Quality assurance product development; from concept to a clinical device

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Disclosure

- I am employed by Sun Nuclear
- I have financial investment in Sun Nuclear

Outline

- RT Landscape
- QA Drivers
- Challenges
- Development
- Verification
- Support

RT landscape

Primary Systems in RT	QA Systems for RT
• Acceptance & Commissioning	• Water & solid phantoms, detector arrays, electrometers, ion chambers, diodes
• Planning	• Software, detector arrays
• Imaging	• Solid phantoms, software, ion chambers
• Radiation Delivery	• Software, detector arrays, solid phantoms, lasers
• R&V/OIS	• Software
• Personnel	• Software
Without these, RT cannot be delivered	Without these, residual failure modes in primary systems have no backup

Quality = the standard of something as measured against other things
Assurance = a declaration intended to inspire confidence

QA Independence – A critical Driver

Quality Assurance is

- the maintenance of a desired level of quality in a service or product,
- by means of attention to every stage of the process of delivery or production.

"Seventy percent of the institutions visited (by RPC 1996 – 2004) had discrepancies in one or more significant dosimetry parameters." (measurements with an ionization chamber in a water phantom).

G S Ibbott 2010 J. Phys.: Conf. Ser. 250 012001

QA Independence – A critical Driver

RT Technology Evolution: Geometric in complexity

- Blocked fields → Electronic Wedge → MLC → IMRT → VMAT → HDRT non-coplanar
- Independent QA does more than just maintain desired quality,
  - **it also drives improved RT by pointing out systemic errors and OFI's**

OFI – opportunity for improvement

How do you know without an independent check??

SAM Question

Independent quality assurance in radiotherapy LINAC performance reduces residual risk inherent in the treatment system's integrated QA.

a) True

b) False

Answer: a

"A critical aspect of a QA program is independence; that is, the QA procedures conducted to assure the quality and accuracy of the product or process (in this case the delivery of radiation therapy) must be independent of the product or process itself. The failure to establish independence can lead to the risk that the QA device merely mimics the performance of the parameter being measured, masking an error or change."

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QA Drivers – how do we know what to develop?

- Treatment device enhancement
  - Electronic wedge, MLC, IMRT, IGRT, VMAT, HDRT
- Treatment plan compliance to Treatment device
  - Complexity of device enhancements on beam modeling
- Consensus
  - AAPM Task Groups, Vendor requests, and individuals "from members like you"
- Clinical Constraints
  - Time, resource consolidation, certification audit
- QA Technology Evolution
  - New pathways to achieve the verification
    - digital vs. analog
    - calculation vs. measurement
    - detectors
    - microprocessors
    - Communications
    - computers, databases, etc

Historical QA Driver examples

Enhancement	Response
• **LINAC evolution with high dose rates and electrons**	• **Electrometry to enable Pion and Ppol**
• Electronic Wedge	• 1D arrays
• IMRT	• Resource constraint required 2D arrays
• IMRT beam modeling	• High spatial resolution 2D arrays • 3D dose reconstruction and DVH QA
• SRS precision	• Improvements in Winston Lutz tests
• TG-142	• Imaging & Workflow QA software
• TG-100	• Still no response
• MR guided RT	• Device compliance in magnetic fields
• Accreditation Audits	• Consolidation of QA data and WEB review

QA Challenges

- Multi-Vendor environments
  - Data encryption - Data formats – encrypted or proprietary – make it difficult to evaluate performance
- Modality Evolution
  - Treatment and imaging modality continue to evolve
    - Tomo, Cyberknife, SRS, IMRT, VMAT, IGRT, MR LINAC, Protons
- Complexity
  - Non-standardized processes, equipment; potential for human error
- Innovation
- Independence

Product goals

- Detectability criteria to meet clinical goals – Performance Objectives
- Clear User Workflow – Transparency, no black box
  - Automation
  - Flexibility
  - Creativity
  - Imagination
- Flexibility – Avoid unnecessary constraints, Enable user to adapt
- Data management – Useful summary reports and trends

Development Time

From Concept to Release: Typically 1 to 3 years

1: Concept phase
- Does the proposed product solve a problem?
- Can a solution be built cost-effectively?
- Will end-users buy it?
- Retire key technological risks

2: Develop & Test phase
- Formalize requirements (design inputs)
- Perform Risk Analysis and define mitigations if needed
- Build prototypes and test…wash, rinse, repeat as-needed
  - Typically 2-3 iterations are needed (this is often the "long pole in the tent" due to long lead times on materials!)
- Build final prototypes and validate
- Submit for Regulatory clearances as needed

3: Launch phase
- Create Manufacturing material inspection instructions, and assembly & test instructions
- Train employees on how to build the product
- Train Support personnel on how to support the new product effectively
- Train Sales personnel on how to effectively sell the new product
- Finalize Marketing materials and launch!

4: Post-release / Monitor phase
- Watch customer complaints…did we get it right?
- Do Support cases show any trends pointing to a systematic problem?
- Are there enhancements needed to improve the product?

Verification at SNC

Engineering Environment

Design Acceptance Testing:

- Mechanical
- Electrical
- Software

Clinical Environment

Performance Acceptance and Validation Testing

- Data acquisition
- Analysis – criteria to meet clinical goals
- Clinical LINAC, RV, and TPS environment at SNC since 2005

R&D TEST BENCH

Sun Nuclear's TrueBeam

Support

- Training
  - On-Site
  - Factory
- User Guides
- Software Updates
- Maintenance Agreements
- Qualified Staff
- After Hours

Without support, we do not have a product.

At SNC, we have more then 40 support personnel around the world with various backgrounds including clinical physics.

Summary

Integration of QA into the vendor delivery system

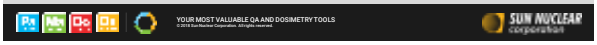
-- and --

- Independent QA under guidance of the clinical physicist

Both are essential to maintain a quality product in radiotherapy and inspire confidence in the clinic of quality treatment.

Independent QA serves as an auditor of the clinic's delivery systems, reducing their residual risk.

Thank You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