (if relevant)	Applications training in configuration and clinical operation.
38	User care (if relevant)	The equipment shall only be used in accordance with departmental policies, procedures and work instructions, and consistent with manufacturer's use instructions, to ensure safety and protection.
Warranty and maintenance		
39	Warranty	At least 12 months
40	Maintenance tasks	Software updates as required.
41	Type of service contract	Service contract, including software upgrades and access to help desk.
42	Spare parts availability post-warranty	4 years minimum

Medical device specifications		
43	Software/ hardware upgrade availability	To be specified by manufacturer.
Documentation		
44	Documentation requirements	Comprehensive user manual, including emergency procedures.
Decommissioning		
45	Estimated lifespan	5 years
Safety and standards		
46	Risk classification	Australia TGA: Class IIB
47	Regulatory approval/ certification	Radiation regulatory approval for equipment possession, use and premises.
48	International standards	IEC, Medical Electrical Equipment, Part 1: General Requirements for Safety, Rep. IEC 60601-1:2005+AMD1:2012. Radiation Protection and Safety of Radiation Sources, International Basic Safety Standards, No. GSR Part 3, IAEA, Vienna, 2014 *(23)*. IEC, Medical electrical equipment – Safety of radiotherapy record and verify systems, IEC 62274:2005.
49	Regional/local standards	Country-specific and regional standards may apply.
50	Regulations	USA: 21CFR892.5050 Medical charged-particle radiation therapy system.

Annex 7. WHO template for superficial/ orthovoltage X-ray unit technical specifications

Medical device specifications		
i	Version No.	1
ii	Date of initial version	10 October 2019
iii	Date of last modification	13 November 2020
iv	Date of publication	13 November 2020
v	Completed/ submitted by	Working group (WHO/IAEA)
Name, category and coding		
1	WHO category/ code	(under development)
2	Generic name	Superficial/orthovoltage X-ray unit
3	Specific type or variation (optional)	Not applicable
4	GMDN name	(to be completed if final user owns valid license or permission)
5	GMDN code	(to be completed if final user owns valid license or permission)
6	GMDN category	(to be completed if final user owns valid license or permission)
7	UMDNS name	(to be completed if final user owns valid license or permission)
8	UMDNS code	(to be completed if final user owns valid license or permission)
9	UNSPS code (optional)	42202700
10	Alternative name/s (optional)	Not applicable
11	Alternative code/s (optional)	Not applicable
12	Keywords (optional)	External beam radiotherapy

Medical device specifications		
13	GMDN/UMDNS definition (optional)	(to be completed if final user owns valid license or permission)
Purpose of use		
14	Clinical or other purpose	Delivery of kilovoltage X-ray beams for external beam radiotherapy (EBRT).
15	Level of use (if relevant)	Hospital
16	Clinical department/ ward (if relevant)	Radiation Oncology Department
17	Overview of functional requirements	A unit producing collimated kilovoltage X-ray beams for EBRT. The unit shall include a beam generation system, adjustable platform, and treatment collimators to allow a range of field sizes and beam energies.
Technical characteristics		
18	Detailed requirements	• An X-ray tube capable of producing X-ray energies up to 300 kV with a cooling system. A minimum of three X-ray energies, one low energy from 1.0–3.0 mm Al HVL, and two medium energies from 1–3 mm Cu HVL are required. • An X-ray generator with a voltage regulator to operate at a range of potentials up to 300 kV. • A filter for each therapeutic X-ray beam and one additional filter that blocks the entire beam for warm-up of the tube. • A range of X-ray tube current settings so that a constant therapeutic dose-rate can be achieved for each energy from the X-ray unit; • An internal monitor ionization chamber whose response is corrected for ambient conditions such as temperature and pressure or a timer. Dual systems (chamber or timer) are required. It shall be possible to set the output of the machine such that standard reference dosimetry can be maintained within ±2%. • Movement of the X-ray tube relative to the floor in the following directions; vertically, horizontally, as well as rotation around the column or tube stand; including vertical and axial inclination of the tube by rotation. • A locking mechanism with a brake so that the X-ray unit will not move during treatment even in the event of a failure of power. It shall be possible release the vertical brake in the event of power failure to remove the patient. • A computerized control console with an alternative display inside the treatment room. The control console shall have an on/off removable key, allow selectable kilovoltage settings interlocked to filter interlocks on the treatment head and have operation modes controlled by passwords. The control console shall have a feature for backup of system and patient data. The control software shall have the following features: » a check that the correct filter and applicator is selected before the start of treatment; » inhibition of radiation if kV or mA exceeds 3% from the selected value; » inhibition of radiation if planned treatment time exceeded or stop caused by the secondary timer/monitor chamber; » display of digital photos of patient (ID and/or setup photos); » complete log of activities and users; » patient appointments; » ability to correctly log cumulative dose in the event of a treatment interruption or termination; » password protection of data; and » import/export of data to an RVS using Digital Imaging and Communications in Medicine (DICOM) RT protocols.

