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New Paradigms for Quality Management in Radiation Therapy

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Acknowledgment

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- John P. Gibbons
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- Frank Rath (Industrial engineer)
- Bruce R. Thomadsen
- Jeffrey F. Williamson

Outline

- Why do we need a new paradigm for QM?
- What is this new paradigm?
- Example application of the new paradigm

Disclaimer

- Data presented here has not yet been approved by the Therapy Physics Committee of the AAPM and thus does not have official AAPM endorsement

What is on a cancer patient's mind?

- Safety
- Radiation therapy accident article published in NY Times

Listen to this story ……. January 24, 2010

The New York Times

Sunday, January 24, 2010

The Radiation Boom

Radiation Offers New Cures, and Ways to Do Harm

Fatal Radiation

Software problems and poor quality control at St. Vincent's Hospital cause a fatal overdose. Related Article »

1 2 3 4 5 6 7 8 NEXT

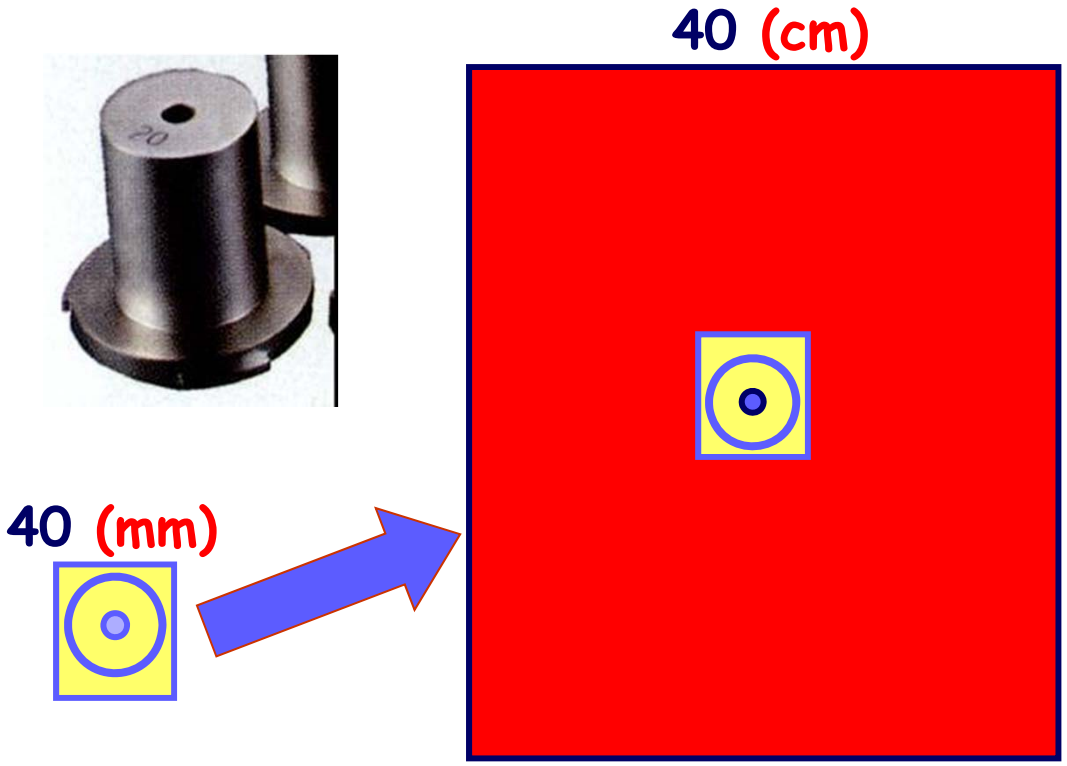
March 16, 2005
Mr. Jerome-Parks's medical physicist ran a series of tests on the equipment. All of them showed that the collimator was wide open, and the hospital realized that a serious overdose of radiation had been administered.

February 2007
After two years of declining health, including loss of sight, hearing and balance, Mr. Jerome-Parks, 43, died of his radiation injuries.

Scott Jerome-Parks

Errors with stereotactic radiosurgery field size

Case 2: confusion 40 mm - 40 cm
Patient died from the accidental exposure



Can current QM standards prevent such events and meet the safety standards of new clinical challenges?

Main goal of QM:

- Patients will receive the prescribed treatment correctly

Failure of QM:

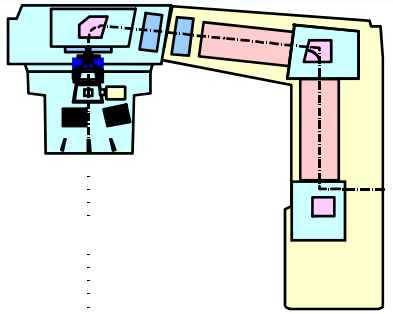
- Insignificant errors in dose to the target

- Major events that can injure or kill patients

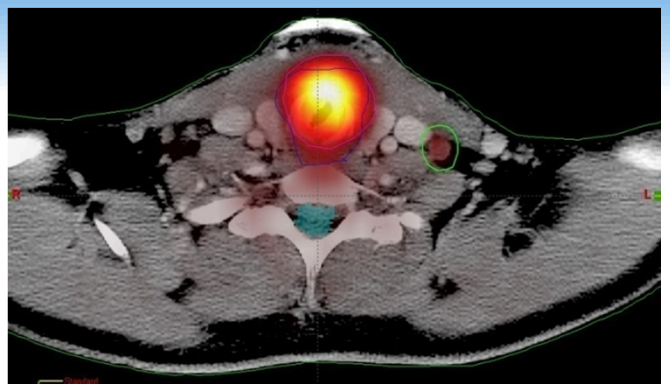
Current quality management standards and their focus

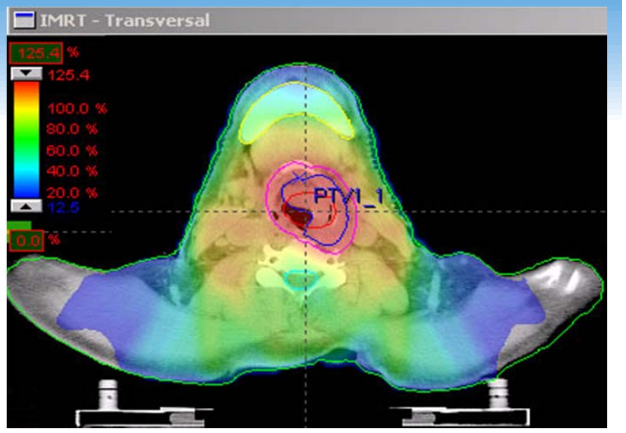
- Focus of current QM/QA guidelines
  - measure functional performances of radiotherapy equipment by measurable parameters
  - set tolerances at desirable but achievable values
- QA/QC programs are prescriptive
- Example: AAPM TG-40, TG-142 recommendations

Examples of current QA paradigms: annual calibration of linac



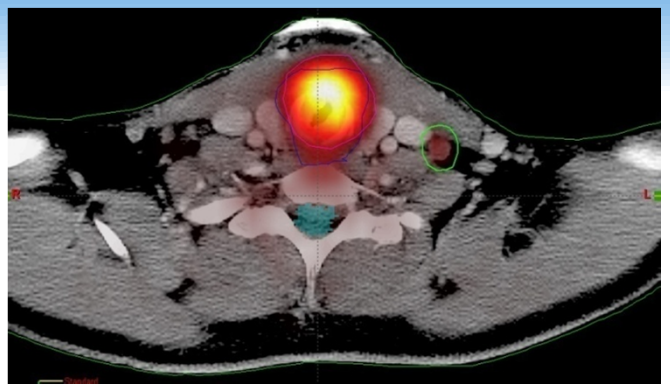
- The annual QA takes several days to complete
- If everything checks out, the effort was mostly wasted
  - ➢ that is it could have been spent checking things with a higher likelihood of failure
- If some problem was found, how long had it been wrong?
- If the problem was significant then a daily check should be in place to prevent it

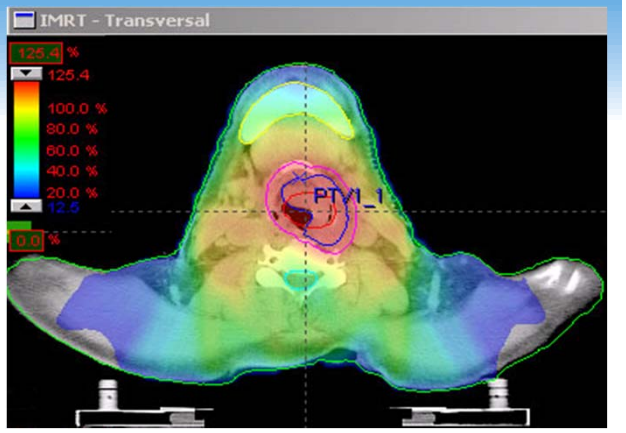




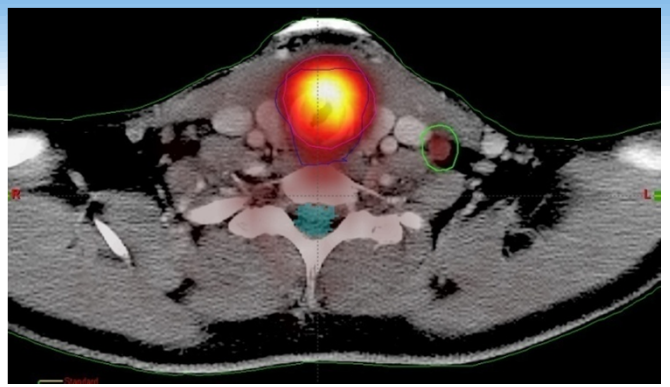
Example: IMRT QA

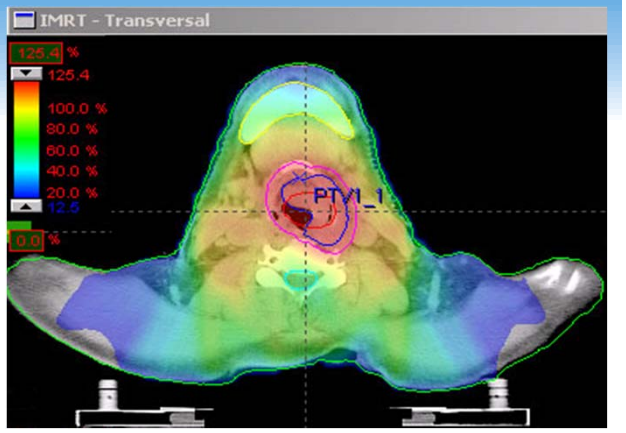
- We measure fluence maps for IMRT QA
- This is certainly something that we would want to have correct





- However, if the system has been commissioned, and then used correctly, why would this be wrong for the patient?
- If you worry about the leaf movement, even if the fluence map indicates correct movement for the first day of treatment, why do you think it might be correct in a week?
- Are there problems found this way? Almost never
- Do need QA for leaf movement, maybe daily





- Do we make a patient go repeat planning because the test results did not satisfy the acceptable criteria?
- What do we do? Find another location that satisfies the test criteria
- Why do we do this?

Problems with current QA paradigm

- These examples suggest that QA as performed currently might not be the optimal use of a physicist's time

- Just performing all the recommended QA might not provide protection against events

The problem

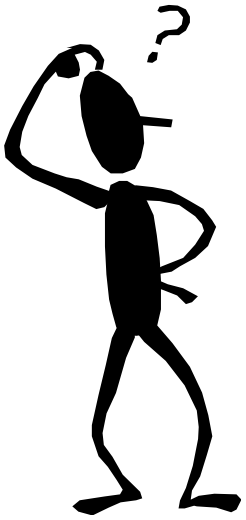
- RT QA guidance is focused on equipment performance even though most RT events have resulted from human performance failures rather than equipment failure

- Lack of adequate guidance for resource allocation
  - The premise: If it can be checked, check it
  - That is…..everything

- Lack of adequate personnel

The problem

- Pressure on medical physicists to implement new technologies
- Lack of guidance on how to implement these technologies
- Delays in publishing QA protocols for emerging technologies

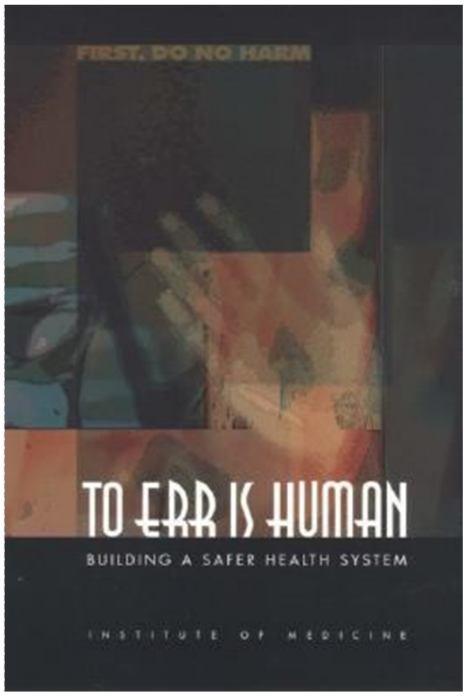


What to Do?

