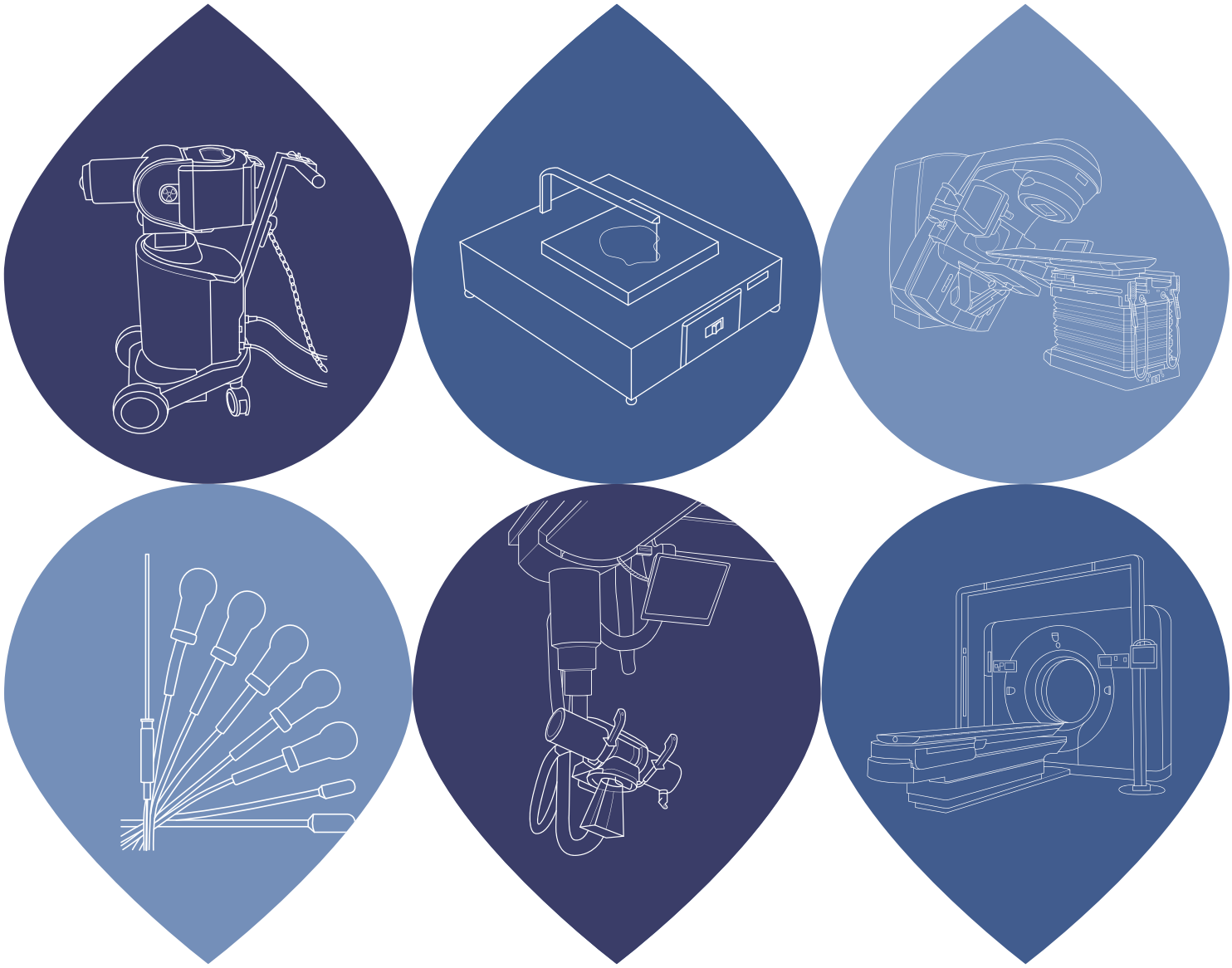
Sustainable management of radiotherapy facilities and equipment



World Health Organization

IAEA
International Atomic Energy Agency

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ISBN 978-92-4-007506-1 (electronic version)

ISBN 978-92-4-007507-8 (print version)

Suggested citation. Sustainable management of radiotherapy facilities and equipment. Geneva: World Health Organization; 2023. Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at http://apps.who.int/iris.

Technical drawing, design and layout: Genève Design.

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Acknowledgements

The World Health Organization (WHO) and the International Atomic Energy Agency (IAEA) cooperated in producing this publication for the WHO Cervical Cancer Elimination Initiative. Development of the publication was led by Princess Nothemba Simelela, Assistant Director-General, Special Advisor to the Director-General on Strategic Priorities, WHO; Mariangela Simão, Assistant Director-General, Access to Medicines and Health Products, WHO; Ren Minghui, Assistant Director-General, Universal Health Coverage/Communicable and Noncommunicable Diseases, WHO; and Najat Mokhtar, Deputy Director-General, Head, Department of Nuclear Sciences and Applications, IAEA. Strategic guidance was provided by May Abdel-Wahab, Director, Division of Human Health, IAEA; Bente Mikkelsen, Director, Department of Noncommunicable Diseases, WHO; and Clive Ondari, acting Director, Health Products Policy and Standards Department, WHO.

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WHO and IAEA address their sincere gratitude to the following professionals who participated in virtual technical meetings for preparation of this publication: Brendan Healy, Medical Physicist, Clinical Operations Lead, Australian Radiation Protection and Nuclear Safety Agency, Melbourne, Australia; Rhodesa U. Cruzet, Medical Physicist and Radiation Protection Officer, Cebu Doctors' University Hospital, Radiation Therapy Center, Cebu City, Philippines; Kennedy Lishimpi, Director and National Coordinator, Cancer Control Services, Ministry of Health, and Consultant Clinical and Radiation Oncologist, Cancer Disease Hospital, Lusaka, Zambia; Maurice Page, Medical Physicist and Biomedical (Clinical) Engineer (retired), France; Borislava Petrovic, Medical Physicist, Radiotherapy Department, Oncology Institute of Vojvodina, Sremska Kamenica, and Faculty of Sciences, University of Novi Sad, Serbia; Paul Ravindran, Chief Medical Physicist, Christian Institute of Health Sciences and Research, Dimapur, India; Sandra Rocha Nava, Biomedical Engineer, Instituto Nacional de Cancerologia, Mexico City, Mexico; Ahmed Ibn Seddik, Medical Physicist, Rabat, Morocco; Shaima Shoeir, Medical Physicist, Children's Cancer Hospital, Cairo, Egypt; Adam Shulman, Medical Physicist, University of Colorado, Colorado Springs (CO), USA; Axel Tibinyane, Medical Physicist, Director, Atomic Energy and Radiation Safety, Windhoek, Namibia; Sasikala Devi Thangavelu, Biomedical Engineer, Kuala Lumpur, Malaysia.

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WHO also thanks the following for extensive independent review and technical comments on this publication: Hélène Aget, Medical Physicist, France; Wahyu Edy Wibowo, Chief Medical Physicist, Installation of Radiation Oncology, National General Hospital Dr Cipto Mangunkusumo, Jakarta, Indonesia; Enkhtsetseg Vanchinbazar, Medical Physicist, National Cancer Centre, Ulaanbataar, Mongolia; and Jacob Van Dyk, Medical Physicist, Toronto, Canada.

WHO thanks the following staff at IAEA: David Ek, Senior Nuclear Security Officer; Timothy Hayes, Control of Radiation Sources Specialist; Mitchell Hewes, Information Technology Security Officer; Ola Holmberg, Unit Head, Radiation Protection of Patients Unit; Alessia Maria Rodriguez Y Baena, Unit Head, Radioactive Material Security; Katherine Wakeham, Section Head, Applied Radiation Biology and Radiotherapy; and Muhammad Waseem, Nuclear Security Officer.

This publication was produced with financial support from Unitaid.

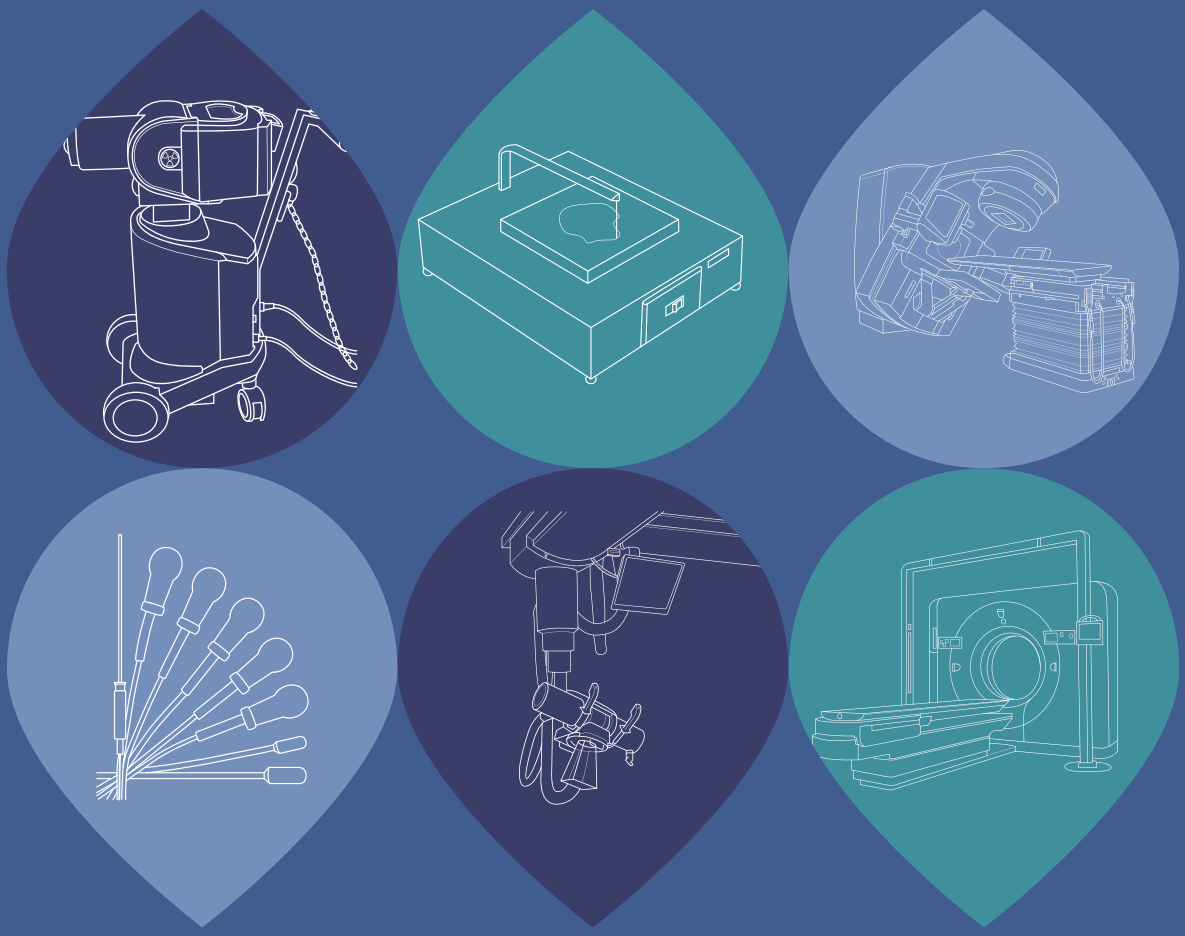
Abbreviations and acronyms

CT	computed tomography
HDR	high-dose rate
IAEA	International Atomic Energy Agency
LINAC	linear accelerator
MLC	multi-leaf collimator
OIS	oncology information system
QA	quality assurance
RTT	radiation therapist
RVS	recording and verification system
TPS	treatment planning system
WHO	World Health Organization

Executive summary

Following adoption of resolutions WHA60.29 on health technologies and WHA70.12 *(1,2)* on cancer prevention and control, the World Health Organization (WHO) published *List of priority medical devices for cancer management* in 2017 to assist countries in prioritizing inclusion of medical devices into their health-care systems *(3)*. WHO and the International Atomic Energy Agency (IAEA) published detailed technical specifications of the radiotherapy equipment required for cancer treatment *(4)*. It was observed, however, that, once the appropriate radiotherapy equipment had been procured, many radiotherapy departments found difficulty in managing the equipment and facilities. The aim of this document is to provide guidance on sustainable management of the equipment and facilities to ensure that cancer patients are treated safely and accurately, with minimum gaps in their treatment. The guidance is intended for a committee of clinical radiation oncologists, medical physicists, radiation therapists and biomedical engineers and financial and planning officers to manage sustainable operation of all the radiotherapy equipment necessary to treat cancer patients, from pre-treatment imaging through to treatment and the facilities to house equipment. Therefore, recommendations are given on sustaining operation of the equipment and facilities, from procurement to replacement of equipment at the end of its life-cycle.

Section 1 lists the elements necessary to sustain: radiotherapy equipment, facility infrastructure, management and well-trained staff. The latter are not, however, covered in this document as the topic has been well documented in other IAEA and WHO publications. Section 2 covers the elements necessary to sustain radiotherapy, consisting of the equipment, facilities and funding, and also both preventive and corrective maintenance. Section 3 outlines the duties of those responsible for the sustainability of radiotherapy service. Section 4 discusses the maintenance of radiotherapy equipment and facilities, from procurement to replacement of the equipment at the end of its life. This includes various options for service contracts, depending on the type of equipment and facility, and penalties to be included in service contracts to ensure a reliable service from the maintenance provider. The annexes give examples for calculating the uptime of equipment, details of machine log books, items to be included in a service contract and negotiation of a service contract.



Chapter 1.

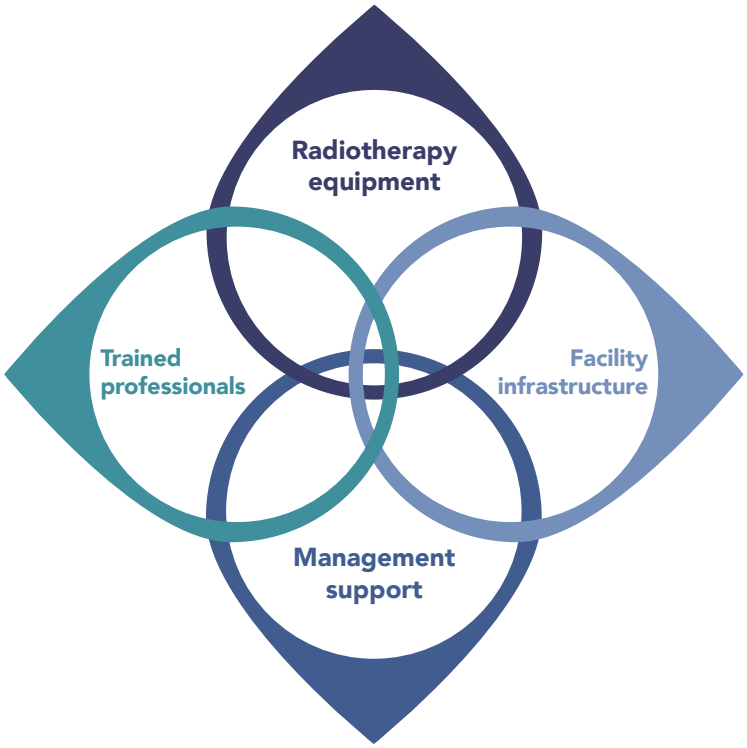
Introduction

1.1 Background

Cancer is a leading cause of death worldwide, accounting for nearly ten million deaths in 2020 *(5)*. Cancers can be treated by a combination of surgery, chemotherapy and radiotherapy *(6)*. Radiotherapy is an essential component of cancer management, as over 50% of all cancer patients are likely to require radiation as part of their treatment management due to its significant contribution to local tumour control and to overall survival from cancers at many sites; it can also be used in disease palliation *(7)*. The greatest population benefit from evidence-based radiotherapy is seen for cervical cancer, with a 5-year overall survival benefit of 18% and a 5-year local control rate of 33% *(8)*. Improved access to radiotherapy is a strategic action for attaining the 90% treatment target of the WHO *Global strategy for eliminating cervical cancer as a public health problem,* for example *(9)*.

Investment in radiotherapy is often thought of only in terms of the cost of a treatment machine; however, as summarized in Fig. 1, the four major considerations in developing and maintaining a radiation treatment programme are support by management, trained professionals, well-maintained facility infrastructure and radiotherapy equipment. If any of these four elements falters, the radiotherapy programme is unlikely to be sustainable.