Medical device specifications		
18	...Detailed requirements	• An internal battery or uninterrupted power supply (UPS) to retrieve patients' treatment data and to control shutdown of the system in the event of mains power failure. • A removable patient support table with wheels and brakes, and the table surface should have a flat top. • Two colour CCTV systems for viewing of the patient from the console (one with pan, tilt and zoom) and a bi-directional audio intercom system. • A set of open ended applicators for operation at a fixed focus to source distance (FSD) less than or equal to 30 cm, for circular field sizes of diameter 2 cm to 8 cm. • A set of closed applicators for an FSD of at least 50 cm, for rectangular field sizes ranging from 6 cm x 6 cm to 20 cm x 20 cm but must include a 10 cm x 10 cm and 20 cm x 20 cm square applicator. • A supply of metal sheets for creating customized cut-out shapes at the end of the applicator.
19	Displayed parameters	Comprehensive parameters at control console.
20	User adjustable settings	At control console and gantry.
Physical/chemical characteristics		
21	Components (if relevant)	Major components of the superficial/orthovoltage X-ray unit include X-ray tube, housing and generator, gantry, collimators and treatment console.
22	Mobility, portability (if relevant)	Fixed or mobile
23	Raw materials (if relevant)	Not applicable
Utility requirements		
24	Electrical, water and/or gas supply (if relevant)	Single-phase electrical power and air-conditioning.
Accessories, consumable, spare parts and other components		
25	Accessories (if relevant)	Dosimetry and quality control equipment, radiation safety equipment.
26	Sterilization process for accessories (if relevant)	Not applicable
27	Consumables/ reagents (if relevant)	Not applicable
28	Spare parts (if relevant)	Onsite spare parts kit is recommended.
29	Other components (if relevant)	Audio visual communication system.

Medical device specifications		
Packaging		
30	Sterility status on delivery (if relevant)	Not applicable
31	Shelf life (if relevant)	Not applicable
32	Transportation and storage (if relevant)	If storage is required prior to installation, the storage area should be secure, clean and dust-free, dry, cool, well-lit, ventilated and vermin-proof.
33	Labelling (if relevant)	Symbols used according to ISO-15233 standards.
Environmental requirements		
34	Context-dependent requirements	Superficial/orthovoltage X-ray units are housed in lead-lined rooms to provide radiation protection for staff and members of the public. Refer to IAEA publications Safety Reports Series No. 47 and Human Health Reports No. 10. It is the responsibility of the hospital to ensure that the manufacturer's recommended operation and storage conditions, as given in their site planning guide, are respected. If the device requires that the operating and/or storage environment be climate-controlled, appropriate temperature and humidity control systems, including monitoring, should be applied to avoid premature material disintegration and/or device failure.
Training, installation and utilization		
35	Pre-installation requirements (if relevant)	Radiation regulatory approval of room shielding and approval to acquire radiation source. It is the responsibility of the hospital to comply with requirements in the manufacturer's site planning guide and ensure services are ready for installation of the equipment. Pre-installation inspection of the site by the installer may be required.
36	Requirements for commissioning (if relevant)	Acceptance testing, commissioning of radiation beams, reference dosimetry, dosimetry audit, baselines for quality control, comprehensive radiation survey.
37	Training of user/s (if relevant)	Applications training in configuration, clinical operation, safety features and service mode.
38	User care (if relevant)	The equipment shall only be used in accordance with departmental policies, procedures and work instructions, and consistent with manufacturer's use instructions, to ensure safety and protection.
Warranty and maintenance		
39	Warranty	At least 12 months
40	Maintenance tasks	Approximately 4 service days per year. Tasks as per manufacturer's preventative maintenance schedule.
41	Type of service contract	Full-service contract, including parts, service and repair or in-house maintenance engineering service.
42	Spare parts availability post-warranty	10 years minimum

Medical device specifications		
43	Software/ hardware upgrade availability	To be specified by manufacturer.
Documentation		
44	Documentation requirements	Comprehensive user manual, including emergency procedures.
Decommissioning		
45	Estimated lifespan	10–15 years
Safety and standards		
46	Risk classification	Australia TGA: Class IIB
47	Regulatory approval/ certification	Radiation regulatory approval for equipment possession, use and premises.
48	International standards	IEC, Medical Electrical Equipment, Part 1: General Requirements for Safety, Rep. IEC 60601-1:2005+AMD1:2012. Radiation Protection and Safety of Radiation Sources, International Basic Safety Standards, No. GSR Part 3, IAEA, Vienna, 2014 *(23)*. IEC, Medical electrical equipment – Part 2–8: Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV, IEC 60601-2-8:2010+AMD1:2015 CSV.
49	Regional/local standards	Country-specific and regional standards may apply.
50	Regulations	USA: 21CFR892.5900 X-ray radiation therapy system Local radiation safety regulations may apply.

Annex 8.
WHO template for high-dose rate (HDR) brachytherapy afterloader technical specifications

Medical device specifications		
i	Version No.	1
ii	Date of initial version	10 October 2019
iii	Date of last modification	13 November 2020
iv	Date of publication	13 November 2020
v	Completed/ submitted by	Working group (WHO/IAEA)
Name, category and coding		
1	WHO category/ code	(under development)
2	Generic name	Brachytherapy afterloader
3	Specific type or variation (optional)	Not applicable
4	GMDN name	(to be completed if final user owns valid license or permission)
5	GMDN code	(to be completed if final user owns valid license or permission)
6	GMDN category	(to be completed if final user owns valid license or permission)
7	UMDNS name	(to be completed if final user owns valid license or permission)
8	UMDNS code	(to be completed if final user owns valid license or permission)
9	UNSPS code (optional)	42202100; 42202102; 42202105; 42202108
10	Alternative name/s (optional)	Not applicable
11	Alternative code/s (optional)	Not applicable
12	Keywords (optional)	Brachytherapy

