Commissioning and Implementing a Quality Assurance Program for New Technologies

Jacob (Jake) Van Dyk
Manager, Physics & Engineering, LRCP
Professor, UWO

University of Western Ontario
Disclosure

- License agreement with Modus Medical Devices, Inc., London, Ontario, Canada
Outline

- Terminology
- New technologies
  - Basic requirements
  - Implementation process
- QC program
- New approaches
- Learning from errors
- Summary

IMRT CWG, IJROBP, 51, 880, 2001
Quality Assurance

• “All those *planned and systematic actions* necessary to provide adequate *confidence* that a *product or process will satisfy given requirements* for quality”  [ISO 9000, 1994]

Poor quality

Good quality
Quality Control

• “The regulatory process through which the actual performance is measured, compared to existing standards and finally the actions necessary to keep or regain conformance to the standard.”

[ISO 9000, 1994]
(Total) Quality Management

- **TQM**: “…that aspect of overall management function that determines and implements the quality policy and, as such, is the responsibility of top management.”

- **QM**: “…all the activities that are intended to bring about the desired level of quality”

QA in Radiation Therapy (RT)

- Two considerations in radiation therapy

Need for accuracy in RT process

Avoidance of treatment errors

![Graph showing relative response of normal tissue and tumor to different doses of radiation.](Image)
Accuracy in RT Process

- General accuracy desired in dose delivered to patient: 5%
- For example, …

<table>
<thead>
<tr>
<th>Uncertainty Type</th>
<th>Uncertainty Range (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A Absorbed dose to reference point in water phantom</td>
<td>2.5</td>
</tr>
<tr>
<td>B Determination of relative dose (Measurement away from reference point)</td>
<td>2.5</td>
</tr>
<tr>
<td>C Relative dose calculations</td>
<td>2.5</td>
</tr>
<tr>
<td>D Patient irradiation</td>
<td>2.5</td>
</tr>
<tr>
<td>E Overall</td>
<td>5.0</td>
</tr>
</tbody>
</table>
Avoidance of Treatment Errors

• Error
  • “The failure of planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning).”

  *Institute of Medicine. To Err is Human: Building a Safer Health System, 2000.*
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So, you are about to buy a …

• CT Simulator
• PET/CT
• MR Simulator
• Treatment Planning System
• Tomotherapy
• Linear accelerator
  • Cone Beam CT
  • Gating system
  • Volumetric arc
• Cyberknife
• …or any other RT technology…

…what do you do?
Process for Getting (New) Technology into Clinical Service

- Clinical needs assessment
- Definition of specifications, selection and purchase process
- Installation
- Acceptance testing
- Commissioning
- Training
- Clinical use
- Quality control (QC)
  - Periodic
  - Patient specific
Clinical Needs Assessment
Sample Questions

- Which patients will benefit?
- How many patients per year?
- Number of procedures/fractions per year?
- Will new procedures provide cost savings over old techniques?
- Would it be better to refer patients to specialist institution?
- Can we handle the technology (infrastructure)?
- Will the technology enhance the academic program?
- What is the organizational risk in implementation of the new technology?
- What is the cost impact?
- What maintenance is required?
- What training is required?

*Table 2.1, Van Dyk, Modern Technology of Radiation Oncology, Vol 1, pg 23, 1999.*
Selection Process

- Process has various possibilities
  - One person makes decisions
  - Preferred: Small task group of relevant players
    - E.g., Rad Onc, Med Phys, Dosimetrist, RT, Engineer
      - *Esp those involved in clinical implementation/use*

- Send out request for information
  - Product description
  - Detailed specifications
  - Facility requirements
  - Budgetary quote, including quote on options
  - Training
  - Warranties
  - Service
Vendor Demonstrations/Site Visits

• Considerations
  • Bring product to institution or
  • Have vendor make product presentation to interested staff
  • Visit factory
  • Visit centers with identical technology in clinical use
    • Discuss advantages and disadvantages
Define Specifications

• Based on manufacturers’ specifications, get other background information (brochures, publications, users, etc)
  • Summarize specifications that are required or preferred
Tender Process

• Tender document
  • Technical specifications
  • Sample tender outline

• Benefits
  • Requires user to think about specs
  • Requires vendor to be specific about capabilities & limitations
  • Provides legally binding contract
  • Provides competitive bidding
Purchase

- Follow-up info on tender response
  - Further details
    - Re: configuration, no. licenses, other questions, price
    - Software/hardware service/upgrade contracts
  - Training
  - Compatibility with image transfer devices (CT, MRI, etc)
  - Compatibility with data transfer to:
    - RT machines, simulators, R&V system
  - Acceptance testing protocol
- Negotiate final price

- Get answers in writing!!

*If it is not in writing, it’s like it has not been promised!*
Acceptance Testing

• Immediately, post-installation
  • Vendor representative present

• All items delivered, installed
  • Accessories, manuals, circuit diagrams

• Technology must
  • Function properly
  • Meet specifications
    • Detailed acceptance tests
Tests Defined by IEC

- **Type test**: “For a particular design of device or equipment, a test by the manufacturer to establish compliance with specified criteria.”

