Linear Accelerator Acceptance Testing and Commissioning

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I. Introduction

The delivery of radiation treatments is reaching new pinnacles with continued advancement in accelerator and computer control technology. Computer-controlled linear accelerators (linacs) are increasingly being used clinically in small, as well as big, institutions. There is a complete shift in the paradigm of the treatment delivery process. Historically, linear accelerators have been used to deliver radiation of uniform intensity through field apertures shaped by blocks. Now the emphasis is to shape the field apertures with a multileaf collimator system and vary the radiation intensities with dynamic motion of the collimator system to deliver conformal radiation to the target volume. The fundamental premise is that the high-dose volume is restricted to the shape of the target tissue while excluding as much normal tissue from the high-dose volume as possible. Therefore, the acceptance testing and commissioning of a computer-controlled linac can be quite complex and may vary from institution to institution depending on its anticipated use.

The process of purchase, acceptance testing, and commissioning of a computer-controlled linac is a major undertaking that can take up a considerable amount of time, effort, and expense. Therefore, it is crucial that a great deal of thought and care go into the initial planning. The primary objective is that the accelerator specifications must meet the clearly defined needs of the facility over the projected lifetime of the accelerator, which can be up to 10 years. It is very important that the selection process for the equipment includes input from radiation oncologists, physicists, therapists, and facility engineers. The selection, acceptance testing, and commissioning of a linac involves;

- evaluation of clinical needs
- review of specifications and purchase agreement
- design and construction of the facility to house the new machine
- installation of the machine, safety checks, and initial radiation survey
- acceptance testing of the machine
- commissioning of the machine for clinical use
- final report and documentation
- training of the staff in the safe and efficacious use of the accelerator
- establishment of the baseline quality assurance parameters and schedule

The purpose of this presentation is to describe the general concepts and philosophies that are useful for a physicist who is charged with the task of bringing into clinical use a new computer-controlled linac.

II. Criteria for Linac Selection

The selection of a linac is critically dependent on its clinical utilization. Fortunately, the choice of commercially available, FDA-approved medical linacs is primarily limited to three major linac manufacturers: Elekta, Siemens, and Varian. Each of these manufacturers offers linacs that are capable of delivering both uniform and modulated intensities of radiation under computer control. Therefore, the task is limited to selecting the most appropriate machine from those commercially available and developing the purchase specifications to meet the clinical needs. This task is best accomplished by the formation of an ad hoc committee in the department that includes at least a physicist, radiation oncologist, therapist, and engineer. The charge of this committee should include

- A systematic review of current and projected clinical needs and types of patients who will be treated on the machine
- A careful review of deliverables, functionality, technical and physical specifications, and cost of all commercially available linacs
- Review of available space, available funds, available or needed support staff, and available in-house technical support and expertise
- Evaluation of future upgrades, warranties, and maintenance contracts
- Evaluation of the quality of the manufacturer's service and technical support
- Final recommendation for the linac

The criteria for selecting a linac can become quite controversial, complex, and time consuming. There is often a pressure from sales representatives of the manufacturers, who at times do not clearly distinguish between what is currently deliverable on the machine and what is planned for it in the future. It is the responsibility of the equipment selection team to discern that by contacting personnel at facilities that have similar machines and are using it clinically. It is good to contact only those facilities that have technical resources and patient distributions comparable to yours. Site visits to the factory or to a manufacturer's designated facility are rarely useful unless a special and new modality or option of treatment delivery is under consideration.

A generic decision tree for the purchase of a medical linear accelerator is shown in Figure 1. We find it very useful in establishing the criteria for selection and evaluating various delivery systems. It can take considerable time and effort to go through some of the steps described in this figure. It is important, however, not to skip any of the steps. The flow sheet ensures that all clinical requirements are considered and that the facility is adequately evaluated for the planned equipment purchase. A critical review of needs and the facility during the planning stage can save aggravation, time, and money later.