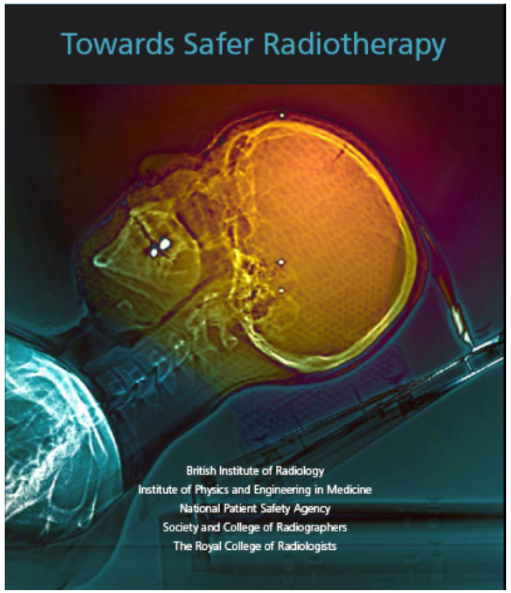
Where are the resources and time to do it all?

What should a time starved physicist do?

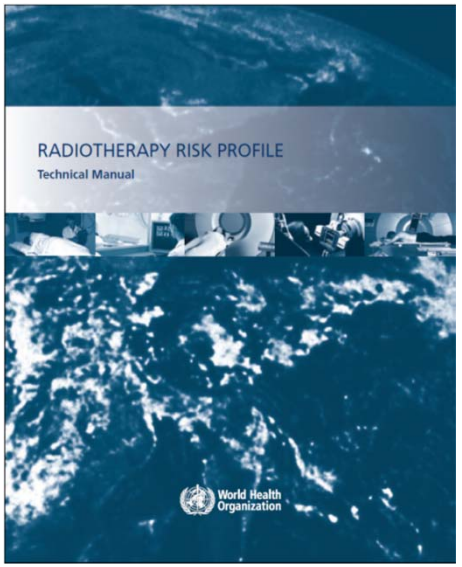
Recent reports



2000



2008



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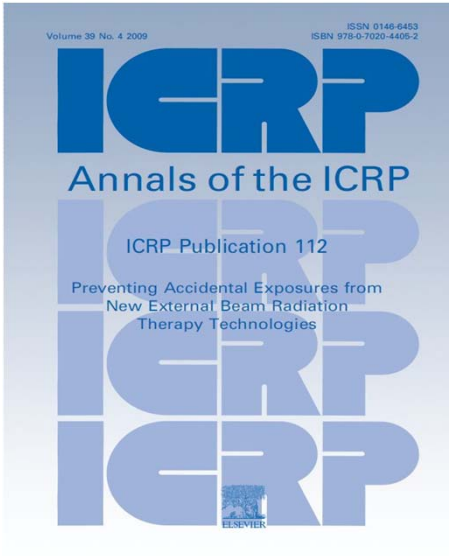


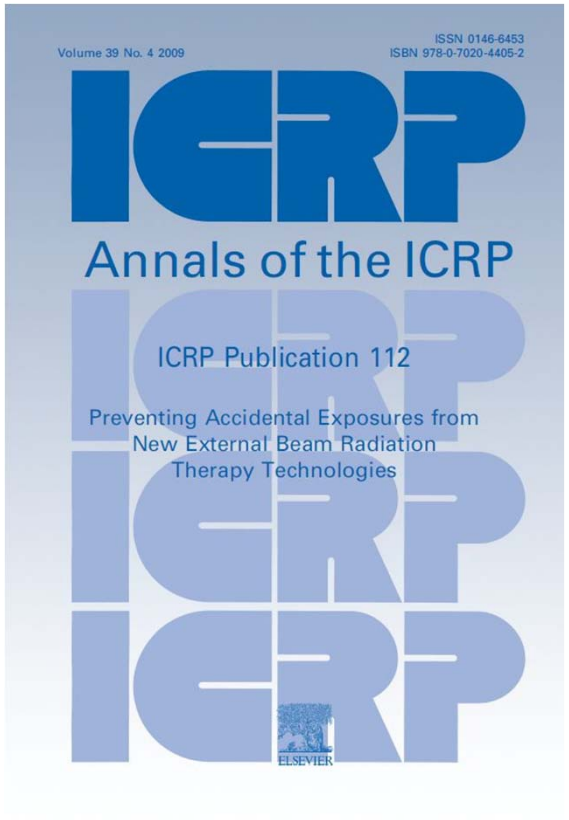
2009

How safe is safe: Risk in radiotherapy (RT)

- Rate of misadministration in RT is 0.2 % (1 in 600)
- Rate of serious injury: airline accidents is 1 in 10 million
  - 16,000 times lower than that of RT
- Rate of serious injury in RT is 1000 times higher
- In reality no one knows
- Risk profiles of anesthesia: similar to airline industry

Ford and Terezakis; Red Journal 78, 321-322, 2010

ICRP 112 Conclusions and recommendations



- As technology & processes change
  - Retrospective approaches are not sufficient
  - All-inclusive QC checks may not be feasible
  - Develop proactive approaches to anticipation of failure modes
  - Evaluate risks from each failure mode

Prospective risk assessment

- Before introducing a new technology or technique figure out, through a formal process, what could go wrong and what the consequences might be

AAPM's TG 100

Application of risk-based analysis methods to radiotherapy quality management

- Charge
  - Identify a structured 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 develop the framework of the QA program

ICRP 112 definition of risk

- "Risk can be regarded as some function of the probability of an event's occurring and the severity of the consequences for the patient should the event occur"

Risk assessment

- Risk assessment is the process of analyzing the hazards involved in a process
- Many risk assessment and analysis tools/techniques exist in industry
- These tools can be easily adapted to RT to enhance safety and quality of treatment process
- TG100 used some of these tools to develop new guidelines for RT QM

TG100 risk analysis methodology

- Process Mapping (Tree)
- FMEA (Failure Modes and Effects Analysis)
- Fault Tree Analysis
- Establishment of a risk based QM program

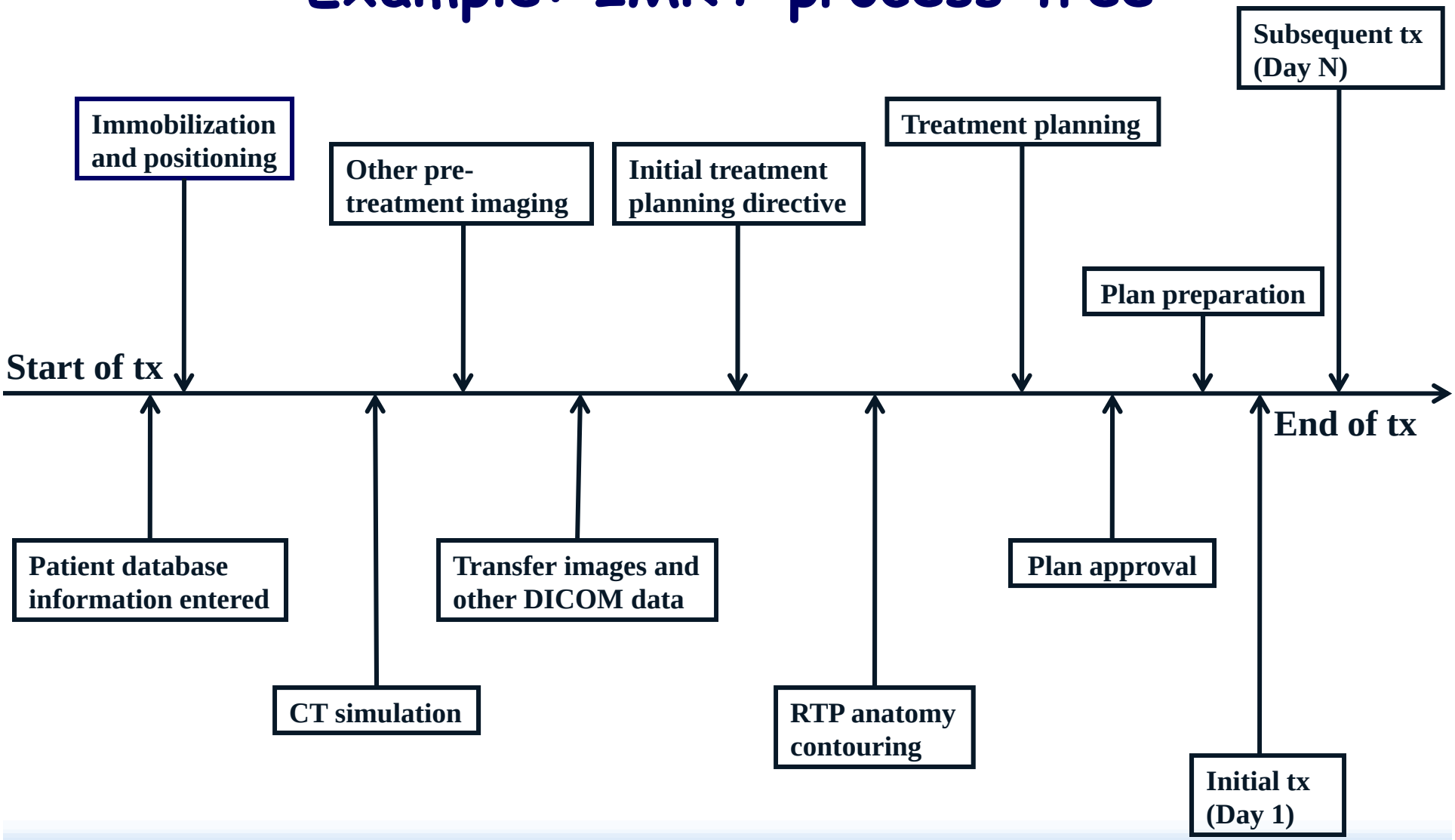
Use IMRT as a case study

TG100 risk analysis methodology

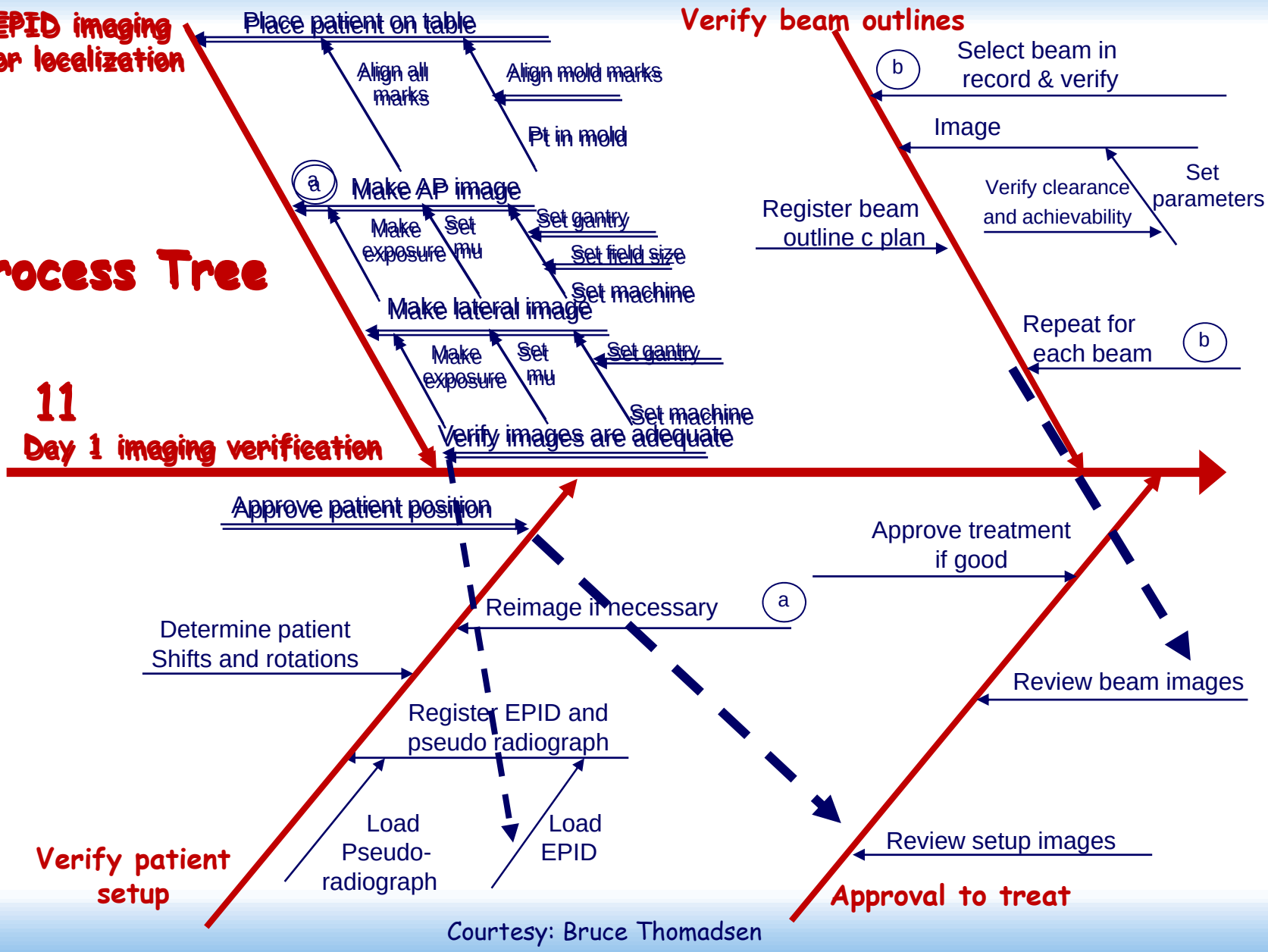
Process Tree

- Visual illustration of the physical and temporal relationships between the different steps of a process that demonstrates the flow of these steps from process start to process end

