Human Performance in Medical Uses of Byproduct Materials

Presentation of HRA-Informed Training Materials - NRC/FSME Staff

Plan for the Day

- Presentation (AM)
  - Introduction to Risks and Causes of Medical Events
  - Perspective on Human Performance & Errors
  - A Framework for Safety Performance
  - Protocol for Investigating Human Error-Related Events
  - Attributing Causes
  - Summary
- Workshop Exercise (PM)
  - Application of Investigation Protocol
  - Discussion of Job Aid Issues

Staff Requirements

Goal is that staff be able to

- appreciate how human performance issues might be relevant to proposed changes or exemptions to license conditions
- consider the role of human performance in reported events
- take human performance into account in evaluating corrective actions after medical events

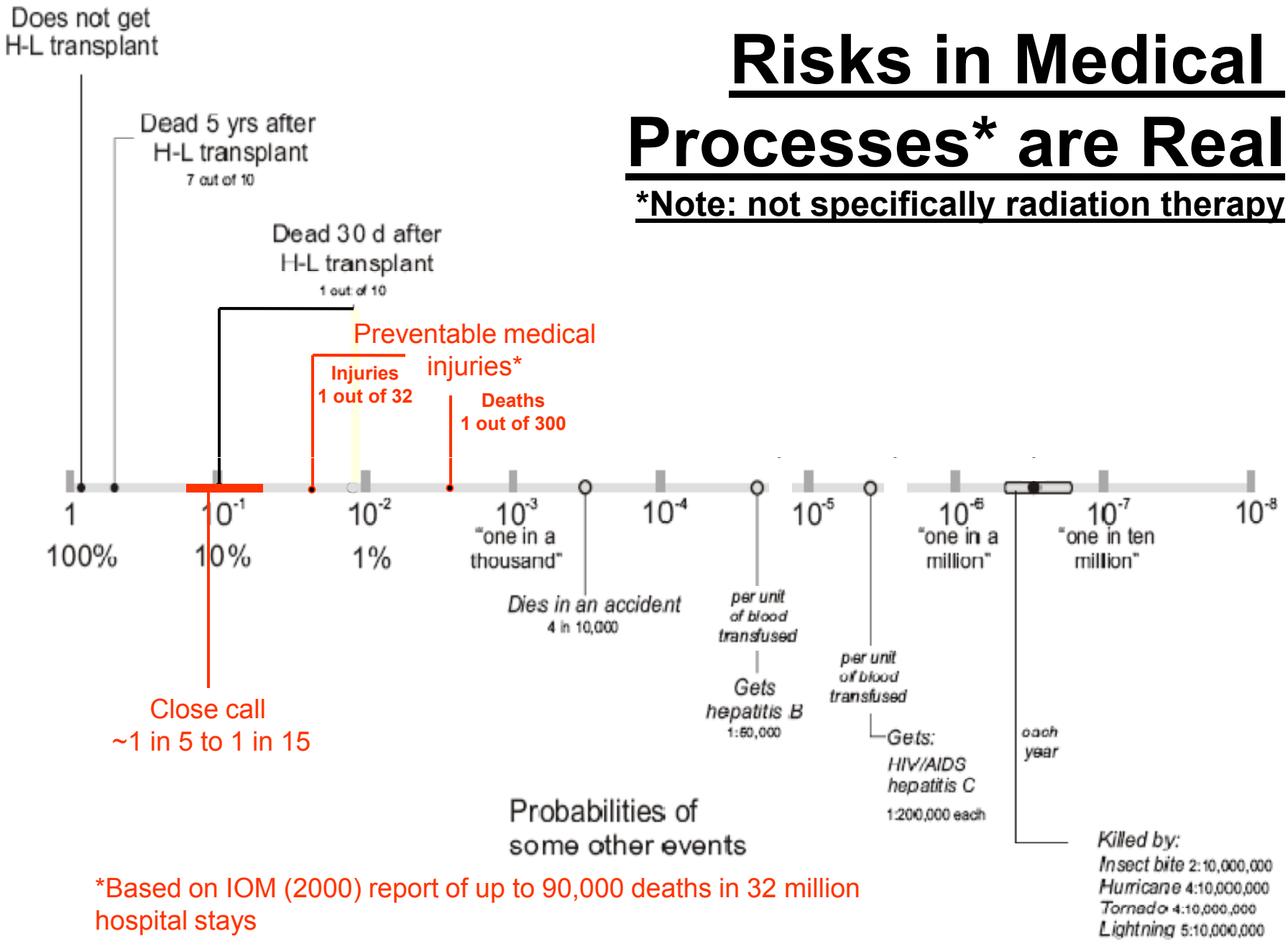
Project Objectives

Approach is to provide

- a basic understanding about human performance
- specific information on human performance topics relevant to activities overseen by NMSS
- resources to support decision making (tools, a 'knowledge base')

