TG-100 and Beyond

SWAAPM Annual Meeting
April 11, 2014

John P. Gibbons, Jr., Ph.D.
Chief of Clinical Physics

MARY BIRD PERKINS
CANCER CENTER

Outline

- Introduction and Motivation
- TG-100 Risk Analysis Methodology
  - Process Mapping
  - Failure Mode and Effects Analysis (FMEA)
  - Fault Tree Analysis (FTA)
- TG-100 Recommendations
- And Beyond…
  - Status of TG-100 Report
  - TG-100 Implementation Efforts
- Conclusion

AAPM TG-100:

APPLICATION OF RISK ANALYSIS METHODS TO RADIATION THERAPY QUALITY MANAGEMENT

- Saiful Huq, chair
- Benedick Fraass
- Peter Dunscombe
- John Gibbons
- Geoffrey Ibbott
- Arno Mundt
- Sasa Mutic
- Jatinder Palta
- Frank Rath
- Bruce Thomadsen
- Jeffrey Williamson
- Ellen Yorke

TG-100 Charges

- *Review and critique the existing guidance from the AAPM and others on QA in Radiation Oncology. Determine the specific areas that need better coverage and develop a suitable general quality assurance program.*
- *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.*
- *After the identification of the hazard analysis for broad classes of radiotherapy procedures, develop the framework of the QA program.*

TG-100 Report

TG-100 Report is contained in Two Parts:

- Part I
  - Theory and Justification
  - Implementation Guidelines
  - Recommendations for users, vendors, AAPM, regulators
  - Examples and exercises
- Part II
  - Example QM Program development for IMRT

