TG - 100

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and
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Disclosure

- I am the secretary/treasurer for the Center for the Assessment of Radiological Sciences (CARS) a non-profit Patient Safety Organization dedicated to improving patient safety in radiotherapy and radiology.

Acknowledgement

- I have used some slides from the presentation that Dr. Saiful Huq, from the University of Pittsburg Cancer Institute and UMPC Cancer Center, gave at the 2014 AAPM Annual Meeting and Exhibition. Special thanks to him.

Learning Objective

- Update TG - 100 status
- A systems approach to quality management
- The basic tools of TG – 100
  - Process Mapping
  - Process - Failure Mode and Effects Analysis (P-FMEA)
  - Fault Tree Analysis (FTA)
- TG – 100 rollout/implementation

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Update on TG – 100 Status

- Approved by AAPM
- Will be published as a single document in Medical Physics
- AAPM Ad-Hoc committee on TG – 100 – Dan Low chairman

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Systems Quality Management

- Systematic application of specific tools that improve process controls producing more consistent and closer to optimal outcomes and reduce the risk of mistakes, errors or hazardous outcomes
  - Process controls – templates, checklists, formal procedures, peer review, adequate training, cross training, process teams (cellular manufacturing), fool proofing, etc.

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Industrial Engineering Based Quality Management (QM) Tools

- Process mapping – Understand the process
  - Define/discover processes

- Failure Mode and Effects Analysis (FMEA) – Identify and assess the risks/hazards in the process
  - Analyze processes and identify weaknesses or risks
  - Focuses attention on those weaknesses or risks and develop controls that improve the process

- Fault Tree Analysis (FTA)
  - Further define and deploy categories of process controls/improvements that will improve QM system overall

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Defining the Process

- Process maps, process flow charts, process trees
- “One picture is worth ten thousand words”
- Process mapping efforts need to include everyone involved and often lead to surprises

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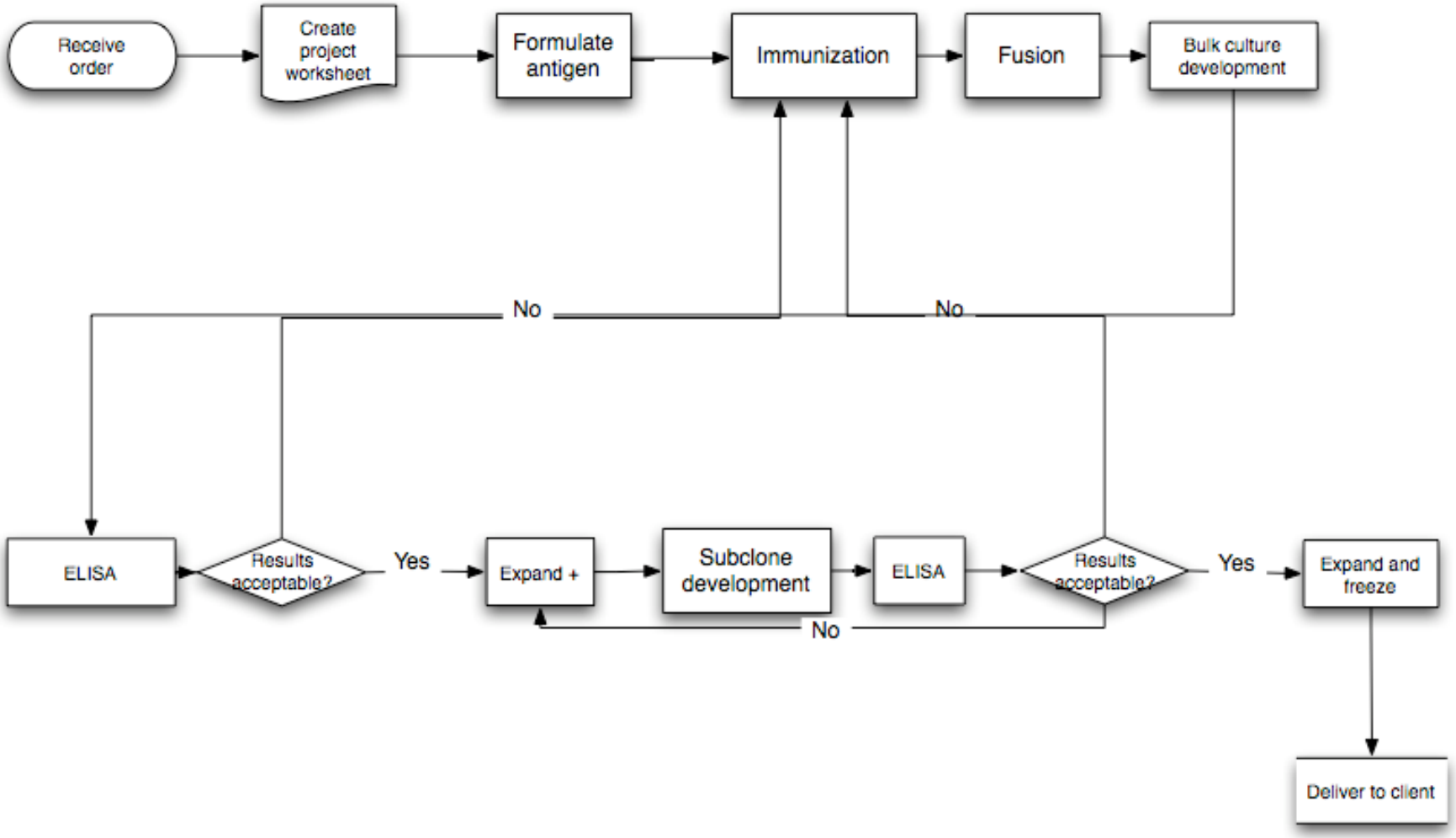
Example- Monoclonal Antibody Production