Medical device specifications		
13	GMDN/UMDNS definition (optional)	(to be completed if final user owns valid license or permission)
Purpose of use		
14	Clinical or other purpose	Delivery of radiation dose from a sealed radioactive source for brachytherapy.
15	Level of use (if relevant)	Hospital
16	Clinical department/ ward (if relevant)	Radiation Oncology Department
17	Overview of functional requirements	A remote-controlled unit that delivers radiation dose from a sealed radioactive source for brachytherapy. The unit shall include a sealed radioactive source, source housing, dummy source, source movement mechanism, guide tubes and applicators, treatment couch and control console to allow automated delivery of brachytherapy.
Technical characteristics		
18	Detailed requirements	• A remote-controlled afterloading system with at least 20 channels for intracavitary high-dose rate (HDR) brachytherapy with a cobalt-60 source of activity 74 GBq ±10% on delivery. The treatment afterloader unit shall automatically verify all unique applicator connections and be easily manoeuvrable within the treatment room. • Precise double drives in the afterloader for a miniaturized cobalt-60 source and a dummy source with continuous digital positioning, including pre-exposure routine dummy test run for safety and catheter length check. • A control unit, which facilitates operation, controlling and monitoring functions, including: » a connection to the dedicated treatment planning system (TPS) via a network; » password-defined access for all users with restricted access to data of high security, e.g. source strength; » a log of user activities and the number of source transfers; » database of uniquely defined standard treatment plans for rigid applicator sets and line sources with automatic update of source dwell times; access to the database for plan editing purposes should be password-controlled and restricted; » unique patient identification and treatment plan preparation; » display of status information, including during a power interruption; » online recording of treatment with visual graphic display of treatment progress; and » hardcopy output of the entire treatment protocol after treatment; • An internal battery or uninterrupted power supply (UPS) to ensure safe source or dummy retraction in the event of a power failure, including a crank for manual source retraction, long-handle forceps and an emergency container thick enough for storage of up to 81 GBq cobalt-60 and large enough to fit the largest possible applicator. • A radiation area monitoring system with audible and visible signal for treatment room and control panel monitoring, warning lights, facility access interlock, patient intercommunication device, two complete CCTV systems with pan, zoom and tilt facility. • A patient treatment table, including head plate, removable leg plates, stirrups, seat plate extension and backrest manoeuvrability in order to treat a patient in the seated position. The tabletop shall be radiolucent to enable X-ray imaging.

Medical device specifications		
18	...Detailed requirements	• Applicators and accessories (usually several quantities of each of the following sets are required depending on the workload and case mix) including: » computed tomography-magnetic resonance (CT-MR)-compatible Fletcher applicator set; » interstitial CT-MR ring applicator set (ring angle 60° from horizontal), e.g. Vienna type; » CT-MR ring applicator set (at least a ring angle 60° from horizontal); » CT-MR vaginal/rectal applicator set; » intrauterine tubes, diameter 3.5 mm, titanium; » intrauterine tubes, diameter 5.0 mm, titanium; » CT-MR vaginal applicator set with intrauterine tube and additional concentric channels; » CT-MR endometrium set diameter 3.5 mm; » CT-MR endometrium set diameter 5.0 mm; » required accessories for the above applicator sets (e.g. transfer tubes, markers and sterilization box); » universal clamping device; and » reconstruction box for use in gynaecological applications.
19	Displayed parameters	Comprehensive parameters at control console.
20	User adjustable settings	At control console
Physical/chemical characteristics		
21	Components (if relevant)	Major components of the brachytherapy afterloader include cobalt-60 source, dummy source, source housing, source drive mechanism through various channels, applicators, treatment couch, and treatment console.
22	Mobility, portability (if relevant)	Mobile within treatment room.
23	Raw materials (if relevant)	Not applicable
Utility requirements		
24	Electrical, water and/or gas supply (if relevant)	Single-phase electrical power and air-conditioning.
Accessories, consumable, spare parts and other components		
25	Accessories (if relevant)	Dosimetry and quality control equipment, radiation safety equipment.
26	Sterilization process for accessories (if relevant)	Not applicable
27	Consumables/ reagents (if relevant)	Not applicable
28	Spare parts (if relevant)	Access to spare parts is required.

Medical device specifications		
29	Other components (if relevant)	Audio visual communication system.
Packaging		
30	Sterility status on delivery (if relevant)	Not applicable
31	Shelf life (if relevant)	Not applicable
32	Transportation and storage (if relevant)	If storage is required prior to installation, the storage area should be secure, clean and dust-free, dry, cool, well-lit, ventilated and vermin-proof.
33	Labelling (if relevant)	Symbols used according to ISO-15233 standards.
Environmental requirements		
34	Context-dependent requirements	Brachytherapy afterloaders are housed in a concrete bunker to provide radiation protection for staff and members of the public. Refer to IAEA publications Safety Reports Series No. 47 and Human Health Reports No. 10. It is the responsibility of the hospital to ensure that the manufacturer's recommended operation and storage conditions, as given in their site planning guide, are respected. If the device requires that the operating and/or storage environment be climate-controlled, appropriate temperature and humidity control systems, including monitoring, should be applied to avoid premature material disintegration and/or device failure.
Training, installation and utilization		
35	Pre-installation requirements (if relevant)	Radiation regulatory approval of room shielding and approval to acquire radiation source. It is the responsibility of the hospital to comply with requirements in the manufacturer's site planning guide and ensure services are ready for installation of the equipment. Pre-installation inspection of the site by the installer may be required.
36	Requirements for commissioning (if relevant)	Acceptance testing, commissioning of source and applicators, reference air kerma rate measurement, baselines for quality control, comprehensive radiation survey.
37	Training of user/s (if relevant)	Applications training in configuration, clinical operation, safety features and service mode.
38	User care (if relevant)	The equipment shall only be used in accordance with departmental policies, procedures and work instructions, and consistent with manufacturer's use instructions, to ensure safety and protection.
Warranty and maintenance		
39	Warranty	At least 12 months
40	Maintenance tasks	Approximately 4 service days per year. Tasks as per manufacturer's preventative maintenance schedule.
41	Type of service contract	Full-service contract, including parts, service and repair or in-house maintenance engineering service.

