

Guide on

How to prepare a procurement planning and maintenance programme for Radiotherapy Equipment

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Purpose of the guide

The purpose of this guide is to summarise the steps and procedures for preparing a Radiotherapy Procurement Plan and designing the corresponding Maintenance Programme, within the framework of the City Cancer Challenge Foundation (C/Can) project in response to the urgent need to reduce inequalities in access to quality radiotherapy treatment in selected cities.

The recommendations made in the document are the result of a technical revision by a panel of external experts, in consultation with the C/Can Technical Cooperation team, based on their experience of the guide's subject. In turn, this will be developed and is expected to be interpreted, analysed and tailored by the radiotherapy project team in C/Can cities, taking into account the local context and the need to build a multisectoral consultative process within the city.

Structure and suggested contents of the document

1. Introduction

As part of the City Cancer Challenge (C/Can) initiative, participating cities conducted a city-wide self-assessment to identify and agree on what their main challenges in improving access to equitable and quality radiotherapy treatments in their own settings are. Within the framework of this initiative, radiotherapy development plans in C/Can's cities have been developed, which projected the procurement of major radiotherapy equipment. Accordingly, several city project teams requested support and technical assistance on radiotherapy technology procurement and maintenance. C/Can, in cooperation with the *TeleECHO*[™] Programme, organised a set of four separate webinars, aimed to promote good practice guidelines for the procurement and maintenance of radiotherapy technology among C/Can cities stakeholders. A task force of experts nominated by relevant international organisations contributed with didactic presentations, while local representatives of C/Can cities shared their experiences through case stories.

The present document provides a comprehensive Guide which summarises, in a structured way, the main recommendations and findings from C/Can *TeleECHO*[™] sessions.

2. Procurement process

2.1. Pre-requisites for successful tendering

Procurement of radiotherapy equipment is a stepwise process which requires thorough preparation and a multidisciplinary team approach. The typical procurement process consists of a series of steps that involve recognising needs, preparation of technical and tender documentation, publishing the tender, evaluating the bids, selecting the winner and signing the contract. However, before the initiation of that process, some pre-requisites must be addressed for a successful tendering process of major radiotherapy equipment.

STRUCTURE OF PROCUREMENT TEAM AND THEIR ROLES

The key for successful tendering is having a team of relevant people and the information they can contribute from their respective fields of expertise. The procurement team should include or have access to a broad spectrum of professionals including, but not limited to:

- Radiation oncologist – knows what types of cancer at which stage need to be treated (see clinical needs assessment).
- Medical physicist – knows which technology and equipment are needed for safe and effective radiotherapy (see technical needs assessment).
- Radiation therapy technologist (RTT) – knows which tools, processes and ancillary equipment are needed for safe and efficient radiotherapy.
- Biomedical engineer – knows the technology and equipment maintenance requirements to ensure uninterrupted radiotherapy services.
- IT specialist – knows IT, equipment software component and network requirements including cybersecurity to ensure uninterrupted and secure information exchange between the radiotherapy equipment.
- Electrician – knows power requirements and local availability and stability for uninterrupted radiotherapy services. Provides cost estimates for electrical supply and components (UPS, power availability, etc.).
- Architect and/or civil engineer – knows building structural properties including load capacity and advises whether any alternation that need to be done to accommodate the equipment is possible or makes architectural drawings for new facility. Provides cost estimates for construction activities.
- Heating, ventilation, and air conditioning (HVAC) specialist – ensures adequate cooling, heating and ventilation conditions will be achieved during the operation and maintenance of equipment. Provides cost estimates for HVAC components.
- Hospital Management representative – provides overall overview of the project and ensures that it stays on track from the hospital's side.
- Finance specialist – advises on the budget availability, payment terms and financial instruments available.
- Procurement specialist – prepares tendering documents with input from others to ensure compliance with the local legislation.

WHOLE LIFE CYCLE OF EQUIPMENT

An equipment whole life cycle cost estimate at the project planning stage will help to estimate the overall cost of equipment ownership and operation, including procurement, running, maintenance expenses and decommissioning. The construction costs to accommodate the equipment must also be considered.

TECHNOLOGY ASSESSMENT

Prior to tendering, the technology available on the market needs to be assessed. This could be done through visits to exhibitions, manufacturing sites, other clinical sites where such technology is installed or gathering information from published material. The aim of the assessment is to gather information about the technology, installation and maintenance requirements, including electrical, structural, HVAC and others to estimate the suitability and the cost of whole life cycle of equipment.