Example- Monoclonal Antibody Production

1. Receive order
2. Create project worksheet
3. Formulate antigen
4. Immunization
5. Fusion
6. Bulk culture development
7. If unsuccessful at achieving bulk culture development then immunize next mouse in queue (step 4)
8. If successful at achieving bulk culture development then perform Elisa test
9. If results of the Elisa test are acceptable then expand
10. If results of the Elisa test are unacceptable then immunize next mouse is queue (step 4)
11. Sub-clone development
12. Elisa
13. If results of the Elisa test are acceptable then expand and freeze
14. If results of the Elisa test are unacceptable then immunize next mouse in queue (step 4)
15. Ship to customer

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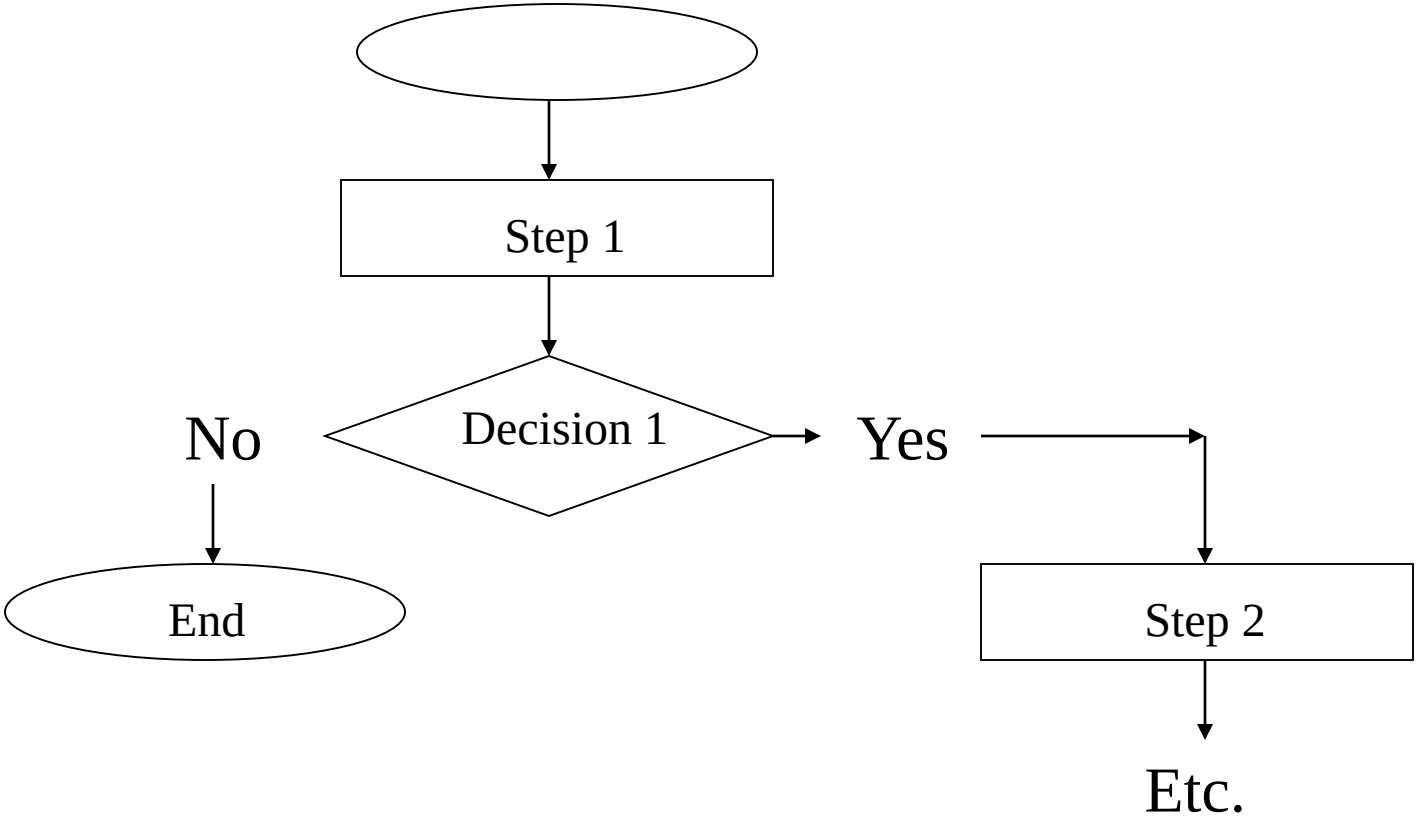
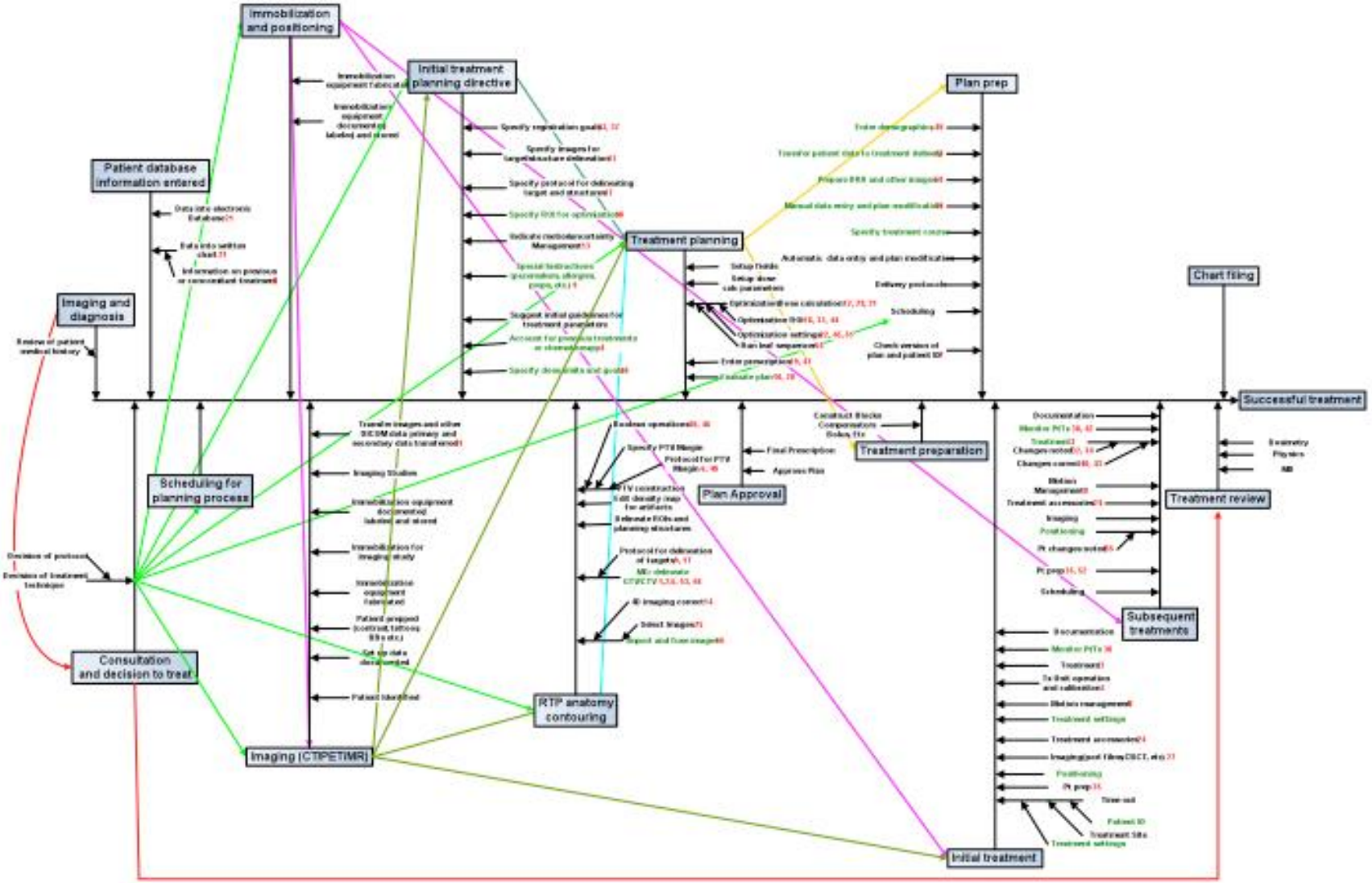
A flowchart is a pictorial representation of a logical decision process, which identifies all of the major steps and decision points involved in progressing from the beginning to the end.