Example: IMRT process tree



Process Tree



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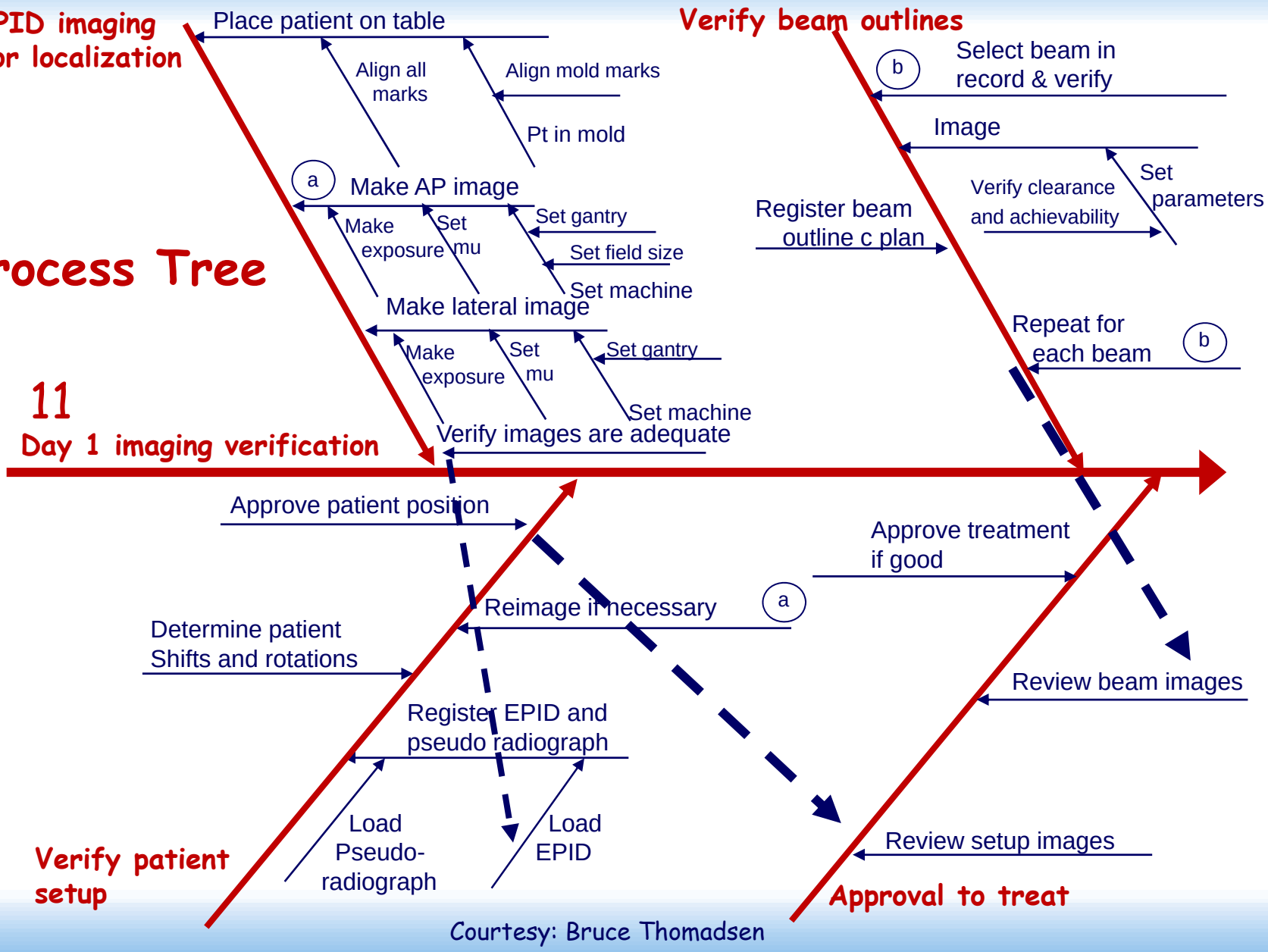

TG100 risk analysis methodology

FMEA

- Assess potential risks involved in the process
- FMEA assesses the likely hood of errors in a process and considers the effects of such error

IMRT failure modes and effects analysis

- FMEA looks at each process and at each step asks the questions:
  - What could possibly go wrong (potential failure mode)
  - How could that happen (what are the causes that result in a failure mode)
  - What effects would such a failure produce (potential effects of failure)
  - The overall risk of each identified failure mode is then scored and prioritized according to RPN
  - A good FMEA then identifies corrective actions to prevent failure from reaching the patient

Example of FMEA

Failure mode:

- First day of Tx: Patient maybe positioned incorrectly relative to the isocenter

Causes of failure:

- Tx machine or simulator laser misalignment
- Therapist error due to inattention
- Poor instruction or setup documentation in the chart
- Inadequate immobilization
- Organ motion or tumor growth

Consequences: severity depends on:

- The magnitude of the displacement from planned isocenter
- Tx technique (stereotactic, 3D conformal or large fields)
- Proximity of critical structures and when in the course of tx the error was detected

Steps to perform a quantitative FMEA

- Identify all possible failure modes (FM)
- Identify all of the potential causes for each FM
- Determine the impact of each FM on the outcome of the process
- Establish a risk based QM program

FMEA

For a given sub-process:

Step	Potential failure modes	Potential causes of failure	Potential effects of failure	O	S	D	RPN	Comment

$$RPN = O \times S \times D \; [\; 1 \leq RPN \leq 1000 \;]$$

What are O, S and D's?

- O : Probability that a specific cause will result in a failure mode
- S: Severity of the effects resulting from a specific failure mode if it is not detected or corrected
- D: Probability that the failure will not be detected
- Risk priority number RPN = O*S*D
- For O, S and D one assigns values from 1 to 10.
- TG100 has developed scales for O,S, and D indices that are tied to radiotherapy outcomes and observations

Examples of FMEA

Sub-process: RTP planning

Step	Potential Failure Modes	Potential Cause of Failure	Potential Effects of Failure	O	S	D	RPN	Comments
Import images into RTP system data base	Wrong patient's images	Miscommunication User error	Wrong dose distribution Wrong volume	3	9	5	135	
	Wrong imaging study (correct patient) Viz.; wrong phase of 4D CT selected for planning; wrong MR for target volume delineation	Ignorance of available imaging studies Ambiguous labeling of image sets Inadequate training Miscommunication User error	Wrong dose distribution Wrong volume	7	8	7	392	
	File(s) corrupted	Network problem	Lost images Wrong dose distribution Wrong volume	4 3	3 9	2 4	24 108	File probably would not open

Examples of FMEA

Sub-process: RTP planning

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O, S, and D values used in FMEA

Rank	Occurrence (O)		Severity (S)		Detectability (D)
	Qualitative	Frequency	Qualitative	Categorization	Estimated Probability of going undetected in %
1	Failure unlikely	1/10,000	No effect		0.01
2		2/10,000	Inconvenience	Inconvenience	0.2
3	Relatively few failures	5/10,000			0.5
4		1/1,000	Minor dosimetric error	Suboptimal plan or treatment	1.0
5		<0.2%	Limited toxicity or under-dose	Wrong dose, dose distribution, location or volume	2.0
6	Occasional failures	<0.5%			5.0
7		<1%	Potentially serious toxicity or under-dose		10
8	Repeated failures	<2%			15
9		<5%	Possible very serious toxicity	Very wrong dose, dose distribution, location or volume	20
10	Failures inevitable	>5%	Catastrophic		>20

FMEA

Major process	Step	Potential failure mode	Potential causes of failure	Potential effects of failure	O	S	D	RPN
Transfer images & DICOM Data	Transfer Primary data set	Incorrect dataset associated with patient	Pull up wrong patient's record	Very wrong dose disn Very wrong vol	1	9	9	81
	Phy B				5	9	3	135
	Phy C				6	8	7	336
	Phy D				3	9	6	162
	Phy E				3	9	8	216
	Phy F				3	8	3	72
	Phy G				5	9	3	135
	Phy H				5	9	8	360
				Avg	3.88	8.75	5.88	188

FMEA results

- 91 steps
- 216 possible failure modes with many causes associated with them
- Individual RPNs ranged from 2 to 720
- Average RPNs ranged from 19 to 388. We designed our QM program based upon average RPN
- The top 20% of the failures had average RPN greater than 179

FMEA- mark process map

- Prioritize the potential failure modes based on RPN and severity function
- Mark the highest rank steps on the process map
- Shows if potential failures are uniformly distributed through the processes or clustered
- If clustered, should consider the major step as a hazard

FMEA by RPN

Major Processes	Step	Potential Failure Modes	Potential Causes of Failure	Potential Effects of Failure	AVG O	AVG S	AVG D	AVG RPN
4 - Other pretreatment imaging for CTV localization	6. Images correctly interpreted (e.g. windowing for FDG PET)	Incorrect interpretation of tumor or normal tissue.	User not familiar with modality or inadequately trained) (Poor inter-disciplinary communication)	Wrong volume	6.50	7.44	8.00	387.75
7 - RTP Anatomy	Delineate GTV/CTV (MD) and other structures for planning and optimization	>3*sigma error contouring errors: wrong organ, wrong site, wrong expansions	User error Inattention, lack of time, failure to review own work	Very wrong dose distributions Very wrong volumes.	5.29	8.43	7.86	366.00
12 - Day N Treatment	Treatment delivered	LINAC hardware failures/wrong dose per MU; MLC leaf motions inaccurate, flatness/symmetry, energy – all the things that standard physical QA is meant to prevent.	Poor hardware design Poor hardware maintenance Inadequate department policy (weak physics QA process) Poorly trained personnel	Wrong dose Wrong dose distribution Wrong location Wrong volume	5.44	8.22	7.22	354.00

FMEA by Severity (S)

