

RadioOnkologie



UniversitätsKlinikum Heidelberg

Quality Assurance for particle beam therapy PTCOG Educational Workshop, Essen 2013

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- Introduction: why QA is needed ?
- General Aspects of QA
- QA for particle therapy some examples
- Conclusions

Fatal Errors in TP

January 24, 2010

THE RADIATION BOOM

The New York Times

Radiation Offers New Cures, and Ways to Do Harm

621 mistakes in NY state 2001-2009: At average 2 mistakes contributing

Quality assurance flawed	Data entry or calculation errors by personnel	Blocks, wedges or collimators misused		Treatment plan flawed		Staffing	
355	252	174	133	96	77	60	52
Patient's physical setup wrong					Hardware malfunction		are tion

- Computer, software or digital information transfer malfunction 24
 - Override of computer data by personnel 19
 - Miscommunication 14
 - Unclear/other 8

Source: NY State Dept. Of Health

Common Sources of Error

IAEA: Lessons Learned from Accidental Exposures in Radiotherapy, Safety Reports Series No. 17, IAEA, Vienna (2000):

Most TP errors can be summarized by a lack of:

- Education
- Verification
- Documentation
- Communication

Framework

Acceptance test

Assure that the *specifications* of a product and *safety* standards are fulfilled (radiation and electrical hazards) Tests are performed in the presence of a manufacturer's representative.

Commissioning

Characterization of the equipment's performance over the whole range of possible operation following acceptance incl. the preparation of procedures, protocols, instructions, data for clinical service. It includes development of SOPs and QC tests and training.

Periodic QA

Procedures which are performed regularly and which allow to assess, if the initial requirements are still fulfilled; may involve different procedures than during commissioning;

Patient specific QA

Procedures performed on patient specific treatment plan or equipment.

Framework: QA and QC

Quality assurance:

All planned and systematic actions necessary to provide confidence that a product will satisfy given requirements for quality and safety.

Quality Control:

The **regulatory process** through which the actual quality performance is measured, compared with existing standards, and the actions necessary to keep or regain conformance with the standards.

The QC process:

- (a) the definition of a specification;
- (b) the measurement of performance associated with that specification;

(c) the comparison of the measurement with the specification;

(d) the possible action steps required if the measurement falls outside the specification.

As part of step (d), one needs to define, which deviation from the reference is tolerable (the tolerance).

Vendor responsibility



- Specifications of system capabilities and limitations
- System documentation (system design and use)
- User training: (1) basic training
 (2) commissioning process
 (3) system management
 (4) implementation of a QA program
- Information on updates, system alterations
- Communication regarding bugs, error reporting

User responsibility

- Supervision, management of system
- Implementation of the system and upgrades
- Record keeping associated with implementation
- User training: clinical use interpret. output
- Communication: with the vendor and the users esp. regarding errors, limitations and updates.



Legal Aspects of QA

- Intl. Recommendations (IAEA TecDoc 1040 QA in RT, ICRU)
- AAPM TG 24 "*Physical aspects of QA in R*T, 1998" and TG 40 "Comprehensive QA for RO, 1994", etc...
- In progress: TG 224 Proton Machine QA (start 2012)
- European directives (e.g. Medical Device Directive)
- <u>National radiation protection regulation</u>
- National Guidelines for medical application of radiation
- National and International standards (ISO, IEC), e.g.:
 - DIN 6870-1: Quality management system in medical radiology Part 1: Radiotherapy

• IEC 62C536 (draft): Medical electrical equipment - Basic safety and ess. performance requirements for light ion acc.

There are *few detailed and hard requirements*. User always has to define a specific QA program.

Framework: Steps in QC

- 1. Definition of the **specifications** (performance and test characteristics)
- 2. Definition of tolerances
- 3. Definition of detailed tests for all characteristics via **SOP's**
- 4. Performing tests and **Comparison** w. specs
- 5. Possible Action steps if outside tolerance

The tolerance is the largest acceptable deviation of a test characteristic from the reference value.

Tolerances are always specific for a certain facility

The involved uncertainties of measured values have to be included.



Beam width out of tolerance

Sources of uncertainty (TPS-QA)

- Dose measurements (Ion chamber, film, etc)
- Setup of phantoms
- Beam delivery (esp. in scanning, dose, field homogeneity, stability)
- Geometric parameters (acc. of readings, instruments)
- Differences between commissioning and constancy checks
- Dose calculation algorithm
- Approximations of the beam model

Examples of Test procedures @ HIT

HIT Betriebs-Gesellschaft am Universitätsklinikum Heidelberg mbH Im Neuenheimer Feld 450 69120 Heidelberg Geschäftsführer: Prof. Jürgen Debus

Documentation of comissioning procedures and tests of safety and performance characteristics at the Heidelberg Ion Beam Therapy Center

> Version 1.0 Stand: 18. Juli 2008



A. Introduction

- B. Measurement conditions and -tools
- C. Commissioning
- D. Safety tests

E. Acceptance and constancy tests

- E.1 Beam quality
- E.2 Dosimetry
- E.3 Patient positioning
- E.4 Treatment planning
- F. Patient related tests
 - F.1 Workflow verification
 - F.2 Dose verification

Daily QA

•Daily checks:

- Tests of the control system:
 beam position, feedback loop, interlocks, ...
- Film homogeneity, field alignment
- Monitor calibration f. 6 energies
- Dose in reference field
- Safety checks:
 - Laser/imager alignment
 - Emergency switches
 - treatment table



Required time

- Safety- & alignment: 20 min
- Monitor calibration: 15 min
- Dosimetry in ref.-field: 10 min

Beam quality

Ion type (purity<10⁻⁴)

Intensity (HIT: 15 steps)
- p: 8x10⁷-2x10¹⁰ ions/s,
- ¹²C: 2x10⁶-5x10⁸ ion/s

Bragg peak position

Beam position

- scan position, not only on central axis
- focus & energy dependent
- online correction or interlock

Beam width (HIT: 6 steps)

- Energy dependent (p: 7-20 mm/12C: 3-20 mm)
- Protons: depth dependent (scattering)

Dependence on gantry angle

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Measurement of depth dose with the Peakfinder

Water absorber of computer controlled variable thickness



Fld

IC

beam

Ref.

IC

Measure relative depth dose distribution (integrated laterally) with a resolution of 10 µm using the Peakfinder from PTW, Freiburg

Very efficient tool for fast measurement of Bragg peaks

Verification of MC-generated database



Measurement of min. 10 energies for C-12 and protons

Measurement of beam position & width

Siemens IC-MWPC



QA Example: homogeneity of 2D scans

270MeV/u C12 , 6mm fwhm, dx=2mm w/o feedback loop for position correction:



Excellent stability of the beam (position, width) and good performance of the monitoring and scanning system, but ...

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Accuracy of Robotic Positioning



Now a laser tracker is used to monitor movement during operation

MC application to active beam delivery @ HIT

FLUKA dose calculations of scanned fields for comparison with measurements and TPS calculation to *support TPS-commissioning*



A MC is very valuable to decide if the TP or the delivery is right However, it has to be verified and is not automatically correct

Radiobiological QA @ HIT



- No real biological QA
- Test only constancy of algorithms
- Benchmark of new algorithm vs. old algorithm
- Check input in data base

Conclusion

- Carefully analyze the clinical needs and document the specifications
- Define test characteristics, tolerances, actions and SOPs
- Analyze uncertainties
- Don't forget about verification, documentation, education, communication!

Thanks for your attention !