Medical device specifications		
42	Spare parts availability post-warranty	10 years minimum
43	Software/ hardware upgrade availability	To be specified by manufacturer.
Documentation		
44	Documentation requirements	Comprehensive user manual, including emergency procedures.
Decommissioning		
45	Estimated lifespan	10–15 years with cobalt-60 source exchange every 5 years.
Safety and standards		
46	Risk classification	US FDA: Device Class 2, Australia TGA Class IIB.
47	Regulatory approval/ certification	Radiation regulatory approval for equipment possession, use and premises.
48	International standards	IEC, Medical Electrical Equipment, Part 1: General Requirements for Safety, Rep. IEC 60601-1:2005+AMD1:2012. Radiation Protection and Safety of Radiation Sources, International Basic Safety Standards, No. GSR Part 3, IAEA, Vienna, 2014 *(23)*. IEC, Medical Electrical Equipment, Part 2–17: Particular requirements for the basic safety and essential performance of automatically controlled brachytherapy afterloading equipment, Rep. IEC 60601-2-17:2013. ISO, Radiological protection – Sealed radioactive sources – General requirements and classification, ISO-2919:2012. ISO, Radiation protection – Sealed radioactive sources – Leakage test methods ISO-9978:1992. IEC, Guidance on error and warning messages for software used in radiotherapy, IEC TR 63183:2019.
49	Regional/local standards	Country-specific and regional standards may apply.
50	Regulations	USA: 21CFR892.5700 Remote-controlled radionuclide applicator system Local radiation safety regulations may apply.

Annex 9.
WHO template for C-arm X-ray unit technical specifications

Medical device specifications		
i	Version No.	1
ii	Date of initial version	10 October 2019
iii	Date of last modification	13 November 2020
iv	Date of publication	13 November 2020
v	Completed/ submitted by	Working group (WHO/IAEA)
Name, category and coding		
1	WHO category/ code	(under development)
2	Generic name	C-arm fluoroscopic X-ray unit
3	Specific type or variation (optional)	Not applicable
4	GMDN name	(to be completed if final user owns valid license or permission)
5	GMDN code	(to be completed if final user owns valid license or permission)
6	GMDN category	(to be completed if final user owns valid license or permission)
7	UMDNS name	(to be completed if final user owns valid license or permission)
8	UMDNS code	(to be completed if final user owns valid license or permission)
9	UNSPS code (optional)	42201800
10	Alternative name/s (optional)	Not applicable
11	Alternative code/s (optional)	Not applicable
12	Keywords (optional)	Brachytherapy

Medical device specifications		
13	GMDN/UMDNS definition (optional)	(to be completed if final user owns valid license or permission)
Purpose of use		
14	Clinical or other purpose	X-ray imaging of patients for radiotherapy treatment planning.
15	Level of use (if relevant)	Hospital
16	Clinical department/ ward (if relevant)	Radiation Oncology Department
17	Overview of functional requirements	A unit providing planar X-ray imaging of patients for brachytherapy treatment planning. The mobile unit shall include stand, control console, display, C-arm, X-ray source and detector to allow imaging, including fluoroscopic imaging, of brachytherapy applicators. The unit shall be Digital Imaging and Communications in Medicine (DICOM)-compatible for transfer of images to a treatment planning system (TPS).
Technical characteristics		
18	Detailed requirements	• A high-frequency X-ray generator with potential in the range of 40–110 kV and X-ray tube with dual focal spots. • A fluoroscopic mode, including foot switch and last image hold capability as well as a radiographic mode. • A flat panel imaging detector with dimensions at least 21 cm x 21 cm. • Dual high-resolution flat display screens of at least 18-inch diameter with last image hold capability. • A C-arm gantry with orbital movement of at least 120° (– 30° to + 90°). • Motor-driven vertical travel greater than or equal to 40 cm. • Horizontal travel greater than or equal to 20 cm. • Focus-image receptor distance greater than or equal to 90 cm. • Free space greater than or equal to 76 cm. • A braking system for gantry control. • A DICOM 3.0 interface for digital networking of images (transfer of digital images to a brachytherapy TPS or hospital picture archiving and communication system [PACS]). • Hard disk image storage capability as well as external storage capability.
19	Displayed parameters	Comprehensive parameters at control console.
20	User adjustable settings	At control console