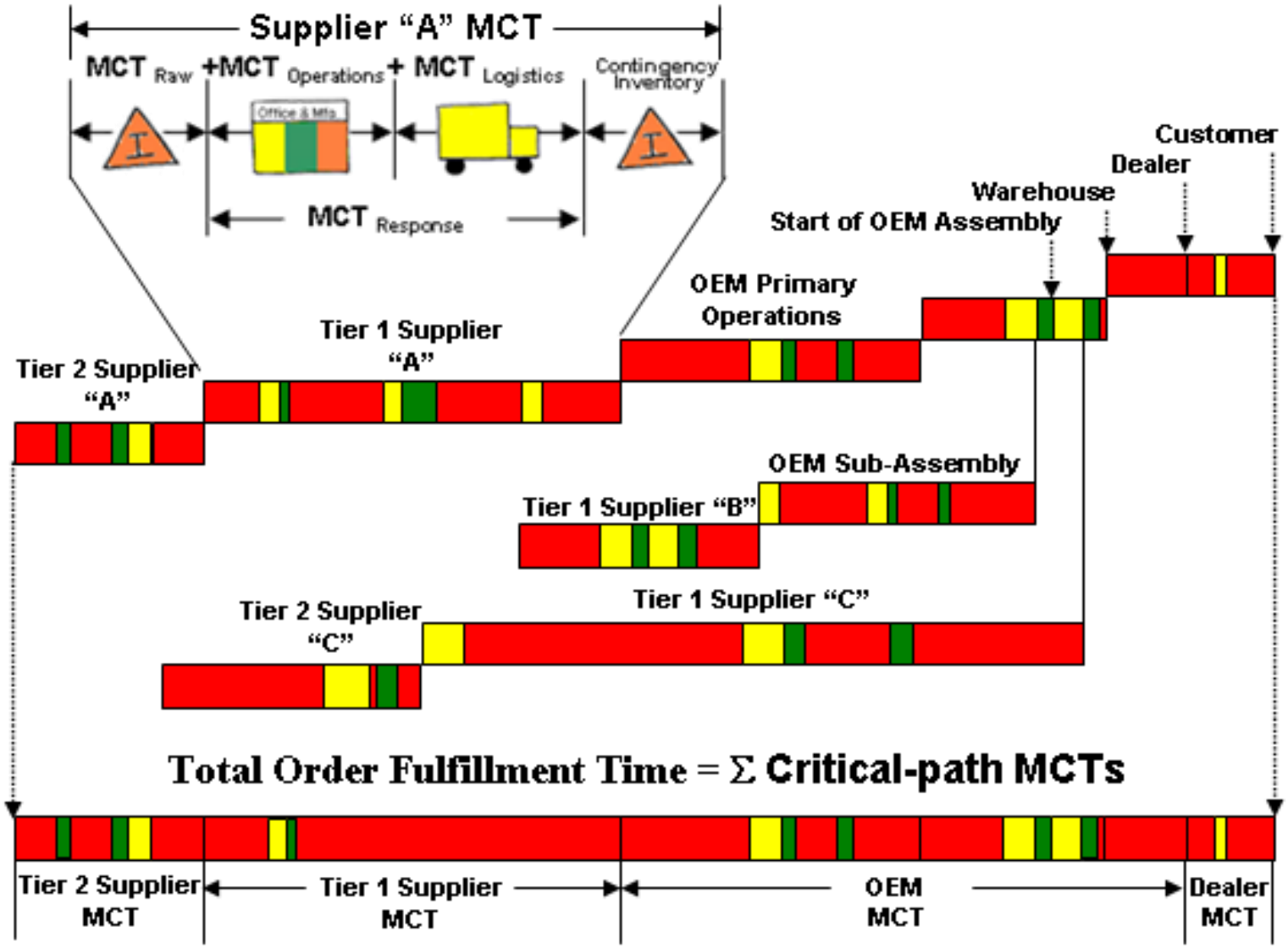
Flowcharts provide a global overview of a "procedure" clearly identifying how each step is related to the others in order to accomplish a particular objective.