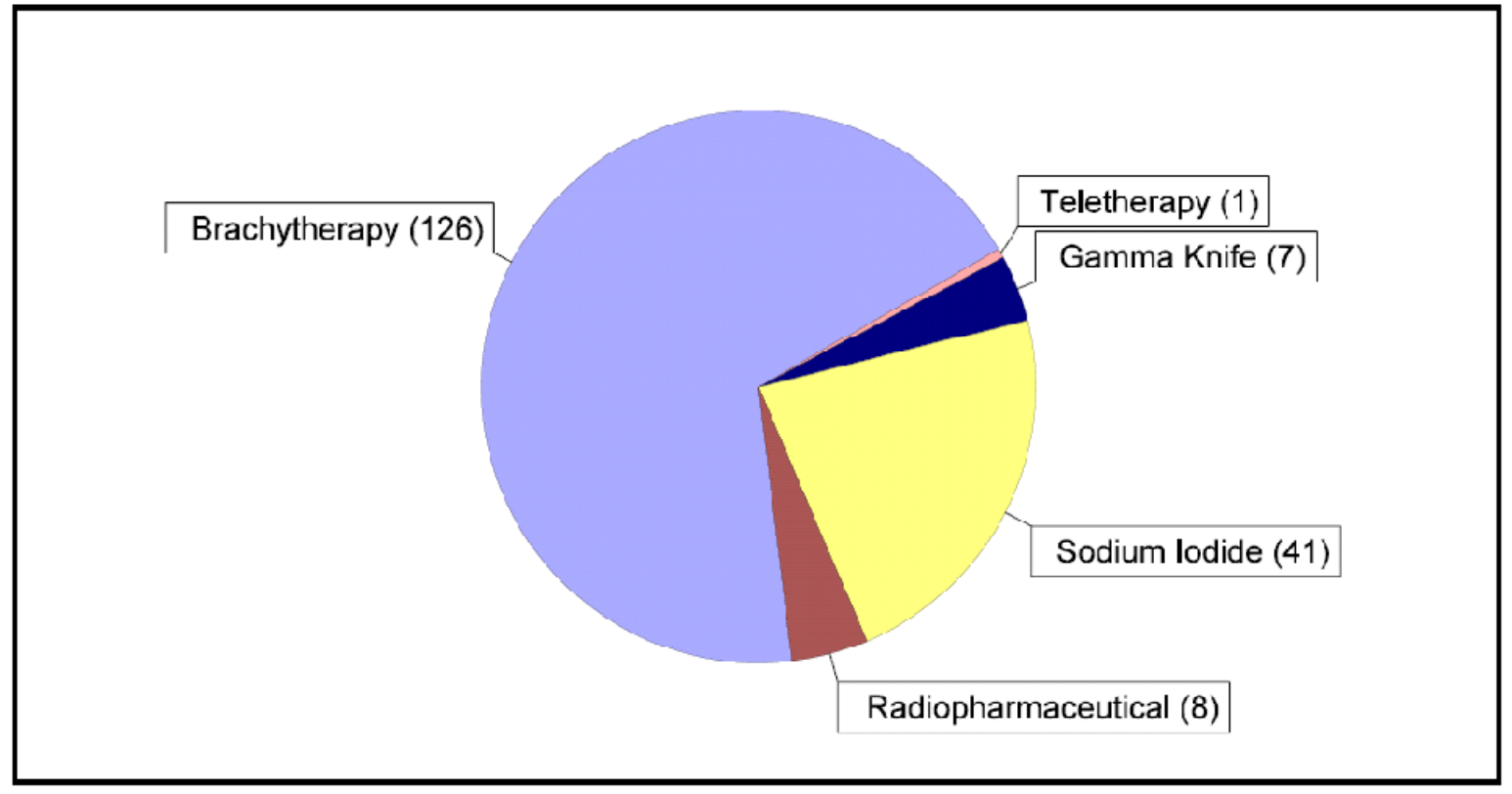
Risks in Medical Processes* are Real

***Note: not specifically radiation therapy**



*Based on IOM (2000) report of up to 90,000 deaths in 32 million hospital stays

NMED Types of Procedures

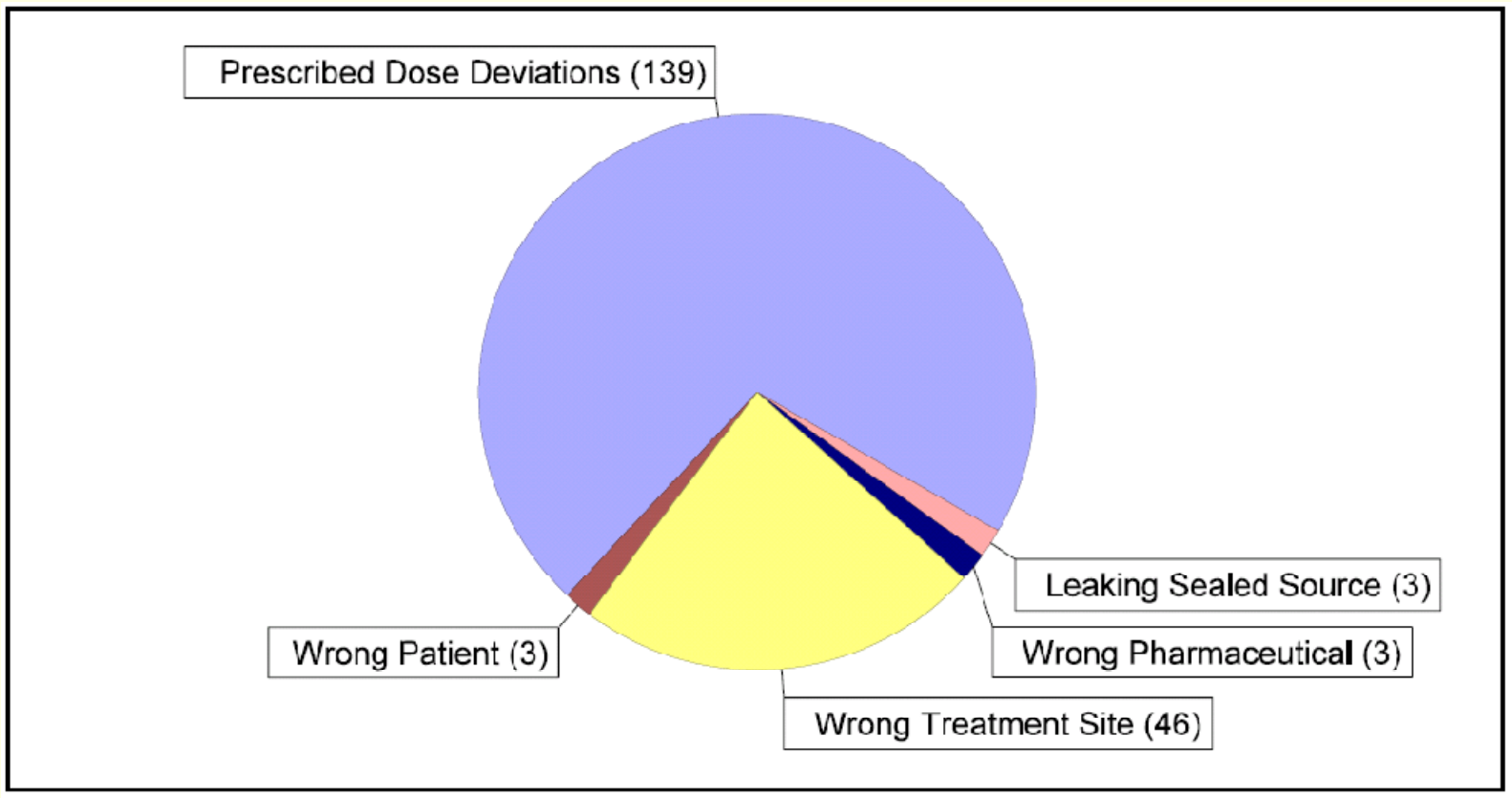


Source: NMED 2nd Quarter Report FY2007 (last 16 quarters)

Medical Events

- NMED Summaries of medical event data
- NMED Example medical events

Types of Medical Events



Source: NMED 2nd Quarter Report FY2007 (last 16 quarters)

Example of Medical Event (1)

- NMED Event 040125
  - Outcome:
    - Patient received extra dose during gamma knife treatment (2,700 cGy vs 1,800 cGy)
  - Why
    - Use of wrong helmet
      - 14mm collimator used vs. 8mm intended
    - Forgot to change helmet at appropriate point of treatment
  - Fix
    - Added step in procedure to ensure triple check of each shot
      - Physician, physicist & nurse
    - Added larger labels on helmets so visible on TV

Example of Medical Event (2)

- NMED Event 010813
  - Outcome
    - Patient received 2,780 cGy dose instead of 2,000 cGy prescribed using gamma knife
  - Why
    - Treatment time incorrectly entered
  - Fix
    - Verification step improved as corrective action

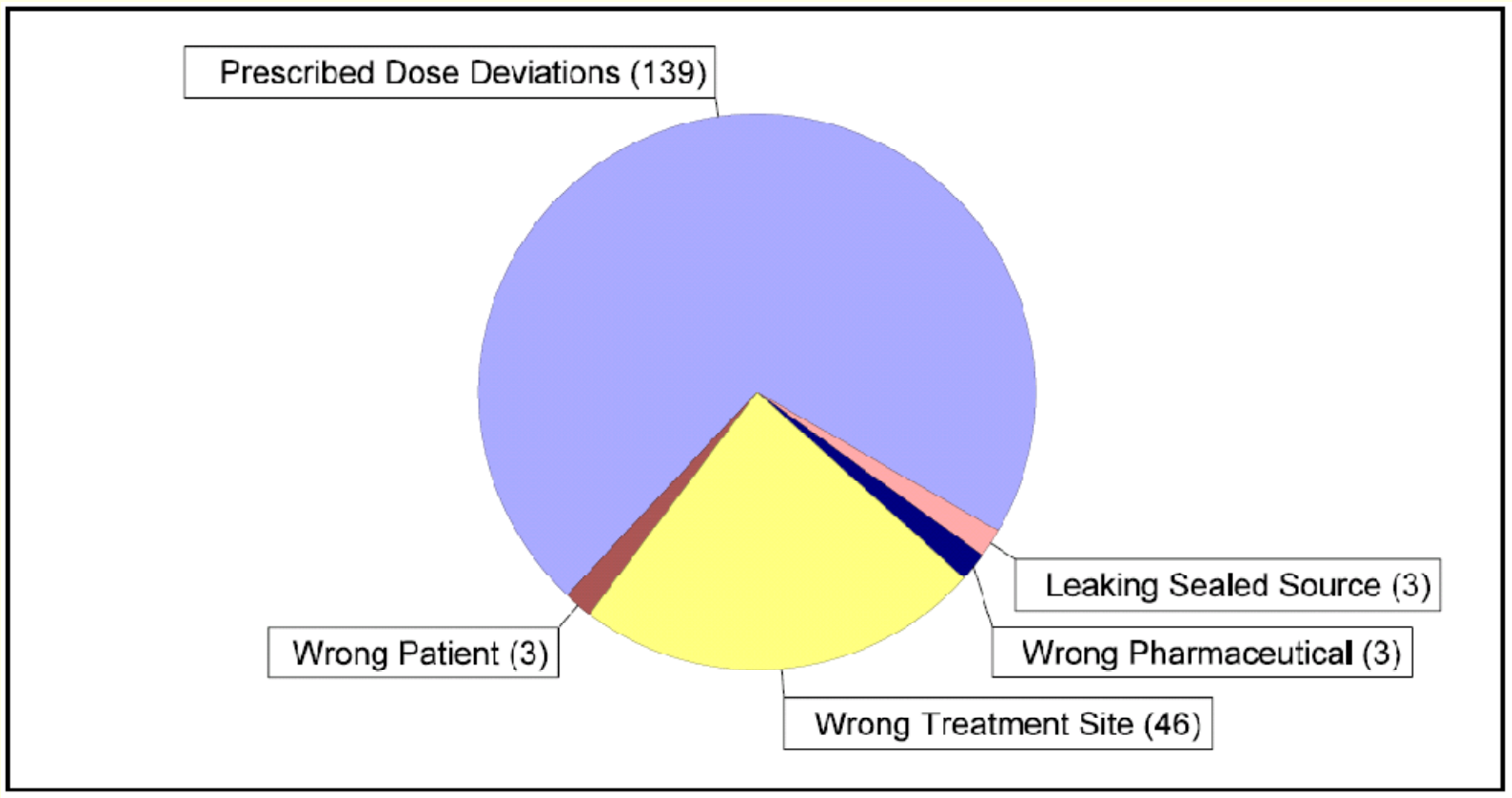
Example of Medical Event (3)

