Task Group 182: Electronic Intracavitary Brachytherapy QM based on Risk Analysis

Session #3:

ZEISS INTRABEAM® System and Simple Design of Quality Management Program

presented by

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Disclosures: NONE

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Scope of this session:

- Model a risk based Quality Management (QM) program
  - Risk analysis model: TG 100 based FMEA tool
  - Intracavitary Breast IORT for early stage breast cancer
  - ZEISS INTRABEAM® System
- Importance of QC & QA activities for a robust QM program

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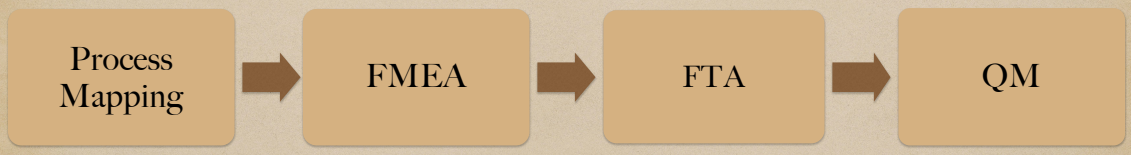
Outline

- ZEISS INTRABEAM® system
- Intracavitary Breast IORT procedure
- Design risk based QM program



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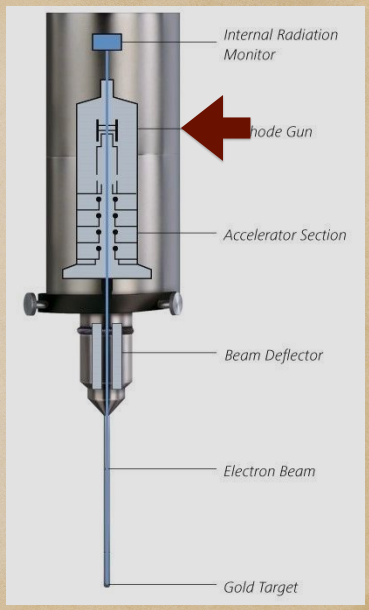
ZEISS INTRABEAM® system

- X-ray probe (XRS source): 50kV, 40µA
  - Electron Gun
  - Accelerator Section
  - Beam Deflector
  - Drift tube:10cm length, 3.2mm diameter
  - Gold target: (0.5 µm)
  - Internal Radiation Monitor(IRM)



4. INTRABEAM SYSTEM PRS 500 with XRS 4 software version 2.2

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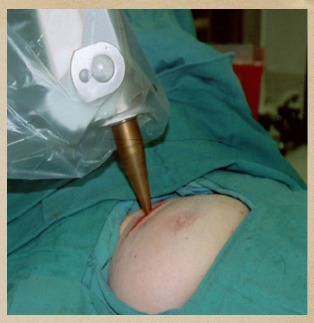
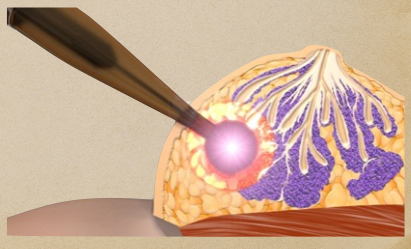
ZEISS INTRABEAM® system cont'd….

- Superficial kV X-rays (HVL in mm of Al)
- Nearly spherical dose distribution
- Mean energy in water:

  28keV at the surface of the applicator
- Dose fall off at the rate of $1/r^3$ in tissue





6. Ebert, M. A., & Carruthers, B. (2003) Medical Physics, 30(9), 2424–243

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ZEISS INTRABEAM® system (cont'd)

- Spherical Applicator set
  - Solid, hollow applicators
  - Water equivalent plastic: Polyetherimide material
  - Size:1.5cm – 5cm in 0.5cm increments

Image courtesy Carl Zeiss Meditecc.

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ZEISS INTRABEAM® system cont'd….

- Surgical Arm (Floor Stand)
  - 6 degrees of motion
- Treatment Console
- QA devices
  - PAICH(Probe Adjuster & Ion Chamber Holder)
    - XRS Probe straightening tool
    - Output constancy check
  - Soft x-ray ionization chamber (PTW 23342)
  - PDA (Photo Diode Array)
    - Deflection/Isotropy check

courtesy Frank Weigand of Zeiss, Inc.