Software is available – Visio (OmniGraffle Professional for Mac) and freeware is also available

IMRT Process Tree



Lean and Value Stream Mapping



PFMEA

- Provides an overall picture of an entire process showing the weakest, highest risk or most hazardous process steps
- Methodology of PFMEA – encourages process improvements that prevent the causes of failure modes or detect them prior to anything serious happening

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PFMEA

- For each process step
  - Identify the intended function or output
  - What could possibly go wrong (potential failure mode)
  - How that could happen (potential cause of the failure mode)
  - What could happen if the failure mode occurred (effects of the failure mode)

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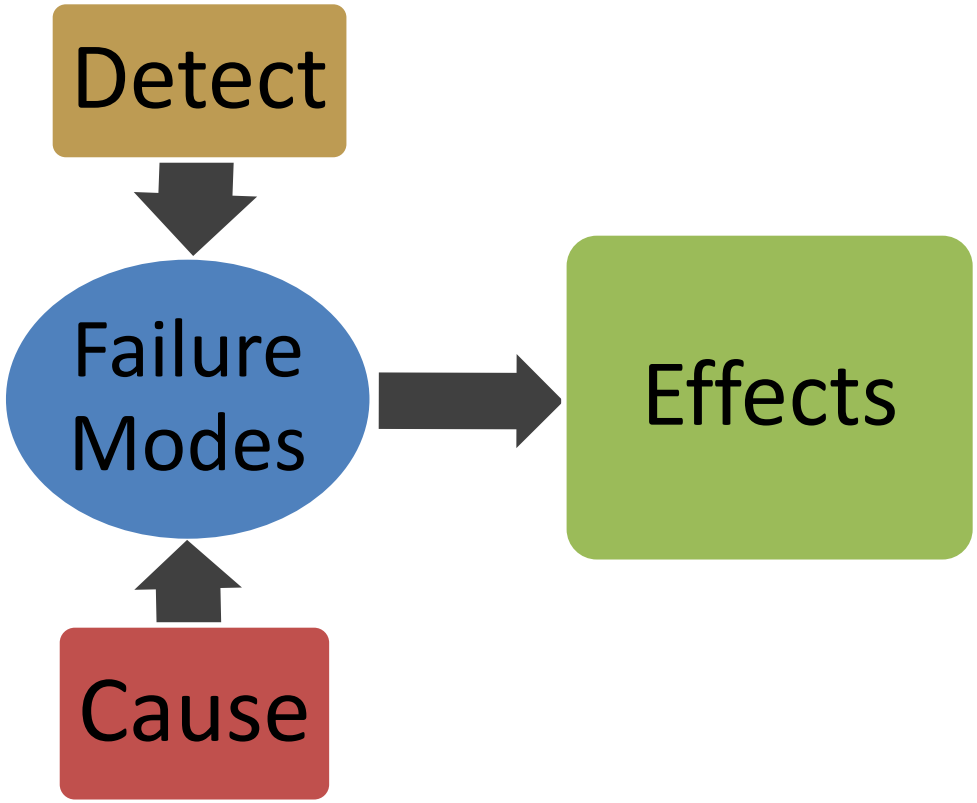
PFMEA