- NMED Event 030134
  - Outcome
    - Patient received 700 cGy to wrong site using HDR brachytherapy
  - Why
    - Incorrect catheter selected for use
      - Incorrect catheter entered in treatment plan
      - 30 cm too short
    - "Inadequate procedure" was contributing cause
  - Fix
    - Remedy was to "fix procedure"

Example of Medical Event (4)

- NMED Event 030015
  - Outcome
    - Patient received 125 cGy instead of 500 cGy to correct site using HDR brachytherapy
  - Why
    - Treatment programming entry error
      - Dose was supposed to be 4 fractions of 500 cGy each, not total of 500 cGy
    - Lack of familiarity with software system & absence of procedure for using system
  - Fix
    - Add step in procedure
    - Med physicist must do manual calc to check treatment plan

Types of Medical Events



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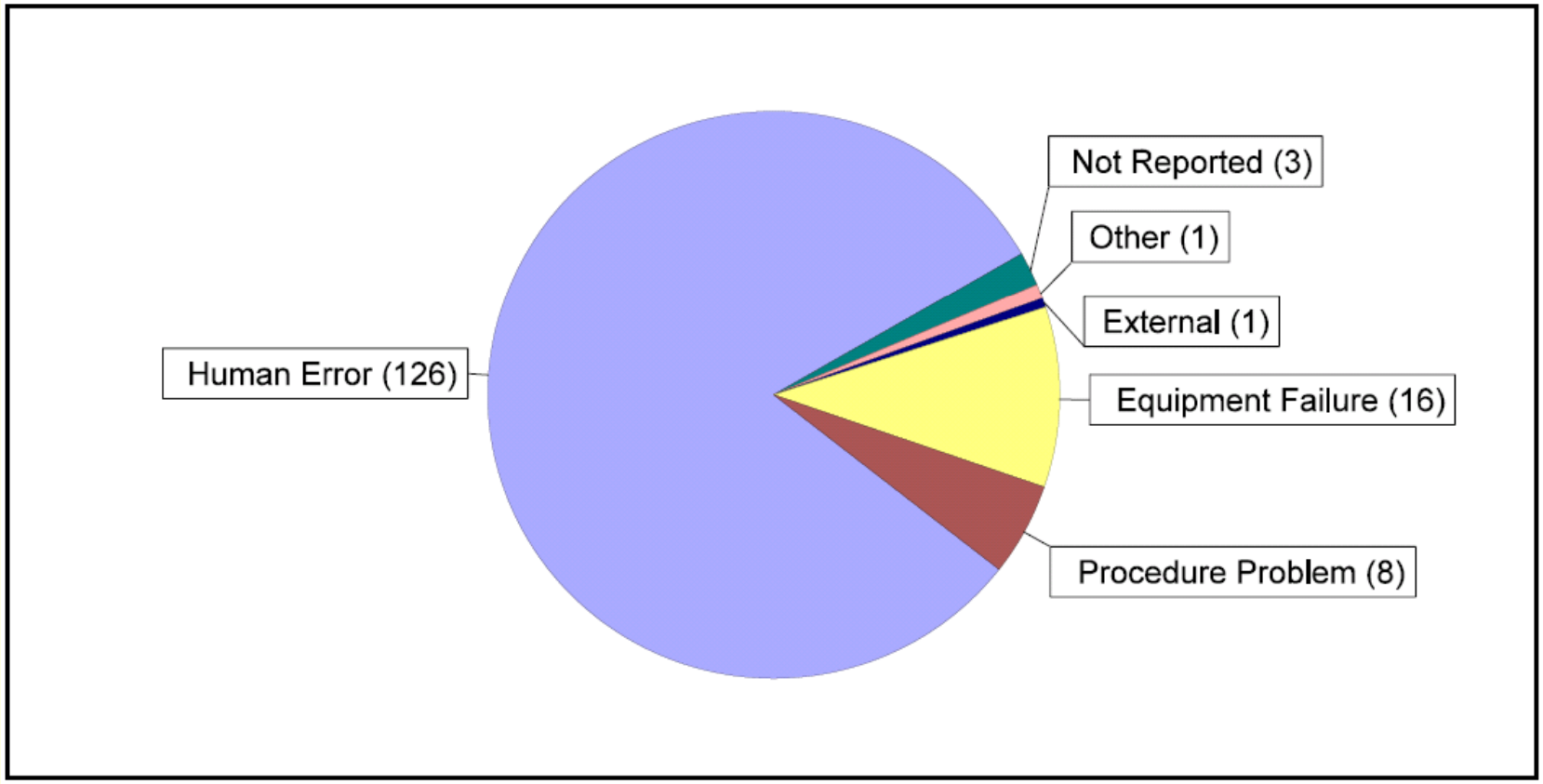
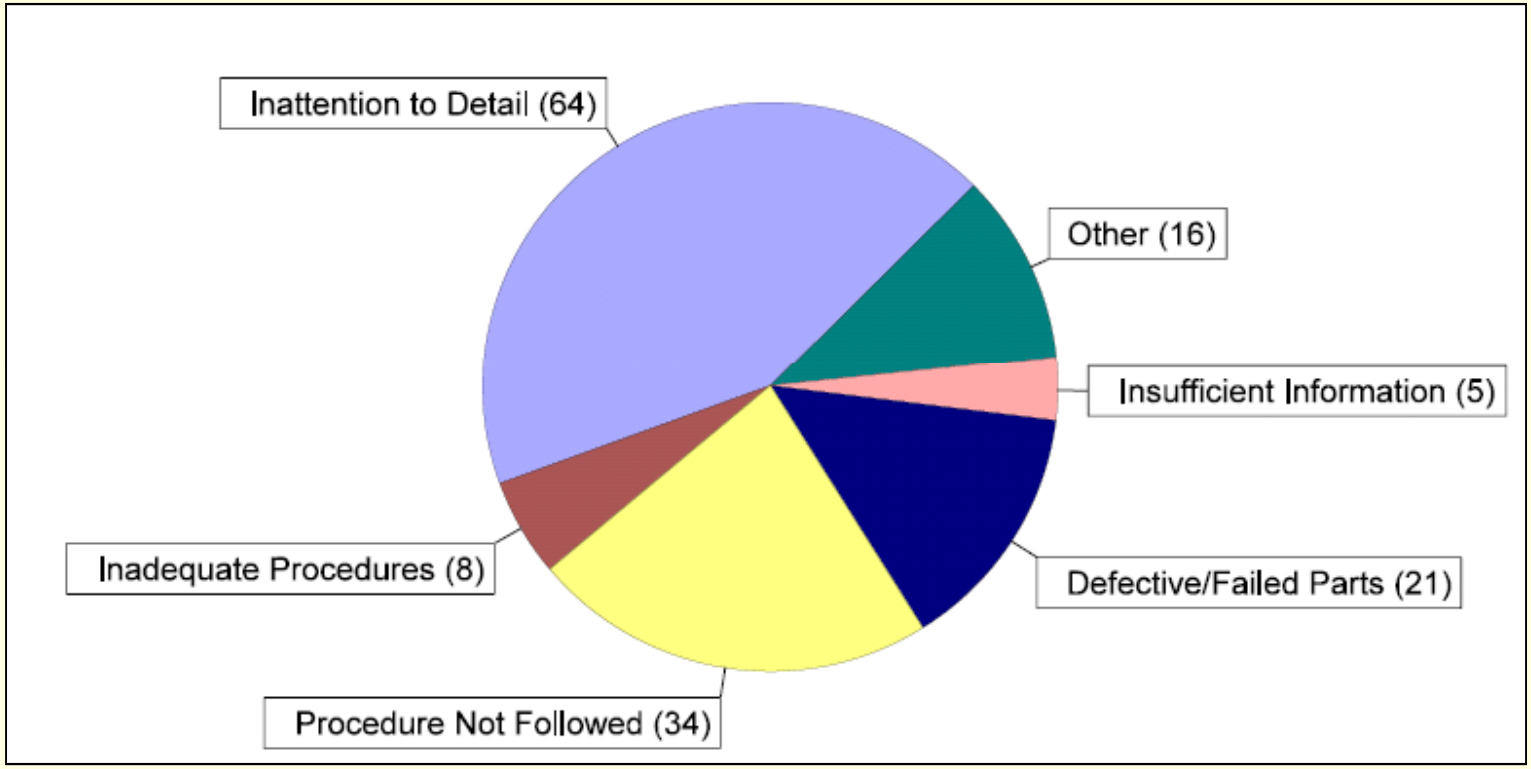
NMED Medical Event Causes



Source: NMED 2nd Quarter Report FY2007 (last 16 quarters)

NMED Medical Event Causes



Source: NMED 3rd Quarter Report FY2006 (last 16 quarters)

What Do We See Over and Over in These Events?

