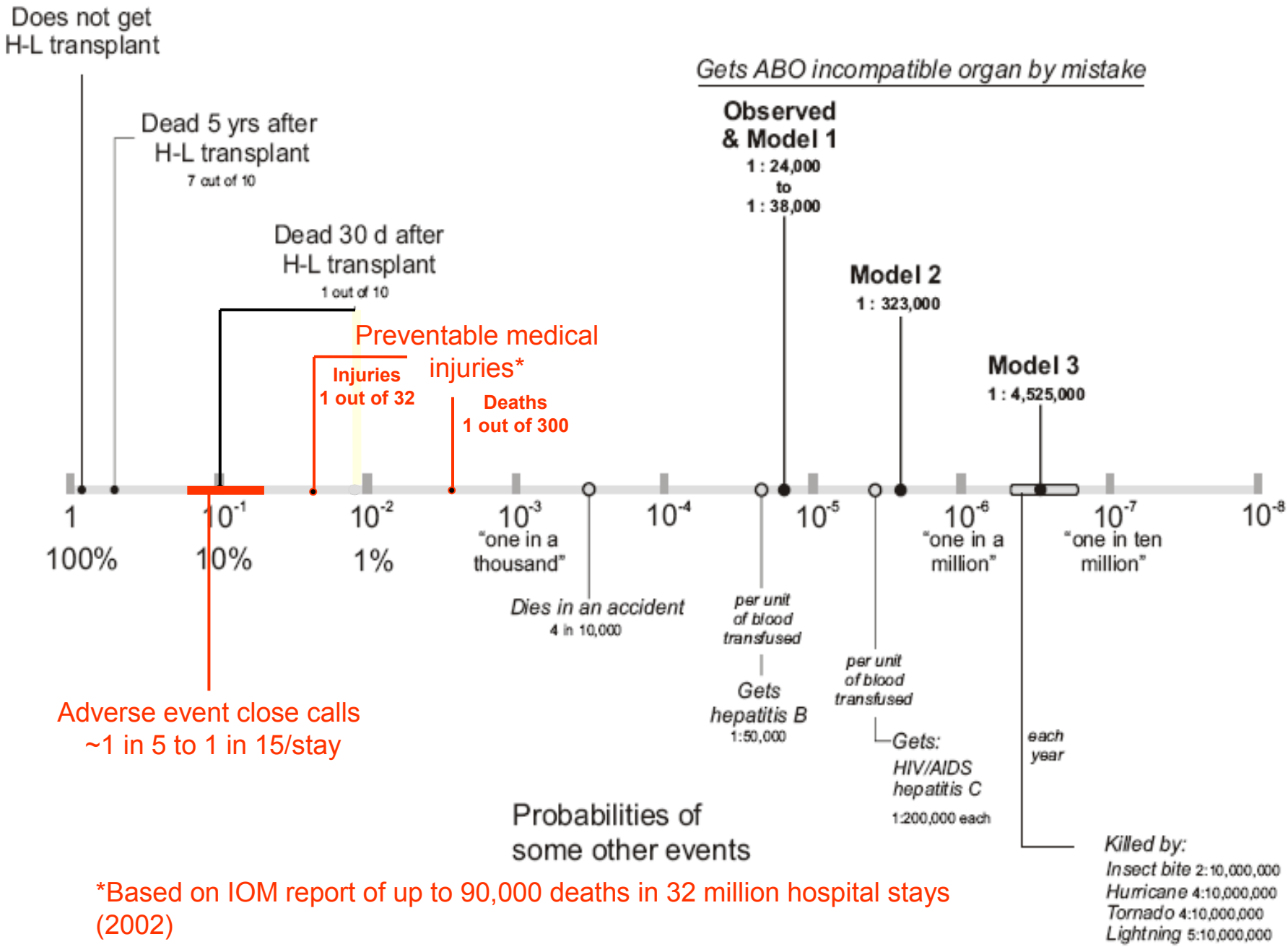
Human Performance in Medical Uses of Byproduct Materials

