Quality and Safety In Modern Brachytherapy an AAPM Educational Symposium

Moderator:

Daniel Scanderbeg, PhD – University of California, San Diego

Presenters:

Jay Reiff, PhD – Drexel University College of Medicine

Daniel Scanderbeg, PhD – UCSD

Susan Richardson, PhD – Washington University

Disclosures/COI

None

Outline

1) Jay Reiff
   - NRC regulations
   - Common errors with HDR brachytherapy

2) Dan Scanderbeg
   - Proactive risk management
   - Failure Mode and Effects Analysis (FMEA)
   - Example and Results (UCSD & WashU)

- 3) Susan Richardson
   - Risk management and mitigation
   - Fault Trees and Root Cause Analysis

Educational Objectives

- Be familiar with current NRC regulations and relationship to common errors
- Understand failure mode and effect analysis and its application to brachytherapy programs
- Understand common failure modes and ways to mitigate them

COMMONLY REPORTED HDR ERRORS

AND

THE RELEVANT NRC REGULATIONS

Jay Reiff, Ph.D.
Drexel University College of Medicine

INTRODUCTION

- In the most recent PRO, Dr. Richardson summarizes events reported to the NRC from January, 2009 through December, 2010
- LDR
- HDR
- Gamma Knife
- Radiopharmaceutical Administration

INTRODUCTION

- Updated HDR reported events through July 16, 2012
- Events reported from 1999 through today are available to the public at http://www.nrc.gov/reading-rm/doc-collections/event-status/event/

What is a "Reportable Event"?

- Administration of, or radiation from, a byproduct material which will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician

What is a "Reportable Event"?

- A dose that differs from the prescribed dose by more than 0.05 Sv (5 rem) EDE, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin

AND

What is a “Reportable Event”?

- The total dose delivered differs from the prescribed dose by at least 20%
- The fractionated dose delivered differs from the prescribed dose, for a single fraction, by at least 50%

What is a “Reportable Event”?

- A dose that exceeds 0.05 Sv (5 rem) EDE, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from treating the wrong person or from a leaking sealed source

What is a "Reportable Event"?

- A dose to the skin, an organ, or tissue other than the treatment site that receives at least 50% more dose than expected from the administration defined in the written directive

Commonly Reported Events

- In the 42.5 month period from January, 2009 through mid July, 2012, 54 HDR related events were reported to the NRC

- Errors fell into 3 main categories

Commonly Reported Events

- Incorrect dose delivered
- Incorrect site treated
- Mechanical failure

Commonly Reported Scenarios

- Incorrect dose delivered and incorrect site treated are often, but not always related
- Sites most often reported include GYN, breast, and bile duct

Commonly Reported Scenarios

- Vaginal cylinder slid out (3 – 5 cm) between imaging and treatment
- Decreased dose to intended region
- Dose to unintended region
- Red spots on upper thighs

Commonly Reported Scenarios

- Bile duct treatment
- At time of treatment it was noticed that the catheter slid out 2 cm
- Dwell position was modified by 2 cm but in the wrong direction
- 4 cm positioning error

Commonly Reported Scenarios

- Multi-catheter APBI devices
- Length was incorrectly measured due to a faulty measuring device (kinked wire)
- Length was incorrectly measured due to a blockage in the catheter/applicator system
- Error range: 2 – 10 cm

Commonly Reported Scenarios

- Various anatomic sites
- Treatment planning system gave dwell times for a single fraction
- Facility divided these times by the number of prescribed fractions resulting in an underdose to the patients

Commonly Reported Scenarios

- Mechanical failures
- During a source exchange the source failed to extend all the way out – got stuck in the afterloader outside the safe
- During a source exchange the source stuck going into the container

Commonly Cited Reasons

- HUMAN ERROR
- Failure to follow documented procedures (management deficiency)
- Lack of communication
- Lack of training

How To Reduce the Likelihood of Repeating These Errors

I now turn the podium over to
Dr. Daniel Scanderbeg

Proactive Risk Management

WHY?

- TJC (formerly JCAHO) – July 1, 2001
- Standards in Support of Patient Safety and Medical/Health Care Error Reduction
- LD 5.2 :“Leaders ensure that an ongoing, proactive program for identifying risks to patient safety and reducing medical/health care errors is defined and implemented.”
- Healthcare organizations required to analyze one high-risk process annually

Radiation Oncology

- High-risk processes
- NY Times article series 2010-2011

Radiation Errors Reported in Missouri

By WALT BOGDANICH and REBECCA R. RUIZ
Published: February 24, 2010

THE RADIATION BOOM

A Pinpoint Beam Strays Invisibly, Harming Instead of Healing

By WALT BOGDANICH and KRISTINA REBELO
Published: December 28, 2010

Philadelphia V.A. Hospital Botched 92 Treatments

Prostate Cancer Patients Receive Too Little or Too Much Radiation

Failure Modes and Effects Analysis

WHAT?

- SAE – “Formal and systematic approach to identifying potential system failure modes, their causes, and the effects of the failure mode occurrence on the system operation…”

WHEN?

- Originated US Military in 1940s
- Officially accepted by SAE for aerospace engineering in 1967 as recommended practice

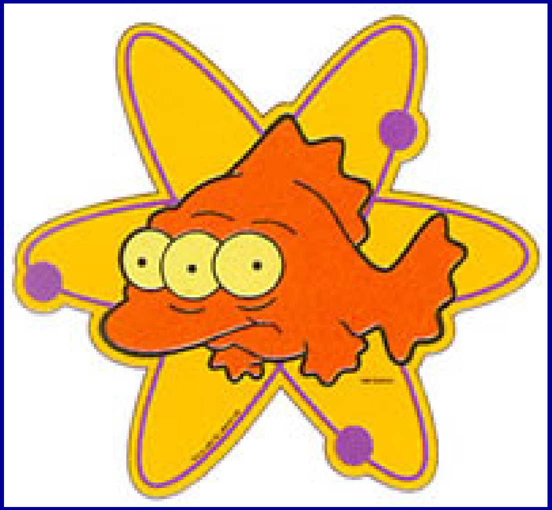
EXAMPLES:

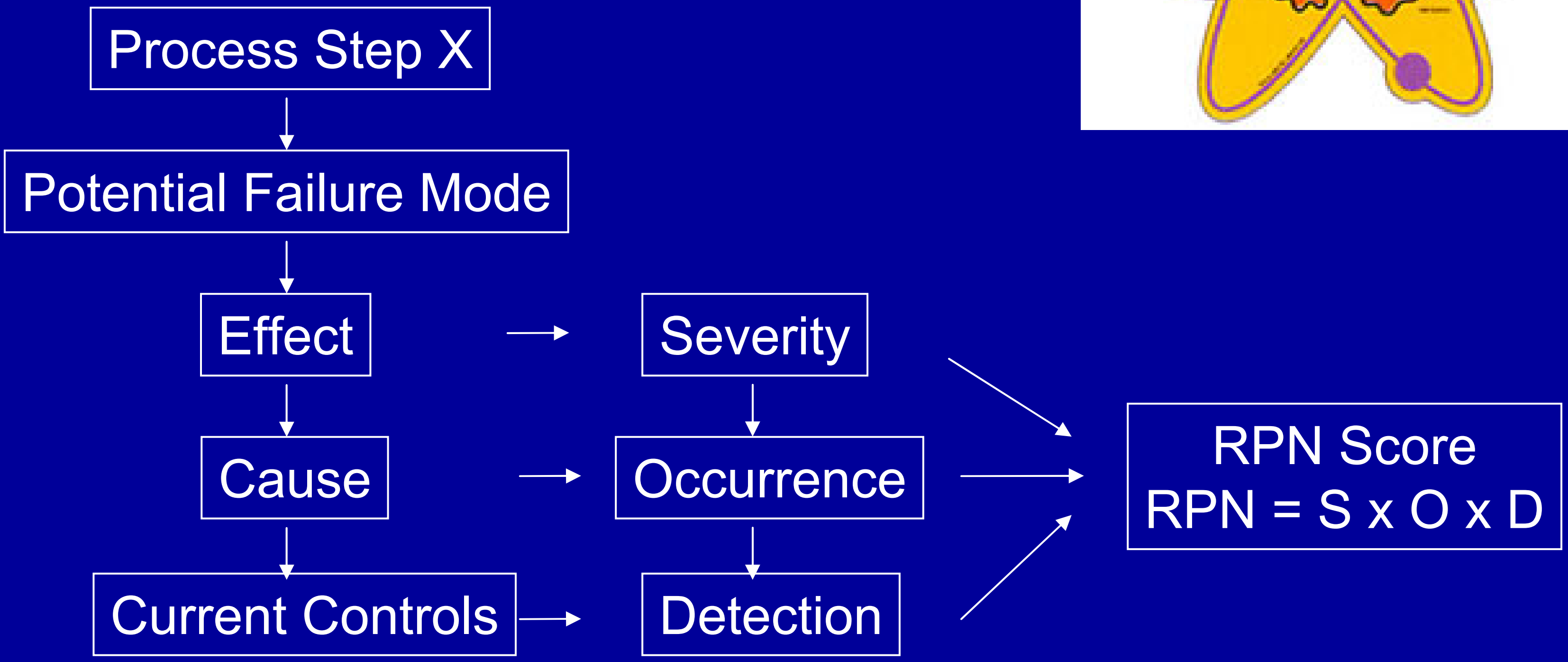
- Semiconductor industry (MetroPhotonics)
- Airline (Boeing 737 series)
- Automotive industry (Ford/Chrysler)
- Medicine (Medication dispensing)

Failure Modes and Effects Analysis

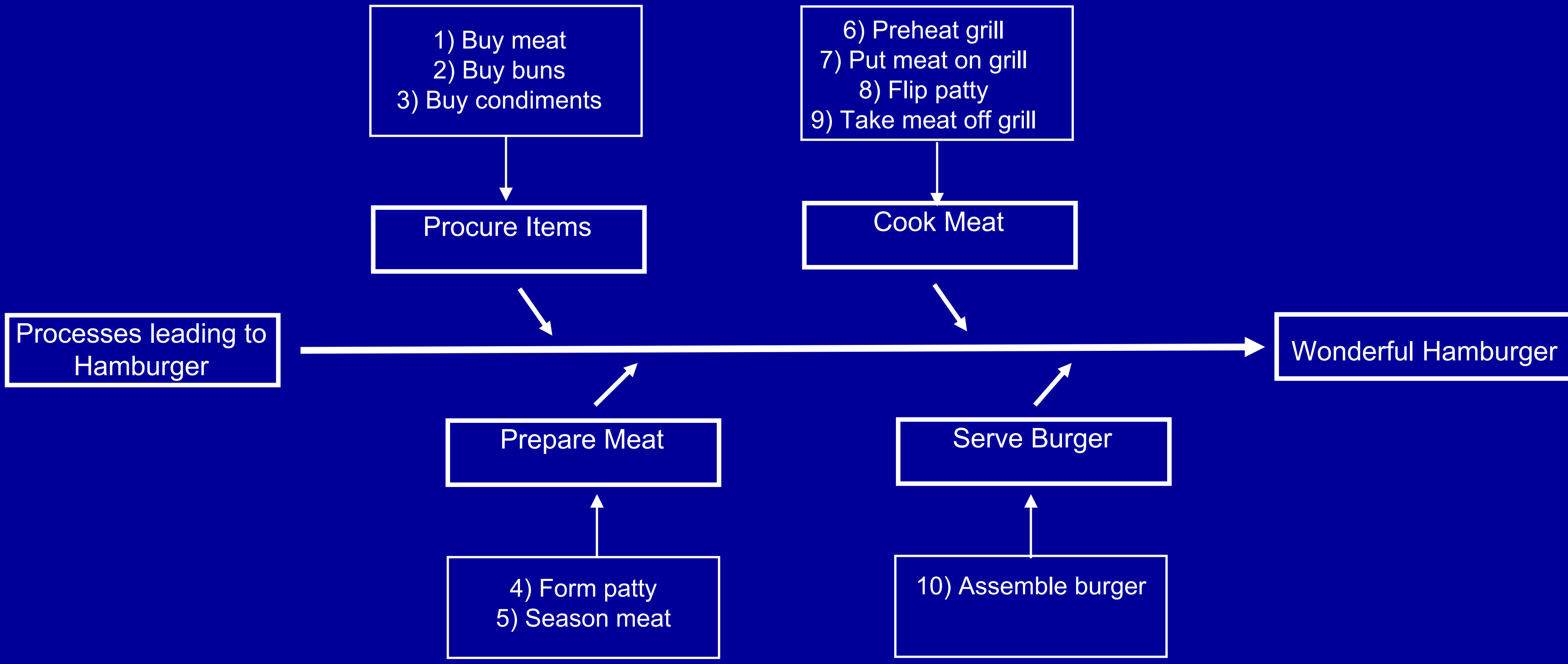
HOW?