Fig. 1. Four major considerations in developing a sustainable radiation treatment programme

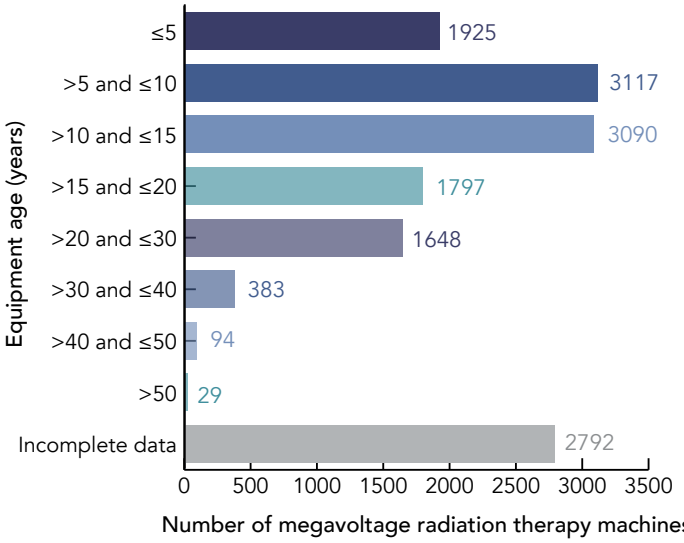


Thus, an entire package of radiotherapy equipment (hardware and software) should be procured *(4)* (see section 2.1). The factors that influence the sustainability of radiotherapy are often underestimated by decision-makers, as radiotherapy equipment should also be supported by robust facility infrastructure, such as a stable power supply, clean water and adequate air-conditioning. Buildings with shielded structures should be constructed *(10)* to the relevant standards for radiation protection *(11)* and local building standards. If radioactive sources are used, appropriate security measures should be installed on the premises to prevent unauthorized removal of radioactive material and sabotage *(4,12,13)*. Furthermore, for safe use of radiation sources and operation of facilities, a country should have the appropriate government, legal and regulatory frameworks for radiation safety. Use of radiotherapy also requires a well-educated professional workforce of sufficient numbers, including medical physicists, radiation oncologists, radiation therapists (RTTs), nurses, biomedical engineers and IT engineers; further recommendation on medical exposures are provided in IAEA Safety Standards Series No. SSG-46 *(15)*. All the equipment should be well maintained and the staff well trained. The machines are sophisticated, and the entire chain of radiotherapy equipment, from imaging to treatment equipment, is inter-dependent. Thus, faults in the equipment chain (see Fig. 2) can compromise the safety of patients or the quality of their care. Not only should the equipment work correctly but a QA programme must be established and maintained.

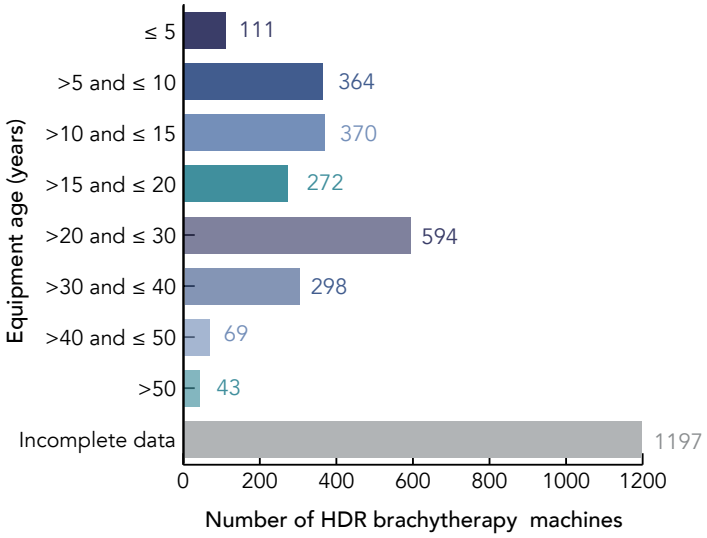
The practice of radiotherapy relies on accurate, safe use of complex medical devices, radiation sources and multifaceted software applications. For successful treatment of cancer with radiotherapy, the medical equipment should be fully operational, with limited downtime (when it is not used owing to a fault), so that the maximum number of patients are treated safely and without interruptions to their treatment. Interruptions to radiotherapy can lead to unsuccessful clinical outcomes, such as tumour recurrence, clinical complications and even death. To maintain safe, secure operation and functionality of the radiotherapy equipment chain (see section 2.1), *IAEA Safety standards series No. SSG-46, Radiation protection and safety in medical uses of ionizing radiation (15)* states that provision be made by the licensees for maintenance of radiotherapy equipment for its life-cycle. Current evidence suggests, however, that suboptimal use of medical devices is closely linked to inadequate maintenance services. One cause of suboptimal performance of radiotherapy equipment is operation of some external beam machines and brachytherapy afterloaders beyond their recommended life-cycle (see Fig. 2). A recent IAEA/WHO survey[a] showed that linear accelerators (LINACs) operated beyond their expected life-cycle are more likely to have long outages and cannot be used to treat patients.

Fig. 2. Age of radiotherapy equipment

A. Age (years) of 14 875 megavoltage radiation therapy machines in 2021



B. Age (years) of 3318 high-dose rate (HDR) brachytherapy machines in 2021



Source: IAEA DIRAC *(16)*

a IAEA, WHO. Survey on sustainability of radiotherapy equipment (in press).

This document was written in response to World Health Assembly resolutions 70.12 and 73.2 (2,9), which mandated WHO to prepare global reports on cancer and technical packages on three global cancer Initiatives, the Cervical Cancer Elimination Initiative, the Global Initiative for Childhood Cancer and the Global Breast Cancer Initiative. All three have identified better access to diagnostic and treatment technologies for cancer management among their strategic priorities.

1.2 Purpose of the document

The purpose of this publication is to provide recommendations to Member States to improve the sustainability of radiotherapy equipment and facilities by ensuring that provision is made for corrective and preventive maintenance for the life-cycle of equipment. In general, this implies that the "uptime" of radiotherapy equipment be maintained at ≥ 95% (see section 2.5), with less than 5% outage times, which will improve access to good-quality, appropriate, safe radiotherapy. This document provides advice on maintaining radiotherapy equipment and facilities and making provision for replacement of the equipment at the end of its life-cycle. It does not address staffing or training and education of staff and does not provide guidance on establishment of a QA programme, as these are covered in other publications *(14,17,18).*

1.3 Scope

The four chapters describe the problems, the requirements to maintain radiotherapy equipment, the roles and responsibilities of those responsible for the sustainability of the equipment and the requirements for maintenance throughout the life-cycle of radiotherapy equipment and facility infrastructure, including replacement of equipment at the end of its life-cycle and management of disused radioactive sources. This document accompanies the WHO/IAEA publication on technical specifications for radiotherapy equipment *(4)*; the equipment packages defined in the specifications are reproduced in Annex 1.

1.4 Intended readership

This publication is intended primarily for health authorities, policy-makers, managers, procurement officers and health professionals working in radiotherapy departments who are responsible for planning, procuring, maintaining or using radiotherapy equipment for cancer treatment. Manufacturers, equipment suppliers and biomedical engineering service providers could benefit from the recommendations in this document in drawing up appropriate service agreements to maintain the equipment and reduce the time it is not operational. Nongovernmental agencies will find useful information for supporting in-kind donation or procurement of radiotherapy equipment as a supplement to other WHO documents *(19,20)*.

1.5 Contributors

An expert development group was constituted in 2021, with two experts from each of the six WHO regions and staff from relevant WHO and IAEA technical programmes. The members consisted of professionals involved in planning and using radiotherapy services, including national cancer control coordinators, radiation oncologists, health technology managers, clinical medical physicists and biomedical engineers. The group provided input at all stages of development, providing expert advice to the WHO consultant who drafted the document and then reviewing the first draft. The group met at one virtual meeting on 18–19 October 2021.

An external review group composed of experts and staff from selected WHO and IAEA technical programmes reviewed the draft document and commented on its technical accuracy, clarity of language and implications for implementation. Their feedback was included in the final version.

1.6 Management of conflicts or interests

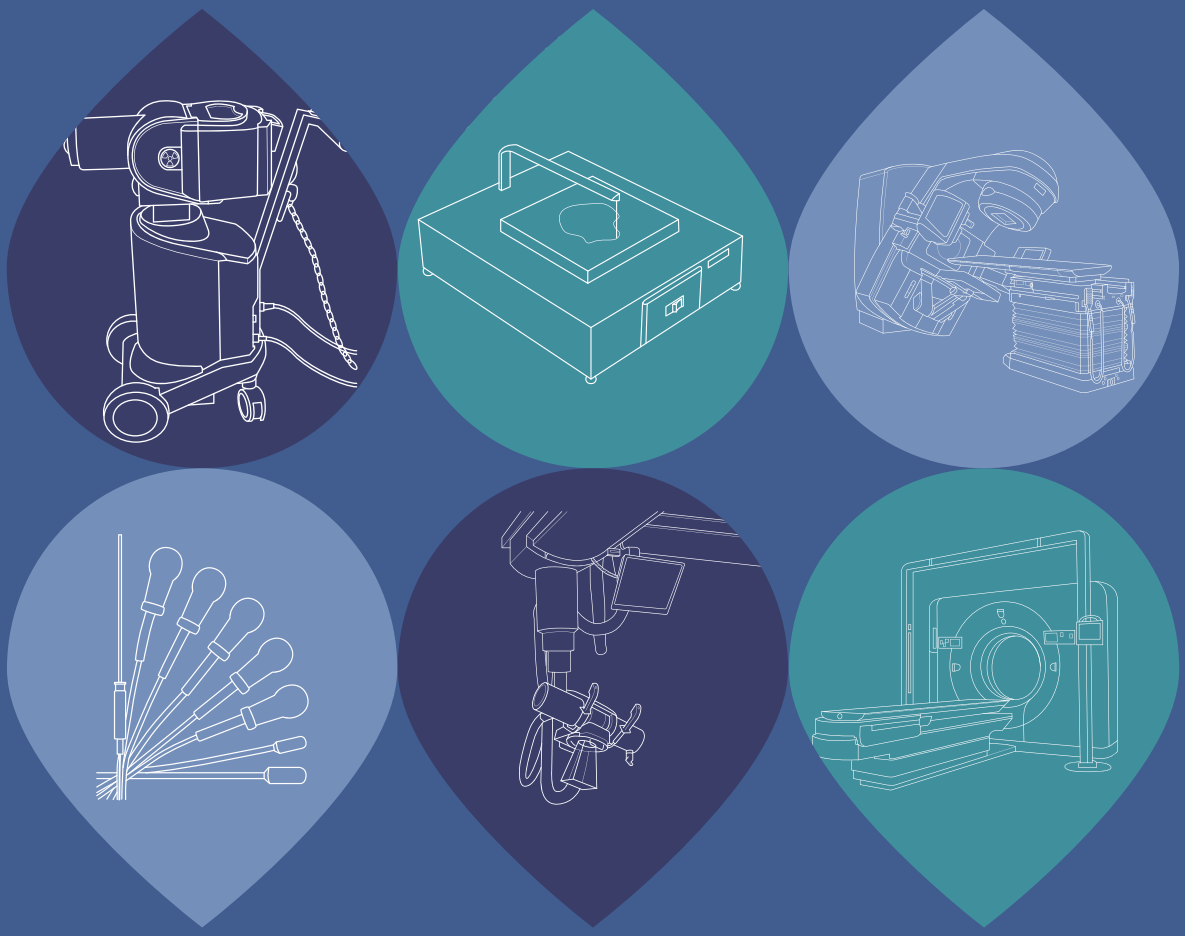
Disclosure and appropriate management of relevant financial and non-financial conflicts of interest of expert groups and other external experts and contributors is a critical WHO procedure. According to WHO regulations, all experts must declare any interests before participating in WHO processes and meetings. All members of the expert development group therefore completed the standard WHO form for declaration of interests, which were reviewed one by one to determine any conflicts of interests, in accordance with WHO regulations, before the experts were invited to participate. The conclusions of the review were communicated at the start of the meeting to those experts who were invited.

1.7 Method for content development

At the meeting of the expert development group, each member outlined the processes used in their country for making decisions on equipment procurement and maintenance and the parameters used to judge the acceptable down time of machines. The members were then asked to list the five main causes of equipment failure in their region, with an up time of less than 95%, and to propose solutions. Once the data had been collated, the contents of the document were drawn up, which were discussed and agreed upon by the group.

The WHO consultant performed a literature search of the problems encountered in maintenance of radiotherapy equipment in low- and middle-income countries and prepared the first draft of the document. The expert development group added comments to the draft, which were incorporated to produce the next version, which was sent to the review group for comment.

From the beginning, it was intended that this document would accompany the WHO/IAEA document, *Technical specifications of radiotherapy equipment for cancer treatment (4)*, as the present document provides guidance on maintaining radiotherapy equipment and the facilities for housing the equipment to ensure a fully functional radiotherapy service.



Chapter 2.

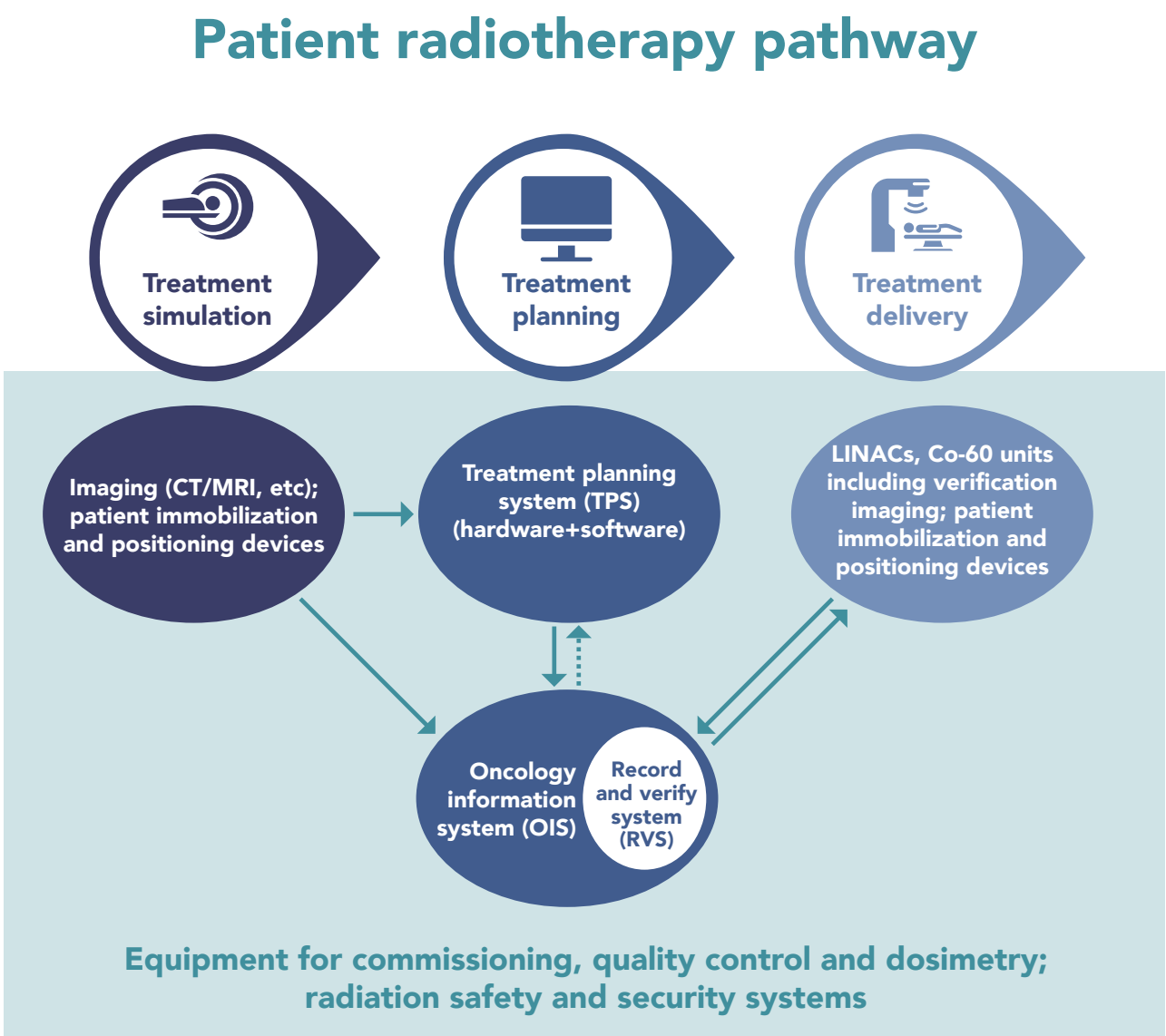
Maintaining a chain of radiotherapy equipment

2.1 The radiotherapy equipment chain

A package of radiotherapy equipment is required to treat a patient safely with radiotherapy (see Annex 1). Too often, stakeholders concentrate on treatment machines, such as a LINAC, cobalt-60 teletherapy unit or an HDR brachytherapy afterloader, and ignore the other systems involved in radiotherapy. In practice, high-quality radiotherapy cannot be offered unless all the devices in the chain (Fig. 3) are operating optimally. Radiotherapy devices are interconnected, and many items in the chain are interdependent; for example, if the X-ray tube on the computed tomography (CT) simulator is replaced, the electron density calibration in the treatment planning system (TPS) should be verified, which requires ancillary specialized quality control equipment. Furthermore, facility infrastructure is often directly linked to radiotherapy equipment. For example, the interlock on the door to the treatment room should be activated before the treatment beam can be initiated. Therefore, any issue in the radiotherapy equipment chain and the facility may compromise the outcome of radiotherapy and the sustainability of the radiotherapy department. This document therefore also discusses the sustainability of facility infrastructure, such as buildings, air-conditioning and the water and power supply necessary to operate the devices in the radiotherapy equipment chain (Fig. 3).