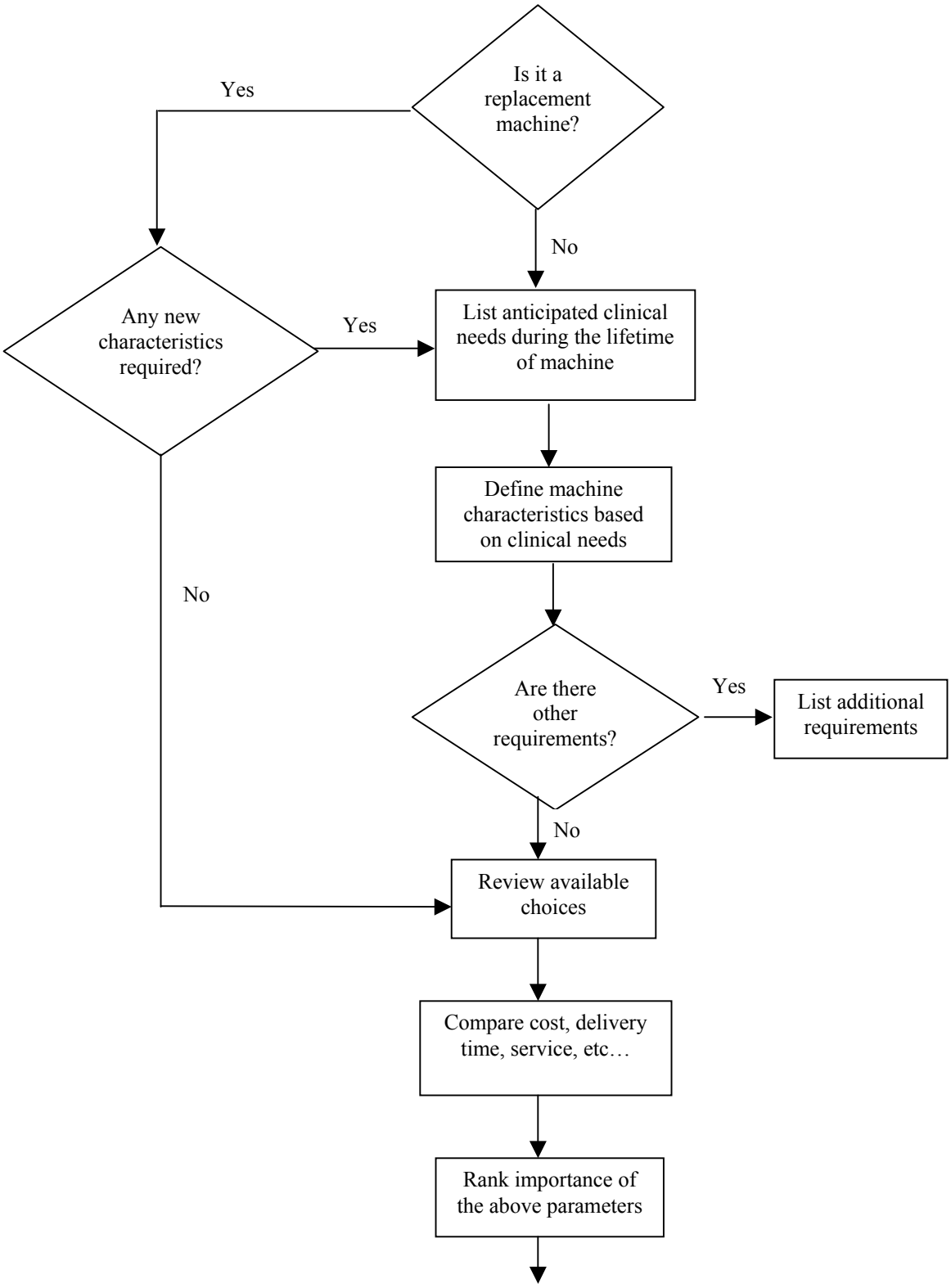

Figure: Decision tree (continued on next page)