Training Materials for USNRC

Training Objectives

- To provide an understanding of the causes of human errors in medical events
- To provide a basis for evaluating medical events related to human error
- To provide a basis for making judgments about proposed changes or exemptions to license conditions, or for changes after medical events

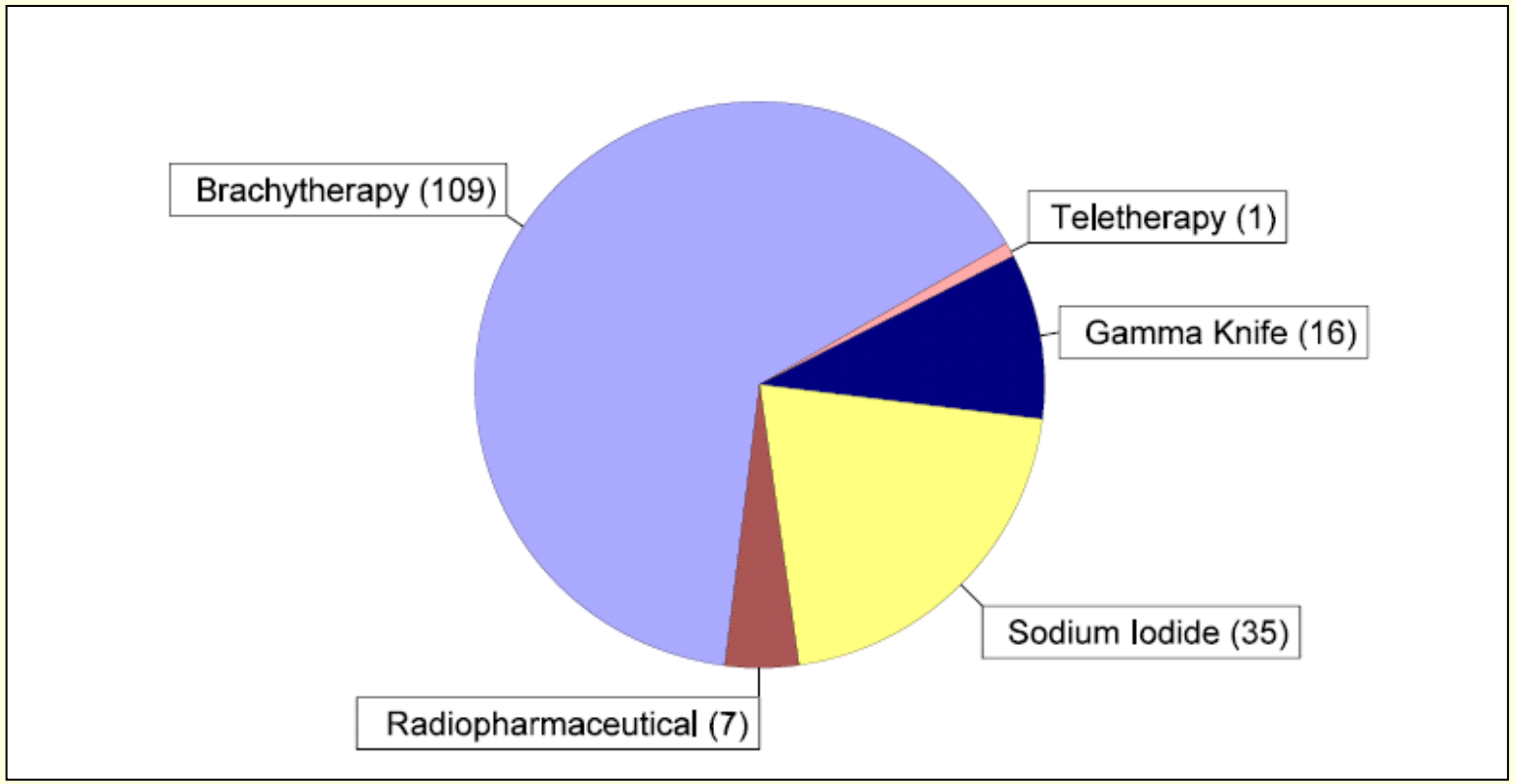


*Based on IOM report of up to 90,000 deaths in 32 million hospital stays (2002)