Medical device specifications		
Physical/chemical characteristics		
21	Components (if relevant)	Major components of the C-arm fluoroscopic X-ray unit include X-ray tube, housing and generator, X-ray detector system, C-arm, display and control console.
22	Mobility, portability (if relevant)	Mobile
23	Raw materials (if relevant)	Not applicable
Utility requirements		
24	Electrical, water and/or gas supply (if relevant)	Single-phase electrical power and air-conditioning.
Accessories, consumable, spare parts and other components		
25	Accessories (if relevant)	Not applicable
26	Sterilization process for accessories (if relevant)	Not applicable
27	Consumables/ reagents (if relevant)	Not applicable
28	Spare parts (if relevant)	Onsite spare parts kit is recommended.
29	Other components (if relevant)	Not applicable
Packaging		
30	Sterility status on delivery (if relevant)	Not applicable
31	Shelf life (if relevant)	Not applicable
32	Transportation and storage (if relevant)	If storage is required prior to installation, the storage area should be secure, clean and dust-free, dry, cool, well-lit, ventilated and vermin-proof.
33	Labelling (if relevant)	Symbols used according to ISO-15233 standards.

Medical device specifications

Environmental requirements		
34	Context-dependent requirements	C-arm fluoroscopic X-ray units are operated in brachytherapy rooms that provide radiation protection for staff and members of the public. It is the responsibility of the hospital to ensure that the manufacturer's recommended operation and storage conditions, as given in their site planning guide, are respected. If the device requires that the operating and/or storage environment be climate-controlled, appropriate temperature and humidity control systems, including monitoring, should be applied to avoid premature material disintegration and/or device failure.
Training, installation and utilization		
35	Pre-installation requirements (if relevant)	It is the responsibility of the hospital to comply with requirements in the manufacturer's site planning guide and ensure services are appropriate for operation of the equipment.
36	Requirements for commissioning (if relevant)	Acceptance testing, commissioning of imaging system, baselines for quality control, comprehensive radiation survey.
37	Training of user/s (if relevant)	Applications training in clinical operation, safety features and service mode.
38	User care (if relevant)	The equipment shall only be used in accordance with departmental policies, procedures and work instructions, and consistent with manufacturer's use instructions, to ensure safety and protection.
Warranty and maintenance		
39	Warranty	At least 12 months
40	Maintenance tasks	Approximately 4 service days per year. Tasks as per manufacturer's preventative maintenance schedule.
41	Type of service contract	Full-service contract, including parts, service and repair or in-house maintenance engineering service.
42	Spare parts availability post-warranty	10 years minimum
43	Software/ hardware upgrade availability	To be specified by manufacturer.
Documentation		
44	Documentation requirements	Comprehensive user manual, including emergency procedures.
Decommissioning		
45	Estimated lifespan	10 years

Medical device specifications		
Safety and standards		
46	Risk classification	US FDA: Device Class 2
47	Regulatory approval/ certification	Radiation regulatory approval for equipment possession, use and premises.
48	International standards	IEC, Medical Electrical Equipment, Part 1: General Requirements for Safety, Rep. IEC 60601-1:2005+AMD1:2012. Radiation Protection and Safety of Radiation Sources, International Basic Safety Standards, No. GSR Part 3, IAEA, Vienna, 2014 *(23)*. IEC, Medical electrical equipment – Part 1–3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment, IEC 60601-1-3:2008+AMD1:2013 CSV. IEC, Medical electrical equipment – Part 2–28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis, IEC 60601-2-28:2017. IEC, Medical electrical equipment – Part 2–54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy, IEC 60601-2-54:2009+AMD1:2015+AMD2:2018 CSV.
49	Regional/local standards	Country-specific and regional standards may apply.
50	Regulations	USA: 21CFR892.1650 Image-intensified fluoroscopic X-ray system Local radiation safety regulations may apply.

Annex 10.
WHO template for ultrasound imaging system technical specifications

Medical device specifications		
i	Version No.	1
ii	Date of initial version	10 October 2019
iii	Date of last modification	13 November 2020
iv	Date of publication	13 November 2020
v	Completed/ submitted by	Working group (WHO/IAEA)
Name, category and coding		
1	WHO category/ code	(under development)
2	Generic name	Ultrasound imaging system
3	Specific type or variation (optional)	Not applicable
4	GMDN name	(to be completed if final user owns valid license or permission)
5	GMDN code	(to be completed if final user owns valid license or permission)
6	GMDN category	(to be completed if final user owns valid license or permission)
7	UMDNS name	(to be completed if final user owns valid license or permission)
8	UMDNS code	(to be completed if final user owns valid license or permission)
9	UNSPS code (optional)	42201700
10	Alternative name/s (optional)	Not applicable
11	Alternative code/s (optional)	Not applicable
12	Keywords (optional)	Brachytherapy