Fig. 3. The radiotherapy equipment chain

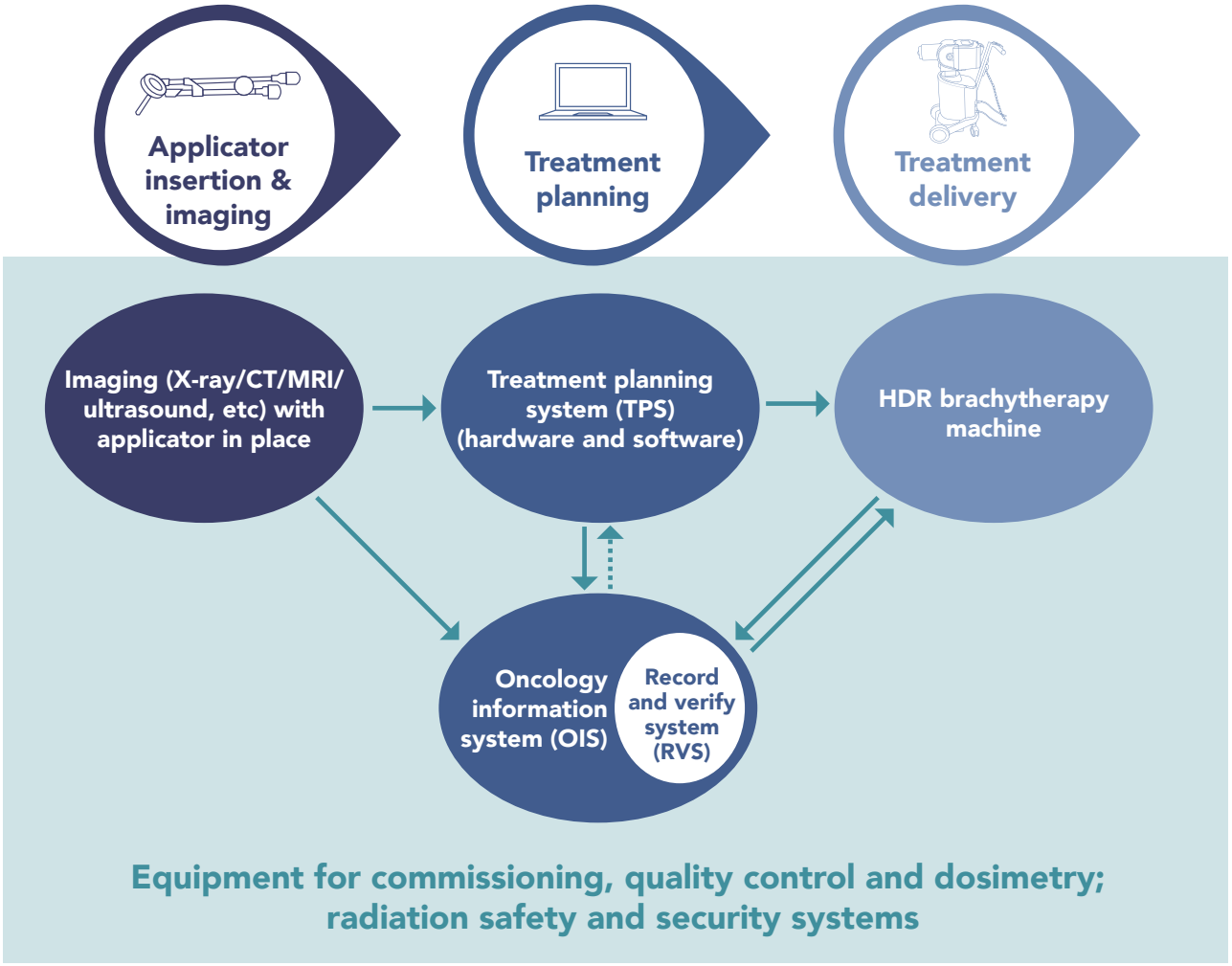
3A. External beam radiotherapy equipment



The arrows show the communication between different equipment, which is based on specific standards (e.g. DICOM, HL7)

3B. HDR brachytherapy equipment

Patient brachytherapy pathway



The IAEA/WHO *Technical specifications of radiotherapy equipment for cancer treatment (4)* describes the devices in the radiotherapy equipment chain in detail and should be used in conjunction with these guidance notes.

The devices in the radiotherapy equipment chain are:

- imaging (conventional simulator, CT simulator, C-arm and ultrasound for brachytherapy)
- TPS
- oncology information system (OIS), including a recording and verification system
- treatment machine (orthovoltage unit, cobalt-60 teletherapy unit, LINAC, HDR brachytherapy afterloader) and accessories such as a treatment couch, onboard imaging such as electronic portal imaging device and kV imaging where appropriate for the package
- immobilization and positioning devices
- treatment applicators for brachytherapy
- QA and dosimetry equipment for all equipment, including imaging, treatment machines and TPS
- facility infrastructure (suitable building, power, water, air-conditioning)

2.2 Facility infrastructure

The facility infrastructure *(10)* that houses the radiotherapy equipment should have a reliable, stable power supply, an air-conditioning and ventilation system, a water supply, information technology resources and access safety and security systems. In case of failure of the external power supply, an emergency diesel power generator could be used to run systems that are controlled only by timers and do not require complex power conditioning, such as cobalt-60 teletherapy and HDR brachytherapy units. A generator generally does not have sufficient capacity or stability and is not cost–effective for powering a LINAC or orthovoltage unit, and this equipment should not be used in such a way. An uninterruptible power supply or battery back-up system should be installed to capture active information at the time of an outage and to allow shut-down of all the software-driven systems and components in a controlled manner. Servers should be programmed to shut down automatically when the mains power supply is interrupted.

The door to the treatment room should have a back-up system that is well maintained to prevent a patient and/or staff from being trapped in the room. This requires regular preventive maintenance, as recommended by the manufacturer of the door. In the event of a power failure, it should be possible to open the door manually from inside the treatment room. The procedures for freeing a patient or staff trapped in a treatment room should be clearly documented and staff trained in how to respond.

The design of the facility should include an air-conditioning system sufficient to maintain the temperature and humidity in the treatment room within the parameters defined by the equipment manufacturers. In addition, high-energy LINACs (with high-energy photon beams and high dose rate modes) create ozone; therefore, 2–10 air exchanges of room volume per hour are necessary, depending on the radiotherapy technique and energy used *(10)*.

Water is used to cool LINACs (and may be required for some orthovoltage units). Therefore, a clean, reliable, uninterrupted water supply is critical for the proper functioning and durability of radiotherapy equipment. Additional filtration can prevent problems such as corrosion, water leaks and equipment downtime due to blockages in the water system. Closed-loop systems are less costly and preferred, with open system bypasses serving only as a back-up.

Radiotherapy based on an active source facility design should include security considerations according to the guidance of the IAEA in *Security of radioactive material in use and storage and of associated facilities (12)*. The designer of a facility should be reminded to consider the structure of the security system (e.g. cameras, intrusion detectors, access controls, delay barriers).

Computer-based systems for the safe use and security of radioactive sources may be targeted by cyber-attacks. The designers of a facility should consider establishing a computer security programme and defensive architecture, as outlined in IAEA Nuclear Security Series No. 42-G, *Computer security for nuclear security (13)*.

2.3 Funding a radiotherapy programme

Funding for a radiotherapy programme comprises not only the initial cost of equipment but should include continual funding for the lifetime of the radiotherapy services. The funding should be sufficient to cover:

- radiotherapy staff (radiation oncologists, medical physicists, RTTs, biomedical engineers, oncology nurses, IT engineers), who should be paid a competitive salary to retain them in the radiotherapy department, including funds for their continuing professional development;
- corrective maintenance of all radiotherapy equipment and systems and facility infrastructure and services, either through service contracts with the manufacturer(s) or local agent(s), an in-house biomedical engineer (see section 4) or a combination;
- preventive maintenance of all the radiotherapy equipment and systems and the facility infrastructure and services, through service contracts with the manufacturer(s) or local agent(s), an in-house biomedical engineer (see section 4) or a combination;
- periodic replacement of radioactive sources, if used (Co-60 or Ir-192 sources for HDR brachytherapy should be replaced every 3 years and every 3–4 months, respectively, whereas the Co-60 source, for a teletherapy machine should be cascaded or replaced every 5–7 years *(21)*. This a very costly exercise; for brachytherapy, it is expected that the cost of a Co-60 source may be less than that for Ir-192 HDR sources during the life-cycle of the equipment, as fewer sources are required; however, this depends on the infrastructure, workload and applications. The expected life-cycles of computerized technologies such as the TPS, OIS and data storage equipment can be extended by upgrading and updating the hardware and/or software, with consideration of computer security.);
- spare parts, including those that are to be replaced frequently and costly spare parts that are expected to be replaced during the life-cycle of the equipment (see Annex 4);
- ancillary costs, which depend on the location of the radiotherapy department, such as travel expenses for an engineer employed by the manufacturer or local agent for a site visit, customs clearance for spare parts and equipment;
- local spare parts and tools that are to be replaced frequently, which can be replaced by an in-house biomedical engineer who has undergone regular training by the manufacturer, who should have access not only to spare parts but also to the appropriate tools for the job;
- QA, dosimetry and safety equipment, calibration of dosimetry and safety instruments, and periodic testing of security equipment (Calibration of equipment often requires shipment of the instruments abroad, so that it is often away for long periods, and the radiotherapy department may have to borrow identical equipment during this period or have access to back-up instruments.);
- personal dosimetry services;
- costing and maintenance of facility services, such as the buildings, air-conditioning, power and water supplies, radiation warning lights,security system, doors to treatment rooms;
- consumables, such as drugs, disposable material including film for QA measurements, immobilization devices, office and other supplies;
- costs associated with radiotherapy and passed on to other hospital services, such as those for hospitalization, laboratory work and diagnostic tests;
- costs of compulsory governmental licences, such as those issued by radiation protection regulatory bodies, and insurance premiums to cover liability, which are usually required for the whole department or institution and might have to be renewed periodically, with costs; and
- replacement of radiotherapy equipment at the end of their life-cycle (see section 4.7).

Radiotherapy is clearly costly, because of the initial expense, costs of staff and maintenance of all the devices in the equipment chain, facility infrastructure and services for the lifetime of the department. All these aspects should be properly estimated and budgeted when planning a radiotherapy department. The high cost of service contracts, QA equipment, immobilization devices and of adhering to safety and security regulations are often overlooked when procuring radiotherapy equipment. This is to be avoided, as it may result in an unsustainable radiotherapy service. If funds are not available, the choice of equipment package (Annex 2) should be reconsidered, and it might be prudent to choose equipment from package 1, for instance. Sustaining the equipment in package 1 will cost less than sustaining that in package 2. To ensure the sustainability of radiotherapy services, funds should be available

for both corrective and preventive maintenance for the lifetime of the equipment and the facility infrastructure, as well as for replacement of the equipment at the end of its life-cycle.

The typical cost of annual service contracts for most of the equipment in the radiotherapy chain represents 8–15% of the initial total cost of the machine *(21)*, although this may increase to 30% or more for a CT simulator, especially if the contract includes replacement of the X-ray assembly.

2.4 Preventive and corrective maintenance

The devices in the radiotherapy equipment chain are made up of various parts, moving and non-moving, active and passive, and, at any time during the life-cycle of the equipment, these parts can fail due to wear and tear. To ensure mechanical, electrical and radiological safety, it is therefore important to pay regular attention to the equipment through planned preventive and corrective maintenance *(22)* requirements for medical exposure are established in IAEA Safety Standards Series No. GSR Part 3 *(23)*. In many countries, radiation-emitting equipment is subject to specific regulations that require verification of maintenance and performance with specific quality control (e.g. in the European Union, RP 162) *(24)*. The options for conducting both planned and corrective maintenance are discussed in section 4.

For the sustainability of the radiotherapy department, preventive maintenance should be planned for all the devices in the equipment chain and the facility infrastructure, so that problems can be resolved before a failure occurs and appropriate arrangements can be made, such as ordering spare parts. The manufacturer of radiotherapy equipment usually recommends a preventive maintenance schedule, with daily, weekly, monthly, quarterly, semi-annual or annual procedures for equipment or systems. The maintenance conducted will depend on the schedule to ensure that all susceptible components are checked, replaced and/or cleaned. Planned preventive maintenance of software, such as that used for TPS, simulator and OIS, should also include back-up and archiving of data. Preventive maintenance should be performed by an engineer certified by the manufacturer or by the authorized representative. Alternatively, an in-house biomedical engineer trained by the manufacturer could perform some or all of the planned preventive maintenance. Time for maintenance should be included in the department schedule, including time for routine quality control (QC) by the medical physicist before re-authorizing equipment or systems for clinical use.

Planned maintenance of facility infrastructure should include items such as back-up power systems, air-conditioning, the water supply, the doors to treatment or imaging rooms and radiation safety and security systems. The suppliers of these products can give advice on a schedule of planned preventive maintenance. The physical infrastructure for radiotherapy also requires maintenance.

Corrective maintenance is conducted in response to a breakdown of equipment in the radiotherapy equipment chain and involves the work required to resolve a problem in order to restore the equipment to a safe condition to treat patients. Corrective maintenance may require a more experienced engineer than the person who performs planned preventive maintenance, as more knowledge of the equipment may be required in order to diagnose the problem and repair the fault. As radiotherapy equipment is sophisticated, some problems may be caused by more than one fault, which could have repercussions throughout the radiotherapy equipment chain. It is therefore important to maintain and check inter-connectivity and to verify information exchange between pieces of equipment to ensure consistency throughout the chain. For example, if the TPS is upgraded or updated, it is important to check that CT images can still be transferred from the pre-treatment imaging device to the TPS and then, once a plan has been computed, to ensure that the parameters are correctly transferred from the TPS to the treatment delivery device such as the LINAC or cobalt-60 teletherapy unit via the OIS. An example of a problem that could occur in the chain, with catastrophic consequences for the patient, is transposition of the left and right side of the patient.

The expected life-cycle of radiotherapy equipment can be extended if it is well maintained. If maintenance is not carried out regularly and on time, the equipment will deteriorate to a point at which it is beyond economical repair, and it would cost more to repair than to replace it, or spare parts may no longer be available because the

manufacturer's support of the equipment has ended. For example, if an X-ray tube is not regularly warmed up according to the recommended routine sequence, the life-cycle of the equipment may be significantly reduced.

Not all the equipment in the radiotherapy equipment chain requires the same level of preventive and corrective maintenance. For example, immobilization devices and applicators should undergo regular visual inspection, the results documented and damaged items taken out of service, repaired or replaced, whereas full provision for preventive and corrective maintenance is required for the major treatment and imaging machines and the information technology systems.

Some manufacturers offer remote monitoring of the condition of radiotherapy equipment and can therefore review it, correct minor issues, update software and predict whether parts require replacement before a major problem develops. This has the advantage of minimizing the downtime of the machine, as potentially faulty parts can be ordered and replaced at a planned time without unscheduled outage of the machine. Any change made to equipment remotely should be recorded in the same way as changes made by an engineer on site; the fault should be fully documented and the equipment not be returned to clinical use until the medical physicist has completed the relevant QC checks. The main disadvantages of remote monitoring are additional cost to that of the service contract, a requirement for good Internet connectivity and additional computer security measures. Furthermore, as remote monitoring is available or possible only from certain manufacturers, faults in all the devices in the radiotherapy equipment chain or the interconnectivity between the devices cannot be monitored. If remote monitoring is considered to be beneficial, it is recommended that it be installed during the warranty period, so that it can be tested for quality and cost–effectiveness in the local situation and is protected by a computer security programme.

2.5 Equipment uptime

"Uptime" is used as an objective parameter to measure the availability of radiotherapy equipment for clinical use. It should be clearly defined and its value specified in the service contract. When uptime is defined as the time available for clinical service as a percentage of normal operating hours, it excludes the time for scheduled preventive maintenance and routine QA after corrective maintenance. As uptime is usually calculated on the basis of 250 operating days per year, the service contract should include the start and end times of the operating day and the operational days of the week. The uptime of all equipment in the chain should be 95% or greater. Thus, if each piece of equipment is not available for 5% of the time, the radiotherapy department is not operating for a larger proportion of the time, depending on the number of machines and their operational inter-dependence. A limit should therefore be set for the uptime of the entire radiotherapy equipment chain. It is unacceptable for the equipment in a radiotherapy department not to be working for more than 5% of the time, which would be 12.5 days, the uptime should not be the only basis for judging the performance of radiotherapy equipment. Another parameter could be the maximum number of consecutive days on which the machine cannot be used to treat patients. This should be subtracted from the uptime in the service contract, and penalties should be applied if the equipment does not achieve the values agreed (see section 4.6). Uptime should be documented for all devices in the radiotherapy equipment chain. An example of calculating uptime is given in Annex 3.

Radiotherapy equipment may have a fault in one mode of operation but can still operate in other modes; for example, a LINAC may have a fault only with electron treatment, or a dual photon energy machine might have a fault in only one of the photon energies. In some institutions, such situations are not included in calculations of uptime and contract penalties. This situation, however, represents radiotherapy equipment that is not optimized for the patients who require treatment with that particular mode of operation. Even if the mode of operation is not used frequently to treat patients, the equipment is not meeting its specifications, and penalties should be applied to the manufacturer if there is a service contract. The time during which the mode of operation is not working can be added to the calculation of uptime as time during which the radiotherapy equipment could not be used to treat patients.

2.6 Spare parts

The manufacturer or local agent who supplies radiotherapy equipment should guarantee the availability of spare parts for the life-cycle of the machine. Some major spare parts (see Annex 4) are costly, such as a new X-ray tube assembly for a CT simulator or HDR brachytherapy applicators; however, the manufacturers can predict when they are likely to be due for replacement. These components should not be stored in the radiotherapy department, as they have a defined shelf-life and should be ordered only when required. Spare parts that are less costly are more likely to require frequent replacement, such as a bulb for teletherapy machine; however, they are essential, and their lack of availability could lead to unnecessarily long disruptions in radiotherapy services. It is therefore advisable to procure such spare parts in advance and keep a stock locally. As some parts have a limited shelf life, the local stock of spare parts for each device should be discussed with the manufacturer or local agent at the time of purchase. In a country that has more than one machine of the same type (manufacturer and model), it might be easier to pool the stock of essential spare parts in a central location. It is essential, however, that they are available to all radiotherapy departments in the country within a reasonable time. In addition, the supplier, agent or in-house biomedical engineer should keep a stock of preventive maintenance kits and the required tools.