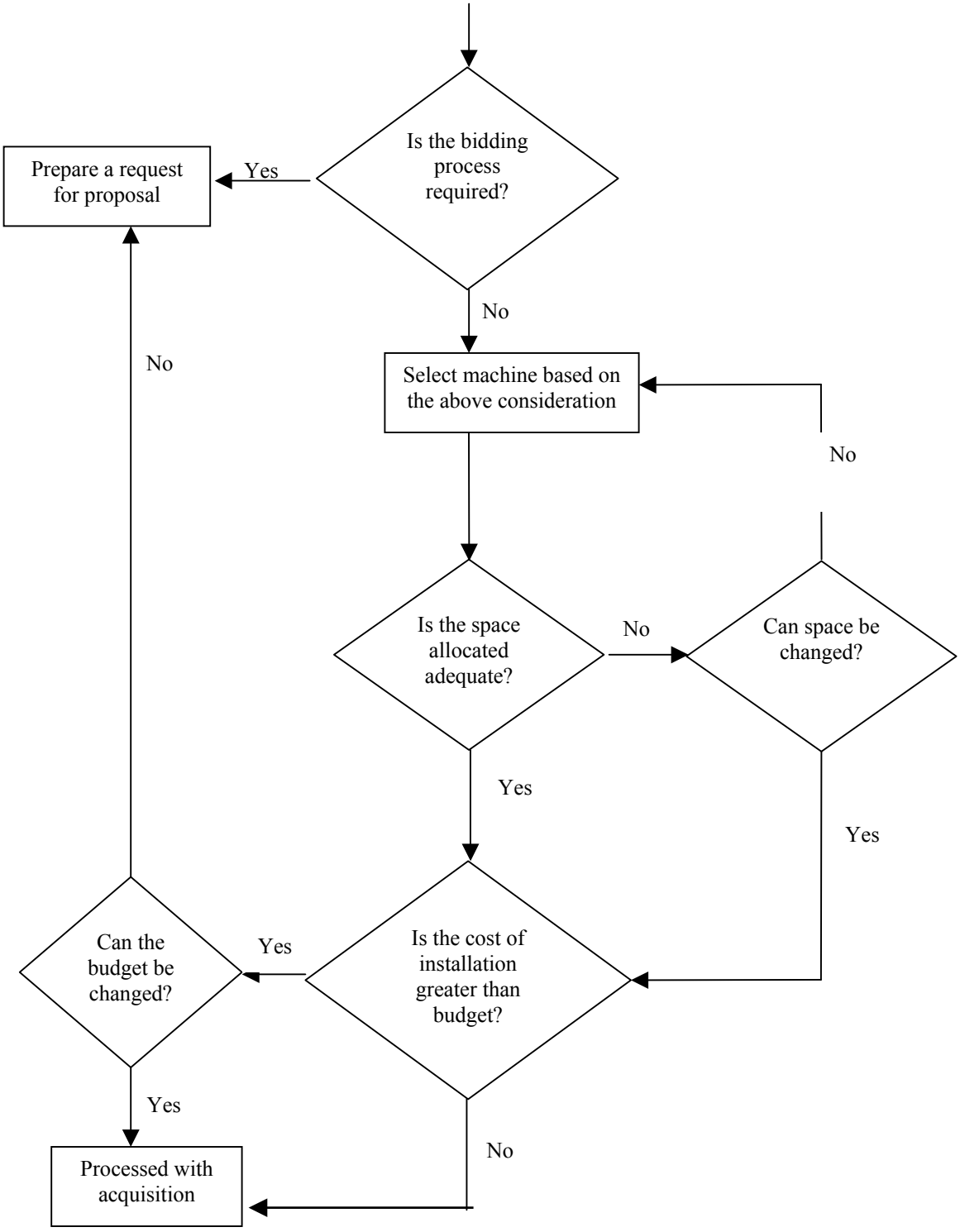

Figure: Decision tree (cont.)

III. Machine Specifications and Purchase Agreement

The recommendations of the equipment selection committee are followed by the development of comprehensive machine specifications and a binding purchase agreement. If the equipment is purchased through a bid process, then the machine specifications are developed before the decision is made to select a manufacturer. Otherwise, the final specifications may be developed in close collaboration with the manufacturer's representative. All manufacturers have developed product specifications for the functional performance of their equipment in response to requirements from potential users and in commercial competition with other manufacturers. These are available in the form of product data and specification sheets, which can serve as a good starting point for the purchase agreement. Any special requirement can then be added as an addendum. This saves lot of time and effort from being expended in repetitive work. An example of an addendum to the purchase agreement is presented in the Appendix, which illustrates how special requests are included in the agreement.

It is imperative that the facility physicist develops a comprehensive acceptance-testing document with a detailed test procedure to verify each term of the agreement and machine specifications. This document should be shared with the manufacturer's representative before the installation begins so that all ambiguities are clarified in advance. It is not prudent to depend on the manufacturer-supplied acceptance test procedure exclusively. However, it should be reviewed thoroughly before acceptance testing. IEC publication 976, entitled *Medical Electron Accelerators: Functional Performance Characteristics,* is an excellent resource to set up test procedures.

It is essential that the physicist review the facility layout with the planning and installation department of the accelerator manufacturer. They can provide very useful information on workflow, equipment layout and special requirements. A joint meeting of the equipment planning coordinator, architect, contractor, and physicist in the earlier stages of construction is very helpful and productive. This meeting can resolve all potential problems regarding electrical power supply, conduit layout, air conditioning, and chilled water requirements for the machine. The shielding design and its final approval are solely the responsibility of the physicist, even if generic vault design and shielding barrier thick nesses are available from other sources.

IV. Accelerator Installation

The physicist and facility engineer (if available) should work closely with the installation engineer. A close collaboration during the installation can reduce the acceptance testing time considerably. It is important that the facility personnel do not interfere in the work of the installation engineer but observe the progress in the background. As soon as the accelerator is capable of producing a radiation beam, a series of tests should be conducted to assure the safety of all concerned. These include

- Testing of door interlocks
- Testing of proper operation of the emergency off switches

- A preliminary calibration of the machine output in all modes
- A radiation survey in both controlled and uncontrolled areas around the treatment vault at the highest available dose rate and under worst irradiation conditions (without phantom)

A full radiation survey including the photon and neutron leakage measurements will still have to be completed to comply with regulatory requirements after a full calibration. The preliminary survey is done to assure the safety of individuals during the acceptance testing and commissioning.

V. Acceptance Testing

The installation is followed by acceptance testing by the physicist to ensure that the machine meets the product specifications and the purchase agreement. These tests are conducted according to the acceptance testing procedure agreed on between the manufacturer's representative and the facility physicist. Each facility should have the necessary equipment for acceptance testing. This includes a 3-D water phantom scanner with computer interface, ion chambers, and electrometer X ray films; film laser scanner; and precision level. It is important to know that each machine comes with the functional performance test values performed in test cells in the factory. These are helpful for comparison during acceptance testing. IEC Report 977 provides suggested values of functional performance that all manufacturers voluntarily comply with. A summary of the suggested values of functional performance is given in the Table. Some of these values are required to be more stringent for special application of the linac. For example, it is not unusual to require a radiation isocenter tolerance within 1 mm diameter of the linac scheduled to be used for high precision radiation therapy and radiosurgery.

