1

Disclosures

The presenter has no real or apparent conflicts of interest.

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.

2

TG-182 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 (Oberkochen, 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

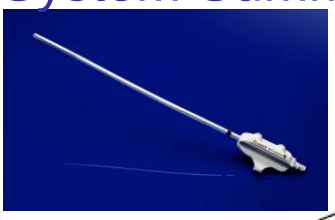
3

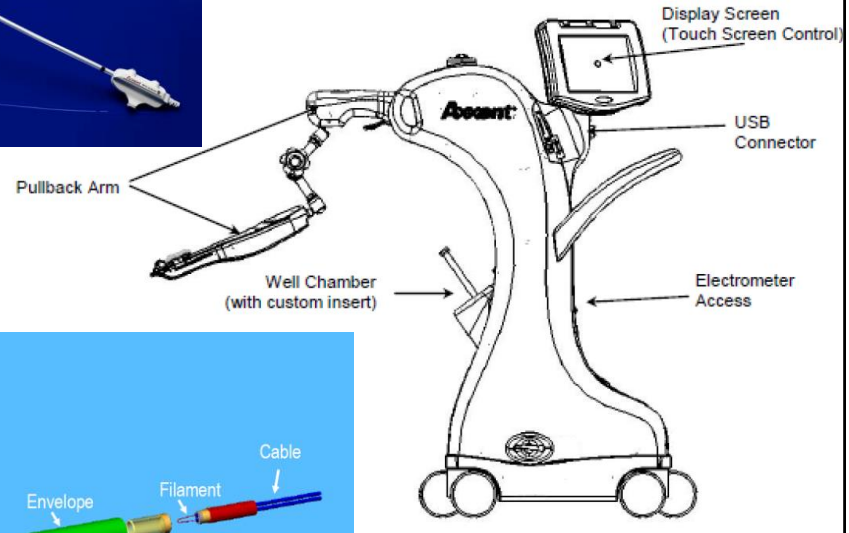
Learning Objectives

- Understand the Xoft electronic brachytherapy (eBT) system from the perspectives of dosimetry and QM.
- Examine a sample clinical workflow, associated QA+QC, FMEA, and FTA.
- Learn how FMEA and FTA influence the QM design.

4

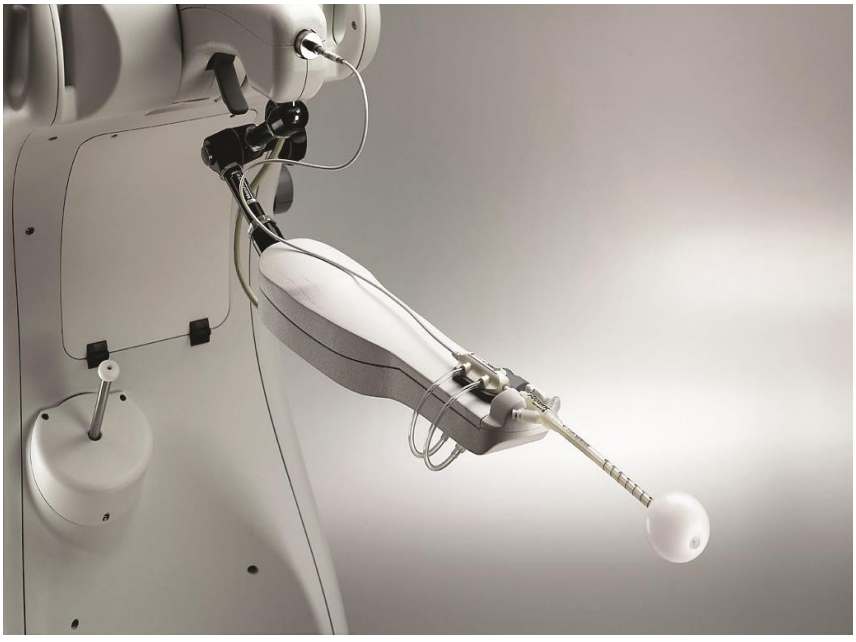
System Summary: Overall





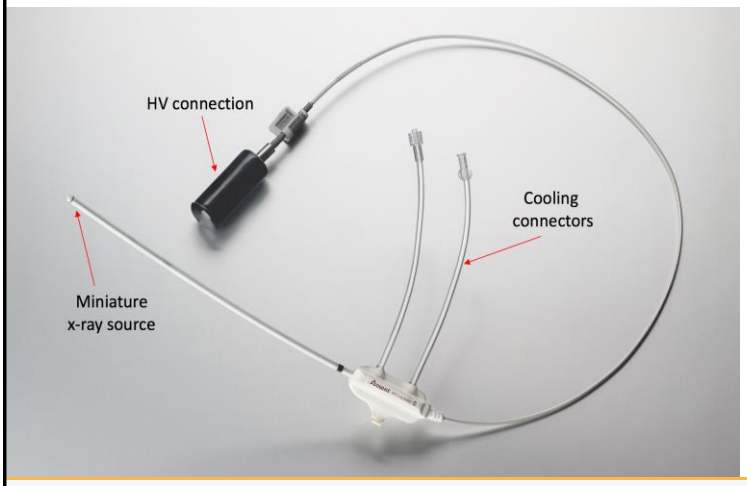
5

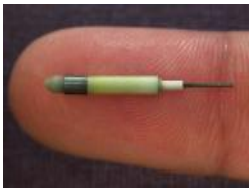
Xoft System & Source

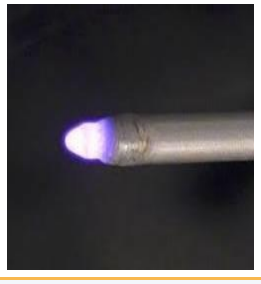


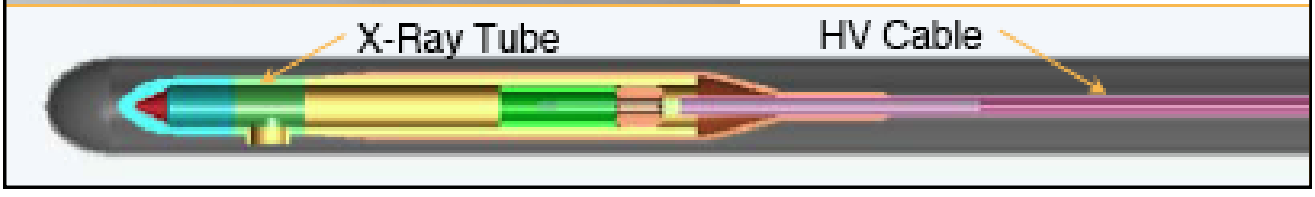
6

Xoft Source



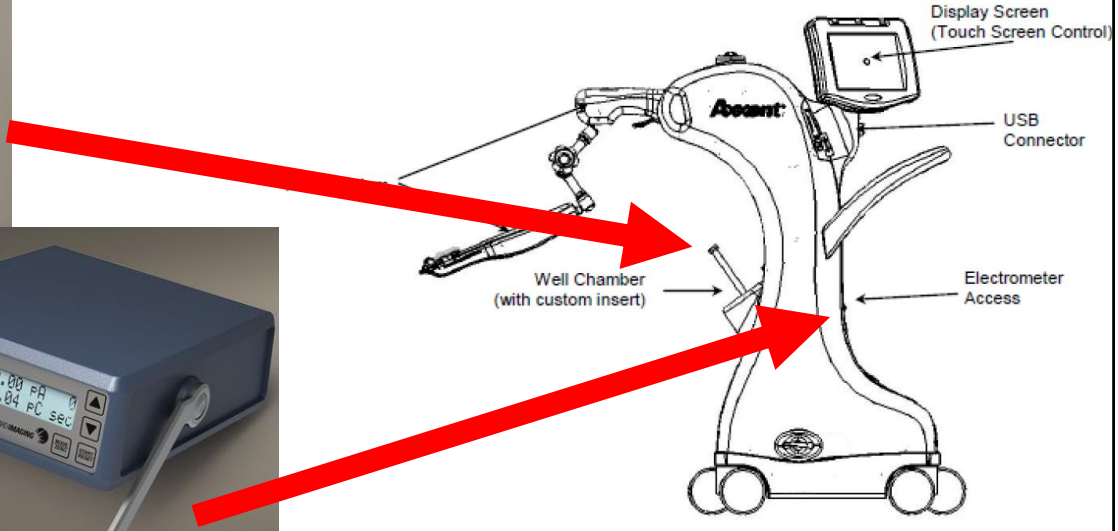






7

System Summary: Calibration



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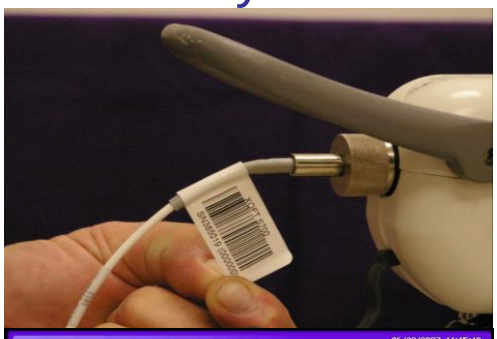
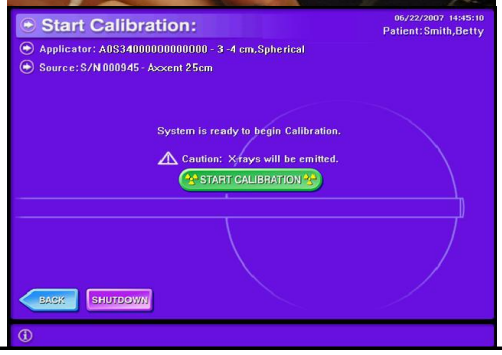
System Summary: Calibration