Medical Events

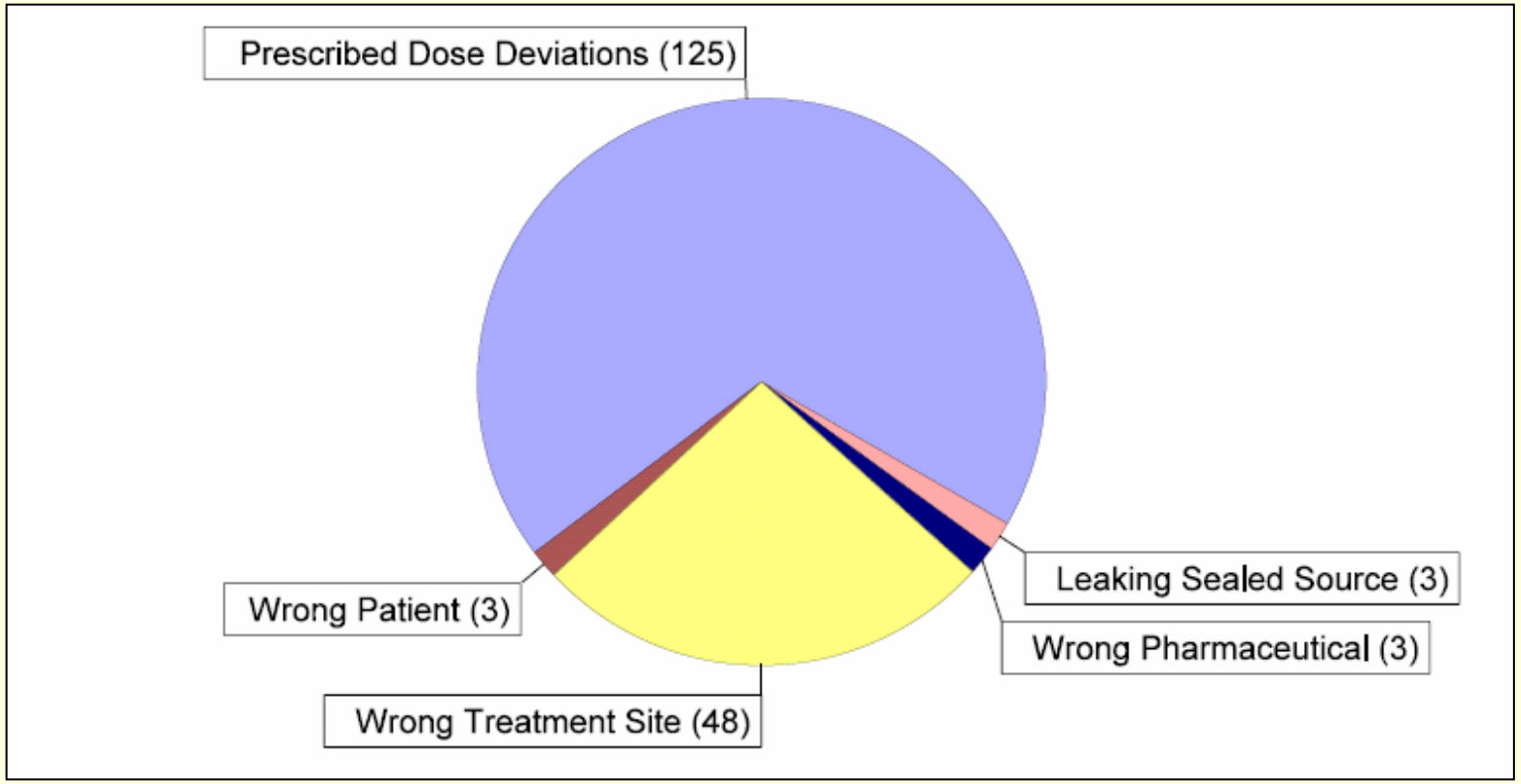
- NMED Summaries of medical event data
- NMED Example medical events