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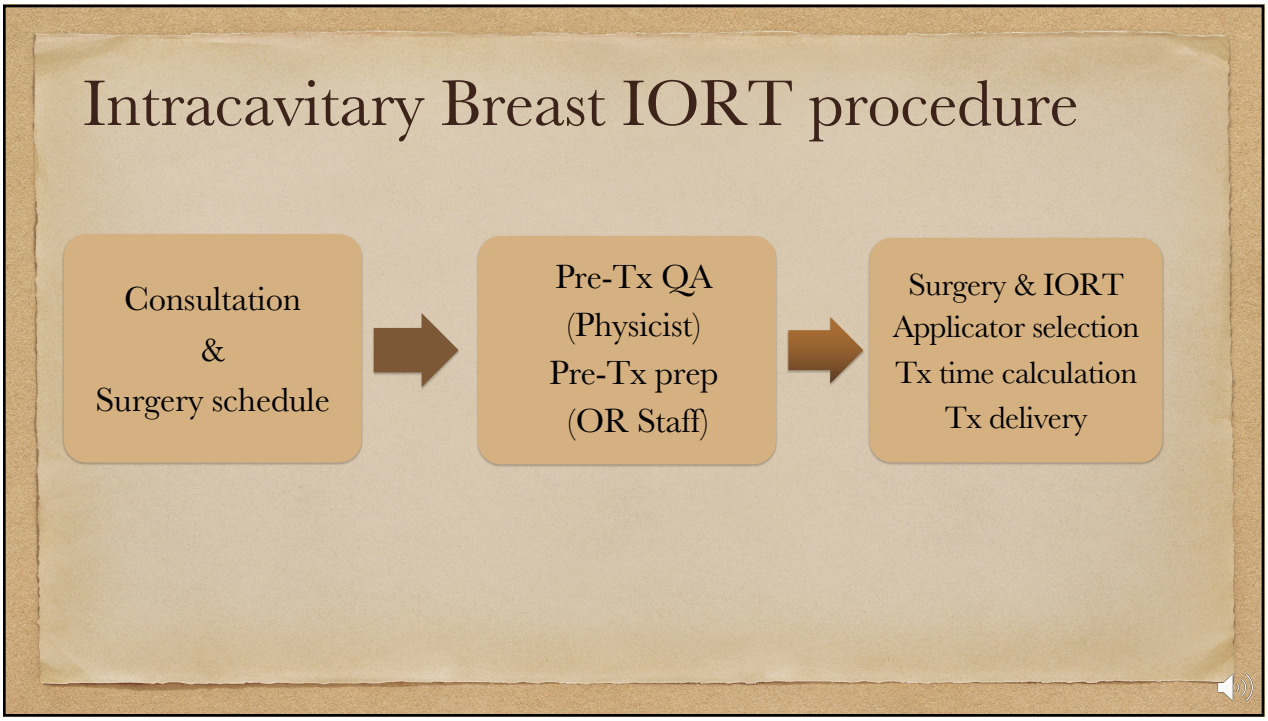
Intracavitary Breast IORT procedure
Consultation
&
Surgery schedule
Pre-Tx QA
(Physicist)
Pre-Tx prep
(OR Staff)
Surgery & IORT
Applicator selection
Tx time calculation
Tx delivery