- Based upon process controls currently in place –
  - The likelihood of the cause of the failure mode occurring
  - The probability of detecting the failure mode before anything serious happens is
  - How serious the results or effects of the failure mode are
- The risk for each failure mode/occurrence of cause/severity of effect combination, for each process step is then scored (RPN) and are prioritized by RPN
- Properly executed PFMEA directs focus on what process controls can be implemented that will prevent the failure modes from reaching the patient

Process FMEA – for each step in a process and process controls currently in place



PFMEA

Step	Potential failure modes	Potential causes of failure	Potential effects of failure	Current controls	O	S	D	RPN	Recommended actions	O	S	D	RPN	Comments

Step	Potential failure modes	Potential causes of failure	Potential effects of failure	Current controls	O	S	D	RPN

Current controls	O	S	D	RPN	Recommended actions	O	S	D	RPN

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PFMEA

- Assess the risk level for each failure mode, cause and severity effect combination – Risk Priority Number – using the following scales

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Occurrence of the cause of failure mode
Detection of failure mode
Severity of the effect when a failure mode occurs

Rank	Occurrence	Detection	Severity
	Probability that the cause will occur and lead to the failure mode	Probability that the failure mode will be detected before resulting in the end effect	Seriousness of the end effect when it occurs
1	Remote probability	Always	No effect
2	Low probability	High likelihood	Minor effect
3			
4	Moderate probability	Moderate likelihood	Moderate effect
5			
6			
7	High probability	Low likelihood	Serious effect
8			
9	Very high probability	Very low likelihood	Injury
10	100% probable	Never	Death

FMEA ranking scales for Occurrence, Detection and Severity.

PFMEA

- Assess the risk level for each failure mode, cause and severity effect combination – Risk Priority Number (RPN)

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

- Highest RPNs are addressed first and then lower RPNs
- Process steps with relatively low RPNs but high severity ranking should also be looked at (O = 1, D = 1, S = 10)