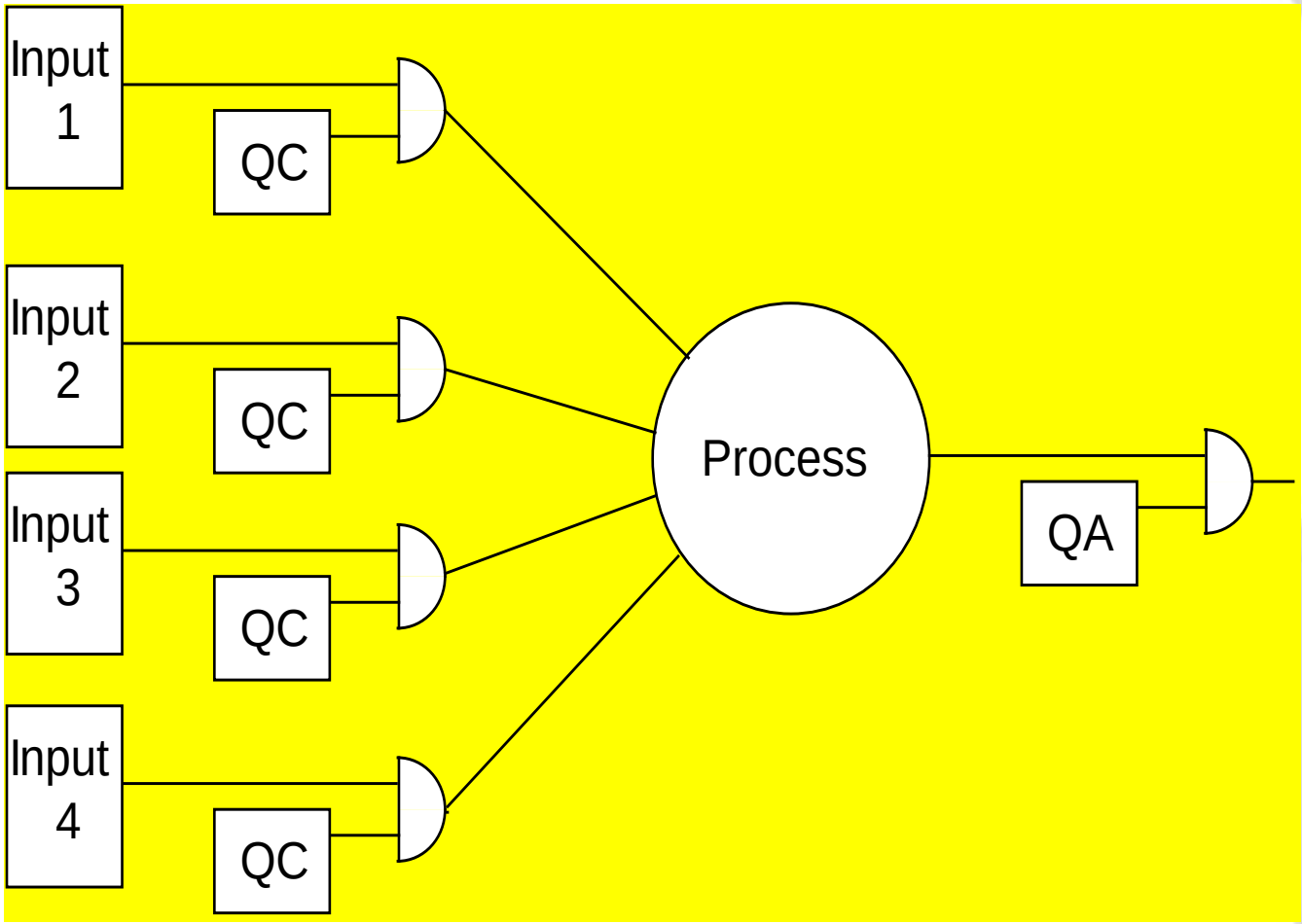
TG-100 Definitions

- Quality:
  - Features which meet the needs of the patient (medical, psychological, and economic)
  - Process which delivers Tx in accordance with existing standards
  - Free from errors or mistakes
- Failure: Not meeting a desired level of quality.

TG-100 Definitions

- Quality Management (QM): All activities designed to achieve quality
  - Quality Control (QC): Procedures that verify the status of a specific Tx parameter
  - Quality Assurance (QA): Procedures that verify quality goals are met

QC/QA in a Quality Management Program



Bruce Thomadsen, Quality Management in Radiation Therapy-General Concepts, AAPM 2004 Refresher Course

TG-100 Motivation

Problems with traditional Quality Management (QM) approaches:

- Excessive demand on physics resources
- Delay in QM protocols for new technologies
- No QM protocol covers all permutations of practice
- Emphasis on device-specific QA
- QA traditionally done retrospectively

  (e.g., Root Cause Analysis (RCA))