- People are prone to:
  - Data entry errors
  - Miss errors during checking
  - Make assumptions when knowledge is lacking
  - Take short cuts
- To understand error, consider:
  - The nature of human behavior
  - The nature of people's tasks

Why do people make errors?

A New (?) Perspective on Error

Recently a ‘new view’ of error has been advanced:

- ‘Human error’ is not the cause of a mishap.
- Errors do not occur randomly.
- Errors are not isolated breakdowns.
- Errors result from the same processes that allow a system’s normal functioning.

Basic Behavioral Biases

- People's behavior is almost always rational
  - adaptive – i.e. goals are achieved
  - satisficing – best under the circumstances
- People's actions will tend to be
  - practical
    - people do what works
  - economical
    - people act so as to conserve resources

As a Consequence…

- People follow familiar paths
  - Maximizes use of habits (good *and* bad)
  - Minimizes ‘cognitive strain’
- People use ‘rapid pattern-matching’ to detect and interpret faults and errors
  - Very effective at detecting most problems, but
  - Not very effective at detecting our own errors
- “shortcuts, heuristics, and expectation-driven actions.”
- efficiency-thoroughness trade-offs

Three Kinds of Unsafe Acts

- Slips, lapses, trips and fumbles: Where the plan of action is adequate, but the actions do not go as planned
- Mistakes: Where the actions follow the plan, but the plan is inadequate to achieve its desired results
- Circumventions: Deliberate deviations from standard operating procedures

Effects of economizing

- in the allocation of attention

  …slips
- in the application of mental effort

  …mistakes
- in the expenditure of time or physical effort

  …circumventions

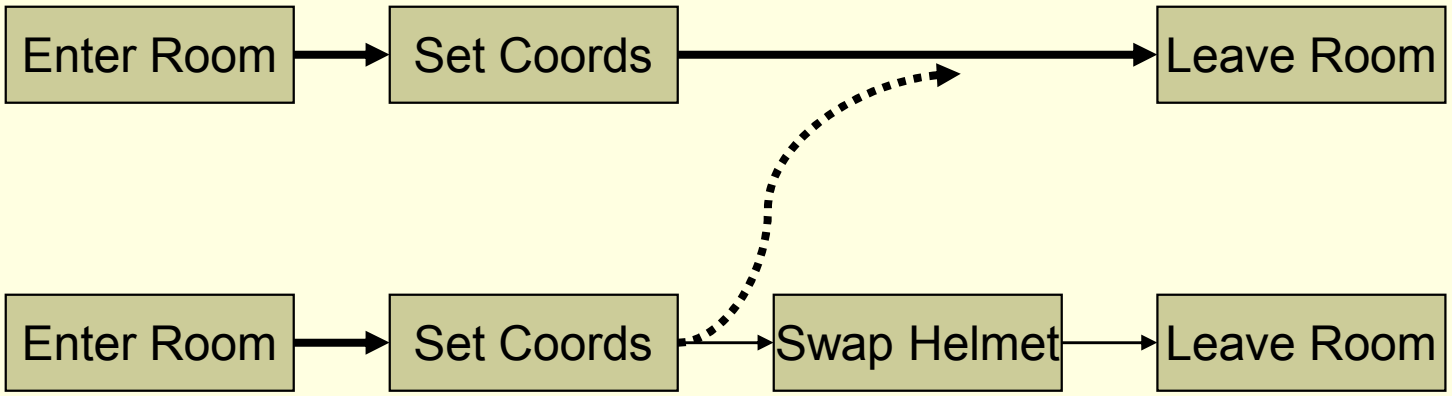
New Perspective on Unsafe Acts: Slips

- Attention will drain away from well-practiced actions, allowing them to be done with less mental effort
- If the small amount of attention devoted to monitoring such actions is diverted, there is opportunity for error

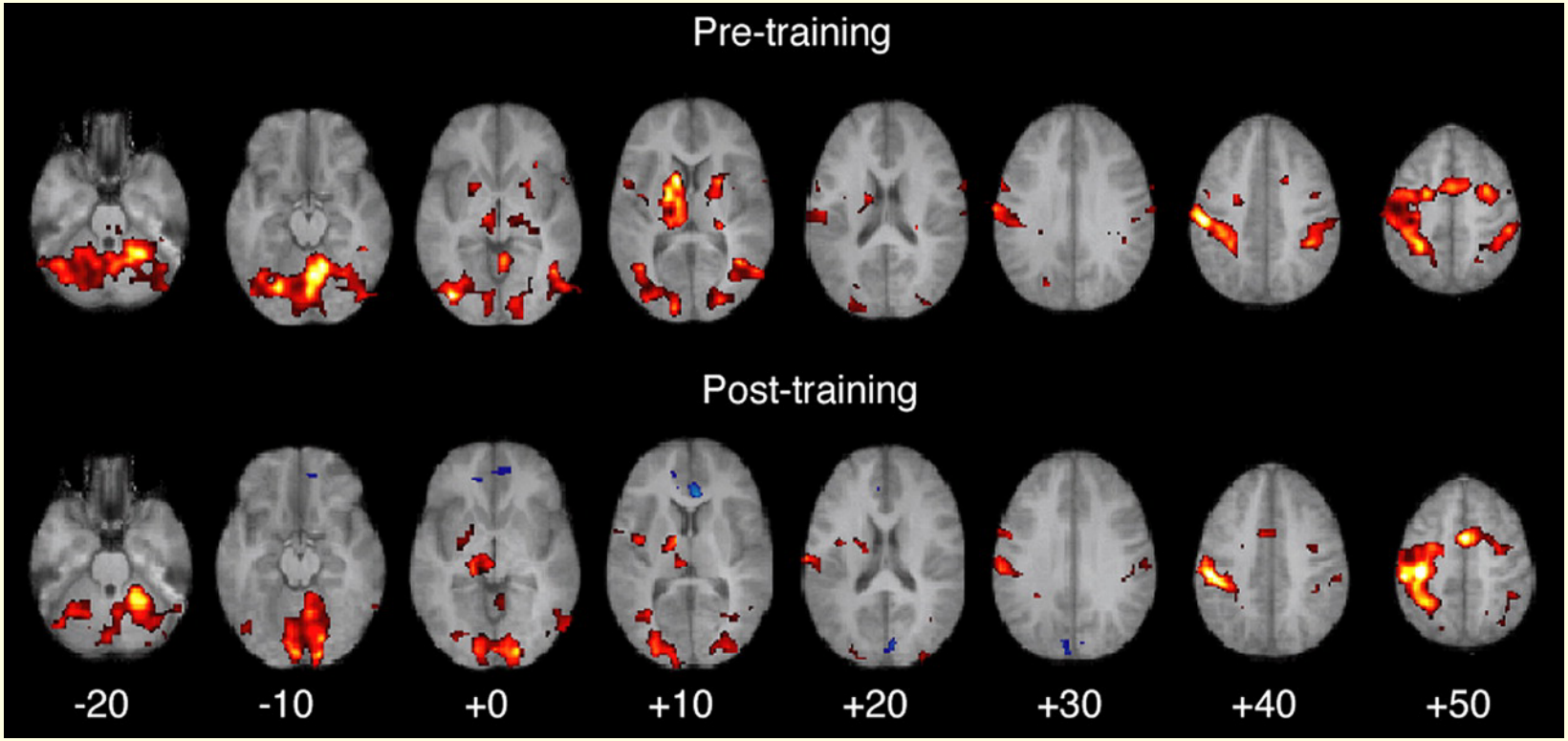
Examples of Slips

- conditions for a ‘capture’ slip
  - well-practiced action
  - intention to deviate
  - intrusion of ‘stronger’ habit
  - failure to recognize

Failure to Change Collimator Helmet



Practiced actions become ‘automatic’…



…whether we want them to or not.