NEW RT EQUIPMENT VS REFURBISHED

While refurbished equipment from OEM¹ may come at a better price, it is important to keep in mind the cost of the whole life cycle of the equipment. The other aspect to consider is future hardware and software upgradability.

SINGLE VS BUNDLE PROCUREMENT

If more than one piece of equipment is required in the near future, then purchasing several units or a bundle often comes at a better price. You can also specify in the tendering documents that the other unit is to be delivered at a later date. The biggest benefit of that though, comes from the fact that the system integration and interoperability would be a single manufacturer responsibility. The treatment units from the same vendor could also be dosimetrically and geometrically matched to enable patient transfer from one unit to the other without the need of re-planning.

INTEGRATION INTO EXISTING EQUIPMENT

Integration of a new system into the existing environment has to be considered before tendering. It might be that you need to upgrade the existing systems to be compatible with the new equipment. It may also limit the options of the new equipment. The integration should be part of the tendering process.

¹ Original Equipment Manufacturer

STAFF AVAILABILITY AND TRAINING

Available staffing numbers have to be assessed early on to determine if they are sufficient to operate new equipment. If not, additional staff must be hired, keeping in mind that training could take longer than equipment installation. Therefore, the staffing issues have to be addressed before the tendering process starts. Only properly trained staff in sufficient numbers will ensure safe and effective utilisation of treatment equipment.

A plan to train personnel should be developed, and the training should be completed before installation of the equipment. This plan should include which staff will be trained, the host institution that will provide the training, the material that will be taught and when the training will take place. Training may also be necessary for maintenance technicians and support personnel, especially if a LINAC is to be installed. [6].

PROJECT TIME PLAN AND RISK ASSESSMENT

A project timeline needs to be developed with resource allocation, staff training, tendering of equipment and construction works carefully planned, in order to ensure uninterrupted project flow and to recognise where potential bottlenecks may occur. Risk assessment and risk mitigation strategies have to be put in place in case something is not going according to the plan. A risk assessment determines the affordability and sustainability of the project and concerns not only the buildings and equipment, but also the maintenance, running costs, consumables supply, staffing and access. Appendix I of Ref. [8] shows a detailed example of a radiotherapy project risk register, which provides the team with alerts to potential challenges in the project and their origin, e.g. regulatory, financial, design, equipment, staffing.

2.2. Defining the clinical needs and establishing the technical specifications

The success of a radiotherapy programme depends largely on adequate planning beforehand. Although the treatment cost is highly competitive compared with other cancer therapy approaches [5], there are two important aspects that influence its feasibility and effective use: the high initial cost of equipment and the complexity of the therapeutic procedure.

To avoid inefficiencies in the use of resources and minimise times of equipment commissioning and setup for clinical use, it is essential to have a realistic plan that includes the fundamental actors involved in the process: management healthcare agents, managers, radiation oncologists, medical physicists, RTTs, maintenance engineers, etc.

A good general reference guide to address this task is the one published by IAEA in 2011 [7].

CLINICAL NEEDS (PATIENTS)

The main input data to define the equipment needs for cancer treatment in a particular area is the number of patients currently requiring radiotherapy, coupled with a forecast for the next 10-15 year period (average equipment lifetime). To obtain this number we need to know the current and expected incidence cancer figures, as well as the radiotherapy percentage of use in every pathology, the so-called current radiotherapy utilisation rate (RUR).

The incidence of cancer determination must be based on the most accurate registries available for the area of interest, as the incidence depends not only on the geographical area considered or the population income, but also on the different catchment areas inside a particular country. If local accurate data are not available, a possible source of information is the International Agency for the Research of Cancer (IARC) that publishes patterns of cancer incidence for a wide variety of countries. It is remarkable that, although the current patterns vary between regions with different income, countries with an intermediate and low income are getting closer to high income countries' patterns [17,18].

Although the clinical indication rates for radiotherapy treatment per pathology are based on clinical studies published in the scientific literature, we need to consider that the actual rates may depend on many local factors. These include the availability of radiotherapy due to geographical dispersion and local indication preferences, as radiotherapy is often competitive with other therapy approaches, especially surgery. An average range, commonly accepted for the use of radiotherapy in diagnosed cancer patients is 50%-70% and could even reach 80% in some cases [5].