Medical device specifications		
13	GMDN/UMDNS definition (optional)	(to be completed if final user owns valid license or permission)
Purpose of use		
14	Clinical or other purpose	Imaging to guide applicator placement for brachytherapy.
15	Level of use (if relevant)	Hospital
16	Clinical department/ward (if relevant)	Radiation Oncology Department
17	Overview of functional requirements	A mobile ultrasound unit for imaging of the treatment applicator during placement for brachytherapy. The unit shall include trans-abdominal transducers, detection system, display, and image capture and storage to allow visualization of various applicators.
Technical characteristics		
18	Detailed requirements	• A mobile clinical ultrasound imaging unit capable of operating in the following modes: 2D mode and M-mode (motion mode). • Two active transducer ports. • Two high-frequency convex transducers for trans-abdominal gynaecological examinations covering a frequency range of 2.0–5.0 MHz. • (Package 2) Two biplane transrectal transducers for sagittal and transverse imaging covering a frequency range of 3.0–12.0 MHz. • A single high-resolution monitor, at least 18-inch, for image display and image processing. The displayed image shall contain not less than 256 grey levels in 2D mode. • Keyboard with one button control. • A universal serial bus (USB) port, video output, onboard thermal printer and A4 laser printer. • Image processing measurements: length, height, width, angle, area and volume calculations. • Image storage in a clinically useful format and resolution on a hard drive and with capability to transfer images to external media with the Digital Imaging and Communications in Medicine (DICOM) standard. • A supply of water soluble and hypoallergenic ultrasound gel.
19	Displayed parameters	Comprehensive parameters at control console.
20	User adjustable settings	At control console
Physical/chemical characteristics		
21	Components (if relevant)	Major components of the ultrasound unit mobile frame, display, console, and transducers.
22	Mobility, portability (if relevant)	Mobile
23	Raw materials (if relevant)	Not applicable

Medical device specifications		
Utility requirements		
24	Electrical, water and/or gas supply (if relevant)	Single-phase electrical power and air-conditioning.
Accessories, consumable, spare parts and other components		
25	Accessories (if relevant)	Not applicable
26	Sterilization process for accessories (if relevant)	Low temperature sterilization for probes.
27	Consumables/ reagents (if relevant)	Water-based gel
28	Spare parts (if relevant)	Access to spare parts is required.
29	Other components (if relevant)	Not applicable
Packaging		
30	Sterility status on delivery (if relevant)	Not applicable
31	Shelf life (if relevant)	Not applicable
32	Transportation and storage (if relevant)	If storage is required prior to installation, the storage area should be secure, clean and dust-free, dry, cool, well-lit, ventilated and vermin-proof.
33	Labelling (if relevant)	Symbols used according to ISO-15233 standards.
Environmental requirements		
34	Context-dependent requirements	It is the responsibility of the hospital to ensure that the manufacturer's recommended operation and storage conditions, as given in their site planning guide, are respected. If the device requires that the operating and/or storage environment be climate-controlled, appropriate temperature and humidity control systems, including monitoring, should be applied to avoid premature material disintegration and/or device failure.
Training, installation and utilization		
35	Pre-installation requirements (if relevant)	Not applicable
36	Requirements for commissioning (if relevant)	Acceptance testing, commissioning of transducers, baselines for quality control.
37	Training of user/s (if relevant)	Applications training in configuration, clinical operation, safety features and service mode.

Medical device specifications		
38	User care (if relevant)	The equipment shall only be used in accordance with departmental policies, procedures and work instructions, and consistent with manufacturer's use instructions, to ensure safety and protection.
Warranty and maintenance		
39	Warranty	At least 12 months
40	Maintenance tasks	Approximately 4 service days per year. Tasks as per manufacturer's preventative maintenance schedule.
41	Type of service contract	Full-service contract, including parts, service and repair or in-house maintenance engineering service.
42	Spare parts availability post-warranty	9 years minimum
43	Software/ hardware upgrade availability	To be specified by manufacturer.
Documentation		
44	Documentation requirements	Comprehensive user manual.
Decommissioning		
45	Estimated lifespan	5–10 years
Safety and standards		
46	Risk classification	US FDA: Device Class 2
47	Regulatory approval/ certification	
48	International standards	IEC, Medical Electrical Equipment, Part 1: General Requirements for Safety, Rep. IEC 60601-1:2005+AMD1:2012. IEC, Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment, IEC 60601-2-37:2007+AMD1:2015 CSV. IEC, Ultrasonics - Pulse-echo scanners - Part 1: Techniques for calibrating spatial measurement systems and measurement of point-spread function response, IEC 61391-1:2006+AMD1:2017 CSV. IEC, Ultrasonics - Pulse-echo scanners - Part 2: Measurement of maximum depth of penetration and local dynamic range, IEC 61391-2:2010. IEC, Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields, IEC 62359:2010+AMD1:2017 CSV.
49	Regional/local standards	Country-specific and regional standards may apply.
50	Regulations	USA: 21CFR 892.1560 Ultrasonic pulsed echo imaging system.

Annex 11. WHO template for brachytherapy treatment planning system (TPS) technical specifications

Medical device specifications		
i	Version No.	1
ii	Date of initial version	10 October 2019
iii	Date of last modification	13 November 2020
iv	Date of publication	13 November 2020
v	Completed/ submitted by	Working group (WHO/IAEA)
Name, category and coding		
1	WHO category/ code	(under development)
2	Generic name	Treatment planning system
3	Specific type or variation (optional)	Not applicable
4	GMDN name	(to be completed if final user owns valid license or permission)
5	GMDN code	(to be completed if final user owns valid license or permission)
6	GMDN category	(to be completed if final user owns valid license or permission)
7	UMDNS name	(to be completed if final user owns valid license or permission)
8	UMDNS code	(to be completed if final user owns valid license or permission)
9	UNSPS code (optional)	Not applicable
10	Alternative name/s (optional)	Not applicable
11	Alternative code/s (optional)	Not applicable
12	Keywords (optional)	Brachytherapy