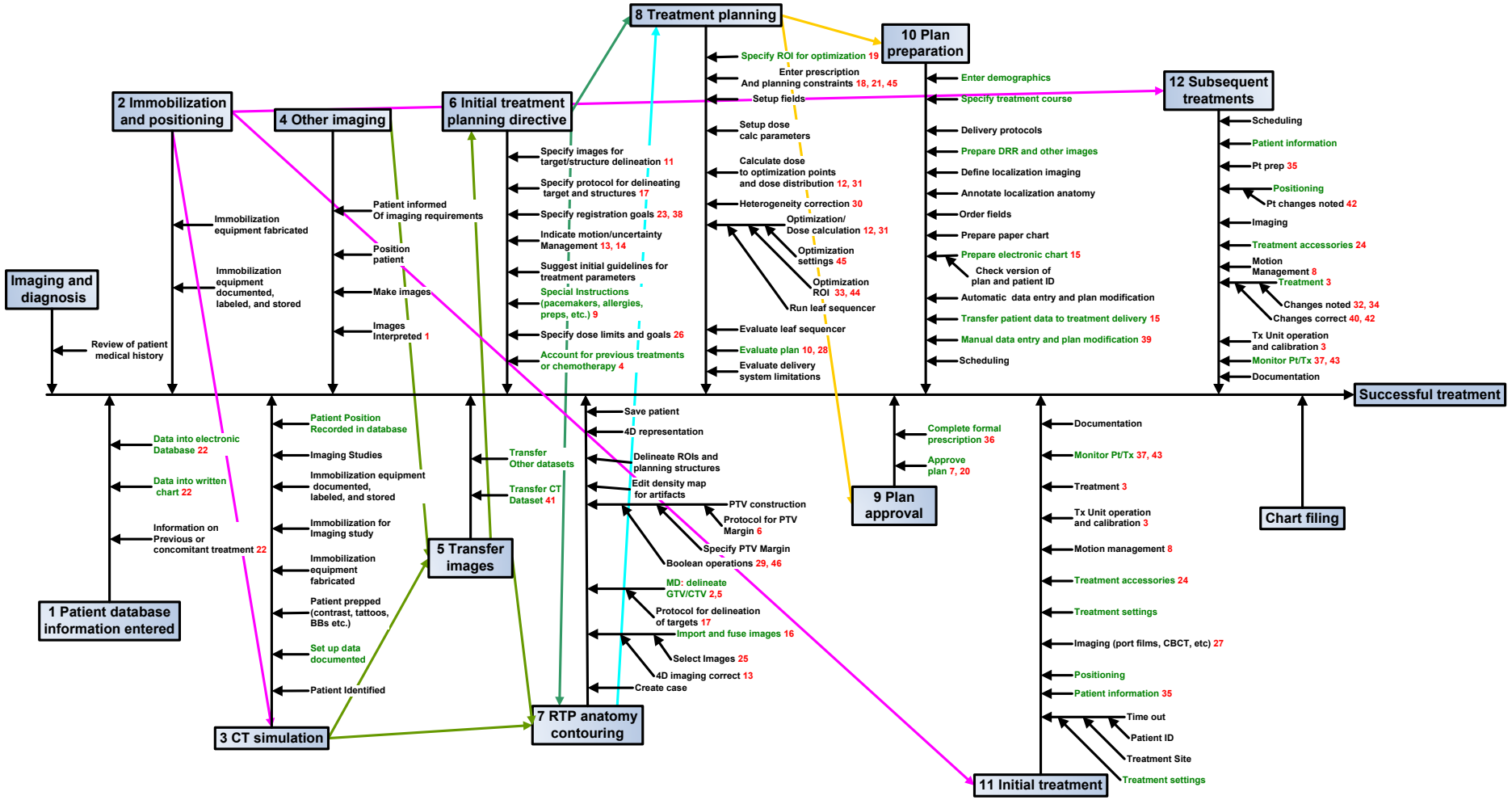
Major Processes	Step	Potential Failure Modes	Potential Causes of Failure	Potential Effects of Failure	AVG O	AVG S	AVG D	AVG RPN
12 - Day N Treatment	Treatment delivered	Gantry or other LINAC hardware (e.g. OBI) collides with patient	Carelessness Poor departmental policy	Non-radiation-related physical injury	3.33	9.11	5.44	162.78
10 - Plan Preparation	Prepare e-chart	1. Incorrect Tx info, 2. Wrong Rx, 3. Wrong patient/plan	Manual entry: Large error Inadequate standard/ procedure / practice Used incorrectly procedure/practice Inadequate training/orientation	Very wrong dose Very wrong dose distribution Very wrong location Very wrong volume	5.44	8.89	5.56	272.89
11 - Day 1 Treatment	Gather patient treatment information	3. Incorrect treatment data	Hardware failure	Very wrong dose Very wrong volume	2.33	8.89	4.78	102.89

Top 6 RPN

	Major Sub-Processes	Step	Potential Failure Modes	Potential Causes of Failure
1	Other pretreatment imaging for CTV localization	Images correctly interpreted (e.g. windowing for FDG PET)	Incorrect interpretation of tumor or normal tissue	Inadequate training (user not familiar with modality Lack of communication (inter-disciplinary)
2	RTP Anatomy	Delineate GTV/CTV (MD) and other structures for planning and optimization	Contouring errors: wrong organ, wrong site, wrong expansions	Lack of standardized procedures; Hardware failure (Defective materials/tools/equipment); Human failure(Inattention; failure to review work); Lack of staff
3	Day N treatment	Treatment delivered	Linac hardware failure/wrong dose per MU; MLC leaf motion inaccurate; flatness/symmetry, energy – all the things that standard physical QA is meant to prevent	Poor hardware design; Inadequate maintenance; software failure; Lack of standardized procedures; Human failure; standard linac performance QM failure; Inadequate training
4	Initial treatment planning directive (from MD)	Retreatment, previous treatment, brachy etc	Wrong summary of other treatments, Other treatments not documented	Lack of staff; Human failure (inattention; reconstructing previous treatment; wrong info obtained); information not available; Lack of communication
5	RTP anatomy	Delineate GTV/CTV (MD) and other structures for planning and optimization	Excessive delineation error resulting in <3σ segmentation errors	Lack of standardized procedures; Availability of defective materials/tools/equipment; Human failure (inattention; Failure to review work; etc); Inadequate training
6	RTP Anatomy	PTV construction	Margin width protocol for PTV construction is inconsistent with actual distribution of patient setup errors	Lack of standardized procedures; Lack of communication; Inadequate training; Human failure (inattention; failure to review work; etc)

Process tree (map)

I wouldn't try to read it…will hurt your eyes



Proce

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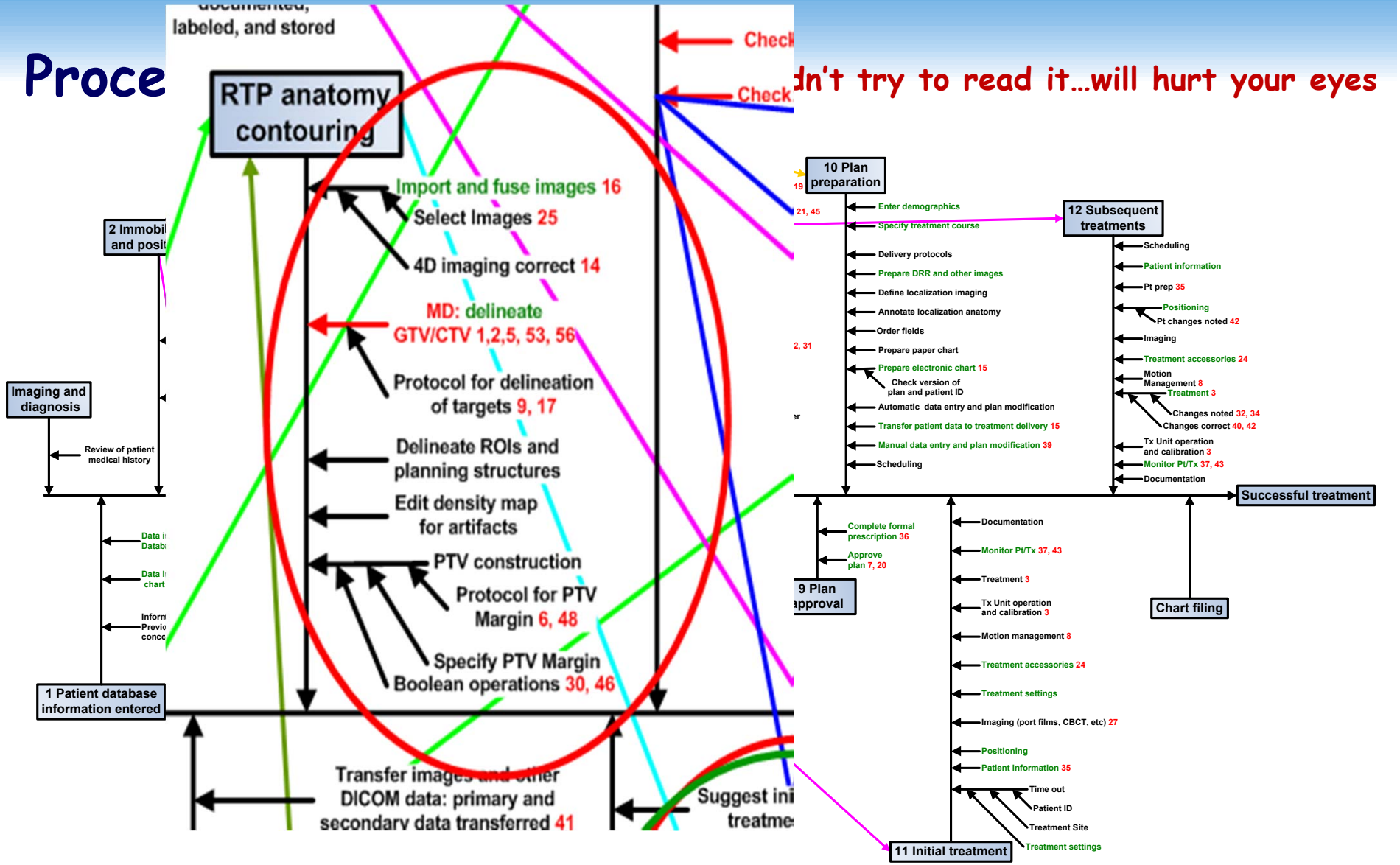