CLINICAL NEEDS (PROCEDURES)

Once the target population is known, we need to identify what kind of therapies are needed. The first distinction is between external radiotherapy, brachytherapy or both, and the second is between conventional (3D) or more complex/accurate external radiotherapy techniques (intensity modulation, stereotactic, adaptive techniques, etc.). Additionally, information on the distribution of stage of disease would be required, as this will dictate the proportion of palliative/curative treatments. In low-income and middle-income countries, a higher proportion of patients present with advanced stages of cancer than in high-income countries, because of a lack of effective screening programmes, poor access to health care, and low levels of health education.

In a limited resource setting it may be advisable to use the simpler treatment techniques for palliation and the more advanced techniques for treatments with curative intent. Therefore, the patient specific features will be an essential information to know in order to satisfy their needs. In general, in those areas with lower income and poorer diagnostic and therapeutic resources, the palliative treatment rate will be higher and therefore it may not be necessary, and in some cases even counter-productive, to purchase equipment with all licenses and options enabled.

TECHNICAL NEEDS (EQUIPMENT)

The basic equipment for external radiotherapy are cobalt units and linear accelerators (LINACs). LINACs have undergone major technological development and are available in the classical C architecture, ring layout or mounted on a robotic arm. They can generate simple radiation beams or intensity modulated beams with IMRT or VMAT technologies to obtain more complex dose distributions shapes. They can also include different IGRT systems for patient setup, surveillance and patient motion management using planar or three-dimensional imaging systems based in X-ray or even MRI, surface guided systems, echography or active transducers.

Depending on the complexity of treatment, more complex (CT based or planar X-Ray) image acquisition systems, treatment planning systems, oncology information systems (with record & verify), dosimetric equipment for quality assurance, immobilisations systems and/or mould-room equipment might be needed.

For brachytherapy treatment, the most common units used nowadays are high dose rate afterloader systems using Co-60 or Ir-192 sources, with similar clinical outcomes, but different radiological safety requirements and different source replacement needs.

Approaches for the calculation of the number of required external radiation therapy units differ for high income countries in comparison to low- and middle-income countries (LMICs), depending on population and cancer incidence [5, 19]. The IAEA approach for LMICs states that 50% of patients with a cancer diagnosis will benefit from radiation therapy at some stage of the disease and 10% of these patients will be re-treated. With these figures and considering that a radiotherapy treatment unit is able to deliver between 400 and 600 courses of treatments per year [5], it can be concluded that one therapy unit is required per 700-1000 new cancer cases annually. The brachytherapy treatments are commonly associated to external radiotherapy and are assumed essential for cervical cancer, therefore at least one unit per hospital performing external radiotherapy is required.

STAFFING NEEDS

Performing a safe and efficient external treatment programme depends not only on the equipment, but also to a greater extent on the availability of qualified personnel with adequate training who work together as a team.

A radiation therapy unit consists mainly of three groups of professionals: radiation oncologists, medical physicists and radiation therapy technicians with the support of nursing staff, maintenance engineers and computer experts.

The needs of every group of professionals depend on the total patient number as well as on the type, complexity and diversity of the therapies offered. A reference guide to make an assessment is the IAEA Human Health Reports document 13 [9].

EQUIPMENT TECHNICAL SPECIFICATIONS

The equipment for radiotherapy need to be acquired based on a clear set of technical specification designed to fulfil the demand and incorporate specific features required to perform the radiotherapy technique in question.

Before a purchase process is started, it is essential to know all the options available on the market. Given the rapid development of these technologies and their enormous complexity, only by adding previous experience to questionnaires or presentations performed by sales representatives, an optimum knowledge can be achieved.

Making a proper set of technical specifications is a complex task in which we must address the clinical requirements as well as product data provided by the companies and published technical guides, studies including technology comparative analysis or even public documentation of similar purchase processes.

It is essential that the technical specifications meet the regulation and quality requirements specified in the country current law and, as a general rule, must be as general and inclusive as possible so that they can allow the free and fair competition between providing companies and technologies. Not only will quantitative data for every parameter be taken into consideration, but also the global efficiency of the radiotherapy programme, evaluating aspects as integration of the equipment and information systems in the radiotherapy unit or the possible acquisition of beam matched twin treatment units that help us to minimise the treatment downtimes when breakdown occur or maintenance programme takes place.