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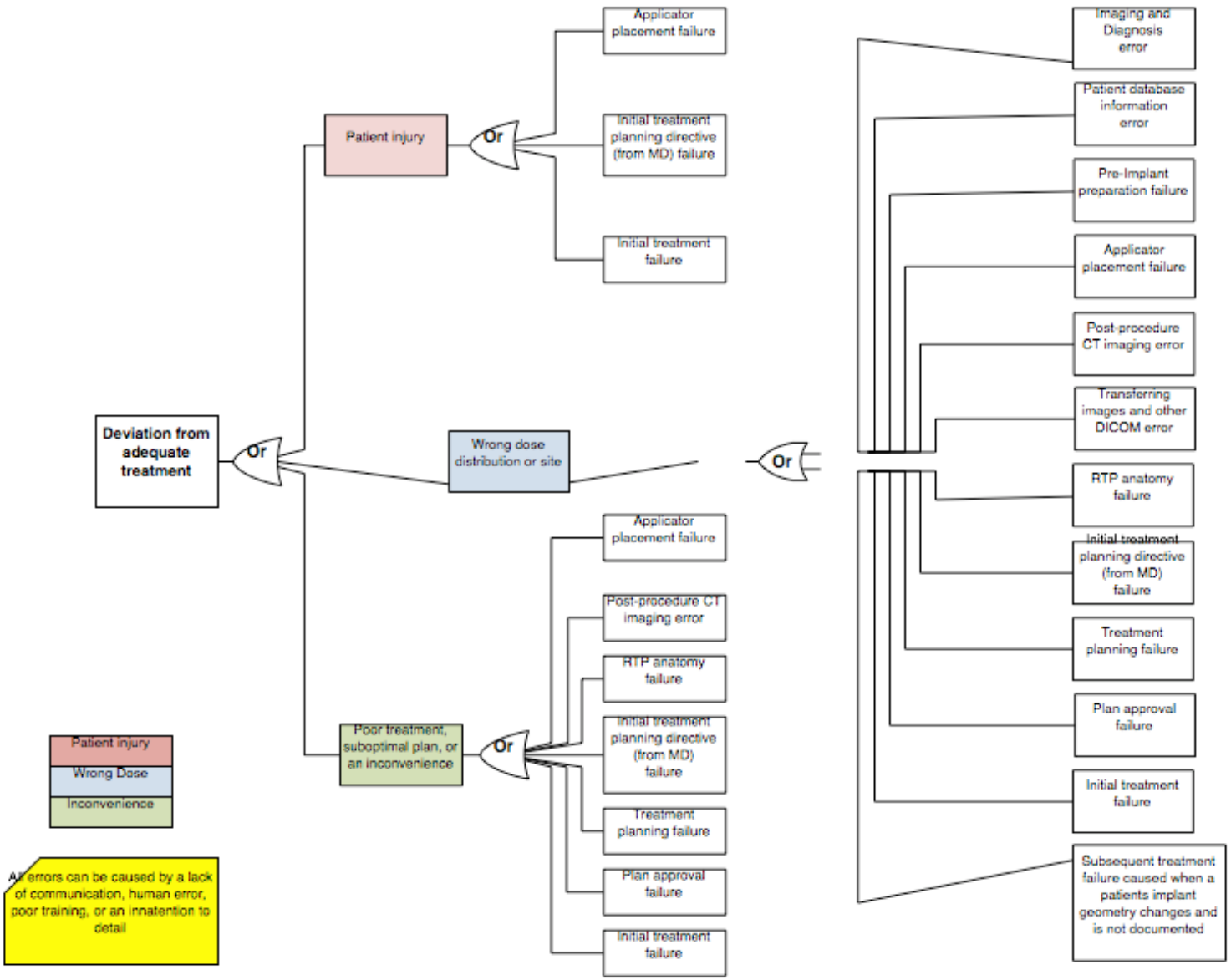
FMEA by RPN – AAPM TG100