- Assemble group of people (experts) in field
- Make a process tree for a given procedure
- Brainstorm to discover potential failure modes
- Assign numbers to these modes



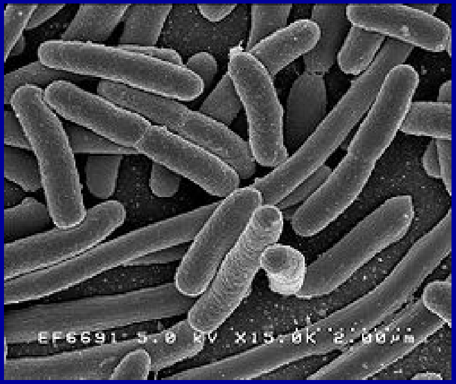


Simple Example



Simple Example

Process Step	Potential Failure Mode	Effect of Failure Mode	O rank	S rank	D rank	RPN score
1) Get meat	**Store is out of meat**	**Cannot make a burger**	**2**	**10**	**1**	**20**
2) Get buns	**Store is out of buns**	**Cannot make a burger w/ bun**	**2**	**5**	**1**	**10**
6) Preheat grill	**Out of charcoal/propane**	**Cannot BBQ burger**	**4**	**10**	**1**	**40**
7-9) Cooking	**Undercook meat**	**Inedible – e coli !!!**	**3**	**10**	**2**	**60**
7-9) Cooking	**Overcook meat**	**Inedible**	**3**	**10**	**2**	**60**



How can I implement this in my clinic?

- What if I don't have the resources to do this?
- Implementation of FMEA for brachytherapy via "Q-D" Method

University of California, San Diego, La Jolla, CA

- Medium size clinic
  - 1 HDR, LDR, 2.5 MDs, 1.75 PhDs, 0 CMDs, ~ 120 patients/year
- Two person team
- ~ 15 man-hours

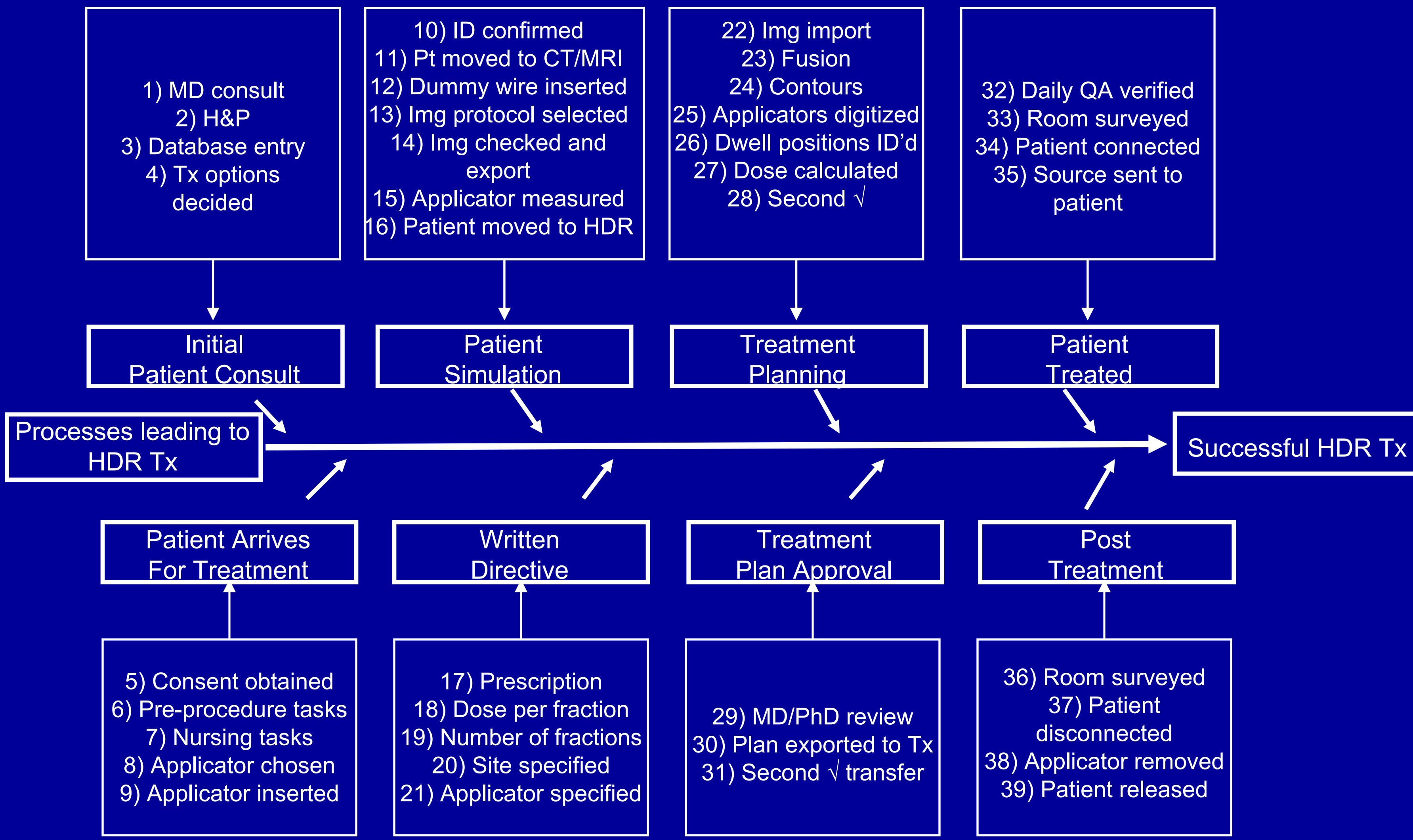
Washington University/Barnes Jewish Hospital, St. Louis, MO

- Large size clinic
  - 2 HDR, LDR, 6 MDs, 2 PhDs, 3 CMDs, ~ 350 – 400 patients/year
- One individual
- ~ 20 man-hours