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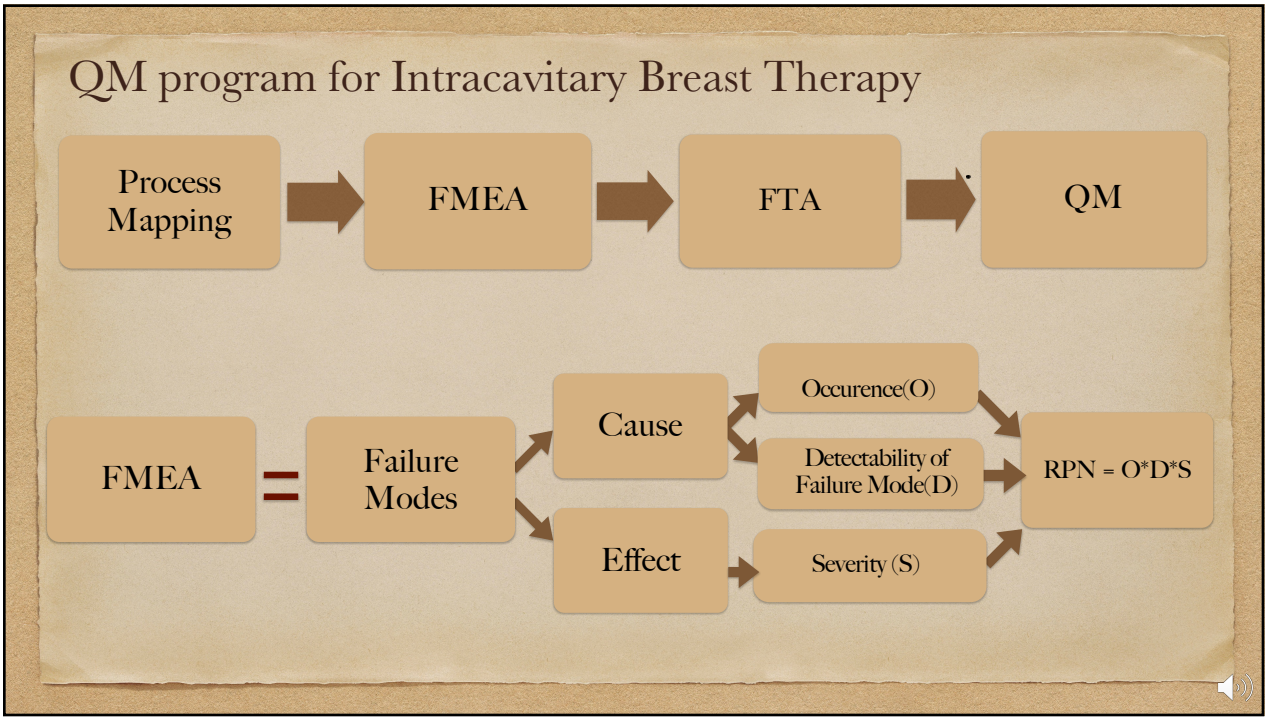
QM program for Intracavitary Breast Therapy
Process Mapping
FMEA
FTA
QM
FMEA
=
Failure Modes
Cause
Effect
Occurence(O)
Detectability of Failure Mode(D)
Severity (S)
RPN = O*D*S

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Intracavitary Breast IORT procedure

Consultation & Surgery schedule

Pre-Tx prep (Physicist)
Pre-Tx prep (OR Staff)

Surgery & IORT
Applicator selection
Tx time calculation
Tx delivery

Process Mapping

FMEA

FTA

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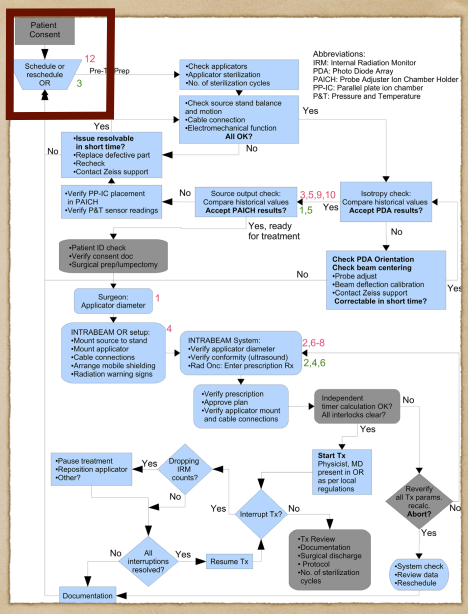
Process Mapping:

Consultation & Surgery Schedule

- Patient Consultation
- Schedule procedure day
- Staff schedule (Surgery & Radonc)
- System parts availability



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FMEA for "Consultation & Surgery

Process Steps	Failure Modes	Cause	Effect of Failure	AVG (O)	AVG (S)	AVG (D)	RPN= O*S*D
Radiation Oncologist Schedule	RadOnc is not available	Oncologists not alerted	Tx delayed or aborted	6	3.5	1.25	24.75

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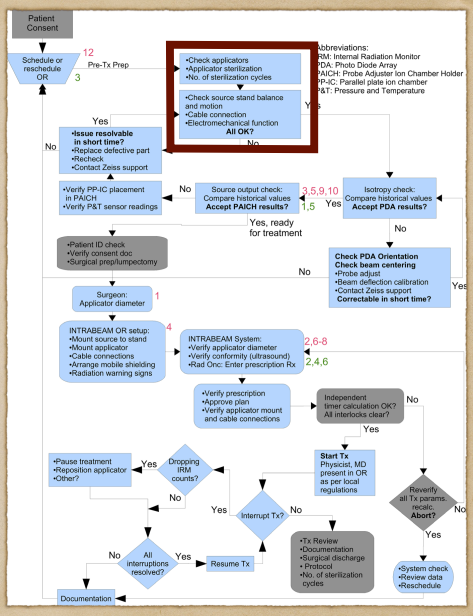
Process Map:

Pre-Treatment procedure

- All applicators are available
- Surgical stand check
- Console & XRS probe check
- Isotropy check
- Source output check



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FMEA Analysis for "Pre-Tx Procedure"

Processes	Process steps	Failure Modes	Cause	Effects of failure	AVG (O)	AVG (S)	AVG (D)	RPN = O*S*D
Applicator availability	Appl Present	Appl not present	Applicator misplaced	Tx aborted	5.5	3.5	1.5	30.8

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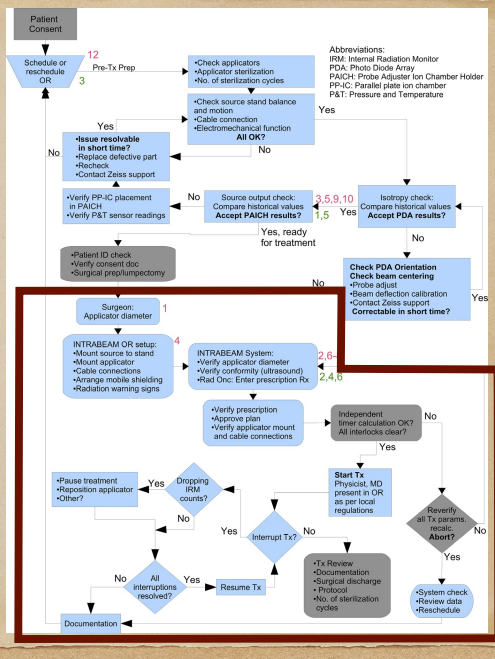
Process Map:

Surgery & IORT procedure

- Applicator selection
- Time calculation
- Treatment delivery



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FMEA Analysis for "Surgery & IORT"

Process	Process Steps	Failure Modes	Cause	Effects of failure	AVG (O)	AVG (S)	AVG (D)	RPN = O*S*D
Applicator Selection	Fit lumpectomy cavity	Applicator too small	Surgeon error in fit	Wrong/heterogenous dose	5.8	6.8	5.8	266.3
			Correct size not available	Wrong/heterogenous dose	5.8	6.8	3.8	185

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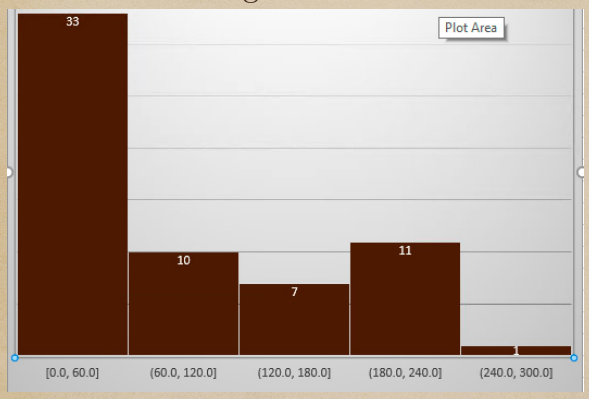
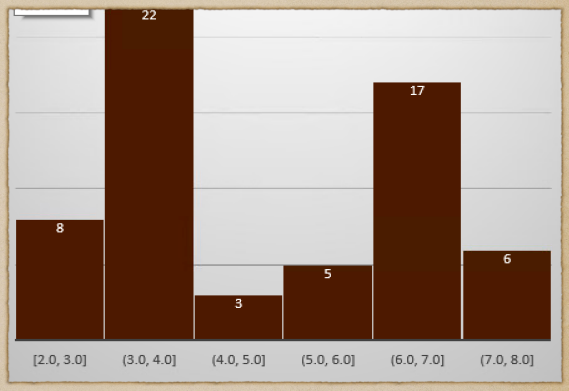
Histogram: RPN



Histogram: S values



# of failure modes = 61

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Fault Tree Analysis(FTA)