A very comprehensive guideline with generic technical specifications for radiotherapy equipment commonly used in the treatment of cancer can be found in Ref. [4].

FURTHER STAGES OF THE PROCUREMENT PROCESS: SOLICITATION DOCUMENTS, VENDORS' DEMONSTRATIONS, BIDDING PROCESS, EVALUATION OF OFFERS, PROCUREMENT CONTRACTS

Generally, the purchase of equipment will be performed by a public tendering process taking into consideration country specific current regulation. This public tendering process can be designed in different administrative ways in order to optimise the procedure and adapted to the specific purpose.

Once we know the available commercial products by making use of the previous knowledge and the sales representative's presentations, we must estimate the average prices of every product by making the best combination of the pieces of information available, once we do the request for quote inquiries to the companies and look into the prices of recent purchases.

With the technical and the budgetary information, a public tendering specifying the technical and administrative requirements to be accomplished will take place. In addition, the technical assessable parameters, the improvements that the participants may include in their offers, and the percentage valuation of every aspect will also be specified in the tendering process. In addition, the budgetary limits of the purchase and the valuation associated to direct discounts of the price or warranty enlargements must be clear. Moreover, aspects related to building facilities, radiation safety devices and old equipment decommissioning, including disposing of radioactive waste when applicable, must be specified.

The administrative authorities will designate a committee for the selection of the equipment according to the current law. Members of the procurement team described in section 2.1 should be part of this committee. In addition, auditors that ensure that the procedure is being carried out in the proper formal way must be involved.

After the deadline for the offer presentations, the tender opening will take place publicly, keeping the economic offer closed so that interferences in the technical evaluation can be prevented.

The offers assessment will take place and a score will be assigned to every participant in a justified and signed report. This report will be delivered to every participant giving a period for appealing, every of which must be addressed and answered in time and form in a justified way.

In a later session in which the offering commercial representatives will be invited, the final technical assessments will be made public and the price offers will be opened for those participants fulfilling the minimum technical and administrative requirements. With all the information, the final score will be made and the provisional winner of the tendering process will be announced, giving a time period for possible claims.

Once this period is over and the possible claims are answered, the final winner will be stated and the contract signature will take place in due course. In this contract a set of final conditions, including times for delivery and payment conditions will be specified.

2.3. Installation, acceptance, commissioning, quality & risk management

After the procurement contract has been awarded, assessment of environmental, legal, technical and professional aspects related to developing a plan for the construction of a radiotherapy facility need to be established. Details on how to perform this process are described in Ref. [8].

The process of finalising the detailed plan of the facility will involve many steps and will depend upon whether this is a new facility or the remodelling of an existing facility. The planning may involve external experts, but must always include the local hospital staff who will actually be performing the radiation therapy treatments, as well as representatives of the local funding agency, such as the hospital administration and the equipment manufacturer.

LOCATION AND SITE

Before initiating construction or remodelling of a radiotherapy facility, approval has to be obtained by the national regulatory authority. Guidance on the practical implementation of the IAEA's standards of safety in medical exposure can be found in Ref. [10], while more specific guidance for regulators and users of radiation sources in radiotherapy can be found in section 5 of Ref. [11].

When locating a new radiation therapy facility, operational efficiency, initial cost, as well as provision for future expansion, the need for replacement of units with higher energy units and future increases in workload should be considered. Radiation therapy facilities are often located on the periphery of the hospital complex to minimise radiation exposure arising from treatment rooms being adjacent to high occupancy areas. The option of being able to construct rooms below ground level, with the potential for a reduced need for substantial shielding, may also influence the choice of site. When considering expansion of an existing radiation therapy facility, consideration should be given to the areas directly adjacent to, above and below the proposed expansion site. The size of the treatment room will depend on many factors, including the treatment equipment, the in-room imaging equipment and the intended techniques of the various treatments to be carried out. Further guidance on the location and site of radiation therapy facilities as well as their design and shielding requirements is given in Refs [8, 11 and 12].