Results

Process Maps

- Similar at both institutions



Results

Failure Modes

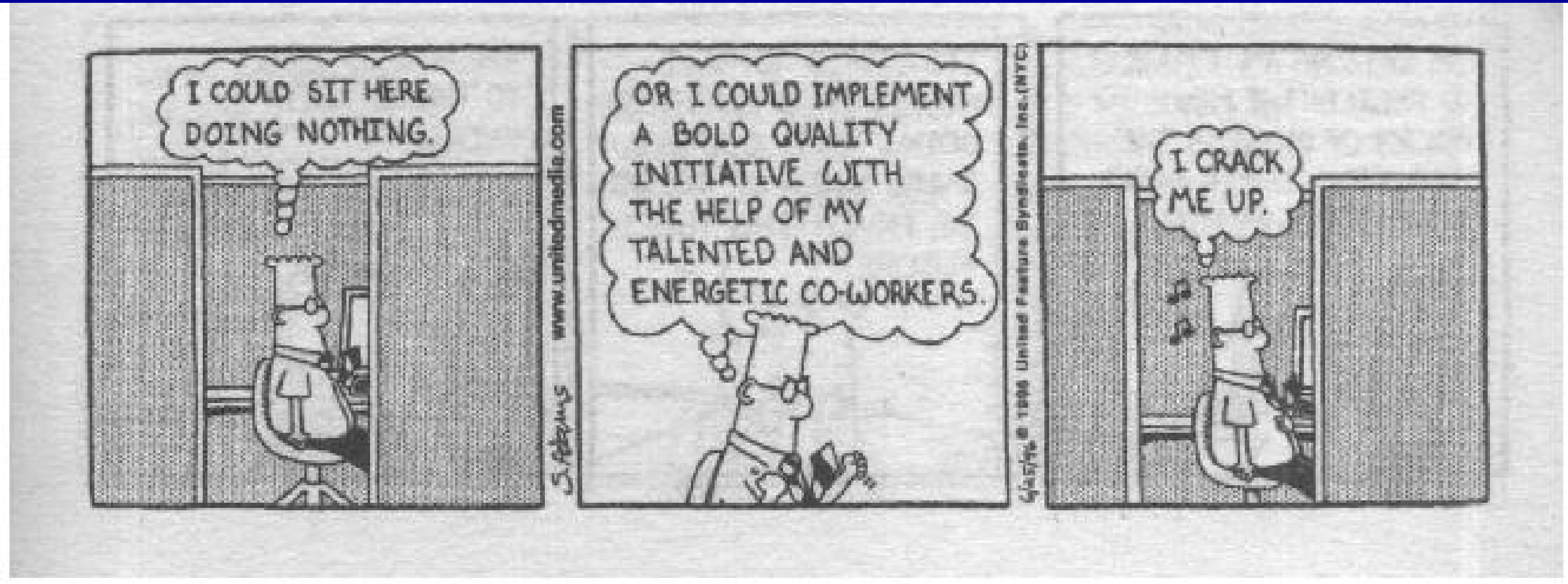
- Similarities
  - Highest RPNs at each institution similar
    - Wrong applicator length (measured or entered)
    - Wrong connections of TGTs
    - Wrong applicator inserted or documented

Discussion

- RPN score (magnitude) → Detection scaling factor
  - Clinic size/flow
  - Dedicated brachy staff → More second checks
  - Similar overall FMs and rankings (scaling)
  - Results limited to dosimetry/physics
  - Results can lead to tools to improve clinic → RCA

Summary

- FMEA is a tested and verified tool in quality management
- Implementation in Radiation Oncology is an effective proactive approach to quality management
- Results from two institutions consistent with each other and with common errors reported to NRC
- Use existing literature/QD method for clinic and customize to clinic specific processes/procedures