Suggested Values of Functional Performance
(Extracted from IEC Report 977)

DOSE MONITORING SYSTEM	
Reproducibility	0.5%
Proportionality (> 1 Gy/ < 1 Gy)	± 2% / ± 2 cGy
Dependence on gantry angle	± 1.5%
Dependence on rotation of the gantry (moving)	± 2%
Stability of Calibration	
10,000 cGy delivery	2%
One-day	± 1%
One-week	± 1%
Stability in moving beam therapy, preset versus delivered	
Terminate irradiation by gantry angle; dose:	5%
Terminate irradiation by dose monitor system; angle:	3°

DEPTH ABSORBED DOSE CHARACTERISTICS

X Radiation	
Penetrative quality	(mfr)
Deviation from stated value	± 3%, ± 3 mm*
Relative surface dose for 10 × 10 cm field	(mfr)
Relative surface dose for maximum field	(mfr)
Electron Radiation	
Relative surface absorbed dose	(mfr)
Depth of maximum absorbed dose	≥ 0.1 cm
Practical range / depth of 80% absorbed dose	≤ 1.6
Penetrative quality	(mfr)
Deviation from stated value	± 3% ± 2 mm*
Stability of penetrative quality, electrons, variation with Gantry angle and dose rate	+ 1%, + 2 mm*

UNIFORMITY OF RADIATION FIELDS

X Radiation	
Flatness (max/min ratio)	
5 × 5 to30 × 30 cm	106%
to maximum square	110%
Stability of flatness with angular position of gantry and Beam limiting system	
< 30 MeV	3%
> 30 MeV	4%
Symmetry (ratio of symmetrical points)	103%
Maximum ratio of absorbed dose (at d_{max})	
5 × 5 to 30 × 30 cm	107%
to maximum square	109%
Wedge filtered X ray fields	
Wedge factor	± 2%
Wedge angle	± 2°
Electron Radiation	
Flatness (shape of isodose contours)	
80% contour to geometric edge, at base depth	15 mm
90% contour to geometric edge/corner at S	10 / 20 mm
Symmetry (ratio of symmetrical points)	105%
Maximum ratio of absorbed dose at 0.5 mm depth to absorbed dose on axis at S	109%

PENUMBRA	(mfr)

INDICATION OF RADIATION FIELDS	
X Radiation	
Numerical field indication (% is of field size)	3 mm, 1.5%*

Table, continued

Greater than 20 × 20 cm to maximum square	5 mm, 1.5%
Light field indication, edges (% is of field size)	
At normal treatment distance, 5 × 5 cm to 20 cm × 20 cm	2 mm, 1%
At 1.5 × normal treatment distance, 5 × 5 cm to 20 × 20 cm	2 mm, 2%
Center: NTD / 1.5 × NTD	2 / 4 mm
Reproducibility: Numerical field, light field edge	2 mm
Electron Radiation	
Numerical field indication	2 mm
Light field indication, edges	2 mm
Geometry of X ray beam limiting systems	± 0.5°
Illuminance and penumbra of light field	
Average illuminance	40 lux
Edge contrast ratio	4

INDICATION OF RADIATION BEAM AXIS	
Entry, X radiation (NTD + 25 cm)	± 2mm
Entry, electron radiation (NTD + 25 cm)	± 4 mm
Exit, X radiation (NTD –to+ 50 cm)	± 3 mm
ISOCENTER	
Displacement of X ray beam axis	± 2 mm
Displacement of indication of isocenter	± 2 mm
Indication of distance along radiation beam axis from isocenter	± 2 mm
ZERO POSITION OF ROTATIONAL SCALES	
Gantry, beam limiting device, table, tabletop	± 0.5°
CONGRUENCE OF OPPOSED RADIATION FIELDS AT ISOCENTER	1 mm
MOVEMENTS OF THE PATIENT TABLE	
Horizontal displacement for 20 cm vertical change	2 mm
Displacement of rotation axis from isocenter	2 mm
Angle between table and table top rotation axes	0.5°
Table height: 30 kg, retracted; 135 kg, extended	5 mm
Tabletop lateral tilt from horizontal	0.5°
Deviation of table top height with lateral displacement	5 mm

* = Whichever is greater. NTD = normal treatment distance. SMD = standard measurement depth.