Process map marking

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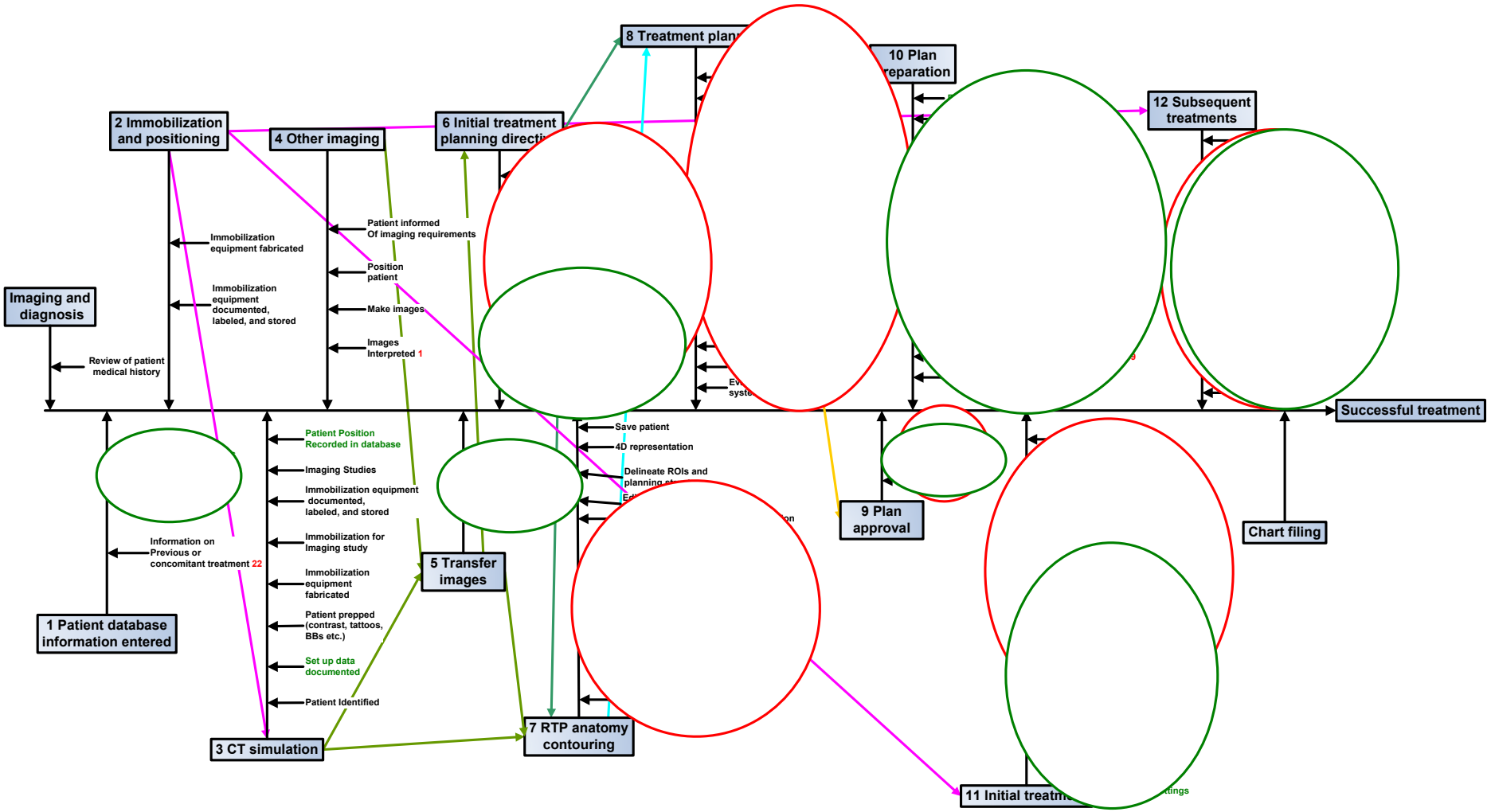
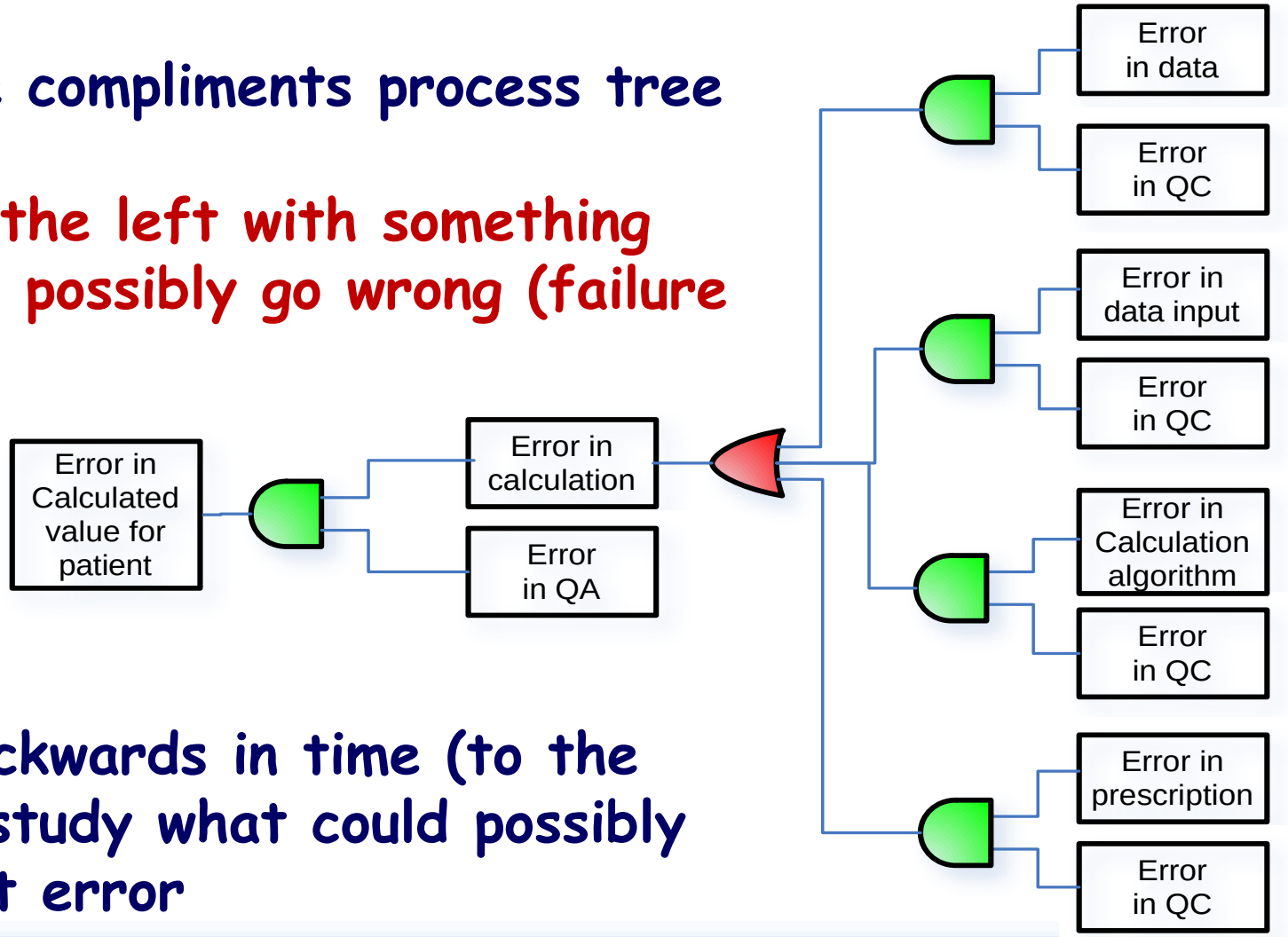


Fault tree

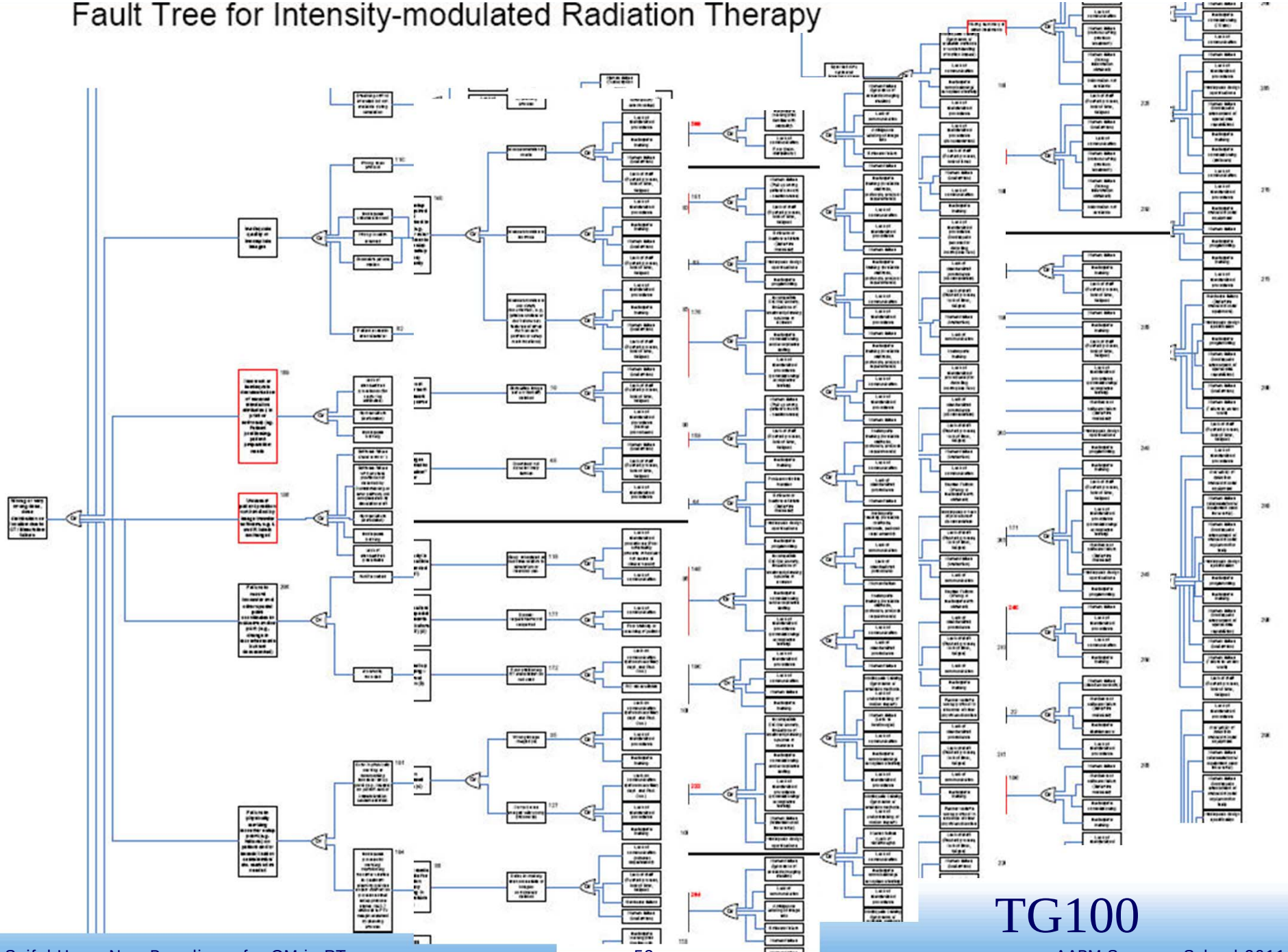
- FMEA helps lay out the fault tree
- Fault tree helps an individual or a dept see which steps in their practice are not covered by QM and visualize potential locations for effective QM measures
- The RPN and S values direct attention to the errors most in need of remedy
- Every step needs some QM to block the effects of failure from affecting the patient

Fault tree

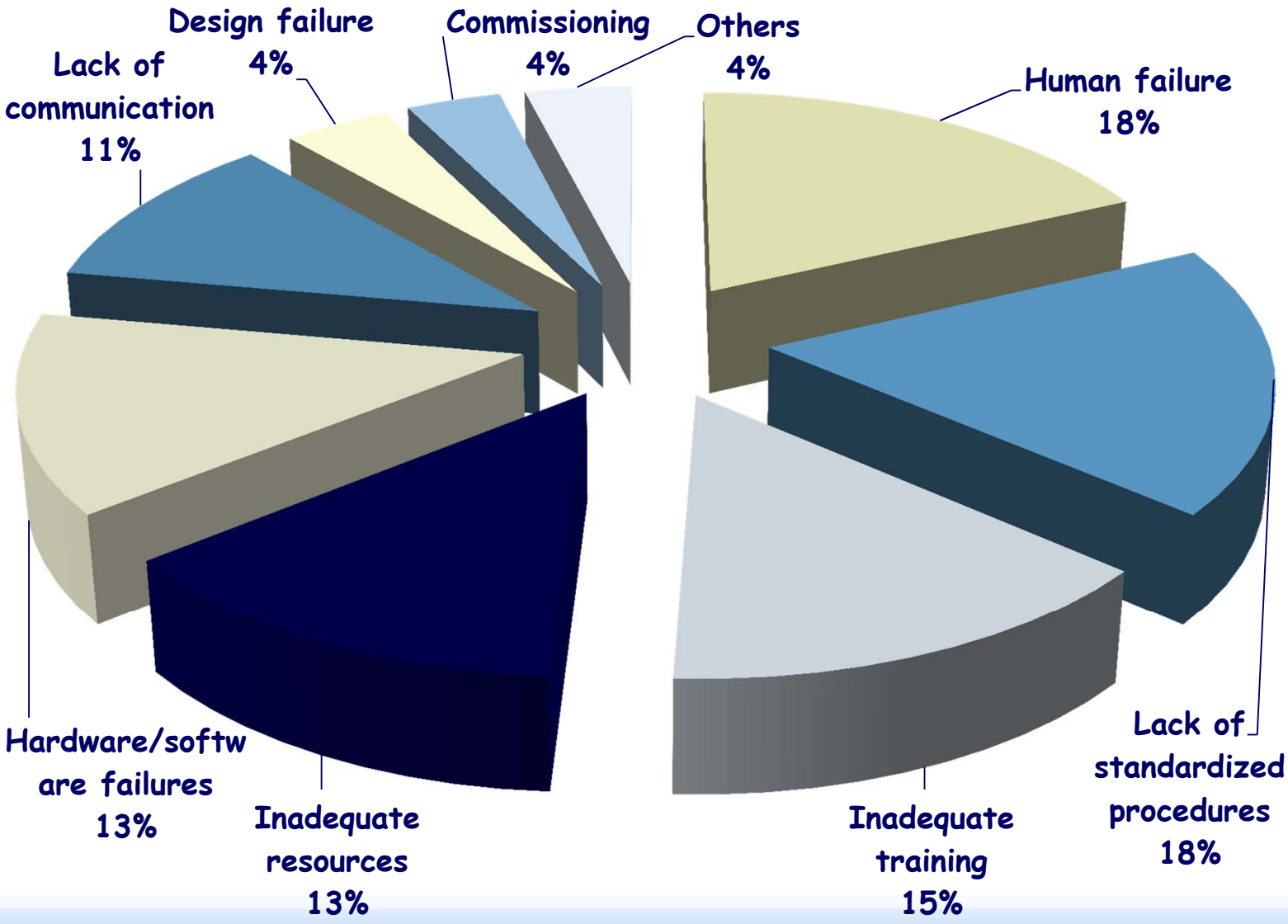
- Fault tree compliments process tree
- Begins on the left with something that could possibly go wrong (failure mode)
- Works backwards in time (to the right) to study what could possibly cause that error