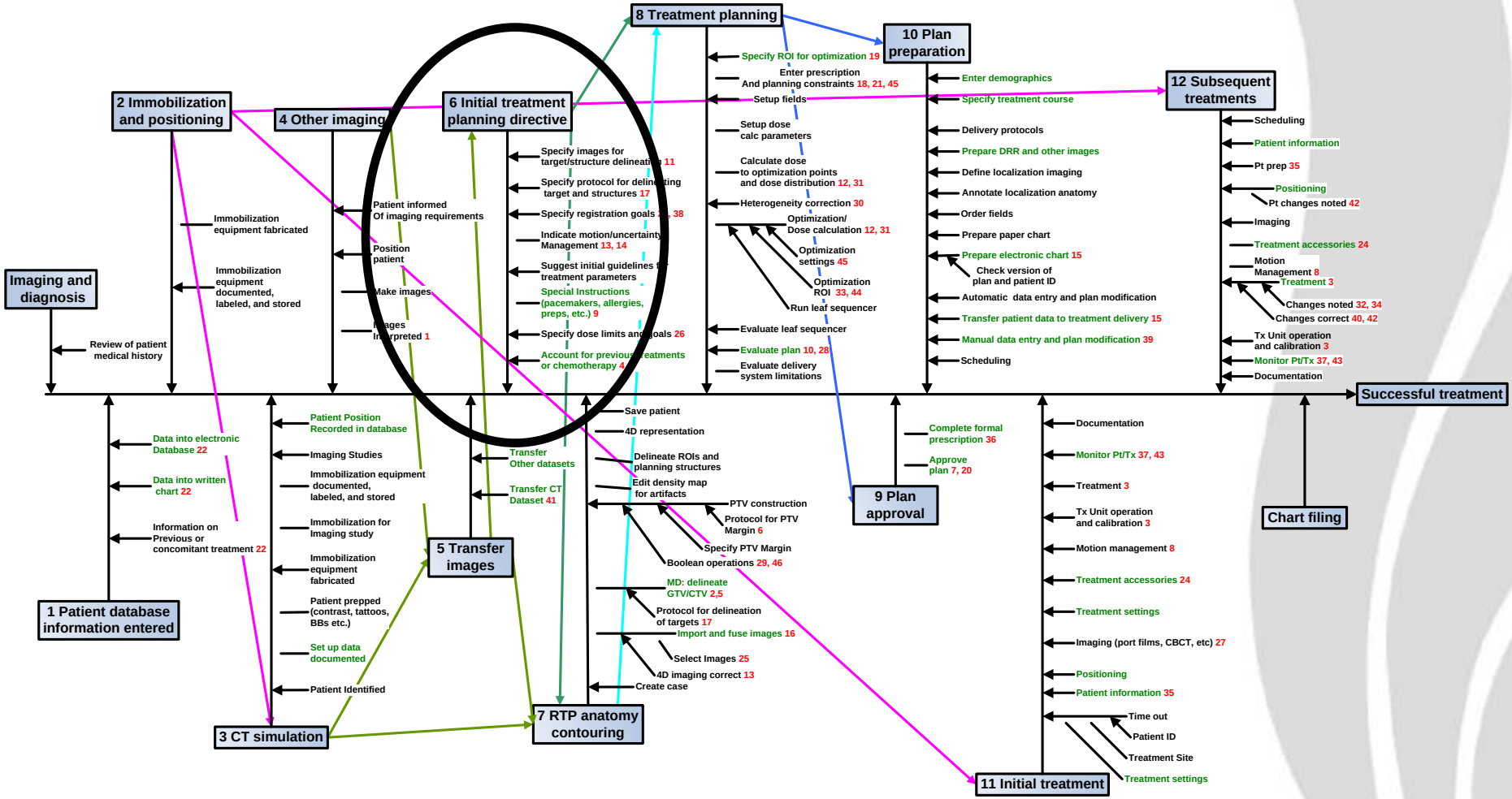
TG-100 QA Methodology

- Prospective Approach to QM
- Emphasis on Team Approach (i.e., *all* staff involved in procedures participate)
- Three QM Tools Used:
  - Process Mapping
  - Failure Mode and Event Analysis (FMEA)
  - Fault Tree Analysis (FTA)

Process Map

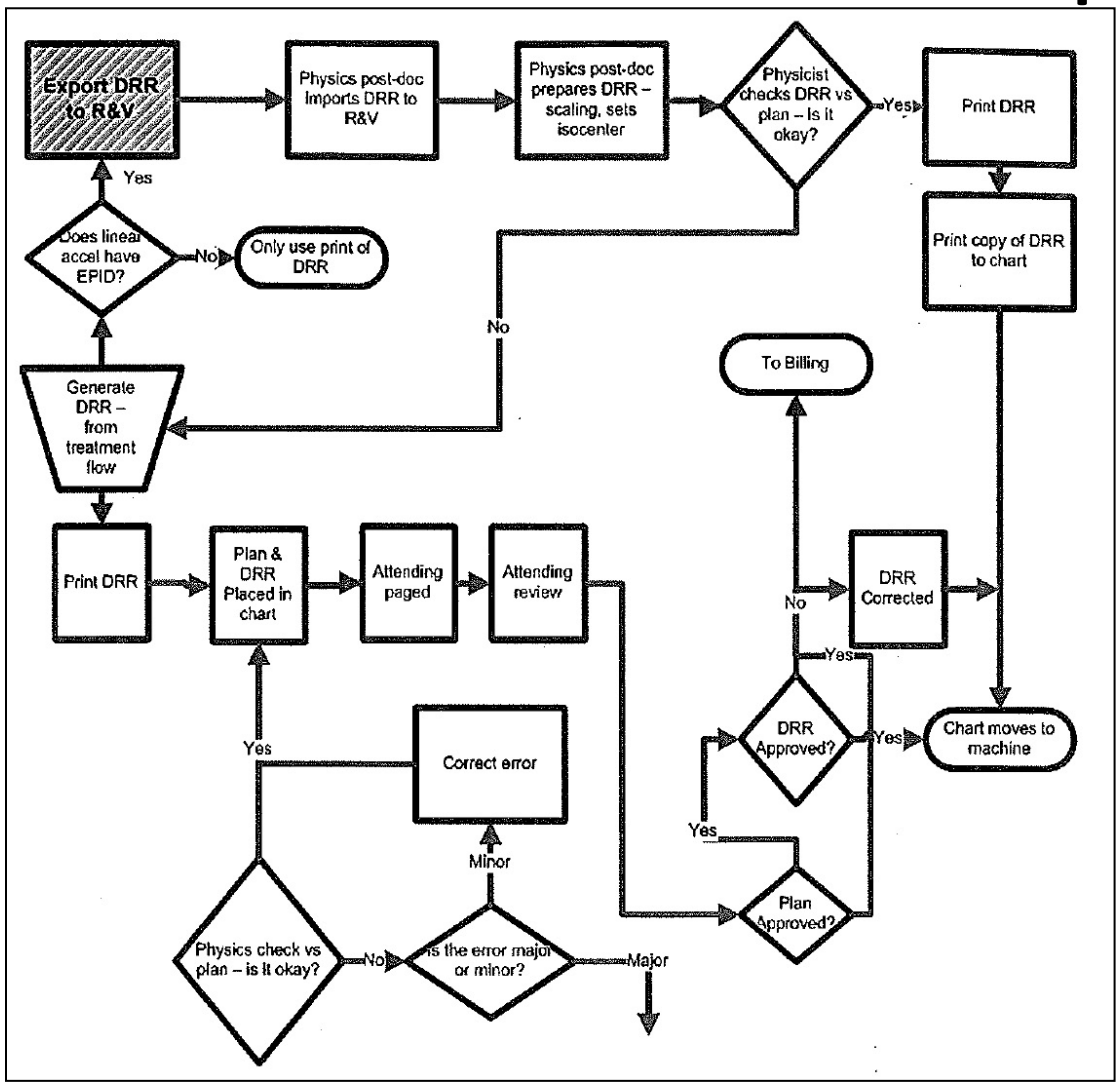
- Definition: An illustration of the temporal relationships between different steps in a process
- May be displayed graphically in a tree or flow-chart diagram

