Electronic Brachytherapy Quality Management based on Risk Analysis: The Report of AAPM TG 182

Bruce R. Thomadsen (chair)	Sujatha Pai
Peter J. Biggs	Sushakumari Pillai
Gene A. Cardarelli	Michael R. Ringor
James C. H. Chu	Mark J. Rivard
Robert A. Cormack	Timothy J. Waldron
Wenzheng Feng	Barrett S. Caldwell
H. Thompson Heaton II	Randall W. Holt
Jessica R. Hiatt	Tina L. Pike
Jonathan N. Law	Habib Safigholi
Jeffery P. Limmer	Christopher Stacey
Zoubir Ouhib	Frank Weigand

Disclosures

This presentation includes **DRAFT** societal guidance.

Specific commercial equipment, instruments, and materials are listed to fully describe the necessary procedures. Such identification does not imply endorsement by the presenter or authors, nor that these products are necessarily the best available for these purposes.

Learning Objective

Understand the contents and status of the draft TG-182 report.

Task Group **Charge**

1. Review the manufacturers'-suggested quality assurance (QA) procedures.
2. Develop a rational, risk-based set of quality management (QM) procedures, both for the treatment units and for patient treatment plans, including techniques, frequencies and tolerances, statements on required training, connectivity with computer networks and on licensing and regulations. The report should cover all anatomical sites and treatment facilities.
3. Suggest designs for needed tools that do not yet exist.
4. Suggest quality improvement procedures.

Task Group **Scope**

1. Provide guidance to medical physicists to develop eBT QM procedures specific to their clinic, staffing, resources, etc. following TG-100 methods.
2. Consider two eBT systems:
   AXXENT by Xoft, an iCad company (San Jose, CA)
   INTRABEAM by Carl Zeiss Meditech (Jena, Germany)
3. Example workflow, FMEA ,and FTA for APBI are given for both eBT systems, and vaginal cuff BT for one eBT system.
4. Nothing in the report should be taken as prescriptive, nor should the recommendations be incorporated into regulations.

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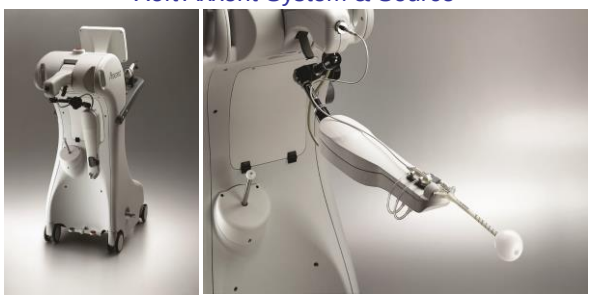
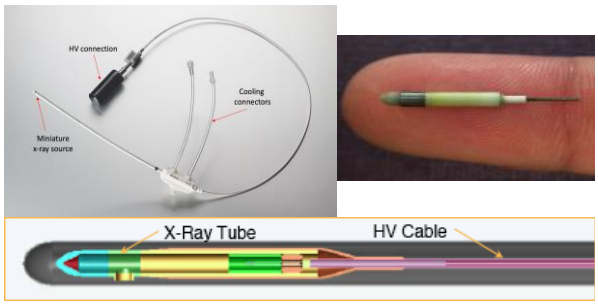
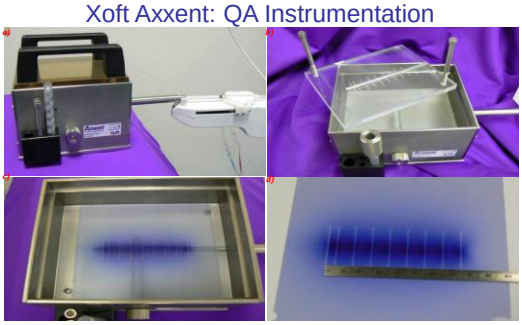
Xoft Axxent System & Source



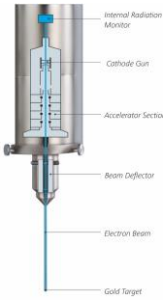
Xoft Axxent Source



Xoft Axxent: QA Instrumentation



Zeiss INTRABEAM System & Source



Zeiss INTRABEAM: QA Instrumentation

The report of Task Group 100 of the AAPM: Application of risk analysis methods to radiation therapy quality management

M. Saiful Huq[a)]
Department of Radiation Oncology, University of Pittsburgh Cancer Institute and UPMC CancerCenter, Pittsburgh, Pennsylvania 15232