As many spare parts will probably have to be shipped from abroad, it is important to consider the time necessary for shipping and customs clearance of the parts, if pre-clearance of medical equipment is not available. The radiotherapy department should consider the cost not only of the spare parts but also those of shipment and customs clearance.

2.7 Record-keeping

According to the *IAEA Safety standards series No. SSG-46, Radiation protection and safety in medical uses of ionizing radiation (14)*:

> All servicing should include a report describing the equipment fault, the work done, the parts replaced and adjustments made, which should be filed as part of the programme of quality assurance. A record of maintenance carried out should be kept for each item of equipment.

To manage equipment effectively, records should be kept to determine whether the situation is improving and to learn from past actions. A record of maintenance (corrective and preventive) and QC should be kept for each device in the radiotherapy equipment chain for its life-cycle and also for facility infrastructure. The system can be manual or computerized. It should include information on any defects found by users (a fault log book), remedial actions taken (both interim repairs and subsequent repairs, including all spare parts replaced) and the results of testing before the equipment is reintroduced for clinical use.

A fault log book should be kept for each device in the radiotherapy equipment chain, close to the device and completed by the RTTs. An example of a fault log book is given in Annex 2. All faults, both major and minor, should be logged, as minor faults can lead to major faults if they are not rectified. The data entered in the fault log book will be used by the medical physicist and the in-house biomedical engineer to calculate the uptime of the machine (see Annex 3), check the stock of minor spare parts so that they can be replenished as needed and plot the frequency of certain types of fault and machine parameters in order to predict when the fault may recur. If an external engineer (usually employed by the manufacture or local agent) works on the equipment or facility, a detailed service report (see Annex 2) should be kept and stored in the maintenance record system.

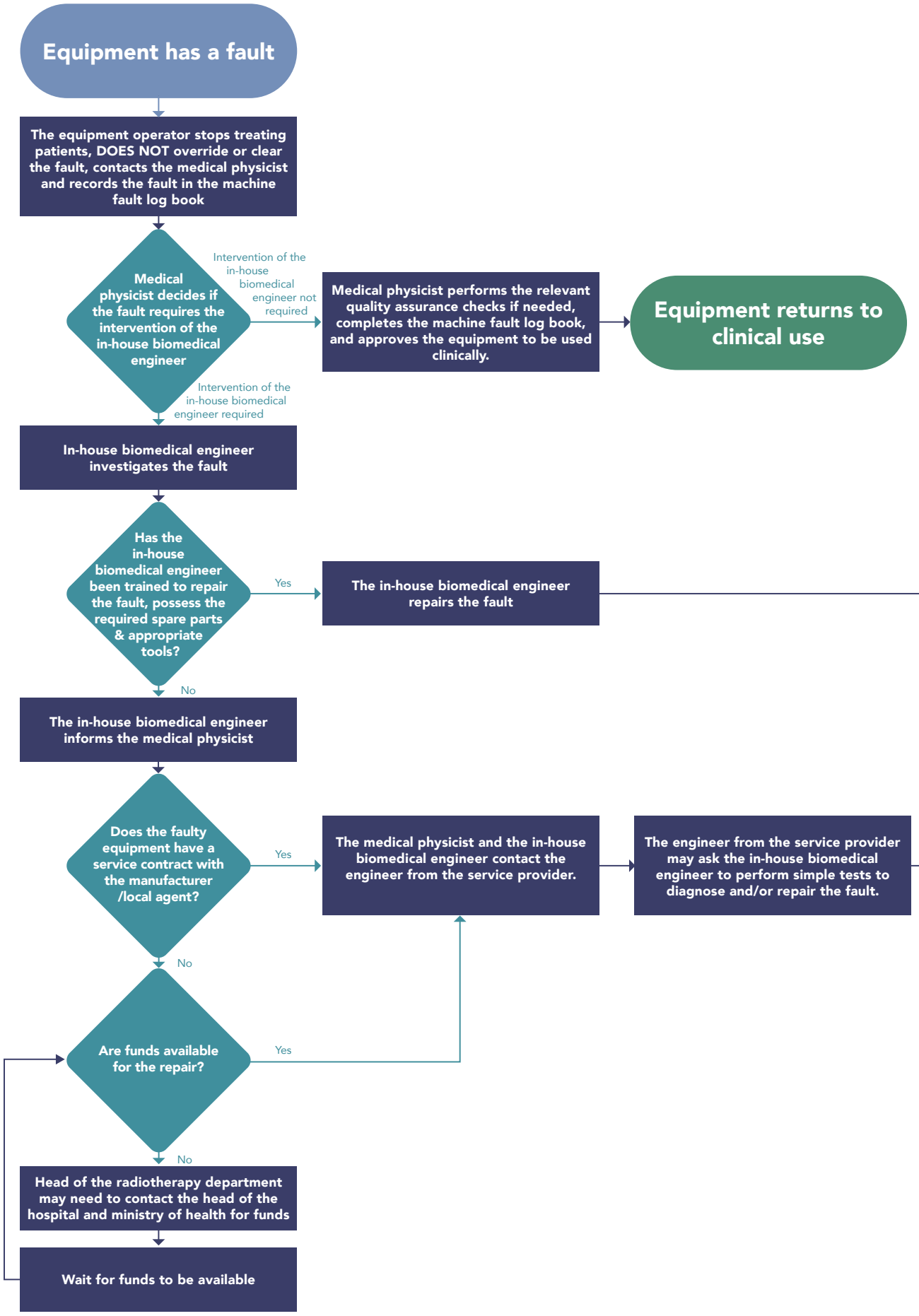
It is also recommended that an inventory be kept of all the equipment in the hospital *(25)* for use in drawing up budgets, managing service contracts and ordering spare parts and consumables. Inventories of ionizing radiation sources are usually required by regulatory bodies for radiation safety. Analysis of such inventories can indicate significant opportunities for saving costs. The cost of maintenance of identical equipment can vary widely, not only between countries and regions but also in the same country. Preventive maintenance could be done on several devices in the same week by the same engineer employed by the manufacturer or the local agent to avoid charges for long-distance travel. If there are several radiotherapy services with similar equipment in a region, costs could be saved by coordinating the schedule of services or requesting the manufacturer or agent to station an engineer centrally.

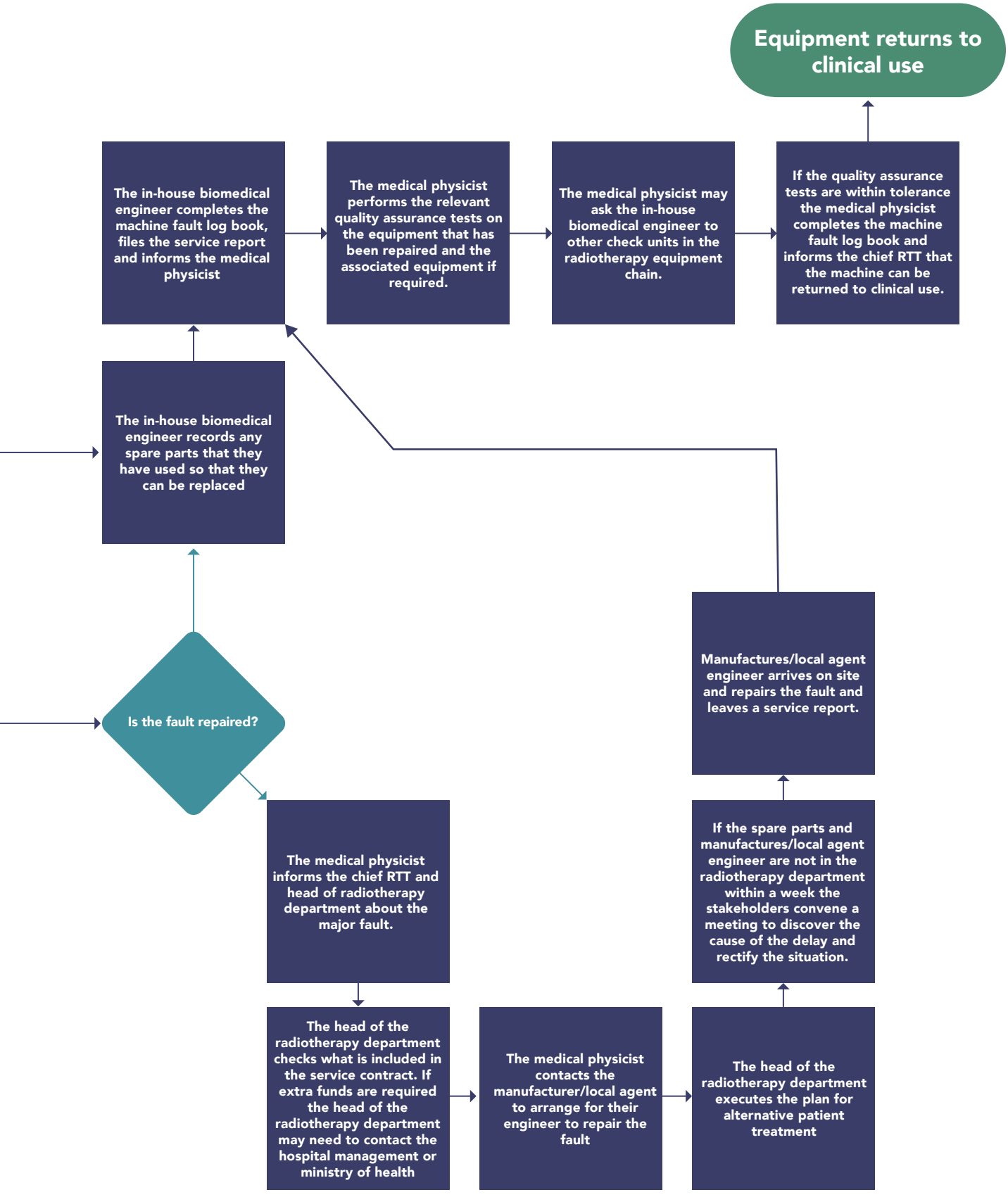
2.8 Action to address a fault in any part of the chain

Faults that require corrective maintenance may occur in any component of the complex radiotherapy equipment chain. Some maintenance tasks can be undertaken quickly by a trained in-house biomedical engineer, providing he or she has the spare parts and tools, while others are more complicated and require that the equipment be taken out of clinical use for fault diagnosis and repair. If a mode of operation is suspended while waiting for spare parts or a more experienced engineer, patient treatment should not be unreasonably adjusted to suit the reduced functionality of the radiotherapy equipment, and the fault should be repaired as quickly as possible. Not all faults require interruption of patient treatment, and there should be clear procedures for dealing with urgent and less urgent faults. A situation that will not require immediate cessation of treatment, for example, is replacement of a radiation safety warning light bulb if others are functional and visible. If dosimetry equipment has been damaged, it should be replaced or repaired (or borrowed from a neighbouring hospital) before the next QA session.

Faults in any equipment on the radiotherapy equipment chain and facility infrastructure should be dealt with systematically and be well documented. Fig. 4 outlines the procedure to be used for both minor faults that can be repaired by the in-house biomedical engineer and major faults that require outside assistance. All faults should be reported to the medical physicist by the operator after being documented in the machine fault log book (see Annex 2). The medical physicist then decides whether the fault requires the intervention of an external or in-house biomedical engineer. It is essential that interlocks or fault errors are not ignored or overridden but documented in the machine fault log book.

Fig. 4. Actions to be taken when a fault is found in the radiotherapy equipment chain




Equipment returns to clinical use
The in-house biomedical engineer completes the machine fault log book, files the service report and informs the medical physicist
The medical physicist performs the relevant quality assurance tests on the equipment that has been repaired and the associated equipment if required.
The medical physicist may ask the in-house biomedical engineer to other check units in the radiotherapy equipment chain.
If the quality assurance tests are within tolerance the medical physicist completes the machine fault log book and informs the chief RTT that the machine can be returned to clinical use.
The in-house biomedical engineer records any spare parts that they have used so that they can be replaced
Is the fault repaired?
Manufactures/local agent engineer arrives on site and repairs the fault and leaves a service report.
The medical physicist informs the chief RTT and head of radiotherapy department about the major fault.
If the spare parts and manufactures/local agent engineer are not in the radiotherapy department within a week the stakeholders convene a meeting to discover the cause of the delay and rectify the situation.
The head of the radiotherapy department checks what is included in the service contract. If extra funds are required the head of the radiotherapy department may need to contact the hospital management or ministry of health
The medical physicist contacts the manufacturer/local agent to arrange for their engineer to repair the fault
The head of the radiotherapy department executes the plan for alternative patient treatment

The in-house biomedical engineer may be able to repair some minor faults, if he or she has been trained by the manufacturer and has the appropriate spare parts and tools. For major faults for which the in-house biomedical engineer has not been trained or does not have the appropriate spare parts or tools, if the radiotherapy department has a service contract with the manufacturer or local agent and, if the in-house biomedical engineer has certification that is recognized by the manufacturer, he or she may be able to contact the manufacturer and receive simple instructions for diagnosing the fault remotely. For major faults, the engineer employed by the manufacturer or authorized representative might have to be on site to diagnose the problem, order any spare parts and repair the equipment. This can be challenging if the engineer from the manufacturer has to travel from abroad and requires transportation and an entry visa. Funds might have to be found for the spare parts, depending on whether the radiotherapy department has a service contract in which spare parts are included, and the spare parts might have to be shipped from abroad and will have to clear customs on arrival.

If there is a major fault, the head of the radiotherapy department and hospital management should be informed so that they can ensure the necessary funds. Depending on the situation, the hospital management might have to convene a meeting of stakeholders (see section 3) to secure prompt allocation of funds, a visa for the engineer and quick clearance of the spare parts through customs. If the repair is expected to take some time, a plan for patients should be implemented, such as transfer to another machine in the radiotherapy department, with additional shifts. If the repair is expected to take more than a few days, patients might be prescribed a break in treatment and transferred to a local hospital or a hospital in another part of the country or abroad. When there are treatment breaks, the radiation oncologist might have to adjust the treatment prescription to account for gaps in the treatment schedule. Reports such as that of the United Kingdom Royal College of Radiologists provide guidance on addressing unscheduled interruptions of treatment *(26)*.

Once the repair has been completed, the engineer sent by the manufacturer or local agent should document full details of the repair and any checks performed, usually in the form of a service report. After the fault has been repaired, the machine should not be used to treat patients until the relevant independent QC checks have been performed by the responsible medical physicist. The QC checks and results should be documented, and, once the values have been found to be within tolerance, the medical physicist should enter the time in the log book and inform the RTTs that the equipment is ready for clinical use. During the repair and QC checks, the medical physicist should not be under undue pressure to reauthorize treatment of patients before the system has been fully tested.

2.9 Donated equipment

Donated equipment is any equipment given to a radiotherapy department, including equipment that has been refurbished, used and new. Donated equipment may include small equipment such as dosimetry devices (e.g. electrometers, ion chambers, water phantoms) and/or large equipment (e.g. cobalt-60 teletherapy units, LINACs, CT scanners). Some donations *(19)* circumvent the regulatory, selection and procurement systems of the recipient country and institution, when they exist. Consideration should be given to local requirements, such as the burden of disease and level of care, the number of trained staff, the availability of technical expertise to provide maintenance. Sometimes, representatives of local manufacturers and equipment distributors, who may be expected to provide maintenance, are bypassed in such negotiations. Difficulties related to the purchase of consumables and the availability of service and spare parts could transform donated equipment into a liability rather than an asset.

From the perspective of radiotherapy departments, donated equipment should be treated in the same way as equipment procured at the request of a professional radiotherapy team. Before any donation is accepted, the equipment should be assessed to determine whether it is suitable for treating common cancers and is compatible with other devices in the local radiotherapy equipment chain. The equipment specifications *(4)* should be fully assessed and agreed by local radiotherapy professionals (medical physicists and biomedical engineers). In addition, the health authority and the national radiation safety and/or medical device regulator may have conditions for the acquisition, maintenance and use of donated or refurbished equipment, which should be fulfilled before an import license is granted.