Fault Tree for Intensity-modulated Radiation Therapy



Causes of failure

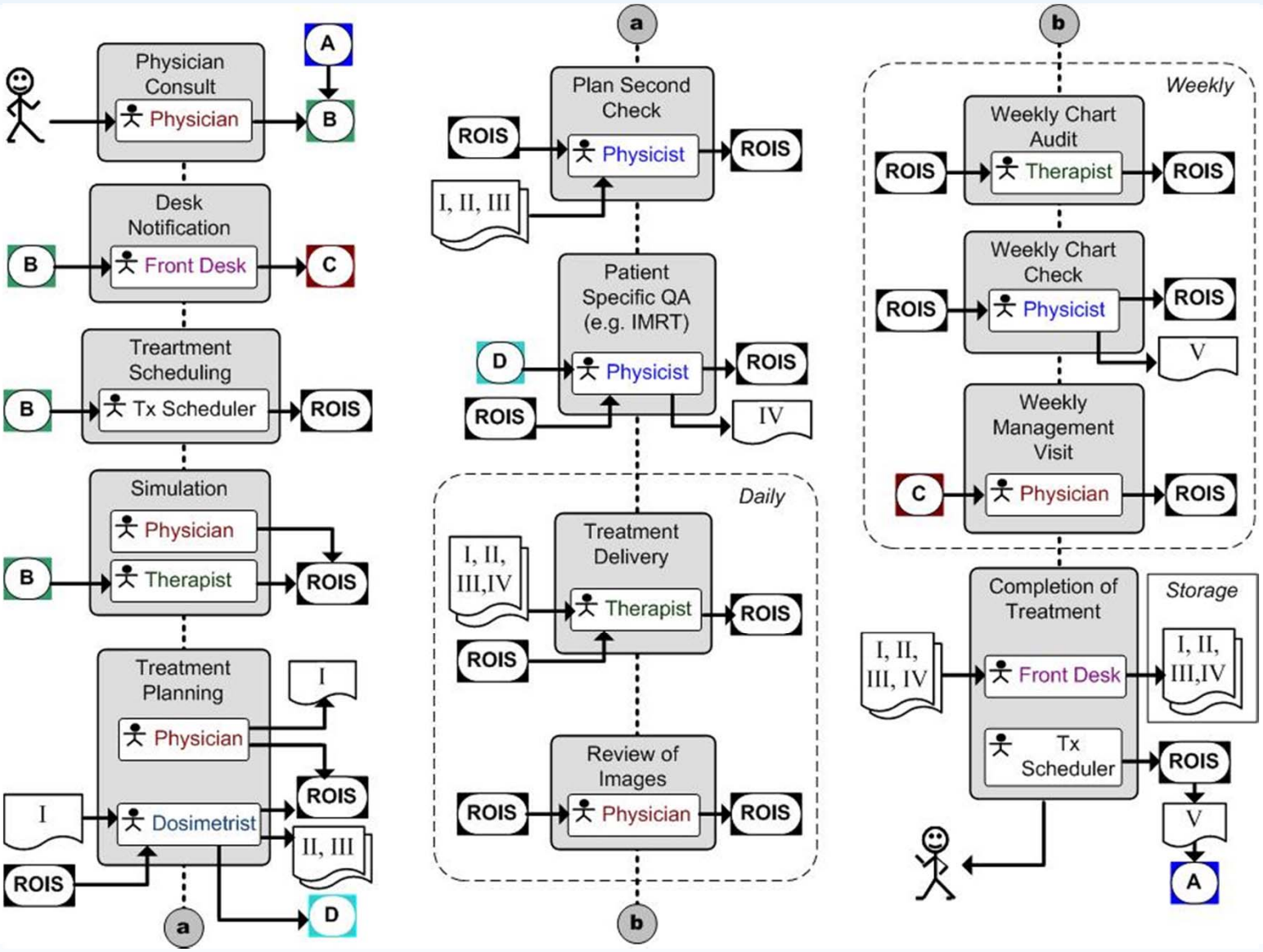


Training Program !!

Most commonly cited causes of high risk failures

- Human factors
  - Inadequate training
  - Miscommunication within and between departments
- Lack of consistent procedural guidelines
- Lack of attention by people performing task
- Time pressure
- People as well as linacs, need to be "commissioned"

Human Interactions in Radiation Oncology



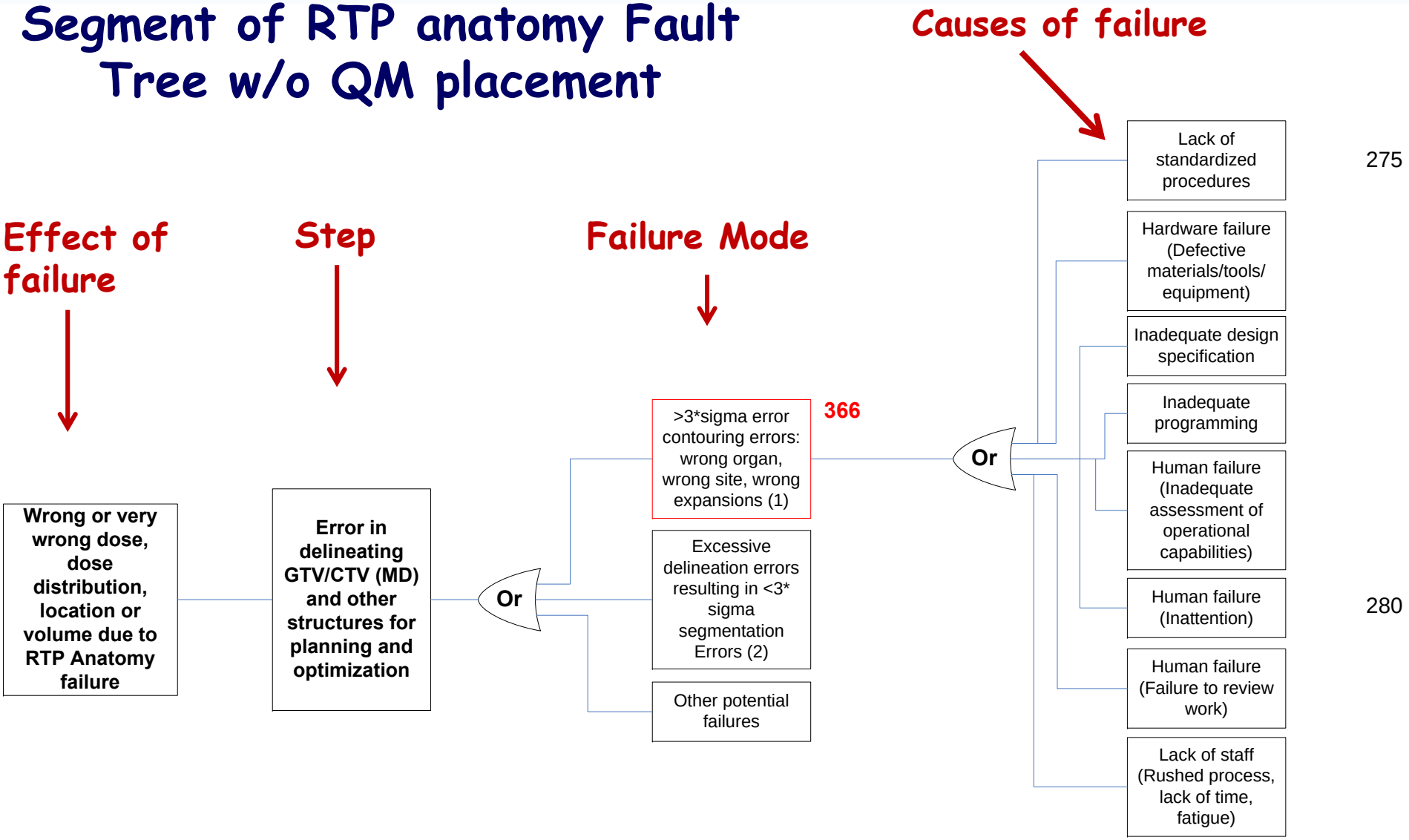
Courtesy: Bill Hendee

Design of QM program

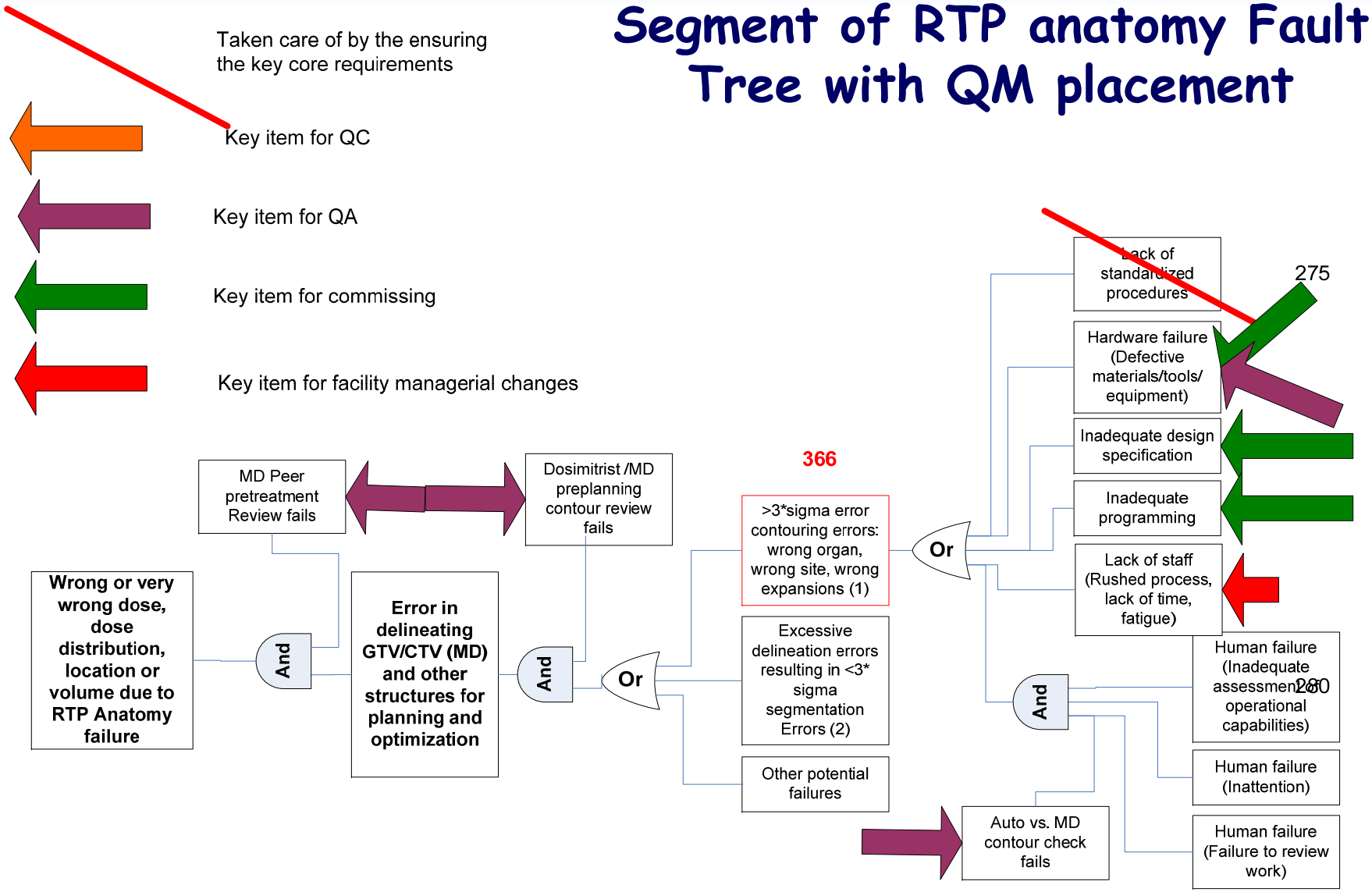
- Use the FTA and FMEA risk and process oriented information to design a QM program for the process being investigated

- Example
  - Sub-process: RTP anatomy
  - Step: Delineate GTV/CTV and other structures
  - FM: > 3σ contouring error, wrong organ, site, or expansions
  - RPN = 366
  - Rank: #2