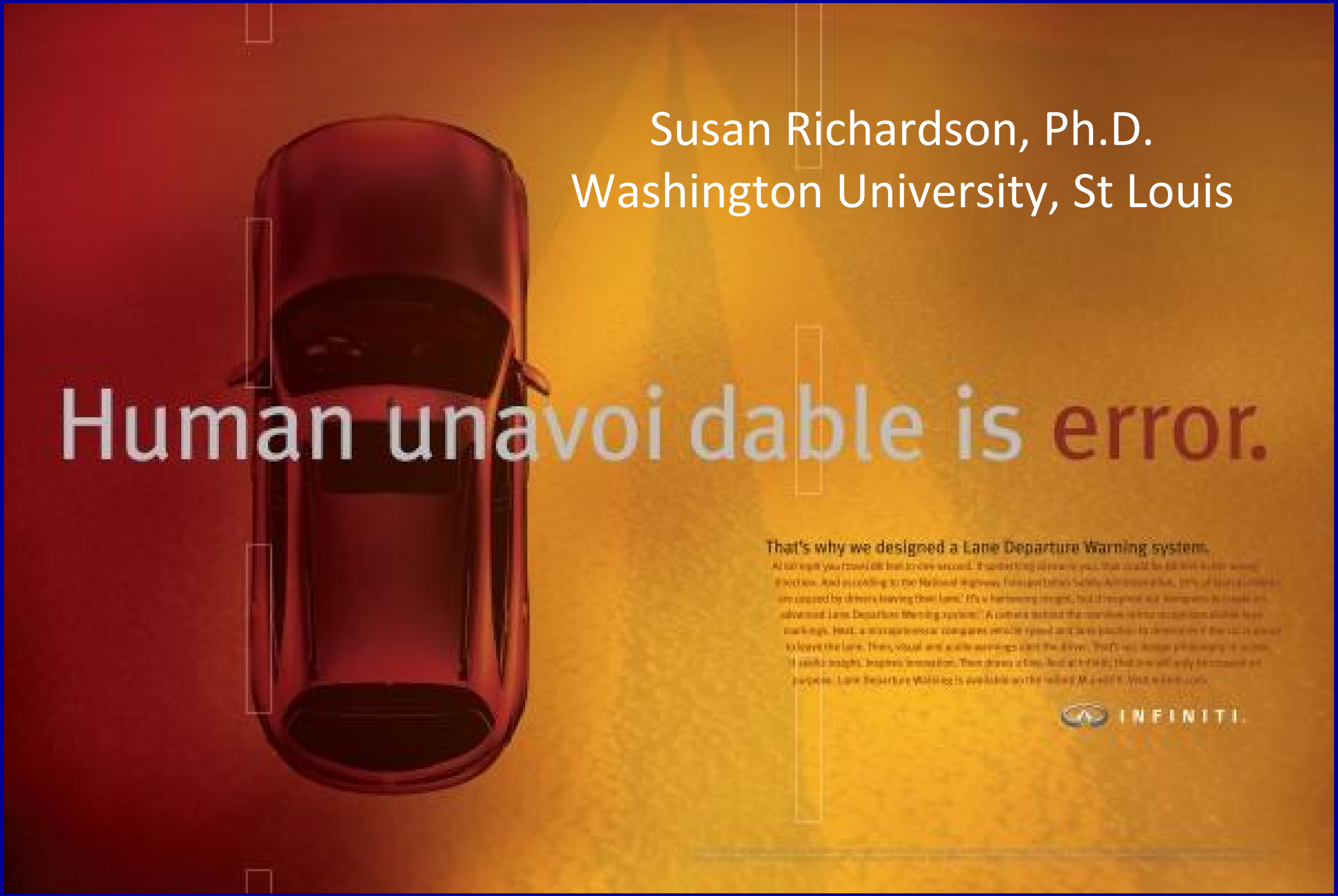
Error Mitigation

I now turn the podium over to

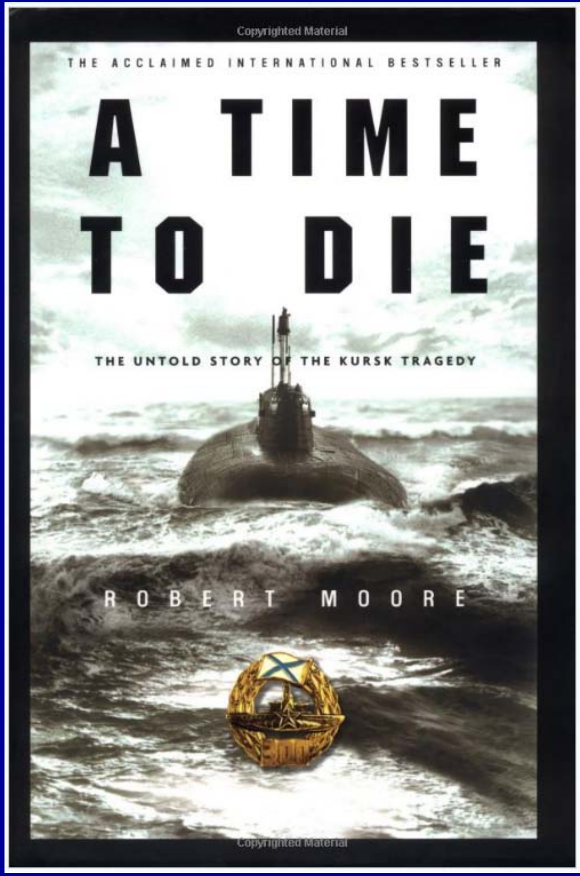
Dr. Susan Richardson

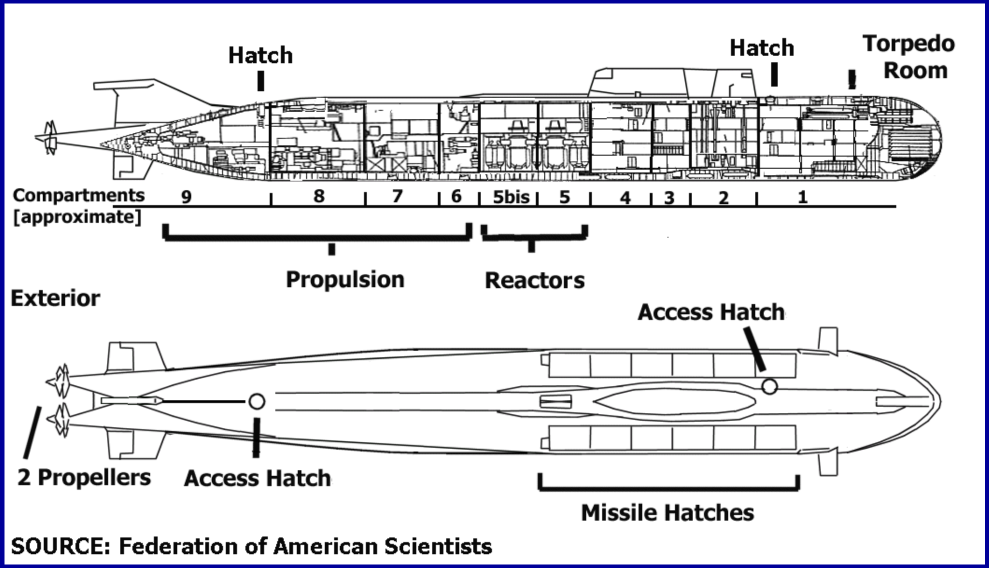
Error Mitigation in Brachytherapy

Susan Richardson, Ph.D.
Washington University, St Louis



What does a sunken submarine have to do with brachytherapy?





K-141 *Kursk*
was a nuclear-powered cruise missile submarine of the Russian Navy…

…lost with all hands when it sank in the Barents Sea on 12 August 2000

Quick Overview of Events

1. During a routine exercise, failure of welds and/or gaskets in a torpedo resulted in a chemical reaction that culminated in an explosion of the fuel and a kerosene tank.

INITIAL PROBLEM

2. The blast blew off a torpedo tube door that was not closed properly. This flooded the compartment and caused the ship to being sinking.

SAFETY DESIGN FLAW

3. The explosion ripped through three compartments of the ship, which should have been insulated from the blast by a bulkhead, but was not, because it could travel between compartments via a ventilation shaft.

SAFETY OVERSIGHT DESIGN FLAW

Attempted Rescue

4. Although other Russian ships in the exercise heard the explosion on sonar, none reacted, all believing it was part of the drill.

BAD COMMUNICATION
FAILURE TO REACT
BAD ASSUMPTIONS

5. A Russian rescue vessel was deployed but failed to reach the submarine because its batteries wouldn't stay charged.

LACK OF PREPARATION
LACK OF CONTINGENCY PLAN

Attempted Rescue

6. After 7 days, a Norwegian rescue vessel docked with the rescue hatch, however, they were told the hatch opened *counter-clockwise*, however, it actually opened *clockwise.*

EQUIPMENT FAILURE
COMMUNICATION FAILURE

All 118 sailors and officers aboard *Kursk* perished.