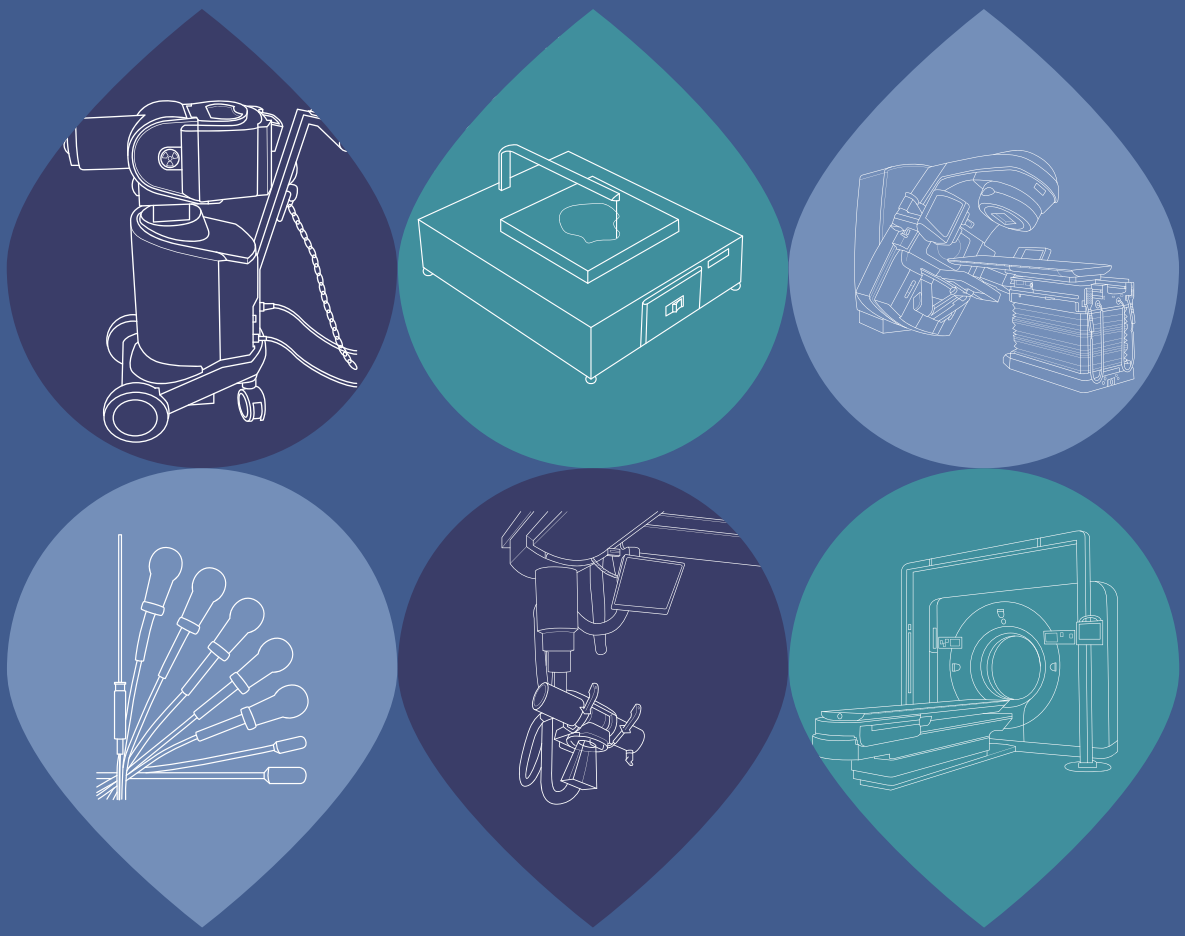
Once due diligence is applied to donated equipment, the recipient can accept the donation, providing the equipment and its use are approved by the medical devices and radiation protection regulatory bodies; however, the recipient can also refuse a donation if the equipment is inappropriate, the infrastructure is inadequate or the running costs, including maintenance of the equipment, cannot be met.

The donor country may also have regulations, such as the European Union regulation on export of used electrical and electronic equipment within and outside the European Union *(27)*, which requires that donated equipment should be in working order and have recently passed quality checks.

As the donated equipment may consist of used equipment from another radiotherapy department, it is essential to know the age of the equipment and whether it has been maintained by the manufacturer or local agent, whether full service records are available and whether spare parts are readily available for its foreseeable life-cycle. It is therefore recommended that any equipment that is older than half its expected life-cycle not be accepted (see section 4.7).

It is important to understand what is included in the donation and the financial implications for the radiotherapy department, such as whether:

- the radiotherapy department has suitable infrastructure to house the machine, such as a suitable site, power supply, air-conditioning, water and, where applicable, radiation shielding has been calculated or beam data for the equipment are readily available;
- the age of the equipment is within half its expected life-cycle *(4)*;
- the equipment is compatible with that already in operation in the radiotherapy department, including accessories such as immobilization devices;
- funding is available for customs clearance and any taxes;
- funding is available for installation;
- funding is available for preventive and corrective maintenance for the remaining life-cycle of the equipment, as for the other radiotherapy equipment in the radiotherapy department;
- if radioactive sources are required, such as for brachytherapy afterloaders or cobalt-60 teletherapy units, whether funding is available for regular source replacement;
- there are sufficient staff in the radiotherapy department who are formally trained in use of the new equipment;
- spare parts are available from the donor, their designated manufacturer or local agent for the remaining life-cycle of the machine;
- the manufacturer or authorized representative will offer a service contract if requested;
- dosimetry and safety instruments are calibrated, and a calibration certificate is included in the donation; and
- a copy of the log book of the donated equipment and maintenance reports since its commissioning is available, so that the recipient can ensure that the equipment was working according to specifications before being donated.



Chapter 3.

Responsibility for the sustainability of the radiotherapy equipment chain

Maintenance of radiotherapy equipment to ensure a sustainable radiotherapy service is complex and requires the involvement of the medical physicist and many other professionals *(28)*. It is important that they all understand their roles and responsibilities and those of the others in the team. The membership of the team will depend on whether the radiotherapy department is a stand-alone or a national centre. Stand-alone centres should have a focal point to deal with issues such as clearing spare parts quickly through customs or facilitating visas for service personnel. The main stakeholders are representatives of the government, the regulatory body for radiation safety, hospital management, the head of the radiotherapy department, a medical physicist from the radiotherapy department, an in-house biomedical engineer assigned to the radiotherapy department and a representative of the RTTs. The roles and responsibilities are outlined below, mainly for a national centre, although the same principles apply to a stand-alone centre.

The head of the radiotherapy department, the medical physicist, the in-house biomedical engineer, the hospital infrastructure engineer and the chief RTT should meet regularly to discuss the maintenance records of the radiotherapy equipment and facilities and the equipment that requires replacement, especially if the uptime is below 95%. All stakeholders should meet at least once a year, before annual review of the service contracts, to review the uptime and discuss the maintenance plan and equipment that requires replacement. They should also meet if there is a long outage of the equipment to try to resolve the situation. The roles of each stakeholder are outlined below.

Representative(s) of the government

Often, the representative(s) of the government will be from the department of health and/or the national procurement office and will assume responsibility for various aspects associated with maintenance of the radiotherapy equipment chain and the facility, including customs clearance, visa facilitation, contract negotiation, allocation of funds for service contracts and maintenance of the facility, and issuance of authorizations to transfer patients to other hospitals in the event of prolonged machine failure.

According to *AEA Safety standards series No. SSG-46, Radiation protection and safety in medical uses of ionizing radiation (14)*

> ... government has a responsibility to facilitate and ensure that the health authority, the relevant professional bodies and the radiation protection regulatory body communicate and cooperate in working towards establishing the facility infrastructure necessary for radiation protection and safety in medical uses of ionizing radiation.

This includes maintenance of the radiotherapy equipment chain, the facility infrastructure and safety and security. A major challenge to repairing equipment in resource-constrained countries is shipment of major spare parts and travel of an engineer employed by the manufacturer from abroad. It is therefore recommended that the government facilitate prompt customs clearance of spare parts and arrange for a visa for the engineer to be issued promptly, perhaps by issuing a multiple entry visa.

The role of the health authority typically includes determining policy, which in turn may dictate the resources allocated to radiotherapy departments.

The regulatory body for radiation safety

The role of the regulatory authority for radiation safety typically includes licensing medical facilities which oversee radiotherapy equipment. According to *IAEA Safety standards series No. SSG-46, Radiation protection and safety in medical uses of ionizing radiation (14)*,

> the regulatory body should ensure that installation, maintenance or servicing of medical radiological equipment is appropriately authorized.

Therefore, permission to import radiotherapy equipment should be granted only if the equipment fulfils national standards or the specifications recommended by WHO or IAEA *(4)* and maintenance is planned for the life-cycle of all the equipment in the radiotherapy chain.

Hospital (or cancer programme) management

Hospital management has overall responsibility for radiotherapy service delivery, which includes maintenance and sustainability, which is delegated to responsible radiotherapy professionals. The hospital management should ensure the following.

- Service contracts are negotiated (see Annex 6) with the manufacturer(s) or their local agent(s); monitor the contracts for radiotherapy equipment and systems annually to ensure that the terms of the agreement are being met and that the radiotherapy department receives the necessary services.
- Provision is made for maintenance (corrective and preventive) of the facilities housing the radiotherapy department, including the building, power supply, air-conditioning and water supply.
- Funding is available for preventive and corrective maintenance for the radiotherapy equipment chain for the life-cycle of the machines, including management of disused radioactive sources.
- Funds are available for consumables, such as immobilization devices, regular calibration of the dosimetry and safety equipment, spare parts for common faults in radiotherapy equipment and facility infrastructure.
- Funds are available for maintenance of certification and continuing professional development of staff in the radiotherapy department, including radiation oncologists, medical physicists, RTTs and in-house biomedical engineers, if appropriate.
- Funds are available for routine operating costs associated with monitoring staff for exposure to radiation.
- A plan is established to transfer patients to other in-house treatment machines and hospitals locally, in the country or abroad, in the event of catastrophic equipment or system failure. The transfer plan should be designed to be triggered promptly to minimize interruptions to patients' treatment.
- A replacement schedule is established for all the equipment in the radiotherapy equipment chain.
- Funds are available for rapid allocation (within a few days) for replacement of major parts.
- Sufficient tools and spare parts are available on site for routine repairs.
- Rules and procedures are established to control access of individuals to areas where radioactive material is present, including repair and maintenance staff and contractors *(28)*.

Head of the radiotherapy department

The head of the radiotherapy department is responsible for many activities, including for executing the plan to manage patient treatment in the case of machine outages, provide support to the medical physicist to sustain the radiotherapy equipment and training of staff in the operation of the equipment.

Medical physicist

The medical physicist assumes overall management of the physical, safety and technical aspects of equipment and collaborates with service engineers in developing and maintaining a quality management programme for all the equipment to ensure that the equipment operates optimally *(28)*. The medical physicist should supervise preventive and corrective maintenance and document the relevant information, such as maintaining the fault log book system. The medical physicist should not act as a front-line service engineer but is responsible for independent reauthorization of equipment as safe for treatment after maintenance.

IAEA Safety standards series No. SSG-46, Radiation protection and safety in medical uses of ionizing radiation (14) states

> that QC should be performed by the responsible medical physicist after maintenance and after installation of any new software or modification of existing software for all equipment in the radiotherapy equipment chain. This ensures that the function of the equipment has not been affected by any alteration made during maintenance or repair.

Once the medical physicist has verified that the QC measurements are within tolerance and has documented the results, he or she is responsible for re-authorizing clinical use of radiotherapy equipment.

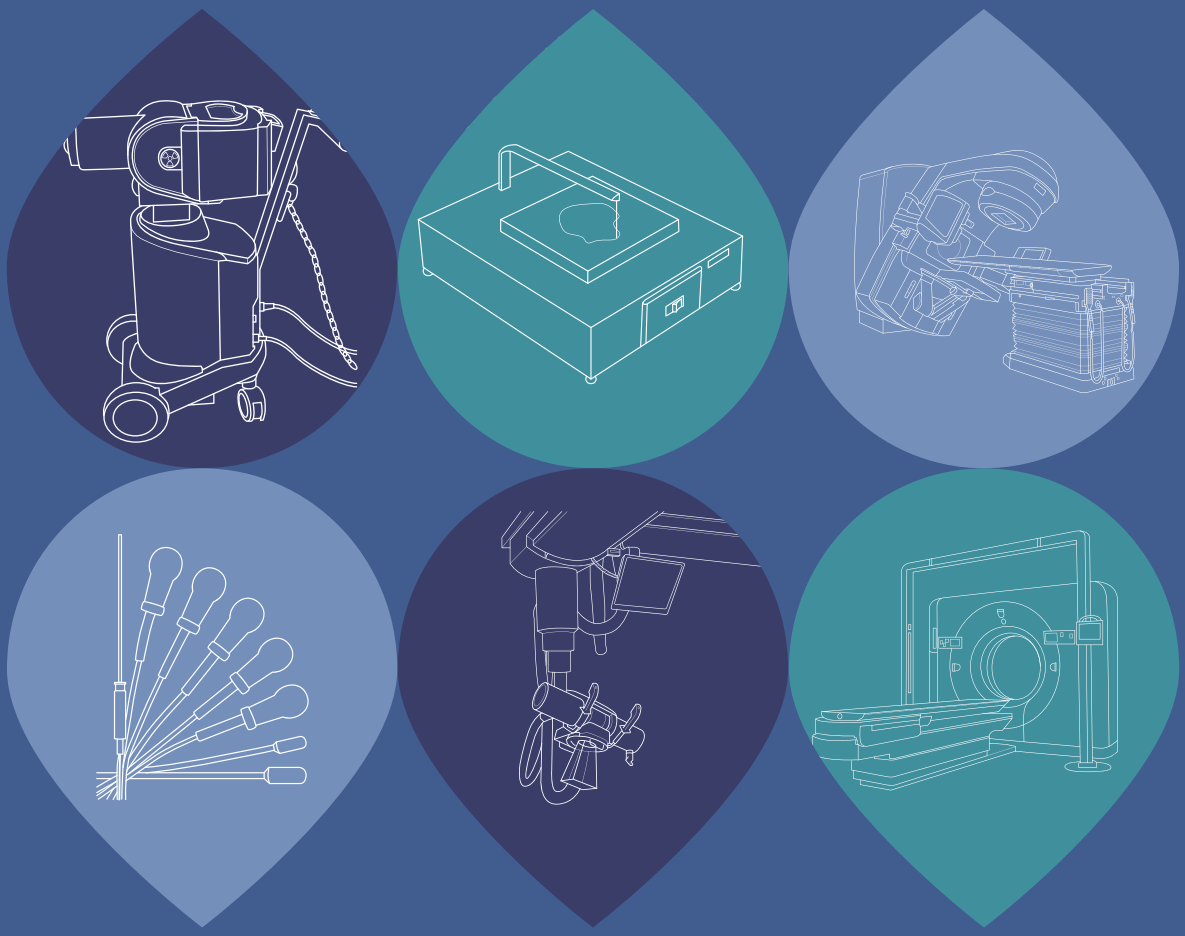
In-house biomedical engineer

The role of the in-house biomedical engineer is to perform health technology management, including: needs assessment and procurement planning as a member of the procurement committee, inventories, and overseeing maintenance management, which depends on the service contract with the manufacturer or authorized representative. If appropriately trained biomedical engineers are available locally, the time to repair simple faults will be considerably shorter than that required for an external service agent to arrive on site. The in-house biomedical engineer should be trained specifically by the manufacturer(s) in maintenance of all the equipment, hardware and software in the radiotherapy equipment chain, and the training should be certified by the manufacturer. This is, however, often costly and should be negotiated during equipment procurement. The in-house biomedical engineer should receive continuous training and re-certification throughout the life-cycle of the equipment. He or she may also be trained in performing some preventive maintenance on certain equipment in the chain.

The in-house biomedical engineer also has a more administrative role, which is documenting faults in the machine fault log book and, sometimes, predicting whether a fault may occur on the basis of experience in monitoring the performance of the machine. When an external engineer is on site to repair either equipment or the facilities, the in-house biomedical engineer should file service reports, detailing the changes made. In collaboration with the medical physicist, the in-house biomedical engineer should calculate the uptime of the radiotherapy equipment, keep an inventory of the local stock of spare parts and replenish stock as appropriate to ensure an adequate supply of spare parts for preventive maintenance and minor faults.

Radiation therapist

Interlocks and faults that may occur in radiotherapy equipment should not to be ignored, overriden or cleared by RTTs and should be recorded in the fault log book as well as in patient records, if applicable. RTTs should report all faults to the medical physicist and re-start patient services only once they have received approval from the medical physicist.



Chapter 4.

Maintenance for the life-cycle of the radiotherapy equipment chain and facility infrastructure

All the devices and software in the radiotherapy equipment chain should be maintained throughout their life-cycles so that they perform at the level stated in their specifications *(4)*. Facility infrastructure is just as important as equipment and should also be maintained to an equally high standard. To ensure the sustainability of radiotherapy equipment and systems, maintenance should be considered during procurement, throughout the warranty period, during its clinical use and when considering replacement and decommissioning, including management of disused radioactive sources.

4.1 Service requirements during procurement

Service contracts should be negotiated during procurement of radiotherapy equipment and the price of the contract agreed for the life-cycle of the device. At this stage, the procurer should insist on adherence to essential items in the service contract to sustain the radiotherapy department (see Annex 5). For example, the tender should include a requirement that the uptime of the radiotherapy equipment be at least 95%. If the service provider cannot guarantee this, alternative solutions should be found, including a different service provider.

Lifetime costing (see section 2.3) of the equipment should be considered during procurement. A manufacturer or local agent might give a reasonable quote for radiotherapy equipment, but, when all the components required for the sustainability of the equipment during its life-cycle are considered, the quote may be considerably higher than that of another manufacturer or local agent. If funds are not available for the life-cycle costs, a different equipment package (Annex 1) or supplier should be considered.

It is unlikely that the entire radiotherapy package will be procured from a single manufacturer. Nevertheless, the installation engineers from the different manufacturers should confer to ensure that the equipment in the radiotherapy chain communicates appropriately as necessary. Negotiations after award could include a visit by the manufacturer or local agent to the site before the equipment is installed to ensure seamless interconnectivity and data transfer.

Often, radiotherapy equipment is procured by a ministry of health, which has the advantage of a strong negotiating position for equipment and maintenance contracts, especially if more than one piece of equipment is being procured. The disadvantage is that a ministry of health seldom has sufficient technical knowledge about the radiotherapy equipment that is appropriate for treating common cancers and what can be negotiated during the tender process to ensure a sustainable radiotherapy department. Unfortunately, maintenance contracts are sometimes scaled back or removed completely from a contract when the cost is high, with no provision for an alternative solution. If the ministry of health does not have the relevant technical experience, it should seek advice from experienced medical physicists and biomedical engineers in the country, who understand the clinical and technical qualities of the radiotherapy equipment chain. It is therefore highly advisable that ministries of health have a medical technology unit that can provide expert advice on this topic, as recommended by WHO *(29)*.