Benedick A. Fraass
Department of Radiation Oncology, Cedars-Sinai Medical Center, Los Angeles, California 90048

Peter B. Dunscombe
Department of Oncology, University of Calgary, Calgary T2N 1N4, Canada

John P. Gibbons, Jr.
Ochsner Health System, New Orleans, Louisiana 70121

Geoffrey S. Ibbott
Department of Radiation Physics, UT MD Anderson Cancer Center, Houston, Texas 77030

Arno J. Mundt
Department of Radiation Medicine and Applied Sciences, University of California San Diego, San Diego, California 92093-0843

Sasa Mutic
Department of Radiation Oncology, Washington University School of Medicine, St. Louis, Missouri 63110

Jatinder R. Palta
Department of Radiation Oncology, Virginia Commonwealth University, P.O. Box 980058, Richmond, Virginia 23298

Frank Rath
Department of Engineering Professional Development, University of Wisconsin, Madison, Wisconsin 53706

Bruce R. Thomadsen
Department of Medical Physics, University of Wisconsin, Madison, Wisconsin 53705-2275

Jeffrey F. Williamson
Department of Radiation Oncology, Virginia Commonwealth University, Richmond, Virginia 23298-0058

Ellen D. Yorke
Department of Medical Physics, Memorial Sloan-Kettering Center, New York, New York 10065

Huq et al., Med Phys 43; 4209-4262 (2016).

TG-100 Charges

1. Review and critique existing guidance from current AAPM in documents …
2. 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.
3. After the identification of the hazard analysis for broad classes of radiotherapy procedures, develop the framework of the QA program.

TG-182 + TG-100 = Modern QM (for eBT)

1. TG-182 approved to start work in 2008 (8 years preceding TG-100 release)
2. TG-182 is first BT-related AAPM TG Report to embrace TG-100 concepts
3. TG-182 provides several example FMEA and FTA to benefit clinics with facility specific QM and risk-based practice.

General FMEA Worksheet from TG-100

Process Step	Potential Failure Mode	Potential Cause of Failure Mode	Effects of Potential Failure Mode	Current controls	Occurrence - Cause	Detect-ability of Failure Mode	Severity of Effect from Failure Mode	RPN	Corrective Action

Fig. 8. Traditional failure modes and effects analysis worksheet.

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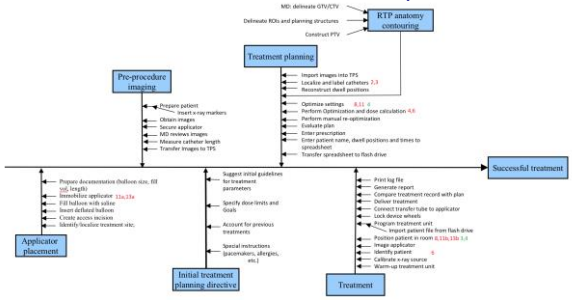
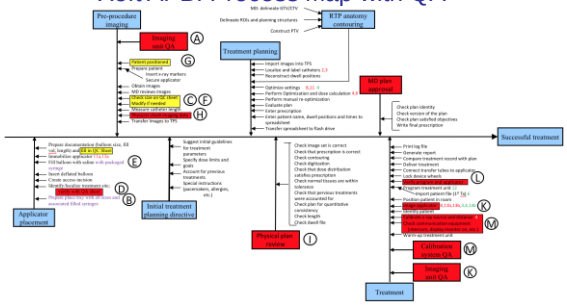
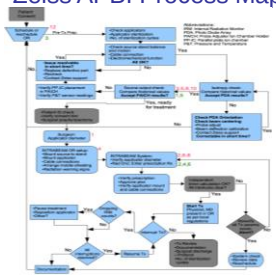