That's really unfortunate, but that's just an amazing coincidence of events and that won't happen to me.

- Probably! BUT.
- The most famous brachytherapy radiation accident in history occurred in 1992 in which a patient died after the radioactive source broke off in her.
  - Nursing assistants, hospital staff, waste disposal workers, and the general public were all irradiated unnecessarily as a result.

Quick Overview of Events *(in Indiana)*

1. During a routine *patient treatment* ~~*exercise*~~, failure of *source* welds ~~and/or gaskets in a torpedo resulted in~~ *from* a chemical reaction ~~that~~ culminated in ~~an explosion of the fuel and a kerosene tank.~~ *the HDR source breaking off in a patient.*

→ INITIAL PROBLEM

2. ~~The blast blew off a torpedo tube door that was not closed properly. This flooded the compartment and caused the ship to being sinking.~~ *The HDR console indicated the source was parked and "safe".*

→ SAFETY DESIGN FLAW

Attempted rescue *of the source*

3. The ~~explosion ripped through three compartments of the ship,~~ *handheld survey meter was available for use* ~~which should have been insulated from the blast by a bulkhead,~~ but was not *used*.

SAFETY OVERSIGHT

Attempted rescue *of the source*

4. Although ~~other Russian ships in the exercise~~ *the staff present* heard the ~~explosion~~ *prime alert radiation monitor in the room,* ~~on sonar,~~ no one reacted, all believing it was ~~part of the drill.~~ *malfunctioning.*

BAD COMMUNICATION
FAILURE TO REACT
BAD ASSUMPTIONS

OK, I'M CONVINCED. SO HOW SHOULD WE MITIGATE THESE ERRORS?

Strategies

- Error trees
- FMEA
- Fault Trees
- RCA
- Probabilistic Risk Assessment
- Hazard Analysis
- Double Failure Matrix
- Composite Risk Index
- Traceability Matrix
- Safety Management Organization Review Technique
- Fishbone Analysis
- etc

Fault Tree Analysis

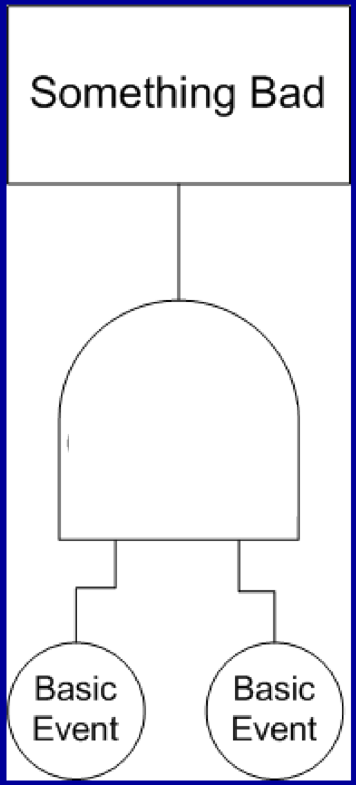
- This can be a segue from your FMEA
- FMEA is an ***inductive*** approach; Fault Trees are a ***deductive*** approach.
  - Inductive methodology: reasoning from individual cases to a general conclusion
    - “What affect does this fault have on my system?”
  - Deductive methodology: reasoning from the general to the specific
    - “My system ‘X’ has failed. What modes or components of my system contributed?”

“Who was the murderer?
Well Watson, that’s the killer question.”

Fault Tree Basics

An undesired effect is taken as the root ('top event') of a tree of logic

Then, each situation that could cause that effect is added to the tree as a series of logic expressions



Variable gate types

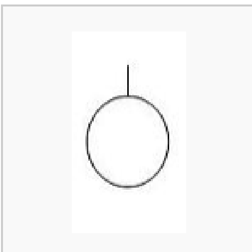
Variable event types

Symbols used in Fault Trees

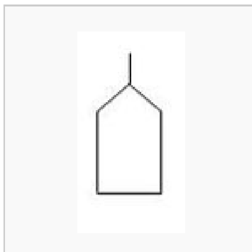
Event Symbols

[edit]

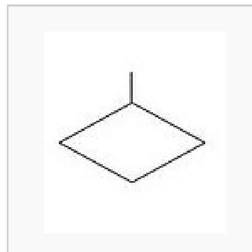
Event symbols are used for *primary events* and *intermediate events*. Primary events are not further developed on the fault tree. Intermediate events are found at the output of a gate. The event symbols are shown below:



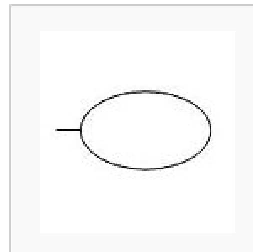
Basic event



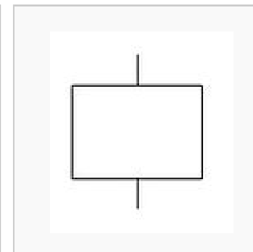
Initiating event



Undeveloped event



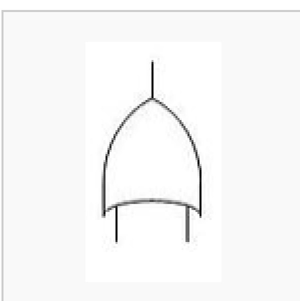
Conditioning event



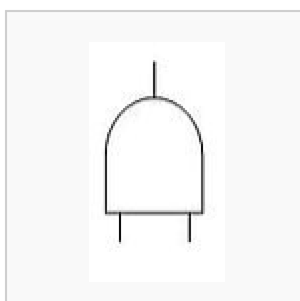
Intermediate event

Gate Symbols

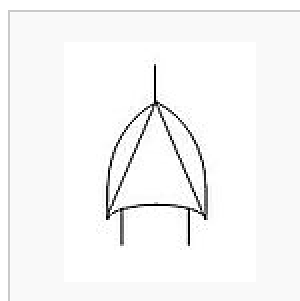
Gate symbols describe the relationship between input and output events. The symbols are derived from Boolean logic symbols:



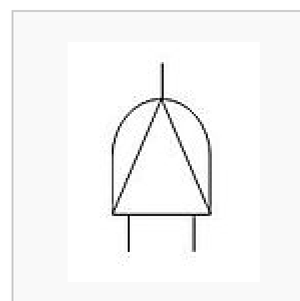
OR gate



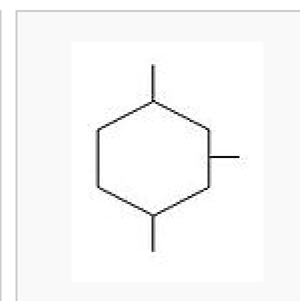
AND gate



Exclusive OR gate

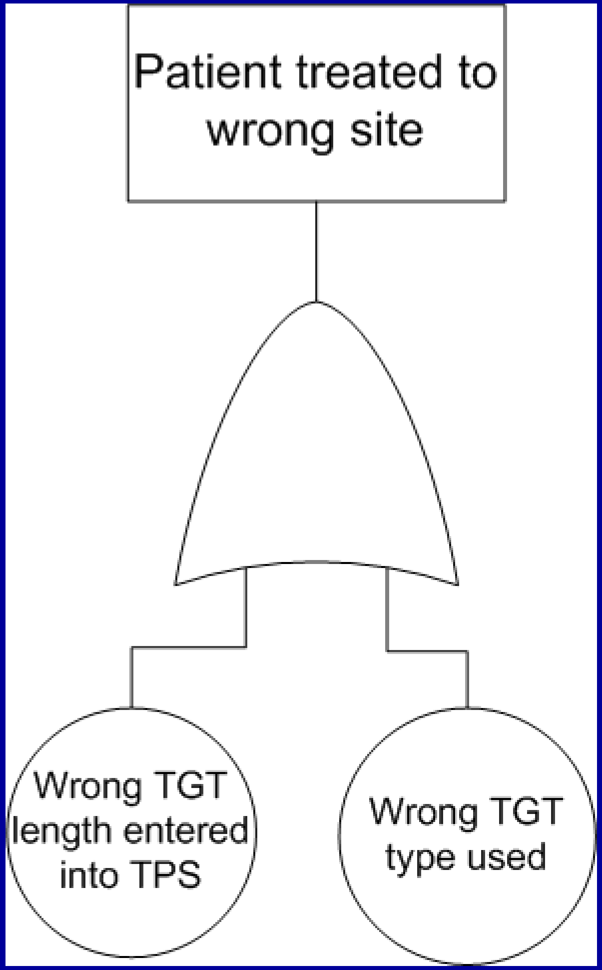


Priority AND gate



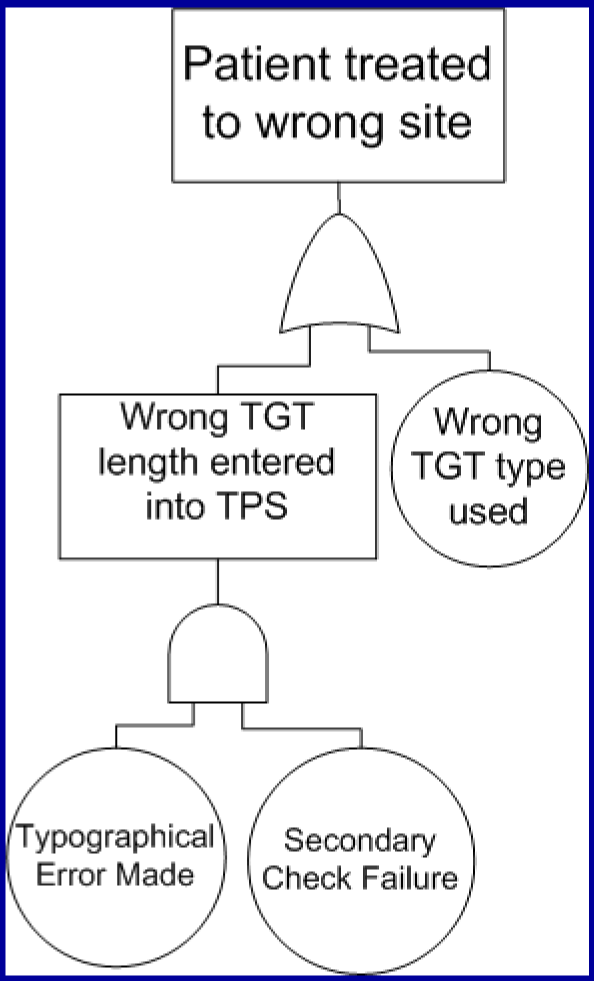
Inhibit gate

Simple Fault Tree



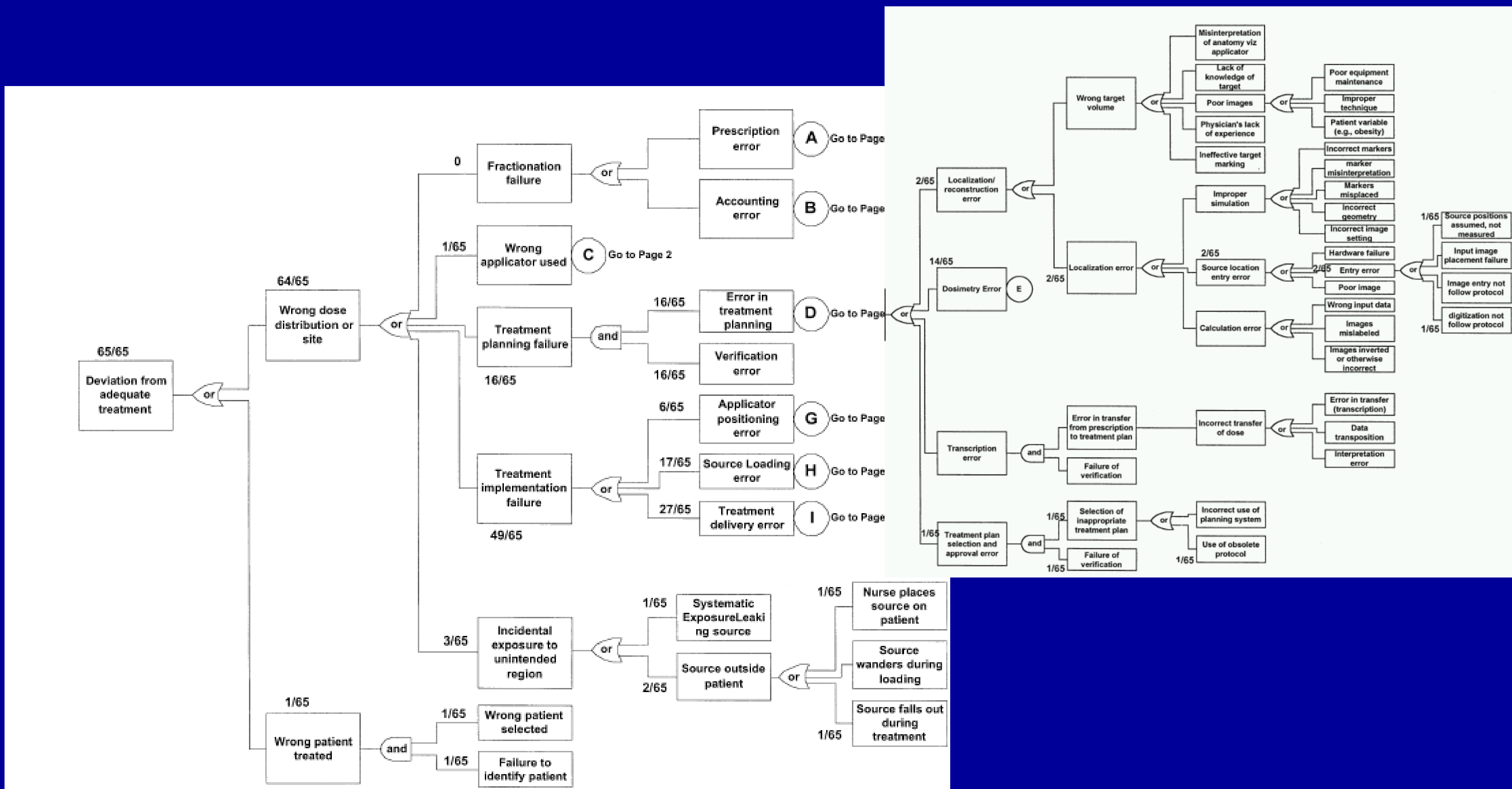
In general, AND gates provide protection as multiple events must occur. OR gates are opportunities for improvements or enhanced QC

Building in QA



And gates give you the extra layer of protection

Realistic Fault Tree



ANALYSIS OF TREATMENT DELIVERY ERRORS IN BRACHYTHERAPY USING FORMAL RISK ANALYSIS TECHNIQUES

BRUCE THOMADSEN, PH.D.,*†‡§‖ SHI-WOEI LIN, M.S.,¶ PATRICK LAEMMRICH, M.S.,**
TONIA WALLER, M.S.,†† ARIF CHENG, M.S.,¶ BARRETT CALDWELL, PH.D.,‡‡
REBECCA RANKIN, R.N., M.S., C.P.H.Q.,§§ AND JUDITH STITT, M.D.†1

Int. J. Radiation Oncology Biol. Phys., Vol. 57, No. 5, pp. 1492–1508, 2003

0360-3016/03/$–see front matter

Assign Probability Functions

- Assign a probability for each step in your fault tree
- Use Boolean logic to calculate failure rates

S = Successes

F = Failures

Reliability . . . . $R = \dfrac{S}{(S + F)}$

Failure Probability . . . $P_F = \dfrac{F}{(S + F)}$

$$R + P_F = \frac{S}{(S + F)} + \frac{F}{(S + F)} \equiv 1$$

λ **= Fault Rate =** $\dfrac{1}{MTBF}$

For 2 Inputs

$R + P_F \equiv 1$

OR Gate

Either of two, independent, element failures produces system failure.

$$R_T = R_A R_B$$

$P_F = 1 - R_T$
$P_F = 1 - (R_A R_B)$
$P_F = 1 - [(1 - P_A)(1 - P_B)]$

$$P_F = P_A + P_B - P_A P_B$$

[Union / $\cup$]

...for $P_{A,B} \leq 0.2$
$P_F \cong P_A + P_B$
with error $\leq$ 11%