9

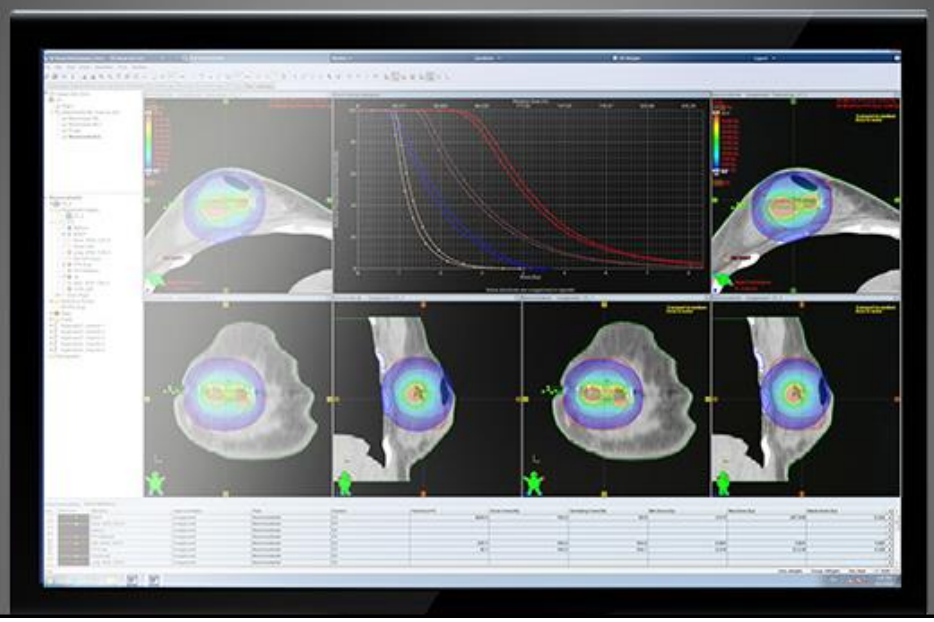
System Summary: Calibration


```
Post-Treatment Summary Report
Software Version: V2.04 Apr 19 2016 18:55:17
Physician: Smith
Institution: Acme Cancer Center
Patient ID: 123ABC
Patient Name:  Doe, Jane
Patient ID (Plan): 123ABC
Patient Name (Plan): Doe Jane,,,,

Applicator barcode:  A0S34ABC123DEF456
Source barcode:  P0000BBBBBB000000
CAL_START: 03/02/2016  00:31:54 AM
HV Setpoint (kV):  50.00
Beam Setpoint (uA): 300.00
Max / Min / SD (nA): 111.33, 111.19, 0.03
Standard air kerma rate (uGy / min):  10000
Applicator Adjustment (%):  106
Ambient temperature in degrees C: 22.1
Ambient pressure in mmHg: 760.25
Compensated air kerma rates (uGy / min): 11402, 11368, 12774, 12750, 12808, 12774, 12699, 12662
Ratio of standard/compensated air kerma rate * Applicator Adjustment: 0.930
Channel 1 Depth (cm): 25.00
Measured Source Length (cm): 25.00
Unadjusted dwells
Dwell, Position (cm), Duration (s)
1, 24.50, 6.2
2, 24.00, 27.6
3, 23.50, 14.2
4, 23.00, 10.6
5, 22.50, 25.2
Adjusted dwells
Dwell, Position (cm), Duration (s)
1, 24.50, 5.8
2, 24.00, 25.7
3, 23.50, 13.2
4, 23.00, 9.9
5, 22.50, 23.4
Estimated Treatment Time (s): 78.0

TREATMENT_START: 03/02/2016  02:05:37 AM
TREATMENT_COMPLETE: 03/02/2016  02:11:01 AM

Actual Treatment Time (s) - All Channels: 78.0
Source Fractions Completed, Limit: 5, 10
Source Treatment Minutes, Limit: 27, 170
Source Days From Initial Use, Limit: 2, 35

Treatment Errors:
None


Physician Signature     Date      Physicist Signature     Date

160229172546.LOG
```

10

System Summary: Treatment Planning

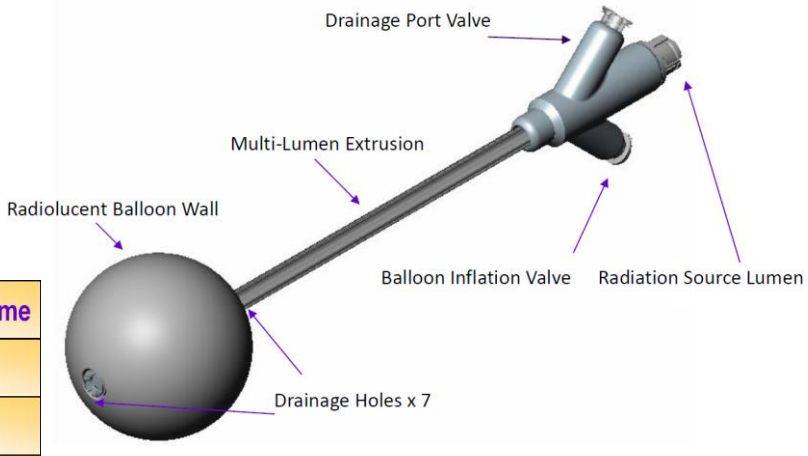
BrachyVision TPS (Varian)



11

System Summary: Applicators (breast)

Balloon Configuration	Balloon Fill Volume
3-4 cm Spherical	30-45 cc
4-5 cm Spherical	45-75 cc
5-6 cm Spherical	65-130 cc
5x7 cm Ellipsoidal	90-125 cc



12

System Summary: Applicators (skin)

stainless steel applicators

diameters: 1, 2, 3.5, 5 cm
integrated flattening filter

end caps
sized to fit cones
required for cal. & Tx

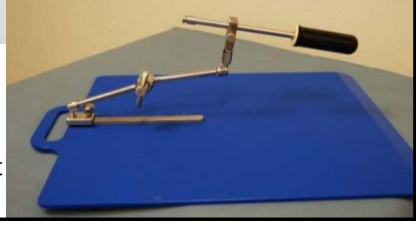
13

System Summary: Applicators (vaginal)

reusable (300 Fx or 100 sterilizations)

diameters: 2, 2.5, 3, 3.5 cm

vaginal applicator clamp and base plate
– maintains applicator stability/placement



14

System Summary: Applicators (cervical)

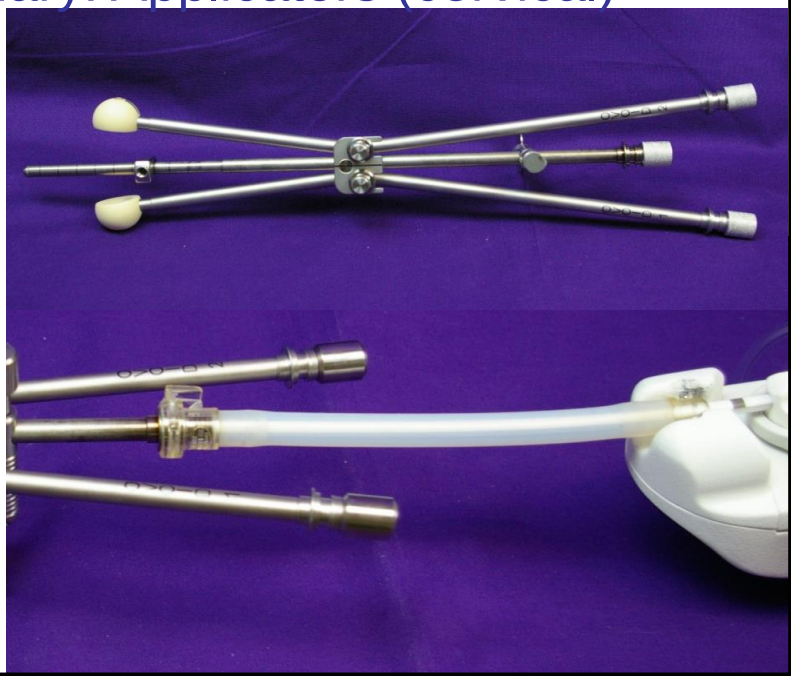
Henschke type applicator

thin wall Ti (CT compatible)

tandem angles: 0°, 15°, 30°, 45°
ovoid diameters: 2, 2.5, 3 cm

flexible source channel

use extended-length source (50 cm)

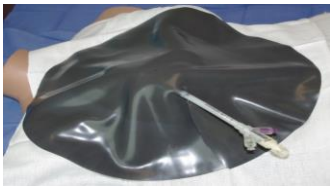


15

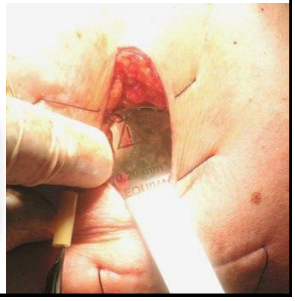
System Summary: Patient shields

place upon patient (e.g., pelvis)
0.5-mm Pb equivalent
3 sizes available:
41 x 82 cm^2 (small)
51 x 102 cm^2 (medium)
51 x 119 cm^2 (large)

flexible shield for breast Tx
0.45-mm Pb equivalent
38 cm diameter

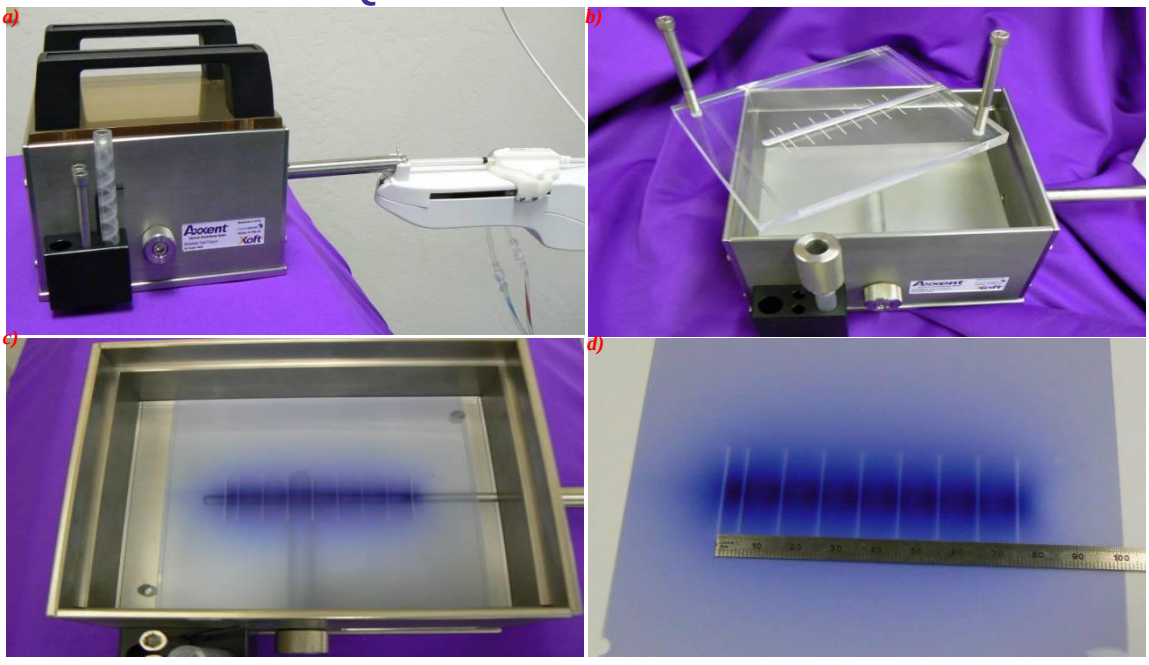


rigid chestwall shield (stainless steel)
7, 6, 5, 4, 3 cm diameters
0.2-mm Pb equivalent



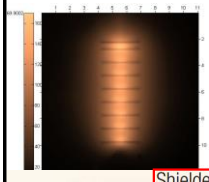
16

QA Instrumentation



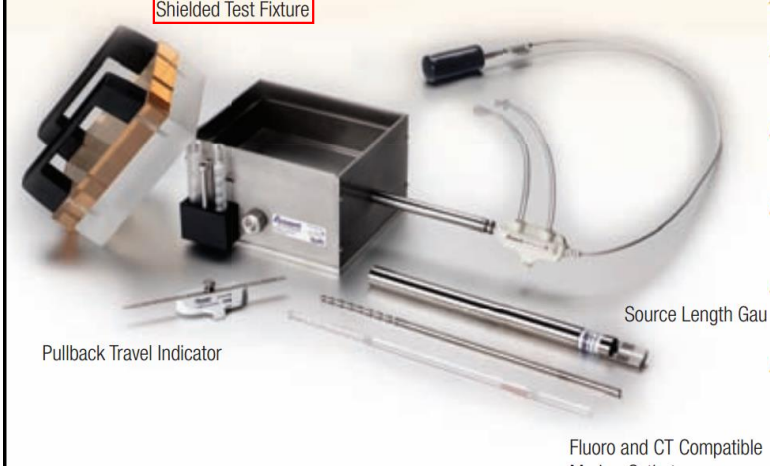
17

System Summary: Physics QA



Shielded Test Fixture

http://www.xoftinc.com/assets/pdf/axxent_accessories.pdf



Axxent Physics Accessories Kit

- Pullback Travel Indicator verifies the pullback distance accuracy.
- X-ray Source Length Gauge confirms the source length is within the specification and provides the source length correction dimension.
- Applicator Depth Gauge verifies the balloon applicator lumen length is within the specification and gathers the applicator length corrections dimension.
- CT-compatible Marker Catheter represents possible X-ray source pullback positions within a balloon applicator and is visible using a CT scanner.
- Fluoro-compatible Marker Catheter represents potential X-ray source pullback positions within a balloon applicator and is visible with fluoroscopic imaging.
- Storage and carrying case permit convenient portability and ensure the protection of the kit.