Linacs equipped with special modes must be tested separately for each modality. For example, test TBI mode for maximum MU and dose rate; test high-dose-rate total skin electron therapy mode for maximum MU, dose rate, and field size interlocks; test electron arc mode for MU/degree and dose rate. Dynamic motion of the multileaf collimators should also be tested independently. AAPM has recently published a task group (TG-50) report on multileaf collimator dosimetry that describes the required testing procedures for multileaf collimator systems. There will be additional reports published on acceptance testing of intensity-modulated radiotherapy modules in the near future. In the meantime, physicists should follow the test procedures suggested by the manufacturers.

Other important aspects of acceptance testing are to assure the safety of the patients and machine operators and to provide critical baseline data for future quality assurance reviews. AAPM makes available three useful task group reports (TG-35, TG-40, and TG-45) that provide detailed discussions on accelerator safety, comprehensive quality assurance, and a code of practice for radiotherapy accelerators. It is essential that each physicist who is embarking on acceptance testing and commissioning a linac carefully read these reports.

VI. Commissioning

Satisfactory acceptance testing simply assures that the accelerator satisfies all agreed-upon specifications and pertinent safety requirements. The process of commissioning a linac for clinical use includes comprehensive measurements of dosimetric parameters that are necessary to validate the treatment planning systems used to select optimal radiation modality and treatment technique for individual patients. Commissioning also includes entry of beam data into a treatment planning system and testing of its accuracy, development of operational procedures, and training of all concerned with the operation of the accelerator.

Data collected during acceptance testing are often not adequate to commission a machine in the treatment planning system. Machine-specific beam data for commissioning is highly dependent on the dose calculation algorithms used in the treatment planning systems. The model-based dose calculation algorithms (convolution/superposition) require much less measured data than correction-based algorithms (equivalent TRP/TAR, etc.). Irrespective of the dose calculation algorithm, it is essential to have a minimum dataset that includes percentage depth dose, isodose distribution, and output characterization for a series of field sizes. It is very important that the measured dosimetric characteristics of the commissioned linac are compared with published data on the same make and model, if available. Radiological Physics Center (RPC) in Houston is a great resource for such data. RPC has measured data on practically all types of clinical machines in its database.

Physicists must avoid the pressure to initiate clinical treatments as soon as the acceptance testing is finished. Rushing into clinical implementation without completing proper commissioning can potentially cause harm to the patients. Therefore, an appropriate time that is based on the projected use of the machine must be set aside for this activity. It is imperative that the physicist must have proper instrumentation to collect all necessary data. The AAPM *Code of Practice for Accelerators* (TG-45) provides a detailed discussion on the commissioning philosophy and required machine-specific beam data. It also provides information on commissioning of most special procedures except intensity-modulated radiotherapy, which is fairly new. The National Cancer Institute has funded a work group on intensity-modulated radiotherapy. This group has recently published its report in the red journal (IJROBP 51:880-

914, 2001). The Radiation Therapy Committee of the AAPM has also formed a subcommittee, chaired by the author, to monitor the scientific activities on this subject, publish a guidance document for IMRT and propose the formation of new task groups. The subcommittee is ready to publish a guidance document that will assist clinical physicists who are interested in setting up an IMRT program.

VII. Quality assurance of the treatment delivery system

Quality assurance (QA) is defined as "all those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirement for quality". In radiation therapy, this has been defined as "all those procedures that ensure consistency of the medical prescription and the safe fulfillment of the prescription as regards the target volume, together with minimal dose to normal tissue, minimal exposure of personnel, and adequate patient monitoring aimed at determining the end result of treatment". QA is concerned with ensuring that the results achieved match the stated aims. Therefore, QA requires that aims are clearly defined and that endpoints are measurable in relation to standards. It is difficult to accurately quantify the effectiveness of QA, but it has been shown that careful quality control procedures do detect systematic and random errors that would have gone undetected otherwise. It is important to note that these errors add up quadratically. The cumulative error is influenced by the component that has the biggest error. Therefore, effective QA minimizes the dominant error. In general, the errors introduced by physical components in the radiotherapy process are much smaller than are errors introduced by the clinical component.

The aim of a quality assurance program for radiotherapy equipment is to maintain acceptable safety standards for the patient, staff, and general public while the equipment performs satisfactorily (based on functional performance specifications) throughout its lifetime. QA programs for all radiotherapy equipment should incorporate detailed considerations of the following general areas:

(a) Specification of the equipment, to include functional performance characteristics and tolerance limits;
(b) Acceptance testing of equipment, to ensure compliance with specifications;
(c) Equipment commissioning, to ensure that sufficient data are available to use that equipment clinically for its intended purpose;
(d) Establishing an on-going quality control program, to include tests and frequencies that evaluate its performance against baseline data obtained at commissioning. Tolerance limits and actions mandated by observed deviations should be predefined;
(e) Establishing a preventive maintenance program (to monitor and document operating conditions, faults, and parts replacement);
(f) Establishing a system of tests after repairs, to include a degree of independence for personnel responsible for repair and those responsible for performance verification;
(g) Setting up a system of documentation throughout the life of the equipment;
(h) Appropriate staff training in the safe clinical use of the equipment;
(i) Establishing internal and external quality audit procedures;
(j) Ensuring that associated quality assurance systems or procedures are in place for supporting or interrelated equipment and accessories;
(k) Ensuring that safe decommissioning and disposal methods are in place where necessary;

(l) Ensuring that electronic data communication is based on open industry standards where applicable;
(m) Ensuring that all regulatory mandates are met adequately.