← "Rare Event Approximation"

AND Gate

Both of two, independent elements must fail to produce system failure.

$$R_T = R_A + R_B - R_A R_B$$

$P_F = 1 - R_T$
$P_F = 1 - (R_A + R_B - R_A R_B)$
$P_F = 1 - [(1 - P_A) + (1 - P_B) - (1 - P_A)(1 - P_B)]$

$$P_F = P_A P_B$$

[Intersection / $\cap$]

Root Cause Analysis

- A root-cause-analysis tree begins with an event. From there, it works backward in time, considering the magnitude, locations, and timing of events or actions and conditions that ultimately led to the event.
- The purpose is to determine the *cause* of the event.
- Works well to analyze events from your institution

Human Error Reduction

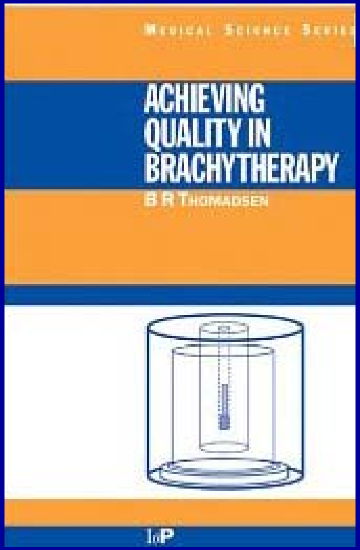
1. Skill-based errors
   - Share lessons learned
   - Individually address the error precursors that led to the occurrence.
2. Rule-based errors
   - Find out why there was a misinterpretation of the rule and taking action to prevent future misinterpretation.
3. Knowledge-based errors
   - Training is effective in addressing this kind of errors.

Ideas for preventing errors

- Interlocks
- Protocols & standardization of treatment
- Forms
- Independent second person
- Have contingency plans
- Review and re-review your QM system often
- Measure your TGT length!
- Come to more brachytherapy talks at AAPM

Resources

- Fault Tree Handbook – Nureg 0492
- *Achieving Quality in Brachytherapy* by B.R. Thomadsen
- Many publications by Eric Ford, Bruce Thomadsen, TG 100, etc.
- IAEA "Prevention of accidental exposures" series
- www.fault-tree.net
- ICRP 97



Thank you!

Discussion/Questions

- Thank you for your attention
- Questions/Comments?