Process Mapping → FMEA → FTA

- Address the high risk (higher RPN value) failure modes
- Graphical representation to identify the cause & effect relationship
  - Use logical diagram (OR gates & AND gates)
- Easy to identify the potential locations of quality measures

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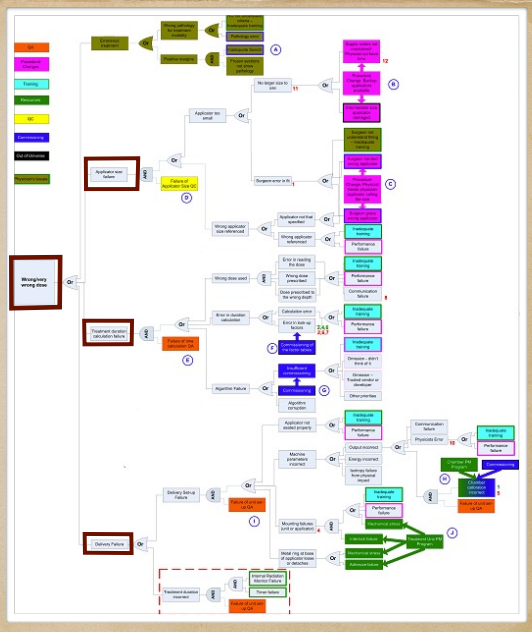
FTA cont'd..

- Highest RPN score: Wrong Dose
- Causes ?
  - •Applicator size failure
  - •Tx Time calculation error
  - •Delivery failure



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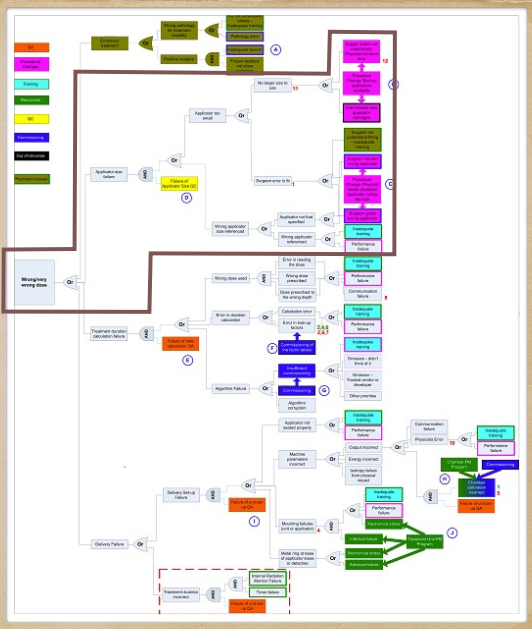
FTA cont'd..

- Highest RPN score: Wrong Dose
  - •Applicator size failure
  - •Tx Time calculation error
  - •Delivery failure



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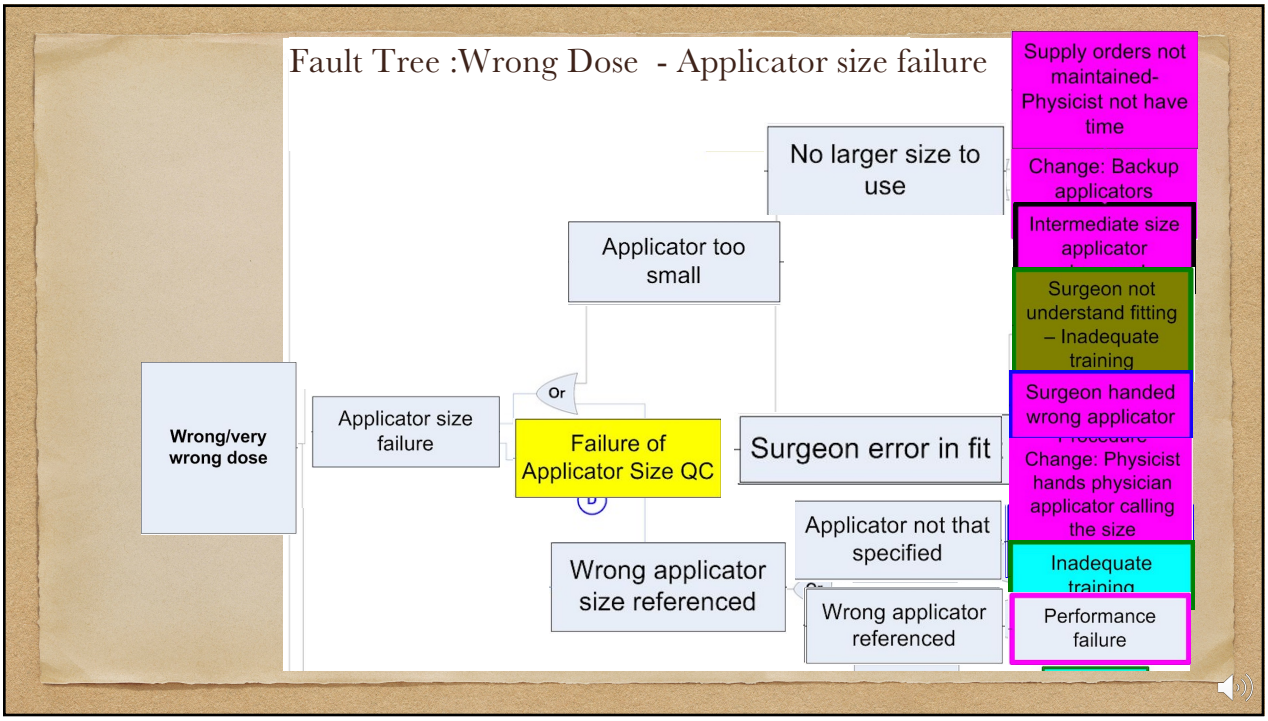