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Electronic intracavitary brachytherapy quality management based on risk analysis: The report of AAPM TG 182

6.B. COMPARISON WITH VENDOR RECOMMENDED QA

6.B.1. Comparison with Xoft QA recommendations

The manufacturer recommends the following QA on the Xoft unit:

1. New source assay tests

a. Air-kerma strength assay
b. Position pullback calibration
c. Source radiation position verification

2. Daily QA

a. Interlock tests

i. Source not in nest
ii. Applicator not detected
iii. Wheels unlocked

b. Pause button
c. Treatment Stop button

3. Quarterly QA

a. Interlock tests

i. Invalid or missing electrometer reading
ii. Source not in ion chamber
iii. Source electrical connector or no filament
iv. Pullback force limit exceeded
v. Coolant flow not detected
vi. Power failure

b. Reviewing supporting procedures

Bruce R. Thomadsen[a)]
Department of Medical Physics, School of Medicine and Public Health, University of Wisconsin, Madison, WI 53705, USA
Peter J. Biggs
Massachusetts General Hospital, Boston, MA 02114, USA
2425 Gulf of Mexico Drive, Longboat Key, FL 34228, USA
Gene A. Cardarelli
Department of Radiation Oncology, Brown University, Providence, RI 02903, USA
James C. H. Chu
Rush University Medical Center, Chicago, IL 60612, USA
Robert A. Cormack
Brigham and Women's Hospital, Boston, MA 02115, USA
Wenzheng Feng
Department of Radiation Oncology, Saint Barnabas Medical Center, Livingston, NJ 07039, USA
H. Thompson Heaton II
Hagerstown, MD 21740, USA
Jessica R. Hiatt
University of Massachusetts Memorial Medical Center, Worcester, MA 01655, USA
Jonathan N. Law
Shore Medical Center, Somers Point, NJ 08244, USA
Jeffery P. Limmer
Cancer Center Services Texas Oncology, The Woodlands, TX 77380, USA
Zoubir Ouhib
Lynn Regional Cancer Center, Delray Beach, FL 33484, USA
Sujatha Pai
Radion Inc., Cupertino, CA 95014, USA
Sushakumari Pillai
Oregon Health and Science University, Portland, OR 97239, USA
Michael R. Ringor
Faith, Hope and Love Cancer Center, Lafayette, IN 47905, USA
Mark J. Rivard
Department of Radiation Oncology, Brown University, Providence, RI 02903, USA
Timothy J. Waldron
University of Iowa Hospitals & Clinics, Iowa City, IA 52242, USA
Barrett S. Caldwell
Purdue University, West Lafayette, IN 47907, USA
Randall W. Holt
Pacific Crest Medical Physics, Chico, CA 95973, USA
Tina L. Pike
Affinity Health System, Appleton, WI 54915, USA
Habib Safigholi
Sunnybrook Health Sciences Centre, Toronto, ON M4N 3M5, Canada
Christopher Stacey
University College London Hospitals, London NW1 2PG, UK
Frank Welgand
Carl Zeiss Meditec AG, 73447 Oberkochen, Germany

6.D. COMPARISON WITH EXISTING LITERATURE

Hiatt et al. discussed commissioning of a Xoft electronic brachytherapy system for intracavitary breast irradiation.[18] The suite of tests they performed included:

1. Well-chamber consistency
2. Beam stability
3. Source positional accuracy
4. Output stability
5. Timer linearity
6. Marker and source position coincidence
7. Controller functionality and safety interlocks
8. Treatment planning system data verification

Thomadsen et al. Med Phys 49, e65-e91 (2020)

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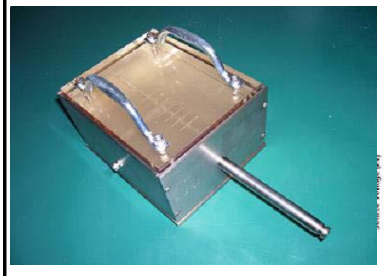
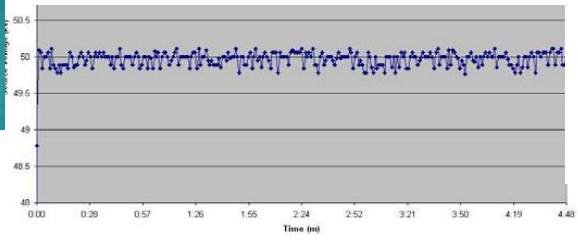
A commissioning procedure for breast intracavitary electronic brachytherapy systems

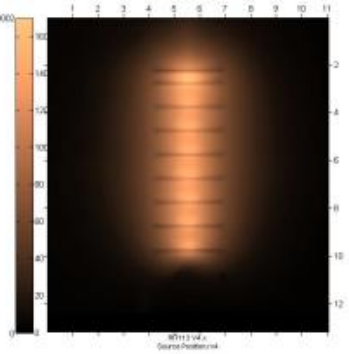
Jessica Hiatt, Gene Cardarelli, Jaroslaw Hepel, David Wazer, Edward Sternick
Department of Radiation Oncology, Rhode Island Hospital, Providence, RI, U.S.A.
jhiatt@lifespan.org

Received 15 October 2007; accepted 7 March 2008

In this work, we report a comprehensive quality assurance (QA) process for the commissioning of an Electronic Brachytherapy (EB) system at one of the first U.S. sites to apply the device clinically. Thus far, EB systems have been released only for intracavitary breast treatments. As such, EB as an Accelerated Partial Breast Irradiation (APBI) treatment modality is relatively unstudied and is unfamiliar to many medical physicists. We present our documented experience as a guide for other institutions' EB commissioning process. Our tests included eight elements: A) well-chamber constancy, B) beam stability, C) source positional accuracy, D) output stability, E) timer linearity, F) dummy marker/source position coincidence, G) controller functionality and safety interlocks, and H) treatment planning data verification following the AAPM TG-43 recommendations. Together with TG-43, our methodology provides a comprehensive EB system check for medical physicists commissioning such a device.







Hiatt et al. JACMP 9, 58-68 (2008)

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A revised dosimetric characterization of the model S700 electronic brachytherapy source containing an anode-centering plastic insert and other components not included in the 2006 model

Jessica R. Hiatt
Department of Radiation Oncology, Rhode Island Hospital, The Warren Alpert Medical School of Brown University, Providence, Rhode Island 02903

Stephen D. Davis
Department of Medical Physics, McGill University Health Centre, Montreal, Quebec H3G 1A4, Canada

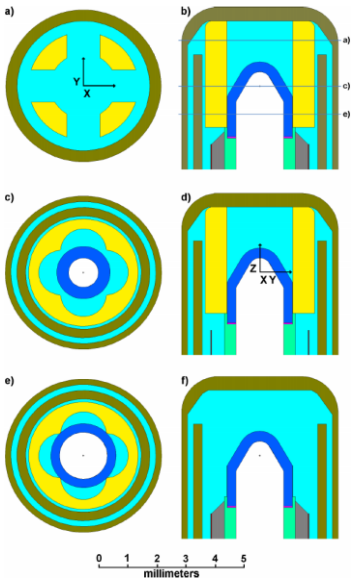
Mark J. Rivard[a)]
Department of Radiation Oncology, Tufts University School of Medicine, Boston, Massachusetts 02111

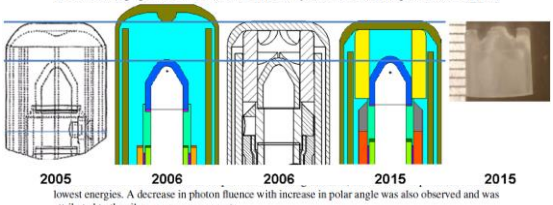
(Received 3 March 2015; revised 13 April 2015; accepted for publication 15 April 2015; published 15 May 2015)

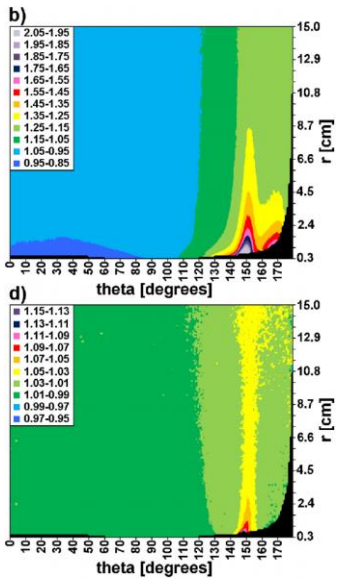
Purpose: The model S700 Axxent electronic brachytherapy source by Xoft, Inc., was characterized by Rivard *et al.* in 2006. Since then, the source design was modified to include a new insert at the source tip. Current study objectives were to establish an accurate source model for simulation purposes, dosimetrically characterize the new source and obtain its TG-43 brachytherapy dosimetry parameters, and determine dose differences between the original simulation model and the current model S700 source design.

Methods: Design information from measurements of dissected model S700 sources and from vendor-supplied CAD drawings was used to aid establishment of an updated Monte Carlo source model, which included the complex-shaped plastic source-centering insert intended to promote water flow for cooling the source anode. These data were used to create a model for subsequent radiation transport simulations in a water phantom. Compared to the 2006 simulation geometry, the influence of volume averaging close to the source was substantially reduced. A track-length estimator was used lowest energies. A decrease in photon fluence with increase in polar angle was also observed and was attributed to the silver epoxy component.