The QA guidelines for equipment with mature technology are often developed by associated scientific/professional organizations. These guidelines are published either in peer-reviewed journals or as stand-alone reports. The problem is with emerging technologies for which little guidance is available for quality assurance. In these circumstances, the responsibility lies with individual radiation physicists to develop quality control procedures for those technologies to ensure their safe and accurate use in the clinic. In the United States, the AAPM has produced several task group reports that provide guidelines for radiation physicists to use in developing QA procedures for various processes in radiation therapy treatment delivery. These reports are widely accepted by the scientific community. ACMP, ACR, and NCRP also have produced several reports pertaining to QA. International reports on this subject include publications by ESTRO, ICRU, WHO, IAEA, and IEC. The radiation physicist should use these reports as guidelines to establish a customized QA program that caters to each clinical practice. Test procedures and frequencies of the tests should be selected on the basis of clinical use of equipment. The purpose of a QA program for equipment is to identify and minimize the sources of uncertainty and error, taking into consideration the economic, medical, legal, and regulatory implications. Turbulent times in the health-care field are rapidly changing public expectations. The value of a service or process is becoming ever more important. Therefore, the design of a QA program is often a balance of quality and accountability.

VIII. Safety Considerations

Computer-controlled linear accelerators with multileaf collimators are capable of delivering any radiation intensity pattern. Electronic portal imaging devices can provide real-time treatment verification. Vendors are developing and introducing new technologies for clinical use at a staggering rate. Their only obligation is to satisfy the appropriate regulatory mandates to assure minimum standards of product quality and patient safety. For example, all radiotherapy planning and delivery equipment is required to satisfy the Food and Drug Administration (FDA) guidelines before it can be sold for clinical use in the United States. International guidelines for radiotherapy equipment are set by the International Organization for Standardization (ISO). However, the equipment that satisfies FDA and ISO requirement is not necessarily perfect or free of faults or shortcomings. Therefore the onus is on the end user to perform independent testing and to establish quality assurance procedures to assure patient safety.

IX. Regulatory mandate

In the U.S., the use of external beam radiotherapy equipment (with the exception of radioisotope machines) is regulated by each individual state through a licensing or registration procedure. The Quality Management Program of the USNRC brought tremendously increased control of radiation-producing equipment, with the intention of increasing patient safety. Every state requires that all radiation-producing equipment be registered with the appropriate licensing agency of the state, and the equipment must be operated in accordance with the agency's regulations. These are generally in the nature of statutory law.

Most states have adopted regulations either from the regulatory guides of NRC or from documents produced by the Conference of Radiation Control Program Directors (CRCPD). These regulations are entitled "Suggested State Regulations for the Control of Radiation" (SSRCR). The agreement states are better able to enforce these regulations because they have more qualified personnel in their radiation control program who can ensure compliance. Non-agreement states have limited staff to enforce or develop regulations for safe use of radiotherapy equipment. Some states have adapted AAPM reports verbatim into their regulations. This is of great concern because AAPM reports are meant to be scientific reports, which provide guidance to radiation physicists to develop their own QA program. These should not be used as a standard of practice. Irrespective of how the radiation control program is implemented, QA procedures are usually a major requirement of all programs.

Another motivation for QA programs in radiation oncology departments is the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) accreditation. JCAHO requires that each hospital applying for accreditation develop a comprehensive set of standards to ensure patient safety. JCAHO is putting increasing emphasis on QA, QA audit, and continuous quality improvement initiatives. This fits in well with the emerging opinion that QA procedures should be based on the value of a service or process. Emphasis is put on clear definition of objectives of a QA program and continuous monitoring of its efficacy. One cannot simply follow recommended guidelines published in scientific reports.

Manufacturers of radiotherapy equipment must comply with several regulatory and voluntary mandates that provide the impetus for a well-designed QA program. One of the voluntary initiatives for vendors is ISO 9000 certification. The International Organization of Standards (ISO) has developed a series of standards and guideline documents that assist manufacturers in developing quality management programs. ISO certification is fast becoming a norm in the industry because of the competitive forces and globalization of the economy. ISO certification means that the manufacturer has gone through a rigorous audit of its product quality including design, manufacturing, installation, and service. The ISO works closely with the International Electrotechnical Commission (IEC), which prepares and publishes international standards for all electrical, electronic, and related technologies. IEC has published several important documents that provide specifications and suggested functional performance characteristics of radiotherapy equipment.
In the United States, the Federal Food and Drug Administration (FDA) regulates medical products that present a significant risk to patients. Manufacturers of these devices are required to go through a Pre-Marketing Approval (PMA) process by which the FDA evaluates the safety and effectiveness of these devices. Each manufacturer is required to demonstrate Good Manufacturing Practices (GMP), which is a mandated QA system. GMP covers several general areas of manufacturing. The important GMP for radiotherapy equipment includes design practices and procedures, control for components, device distribution and installation, device evaluation, device manufacturing records, complaint processing, and QA system audits. By satisfactorily demonstrating GMP to the FDA, a manufacturer earns a 510K clearance for marketing that product.

