Radiotherapy Device Purchase, Acceptance Testing, and Clinical Commissioning

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Disclosures

I am on the Board of a non-profit Center for the Assessment of Radiological Sciences; an organization dedicated to improving the safety of radiotherapy.
Learning Objectives

to understand the process of radiotherapy device, purchase, acceptance testing, and clinical commissioning
Purchase, Acceptance Testing, and Clinical Commissioning of a Linear Accelerator; An Example
The Process

- evaluation of clinical needs
  - Ad hoc team of radiation oncologist, physicist, therapist, and facility engineer
- review of specification and purchase agreement
- design and construction of the facility
- installation of the equipment, safety checks, and radiation survey
- acceptance testing of the equipment
The Process

- commissioning of the equipment for clinical use
- final report and documentation
- training of the staff in the safe and efficacious use of the equipment
- establishing baseline quality assurance parameters and schedule
Decision Tree (Linac Purchase)

1. Compare cost, delivery time, service, etc...
2. Rank importance of the above parameters
3. Is the bidding process required?
   - Yes: Prepare a request for proposal
   - No: Continue with the decision process
Select machine based on the above consideration

Prepare a request for proposal

Can the budget be changed?

Is the space allocated adequate?

Is the cost of installation greater than budget?

Can space be changed?

Proceed with acquisition

Decision Tree (Linac Purchase)

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Purchase Agreement

- purchase through bidding process
- if the purchase is not through a bidding process then develop final specifications in close collaboration with the manufacturer’s rep
  - Review IEC 60976 and IEC 60977
- product data and specification sheets can serve as a good starting point for the purchase agreement
- special requirements can be added as an addendum
Important Considerations

- What is the scope of guidance available for the equipment under consideration?
  - TG reports, published literature, vendor provided information
- Is clinical workflow for the equipment well-defined?
- Are there any interconnectivity and interoperability issues?
- Is adequate dosimetry and QA equipment available

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Responsibilities of the Physicist

- develop a comprehensive acceptance testing document with a detailed test procedure to verify each term of the agreement & machine specifications. This document should be shared with the manufacturer’s representative before the installation begins so that all ambiguities are clarified in advance.
  - Manufacturer’s supplied acceptance test procedure may be adequate
Responsibilities of the Physicist

- review facility layout with planning and installation department of the accelerator manufacturer
- ensure optimum design for workflow, equipment layout and special requirements
- coordinate meetings with equipment planning coordinator, architect and the contractor
Responsibilities of the Physicist

- review potential problems regarding electrical power supply, conduit layout, air conditioning, chilled water requirements
- review shielding design even if generic vault design and shielding barrier thicknesses are available
Acceptance Testing

- ensure that the machine meets product specifications and purchase agreement.
- These tests are conducted according to the acceptance testing procedure agreed on between the manufacturer’s representative and the facility physicist.

Acceptance testing is NOT clinical commissioning
Clinical Commissioning

- Fully characterizing the delivery system in the treatment planning system (TPS) for all clinical beams and anticipated treatment techniques
  - Measure data required by the TPS
  - Measure data to validate the beam model
- Quantify the measured versus computed dose for different scenarios
- Perform end-to-end test
- Establish baselines for periodic QA
- Develop standard operating procedures
- Train the therapy staff in safe operation of the equipment
- Prepare final documentation for clinical commissioning

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Homicide Machine Zaragoza, Spain December, 1990

- malfunctioning linac—electron mode
- fault improperly fixed by an inexperienced service engineer
- no post-repair dosimetry checks for 2 weeks
- several patients (27) overdosed
- several known deaths

Establish written policies for equipment repair and post-repair test procedures
Design error in accelerator control software

- AECL Therac 25 computer controlled linac software glitch caused machine to operate in the e- mode with an energy of 25 MeV but with a current that is appropriate for photon beams resulting e- dose at \( d_{max} \) was 160-180 Gy in one sec or less
- six patients overdosed; two (2) died from overexposure

Establish explicit guidelines for dealing with equipment malfunctions
Incorrect use of a \( \rho \rho \) chamber

- A senior physicist puts a label on one side of a chamber, indicating the side on which the beam should be incident (labeled incorrectly although he used it correctly).
- A new physicist used the chamber to calibrate \( e^- \) beams by using the labeled side for beam entry.
- 6-12 MeV (8-20\% overdose), 16 MeV: correct dose.
- Mailed TLD service identified the problem.

**Avoid ambiguities**
Error in correction for atmospheric pressure

- Institution didn’t have a barometer. Physicist used the pressure reported by the airport which was corrected to sea level but which was inappropriate for the site of the physicist which was located at an elevation of 1000 m.
- Incorrect pressure resulted in an overdose of 13% to patients

Do not compromise on test equipment
Lack of consistency between dosimetry at affiliated institutions

- 3 radiation oncologists, 2 physicists work at 3 affiliated hospitals.
- Two sets of dosimetry equipment (ion chamber, electrometer) were used to calibrate the machines at these facilities.
- Use of an incorrect calibration factor (unknown to the physicists) led to a 15% discrepancy in the calibration between two facilities.
- Physician notices a difference at the clinical results at the two facilities but adjusts prescriptions; prescribes 70 Gy to the prostate at one institution and 60 Gy at the other place.

Establish explicit policies and procedures
Treatment with an accelerator operated in the non-clinical mode

- Problem with the selection of electron and x-ray energies
- Chief radiation oncologist asks engineer to alter the machine so that patients could be treated in the non-clinical mode
- Engineer alters the machine and writes the instructions on how to use the machine in the non-clinical mode
- 13 patients were treated correctly; the last patient was treated with a 10 MeV e-beam. The 14th patient needed treatment using 20 MV photon beam.
- Interlock system failed due to a power supply problem resulting in no flattening filter and no monitor chamber in the beam.
- High degree of overexposure.

Never override equipment interlocks
Summary

• Critically evaluate clinical requirements and facility constraints when purchasing new equipment
• Systematically review background information including AAPM Task Group reports, other reports, and training materials
• Develop a plan for acceptance testing and commissioning
• Develop a plan of training for medical physicist and other staff
• Evaluate staff time commitment and manage appropriately
• Perform phantom-based tests, including end-to-end tests
Summary

- Test the effects of not following the correct procedures, and also establish the operational limits on the equipment, outside of which the equipment’s reliability diminishes.
- Produce a commissioning report, which is dated and signed.
- Audit the commissioning data and report by an independent, qualified medical physicist.
- Check the beam outputs of radiation-producing units by an independent agency.
- Check phantom dosimetry by an independent agency, if appropriate.
- Develop a plan for roll-out to staff, including dry-run test cases where appropriate.
Every patient with cancer deserves to receive the best possible management to achieve cure, long term tumor control or palliation: this is the major goal of cancer management.
Every radiation oncology department must establish a comprehensive quality assurance program that provides the organizational structure, responsibilities, procedures, processes and resources for assuring the quality of patient management.
A radiotherapy delivery system is deemed clinically commissioned when:

a) Measured functional specifications match manufacturer’s specifications
b) All clinical beams are fully characterized in the TPS
c) Sufficient baseline data are available for setting up a QA program
d) An independent check validates delivery system output calibration
e) An end-to-end test confirms the expected accuracy of treatment delivery
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The RPC’s credentialing criterion of, 7%/4mm for IMRT is based on:

a) A recommendation from the AAPM Therapy Physics Committee
b) A recommendation from the AAPM Summer School on IMRT
c) Best IMRT practices in the community
d) Statistical analysis of IMRT data from multiple institutions
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