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

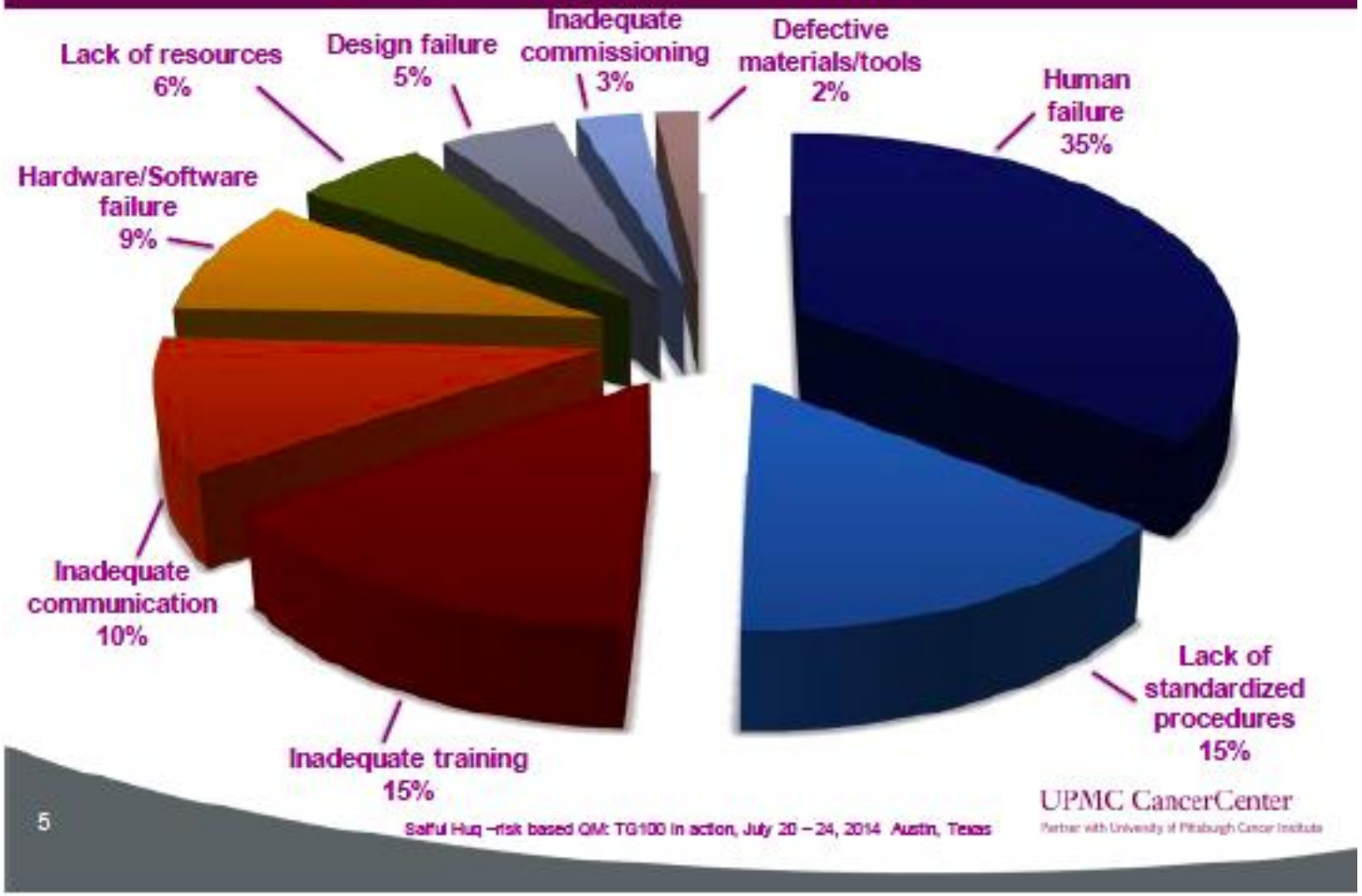
Fault Tree Analysis (FTA)

- After process mapping and PFMEA, FTA provides visual representation of the propagation of failures

Partial FTA from TG100



AAPM TG100 analysis of causes of failure for IMRT



UPMC CancerCenter
Partner with University of Pittsburgh Cancer Institute

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Successful Implementation of TG -100 Methodology in Clinics will Require

- Cross functional team approach
- Training in the use of TG – 100 tools
- Facilitator lead application of the tools

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TG – 100 Implementation across AAPM

- AAPM Ad-Hoc committee on TG – 100 – Dan Low chairman
  - Develop a plan to move TG – 100 methodology forward
    - Define the mechanism to present the concepts of the proposed TG 100 report and
    - Develop an implementation plan for the next generation of radiation therapy quality management

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TG – 100 Implementation across AAPM

- Education/training
  - Workshops: 1-2 day hands on training in the use of TG – 100 tools
  - Annual meeting symposia
  - Spring workshop attached to SCM and Annual Meeting
  - Local Chapter Meetings
- Support
  - Website
  - Software tools - templates
  - Database – repository of process maps, PFMEAs and FTAs to be used as starting points for clinics

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TG – 100 Implementation across AAPM

- Research Plan
  - How is TG-100 implemented?
  - Does TG-100 improve efficiency and safety?
- CARS and University of Wisconsin roll out plan – post publication of TG – 100
  - Budget put together
  - Resources identified and available
  - Ability to start quickly
  - Provide post training support
  - Funding strategy – AAPM and device companies

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Questions?