The support and advice of the national regulatory authority is also of key importance for establishing radiotherapy services, particularly with respect to licensing of the facility; the management of radioactive sources; occupational, public and medical exposure concerns; and the radiation protection of the patients. The process of acquisition, acceptance, commissioning and clinical use of radiotherapy equipment should be subject to the regulations established by the regulatory authority and should consider the authorisation process established for this purpose in the country. Experience has shown that it is desirable to involve the regulatory body early in the process of bringing new radiotherapy equipment into clinical use. It is preferable to clarify and comply with any regulatory requirements at each stage, rather than waiting until the completion of the project to receive and resolve criticisms. The detailed regulatory principles for granting authorisations have been set out in a previous IAEA document (see Ref. [15]).

Assuming that the site has been identified, the prerequisite to developing a feasibility study for radiotherapy is that legal due diligence has been confirmed, i.e., a formal investigation is undertaken to ensure that all legal aspects are met. These include the right to the site and that the regulatory infrastructure to support the safe and effective installation of radiotherapy treatment units is in place.

PRE-INSTALLATION ISSUES:

The design of the radiation therapy facility should make provision for safety systems or devices associated with the equipment and rooms. This includes ventilation systems, electrical wiring relating to emergency off switches, and standby lighting, safety interlocks and warning signs and signals.

A reliable and stable power supply should be available for all modern equipment and IT systems. An emergency diesel power generator alone is generally not sufficiently stable to power a LINAC or orthovoltage unit and should not be used in this way. An uninterruptible power supply or battery backup systems should be installed to capture the active information at the time of the outage and to shut down all software in a controlled manner.

The manufacturer should send in advance the so-called "mechanical implementation guidelines", which serve as reference for the design of the installation. The proposals are discussed with the user until a satisfactory solution is found. The hospital should define the local counterpart (usually members of the ad-hoc procurement team) to take charge of the project and its implementation.

During the construction or refurbishment of the premises that will house the radiotherapy equipment, it is essential to exchange information with the manufacturer about the installation requirements. It is sometimes advisable to have a factory expert visit (once or several times) the site to confirm that the project is executed according to the requirements and to detect and/or correct any deviations in time.

During the construction phase, there must be hospital's representative(s) on-site with the knowledge and authority to supervise and inspect the construction. These persons must have sufficient training to check the specialised requirements of the radiotherapy facility. For example, if concrete is poured with the wrong density, it will be very expensive (or impossible) to rectify this error later.

PROVISIONS FOR TRAINING OF STAFF

Generally, equipment suppliers combine installation visits with on-site training "courses" of very short duration that are not always sufficient for the personnel to be fully qualified to make optimal use of the new technology. It is therefore advisable to include more comprehensive training within the procurement contract. This will not add much to the cost of the procurement compared to the benefit provided. Resources invested early in training may well pay significant dividends later, improving the efficiency of the later planning and implementation. In case this aspect is omitted, funds may not be available for this once the contract is signed.

As radiotherapy is a multidisciplinary modality, it is necessary to train members of the various specialties that make up the equipment, i.e., radiation oncologists, medical physicists, radiotherapy technicians, and above all bioengineering and maintenance staff.

POSSIBLE TRAINING MODALITIES MAY INCLUDE

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- ▶ On-site application training.

 - ▶ Factory training.

 - ▶ Training at other clinics (e.g. IAEA fellowships, UICC fellowships, etc.).

DELIVERY AND INSTALLATION OF EQUIPMENT:

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

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

Under this expert supervision, the local staff must develop the expertise and confidence to carry on after the departure of the expert.

INSTALLATION RECOMMENDATIONS

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- ▶ Hospital's designed counterpart should visit the site frequently during construction to monitor critical aspects.

 - ▶ For instance, checks of the location of the isocentre and lasers during base frame installation.

 - ▶ Work closely with the installation engineers.

Following these recommendations generates the following benefits and disadvantages:

BENEFITS

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- ▶ A collaborative attitude with installers is developed.

 - ▶ Familiarisation with the interior parts of the equipment.

 - ▶ Many alignment tests, if performed together with the installer, can serve as part of the acceptance tests.

 - ▶ Goodwill can result in better alignments and adjustments.

 - ▶ Performance technical specifications define the worst scenario that will be contractually acceptable, so that the equipment might perform better than the specifications; this could be achieved through active interaction with installers.

 - ▶ Parameters that are not met at this stage will not improve over time.

DISADVANTAGES

- ▶ Increases installation time.
- ▶ Potential distraction and inappropriate use of time to complete other tasks.
- ▶ Lost time may become irretrievable.
- ▶ Potential installer displeasure.
- ▶ Possible development of adversarial attitude.