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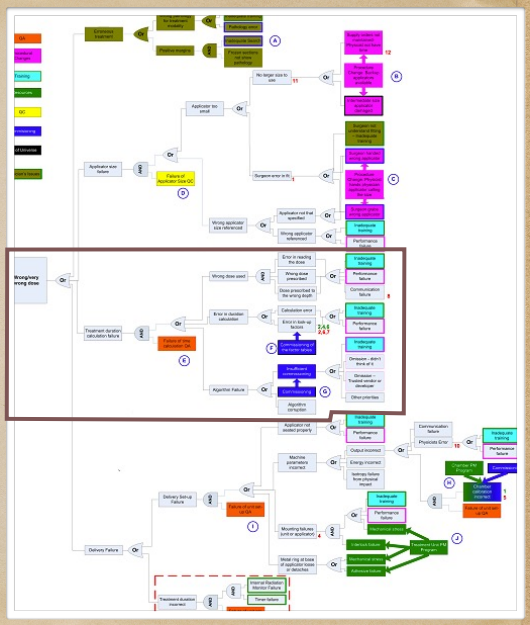
FTA cont'd..

- Highest RPN score: Wrong Dose
  - Applicator size failure
  - Tx Time Calculation error
  - Delivery Failure



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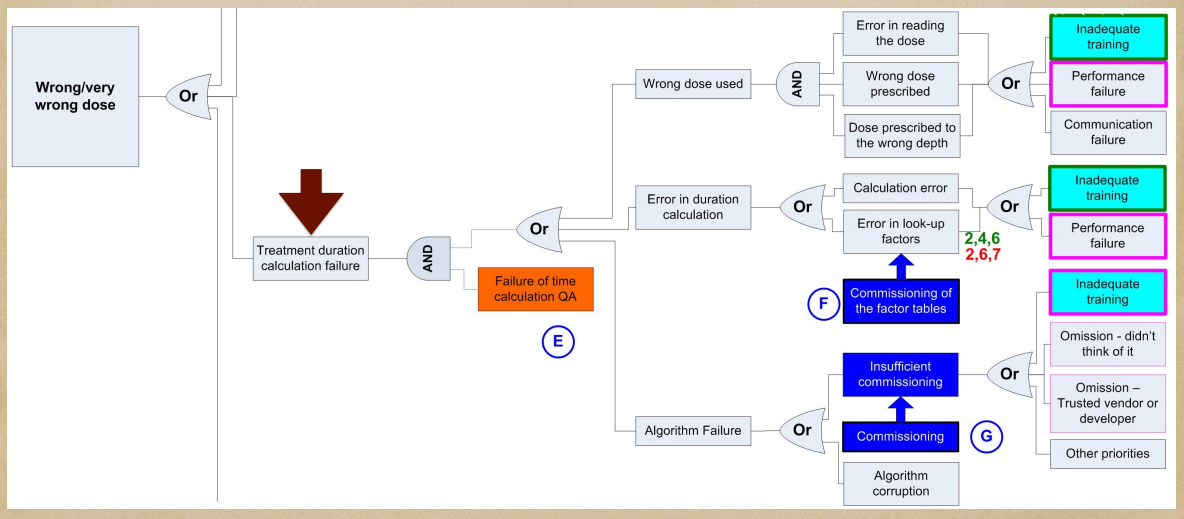
Fault Tree :Wrong Dose-Treatment Time Calculation Failure