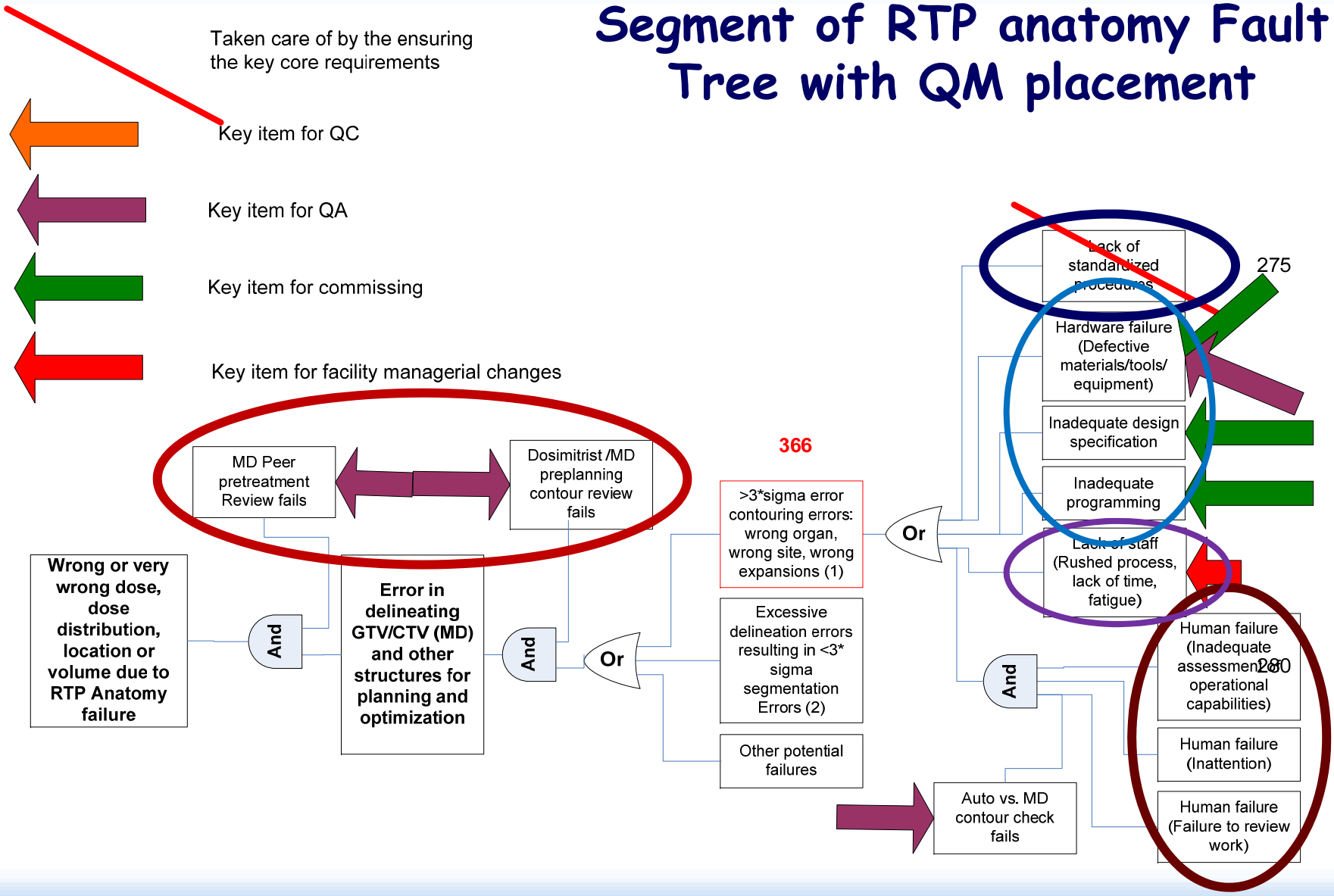
Segment of RTP anatomy Fault Tree w/o QM placement



Segment of RTP anatomy Fault Tree with QM placement



Segment of RTP anatomy Fault Tree with QM placement



Challenges in the implementation of new QM paradigm

- Performing the FMEA analyses require skills gained from experience in such analysis
- Large institutions may have the resources to go through this, but a small, community hospital will not
- That being said, the greatest advantage is to analyze your situation

Guidance to clinical physicists

- Each facility should consider its own needs for addressing potentially hazardous situations
- Assessing risks and performance effectiveness, appropriate QM can be designed to use resources most effectively
- Involve the entire team of professionals in the development of FMEA and QM process
- We expect that the high risk steps and common failure modes identified in the TG100 exercise are relevant to a clinical physicist's institution

Recommendations

- Form a multidisciplinary team consisting of radiation oncologists, medical physicists, dosimetrists, therapists, nurses, engineers
- This team should be responsible for the development of a FMEA-based risk aware QM program
- Priority for FMEA-based effort should be given to high-risk procedures, high severity procedures, new procedures and those that are resource intensive
- FMEA-based methodology be adopted as an ongoing activity aimed towards continuous process improvement

Recommendations

- Future AAPM task groups undertake FMEA-based analysis of important clinical processes
- AAPM establish a website with model FMEAs for various procedures as those analysis are developed
- AAPM should also develop web based training tools to train the medical physics community on an ongoing basis on the newly developed FMEAs for various procedures

Conclusions

- TG100 approach provides a concrete demonstration of how to supplement the TG40 device centered approach with a holistic process-centered approach that considers the interactions between the network of devices, staff and processes that are required to perform radiation therapy

- TG100 analysis also provides specific guidance as to where in radiation therapy planning and delivery process the highest risk events are located

Our job is not to prevent errors, but to keep the errors from injuring the patients.

Lucian Leape

It is impossible to make anything foolproof because fools are so ingenious.

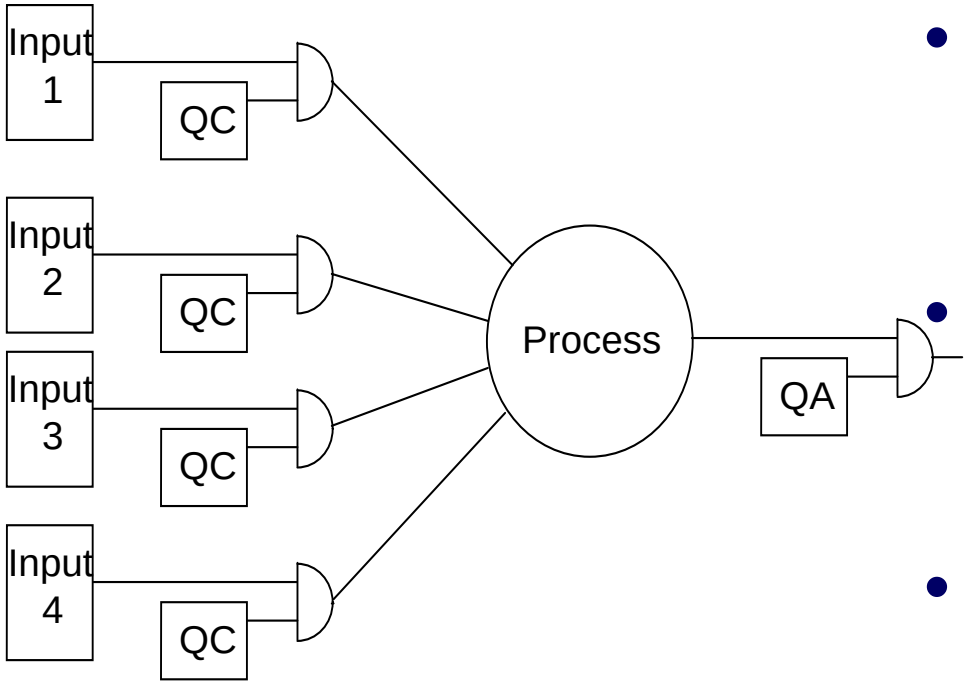
Artur Bloch, Murphy's law

Courtesy: Josef Novotny

Acknowledgment

Special thanks to Professor Bruce Thomadsen from University of Wisconsin for providing some of the slides for this presentation

QA/QC/QM



- QA implies those activities that demonstrate that some particular aspect of a system is within specifications
- QC however, consist of those activities that force a particular aspect of a system to conform to expected standards
- QM consists of all those activities designed to achieve the desired quality goals

Example

- QA : Morning checks on an accelerator before the first patient tx
- QC: Verifying the source strength of a HDR source before entry into tx-planning computer

Patient specific IMRT QA- assumptions for MLC

- The MLC shapes used for each patient cover the range of leaves and positions used in all patients
- The sensitivity of the plans tested during one day or week is adequate to detect problems with MLC function that could affect other patient plans already under treatment
- The frequency of the new patient specific IMRT QA provides sufficient MLC checks to prevent MLC delivery errors from persisting long enough to exceed the geometric and dosimetric accuracy goals over a course of IMRT

Definitions

- Quality:
  - Those product features that meets the needs of the patient, including rational medical, psychological, and economic goals and the professional and economic needs of the caregivers and the institution
  - A clinical process tat is designed to realize cancer treatments that conforms with nationally accepted standards of practices and specifications
  - Freedom from errors and mistakes

- Failure: Not meeting the desired level of quality is Failure.

Definitions

- Errors: Failures consisting of acts, either of commission or omission, that incorrectly execute the intended action required by the process

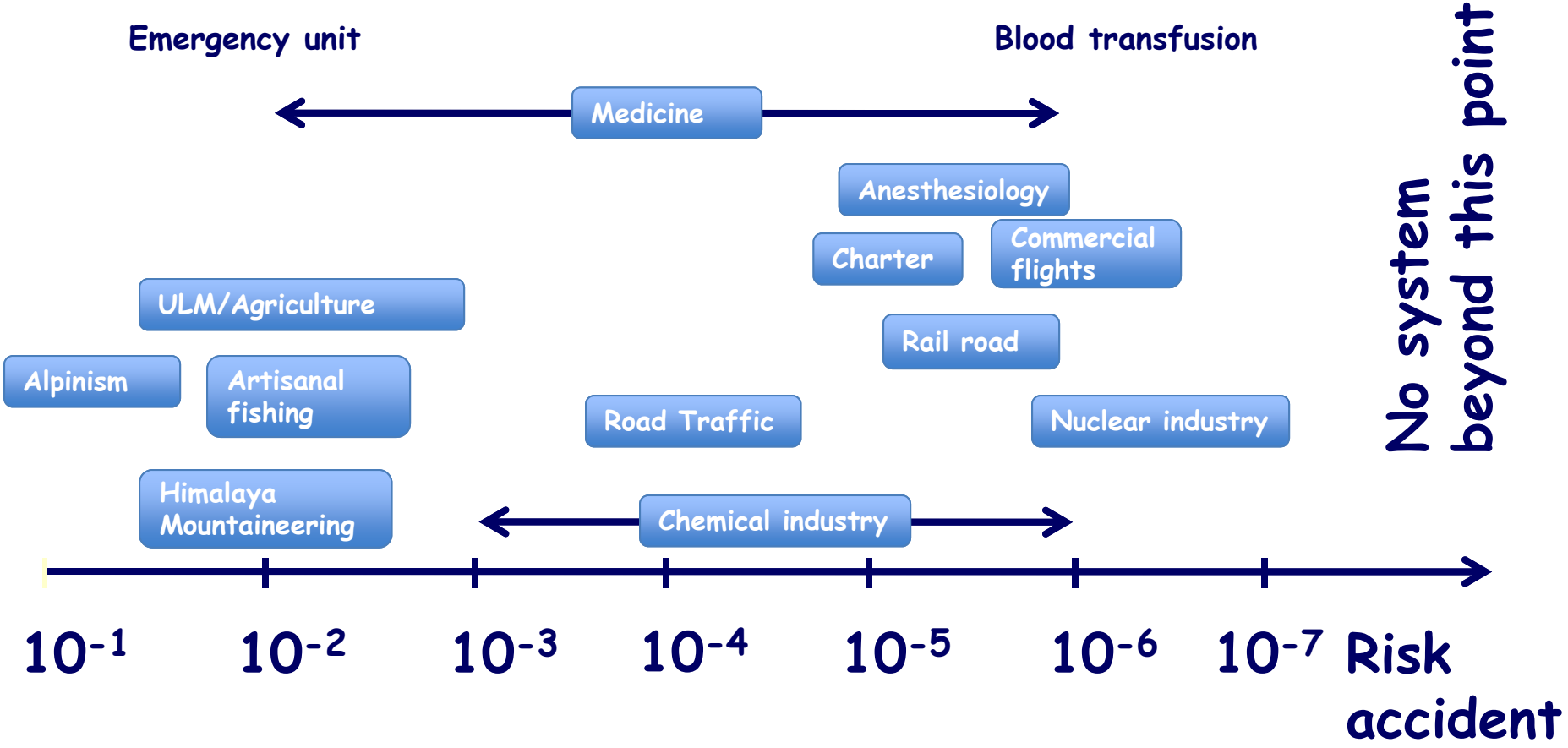
- Mistakes: Failures due to incorrect intentions or plans, such that even if executed as intended, would not achieve the goal

- Near Miss: A situation resulting from a failure that would have compromised quality of the patient's treatment had it not been detected or corrected.

No of steps and failure modes for FMEA of IMRT sub-processes

Process Number	Process Description	# of steps in process	Number of failure modes
1	Patient database information entered	1	3
2	Immobilization and positioning	4	7
3	CT simulation	10	14
4	Other pre-treatment imaging	6	7
5	Transfer images and other DICOM data	3	8
6	Initial treatment planning directive (from MD)	9	9
7	RTP anatomy contouring	15	31
8	Treatment planning	14	53
9	Plan approval	2	11
10	Plan preparation	11	30
11	Initial treatment (Day 1)	7	20
12	Subsequent treatments (Day N)	9	23
	Total	91	216

Magnitude of risk?