TG-100 Process Map



TG-100 Process Map

Flowchart Process Map



Ford et al, IJROBP 74:852-858 (2009)

Failure Modes and Effects Analysis (FMEA)

For each step in the process map:

1. Identify all potential failure modes
2. Identify the root causes of each failure mode
3. Numerically rank each failure mode using a Risk Priority Number (RPN):

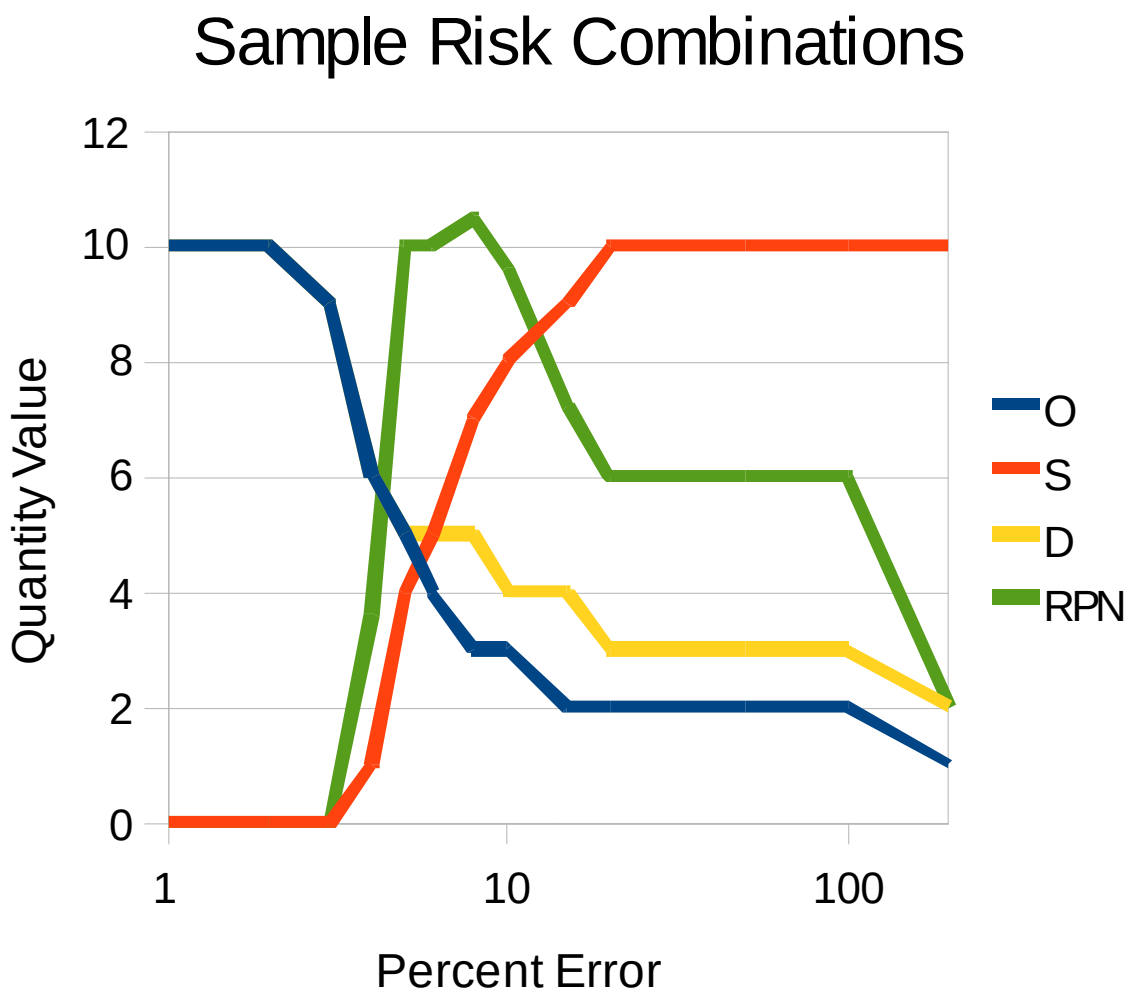
$$RPN = O \cdot S \cdot D$$

O (Occurrence) – Likelihood of failure mode
S (Severity) – Severity of failure mode
D (lack of Detectability) – Likelihood failure mode remains undetected