NMED Types of Procedures



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

NMED Medical Event Types



Source: NMED 3rd Quarter Report FY2006 (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

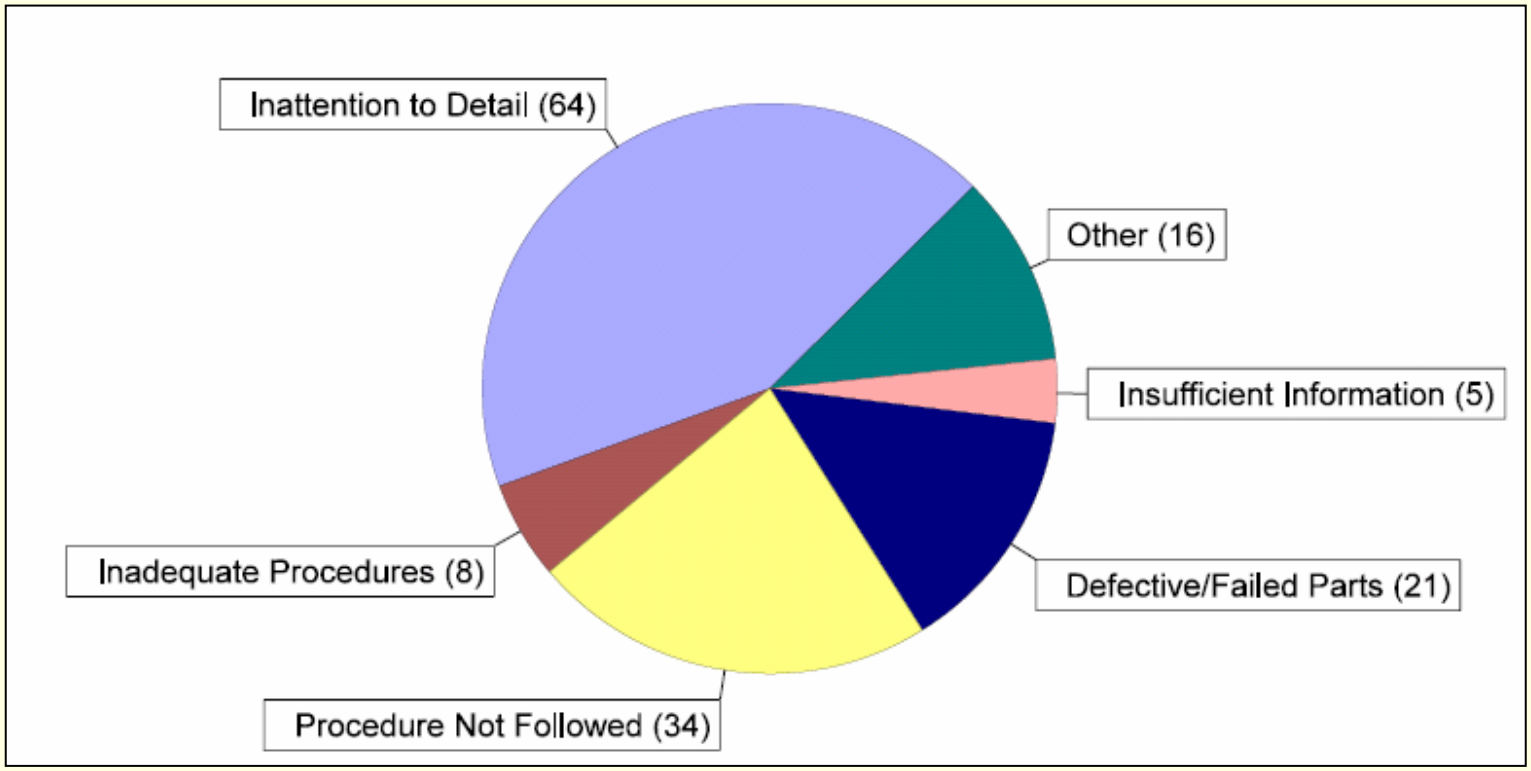
Example of Medical Event (3)

