# 6. Equipment Purchasing for Imaging and Radiation Therapy: Specifications, Acceptance Testing, and Maintenance

## 6.1 Overview

The acquisition of equipment for an imaging or radiation therapy service is fundamental for achieving the objectives of ***local health systems***. The degree of success achieved in the procurement process will significantly influence the quality of the procedures as well as the costs, and a professional approach must therefore be taken to purchasing. It is important to point out that the purchase of this type of equipment consumes a major share of the budget of a medical institution. The procurement process is part of an overall plan that comprises the following stages:

- Analysis of equipment needs, clearly defining the intended use of the system.
- Equipment specifications, outlining the general requirements and detailing specific functional parameters and image quality factors in the case of imaging and nuclear medicine equipment.
- Vendor bid analysis, with emphasis on meeting the specifications.
- Finalization of the contract, which should include all relevant terms and conditions.
- Equipment installation, followed by acceptance testing and on-site training.
- Implementation of a program of preventive maintenance to detect and correct any equipment malfunctions.

- Establishment of a ***quality control*** program to assure constancy of performance and to detect and correct any tendencies toward system malfunction.

## 6.2 Analysis of Equipment Needs

The equipment requirements for each ***local health system*** were discussed in Chapter 4. Once a ***local health system*** has decided on the type of equipment to be purchased, it must carefully select the particular model and brand, since this is an area of rapid progress in which technology becomes obsolete very quickly. The model should be selected according to the following criteria: effectiveness, safety, infrastructure, maintenance, and cost.

To determine effectiveness, it is necessary first to compare the technical specifications of various types of equipment and analyze their impact on the clinical application for which the equipment is being selected. Next, it is necessary to assess what kind of ancillary equipment is required for the main equipment to be effective. For example, if a high-energy radiotherapy machine is to be purchased, it is essential to also have a dosimetry system to calibrate the beam. In addition, there must be provisions for making beam modifiers, such as blocks, bolus, and compensators, as well as some kind of treatment planning unit.

Safety implies knowledge of mechanical, electrical, and radiological ***risks***. It is necessary to know what radiation levels are emitted by the equipment (if any) and to design the necessary protection (for example, structural ***shielding***) in accordance with the radiation protection laws of the country.

With regard to infrastructure considerations, it is necessary to determine what type of specialized personnel will be required to operate a particular model. For example, the expertise of software technicians may be needed for trouble-shooting and maintenance in the case of computerized linear ***accelerators*** but not in that of manually controlled ***accelerators***.

Among the factors to consider in estimating costs are the following: the initial purchase of the main and ancillary equipment; its installation, including ***shielding*** and ***contamination*** prevention; the maintenance program, including spare parts; accessories (films, screens, dosimeters, supplies in general); the cost of operator training and continuing education; and the cost of final disposal of equipment if it contains radioactive ***sources***

## 6.3 Purchase Specifications

Written system specifications should start with an objective statement summarizing the clinical procedures to be performed and outlining any specific needs beyond the normal clinical procedures. In addition, an estimate of the number of procedures per day should be given; the expected location of the equipment, with the room dimensions, should be specified; and any particular site problems should be noted *(33)*.

The specifications should not indicate any particular product or be vendor-specific. This will make it possible for vendors to propose products that the end user may not be familiar with.

As part of the required specifications, it should be stipulated that any equipment that is imported must comply with the sale and/or certification regulations of the country of origin as well as with any other national norms, if there are any. In the case of non-imported equipment, it must be decided which international standards are to be followed (e.g., those of the International Electrotechnical Commission, the International Standards Organization, etc.) *(26)*.

In order to ensure smooth post-installation transfer of equipment from vendor to purchaser, it is advisable, early in the process, to clearly define the standards for equipment acceptance. Hence, purchase specifications should identify the equipment features that are to be tested as part of the acceptance testing process.

In some institutions and medical centers, a third party is recruited to handle equipment acquisition in order to free the hospital staff from the tedious and time-consuming task of writing specifications and carrying out the required follow-up. Third-party consultants may also have more experience and information than hospital personnel because they have been involved in a larger number of similar equipment purchasing transactions. Nevertheless, third-party involvement may distance the future user from the vendor, increasing the likelihood that the equipment received will not meet the user's needs.

In preparing the final contract, care should be taken to ensure that it contains no unreasonable, impractical, or unfair terms or provisions. If accepted by the vendor, such terms may increase the cost indicated in the original bidding process and complicate the future relationship between vendor and purchaser.

In addition to equipment specifications, site planning issues such as equipment location, room size, construction plans, and ***shielding*** requirements should be considered early in the process. This will minimize the possibility of future construction problems, such as lack of sufficient space when equipment and accessories are installed, an inadequate or noisy power source for the equipment, or insufficient air conditioning to protect computer systems and other delicate parts.