ACCEPTANCE TESTING

Radiation sources need to be safely received, registered and stored, the radiation measurement equipment tested and calibrated, the shielding properties of special rooms measured, and the radiation sources tested and calibrated.

Guidelines for performing preliminary radiation survey in both controlled and uncontrolled areas around the vault of newly installed treatment units, to assure the safety of individuals during the acceptance testing and commissioning should be established. The equipment required for these surveys should also be received and tested before use. For accelerators with energies of 15 MV and above, access to a neutron measuring instrument is required (it does not need to be purchased by the hospital, it can be borrowed or rented from other institution).

During the acceptance testing process of an equipment, the supplier demonstrates to the satisfaction of the customer, that the performance of the equipment complies with the specifications that were agreed in the contract. Both mechanical and dosimetric measurements must satisfy the specified values. Acceptance and commissioning tests set reference values and baseline for future quality assurance measurements and verify that the equipment is mechanically functional and operates within certain tolerances around the specified values.

The manufacturer-supplied acceptance testing procedure should be reviewed thoroughly against relevant resources (e.g., IEC publication 976 for LINACs). Then, an agreement between the manufacturer's representative and the facility physicist on these procedures should be achieved. All the results of the acceptance testing must be verified against each term of the agreement and machine specifications. If the equipment tests do not show any deficiencies, the time required for this phase is in the order of 1 to 2 weeks, depending on the complexity of the installation. However, if any problems arise during the testing, current standards require that in most cases, the test series should start from the beginning after the required remedial work has been carried out. Therefore, when planning, it would be advisable to add a few days for this possible contingency.

COMMISSIONING

After acceptance testing, all major equipment will require commissioning, where all the parameters necessary for the clinical use of the equipment are determined. This includes not only teletherapy units, but also imaging devices (simulators), brachytherapy units and TPSs. In the case of accelerators often some of these characteristics may have already been acquired during acceptance procedures. These parameters establish the reference criteria that will be checked during subsequent tests of the quality assurance programme. The main element in this phase is the acquisition of the beam data to feed the treatment planning systems and the total time required for this single activity is usually between 5 and 10 weeks depending on the complexity of the machine. A modest reduction in this time could be achieved if the teletherapy unit is a beam-matched twin to a recently installed one or if factory matched golden beam data is available. During these processes, interruptions can occur due to premature equipment failure requiring intervention by the manufacturer.

A record keeping system should also be in place. The time required to accomplish all this preparation can be substantial (measured in weeks or months). It may be possible to formulate some of the preparatory procedures in parallel with the training and facility planning steps.

Established guidelines for performing the commissioning of accepted equipment should be available in writing in advance (see example in Ref [13] for LINAC's beam data commissioning). It is advisable that commissioning results be verified by an independent person/organisation, through comprehensive peer reviews/quality audits (see guidelines in Ref [14]).

Equipment that is needed to test and commission the teletherapy unit, radioactive sources, the afterloading device, imaging devices, etc., should arrive early enough to be tested before use. Consequently, the arrival of technical expert(s) supporting the acceptance testing or commissioning process should be scheduled so that all the necessary equipment is present, the facility prepared and the staff ready to make use of the expertise.

When calculating the estimated time of the work before declaring the treatment unit ready for clinical use, all phases of the process and the complexity of each of them have to be considered. For obvious healthcare reasons and sometimes also for political reasons, hospital authorities or higher institutions will always try to put pressure on the radiotherapy department to commit to a start date for the first treatment, so it is important that the responsible staff (especially the medical physicist) do not make compromises that could affect the number or quality of tests for clinical commissioning.

The duration and resources used for acceptance and commissioning depend on the type of agreement reached with the supplier. If by contract agreement the manufacturer is responsible for commissioning, then the factory expert in charge will try to perform the minimum standard tests (according to his own protocol) and probably feed the treatment planning system with the so-called "golden beam data". When this happens, it is usual not to perform all the measurements but to perform some of them in order to check that the dosimetric characteristics of the machine's beams coincide with the generic data. In this situation, it is recommended that the local physicist include in the commissioning programme a number of additional tests, the so-called "site tests", as recommended by the IAEA TECDOC-1540.

Whenever a purchase agreement specifies that the manufacturer should provide extra services that usually are performed during commissioning (for instance, beam data collection and modelling into TPS), then additional tests should be included in the manufacturer's acceptance protocol, to ensure that those extra services meet specifications in purchase agreement.