Conclusions: Changes in source design influenced the overall dose rate and distribution by more than 2% in several regions. This discrepancy is greater than the dose calculation acceptance criteria as recommended in the AAPM TG-56 report. The effect of the design change on the TG-43 parameters would likely not result in dose differences outside of patient applicators. Adoption of this new dataset is suggested for accurate depiction of model S700 source dose distributions. © *2015 American Association of Physicists in Medicine.* [http://dx.doi.org/10.1118/1.4919280]







Hiatt et al. Med Phys 42, 2764-2776 (2015)

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Simulation evaluation of NIST air-kerma rate calibration standard for electronic brachytherapy

Jessica R. Hiatt
Biomedical Engineering and Biotechnology, University Massachusetts Lowell, Lowell, Massachusetts 01854

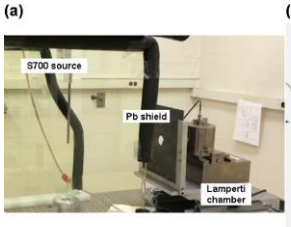
Mark J. Rivard[a)]
Department of Radiation Oncology, Tufts University School of Medicine, Boston, Massachusetts 02111

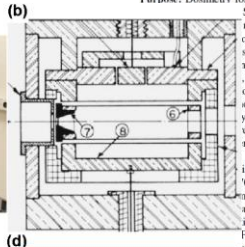
H. Grady Hughes
Los Alamos National Laboratory, Los Alamos, New Mexico 87545

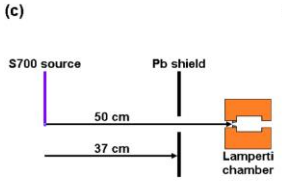
(Received 29 July 2015; revised 31 December 2015; accepted for publication 12 January 2016; published 8 February 2016)

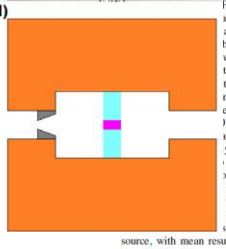
Purpose: Dosimetry for the model S700 50 kV electronic brachytherapy (eBT) source (Xoft, Inc., San Jose, CA) was simulated using Monte Carlo (MC) methods by Rivard measured brachytherapy dosimetry parameters in water for the Xoft Axxent onic brachytherapy source," Med. Phys. 33, 4020–4032 (2006)] and recently sed dosimetric characterization of the model S700 electronic brachytherapy node-centering plastic insert and other components not included in the 2006 , 2764–2776 (2015)] with improved geometric characterization. While these ose distribution in water, there have not previously been reports of the eBT ods beyond that recently reported by Seltzer *et al.* ["New national air-kerma y electronic brachytherapy sources," J. Res. Natl. Inst. Stand. Technol. 119, efore, the motivation for the current study was to provide an independent rma rate at 50 cm in air $K_{air}(d = 50\,\text{cm})$ using MC methods for the model information provided by the vendor and disassembled sources, an MC model '00 eBT source. Simulations were run using the MCNP6 radiation transport perti air ionization chamber according to specifications by Boutillon *et al.* ure standards in the 10-50 kV x-ray region," Metrologia 5, 1–11 (1969)], in i chamber, and in vacuum without the Lamperti chamber. $K_{air}(d = 50\,\text{cm})$ was F4 tally with NIST values for the mass energy-absorption coefficients for air. luated over 2π azimuthal sampling for polar angles of $0° \le \theta \le 180°$ every 1°. averted through tight radial binning. Photon energy spectra were determined both air and vacuum using the F4 tally with 0.1 keV resolution. A total of 10^{11} e run for the Lamperti chamber geometry (statistical uncertainty of 0.14%), the in-air and in-vacuum simulations (statistical uncertainty of 0.04%). The ty in the calculated air-kerma rate determination amounted to 6.8%. ns determined the air-kerma rate at 50 cm from the source with the modeled e $(1.850 \pm 0.126) \times 10^{-4}$ Gy/s, which was within the range of $K_{air}(d = 50\,\text{cm})$ $)^{-4}$ Gy/s measured by NIST. The ratio of the photon spectra in air and in greement above 13 keV, and for $\theta < 150°$ where the influence of the Kovar y components caused increased scatter in air. Below 13 keV, the ratio of the vacuum exhibited a decrease that was attributed to increased attenuation of ss most of the energy range on the source transverse plane, there was good authors' simulated spectra and that measured by NIST. Discrepancies were where the NIST spectrum had a steeper fall-off towards 50 keV.

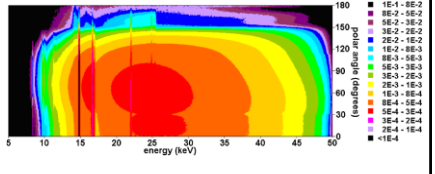
MC simulations of radiation transport, this study provided an independent ured air-kerma rate at 50 cm in air at NIST for the model S700 eBT source, with mean results in agreement within 3.3%. This difference was smaller than the range (i.e., 23%) of the measured values. © *2016 American Association of Physicists in Medicine.*

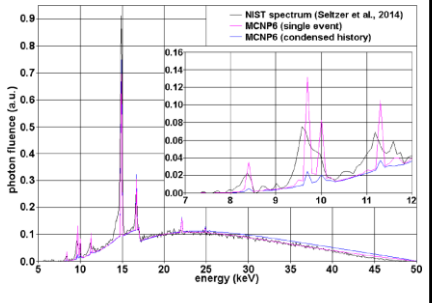












Hiatt et al. Med Phys 43, 1119-1129 (2016)

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Guidelines by the AAPM and GEC-ESTRO on the use of innovative brachytherapy devices and applications: Report of Task Group 167

Ravinder Nath
Department of Therapeutic Radiology, School of Medicine, Yale University, New Haven, Connecticut 06510
Mark J. Rivard[a)]
Department of Radiation Onco
Larry A. DeWerd
Accredited Dosimetry and Cali
William A. Dezarn
Department of Radiation Onco North Carolina 27157
H. Thompson Heaton II
Hagerstown, Maryland 21740
Geoffrey S. Ibbott
Department of Radiation Physi
Ali S. Meigooni
Comprehensive Cancer Center
Zoubir Ouhib
Radiation Oncology, Lynn Reg
Thomas W. Rusch
Xoft, Inc., A Subsidiary of iCA
Frank-André Siebert
Clinic of Radiotherapy, Univer
Jack L. M. Venselaar
Department of Medical Physic

TABLE I. Use of various brachytherapy sources, applicators, or applications.

Section	Name	Year introduced	Primary calibration standard in the U.S.	Primary calibration standard in Europe	ADCL calibration availability	Ability to calculate patient dose distributions[a]	Clinical experience[b]
4.A	HDR ^{192}Ir sources/afterloaders	1964	No	Yes	Yes	Yes	Extensive
4.B	HDR ^{60}Co sources	1960s	No	Yes	No	Yes	Moderate
4.C	LDR ^{125}I and ^{103}Pd sources	1990s	Yes	Yes	Yes	Yes	Extensive
4.D	LDR ^{131}Cs sources	2004	Yes	No	Yes	Yes	Extensive
4.E	Elongated sources	1960s	Yes[c]	Yes	Yes	No	^{103}Pd minimal ^{192}Ir extensive
4.F	Intermediate energy sources	1987	No	Yes	No	Yes	Minimal
4.G	Electronic brachytherapy	1992	Yes	No	Yes	Yes	Extensive
4.H	Intravascular brachytherapy	1990s	Yes[d]	No	Yes	Yes	Extensive
4.I	Neutron-emitting ^{252}Cf sources	1965	Yes	No	No	No[e]	LDR moderate HDR minimal
4.J	^{90}Y microspheres	1980s	No[f]	Yes	No	No	Moderate
4.K	Collimated applicators and sources	1990s	N/A	N/A	N/A	Yes[g]	Moderate
4.L	Breast balloon applicators	1990s	N/A	N/A	N/A	Yes	Extensive
4.M	Brain balloon applicators	2001	N/A	N/A	N/A	No	Moderate
4.N	Non-COMS eye plaques	1990s	N/A	N/A	N/A	Yes	Moderate

Nath et al. Med Phys 43, 3178-3205 (2016)

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QM Approach

1. assemble team of participants
2. understand the process: create workflow (process map)
3. assess the hazards: FMEA and scoring
4. identify failure propagation: FTA
5. address the hazards
6. test and evaluate
7. include in QM Program

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Workflow Redesign & Implementation

1. redesign procedure so errors are not possible
2. correct environmental and technical problems
3. standardize the procedures
4. provide adequate staff and resources (e.g., physical, IT, etc).
5. maintain hardware & software
6. delineate communication methods among staff

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Xoft APBI Workflow

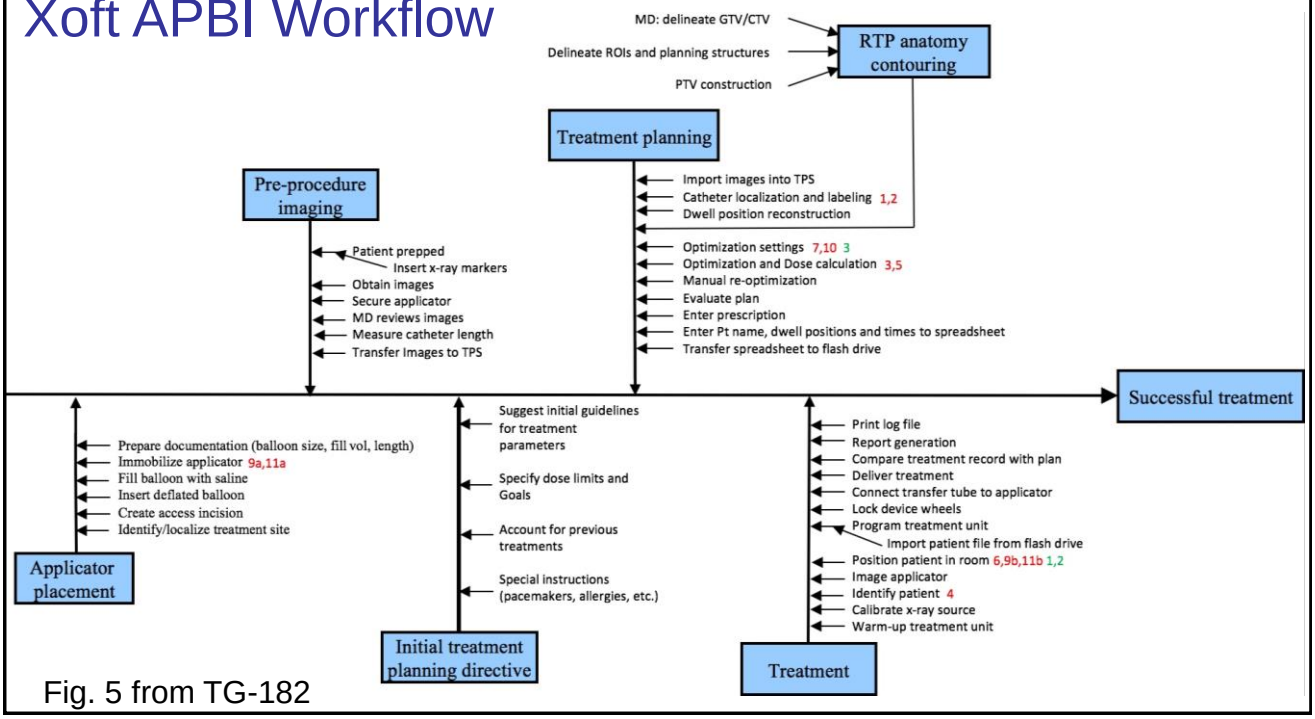

Fig. 5 from TG-182

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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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TG-182 Scoring Key Applied to Examples

Table A1. Values for evaluation of the likelihood of occurrence, O, the severity, S, and the likelihood that a failure will not be detected before it affects a patient, D, used in this analysis and based on that used by AAPM Task Group 100.