New Perspective on Unsafe Acts: Mistakes

- People's decisions about what course of action to take are subject to biases that typically are effective trade-offs
- Sometimes conditions are such that the incomplete nature of the decision-making process is exposed

Efficiency-Thoroughness Trade-Offs: Patterns of Thought

- Availability heuristic
  - acting based on information that is readily brought to mind
- Confirmation bias
  - seeking information that favors a current explanation rather than disconfirming facts
- Frequency gambling
  - favoring responses or interpretations that have previously been made often

Example: Treatment to wrong site

- treatment planning software rejected orientation defined by the neurosurgeon and physicist
  - orientation was “intuitively correct”
- rejection assumed to be erroneous
  - “FLOATING POINT ERROR” also occurred
- other plausible causes not considered
  - films shot in other than the usual room
  - different orientation
- erroneous plan not detected until nearly complete
  - physicist noticed coords clearly for the wrong side

New Perspective on Unsafe Acts: Circumventions

- "…deliberate – but not necessarily reprehensible – deviations from those practices deemed necessary…to maintain the safe operation of a potentially hazardous system."
- Sometimes tasks can't be done as the procedures specify
- Highly skilled people often develop more efficient, more expedient, even safer, ways of doing things

Efficiency-Thoroughness Trade-Offs: Patterns of Rationalization & Action

- Looks OK.
- Not really important.
- Normally OK; no need to check it now.
- It has been checked by someone else earlier.
- Insufficient time or resources; will do it later.
- It worked the last time around.
- Don’t worry - it is perfectly safe and nothing will happen.

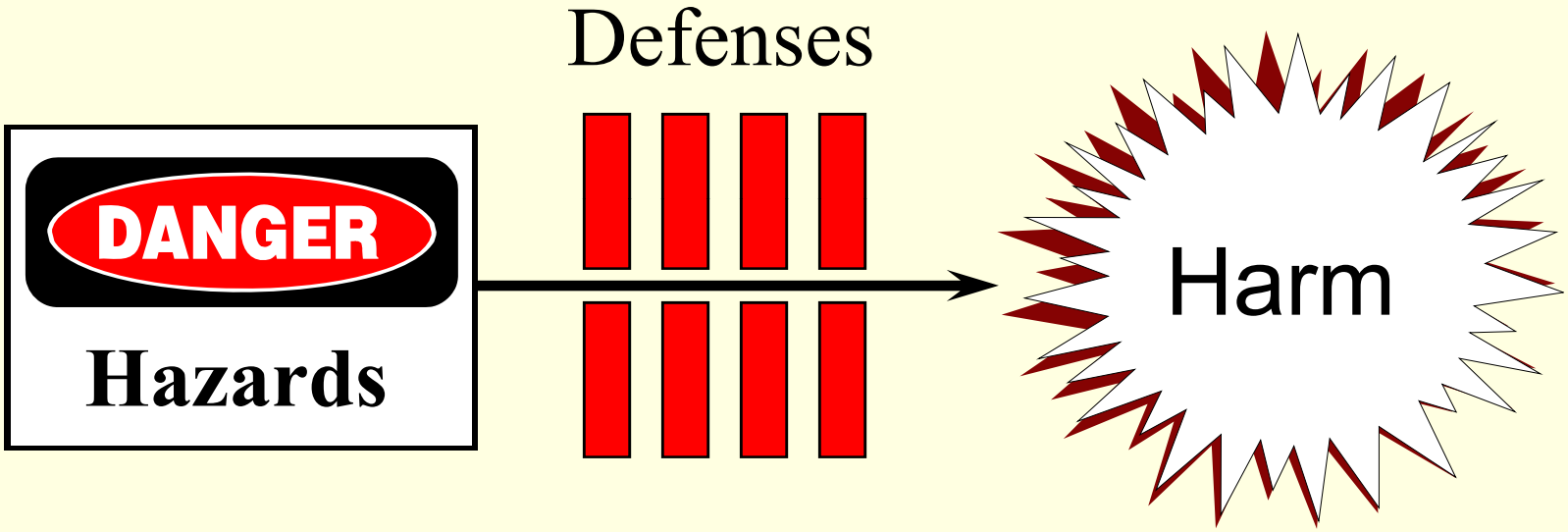
Efficiency-Thoroughness Trade-Offs: Patterns of Organizational Behavior

- Responding to challenges in familiar ways
- Allocating resources to satisfy local demands
- Complacency as time passes since last event

If Trade-offs are Pervasive, Why Aren't There More Events?

- In the great majority of situations, the trade-offs work
- Efficiencies typically free up resources, allowing improved performance
- As a results of trade-offs, errors are common – however *events* are prevented
- There are typically barriers against unwanted outcomes
  - self-monitoring
  - engineered opportunities for recovery