TG-100 O, S and D Values

Rank	Occurrence (O)		Severity(S)		Detectability (D)
	Qualitative	Frequency in %	Qualitative	Categorization	Estimated Probability of failure going undetected in %
1	Failure unlikely	0.01	No effect		0.01
2		0.02	Inconvenience	Inconvenience	0.2
3	Relatively few failures	0.05			0.5
4		0.1	Minor dosimetric error	Suboptimal plan or treatment	1.0
5		<0.2	Limited toxicity or tumor underdose	Wrong dose, dose distribution, location or volume	2.0
6	Occasional failures	<0.5			5.0
7		<1	Potentially serious toxicity or tumor underdose		10
8	Repeated failures	<2			15
9		<5	Possible very serious toxicity or tumor underdose	Very wrong dose, dose distribution, location or volume	20
10	Failures inevitable	>5	Catastrophic		>20

RPN vs. S


Sample Risk Combinations
12
10
8
6
4
2
0
Quantity Value
1
10
100
Percent Error
O
S
D
RPN

FMEA Example: IMRT

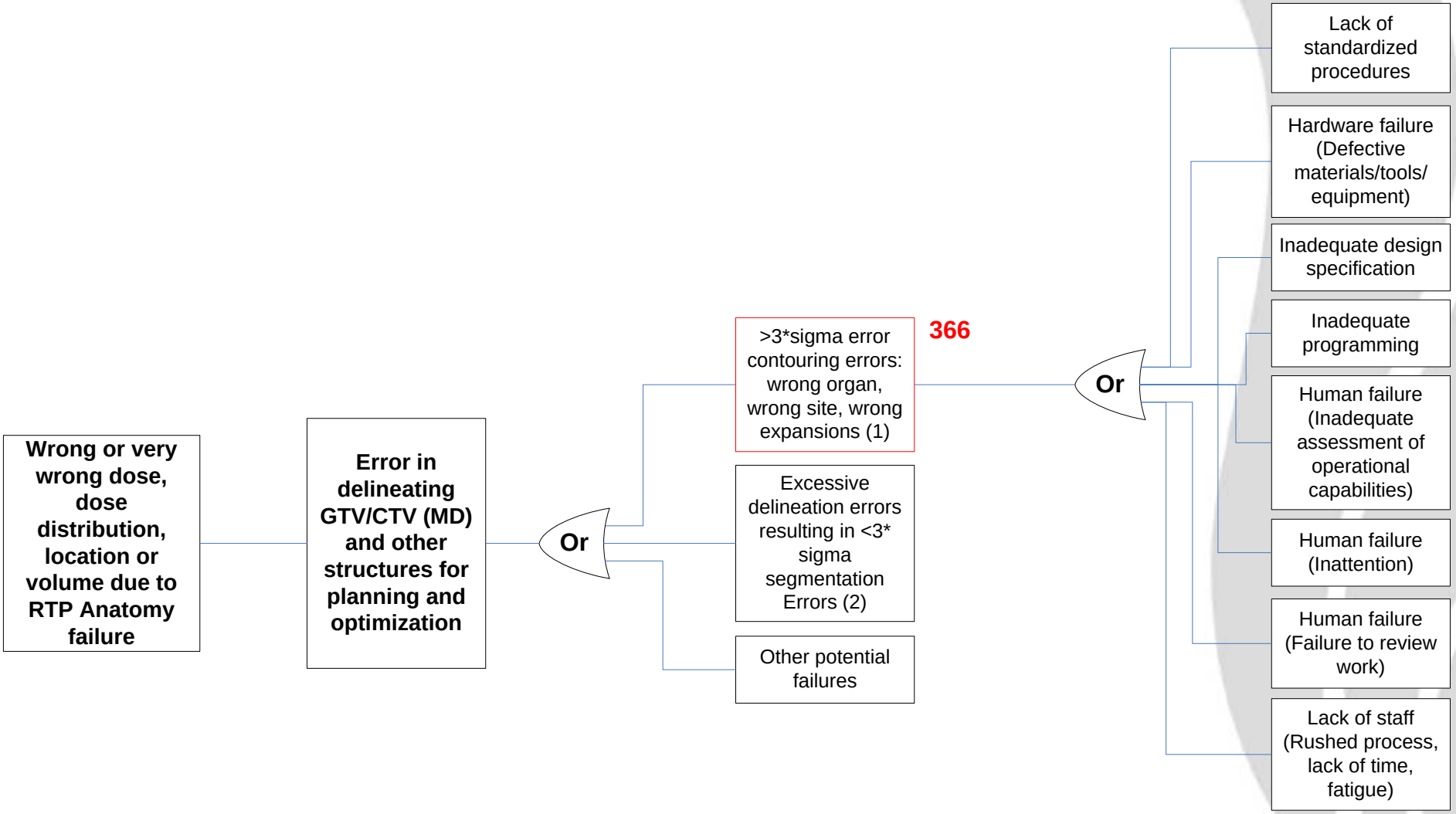
Major Processes	**Step**	**Failure Modes**	**Causes of Failure**	**Effects of Failure**	AVG O	**AVG S**	AVG D	**AVG RPN**
1- Patient Database Information	Entry of patient data in electronic database or written chart	1. Incorrect Patient ID	Errors in manual entry	Very wrong dose	3.78	**7.89**	3.89	**106.78**