Medical device specifications		
13	GMDN/UMDNS definition (optional)	Not applicable
Purpose of use		
14	Clinical or other purpose	Preparation of patient treatment plans for brachytherapy.
15	Level of use (if relevant)	Hospital
16	Clinical department/ ward (if relevant)	Radiation Oncology Department
17	Overview of functional requirements	Software to generate treatment plans for brachytherapy. The software shall include modules for image import and registration, contouring of target volumes and organ at risk, planning of source positions and dwell times, dose calculation, plan review and export, and source modelling. The software shall enable transfer of treatment plans to the brachytherapy treatment unit console.
Technical characteristics		
18	Detailed requirements	A networked workstation with 23-inch monitor and significant storage capacity. Software for dose optimization based on points, planes or volumes based on catheter and source dwell positions obtained by reconstruction from isocentric, orthogonal and semi-orthogonal images. Hardware, software and licenses which allow Digital Imaging and Communications in Medicine (DICOM) compliant image transfer from a computed tomography (CT) scanner, magnetic resonance imaging (MRI) scanner and conventional simulator or a C-arm fluoroscopic X-ray unit. A flatbed film scanner (or equivalent) to allow the manual input of films or digitized images. Reference data sets for the source all applicators offered (library) and for the source. Hierarchical password-controlled security access to source calibration, modelling parameters, library of standard treatment plans and synchronization of source data with the treatment control panel. System manager software for database maintenance and archiving. A printer for A3/4 output of isodose distributions and treatment plan parameters. Software for automatic online transfer of patient and authorized treatment plan data to the treatment afterloader control panel.
19	Displayed parameters	Not applicable
20	User adjustable settings	Not applicable
Physical/chemical characteristics		
21	Components (if relevant)	Major components of the TPS are networked computer workstations, printer and software.
22	Mobility, portability (if relevant)	Fixed, not mobile

Medical device specifications		
23	Raw materials (if relevant)	Not applicable
Utility requirements		
24	Electrical, water and/or gas supply (if relevant)	Single-phase electrical power and air-conditioning.
Accessories, consumable, spare parts and other components		
25	Accessories (if relevant)	Not applicable
26	Sterilization process for accessories (if relevant)	Not applicable
27	Consumables/ reagents (if relevant)	Not applicable
28	Spare parts (if relevant)	Not applicable
29	Other components (if relevant)	Not applicable
Packaging		
30	Sterility status on delivery (if relevant)	Not applicable
31	Shelf life (if relevant)	Not applicable
32	Transportation and storage (if relevant)	If storage is required prior to installation, the storage area should be secure, clean and dust-free, dry, cool, well-lit, ventilated and vermin-proof.
33	Labelling (if relevant)	Symbols used according to ISO-15233 standards.
Environmental requirements		
34	Context-dependent requirements	It is the responsibility of the hospital to ensure that the manufacturer's recommended operation and storage conditions, as given in their site planning guide, are respected. If the device requires that the operating and/or storage environment be climate-controlled, appropriate temperature and humidity control systems, including monitoring, should be applied to avoid premature material disintegration and/or device failure.
Training, installation and utilization		
35	Pre-installation requirements (if relevant)	Network availability

Medical device specifications		
36	Requirements for commissioning (if relevant)	Acceptance testing, commissioning of source model, baselines for quality control.
37	Training of user/s (if relevant)	Applications training in configuration and clinical operation.
38	User care (if relevant)	The equipment shall only be used in accordance with departmental policies, procedures and work instructions, and consistent with manufacturer's use instructions, to ensure safety and protection.
Warranty and maintenance		
39	Warranty	At least 12 months
40	Maintenance tasks	Software updates as required
41	Type of service contract	Service contract, including software upgrades and access to helpdesk.
42	Spare parts availability post-warranty	4 years minimum
43	Software/ hardware upgrade availability	To be specified by manufacturer.
Documentation		
44	Documentation requirements	Comprehensive user manual, including emergency procedures.
Decommissioning		
45	Estimated lifespan	5 years
Safety and standards		
46	Risk classification	USA FDA: Device Class 2
47	Regulatory approval/ certification	Radiation regulatory approval for equipment possession, use and premises.
48	International standards	IEC, Medical Electrical Equipment, Part 1: General Requirements for Safety, Rep. IEC 60601-1:2005+AMD1:2012. Radiation Protection and Safety of Radiation Sources, International Basic Safety Standards, No. GSR Part 3, IAEA, Vienna, 2014 *(23)*. IEC, Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems, IEC 62083:2009.
49	Regional/local standards	Country-specific and regional standards may apply.
50	Regulations	USA: 21CFR892.5700 Remote-controlled radionuclide applicator system.