X. Summary

The discipline of radiation oncology is changing rapidly with continued advancement in treatment-planning, delivery, and treatment verification. A key component of the radiation therapy process is the treatment-delivery system. Linear accelerators offer the most important, practical, and versatile source of radiation for radiotherapy. Enhancements in linear accelerators during the past few years have been made possible largely through advances in computerization of linac hardware and the addition of multileaf collimator technology. The goal of these enhancements is to provide capabilities for more conformal radiation treatments and for potentially less morbidity. The complexity of treatments almost mandates that the treatment-delivery parameters be downloaded automatically into the computer-controlled linear accelerator. It is impossible to input the information manually. Therefore an integrated facility-management system is essential for conformal radiation delivery. It is not sufficient just to look at the dosimetric performance characteristics of the treatment-delivery system. Equal or more attention must be paid to the integration of all key components. The probability of treatment errors is much higher in a non-integrated system. It is anticipated that the focus on treatment delivery systems will broaden from the traditional evaluation of their performance characteristics to a more comprehensive evaluation of system's integration with other components such as treatment-planning systems, CT simulators, and facility-management system.

The complexity of the treatment delivery system mandates good QA and a complimentary preventive maintenance program to ensure safe and accurate treatments for patients. It is difficult to justify the value of comprehensive QA on the basis of hazard analysis because data in this area are sparse. One can only justify QA on the basis of standards of practice in the field. QA tests are both time-consuming and expensive. For example, The IEC recommendation for performance evaluation results in approximately 3000 tests per year on a dual photon beam linac. The number gets substantially higher if tests for dynamic beam delivery, MLC, and EPID are also included. Therefore, it is imperative that physicists develop a performance-based QA program that is efficient and effective.

This refresher course provides information on acceptance testing, commissioning and quality assurance of a computer-controlled linac. It is emphasized that great care and diligence should be exercised in selecting, installing, testing, and commissioning a linac. The time commitment and money can be substantial, and errors and oversights can be costly. Therefore, the responsible physicist must act responsibly and not compromise on any aspect of the process. The physicist's responsibilities can be summarized as follows:

- To develop requirements and specifications for the purchase of an appropriate linac
- To plan the facility (including shielding design)
- To monitor facility construction and machine installation
- To perform acceptance testing and safety checks
- To commission the machine for all designated clinical uses
- To establish treatment procedures and train personnel
- To prepare acceptance testing and commissioning documentation

- To establish quality assurance test procedures, frequencies, tolerance limits and action levels

XI. Reading Material

AAPM Report Series booklets

- The Physical Aspects of Total and Half-Body Photon Irradiation (1986)
- Total Skin Electron Therapy: Technique and Dosimetry (1987)
- Stereotactic Radiosurgery (1995)
- Basic Applications of Multileaf Collimators (2001)

AAPM Task Group Reports

- Clinical Electron Beam Dosimetry; TG-25 (1991)
- Medical Accelerator Safety; TG-35 (1993)
- Comprehensive Quality Assurance; TG-40 (1994)
- Code of Practice for Accelerators; TG-45 (1994)
- Quality Assurance for Clinical Radiotherapy Treatment Planning; TG-53 (1998)

IEC Reports 976 and 977

- Medical Electron Accelerators: Functional Performance Characteristics and Guidelines (1989)

IMRT Collaborative Working Group: Intensity Modulated Radiation Therapy: Current Status and Issues of Interest, IJROBP, 50:880-914, 2001

International Organization for Standardization (ISO).

- Quality management and quality system elements, ISO 9004 (1993).
- Quality management and quality assurance standards, ISO 9000 (1994)
- Quality systems -- Model for quality assurance in design, development, production, installation and servicing, ISO 9001 and ISO 9002 (1994)
- Guidelines for developing quality manuals, ISO 10013-2 (1995)

Appendix

Addendum to Purchase Agreement with Elekta Oncology Systems, Inc.