Fault Tree Analysis (FTA)

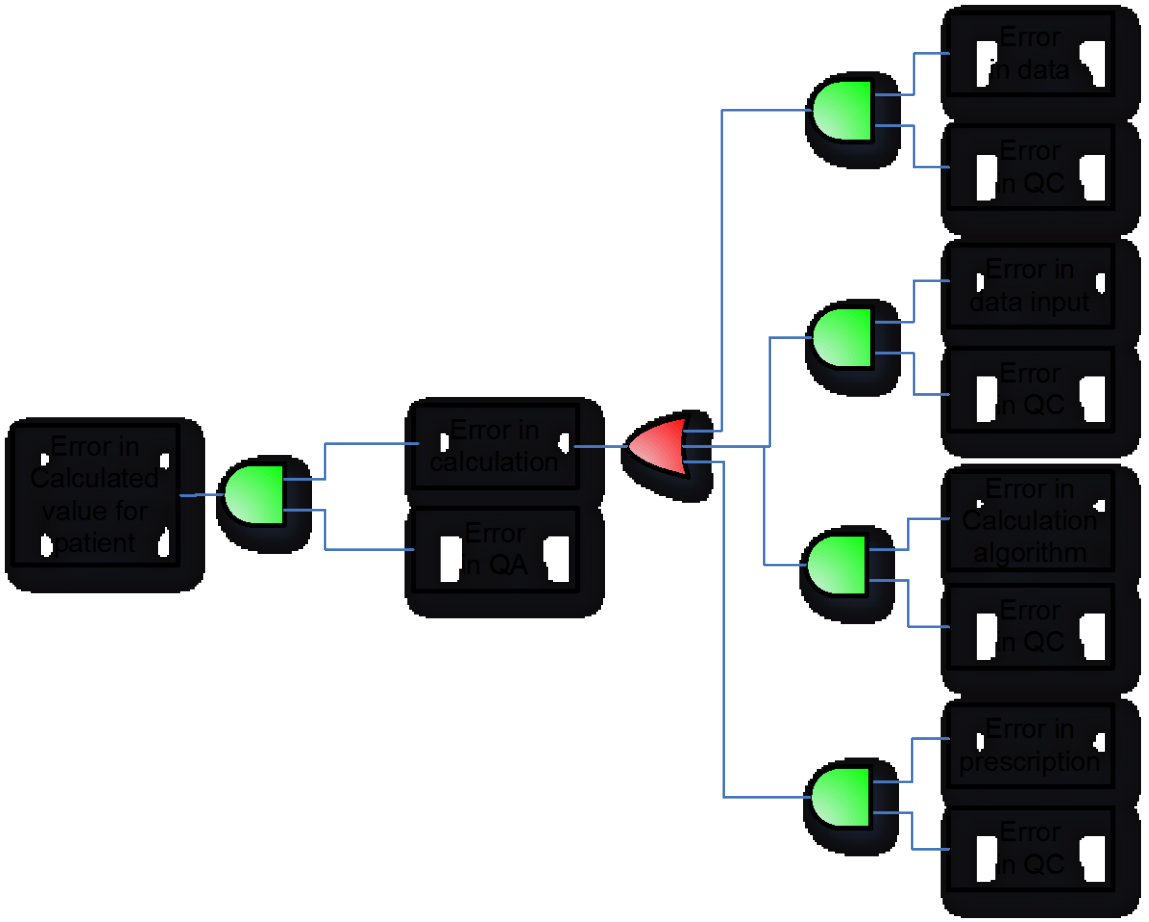
Graphical display of the sequence of a failure mode