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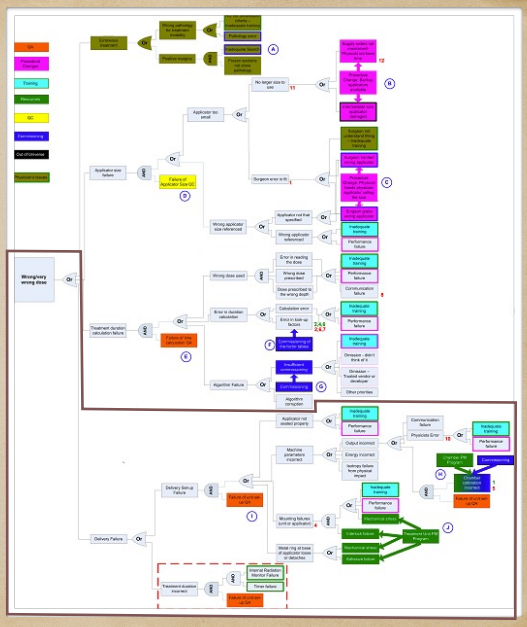
FTA cont'd..

Highest RPN score: Wrong Dose

- Applicator size failure
- Tx Time Calculation error
- Delivery Failure



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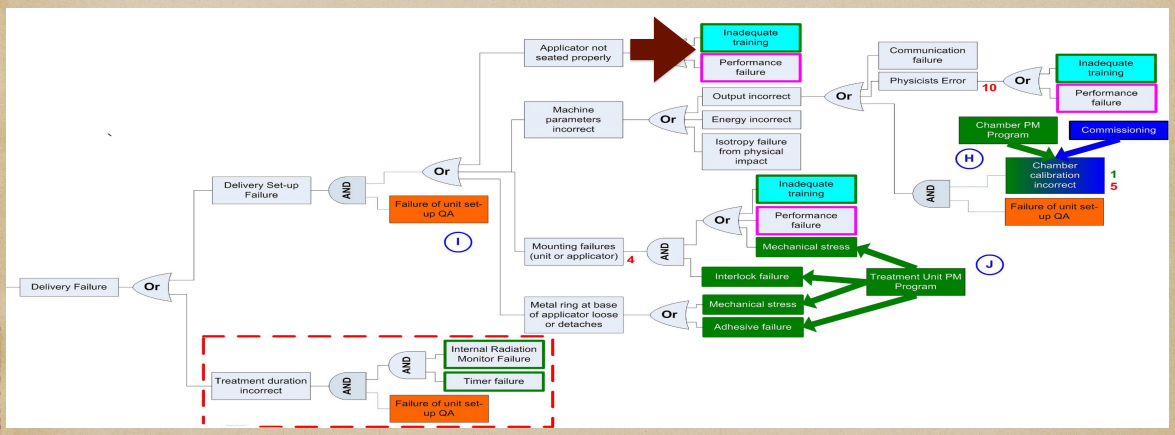
Fault Tree:Wrong Dose - delivery failure



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Quality Management System

- Concentrate on common causes
  - Inadequate training
  - Performance failure
- Eliminate common causes and interrupt failure propagation
  - Re-design the procedure
  - Standardize procedures & checklists
  - Adequate staffing & staff training
  - Routine maintenance of software & hardware
  - Clear line of communications

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SUMMARY

- Model QM model program & Quality checklist
- FMEA sorting based on RPN vs S values
- FTA should incorporate all required QC/QA measures recommended by the vendor
- FTA helps to identify and incorporate additional QA & QC measures

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SUMMARY

- Process Map: Team effort & involvement of multi-disciplinary team members
- Training, facilitator, core team members
- Risk-assessment tools: Task Group 100 & Quality & Safety resources
- Periodic review of QM program:
  - Evaluate the existing QC measures
  - Incorporate institutional ILS

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Thank you!

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Task Group 182 Members

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