Rank	Occurrence (O) of Cause		Severity (S) of Effect		Detectability (D) of Failure Mode	
	Qualitative description	Frequency in %	Qualitative description	Descriptive	Qualitative description (likelihood of detection)	Probability of going undetected in %
1	Remote probability	0.01	No effect	No effect	Detection almost assured	0.01
2	Failure unlikely	0.02	Inconvenience	Inconvenience	Very high likelihood	0.2
3	Low probability – few failures	0.05	Minor effect	Effect only seen when reviewing large populations	High likelihood	0.4
4	Moderate probability	0.1	Noticeable effect	Suboptimal care for a patient	Moderate likelihood	1.0
5	Intermediate probability	<0.2	Limited toxicity	Minor undertreatment or small overtreatment	Intermediate likelihood	2.0
6	Occasional failures	<0.5	Undesired effect	Care that worsens the patient's life	Some likelihood	5.0
7	High probability	<1	Serious effect	Treatment or diagnostic failures that affect patient function	Low likelihood	10
8	Very high probability	<2	Possible very serious toxicity	Very negative effects on patient	Very low likelihood	15
9	Repeated failures	<5	Sentinel failure	Serious injury	Serious detection problem	20
10	Failure inevitable	>5	Catastrophic effect	Death or very serious injury	Detection unlikely	>20

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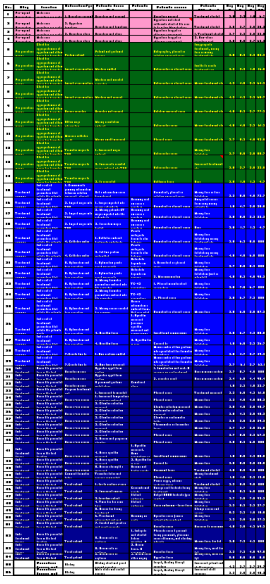
Xoft APBI FMEA



No.	Step	Function	Subsystem/process	Potential Failure Mode	Potential Failure Mode-Detail	Potential causes	Potential Effects of failure	Avg O	Avg S	Avg D	Avg RPN
1	Pre-implant Preparation	Make sure applicators are ready	1. Applicators present	Applicators not present		Applicators misplaced	Treatment aborted	3.0	2.2	1.0	6.7
2	Pre-implant Preparation	Make sure applicators are ready	2. Applicators functional	Applicators not functional		Applicators not check sufficiently ahead of the case to fix in time Manufacture defect	Treatment aborted	3.8	2.7	2.5	30.3
3	Pre-implant Preparation	Make sure applicators are ready	3. Applicators sterile	Applicators not sterile		Applicators dropped or otherwise compromised	1. Treatment aborted	3.7	2.3	2.8	23.8
4	Pre-implant Preparation	Make sure applicators are ready	3. Applicators sterile	Applicators not sterile		Applicators dropped or otherwise compromised	2. Non-sterile applicators used, Infection at Tx site	3.8	5.0	3.7	63.2
5	Pre procedure imaging	Check for appropriateness of application and obtain images for dosimetry	Position patient	Patient not positioned properly		Radiographer, physicist or radiation oncologist error	Inappropriate treatment, wrong dose or wrong treatment site	3.0	5.2	3.3	53.3
6	Pre procedure imaging	Check for appropriateness of application and obtain images for dosimetry	Insert x-ray markers	Markers omitted		Radiographer or physicist error	Inability to create treatment plan	3.3	2.3	1.8	16.0
7	Pre procedure imaging	Check for appropriateness of application and obtain images for dosimetry	Insert x-ray markers	Markers not inserted completely		Radiographer or physicist error	Wrong treatment site	4.3	4.5	3.2	64.3
8	Pre procedure imaging	Check for appropriateness of application and obtain images for dosimetry	Insert x-ray markers	Markers not secured		Radiographer or physicist error	Wrong treatment site	4.3	4.3	3.3	60.7
9	Pre procedure imaging	Check for appropriateness of application and obtain images for dosimetry	Secure applicator	Applicator not secured		Radiation oncologist error	Wrong treatment site	4.0	5.2	3.7	77.3
10	Pre procedure imaging	Check for appropriateness of application and obtain images for dosimetry	Obtain image information	Wrong orientation entered		Radiographer error	Wrong treatment site	4.0	4.5	3.3	61.3
11	Pre procedure imaging	Check for appropriateness of application and obtain images for dosimetry	Measure catheter length	Wrong length measured		Physicist error	Wrong treatment site	3.7	5.3	4.8	92.5
12	Pre procedure imaging	Check for appropriateness of application and obtain images for dosimetry	Transfer images to TPS	1. Incorrect images entered		Radiographer error	Wrong dose distribution	2.7	5.8	3.8	58.7
13	Pre procedure imaging	Check for appropriateness of application and obtain images for dosimetry	Transfer images to TPS	2. Incorrectly oriented images entered into TPS		Radiographer error	Incorrect treatment site	2.8	3.7	3.0	33.5
14	Pre procedure imaging	Check for appropriateness of application and obtain images for dosimetry	Transfer images to TPS	3. File corrupted		Software failure	Delay	2.0	1.8	1.3	4.7

App. B1a from TG-182

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Xoft APBI FMEA

No.	Step	Function	Subsystem/process	Potential Failure Mode	Potential causes	Potential Effects of failure	Avg O	Avg S	Avg D	Avg RPN
1	Pre-implant Preparation	Make sure applicators are ready	1. Applicators present	Applicators not present	Applicators misplaced	Treatment aborted	3.0	2.2	1.0	6.7
2	Pre-implant Preparation	Make sure applicators are ready	2. Applicators functional	Applicators not functional	Applicators not check sufficiently ahead of the case to fix in time Manufacture defect	Treatment aborted	3.8	2.7	2.5	30.3
3	Pre-implant Preparation	Make sure applicators are ready	3. Applicators sterile	Applicators not sterile	Applicators dropped or otherwise compromised	1. Treatment aborted	3.7	2.3	2.8	23.8
4	Pre-implant Preparation	Make sure applicators are ready	3. Applicators sterile	Applicators not sterile	Applicators dropped or otherwise compromised	2. Non-sterile applicators used, Infection at Tx site	3.8	5.0	3.7	63.2
5	Pre procedure imaging	Check for appropriateness of application and obtain images for dosimetry	Position patient	Patient not positioned properly	Radiographer, physicist or radiation oncologist error	Inappropriate treatment, wrong dose or wrong treatment site	3.0	5.2	3.3	53.3
6	Pre procedure imaging	Check for appropriateness of application and obtain images for dosimetry	Insert x-ray markers	Markers omitted	Radiographer or physicist error	Inability to create treatment plan	3.3	2.3	1.8	16.0
7	Pre procedure imaging	Check for appropriateness of application and obtain images for dosimetry	Insert x-ray markers	Markers not inserted completely	Radiographer or physicist error	Wrong treatment site	4.3	4.5	3.2	64.3
8	Pre procedure imaging	Check for appropriateness of application and obtain images for dosimetry	Insert x-ray markers	Markers not secured	Radiographer or physicist error	Wrong treatment site	4.3	4.3	3.3	60.7
9	Pre procedure imaging	Check for appropriateness of application and obtain images for dosimetry	Secure applicator	Applicator not secured	Radiation oncologist error	Wrong treatment site	4.0	5.2	3.7	77.3

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Xoft APBI FMEA (RPN-sorted)

No.	Step	Function	Subsystem/process	Potential Failure Mode	Potential Failure Mode-Detail	Potential causes	Potential Effects of failure	Avg O	Avg S	Avg D	Avg RPN
43	Initial Tx delivery	Deliver Rx dose at Fx1	Assay x-ray source	5. Source strength is incorrect	Assume no backup available	Equipment failure	Treatment aborted	4.0	8.0	9.0	288
45	Initial Tx delivery	Deliver the prescribed dose in the first fraction	Tx patient	1. Fails to produce x-rays		Power supply, internal electronic failure	Treatment aborted	3.2	8.0	9.0	230
20	Treatment planning	Find Tx parameters that satisfy Pt needs	4. Catheter entry	2. 1st dwell position misidentified	Possible inadequate balloon to skin distance	Dosimetrist or physicist error	Wrong dose distribution; wrong treatment site	4.5	4.5	6.0	144
19	Treatment planning	Find Tx parameters that satisfy Pt needs	4. Catheter entry	1. Catheter entered backwards end-to-tip	Possible inadequate balloon to skin distance	Dosimetrist or physicist error	Wrong dose distribution; wrong treatment site	3.8	6.3	5.0	143
24	Treatment planning	Find Tx parameters that satisfy Pt needs	5. Optimization and dose calculation	2. Wrong dosimetry parameters entered into the computer	TG-43 parameters	2. Physicist error	Wrong dose distribution	3.0	6.7	7.3	140
40	Initial Tx delivery	Deliver Rx dose at Fx1	Assay x-ray source	3. Source not properly in chamber		Physicist error	Wrong dose	3.8	5.2	6.8	139
23	Treatment planning	Find Tx parameters that satisfy Pt needs	5. Optimization and dose calculation	2. Wrong dosimetry parameters entered into the computer	TG-43 parameters	1. Physicist misunderstood parameters	Wrong dose distribution	3.0	7.0	6.7	136
52	Initial Tx delivery	Deliver Rx dose at Fx1	Tx patient	8. Balloon leaks or ruptures	1. Integrity not checked before insertion. D assumes no imaging	Physicist's error if present during placement, physician's error otherwise, not checking integrity	Wrong dose, too high	3.5	7.3	4.3	120
21	Treatment planning	Find Tx parameters that satisfy Pt needs	5. Optimization and dose calculation	1. Optimization points placed incorrectly	Detectably depends on process	1. Dosimetrist or physicist error	Wrong dose distribution	3.7	5.8	5.2	114
46	Initial Tx delivery	Deliver Rx dose at Fx1	Tx patient	2. Incorrect energy	Currently not possible	Energy could fluctuate during treatment	Wrong dose distribution	3.0	5.3	6.0	109
30	Initial Tx delivery	Deliver Rx dose at Fx1	Applicator in place	Applicator slipped from position		1. Immobilization not used. D assumes no pretreatment imaging	Dose in wrong location	3.7	5.7	4.8	101