4.2 Service during the warranty period

Warranty is a legally binding assurance by a manufacturer that the equipment (i) is fit for use as represented, (ii) is free from defective material and workmanship and (iii) meets statutory and other specifications. A warranty describes the conditions and period during which the manufacturer will repair or replace any defective item without cost to the owner. The warranty period should cover:

- preventive maintenance, with the number of visits clearly stated for the length of the warranty period;
- software and hardware updates and upgrades;
- spare parts, including shipping costs and customs clearance;
- labour, cost of travel of the manufacturer's or local agent's engineer and a visa, if required; and
- penalties in case of non-compliance with the terms of the warranty agreement.

The warranty should last for at least 1 year after the acceptance test has been co-signed by a representative of the manufacturer and the local medical physicist. Negotiation of extension of the warranty during procurement is an added benefit, as it will allow evaluation of the quality of the maintenance provided and time to train in-house

biomedical engineers. Corrective maintenance during the warranty period should be conducted under the same conditions as under a full service contract (see Annex 5). It is important to establish whether the warranty restarts after a major repair or whether the original warranty period continues. A penalty could be imposed, consisting of an extension of the warranty period, after failure to provide the agreed uptime.

The warranty period is important for the sustainability of the equipment, as it is during this time that faults that are not detected in the factory or that occurred during transport and installation are detected. It is therefore essential that the radiotherapy equipment be working during the warranty period. Unfortunately, radiotherapy equipment is sometimes delivered before staff are trained and the building and services are ready and cannot be installed during the warranty period, thus losing the advantage of the warranty period. The delivery date should be agreed only when the buildings and services are ready and fully trained medical physicists are available to perform the acceptance tests and commissioning.

Radiotherapy equipment should not be stored locally for any length of time, as it is sensitive to environmental conditions and may require continuous connection to special equipment, such as a vacuum pump. If there are unforeseen delays, the buyer should inform the manufacturer or local agent before the equipment is shipped and negotiate an extension of the warranty period.

It is essential that the maintenance programme start immediately at the end of the warranty period to obviate any gaps in maintenance of the equipment.

4.3 Maintenance of equipment during its clinical life-cycle

As all service contracts should include spare parts, upgrades and labour, provision should be made for either an external provider or an in-house biomedical engineer. The customer decides on the best combination of parts and labour to be included in the contract, depending on the local situation. Different contracts may be available for different units in the radiotherapy equipment chain and in the facility infrastructure; for example, equipment in the facility may be serviced by a trained hospital engineer, while a full service contract with the manufacturer or local agent may be available for a particular machine in the radiotherapy equipment chain. Advice on health technology management should be obtained from experienced biomedical engineers. Decisions on individual service contracts and providers can be made once the level of service required for each piece of equipment is determined. A full service contract is not necessary with the supplier of consumable equipment for the radiotherapy equipment chain and the facility, such as brachytherapy applicators or immobilization devices. A licensed radiation source handler should be available for equipment that requires replacement of radioactive sources, such as cobalt-60 teletherapy units and HDR brachytherapy afterloaders.

The situations of no service contract with an external provider, shared maintenance between an external provider and an in-house engineer and a full service contract are discussed below. The types of service contract are compared in Table 1. Provision should be made for spare parts, software and hardware updates and upgrades, and labour in all three contract options, with an external provider or an in-house biomedical engineer. A planned maintenance regime for radiotherapy equipment is recommended by the manufacturer, and this should be adhered to in order to ensure safe performance of the device. If in-house engineers are used, they should be trained in these tasks by the manufacturer. Annex 4 lists the major spare parts that are expected to be replaced during the life-cycle of typical radiotherapy equipment.

4.3.1 No service contract with an external provider

No service contract for maintenance can be perceived as the least expensive option, but neglect of maintenance is very expensive, as it can have unacceptably dangerous consequences or even result in indefinite closure of the radiotherapy department owing to faulty infrastructure or equipment, including information technology, safety and security systems.

When it is decided not to draw up a service contract with an external provider, full provision for corrective and preventive maintenance, parts and labour should nevertheless be made in-house and adequate logistical

arrangements made for spare parts. In this situation, the manufacturer should be contacted to ensure access to up-to-date knowledge about the equipment, such as circuit diagrams and hardware and software upgrades, for training and certification of in-house engineers and to obtain spare parts. The hospital should employ in-house biomedical engineers for radiotherapy equipment and employ or contract structural, mechanical and electrical engineers to maintain the facility infrastructure. In-house biomedical engineers should be trained by the manufacturer to maintain all devices in the radiotherapy equipment chain. Such training might have to be provided by several vendors for different devices, such CT-simulators, LINACs and TPS. It is important that the manufacturer or representative of the manufacturer conduct such training; if this is not the case, the work might invalidate the warranty and remove all liability from the manufacturers. As training is usually very costly and intensive and conducted at the manufacturer's site, it should be included in the contract for procurement of the equipment. As "brain drain" is a challenge in many countries, in-house biomedical engineers should be accepted as an integral part of the professional radiotherapy team and remunerated accordingly. They will also require appropriate tools and calibrated equipment to perform the full range of maintenance services.

If the in-house biomedical engineer does not have the skills, experience, tools or spare parts to diagnose and repair all faults in the equipment, funds should be available for corrective maintenance by the manufacturer or local agent. Such one-off payments are costly, as funds should be found to transport the engineer from abroad or a major city in the country to diagnose the fault, for shipping spare parts, probably from abroad, and for the engineer to return to repair the equipment. In complicated radiotherapy equipment, some faults are intermittent, or a series of faults may occur, and it may take several visits to resolve the fault. During repair of equipment, all the systems with no faults should continue to be properly maintained; for example, the ion pump of a LINAC should be on to maintain a high vacuum in the waveguide.

An in-house biomedical engineer can be trained to replace minor spare parts. There should be a local supply of such spare parts (see Annex 4), or, if they are held centrally, they should be available within a reasonable time. It is important that preventive maintenance be conducted according to the manufacturer's schedule. A well-trained in-house biomedical engineer can perform some maintenance with the correct tools and spare parts, and an engineer from the manufacturer or local agent can then be contracted to perform the remainder of the planned maintenance.

Lack of a service contract with the manufacturer or local agent can be expected to result in extended outages of radiotherapy equipment, when patients cannot be treated and funds should be found for corrective maintenance that cannot be done by the in-house biomedical engineer. Furthermore, a manufacturer or local agent may not be prepared to give priority to users without a contract.

4.3.2 Shared maintenance between the external provider and an in-house biomedical engineer

In a partial service contract with the manufacturer or local agent, an in-house biomedical engineer trained and certified by the manufacturer or local agent could perform some preventive maintenance and minor repairs and an engineer from the manufacturer or local agent perform the remainder under a service contract. The service contract should clearly state who is responsible for what actions and components.

The service contract should include a regular supply of minor spare parts and tools necessary for preventive and minor corrective maintenance as defined by the manufacturer. It is expected that the remainder of the tool kit can be sourced locally. Major spare parts that are expected to be replaced during the life-cycle of the radiotherapy equipment (see Annex 4) should be amortized during the service contract, so that they can be replaced when they fail. Radioactive sources included in the list of equipment, such as for teletherapy machines and HDR brachytherapy afterloaders, can be included in the contract, which should also include removal, repatriation and disposal of old sources. New sources should be installed exclusively by licensed engineers.

The advantage of a partial contract is that some faults can be repaired more quickly by the in-house biomedical engineer than in a full service contract. This depends, however, on which major spare parts are included in the partial contract (see Annex 5).

4.3.3 Full service contract

In a full service contract, corrective and preventive maintenance, spare parts and labour (including travel) are provided by the manufacturer or their designated local agent. As the engineer might have to travel a long distance, either from abroad or in the country, a reasonable response time should be agreed with the manufacturer. If there is no local engineer hired by the manufacturer or local agent, the response time should be negotiated for the contract, or the hospital might decide to employ an in-house biomedical engineer, who could solve minor problems and collaborate with the engineer from the manufacturer or local agents to diagnose faults.

This is the recommended model for a service contract to ensure operational radiotherapy equipment, even though it is perceived as the most expensive. It should be tested for suitability to the local situation during the warranty period.

Table 1. Comparison of possible service contracts

Type of service contract	Pros	Cons
No service contract with the manufacturer or local agent	• Maintenance may be cheaper in the short term.	• Expense of training an in-house biomedical engineer and his or her salary • Arrangements to be made with the manufacturer or local agent for a supply of spare parts • Quality of service requires a well-trained in-house biomedical engineer. • Funds necessary for major and minor spare parts • Individual contracts for major and some minor spare parts as necessary from the manufacturer or local agent • A contract might be required with the manufacturer or local agent for some preventive maintenance. • An appropriate tool kit is necessary for replacement of minor and some major spare parts and planned maintenance, which may be very costly. • The time for repair of a fault is expected to be longer than in the options below if an engineer is required from the manufacturer or local agent. • The cost of minor and major spare parts should be known well in advance, preferably for the life-cycle of the machine.
Shared maintenance between manufacturer and in-house biomedical engineer	• Cheaper than a full contract • Quick repair of minor faults by the in-house biomedical engineer • Manufacturer or local agent likely to be available remotely to advise the in-house biomedical engineer (with appropriate training) in diagnosing a fault • The in-house biomedical engineer can perform some of the planned maintenance. • Provides for guaranteed uptime and response time	• Expense of training an in-house biomedical engineer and his or her salary • Level of service depends on the availability of a good in-house biomedical engineer • An appropriate tool kit is required for replacement of minor spare parts and planned maintenance. • A store of appropriate spare parts should be kept locally (see Annex 4)
Full service contract	• Some major spare parts included in the contract • Minor spare parts included in the contract • Provides for guaranteed uptime and response time	• The most expensive service modality

4.4 Updates and upgrades

Updates maintain the functionality and performance or assure the safety of equipment, which may be software and/or hardware. Updates related to safety are mandatory, cost free and should be installed as quickly as possible.

An upgrade that increases or improves the functionality or performance of software and/or hardware but may, however, either reduce or introduce vulnerability to computer security. The upgrade may introduce both new and revised features or be mandatory for safety reasons. Some software and hardware might have to be upgraded during the life-cycle of the equipment. During negotiations for procuring the equipment, the costs of future upgrades should be agreed to ensure the full functionality of the entire radiotherapy package.

When software is updated and/or upgraded, computers and other hardware components might also have to be upgraded in order for the system to be fully functional. This can be both costly and disruptive to a radiotherapy department if provision is not made to upgrade all relevant computers, including for example TPS computers and the OIS and image-storage server.

Any upgrades and updates should be well planned, as they may interrupt treatment of patients. During planning, the manufacturer could be asked to confirm that the upgrade or update has been successful for the same equipment and the same version numbers of the software in another operational radiotherapy department, as it is important that the functionality of the whole radiotherapy equipment chain be maintained.

The medical physicist should be aware of which features have been changed during an update or upgrade in order to complete recommissioning of the new software and hardware and to check compatibility with the other devices in the radiotherapy equipment chain before the updated or upgraded equipment is used in the treatment of patients. All upgrades and updates should be done by a trained engineer who is aware of any potential problems in order to avoid a breakdown or conflict with any connected equipment. During an upgrade or update, compliance should be assured with the requirements of the computer security programme.

4.5 Planning replacement of radioactive sources and management of disused sources

The Co-60 sources in teletherapy and HDR brachytherapy units should be replaced every 5–7 years and every 3 years, respectively, and the Ir-192 in a HDR brachytherapy unit every 3–4 months *(21)*. For safety, sources should be replaced by a licensed engineer, and shipment of the sources should have the approval of the national radiation regulator.

The security of radioactive material should be addressed throughout its life-cycle, including manufacture, supply, receipt, possession, storage, use, transfer, import, export, maintenance, recycling and disposal, as outlined in IAEA Nuclear Security Series No. 11-G (Rev. 1) *Security of radioactive material in use and storage and of associated facilities (12)*.

It is recommended that the cost of source replacement be included in costing the life-cycle of the radiotherapy equipment and that the price agreed at the time of procurement be fixed for as long as possible and preferably for the life-cycle of the radiotherapy equipment. It is important that the source activity on delivery to the radiotherapy department be within ± 10% of the desired strength.

Replacement of sources with a minimal gap in patient treatment can be difficult to organize in countries when it involves shipment from abroad, servicing of radiotherapy equipment, installation of the new source and disposal of the old source (as outlined in the IAEA *Guidance on the management of disused radioactive sources (31)*). Management should be compatible with the country's overall programme for radioactive waste management.

4.6 Service contract penalties

The service contract should stipulate penalties to ensure that conditions such as the uptime of the radiotherapy equipment are honoured and that the service provider offers an efficient, effective service. The penalties are agreed between the service provider and the radiotherapy department on signature of the contract. For example, not meeting an agreed uptime of at least 95% could be penalized by a reduction in the cost of the maintenance contract the following year, an extension of the contract period by an equivalent time, or a penalty of 5% per day of the annual cost *(4)*.

Once penalties have been agreed upon in the contract, the service provider should understand that they are to be respected. The in-house biomedical engineer and the medical physicist in the radiotherapy department should keep regular documentation of the items stipulated for penalties, such as the uptime and response time, and be present at annual review of the service contract, with evidence such as machine fault log books to support them.

4.7 Replacement of equipment

All the equipment in the radiotherapy chain and the infrastructure have limited life-cycles. Evidence that equipment requires replacement includes unreliability, excessive maintenance time, unstable performance and major external damage. Any lack of support from the manufacturer, such as no longer providing spare parts or maintenance, may end the life of some equipment. Table 2 indicates the expected life-cycles of radiotherapy equipment. As the equipment in a radiotherapy equipment chain has different life-cycles, continual review and replacement are necessary to sustain radiotherapy. For example, for a teletherapy machine that is expected to last 10 years, funds should be available for replacement sources, the CT simulator, TPS and OIS upgrades and updates, patient immobilization devices and calibration of dosimetry and safety equipment. At the end of 10 years, the teletherapy machine should be replaced, and the replacement cycle starts again.

Table 2 shows that a Co-60 teletherapy unit and a conventional simulator have longer life-cycles than a LINAC or a CT simulator. Similarly, for a 15-year life-cycle of an HDR afterloader for brachytherapy, funds should be available for replacement sources, applicators, TPS updates and upgrades and maintenance for associated imaging equipment, such as a C-arm and ultrasound unit. At the end of 15 years, the HDR afterloader and TPS should be replaced, and the replacement cycle starts again.

Within the life-cycle of most radiotherapy equipment, major components will have to be replaced (see Annex 4); for example, the X-ray assembly in a CT simulator will have to be replaced.

In the case of donated equipment (see section 2.9), it is important to know the age of the equipment and of its major components in order to make provision for replacement.

Forward planning is essential to minimize interruption of patient treatment between the end of the life-cycle of equipment and clinical use of new equipment, as the new equipment will have to be installed and pass acceptance tests and measurements before commissioning. Therefore, a clear plan should be prepared for replacement of radiotherapy equipment to treat patients based on Table 2 and funds be allocated, as it may take time to secure the funds and procure the equipment. It is unacceptable to wait until equipment is no longer working or spare parts are no longer available to initiate procurement of replacement equipment.

Any equipment that involves radioactive material should be decommissioned only by licensed engineers and in accordance with national radiation regulations. This includes not only radioactive sources but also parts of equipment that may become radioactive with use, such as some of the components of the head of a high-energy LINAC.

When major equipment in the radiotherapy chain is replaced, the new equipment should be compatible with that which is operational. Procurement of new equipment is an opportunity to refurbish the facility. As it is unlikely that the new equipment will be exactly the same as the old equipment in terms of the electrical power, water supply, air-conditioning and other facility infrastructure services required, these should all be considered when procuring replacement equipment. In addition, it is essential to recalculate the radiation protection shielding requirements of the facility for the new equipment, particularly if the energy of the radiation or technique is different.