- Begins on the left with a failure mode
- Possible errors/mistakes which result in the failure are connected by nodes.
- Nodes may be logical OR or AND gates depending on whether one or all of the errors are required for the failure

Fault Tree – Pre-QM Program



Fault Tree Example – Adding QC/QA



Fault Tree – Post-QM Program

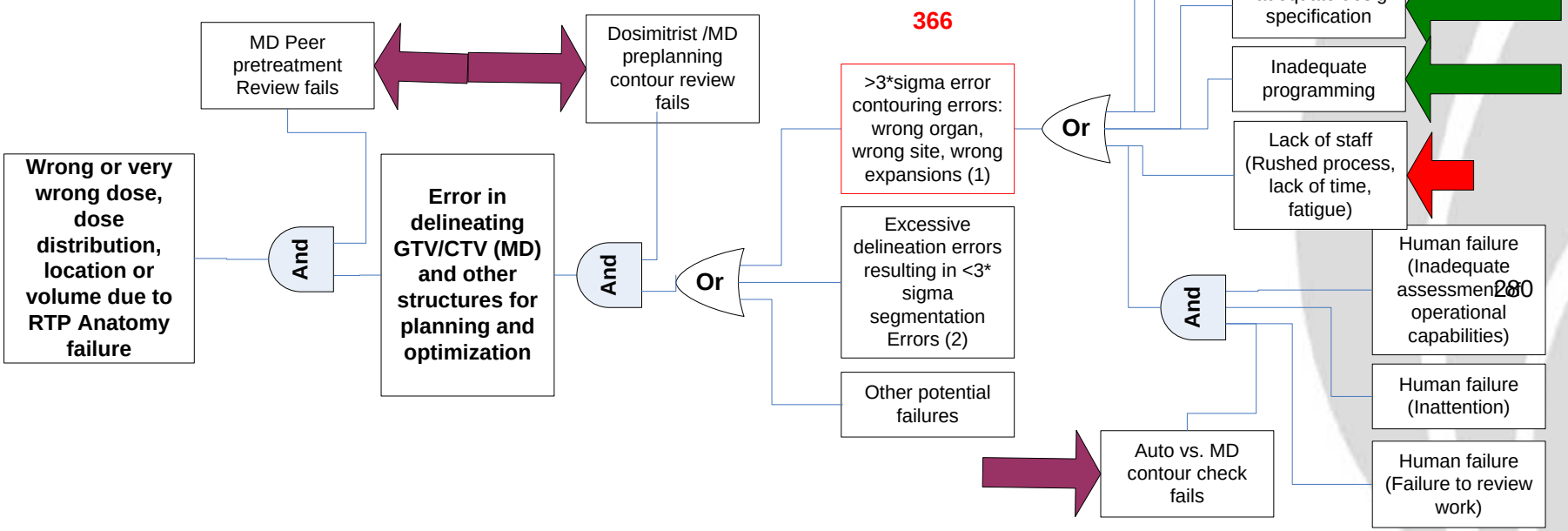
Taken care of by the ensuring the key core requirements

Key item for QC

Key item for QA

Key item for commissing

Key item for facility managerial changes



TG-100: How to Perform a Risk Analysis

1. Define the Process
    1. Assemble a multi-disciplinary team
    2. Develop a process map
2. Perform an FMEA risk assessment
    1. List each process step
    2. Identify failure modes for each step
    3. Identify potential causes of each failure mode
    4. Identify potential effects of each failure mode

TG-100: How to Perform a Risk Analysis

2. Perform an FMEA risk assessment
    5. Identify current process controls
    6. Determine failure likelihood
    7. Calculate the Risk Priority Number (RPN)
    8. Identify Failure Modes with highest RPNs
    9. Develop new process controls

TG-100 Recommendations

- Individual Clinics
  - Every clinic should develop a risk-analysis QM program
  - Key personnel should attend training as required
  - Begin with high-risk procedures (e.g., SBRT)
  - FMEA should be done on ongoing basis

TG-100 Recommendations

- AAPM
  - Future QA Task Groups should use FMEA
  - Assist users with implementation:
    - Establish a WG to provide user guidance
    - Sponsor educational talks at AAPM, Chapter Meetings, CRCPD, etc.
    - Establish a repository website with example FMEAs
  - Work with other societies to promote risk-based QM Programs

TG-100 Recommendations

- Regulators
  - TG-100 Report is not intended for regulatory purposes
  - Should be familiar with TG-100 methodology
  - AAPM and CRCPD should
    - Provide a guidance document for regulators
    - Provide in-depth educational presentations
    - Create a repository of sample QM programs for review