1. General Requirement:

Elekta Oncology Systems (EOS), Inc. shall sell one (1) medical linear accelerators as specified in purchase agreement numbers XXXXXXXX, dated June 22, 2002 to XXXXXXX, XXXXX, XXXX. The systems will be installed at XXXXXX, XXXXX, XXXX. The delivery of the first machine (with 4 MV, 6 MV and 18 MV photons) shall be no later than November 15, 2002. A second machine (with 6 MV and 18 MV photons) will be ordered at a later date (most likely in the first quarter of FY 2003-2004 and subject to XXXX board approval) to replace the second high energy Philips SL20. Elekta Oncology Systems (EOS) shall be responsible for rigging both machines in the department and bear all associated costs. The installation and the acceptance testing of each linear accelerator shall not exceed six (6) weeks from the time of delivery. The acceptance testing shall be performed according to the guidelines provided by IEC document 977. The physics staff at University of Florida shall fully cooperate with EOS installation engineers in meeting this objective and provide all test equipment. Both accelerators shall seamlessly interface with the IMPAC Medical Systems facility management system through iCom interface on day one of clinical use of each machine for conventional treatments. IMRT delivery capabilities based on inverse treatment planning on ADAC Pinnacle system shall be available from day one of clinical use of each machine. IMRT delivery may occur initially by direct input of delivery parameters into RT Desktop database. Eventually, all IMRT delivery must occur directly through IMPAC system. *EOS shall provide a realistic timeline for IMPAC/RT Desktop connectivity before the execution of this purchase agreement*. EOS shall be fully responsible for providing a FDA cleared hardware and software package for IMRT planning and delivery if for some reason IMRT interface between ADAC and IMPAC/RT Desktop is not available from day one of clinical use of each machine.

2. System Configuration and Specifications:

Each accelerator and its ancillary equipment shall meet or exceed the performance specifications described in the product data brochures: SLi Plus Digital Linear Accelerator, MLCi multi-leaf collimator system, Precise Patient Support System, iViewGT electronic portal imaging system, and the Elekta Precise Treatment Desktop (including Premium Therapy modules). In addition each linear accelerator shall satisfy the following:

- The mechanical isocenter (as described by the locus of gantry, collimator, and couch rotational axes) shall be located within a sphere of 0.75-mm radius.
- Each accelerator shall be equipped with a high-dose-rate mode for both photon and electron beams.

- The RT Desktop for each linear accelerator shall finally provide an integrated platform for MLC, EPID, dynamic control of Precise Table, and advanced treatment techniques including IMRT (Step-and-Shoot) and Dynamic Therapy (IMAT and Sliding Window) through DICOM-RT protocols. Note: It is understood by both parties (EOS and XXXXX) that seamless connectivity of all modules on RT Desktop is not available at this time. EOS shall provide the hardware and software upgrades necessary to connect all modules as they become available for clinical patient treatment at no cost to XXX. EOS shall be responsible for providing all required licensing agreements for clinical implementation, recording and printing of IMRT treatments.
- All standard monitors shall be flat panel and of the same size as described in the specification sheets. EOS shall provide a software package that will allow one plane modulation of radiation intensity similar to the one by Varian (EDW) or Siemens (VW).
- Each accelerator shall be equipped with two (2) hand pendants.
- IView system shall be upgraded to iViewGT system at no additional cost to XXXXX on each accelerator as soon as it becomes clinically available.
- EOS shall provide a body frame (designed by Lax) for high precision extra-cranial localization at no additional cost to XXXX.
- EOS shall be responsible for providing seamless transfer of DICOM-compatible images from iView to IMPAC facility management system.
- EOS shall evaluate the adequacy of existing water chiller for controlled water temperature in new machines. EOS shall be responsible for all upgrades, if necessary to the existing chiller system.
- EOS shall be responsible for acquisition and installation of setup laser systems for each accelerator treatment room at no additional cost to XXXXX.

3. Special Requirement:

- EOS shall provide two all-expense-paid visits to the Elekta factory (Crawley, England) for one XXXX hospital engineer to participate in the test cell evaluation of each linear accelerator purchased under this agreement.

4. Warranty:

- EOS initial warranty shall be for two years from the day of acceptance testing of each machine.
- EOS shall guarantee an uptime of 98% calculated yearly during the warranty period
- A penalty for uptime less than 98% per year shall result in the reduction of $5,000 in the cost of the spare parts contract for each machine for the subsequent year for each 1-% additional downtime.
- Each week of delay in installation and acceptance testing of an accelerator shall result in an increase in the warranty coverage from EOS for the accelerator by one month.

5. Net System Price:

The net price for the systems as specified in purchase agreement number PTXXXXXXX and the addendum to the purchase agreement shall be **$ x,xxx,xxx**

6. **Technology Transfer Center:**

EOS proposes to remove the existing SL-20 machine, refurbish it to Sli series machine and install it into the spare vault at xxxxx. The refurbished machine will be the state-of-the art Elekta Sli series machine with the latest technology. This machine will be used solely for translational research by researchers from ELEKTA consortium and XXXX. ELEKTA shall be fully responsible for the spare parts and maintenance of this machine. This machine will be a core facility for the proposed ELEKTA International Technology Transfer Center (EITTC) at XXXX. This center will be used by ELEKTA to field test new technical innovations in a clinical setting and train end users. Any use of other XXXXX facilities and resources for EITTC activities shall be negotiated separately at an appropriate time.

Addendum prepared by:

_____ Date:_____

_____

Accepted by Seller's Duly Authorized Representative:

_____ Date:_____

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