App. B1b from TG-182

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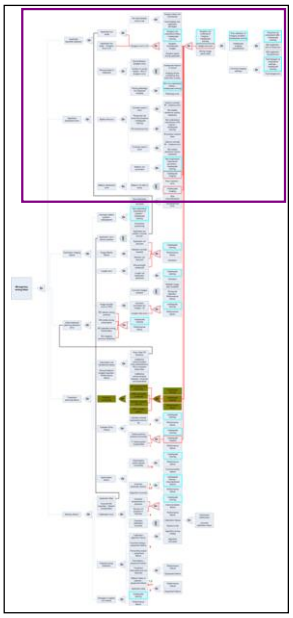
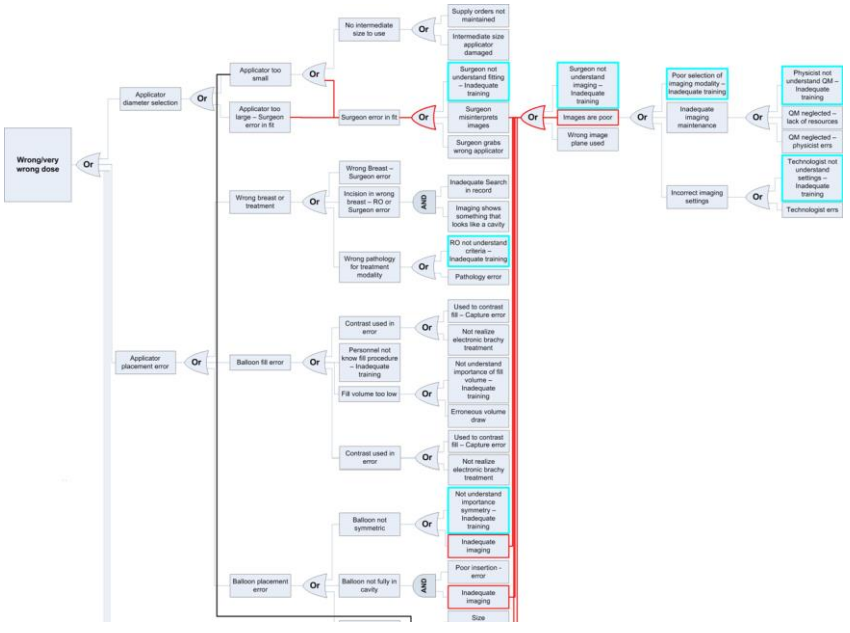
Xoft APBI FTA

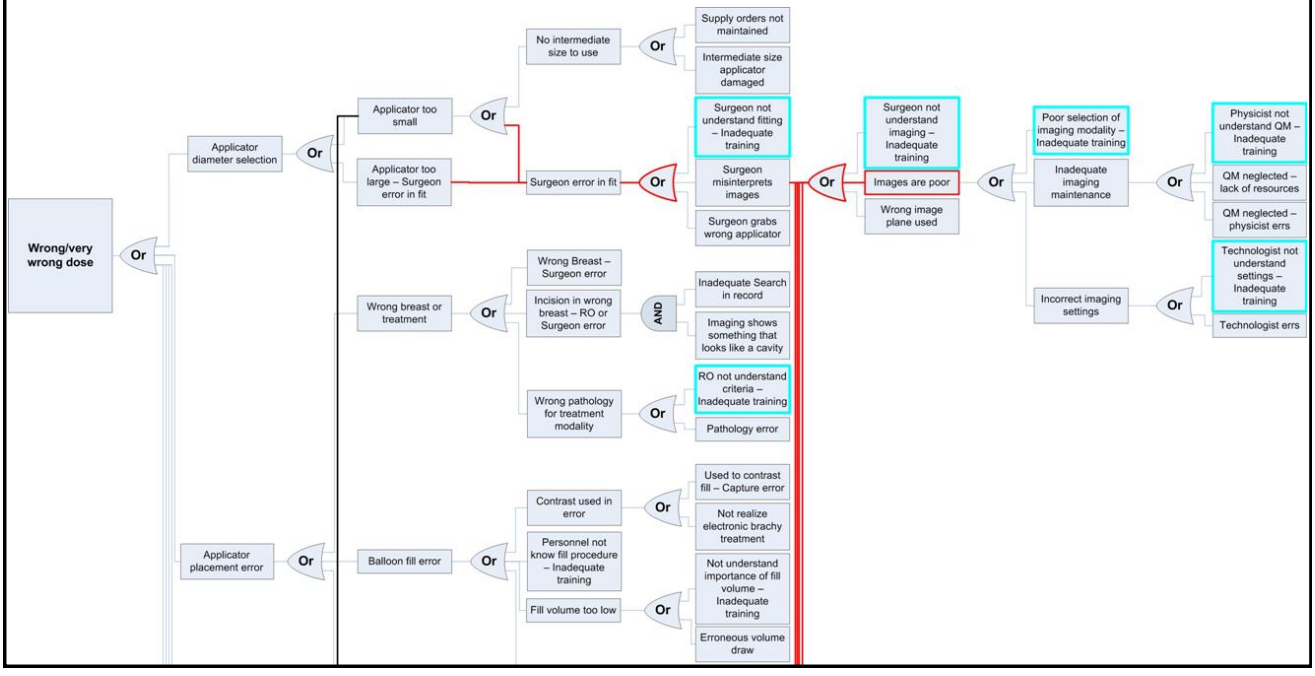




App. C1a from TG-182

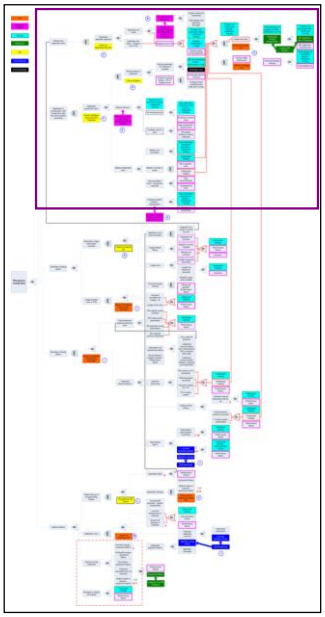
32

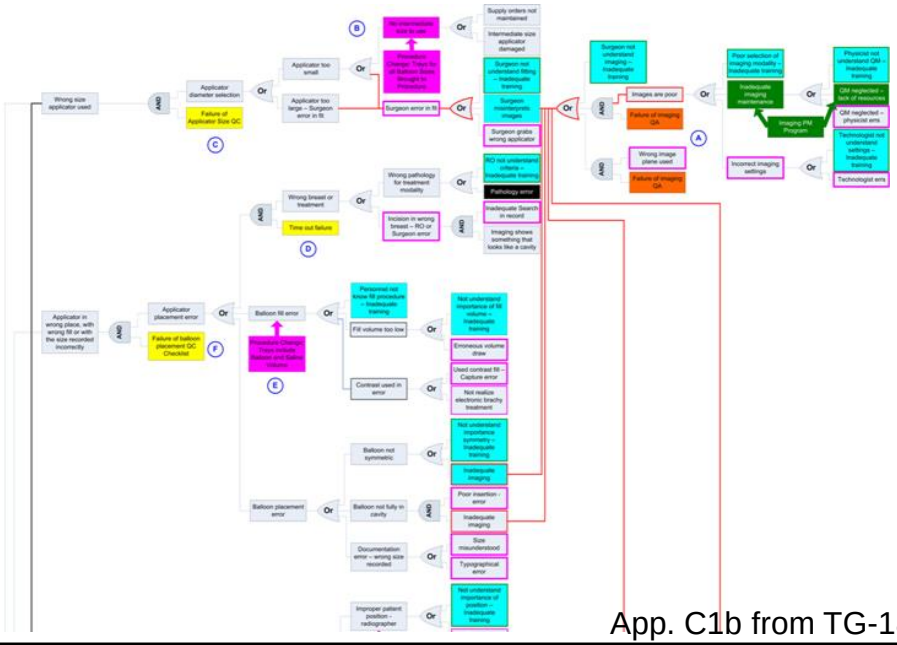
Xoft APBI FTA



33

Xoft APBI FTA (revised)





App. C1b from TG-182

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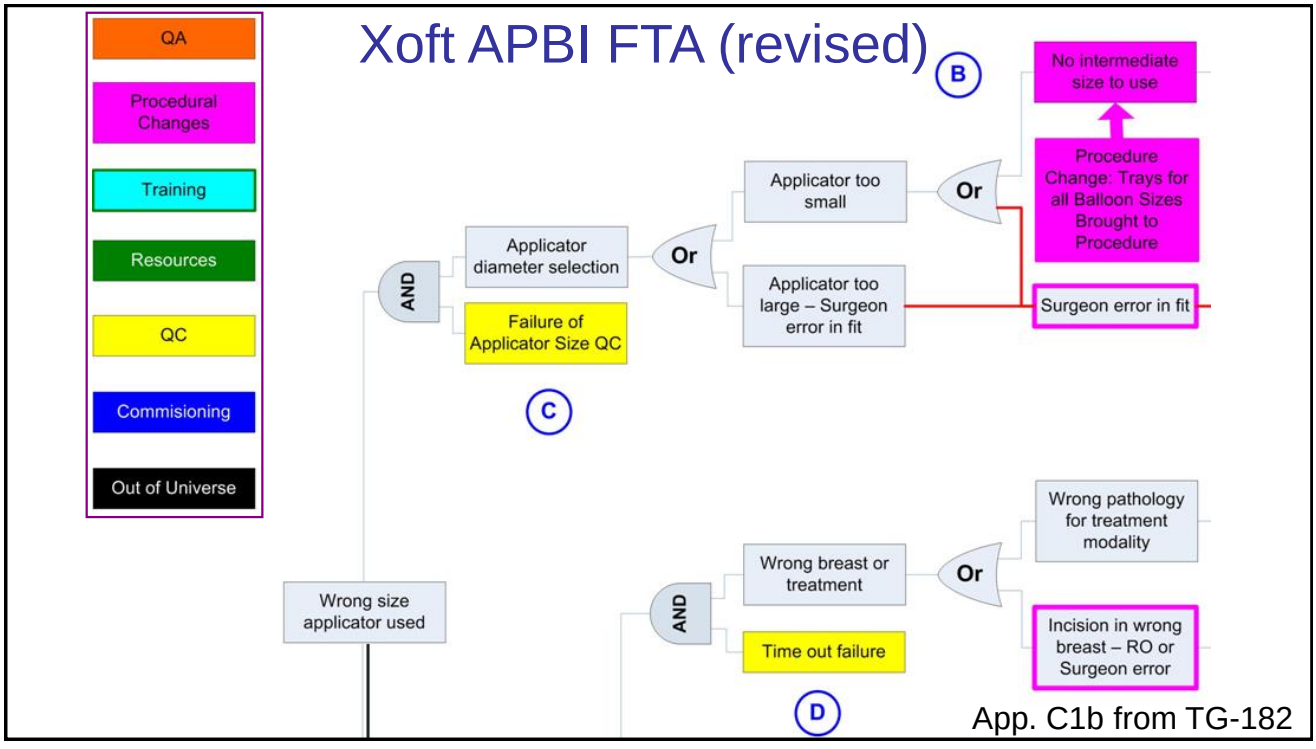
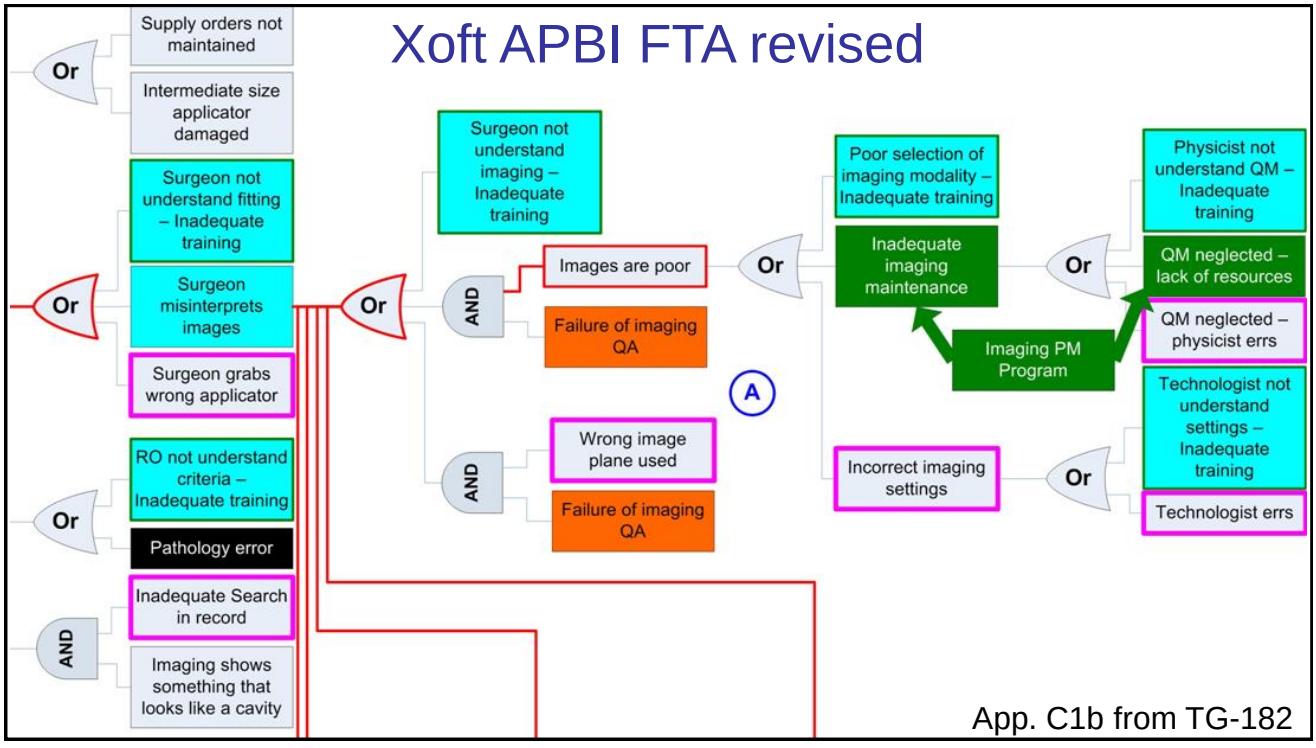