And Beyond…

Status of TG-100 Report

- August 2013 – Parts I and II approved by Therapy Physics Committee
- Fall 2013 – Science Council expressed concerns over implementation of recommendations
- January 2014 – Formed Ad hoc committee on review of TG-100 Report
- Final Report and Recommendations should be release this summer

Emerging FMEA Publications

- Ford et al, “Evalution of Safety…”, IJROBP 74: 852-858 (2009)
- Ford et al, “Streamlined FMEA…”, Med Phys (2014, in press)
- Ekaette et al., “Probablistic FTA of a radiation system”, Risk Anal 27: 1395-1410 (2007)
- Ciocca et al, “Application of FMEA to intraop…”, IJROBP 82 (2012)
- Sawant et al., “FMEA-based QA for DMLC”, Med Phys 37 (2012)
- Perks et al, “FMEA for delivery of lung SBRT”, IJROBP (in press)
- Denny et al, “FMEA in a rad onc setting…”, J Hlthcare Quaity 2012

TreatSafely

TreatSafely

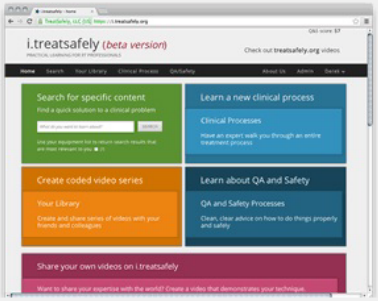
IMPROVING QUALITY AND SAFETY IN RADIATION MEDICINE

Home | QI ToolBox | Workshops | Online Learning | About

IMPROVING QUALITY AND SAFETY IN RADIATION MEDICINE

TreatSafely is dedicated to the development of novel teaching and mentoring programs that improve quality and safety in radiation medicine.

INTRODUCING I.TREATSAFELY.ORG



We've just put the finishing touches on our newest offering - **i.treatsafely.org**.

This video-based peer-to-peer training site has been developed to provide practical guidance on enhancing the quality and safety of radiation therapy. The content is provided by users like you and can be used for **educational and training purposes** as well as to **standardize practice within and across clinics**.

Once you have had a look we'd love to hear your comments, suggestions, and ideas for improving the site.

MINIMIZING ERROR, MAXIMIZING QUALITY - GLOBALLY

Signup for Updates

Let us keep you up-to-date and in the loop. Enter your email address below to receive news and updates regarding upcoming workshops and online learning opportunities.

email:

Signup

Workshops at your site

Our Minimizing Error, Maximizing Quality Workshops are intensive

www.treatsafely.org

TreatSafely Workshop

Mary Bird Perkins Cancer Center

August 18-19, 2012

www.treatsafely.org

TreatSafely Workshop

Mary Bird Perkins Cancer Center

August 18-19, 2012

Conclusions

- TG-100 differs from traditional methods in its recommendations of a prospective approach to QM
- TG-100 defines three tools for developing QM program:
  - Process Mapping
  - Failure Modes and Effects Analysis
  - Fault Tree Analysis
- The TG-100 Reports should be available later this year, with educational sessions to follow in years to come

The term _____ implies all activities designed to achieve quality

0% 1. Quality Assurance

0% 2. Quality Audit

0% 3. Quality Control

0% 4. Quality Factor

0% 5. Quality Management

The term _____ implies all activities designed to achieve quality

1. Quality Assurance
2. Quality Audit
3. Quality Control
4. Quality Factor
5. Quality Management

References: 1. M.S. Huq et al., AAPM TG-100 Part I Report (2014)

An illustration of the temporal relationships between different steps in a process is called:

0% 1. FMEA

0% 2. Fault Tree Analysis

0% 3. Root Cause Analysis

0% 4. Process Map

0% 5. Risk Benefit Analysis

An illustration of the temporal relationships between different steps in a process is called:

1. FMEA
2. Fault Tree Analysis
3. Root Cause Analysis
4. Process Map
5. Risk Benefit Analysis

References: 1. M.S. Huq et al., AAPM TG-100 Part I Report (2014)

In the field of QM, FMEA stands for

0% 1. Federal Emergency Management Agency

0% 2. Failure Mode and Effects Analysis

0% 3. Florida Music Educators Association

0% 4. Family Member Employment Assistance

0% 5. Foreign Material Exclusion Area

10

In the field of QM, FMEA stands for

1. Federal Emergency Management Agency
2. Failure Mode and Effects Analysis
3. Florida Music Educators Association
4. Family Member Employment Assistance
5. Foreign Material Exclusion Area

References: 1. E. Ford et al., Int J. Radiat Oncol Biol Phys 74:852-858 (2009)
2. M.S. Huq et al., AAPM TG-100 Part I Report (2014)