Table 2. Replacement schedule for equipment in the radiotherapy chain and calibration schedule for dosimetry and safety equipment for external beam radiotherapy and brachytherapy[a]

Equipment	Year of use of teletherapy machine														
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
LINAC											- - - -	- - - -	- - - -	- - - -	- - - -
Cobalt-60 teletherapy unit						Source replacement					Source replacement				
Superficial or orthovoltage X-ray unit															
CT simulator						- - - -	- - - -	- - - -	- - - -	- - - -					
Conventional simulator															
TPS						Life-cycle can be extended with updates and upgrades of software and hardware									
OIS						Life-cycle can be extended with updates and upgrades of software and hardware									
Patient immobilization devices						- - - -	- - - -	- - - -	- - - -	- - - -					
Mould room equipment															
Dosimetry, quality assurance and radiation safety equipment[b]			Calibration of equipment			Calibration of equipment			Calibration of equipment						
Co-60 Brachytherapy afterloader			Source replacement			Source replacement			Source replacement			Source replacement			
Brachytherapy applicators															
C-arm fluoroscopic X-ray unit															
Ultrasound unit															

Key

- - - - - Range of life-cycle

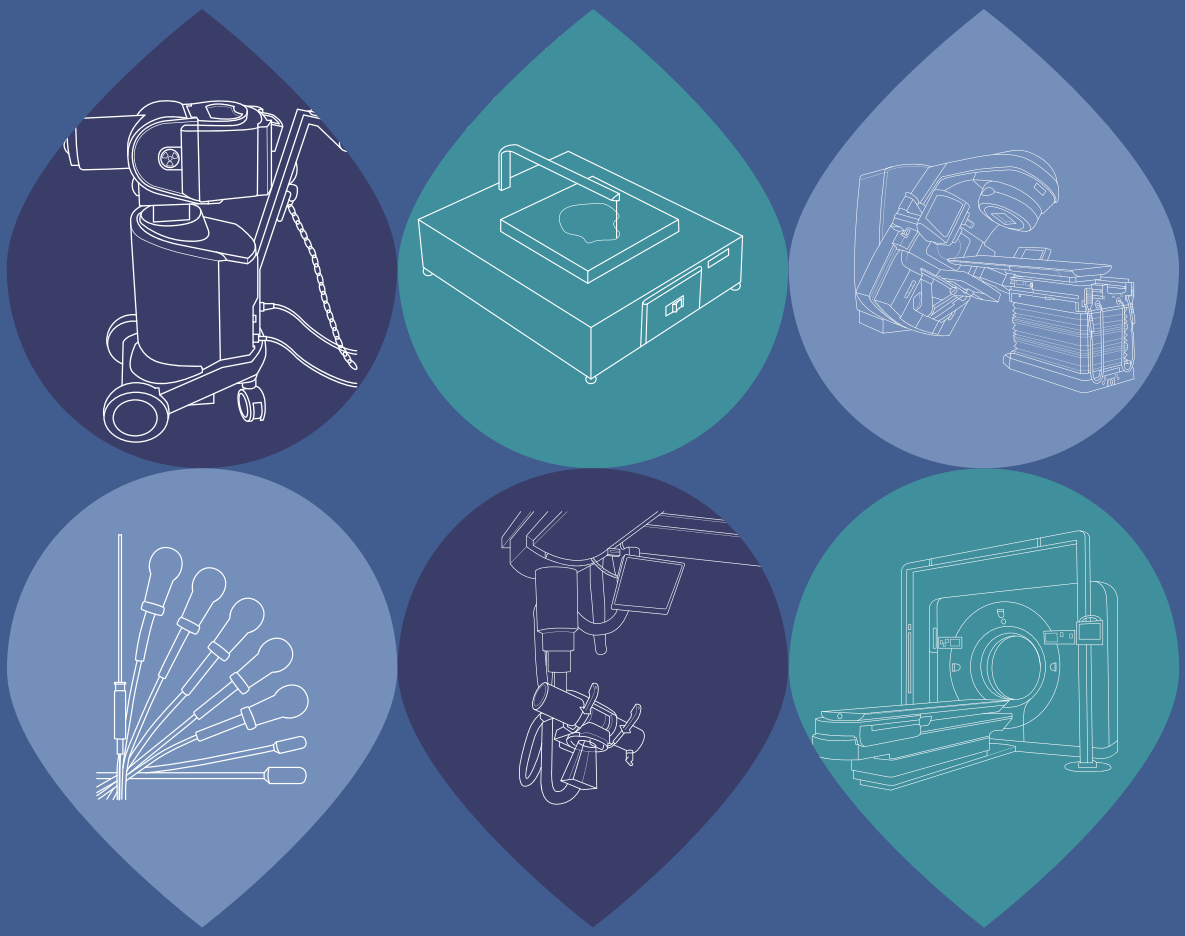
Warranty period

Life-cycle of the radiotherapy equipment

Extended warranty period

[a] Excluding time for regular planned maintenance, which depends on the type of equipment and the schedule recommended by the manufacturer.

[b] The frequency of calibration of dosimetry and quality assurance equipment depend on the local regulatory body; therefore, the time given is only an indication.



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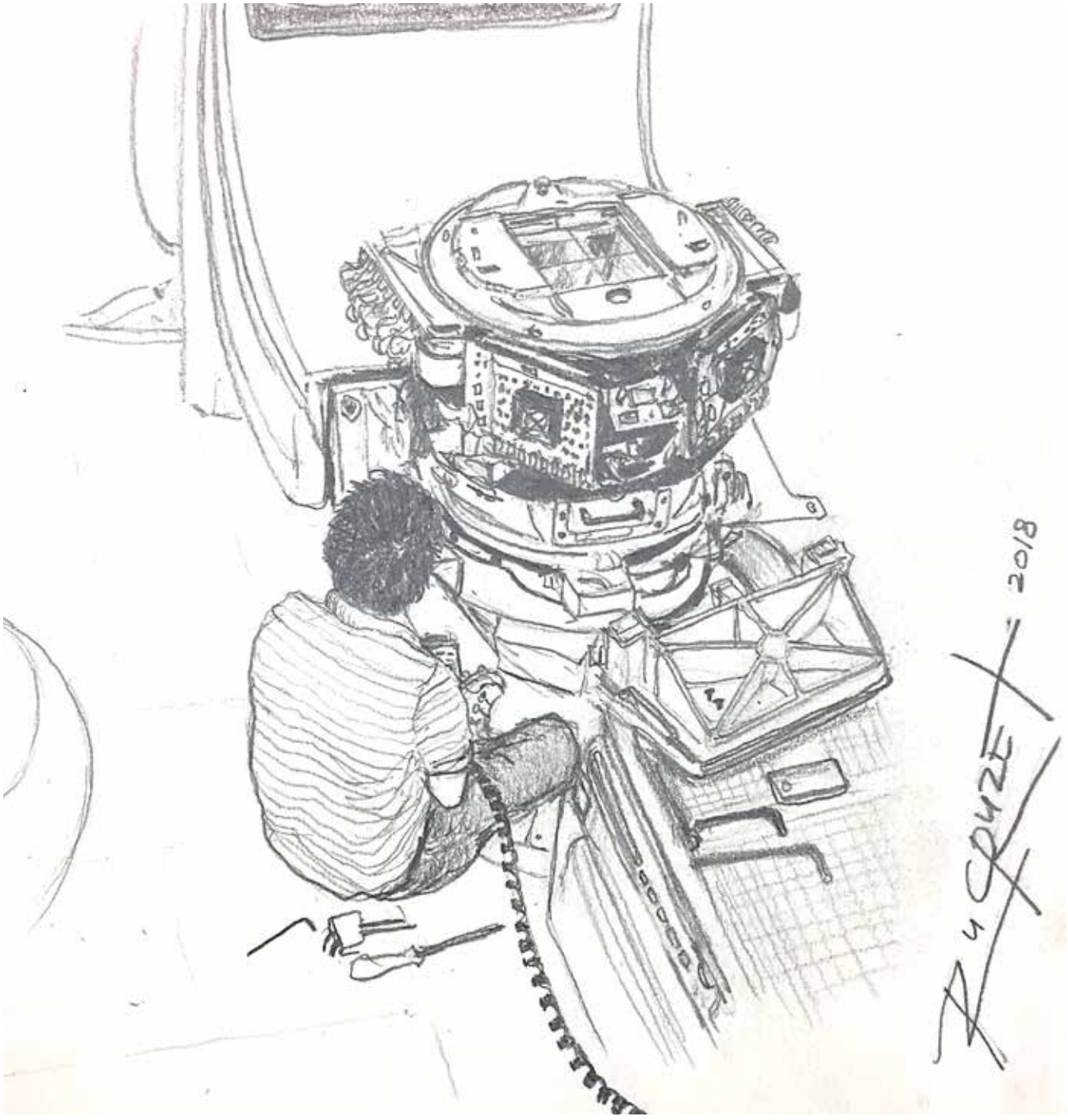

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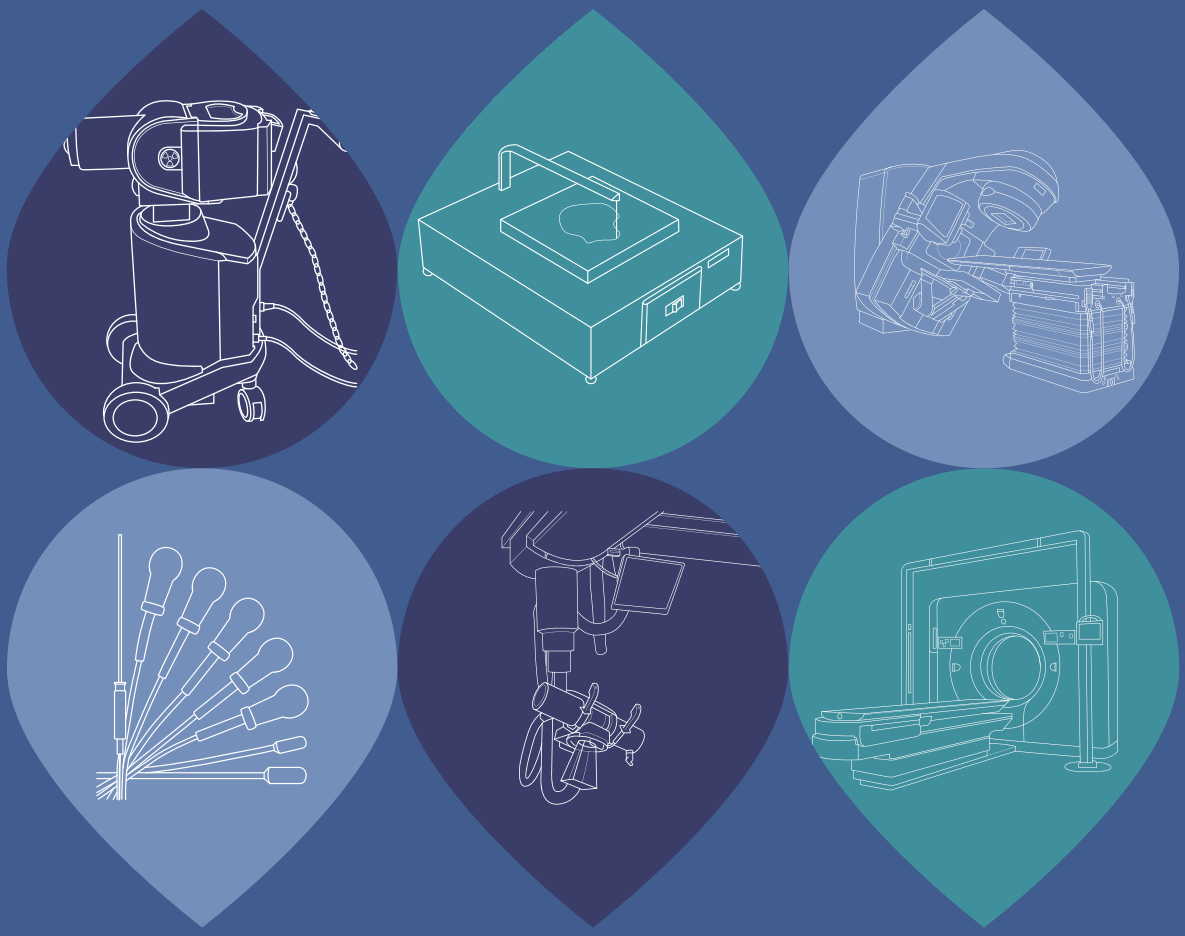


Annexes

Annex 1. Equipment packages

Table A1.1. Equipment packages for external beam therapy

Component	Package 1	Package 2	Package 3
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 necessary	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 recording and verification 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
QA and calibrated dosimetry and safety monitors	QA and calibrated dosimetry and safety monitors for imaging and treatment equipment	QA and calibrated dosimetry and safety monitors for imaging and treatment equipment	QA and calibrated dosimetry and safety monitors for imaging and treatment equipment
Immobilization devices	Immobilization devices	Immobilization devices	Immobilization devices

Table A1.2. Equipment packages for brachytherapy

Component	Package 1	Package 2	Package 3
Treatment unit	HDR remote after loading 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)[a]; 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
QA and calibrated dosimetry and safety monitors	QA and calibrated dosimetry and safety monitors for imaging and treatment equipment	QA and calibrated dosimetry and safety monitors for imaging and treatment equipment	QA and calibrated dosimetry and safety monitors for imaging and treatment equipment
Immobilization devices	Immobilization devices	Immobilization devices	Immobilization devices

Source: WHO, IAEA. Technical specifications of radiotherapy equipment for cancer treatment. Geneva: World Health Organization; 2021 (https://www.who.int/publications/i/item/9789240019980).

C-arm, c-shaped arm medical imaging device; CT, computed tomography; CT-MR, computed tomography-magnetic resonance; 2D, two-dimensional; 3D, three-dimensional; 4D, four-dimensional; DICOM, digital imaging and communications in medicine; 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; MV, megavolts; OIS, oncology information system; PET, positron emission tomography; QA, quality assurance; RVS, record and verify system; SAD, source axis distance; SBRT, stereotactic body radiotherapy; SRS, stereotactic radiosurgery; TPS, treatment planning system; VMAT, volumetric modulated arc therapy

[a] Applicators that are CT-compatible should be procured if planned treatment is based on 3D CT.

Annex 2. Machine fault log book

Each device in the radiotherapy equipment chain should have a machine fault log book that is kept in an easily accessible place close to the equipment. The fault log book should be completed by whoever is operating the equipment at the time of the fault. This is usually a radiotherapy technologist but might be an in-house biomedical engineer or a medical physicist. All users of the equipment should be trained in completing the fault log book to ensure that faults are accurately recorded, with a sufficient description of the fault and a copy of any error message on the machine or its system. It is essential to enter all faults and to record as much information as possible.

A service report and a quality assurance report shall be completed by the engineer (internal or external) and the medical physicist for each fault logged that requires an intervention, whether by an in-house biomedical engineer, an engineer from the manufacturers or local agent or if the equipment is repaired remotely. An external engineer should give (or send) the service report to the medical physicist before leaving the site so that he or she is aware of the changes made to the equipment. The service report should contain a full description of the fault, including the diagnostic tests performed to identify it, how the fault was rectified and a list of the spare parts used. If an external engineer is contacted, the response time should be recorded, including the date and time:

- the fault was found in the machine,
- the external engineer was contacted,
- the external engineer replied to the call and gave advice,
- the external engineer arrived on site,
- the spare parts were ordered,
- the spare parts arrived on site, and
- the machine was repaired and handed back to the in-house biomedical engineer and the medical physicist.

The medical physicist should understand what was changed in the radiotherapy equipment during the repair so that he or she can adjust the quality control tests appropriately. Once the machine has passed the relevant quality control tests, it is the responsibility of the medical physicist to sign the fault log book, indicating when the equipment can return to clinical use.

Examples of headings in a machine fault log book:

- date and time
- fault description
- fault error code
- medical physicist notified (yes or no)
- action taken and remarks
- name and signature of the person entering the fault
- date, time of repair of the fault
- date, time, name and signature of medical physicist who authorized return of the machine for clinical use.

The fault log book and service report are important documents, as they are used to calculate the measured contract specifications for annual review of the contract, such as uptime and response time.

Annex 3. Calculation of uptime

Uptime is defined as the time a machine is available for clinical service (including scheduled quality control and preventive maintenance) as a percentage of the number of operating days per year. The data for calculating uptime can be found in the machine fault log book. The uptime can be calculated from:

$$uptime\ (\%) = \left(\frac{250 - days\ machine\ not\ working}{250} \right) \times 100$$

Example 1:

If the machine has an unscheduled downtime of 5 days a year, the uptime is:

$$uptime\ (\%) = \left(\frac{250 - 5}{250} \right) \times 100 = 98\%$$

Example 2:

If the machine has an unscheduled downtime of 12.5 days a year, the uptime is:

$$uptime\ (\%) = \left(\frac{250 - 12.5}{250} \right) \times 100 = 95\%$$

This is clearly an important number, as it is recommended that the uptime specified in the service contract be 95% or greater. If the number of days that the machine cannot be used to treat patients due to a fault is more than 12.5 days, the manufacturer has not achieved the contract specifications and should start to incur penalties.

Example 3:

As there are many instances during a year that a machine has unscheduled downtime, another example, assuming that an 8-h day (9:00–17:00) Monday–Friday is included in the contract, is shown in Table A3.1. The information below can be found in the fault log book.

Table A3.1. Example of calculation of uptime of a radiotherapy machine

Date	Time fault recorded	Date and time machine is back to clinical use (h)	Time machine could not be used to treat patients (h)	Time machine could not be used to treat patients (days)
Monday, 2 February	9:00	Monday, 2 February, 11:45	2 h 45 min = 2.75 h	2.75/8 = 0.344
Tuesday, 10 April	10:00	Thursday 12 April, 14:00	10 April: 7 11 April: 8 12 April: 5 Total: 20	20/8 = 2.5
Thursday 15 March	17:00	Saturday, 17 March: 16:00	15 March: 0 (as contract specifies until 17:00) 16 March: 7 17 March: 0 (as contract specifies Monday–Friday)	7/8 = 0.875
Monday 12 November	9:00	Monday, 19 November: 11:00	12 November: 8 13 November: 8 14 November: 8 15 November: 8 16 November: 8 17 November: 0 (Saturday) 18 November: 0 (Sunday) 19 November: 2	42/8 = 5.25
			Total time machine could not be used to treat patients	8.969 days

If there are no more faults during the year:

$$uptime\ (\%) = \left(\frac{250 - 8.969}{250}\right) \times 100 = 96.4\%$$

Example 4:

Unfortunately, in many countries, the manufacturer cannot achieve the uptime specified in the contract. When the unscheduled downtime is 100 days in 1 year, the uptime is:

$$uptime\ (\%) = \left(\frac{250 - 100}{250}\right) \times 100 = 60\%$$

Annex 4. Parts expected to be replaced during the life-cycle of a radiotherapy equipment package

Items will have to be replaced during the life-cycle of all the equipment in the radiotherapy chain and the facility infrastructure. The items and frequency of replacement will depend on the design, manufacturer and use of the equipment. Table A4.1 gives indications of the spare parts that are expected to be replaced during the life-cycle of the equipment and facility infrastructure.