One common way of purchasing radiological equipment is to establish generic bid specifications in order to take advantage of the competition generated through the process. The bid structure and style will vary from one medical institution to another. There are, however, similarities in certain elements of the bid format—for example, descriptions of the type of equipment desired and key performance requirements. In the case of diagnostic radiology equipment these similarities might include:

- General requirements, clearly identifying the desired equipment (general radiography, trauma, computed tomography, radiography/fluoroscopy, dental, etc.) and the department acquiring it (radiology, emergency, surgery, oncology, etc.).

- Major equipment components, including the main system configuration (***source*** assembly, table system, ***generator***, console, etc.). For example, components of radiographic equipment intended for trauma work in an emergency department would include the following: a WHO radiographic unit (WHIS-RAD) or alternatively a ceiling-suspended ***x-ray*** tube and collimator, ***x-ray generator*** and console, patient table and wall bucky assembly, and other options, such as linear tomography.

- Equipment functional requirements, which should cover the desired system capabilities, including possible projections (views) and image acquisition parameters. For example, functional requirements for general radiography equipment might include the following possible patient positions, views, and parameters:
  - Standing patient, view from shoulders to knee joints with a horizontal ***x-ray*** beam
  - Sitting patient with a horizontal ***x-ray*** beam (dorsal spine, cervical pine, paranasal sinuses)
  - Sitting patient with a vertical ***x-ray*** beam (arm, elbow, wrist)
  - Recumbent patient with horizontal, vertical, or angled ***x-ray*** beam

In the past, the above-mentioned examinations were performed using either a vertical cassette holder or a bucky table. However, with the WHIS-RAD, the design was optimized by combining a single examination stand with a simple examination table to make it possible to perform all the required examinations.

A further example of functional requirements for a combination radiographic/fluoroscopic unit, might include the following:

- Performing general radiography, fluoroscopy, and spot filming
- Auto-***exposure*** control on spot filming, bucky table and bucky radiography modes
- Capacity to obtain cross-table radiographs without patient movement
- Capacity to produce TV fluoro between spot film rapid sequence exposures

- Specific equipment requirements, including a detailed description of the specifications for system hardware components. An example from a bid for an ***x-ray CT*** system would include:
  - Required minimum ***gantry*** aperture size
  - ***Gantry*** tilt angle
  - External or internal beam alignment lights
  - Tube housing anode heat capacity/maximum cooling rates
  - Table capability to accommodate heavy patients

- Computer capabilities should be clearly specified when a computer is to be part of the imaging system, as with CT, digital imaging, and MRI. The requirements may vary depending on the imaging modality under consideration. However, for all modalities image acquisition parameters must be defined, including the number of images per unit time, matrix size, reconstruction time, and ***pixel*** depth. Short- and long-term-storage memory devices and their storage limits will have to be specified taking into consideration the storage capacity needed per image and the institutional policy on long-term storage of medical images.

- Expected system performance and, for imaging equipment, the desired image quality should be specified in quantitative terms, whenever possible. In fluoroscopy, for example, the required contrast and spatial resolutions obtained from the imaging chain should be defined. Patient radiation ***dose*** under various operating conditions should also be documented.

- Other requirements:

  In addition to the technical requirements, other operational, training, and maintenance requirements must be met. The vendor, for instance, should provide copies of the operation and service manuals in a language acceptable to the user (*26*). Arrangements should also be made for the provision of adequate applications training. For some staff, specialized training at a designated training site might be needed.

As an illustration of the type of specifications that might be developed for the purchase of equipment, Appendix IV presents bid specifications for a ***CT scanner*** taken from the American Association of Physicists in Medicine (AAPM) Report 39: *Specification and Acceptance Testing of Computed Tomography Scanners* (*34*).

## 6.4 Bid Analysis and Vendor Selection

The decision to award a contract to a particular vendor is a critical aspect of the purchasing process. This decision should be based not just on the amount of the bid but also on the company's reliability as demonstrated through all the documentation it has submitted in the bidding process.

The degree to which the specifications are met, the guarantees that a vendor offers, and its ability to provide maintenance service for the equipment and training of personnel, as well as to assure the availability of spare parts during the entire useful life of the equipment, are also very important factors to take into account.

## 6.5 Service and Warranty

The supplier should assume the responsibility for delivery and installation of the equipment and for training of personnel prior its use. Competing vendors should be asked to submit, as a supplement to their bids, a service statement describing their maintenance and service response policy. The statement should indicate the firm's minimum and maximum response time for emergency and routine calls; the availability of service on weekends, after hours, and on holidays; and the availability of critical parts that would take more than one day to receive. The vendor should guarantee that parts will be available for a period of at least seven years after the equipment is purchased. It is important to have

a clear idea of the initial investment costs and the operating costs over the life of the equipment, as well as its period of obsolescence.