Xoft APBI FTA (revised)
QA
Procedural Changes
Training
Resources
QC
Commisioning
Out of Universe
B
No intermediate size to use
Procedure Change: Trays for all Balloon Sizes Brought to Procedure
Applicator too small
Or
Applicator too large – Surgeon error in fit
Surgeon error in fit
Applicator diameter selection
Or
AND
Failure of Applicator Size QC
C
Wrong size applicator used
Wrong pathology for treatment modality
Wrong breast or treatment
Or
AND
Incision in wrong breast – RO or Surgeon error
Time out failure
D
App. C1b from TG-182

35


Xoft APBI FTA revised
Supply orders not maintained
Or
Intermediate size applicator damaged
Surgeon not understand fitting – Inadequate training
Surgeon misinterprets images
Or
Surgeon grabs wrong applicator
RO not understand criteria – Inadequate training
Or
Pathology error
Inadequate Search in record
AND
Imaging shows something that looks like a cavity
Or
Surgeon not understand imaging – Inadequate training
Images are poor
AND
Failure of imaging QA
A
Wrong image plane used
AND
Failure of imaging QA
Poor selection of imaging modality – Inadequate training
Inadequate imaging maintenance
Or
Imaging PM Program
Incorrect imaging settings
Or
Physicist not understand QM – Inadequate training
QM neglected – lack of resources
QM neglected – physicist errs
Technologist not understand settings – Inadequate training
Technologist errs
App. C1b from TG-182

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Xoft APBI FTA (revised): Notes

A institute regular imaging QA

B before the procedure, provide trays for each size applicator with syringes filled with the proper range of saline to avoid the accidental use of contrast

C RadOnc and Physics implement a checklist to confirm applicator size

D time out includes patient identity, treatment protocol, laterality, balloon size

E etc

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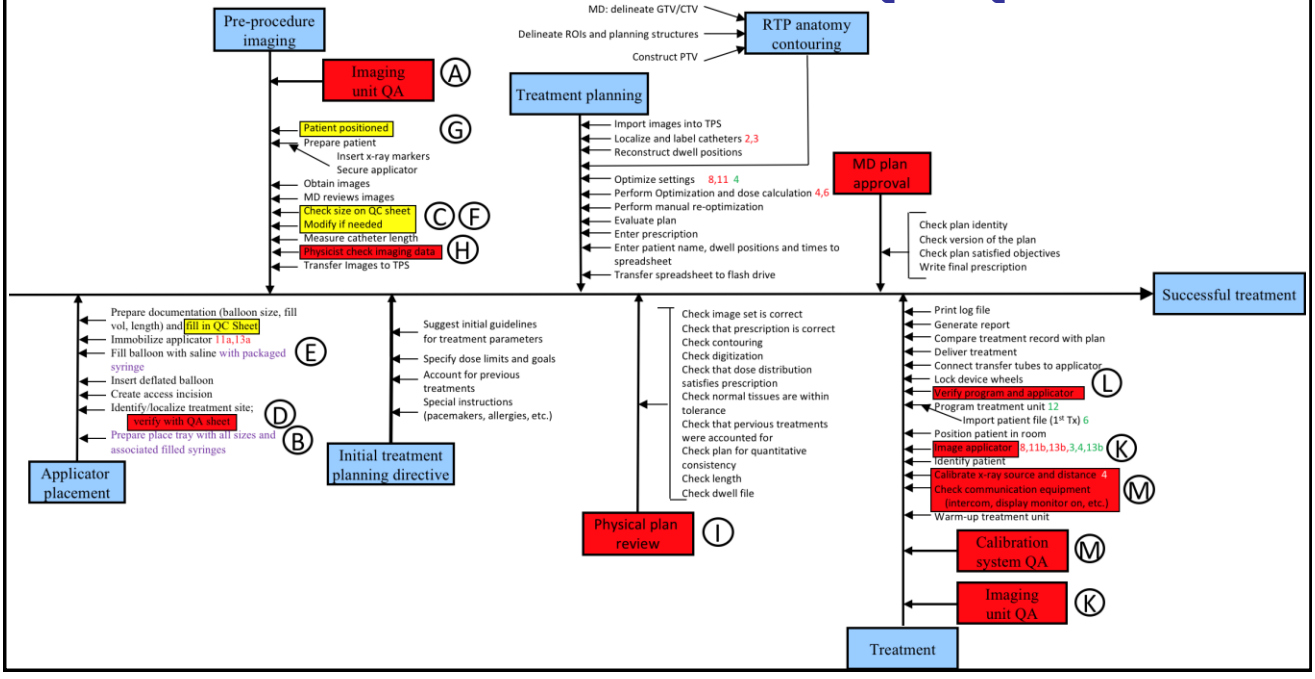
Xoft APBI Workflow with QA+QC



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Improving the treatment planning and delivery process of Xoft electronic skin brachytherapy

Ryan Manger*, Douglas Rahn, Jeremy Hoisak, Irena Dragojević*

Department of Radiation Medicine and Applied Sciences, UC San Diego, Chula Vista, CA

ABSTRACT

PURPOSE: To develop an improved Xoft electronic skin brachytherapy process and identify areas of further improvement.

METHODS AND MATERIALS: A multidisciplinary team conducted a failure modes and effects analysis (FMEA) by developing a process map and a corresponding list of failure modes. The failure modes were scored for their occurrence, severity, and detectability, and a risk priority number (RPN) was calculated for each failure mode as the product of occurrence, severity, and detectability. Corrective actions were implemented to address the higher risk failure modes, and a revised process was generated. The RPNs of the failure modes were compared between the initial process and final process to assess the perceived benefits of the corrective actions.

RESULTS: The final treatment process consists of 100 steps and 114 failure modes. The FMEA took approximately 20 person-hours (one physician, three physicists, and two therapists) to complete. The 10 most dangerous failure modes had RPNs ranging from 336 to 630. Corrective actions were effective at addressing most failure modes (10 riskiest RPNs ranging from 189 to 310), yet the RPNs were higher than those published for alternative systems. Many of these high-risk failure modes remained due to hardware design limitations.

CONCLUSIONS: FMEA helps guide process improvement efforts by emphasizing the riskiest steps. Significant risks are apparent when using a Xoft treatment unit for skin brachytherapy due to hardware limitations such as the lack of several interlocks, a short source lifespan, and variability in source output. The process presented in this article is expected to reduce but not eliminate these risks.

Keywords: Xoft; Skin; Electronic brachytherapy; FMEA; Patient safety; Process improvement

Manger et al. Brachytherapy 17, 702-708 (2018)

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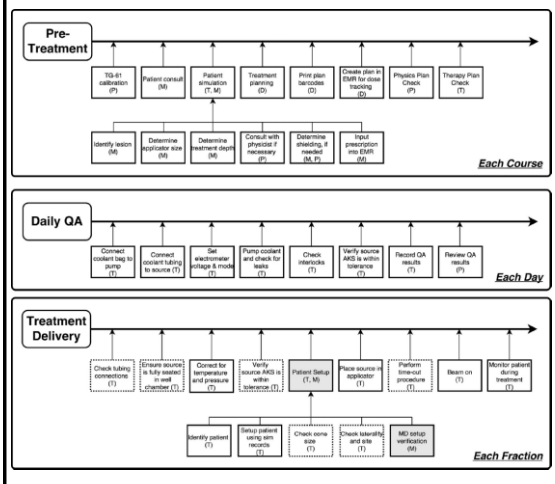

Top 10 RPN-ranked failure modes for the initial process

Step	Failure mode	O	S	D	RPN
Place the source in the applicator	Source not placed completely in applicator (lower dose)	9	10	7	630
Place the source in the well chamber	Source not placed completely in well chamber	10	8	7	560
Start treatment	Failed to verify treatment time, patient identity, and treatment site	9	9	6	486
Measure AKS (during TG-61)	Unstable AKS reading	9	9	6	486
Verify whether the correct source is used for planning	Incorrect source used for planning	10	9	5	450
Calculate treatment plan dwell time (dosimetry)	Incorrect dwell time calculated	7	10	6	420
Connect the source to the coolant tubing	Wrong source used	10	8	5	400
Load plan into the treatment unit	Wrong plan for source in use	9	8	5	360
Verify hard copies of plan, ensuring barcodes are correct	Hard copies of plan and barcodes not checked	8	9	5	360
Place the applicator over the target area	Applicator cone not applied to correct target area	7	8	6	336

RPN = risk priority number; AKS = air kerma strength; O = occurrence; S = severity; D = detectability.