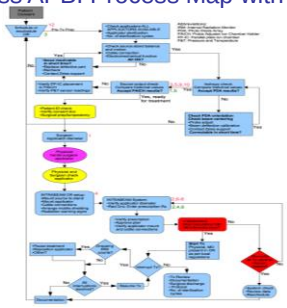
Xoft APBI Process Map with QA



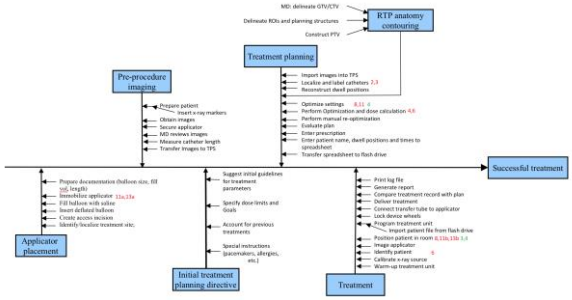
Zeiss APBI Process Map



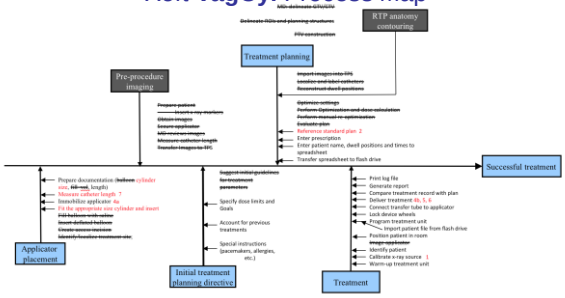
Zeiss APBI Process Map with QA



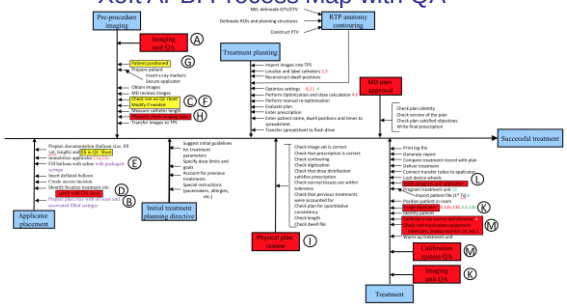
Xoft APBI Process Map



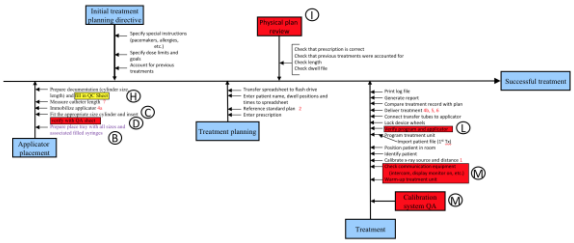
Xoft **VagCyl** Process Map



Xoft APBI Process Map with QA



Xoft **VagCyl** Process Map with QA



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TG-182 Recommendations (1)

1. Each facility should be skilled in TG-100 for risk-assessment-based QM:
   a) attend a workshop, study with a practitioner who has used the techniques clinically, consult with a Patient Safety Organization listed with the Agency for Healthcare Research and Quality, and
   b) practice the techniques as described in Appendix A for procedures in their clinic.

2. eBT QM should come from an analysis similar to that shown in this report.

3. The examples from this report serve as a starting point for facility analysis. Make modifications so analysis reflects how a procedure is locally performed.

TG-182 Recommendations (2)

4. As recommended in the report of TG 100:
   a) Panel of representatives from all involved disciplines performs the analysis.
   b) Before implementing a new QMP, an independent reviewer (knowledgeable and experienced with the procedure and TG-100 approach) should review the analysis. The reviewer should not be associated with the facility starting a new program, yet understand the procedure and initiated processes to assess the analysis quality.
   c) Apply TG-100 methodology on small procedures or small parts of larger procedures, completing one analysis at a time.
5. Perform manufacturer-recommended source strength measurements.
6. Users of Xoft balloon applicators should continue using the 6% attenuation correction built into the controller to account for barium in the balloon.

TG-182 Recommendations (3)

7. Research should be encouraged to develop a method of monitoring the beam stability during treatment for the Xoft unit (see Section 6.4).
8. Absolute dose measurements are difficult to perform. New sources or periodic measurements can be compared with the original measurement to assess dose constancy. TG-167 recommends validation that disease site is radiologically represented by reference data. eBT photon spectrum changes with depth. This effect is sensitive to tissue composition, making dose distribution become increasingly inaccurate with increasing depth.

TG-182 Recommendations (4)

8. Dosimeter response varies with spectral changes. Media mismatch and dosimeter response changes make it difficult to validate dose distributions in normal clinical settings. Physicists can standardize a method to measure dose distributions near a source, e.g., radiochromic film in a plastic phantom.

Report Status

- TG-182 Report has undergone several review cycles with BTSC and WGBCA, back for a 3rd review cycle with TPC. Science Council review and commentary from members is forthcoming preceding journal review.

- Late-2019(?) for approval and publication for AAPM members.