Very unsafe

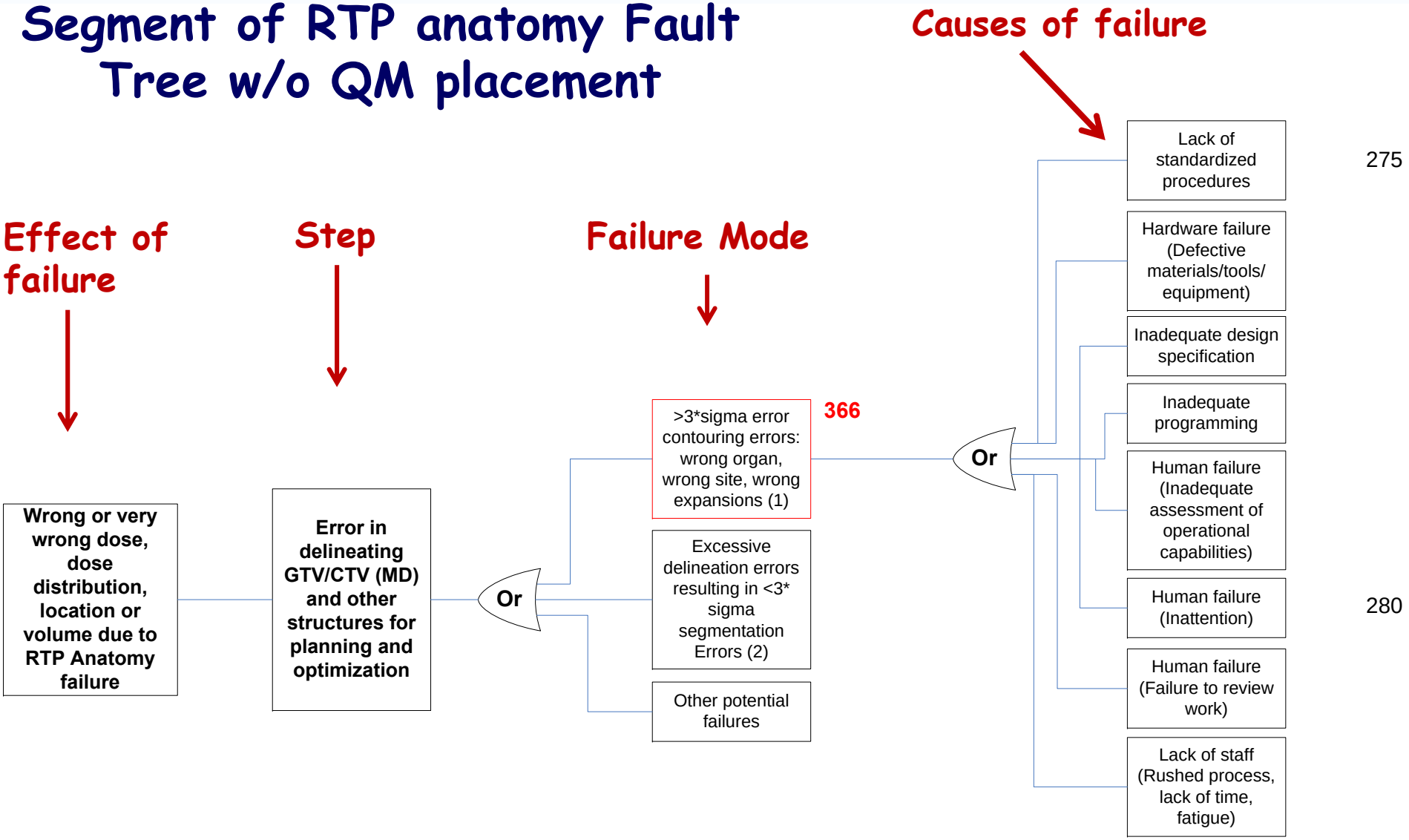
Courtesy: Pierre Scalliet

Very safe

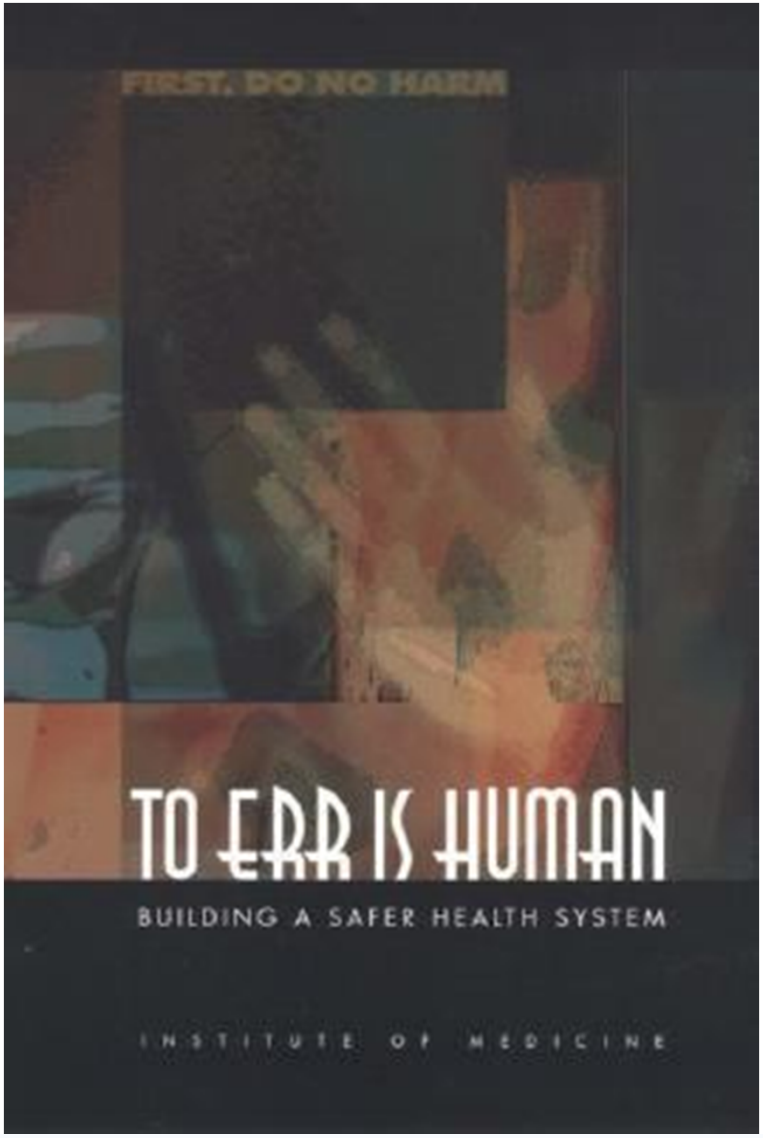
2nd ranked Failure Mode

Rank	RPN	Step#	Process	Step
#2	366	58	7. RTP Anatomy	Delineate GTV/CTV (MD) and other structures
	FM: > 3σ contouring error, wrong organ, site, or expansions			

Segment of RTP anatomy Fault Tree w/o QM placement



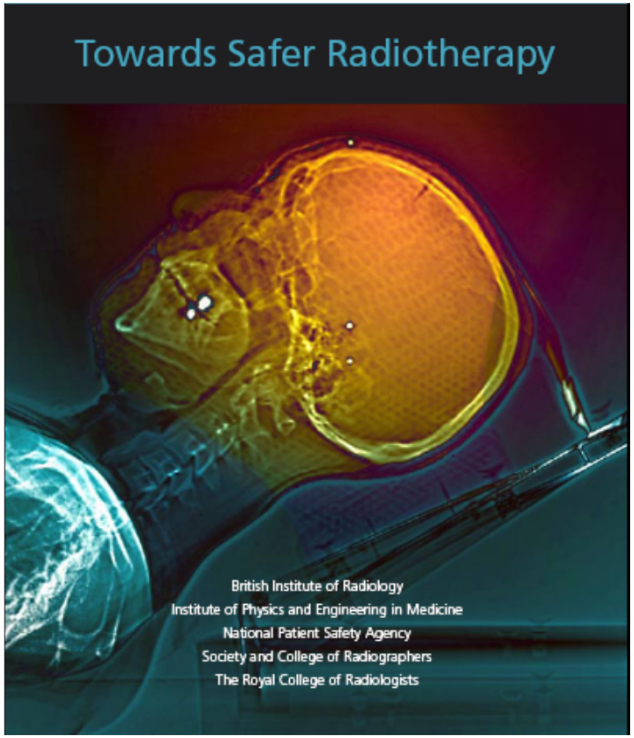
Training program !!



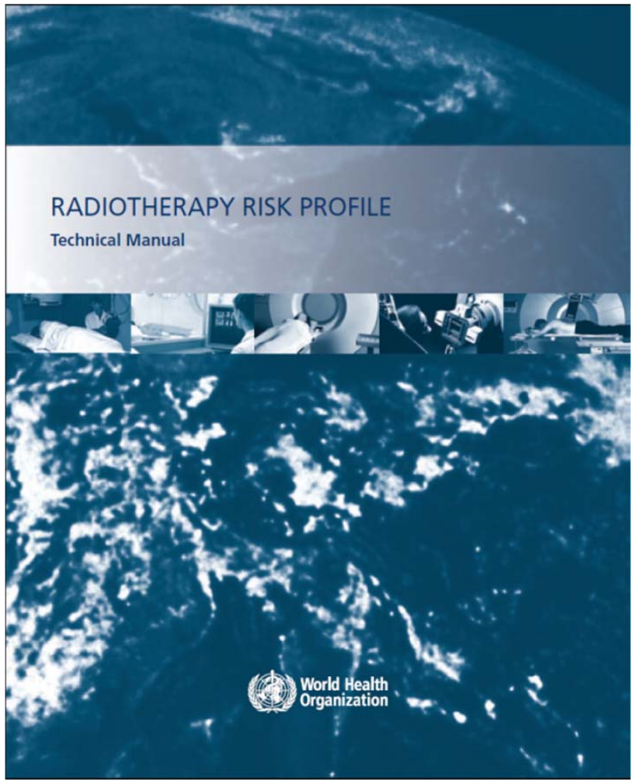
Institute of Medicine, 2000

- Highlighted the need to make patient safety a high priority
- Priority has focused on identifying and reducing preventable events
- Adapt tools of ultra safe systems such as aviation industries ?

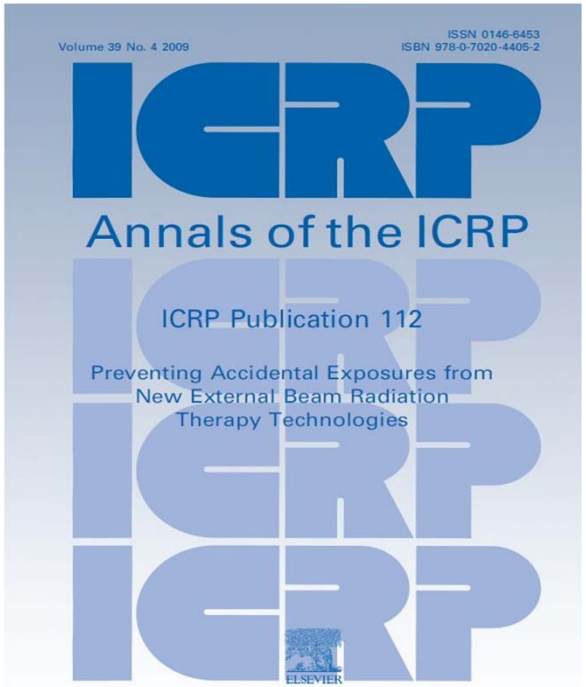
Recent reports



2008



2008



2009

Most commonly cited causes of high risk failures

Category	No of occurences
Human Failures	230
Lack of Standardized Procedures	99
Inadequate Training	97
Inadequate Communication	67
Hardware/Software Failure	58
Hardware	9
Software	44
Hardware or software	5
Lack of staff	37
Inadequate design specifications	32
Inadequate Commissioning	18
Availability of defective materials/tool/equipment	12

TG100 methodology for designing QM program in radiation therapy

- Establish the goals of the QM program
- Prioritize the potential failure modes based on RPN and severity function
- Mark the highest rank steps on the process map
- Mark the same highest ranked steps on the fault tree
- Select QM intervention placement
- Select appropriate QM tools

2nd ranked Failure Mode

Rank	RPN	Step#	Process	Step
#2	366	58	7. RTP Anatomy	Delineate GTV/CTV (MD) and other structures
	FM: > 3σ contouring error, wrong organ, site, or expansions			