QUALITY AND RISK MANAGEMENT

Until recently, the emphasis in radiotherapy quality management, particularly by the Medical Physics community, has been on the technical performance of radiotherapy equipment. In recent years, however, there has been increasing recognition that a major source of quality and safety impairment arises from weakness or variability in radiotherapy processes. Commonly used prescriptive approaches applied to radiotherapy quality management programs often do not address the huge variety of process and technique improvements and developments that help Radiation Oncology continually improve patient care. The prospective approach accommodates not only clinic-to-clinic variability in risk profile, but also provide a methodology for adapting a clinic's quality and safety programme to changes in technology and patient care. It is highly recommended to implement prospective tools, as those detailed in Ref. [16] to produce a quality management programme that will save time and provide guidance on enabling each programme to direct resources toward achieving quality and safety in radiotherapy more effectively.

3. Preventive and corrective maintenance of radiotherapy technology

Preventive maintenance programmes have been shown to decrease linear accelerator down-time [20].

Therefore, any radiotherapy programme requires ongoing maintenance [6]. This maintenance programme should not be an afterthought when purchasing new radiotherapy equipment, but should be carefully thought through to take into account the local conditions and requirements. A suitable strategy must be devised to achieve and maintain acceptable out-of-service interruptions, while maintaining the quality of treatments offered and the fractionation schedules, but without affecting patient and staff safety adversely. A preventive maintenance contract will also help to prevent accidents or incidents.

CONTEXT

Contextual issues must be considered. These include questions like:

- › How reliable is my power supply?
- › How long does it take for spare parts to arrive?
- › Are all parts flown in, or is there a parts store locally?
- › How long does it take for service engineers to arrive?
- › How many service engineers are there?
- › How experienced are the service engineers?
- › If you choose to opt for a pay-per-service option, how streamlined is the hospital procurement system?
- › Do you have a maintenance budget?
- › How are exchange rate fluctuations dealt with?
- › Are there minimum staffing requirements?
- › What uptime is required and/or feasible? Can this be guaranteed by the manufacturer?

Answering these questions may already provide important indicators how comprehensive a service/maintenance contract must be, and what must be included in this contract.

WARRANTY

According to the WHO/IAEA document on “Technical specifications of radiotherapy equipment for cancer treatment” [4], a manufacturer warranty should always be requested during the procurement process. This should be an all-inclusive warranty that includes preventive maintenance, updates and upgrades, especially the ones affecting patient safety, spare parts and labour. The equipment warranty should commence after completion of the acceptance testing and typically runs for one year.

PREVENTIVE AND CORRECTIVE MAINTENANCE PROGRAMME

After the warranty period, careful consideration must be given to determining how the preventive and corrective maintenance programme will be continued.

According to the WHO document on “Medical equipment maintenance programme overview” [2], an inventory must be made of all devices that are included (or excluded) from such a programme. It must be determined how this programme will be implemented:

1. Will it be possible to do small repairs in-house?

If so, the hospital engineers will require adequate training and some spare parts should be kept on site, together with maintenance and service manuals.

2. Is there local support by a specialised maintenance company or supplier?

If so, factory-issued training certificates for the equipment (or for certain components of the equipment) should be requested.

3. Or is there support from the manufacturer for major repairs?

RESOURCES REQUIRED

The resources for such a programme must be available. This includes the finances for physical resources like test equipment, tools, or even the space to store these. It also includes the finances for the human resources in the form of salaries, benefits, or continuing education. Finally, it also includes the finances for the service contract, parts, travel, and shipping. *The resources for a maintenance programme must be included in the budget.* It is therefore imperative that the funders are aware of the long-term cost implications of purchasing a linear accelerator.

THINGS TO CONSIDER

Service contract pricing may be significantly impacted by other factors as well:

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- The installed base density: how many linear accelerators are already installed in the city / region / country?

 - Who pays the import duties?

 - Is a distributor involved, or is the service offered directly by the manufacturer?

 - Is the cost to travel included?

 - Are the service engineers expected to be reachable during normal working hours only, or is a 24-hour availability required?

HOW CAN SUCH A PROGRAMME BE IMPLEMENTED?

Several different pathways can be followed to implement maintenance programme:

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- A basic option can, for example, include remote technical / helpdesk support, planned maintenance and labour, with spare parts being quoted for.