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World Health Organization

IAEA
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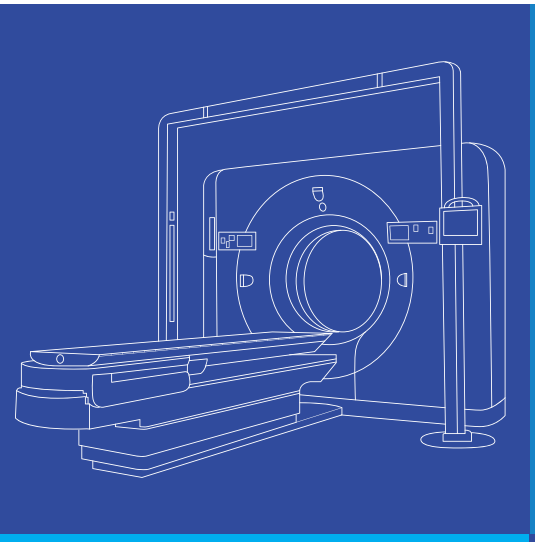
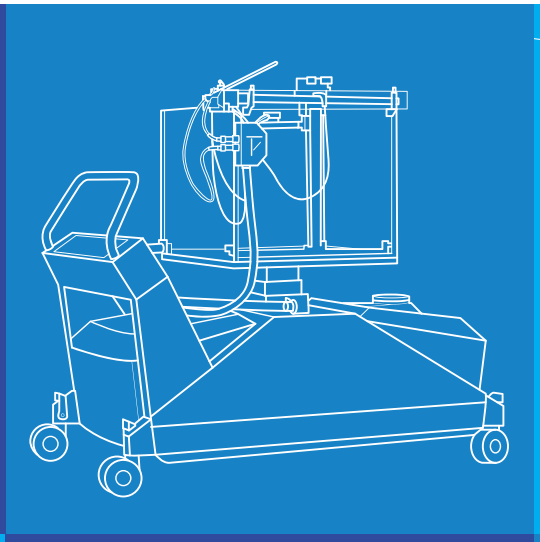
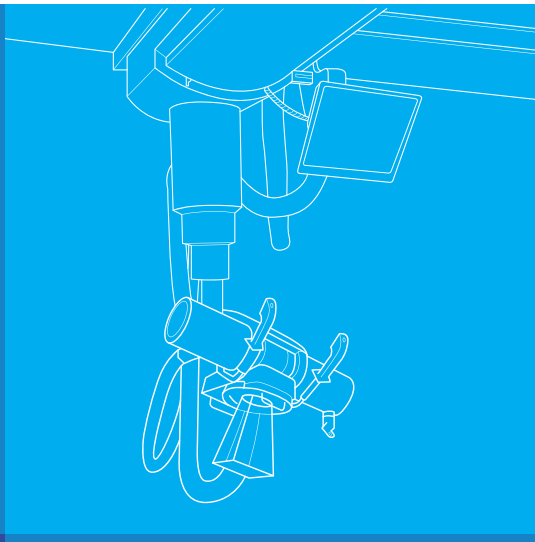
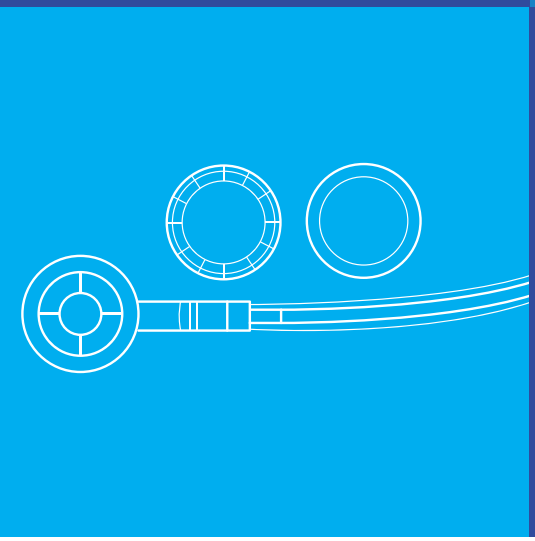
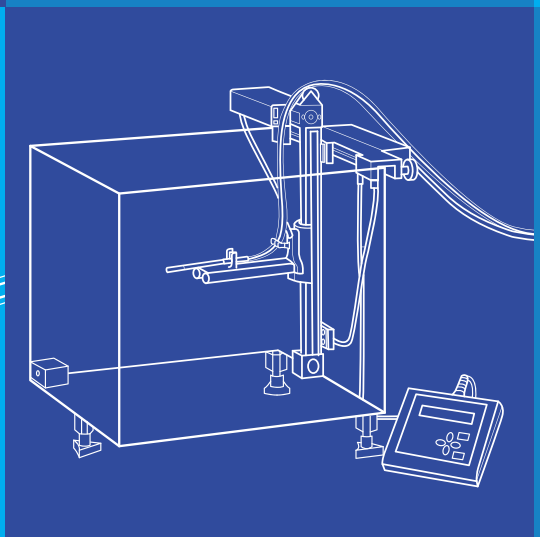
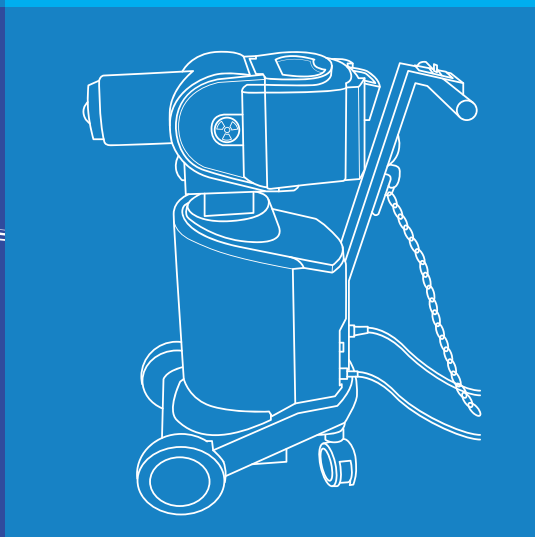

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