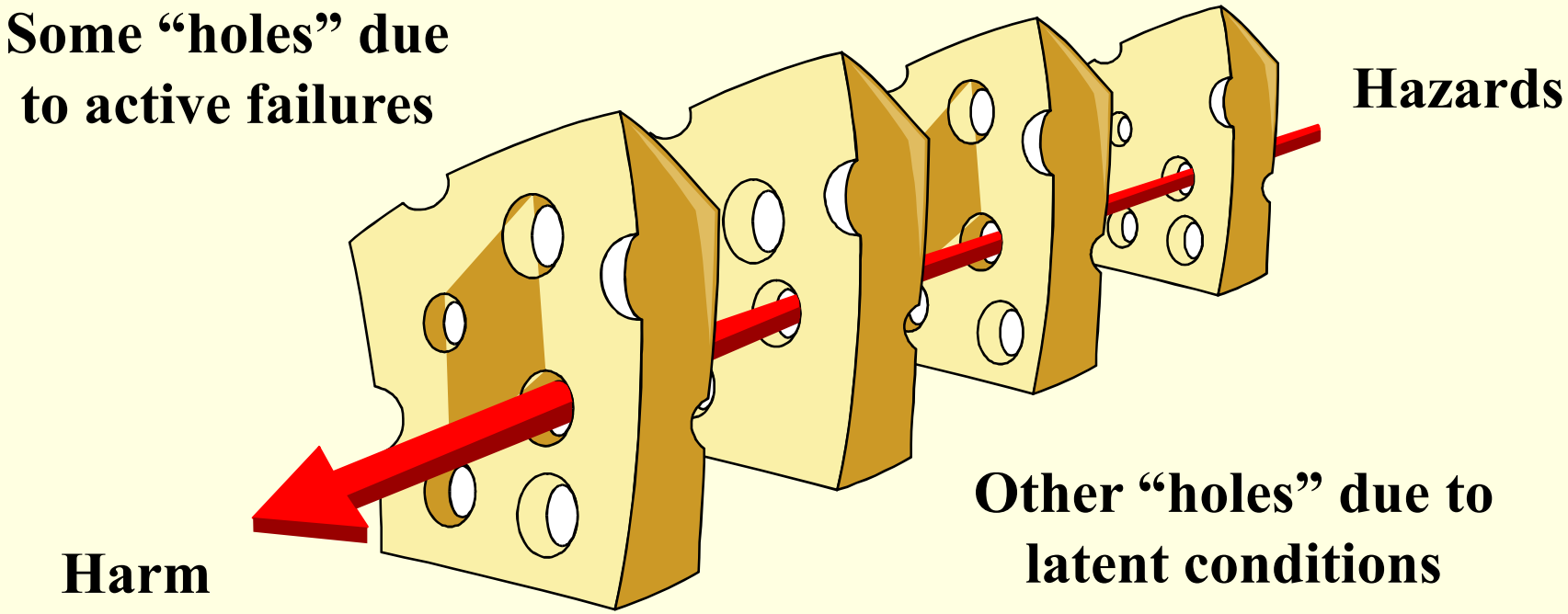
A Framework of Safety Performance



‘Hard’ defenses

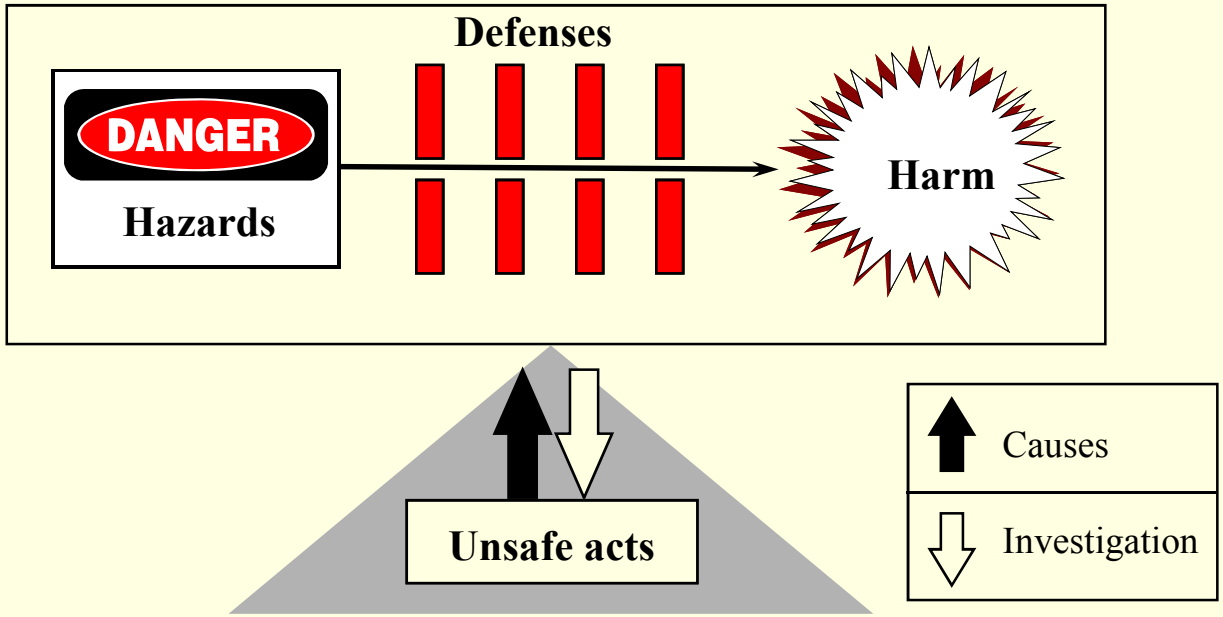
‘Soft’ defenses

The ‘Swiss Cheese’ Model of Event Causation



Successive layers of defenses, barriers, & safeguards

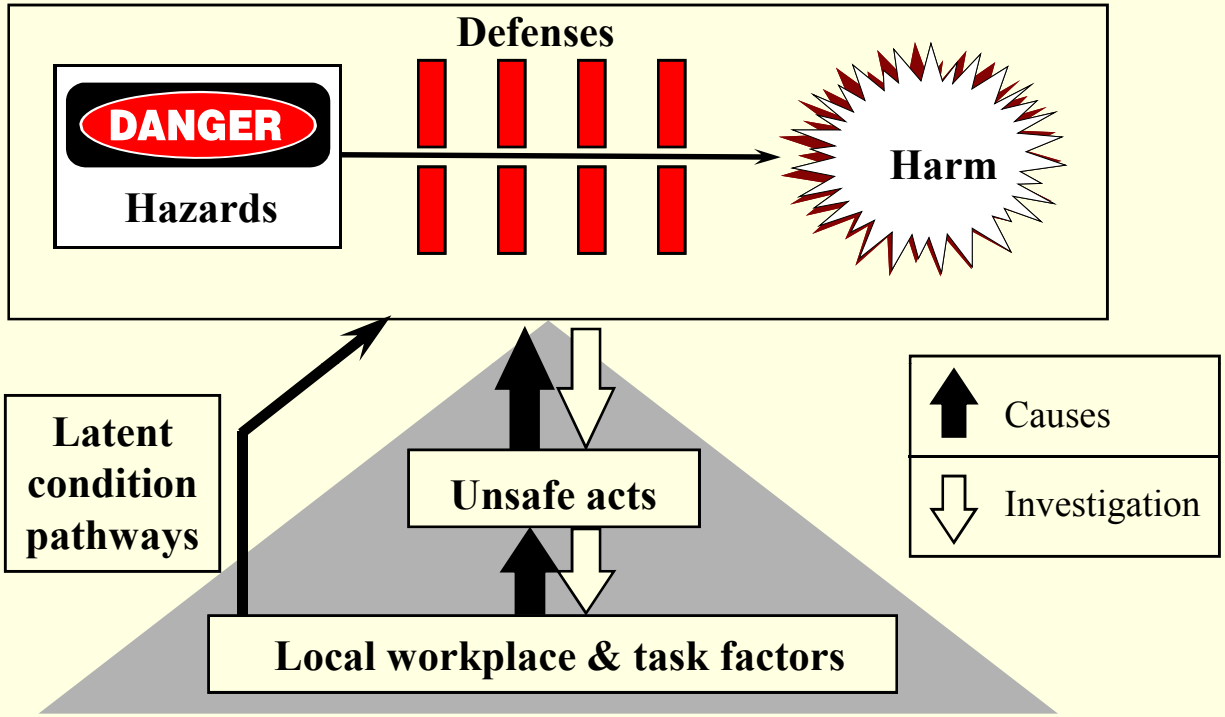
How and Why Defenses Fail: The Human Error View



- In this view, events are caused by individual human errors like "*inattention to detail*" and "*failure to follow procedures*"

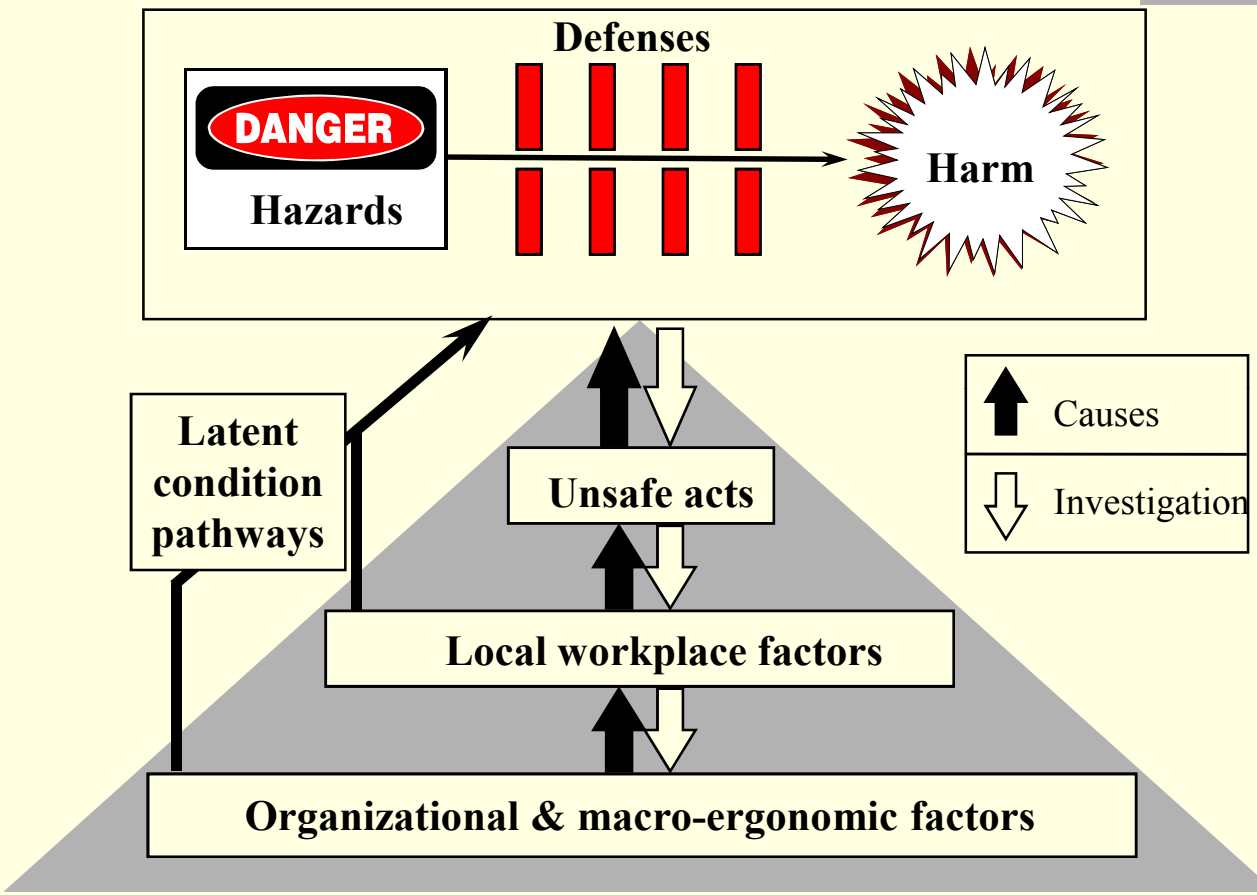
- Examples: NMED 040125 "personnel setting up the treatment neglected to change the helmet" NMED 000787 "…failed to verify that the treatment coordinates set on the patient's head-frame were the same as those established in the written treatment protocol")