- **Site test**: “After installation, test of an individual device or equipment to establish compliance with specified criteria.” “Note: The recommended replacement is ACCEPTANCE TEST.”

- Site test = Acceptance test
For Treatment Planning Systems: Testing Process Recommended by IAEA

• Manufacture to perform series of “type tests”
• Type test results should be documented and made available to user
• “Site tests” (acceptance tests) should be a subset of type tests performed at the time of TPS installation
  • Results compared to results of type tests
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Commissioning

- Prepare system for clinical use
  - Provides experience/training for users
  - Determine appropriate measured data
    - %DD, TAR, TPR, beam profiles, wedge profiles, attenuation data, output factors, brachytherapy source data, etc
- Perform series of commissioning tests
  - Special tests for new features
    - IMRT: Assess leaf positioning errors, small MU issues, MLC leaf sequencing
    - IMAT: Assess combination of leaf positioning & gantry angle
    - Tomotherapy: Assess dose delivery for fan beams
- Provides capabilities & limitations
- Assess results to see if they comply with specifications
- Provides documentation of system performance
- Results of commissioning tests used later for QC tests
Equipment

- Examples
  - CT scan test phantom
  - Water phantom scanning system
- Detectors
  - Ionization chambers: %DD, calibration
  - Diodes/small ion chambers: small fields, profiles, build-up, electrons
  - Parallel plate chambers: build-up, electrons
  - Film
  - TLD, MOSFET
- Phantoms
  - Slab geometry: film, cork - inhomogeneities
  - Anthropomorphic
  - IMRT DQA phantom
- Film densitometer
New Equipment/Phantoms

- RapidArc® Dosimetry
Gating Phantom - Prototype

Modus Medical Devices, Inc
Gating Phantom - Commercial Version

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Problem with Conventional Approach

- QC protocols are prescriptive
  - For established technologies
- New technologies are evolving at very rapid rate
  - IMRT, IGRT, SBRT, ART, 4D – gating
  - New imaging for target volume delineation
    - PET/CT, MR, SPECT, functional CT, …
  - QC protocols are non-existent or limited in approach
- Conventional approach requires
  - Multiple tests/measurements
- Difficult to do it all
  - Required QC tests are more sophisticated
  - Resource limitations
AAPM Task Group 100

• Method for Evaluating QA Needs in Radiation Therapy
  • Chair: Saiful Huq

• Charge
  • “Identify a structured systematic QA program approach that balances patient safety and quality versus resources commonly available and strike a good balance between prescriptiveness and flexibility”

• Current Projects
  • A Failure Modes and Effects Analysis (FMEA) of the IMRT and HDR Brachytherapy processes
AAPM Task Group 100

• For IMRT, 216 Failure Modes identified.
• For each Failure Mode, O, S and D values are assigned by Task Group and multiplied to yield Risk Probability Number

\[
\text{Risk probability number} = O \times S \times D
\]

• \( O \) = Occurrence: describes the probability that a particular failure mode occurs
• \( S \) = Severity: describes the consequences if not detected
• \( D \) = Detectability: describes the probability that the failure mode will not be detected in the absence of QA
• \( O, S, D \) assigned values between 0 to 1
  • In industry, \( RPN < 125 \), little concern
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Relevant ICRP Publications

(ICRP = International Commission on Radiation Protection)

ICRP 44, 1985

ICRP 73, 1996

ICRP 85, 2001

ICRP 86, 2001
Relevant IAEA Publications

1998
Accidental Overexposure of Radiotherapy Patients in San José, Costa Rica

2000
Lessons Learned from Accidental Exposures in Radiotherapy

2001
Investigation of an Accidental Exposure of Radiotherapy Patients in Panama

2004
Accidental Overexposure of Radiotherapy Patients in Białystok

2006
Applying Radiation Safety Standards in Radiotherapy
WHO Patient Safety in Radiotherapy

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Learning from Errors: Themes

- Peer review audit
- Planning protocol checklists
- Independent checking
- Audit of equipment commissioning and processes
- Staff competency assessment (training/education)
- Process and equipment quality control
- Information transfer with redundancy
- Process governance
  - Define accountabilities
  - Formal QA structure
- Error reporting and quality improvement
- Adequate staffing
- *In vivo* dosimetry
- Defense in depth
- QA culture
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“Keep the Patients Safe”

• “Human error per se does not usually kill patients, but human error in a weak system can injure or even kill. A weak safety culture, weak operational practices, weaknesses in the presence of protocols and training, weaknesses in communication and serious weaknesses in the packaging and design of drugs. In short, comprehensive systems weaknesses greatly increase the risk of harm coming to a patient.”

Sir Liam Donaldson, Chief Medical Officer, England, March 2003
http://www.iqa.org/publication/c4-1-78.shtml
Summary

• New technologies are evolving at an unprecedented rate
• Existing QA guidelines are inadequate for new technologies
• New QA guidelines are evolving & attempt to deal with total process
  • However, detailed recommendations remain to be developed
• In the meantime, need to maintain the old paradigm of commissioning and testing parameters specific to new technologies to minimize risk of large uncertainties and errors for these technologies
Key Issues

Education

Verification

Documentation

Communication