All system components should be covered under a comprehensive one-year warranty. The vendor should specify the warranty period for any components not covered for one year.

The final contract with the selected vendor should include a service agreement of at least two years' duration, which should enter into force upon expiration of the warranty period. The cost of any services rendered under the agreement should not change during the two-year period.

## 6.6 Acceptance Testing

Acceptance testing is a crucial part of the purchasing process. Through these tests it is possible to verify that the equipment complies with the specifications provided by the vendor in the bid and it should also be possible to detect any non-compliance or defect.

Final payment for the equipment should not be made until acceptance testing is complete.

Acceptance testing entails verification of the following parameters:

- Manufacturer's technical specifications
- Performance standards of the country of origin, national standards or adherence to international standards, as appropriate
- For equipment emitting ***ionizing radiation***: radiation ***doses*** and compliance with the country's radiation protection laws and regulations

Should the facility not have the required instrumentation and/or personnel to perform the tests, there should be a clause in the sales contract under which the vendor is required to lend the required equipment and/or personnel. For instance, acceptance testing of a cobalt unit requires verification of the symmetry of the radiation beam. Should the facility not have a radiation beam scanner, the installer should be able perform the test with his own equipment. The information acquired during acceptance testing should be used as a baseline for future ***quality control*** testing, for which the owner of the radiologic equipment must have the necessary testing instrumentation.

The design of acceptance testing protocols should incorporate methods and means for testing all parameters selected. To minimize subjective evaluation of equipment performance, it is important to use ***phantoms*** and test tools which can provide quantitative and reproducible data. The additional use of anatomical ***phantoms*** will bring the system setup closer to clinical requirements.

Installation of newly acquired systems should be considered provisional until acceptance testing has been completed. As mentioned earlier, it is advisable to have a written statement in the sales contract detailing the nature and specifications of acceptance testing. If such a statement is not included, it should be decided in advance whether the acceptance testing will be performed according to the manufacturer's procedures or the user's ordinary testing methods. In any case, the testing should include non-invasive measurements of the output of the system.

In the case of diagnostic equipment, measurements should be made of image quality and patient ***dose***. In the case of radiotherapy equipment, the measurements should include radiation beam characteristics such as field flatness and symmetry, and ***penetration quality***, as well as accurate ***absorbed dose*** determinations. All types of machines need to be tested for mechanical integrity and safety, mechanical alignment, and proper collimation.

The number and nature of the problems found through acceptance testing time will vary depending on the complexity of the system. Radiologic equipment, such as angiography units used in special procedures, linear ***accelerators*** and ***SPECT*** systems, generally have the highest number of major problems.

Appendices V and VI give suggested testing parameters and tolerances—which may be used if none are specified by the manufacturer—for all types of diagnostic and radiotherapy equipment.

## 6.7 Preventive Maintenance

The preventive maintenance program consists of periodic procedures and interventions performed on equipment to reduce the possibilities of a malfunction and ensure its continuous, safe, and economical operation.

Preventive maintenance also ensures that the equipment operates according to the manufacturer's technical specifications and in compliance with safety standards. The functional parameters of the equipment should be checked initially during the acceptance testing performed before the machine is put into service and subsequently following any repairs or modifications (*35, 36*).

The frequency with which maintenance is performed will be determined by the manufacturer's recommendations, the workload and how often the equipment is used, the physical and environmental conditions in which it is operated, and the turnover of the personnel who operate it.

Depending on the technical capabilities of the maintenance personnel and the availability of instruments, calibration equipment, and technical information, as well as the technological complexity and amount of equipment, maintenance may be carried out by:

- Staff of the institution;
- External maintenance personnel contracted through the manufacturer, distributor, or a maintenance firm;
- Both internal and external personnel (a combination of the first two modalities).

Regardless of who carries out maintenance activities, a logbook should be kept in which all maintenance procedures and their costs are recorded. In addition, within the institution there should be personnel capable of exercising technical supervision of maintenance services provided by both internal and external personnel.

The person or persons responsible for operating the equipment are also responsible for its upkeep and should promptly report any malfunctions in order to avoid major damage.

## 6.8 Coordination of Preventive Maintenance and *Quality Control* Programs

Preventive maintenance and ***quality control*** involve concepts and activities that are different but complementary. The quality of diagnostic and therapeutic procedures cannot be adequate if the equipment used is not functioning properly due to lack of maintenance (*37*). Both programs are essential to the

continuous improvement of quality, and they are also key factors in the process of health establishment accreditation (*38*).