How and Why Defenses Fail: Workplace & Task Factors



- In this view, the events are caused by errors associated with weaknesses in the procedures, tools & interfaces used by the people & their training
- Examples: NMED 030015 "the licensee's inadequate written procedures for the use of their HDR treatment planning software" NMED 021143 "…event was caused by human error and inadequate training")

How and Why Defenses Fail
Organizational & Macro-ergonomic Issues



• In this view, the events are caused by the influences of organizational forces and influences from outside the workplace that lead to weaknesses in the procedures, tools & interfaces used by the people & their training

Examples of human performance issues in major medical events

- Indiana, PA, Brachytherapy Event
  - November 16, 1992
- INL Investigation of Misadministration Events, 1991-92
  - NUREG/CR-6088 Analysis

HDR Brachytherapy Event, Indiana, PA (NUREG-1480)

- Iridium-192 source used for HDR brachytherapy
- Source detached from cable in patient but not realized
  - Design of equipment
  - Radiation alarms when patient removed from treatment room disregarded as ‘frequent occurrence’
- Source exited after 4 days into bed linen but not detected
- Finally detected as truck carrying waste set off radiation alarms at waste site
- [Discussion of adequacy of corrective actions]

Cause Findings in 1991-1992 Events (NUREG/CR-6088)

- Organizational policy & procedures inadequate
- Lack of RSO and authorized user oversight
- Changes in routine & unique conditions
- Hardware failures (rare but serious)
- Ineffective corrective actions and QM programs
- Poor detection & mitigation of events after occurrence

Ways to Classify Causes of Events

- There are many different ways to classify events and their causes
  - Choosing the right one is important!
    - *"What you look for is what you find"* (WYLFIWYF)
- There ***IS*** no absolutely correct "root cause"
  - The choice should be driven by the use you can make of the analysis
    - "*What you fix is what you find*" (WYFIWYF)

Process for Human Error Investigations

- Break down event history into episodes
  - Significantly prior to the erroneous actions
  - Just prior to the actions
  - At the time of the actions
  - Immediately after the actions

Analysis Process

- For each episode, *identify*:
  - What was the world of work like?
    - What work was being done?
    - What was the context that shaped work performance?
  - What behaviors happened?
    - Who was doing what?
  - What was the knowledge/information & how did it affect the behaviors?
    - What could have misled the work performance?
  - What were the goals & how did they affect the behaviors?
    - What shaped the overall structure of the work?
  - Were there any goal conflicts that affected behaviors?

ER Video

Example: ER Analysis

- Episodes:
  - Significantly prior to the erroneous actions
    - Start of shift forward
  - Just prior to the actions
    - Arrival & treatment of patient
  - At the time of the actions
    - Administration of blood transfusion
  - Immediately after the actions
    - Discovery of wrong blood type transfused

Episode 1: Start of shift

- What was the world of work like?
  - What work was being done?
    - ER nursing staff briefing & unit activities
  - What was the context that shaped work performance?
    - Regular staffing on ‘sick-out’
    - Temporary replacements not worked in ER for many years
    - Nurse manager recently appointed
      - Only nurse with recent unit experience on duty

Episode 1: Start of shift

- What behaviors happened?
  - Who was doing what?
    - Nurse manager was supervising temp staff & also performing as floor nurse
- What was the knowledge/information & how did it affect the behaviors?
    - Few (if any) temp nurses knew routines & protocols for ER
  - What could have misled the work performance?
    - Lack of routine knowledge
    - Distraction & workload on nurse manager in supervising temp staff

Episode 1: Start of shift

- What were the goals & how did they affect the behaviors?
  - Goals were to:
    - Ensure patient treated in timely & safe manner
    - Supervise staff to ensure efficient coverage
  - What shaped the overall structure of the work?
    - Shortage of knowledgeable & experienced staff
- Were there any goal conflicts that affected behaviors?
    - Conflict between need to treat patients & supervise temp staff
      - Limited resources

Episode 2: Arrival & treatment of patient

- What was the world of work like?
  - What work was being done?
    - Preparing patient for surgery
    - Handling patient's friend
    - Supervising temporary staff
  - What was the context that shaped work performance?
    - High tempo (patient critical)
    - Distractions in ER (friend distraught, slow response by other units)
    - Multiple demands on nurse manager (temp staff ignorant)
- What behaviors happened?
  - Who was doing what?
    - Nurse manager directing temp staff
    - Some actions by temp staff unsupervised by nurse manager
      - Temp staff taking 'well intentioned actions'
      - (Created appearance of right action but not checked)

Episode 2: Arrival & treatment of patient

- What behaviors happened?
  - Who was doing what?
    - Nurse manager was supervising temp staff & also performing as floor nurse
- What was the knowledge/information & how did it affect the behaviors?
    - Few (if any) temp nurses knew routines & protocols for ER
      - Missed need to clear infuser of previous case blood
  - What could have misled the work performance?
    - Lack of routine knowledge
    - Distraction & workload on nurse manager

Episode 2: Arrival & treatment of patient

- What were the goals & how did they affect the behaviors?
  - Goals were to:
    - Provide responses to doctors' demands
    - Oversee temp staff actions
  - What shaped the overall structure of the work?
    - Need to stabilize critical patient
    - Need to compensate for shortage of knowledgeable & experienced staff
- Were there any goal conflicts that affected behaviors?
  - Conflict between need to treat patients & supervise temp staff
    - Limited attentional & cognitive resources

Implications of the New View for Attributing Cause

- Perhaps the most commonly cited causes:
  - inattention to detail
  - failure to follow procedures
- There are reasons for this
  - the nature of human behavior
  - the nature of tasks
- Do these causes tell us how to proceed?

Inattention to Detail

- Is it associated with
  - a lack of motivation?
  - a character flaw?
- or, rather, is it
  - an adaptive response
  - a hallmark of skilled behavior

Failure to Follow Procedure

- "…accidents are due to usual actions under unusual circumstances rather than unusual actions under usual circumstances."
- Was a procedure typically used to carry out the task?
  - "rule-book" job actions
- Are procedures for operators or auditors?
  - designed to be *used*?
- What about 'highly proceduralized' activity?
  - are there provisions for keeping procedures and practice in sync?

Example Cause Determination

Failure to reestablish proper trip setpoint after maintenance results in automatic reactor shutdown

Event Description

1. Occurrence Report Number: NE-CH-BH-BNL-BMRR-2000-0001
Failure to reestablish proper trip setpoint after maintenance results in automatic reactor shutdown

16. Description of Occurrence:
On April 18, 2000 at approximately 1125, the BMRR experienced an automatic shutdown when primary water outlet temperature reached 104 degrees F. Normal operating temperature is 114 degrees F. The shutdown was due to a primary water outlet temperature trip setpoint set erroneously low (conservative direction) at 104 degrees F. The automatic shutdown system functioned properly and shutdown procedures were properly followed.

Description of Cause

23. Description of Cause:

The reactor had just been restarted following tri-monthly testing and the performance of a startup checklist. As part of the startup checklist, operators tested the function of the primary water outlet temperature trip system. The trip setpoint is normally set at 134 degrees F. Due to the cold temperature of the secondary water, the operators lowered the trip setpoint to 104 degrees F in order to perform the test. Lowering the setpoint is allowed by BMRR operating procedures.

Description of Cause (cont.)

23. Description of Cause (continued):

When the operator was reestablishing the normal trip setpoint of 134 degrees F following the test, he depressed a push-button marked "RESET" instead of a push-button marked "SETPTS". This resulted in the 104 setpoint being retained in the temperature module's memory instead of the desired 134. Following reactor restart, an automatic shutdown occurred when primary water outlet temperature reached 104 degrees F. Normal operating temperature is approximately 114 degrees F. Note: There are five push-buttons on the module, they are marked: "SETPTS" "MAX" "MIN" "MENU" and "RESET".