 - A more advanced option can include additional corrective maintenance with spare parts, with software updates. Uptime guarantees of 95% or even 98% can be asked for, and penalties can be built in for not meeting pre-agreed levels of uptime, or for not meeting pre-agreed response times. Unique components can either be optional items or included in the contract, potentially on a shared-risk basis. These unique components are often very expensive (for example: waveguide, magnetron, or klystron) and it must be clearly stipulated whether they are included or not. An option is to not include these for all linear accelerators, assuming there is more than one at a site, but to include the replacement of up to one such item per calendar year for the installed base, or similar.

 - The most expensive option includes obsolescence management for hardware and software, and software version upgrades. Major vendors also offer the option of remote monitoring of equipment, which often enables the vendor to flag and address potential issues, before they affect patient treatment. This requires a hospital information technology infrastructure that allows this.

 - Service plan pricing may also be broken down, depending on the sophistication of the equipment or customer specific options and requirements. These options can include, for example, the type of treatment couch or type of multi-leaf collimator, the electronic portal imaging device, a kV cone-beam CT, or how many photon and/or electron energies are used.

OTHER CONSIDERATIONS

It is important to consider all components that have the potential to affect the operation of the linear accelerator, and thus radiotherapy treatment.

This also includes the oncology information system and the treatment planning system – it may be easier to include software version upgrades of these, or even hardware obsolescence cover, in a maintenance contract, rather than to purchase these upgrades or items later. Depending on the complexity of a hospital procurement system, it may be worthwhile including the chiller, air conditioning, or even the servicing of a shielded bunker door as part of a comprehensive maintenance programme. If a system with an uninterrupted power supply (UPS) is purchased, battery replacement and servicing of this unit should also be made allowance for, although this may well fall into the scope of the hospital engineering department.

Network security and firewall configuration should at least be considered [21].

A service schedule should be requested from the service engineer(s), indicating the frequency and duration of each service on all included items.

WHY IS A SERVICE CONTRACT RECOMMENDED?

There should be no shortcuts on preventive maintenance. An agreement that is put in place means that service is merely a phone call away. A guaranteed response time means that preference will be given to such a customer over someone who does not have this, especially if penalty clauses are in place.

Hospital procurement systems can be slow: a contract will mean less administrative problems and less paperwork. In addition, the pricing is known upfront and can be budgeted for. If the contract is in local currency, exchange rate variations are no longer of concern. A contract may also make it more likely that spare parts are kept in a warehouse close by.

ONCE AN OFFER IS TABLED...

Once an offer for a preventive and corrective maintenance programme is tabled, it is imperative that this offer is read very carefully, especially the small print. It should be very clear what is covered and what is not covered under the contract. In addition, careful note must be taken under what conditions the contract is null and void (for example: room too hot or too humid), or what the costs of a contract termination are. The contract should be discussed at the very least with the clinical engineering team, with the responsible medical physicist, and with the finance department. Once the contract is signed, there is no more room for negotiations.

Finally, it may be more cost-effective to sign a multi-year and / or a multi-machine contract.

4. Conclusions

After the procured equipment has been accepted, commissioned and is in clinical use, a monitoring process for gathering and management of data to control current procurement and its implementation is required.

Procurement performance assessment is the measurement of achievements against the objectives.

The monitoring process feeds back information from the implementation of the procured technology, by checking:

▸ Equipment performance:

- repair and maintenance work required (e.g. down time).

▸ Supplier performance:

- the proper occurrence and execution;
- of training, warranty visits and service calls;
- satisfactory history of delivery;
- lack of difficulties during the acceptance testing process.

▸ Technology suitability

- supply of consumables;
- actual use of equipment;
- feedback from equipment users for specification development;
- commitment of practitioners to use the equipment.

▸ Cost effectiveness

- Comparing actual running and life cycle costs with forecast, to check that there are no excessive repairs.
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For details on procurement performance indicators, please refer to Table 1 in Ref. [1].



5. List of contributors

Include a detailed list of all members of the city team that contributed to the drafting of the document, including the participants in the peer review meetings conducted in the city, and all the external experts that reviewed and edited the final draft.

6. References and bibliography

► List all publications referenced in the Radiotherapy Procurement Plan and Maintenance Programme, including the reference publications considered by the guide development team.

► A list of reference publications used in this Guide is provided below.

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<https://citycancerchallenge.org/>