Top 10 RPN-ranked failure modes for the final process

Step	Failure mode	Design limitation	O	S	D	RPN	Prior RPN
Identify the treatment area on patients	Wrong treatment site identified	No	6.3	8.2	6.0	310	315
Review setup (MD)	MD does not review setup	No	10.	7.0	3.8	266	324
Convert pressure reading from inHg to mmHg	Incorrect unit conversion yields wrong temperature-pressure	Yes	4.5	8.0	7.0	252	320
Transfer TG-61 dose rate to treatment planning tables	Incorrect treatment times used for treatment	Yes	5.5	9.0	5.0	248	315
Place the source in the applicator	Source not placed completely in applicator (lower dose)	Yes	3.8	8.4	7.3	233	630
Check stability of AKS readings (during TG-61)	Unstable charge reading	Yes	4.5	9.0	5.5	223	486
Perform pretreatment therapist time-out	No therapist time-out	No	4.8	8.4	5.0	202	486
Monitor patients during treatment	Patient not monitored	No	5.0	7.8	5.0	195	320
Place the applicator over the target area	Cone not applied to target area	No	4.8	7.4	5.5	195	336
Check ion chamber calibration	Ion chamber not calibrated	Yes	3.0	9.0	7.0	189	192

RPN = risk priority number; AKS = air kerma strength; O = occurrence; S = severity; D = detectability; MD = medical doctor.

Manger et al. Brachytherapy 17, 702-708 (2018)

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Risk analysis of electronic intraoperative radiation therapy for breast cancer

Dominique Rash, David Hoffman, Ryan Manger, Irena Dragojević*

UC San Diego Radiation Medicine and Applied Sciences, La Jolla, CA

ABSTRACT

PURPOSE: To evaluate the process and improve safety of intraoperative radiation therapy (IORT) for early-stage breast cancers treated with electronic brachytherapy.

METHODS AND MATERIALS: A multidisciplinary team conducted a failure mode and effects analysis (FMEA) for IORT breast cancer treatments by first developing a process map. This map was then used to identify failure modes for all steps in the treatment workflow. Risk priority numbers (RPNs) were assigned to each failure mode and were calculated as the product of the failure mode's probability of occurrence (O), severity (S), and lack of detectability (D). Corrective steps were implemented to address failure modes with the highest risk, and a revised process was generated.

RESULTS: The steps with the highest risk failure modes were related to source calibration, use of correct plan and dwell times, and the correct site and intent. The introduction of a physician calibration check and an extended time-out checklist reduced the risk of these failure modes. The highest risk steps in the Xoft breast IORT treatment process are associated with source calibration and manual entry of dwell positions for each balloon size and volume combination. High-risk failure modes that could be mitigated with improved hardware and software interlocks were identified.

CONCLUSION: High-risk failure modes are identified with FMEA and addressed with corrective steps. This application of FMEA can be used in principle for clinical processes throughout breast cancer care. This analysis demonstrates the importance of well-designed QC policies, procedures, and oversight in a Xoft electronic brachytherapy program for breast cancer IORT.

Keywords: Breast radiation therapy; Electronic brachytherapy; Safety improvement; Intraoperative radiation therapy

Rash et al. Brachytherapy 18, 271-276 (2019)

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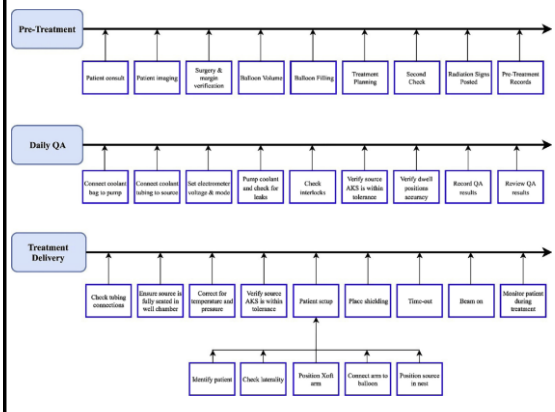

Top 10 severity-ranked failure modes

Step	Failure mode	O	S	D	RPN	Rescored RPN
Identify the patient (S, RO, P)	Patient not identified	2.0	10.0	2.5	50.0	50.0
Identify the treatment site on the patient (S, RO, P)	Wrong treatment site	3.8	8.8	5.5	180.5	123.0
Perform the pretreatment time-out (RO, P)	No pretreatment time-out	2.3	8.8	5.5	108.3	108.3
Lumpectomy performed on correct breast and location (S)	Lumpectomy performed on incorrect tissue	7.0	8.5	6.8	401.6	401.6
Verify dwell time calculation (P)	Dwell times not verified	4.0	8.5	4.5	153.0	115.5
Place the source into well chamber (P)	Source incorrectly placed into well chamber	7.8	8.3	7.8	495.5	207.8
Check the applicator balloon for leaking (S)	The balloon leaks before and during treatment	4.0	8.3	10.0	330.0	330.0
Review physician orders (RO)	Incorrect physician orders	5.3	8.0	5.5	231.0	168.0
Confirm the dwell time for applicator and fill volume	Dwell times not confirmed	4.5	8.0	5.8	207.0	207.0
Record ASK values into the daily quality assurance record	AKS not recorded	4.0	8.0	4.3	136.0	96.0

O = occurrence; S = severity; D = detectability; RPN = risk priority number; AKS = air kerma strength.
Staff associated with each step is identified in the parentheses: surgeon (S), radiation oncologist (RO), and physicist (P).

Top 10 RPN-ranked failure modes

Step	Failure mode	O	S	D	RPN	Rescored RPN
Place the source into well chamber (P)	Source incorrectly placed into well chamber	7.8	8.3	7.8	495.5	207.8
Lumpectomy performed on correct breast and location (S)	Lumpectomy performed on incorrect tissue	7.0	8.5	6.8	401.6	401.6
Check stability of ASK reading during calibration (P)	Unstable dose rate	8.0	7.8	6.0	372.0	201.5
Check the applicator balloon for leaking (S)	The balloon leaks before and during treatment	4.0	8.3	10.0	330.0	330.0
Verbal prescription, applicator, and fill volume confirmation	Balloon and fill volume changed during procedure and a nonupdated plan is used	5.3	6.3	9.3	303.5	131.3
Connect coolant tubing to the source (P)	Coolant not connected to the source	7.8	4.8	7.0	257.7	128.8
Standard plan selected for applicator and fill volume (P)	An incorrect standard plan is selected	7.8	7.3	4.3	238.8	238.8
Physician confirms orders against the radiation plan (RO)	Incorrect physician intent used for treatment	5.3	8.0	5.5	231.0	168.0
Review physician orders (RO)	Incorrect physician orders	8.0	7.0	4.0	224.0	224.0
Place the flexible shield outside the treatment site (RO, P)	Treatment room not shielded by the flexible shield	6.8	5.5	5.8	213.5	139.2

O = occurrence; S = severity; D = detectability; RPN = risk priority number.
Staff associated with each step is identified in the parentheses: surgeon (S), radiation oncologist (RO), and physicist (P).

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Benchmarking failure mode and effects analysis of electronic brachytherapy with data from incident learning systems

Jeremy D.P. Hoisak*, Ryan Manger, Irena Dragojević
Department of Radiation Medicine & Applied Sciences, UC San Diego, La Jolla, CA

ABSTRACT

PURPOSE: Failure modes and effects analysis (FMEA) is a prospective risk assessment tool for identifying failure modes in equipment or processes and informing the design of quality control systems. This work aims to benchmark the performance of FMEAs for electronic brachytherapy (eBT) of the skin and for breast by comparing predicted versus actual failure modes reported in multiple incident learning systems (ILS).

METHODS AND MATERIALS: Two public and our institution's internal ILS were queried for Xoft Axxent eBT-related events over 9 years. The failure modes and Risk Priority Numbers (RPNs) were taken from FMEAs previously performed for Xoft eBT of nonmelanoma skin cancer and breast intraoperative radiation therapy (IORT). For each event, the treatment site and primary failure mode was compared with the failure modes and RPNs from that site's FMEA.

RESULTS: 49 events involving Xoft eBT were identified. Thirty-one (63.3%) involved breast IORT, and 18 (36.7%) involved the skin. Three events could not be linked to an FMEA failure mode. In 87.7% of events, the primary failure mode ranked in the FMEA top 10 by RPNs. In 83.3% of skin events, the failure modes ranked in the top 10 by RPN or severity. In 90.3% of IORT events, the failure modes ranked within the top 10 by RPN or severity.

CONCLUSIONS: Evaluating FMEA failure modes against ILS data demonstrates that FMEA is effective at predicting failure modes but can be dependent on user experience. ILS data can improve FMEA by identifying potential failure modes and suggesting realistic occurrence, detectability, and severity values.

Keywords: Electronic brachytherapy; Failure modes and effects analysis; Incident learning systems

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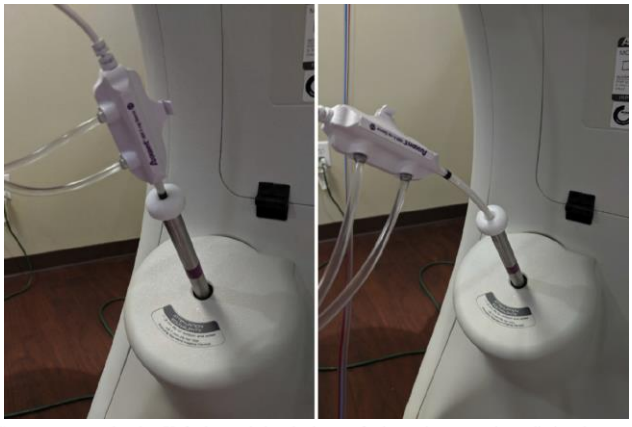

Incident learning system (ILS) event reports related to Xoft electronic brachytherapy for breast intraoperative radiation therapy (IORT) and each event type's failure mode Risk Priority Number (RPN)

Event description	Failure mode	# Of incidents	RPN	Database
Incorrect dose delivery due to miscalibration	Source not fully in dwell chamber	2	495	MAUDE
Balloon failure/fluid leak	Check the applicator balloon for leaking	23	330	MAUDE
Inadequate shield placement	Place shield	1	214	MAUDE
Power failure/arm malfunction, lengthy treatment delay/treatment incomplete	Recovery/storage/transportation procedures not followed	3	N/A[a]	MAUDE
Coolant pump malfunction	Coolant not functional	1	258	MAUDE
Incorrect plan/barcodes	Confirm dwell times for applicator and fill volume	1	207	ROQRS ILS

[a] These failure modes were not anticipated in either the FMEA analysis for breast IORT or for skin, therefore no RPN could be retrospectively assigned.

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Summary

- The Xoft eBT system has been used clinically for 15 years with established dosimetry and calibrations.
- TG-182 Report teaches how each clinic can perform FMEA & FTA to establish a robust clinical workflow with associated QA+QC.