Cause Categories

23. Description of Cause (continued):

The temperature trip test is performed per a written BMRR procedure, which the operator had and was following. As part of the investigation following the occurrence, the procedure was reviewed and was determined to be adequate. The cause of the occurrence was determined to be the operator's failure to properly follow the procedure when reestablishing the temperature trip setpoint. The procedure correctly states that the operator is to depress the "SETPTS" push-button after entering the desired trip setpoint of 134 degrees F. The cause category per DOE Order 232.1A that is considered the best choice for this occurrence for Direct Cause is: "Personnel Error, Procedure Not Used or Used Incorrectly". The cause category for Root Cause considered the best choice for this occurrence is "Personnel Error, Inattention to Detail". The operator's training was current.

Corrective Action

24. Evaluation (by Facility Manager/Designee):

Discussion with the operator following the event showed that he realized his mistake. The operator was counseled by the Facility Manager on the importance of following procedures and attention to detail.

26. Corrective Actions:

1. The operator was counseled by the Facility Manager on the importance of following procedures and attention to detail.

30. Lessons Learned:

Attention to detail must be maintained when reestablishing trip setpoints after maintenance.

Further Questions re: Cause

- Were the buttons
  - similar in appearance?
  - adjacent to each other?
  - similar to those on other equipment user by the operator?
- What exactly was the operator doing?
- Was the correct action
  - performed often?
  - similar to one that is performed often?
- What might the operator have been thinking?

Newport INFT Temperature Meter

Instructions for Setting Limits

3. When you change the value of any setpoint and then decide to revert to the original value instead, just press the 'RESET' button or allow the display to return to 'RUN' at the end of its cycle. The meter does not store a new value for the setpoint in either case.
4. To save a newly-entered setpoint value, press the 'SETPTS' button again.

Instructions for Inspecting Temperatures

Selection of either the PEAK or VALLEY causes the display to flash giving the indication that that it is NOT the current measurement value. If the meter measures a more extreme value while displaying the PEAK or VALLEY measurement, the new value will immediately replace the old.

Unlike the setpoint display, there is no time out period. Press the 'SETPTS' button or 'MENU' button to return to current-value display WITHOUT resetting the PEAK or VALLEY memory.

Press the 'RESET' button to return to run mode and start a new PEAK/VALLEY measurement period.

From the user's point of view…

"When done, to return to normal (RUN) mode and…

MODE	…replace the value."	…leave the value as is."
Setpoints	**SETPTS**	**RESET**
Peak/Valley	**RESET**	**SETPTS**

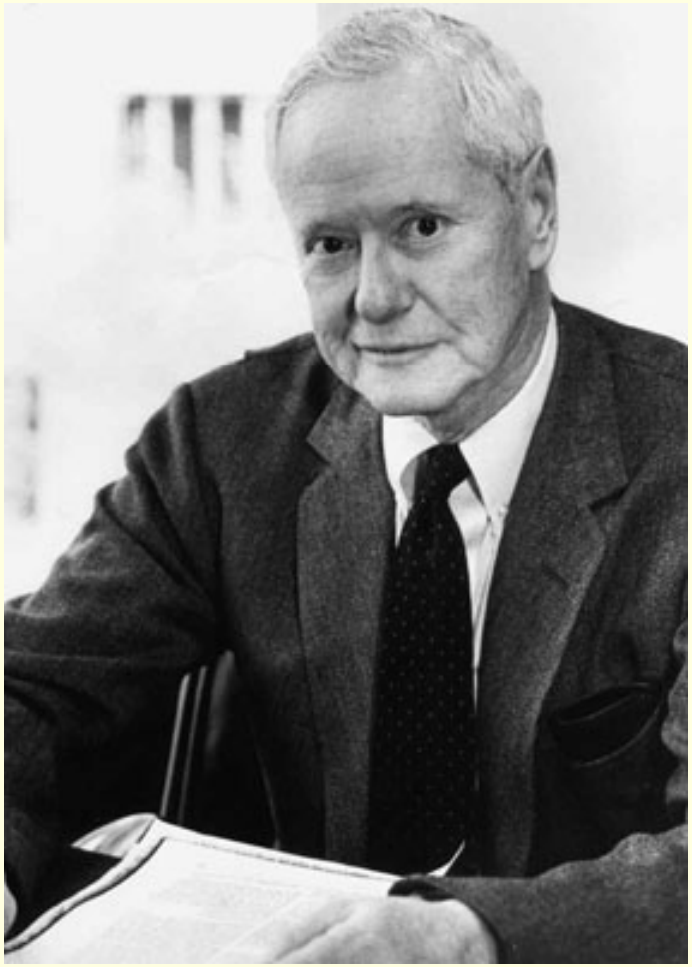
Final Question

"What was the operator thinking?"

Corrective Actions

?

Why don’t things go the way we expect?



Reasons for automation

- eliminate human error
  - replace human where error has high consequences
- lower personnel workload
  - assist when demands are high
- reduce staffing
  - if demands can be lowered sufficiently
- reduce training requirements
  - machine expertise
- because it's possible?

Example: Gamma Knife Models U, B

- operator input of treatment time
  - transcription, entry errors
- manual setting of stereotactic coordinates
  - reading, setting errors
- operator verification of helmet size, gamma angle, and coords
  - failure to change helmet, check settings
- operators enter room after each shot to prepare the next shot
  - demanding, repetitious

Example: Gamma Knife Model C

- imports all treatment parameters directly from the treatment planning computer
- positioning under computer control
- detects helmet size and gamma angle; two independent measurements of coords
- multiple shots (within a user-defined distance and same collimator and gamma angle)

“Calling Dr. Merton…”

“Thus, the possibility of nearly all human errors is eliminated with the Leksell Gamma Knife Model C in APS Mode.” (Goetsch, 2002)

Considerations re: Automated Positioning

- direct import from the treatment planning
  - errors from treatment planning phase?
- computer controlled positioning
  - certainty that proper positioning is achieved?
- detection of helmet size
  - still able (or likely) to be verified by user?
- multiple shots without interruption
  - fewer opportunities to recognize problems?
- availability of functions changes practices

Example: Beatson Oncology Centre, 2006

- Beatson Oncology Centre (BOC) is the major oncology treatment centre in Scotland
- Teletherapy event, but could happen with any modality controlled by computer
  - Varian Varis software (commonly used in rad therapy)
- 15 year old patient dosed in 19 fractions (20 prescribed) each with 58% overdose in January 2006
  - Died October 2006
- Step omitted from planning calculational process
  - Normalization step missed
  - Step omitted from procedure
  - Not detected by checker
  - Planner not qualified to perform this planning process

However…

- Software newly upgraded for planning and treatment tools, to allow automatic transfer of data from planning to treatment program
  - Reduction in human errors expected because potential failure mode eliminated
    - Removed manual transcription of data from planning form to treatment software
    - Also expected to reduce costs by eliminating manual actions
      - Reduced treatment prep time estimated to save $35k for avg facility
  - However because of complexity with this type of tumor, manual calculation of plan was required
    - Only ~6 out of ~5,000 new plans per year
  - Treatment planner omitted new unit conversion step
    - Not identified in procedures
    - Not detected in reviews by senior planners

Systems Approach to Safety

- Goal: To find *effective* and *sustainable changes* to the way systems operate
- Must create an *environment of safety*
- Vigilance essential to identify *emerging* safety risks
- Involves identification of causes of failures at a level *that can be fixed*
- *Eliminating* a hazard beats reducing a hazard's frequency
- *Fixing hardware* is always better than trying to fix human behavior
  - hardware is easier to fix than "wetware"

Recommendations Based on Current Thinking about Human Error

- Errors are hardly ever about individual practitioners, because their errors are a symptom of systemic problems that everyone may be vulnerable to
- Human errors usually cannot be “fixed” by simply insisting the people behave in ways that are in fact contrary to basic behavioral biases

Recommendations Based on Current Thinking about Human Error (cont.)

- Do not get trapped in promises of new technology. Although it may remove a particular error potential, new technology will likely present new complexities and error traps
- Try to address the kind of systematic trouble that has its source in organizational decisions, operational conditions, or technological features

Overall Conclusions

- Risks in medical applications are real and substantial
- Human performance is a key issue in most if not all events
- Understanding human performance contributions involves much more than simply looking at the person involved
- A systematic process for investigations & assessments is provided