As some minor spare parts for equipment can be expected to be replaced frequently, it is advisable that they be available locally. Major spare parts may have to be replaced only once or twice during the life-cycle of the machine. These parts are very costly, should be installed by an experienced engineer and will probably be shipped from abroad.

Table A4.1. Spare parts expected to be replaced during the life-cycle of the equipment in the radiotherapy equipment chain

Facility infrastructure	Spare parts that should be kept in stock locally	Spare parts to be replaced but not to be kept in stock	Costly spare parts expected to be replaced during the equipment life-cycle but not to be kept in stock
Light	• safety warning light bulbs • room light bulbs		
Electricity	• fuses	Batteries for uninterruptible power supply, radiation safety monitoring devices such as survey meters and security systems	
Air	• filters		
Water	• filters • deionized water		
Safety and security	• CCTV camera(s) • patient intercom system • intrusion detector(s) • access control system		
External beam radiotherapy			
Conventional digital simulator	• patient couch spare parts • lasers • field light bulbs	• CR plates	• X-ray detector panel • external lasers • X-ray tube assembly

Facility infrastructure	Spare parts that should be kept in stock locally	Spare parts to be replaced but not to be kept in stock	Costly spare parts expected to be replaced during the equipment life-cycle but not to be kept in stock
CT simulator	• patient couch spare parts • lasers		• X-ray tube assembly
Treatment planning system	• hard disc[a], keyboard, mouse	PC monitor[b]	• computer
OIS	• hard disc[a], keyboard, mouse	PC monitor[b]	• computer
Orthovoltage teletherapy machines			• X-ray tube assembly
Cobalt-60 teletherapy unit	• beam-defining light bulbs • patient couch spare parts • lasers		• Co-60 source • portal imaging panel
LINAC teletherapy machine, package 1	• beam-defining light bulbs • supply of SF6 • patient couch spare parts • fuses (appropriate selection from the manufacturer or local agent) • lasers		• electron gun • vacuum pump • magnetron or klystron • portal imaging panel • waveguide
LINAC teletherapy machine, package 2	• beam-defining light bulbs • supply of SF6 • MLC motors • patient couch spare parts • fuses (appropriate selection from the manufacturer or local agent) • lasers		• electron gun • thyratron, klystron or magnetron, depending on the machine energy(s) and manufacturer • vacuum pump • electronic portal imaging device imaging panel
LINAC teletherapy machine, package 3	• beam-defining light bulbs • supply of SF6 • MLC motors • patient couch spare parts • fuses (appropriate selection from the manufacturer or local agent) • lasers		• electron gun • thyratron, klystron or magnetron, depending on the machine energy(s) and manufacturer • vacuum pump • electronic portal imaging device imaging panel • kV X-ray imaging panel • kV X-ray tube assembly

Facility infrastructure	Spare parts that should be kept in stock locally	Spare parts to be replaced but not to be kept in stock	Costly spare parts expected to be replaced during the equipment life-cycle but not to be kept in stock
Brachytherapy			
HDR remote afterloading unit	• patient couch spare parts • connectors to applicators • transfer tubes	• Source-driving mechanism (cables)	• radioactive brachytherapy sources • applicators
Brachytherapy treatment planning system	• hard disc[a]	PC monitor[b]	• computer
Dedicated HDR C-arm			• X-ray imaging panel • X-ray tube assembly
Dedicated ultrasound equipment	• water-based gel		• transducer
Immobilization devices	• used frequently		
Quality assurance and dosimetry equipment	• radiochromic film • regular calibration of equipment • personal dosimetry services		As the equipment is very fragile, replacement due to breakages should be considered.
Mould room equipment	• low-melting alloy • foam • blocks		

C-arm, c-shaped arm medical imaging device ; CCTV, closed-circuit television; CR, computed radiography; CT, computed tomography; HDR, high dose rate; LINAC, linear accelerator; MLC, multi-leaf collimator; OIS, oncology information system; PC, personal computer; SF6, sulphur hexafluoride.

[a] Hard disc: Should be considered for all equipment that requires use of a computer. One hard drive with the required specifications should be kept in stock.

[b] Screen: rarely requires replacement; however, there are many monitors in the radiotherapy equipment chain. Funds should be available to replace one if necessary.

Annex 5. Items to be included in a service contract

If the option of a service contract is taken, it should address the local situation for sustaining the equipment and systems in the radiotherapy chain and the facility infrastructure. It is suggested that the service contract include clauses related to the items below for all equipment and systems.

Spare parts

1. Minor spare parts kept locally (available for the life-cycle of the machine)
2. Tools for the in-house biomedical engineer to perform preventive maintenance and replace minor spare parts (such as spirit levels, digital voltmeters, oscilloscopes) kept locally
3. Access to major spare parts that may be required during the life-cycle of the radiotherapy equipment (including indicative costs, shipment and installation)
4. Spare parts are available for the life-cycle of the radiotherapy equipment

Transport and travel

5. Cost of travel for manufacturer's or local agent's engineer to site
6. Cost of visa for manufacturer's or local agent's engineer to travel to site
7. Cost of shipment, transport and customs clearance of spare parts to site

Number of on-site visits by the manufacturer's or local agent's engineer per year

8. Number of visits estimated for corrective maintenance per year to achieve the agreed uptime; in a full service contract, the number of visits is "as required".
9. Number of preventive maintenance visits per year as recommended by the manufacturer. Depends on the type of contract (see section 4.3).

Response time

10. Response time for help on telephone or online. May be within 2 h, depending on the local situation.
11. Response time for the manufacturer's or local agent's engineer to be on site from the time of original contact to the time of arrival in the radiotherapy department. This may be within 2 days, depending on the local situation.

Efficiency of radiotherapy equipment

12. At least 95% uptime
13. Clear definition of the uptime to include:
    - Number of days per year that the machine is used to treat patients
    - Clinical working day, such a 8:00 to 18:00
    - Clinical working days per week, such as Sunday to Thursday
14. Maximum number of consecutive days that the radiotherapy equipment cannot be used to treat patients owing to faulty equipment.

Source replacement

15. Source replacement for brachytherapy high-dose rate unit(s)
16. Source replacement for cobalt-60 teletherapy unit(s)
17. Storage of the old source
18. Re-export of the old source to a suitable storage facility

Contract renewal

19. Frequency of renewal of the contract. It is recommended that this be at least annually so that uptime and penalties (see section 4.6) are reviewed with the manufacturer or local agent.
20. Commitment by both parties to the service contract agreement: As the service contract is required for the life-cycle of the radiotherapy equipment, it should be as long as possible. Some manufacturers, however, offer a service contract for only a limited period, such as 5 years.

Other considerations, as applicable

21. Remote monitoring by the manufacturer's or local agent's engineer if funds are available (see section 2.4)
22. Training of the in-house biomedical engineer
23. Training in applications for medical physicists, radiotherapy technologists and radiation oncologists as required
24. The service contract should include penalties (see section 4.6).
25. Online or telephone support by experienced engineers employed by the manufacturer for simple faults and diagnostics that can be performed by the local in-house biomedical engineer
26. Direct access to the manufacturer's help desk
27. Computer hardware and software service and support for software upgrades and updates, including training in use of applications as necessary (see section 4.4)
28. Database and server support, including back-up and archiving
29. Regular analysis of problems that arise with the equipment to reduce their occurrence or resolve them. The analysis may be discussed during the annual meeting (see Annex 6).
30. Funding to provide regular training and certification of in-house biomedical engineers
31. Agreement between the radiotherapy department and the vendor about the responsibilities and procedures in the event of a disaster, such as an earthquake, tsunami, social unrest or monetary and regulatory changes (force majeure).

Annex 6. Tender process for a service contract

The service contract is key to sustainable radiotherapy equipment. All too often, a contract is not signed, or, if it is, it is not monitored to ensure that the expected quality of the service is achieved. A service contract should be provided for the lifetime of each machine. Although this annex provides an overview of setting up and monitoring a service contract, the reader is advised to review the literature for more comprehensive guidance. The main principle is that the process is not very different from buying any commodity from a company. According to Bailey *(1)*, the aim is to obtain the "five rights": the right service of the right quality and right price and the right quantity at the right place and time. As mentioned in section 4, a service contract with an external provider will not be available for all the equipment in the radiotherapy equipment chain; however, these principles should also be applied to in-house biomedical engineers.

A tender for a service contract should be made at the time the radiotherapy equipment is procured. Often, the vendor of the equipment will also bid to provide a service contract. At this stage, therefore, the buyer has maximum advantage to negotiate a good service contract, as the vendor clearly wants to sell the machine. If the service provider consistently fails in meeting the contract performance indicators, it is recommended that a tender be made for another service provider. In some countries, there is no choice about who provides a service contract; however, if there is more than one provider, the contract should go out to tender, similarly to procurement *(2)* of radiotherapy equipment, in accordance with national financial and supply chain management regulations.

The tender process will be conducted by various people and institutions, depending on the local situation. For example, if the radiotherapy department is independent, the head of the hospital and the legal team will be involved; however, if it is a national institute, the process will be conducted by the government. In all situations, it is advisable that a medical physicist be involved in evaluating the bids in order to assess the implications to the radiotherapy department if the external provider cannot achieve the required performance indicators or if the bids are too high and certain specifications should be negotiated. Many specifications of a service contract are not negotiable, but it may be possible to achieve them, such as 95% uptime, by agreeing with the service provider that an engineer trained by the manufacturer is located locally or on site.

The first stage of the tender process is to write the specifications, based on the checklists in Annex 5. It is important not to be too particular about how the performance indicators will be achieved or to be too pessimistic that the indicators cannot be achieved in the local situation. It is the responsibility of the potential service provider to demonstrate how the performance indicators can be achieved. The next stage is for companies to be invited to tender for the contract by following national and local rules and procedures (e.g. advertising on the government or hospital website). It is recommended that the invitation be advertised as widely as possible and particularly internationally. During tendering, companies should be asked how they will achieve the performance indicators, and, when the bids have been received, they should be evaluated against the specifications. Due diligence should be applied to the companies that have been short-listed by comprehensive research into the external provider and its offers. This includes checking their website, press releases and any articles concerning previous sales. It is also recommended that a reference for the external provider be sought from a radiotherapy department in a similar situation that could share information about the service contract specifications and measured performance indicators, such as uptime and response time, to ensure the efficiency of the external provider. It is also useful to ask the potential service contract holder:

- Where will the manufacturer's or local agent's engineer be stationed?
- How many other radiotherapy departments in the region with similar equipment and systems are serviced?
- How will the manufacturer's or local agent's engineer travel to your radiotherapy department: by road or air?
- How are visas obtained for the visit of the manufacturer's or local agent's engineer to the radiotherapy department?
- How are spare parts to be delivered to the radiotherapy department?
- Is the manufacturer's or local agent's engineer trained in radiation safety and knows the implications of the features of the equipment and/or software for radiation protection of patients and staff?
- Who is responsible for the service contract if the local agent loses the licence from the manufacturer during the lifetime of the service contract?

It is also advisable that the company bidding on a tender visit the site to identify any local problems that might arise.

As many of the performance indicators in the service contract are not negotiable, the radiotherapy department should be prepared to reject the contract if it is not acceptable. This might require procurement of a different machine or approaching a different manufacturer.

The service contract is a legal document agreed between the external provider offering the service and (depending on the local situation) the radiotherapy department or a national institute such as a national procurement agency. It is therefore important that the stakeholders (see section 3) understand the terms of the contract and have access to it to ensure, for example, that the radiotherapy department knows how to proceed if equipment has a fault. The service contract should be reviewed regularly by the local team to ensure that it is the most appropriate one for maintaining the radiotherapy equipment.

Annual review

It is recommended that the performance indicators (See Annex 5) be monitored regularly throughout the year. If the service contract holder does not achieve the performance indicators, the contract holder should be contacted immediately. In all situations, each annual meeting should include a representative of the ministry of health, the director of the hospital, the head of the radiotherapy department and a medical physicist, who can interpret and explain the data, to meet with a representative of the service contract holder. The representative should have the power to agree to penalties (see section 4.6); it is unlikely that the regular manufacturer's or local agent's engineer will be in this position. It is not always easy to agree on the measured goals in the service contract throughout the year, such as the uptime and response time; therefore, it is essential to have proof, such as a fault log book and service reports. Once the measured performance indicators for the year have been agreed upon, the penalties (if any) stipulated in the service contract should be applied for the following year.

The suggested service contract conditions and performance indicators to be presented by the radiotherapy department at the annual review (providing they are included in the service contract) are listed in Table A6.1.

Table A6.1. Service contract conditions and performance indicators to be presented at an annual review

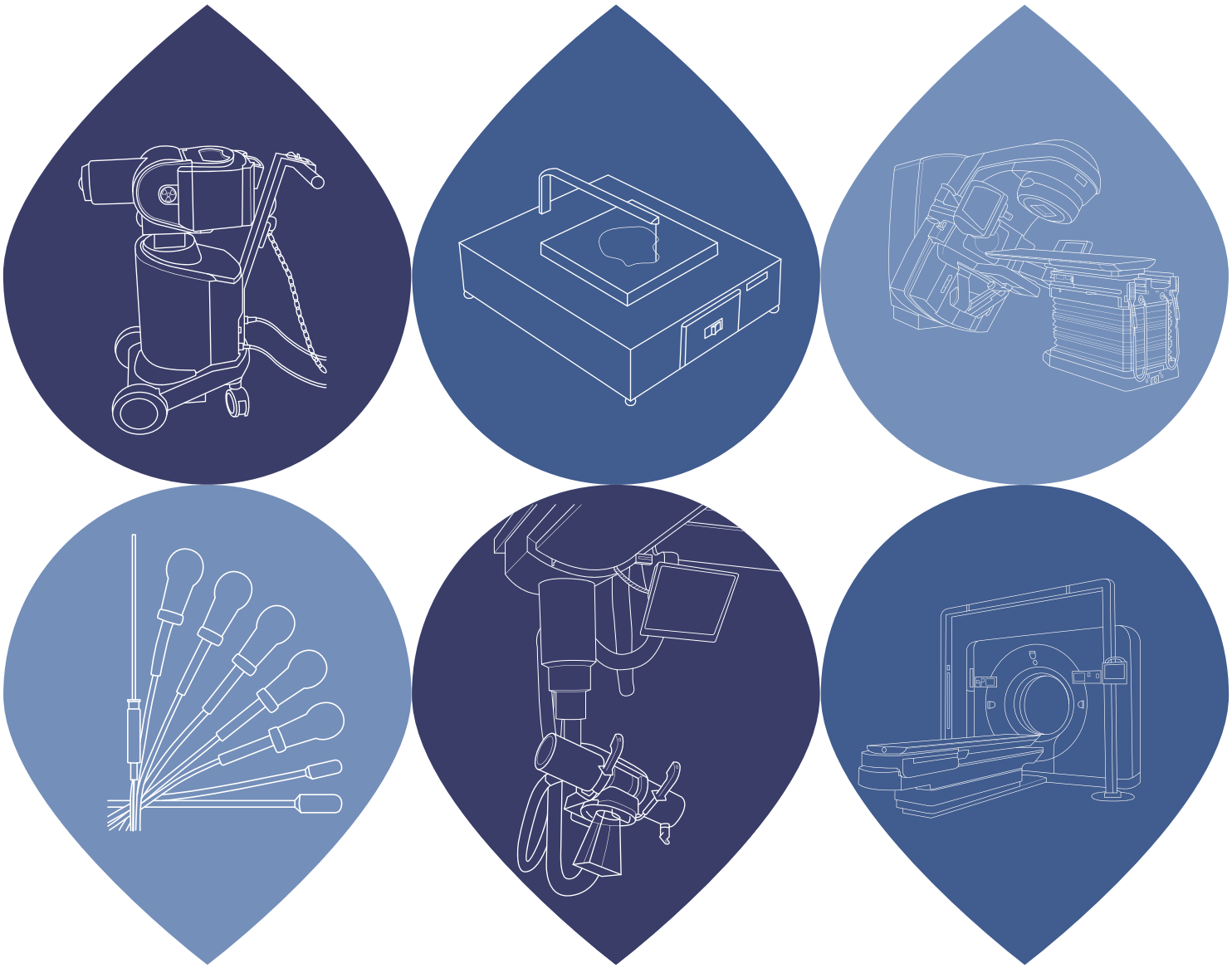
Service contract condition	Performance indicator
Minor spare parts kept locally	According to the contract. Has this been sufficient in the previous year?
Number of preventive maintenance visits according to the time schedule	According to contract
Response time for help by telephone or online	2 h
Response time for arrival of the manufacturer's or local agent's engineer on site	2 days
Uptime	≥95%
Maximum number of consecutive days that the radiotherapy equipment cannot be used to treat patients	According to contract
If applicable, were source replacements made on time?	According to contract
Did you receive clearly written, complete service reports from the manufacturer's or local agent's engineer at the time of their visit to the radiotherapy department?	

The manufacturer could also be asked when they expect a major component of the machine to fail on the basis of the workload and local conditions.

References

1. Bailey KD. Typologies and taxonomies: An introduction to classification techniques. Thousand Oaks (CA): Sage Publications; 1994 (https://methods.sagepub.com/book/typologies-and-taxonomies).

2. Procurement process resources guide. Geneva: World Health Organization; 2011 (https://www.who.int/publications/i/item/9789241501378).



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