- 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

NMED Medical Event Causes



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

Summary of 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 tasks
  - the nature of human behavior

The Nature of Tasks

- Real-world tasks are subject to variations in
  - inputs
  - behavior of others
  - demands and resources
  - working conditions

The Nature of Human Behavior

- People are designed to be able to adapt to changing conditions, demands
- Response is ‘local’ optimization
  - not necessarily what is best
  - rather, what is likely to work
- People’s behavior is rational
  - economy of physical and mental effort
- “…shortcuts, heuristics, and expectation-driven actions.”

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 effective (e.g., “lousy”) at detecting our own errors

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 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

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

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
- Violations: Deliberate deviations from standard operating procedures

Current 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

Current 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

Current Perspective on Unsafe Acts: Violations

- "…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

Implications for Attributing Cause

- Perhaps the most commonly cited causes:
  - inattention to detail
  - failure to follow procedures
- There are reasons for this
  - the nature of tasks
  - the nature of human behavior
- What are these causal attributions telling us?

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

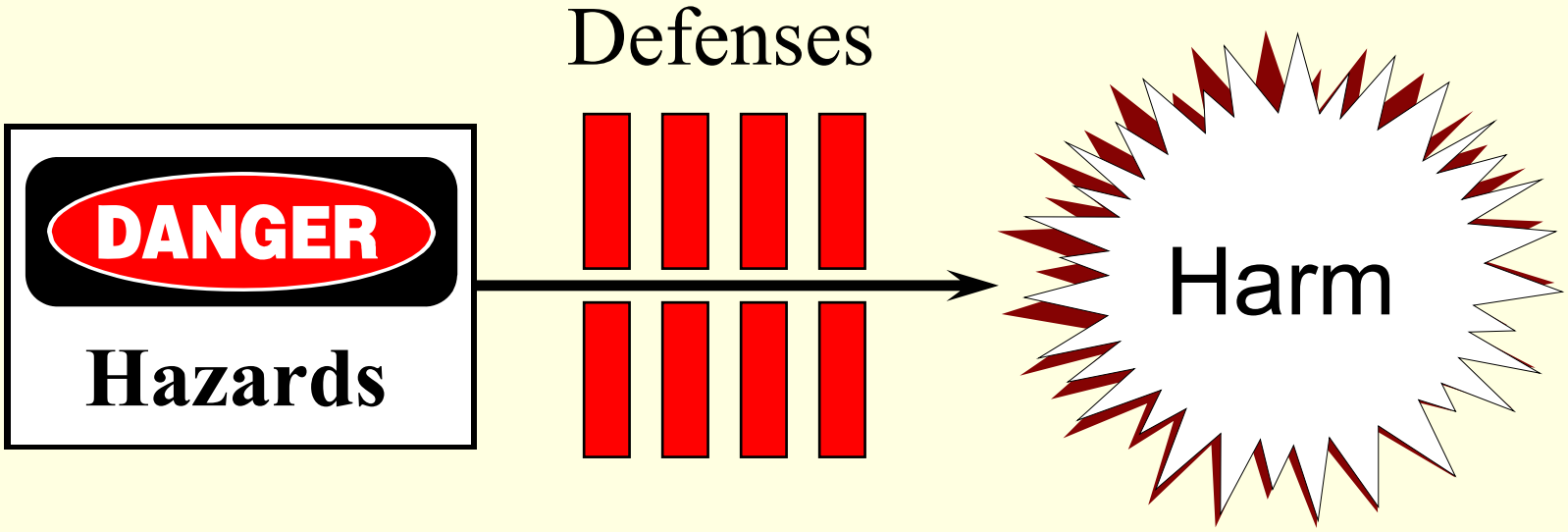
Failure to Follow Procedure

- "…accidents are due to usual actions under unusual circumstances rather than unusual actions under usual circumstances."
- Did people usually follow the procedure?
- Are procedures for operators or auditors?
- What about 'highly proceduralized' activity
  - e.g., aircraft maintenance

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

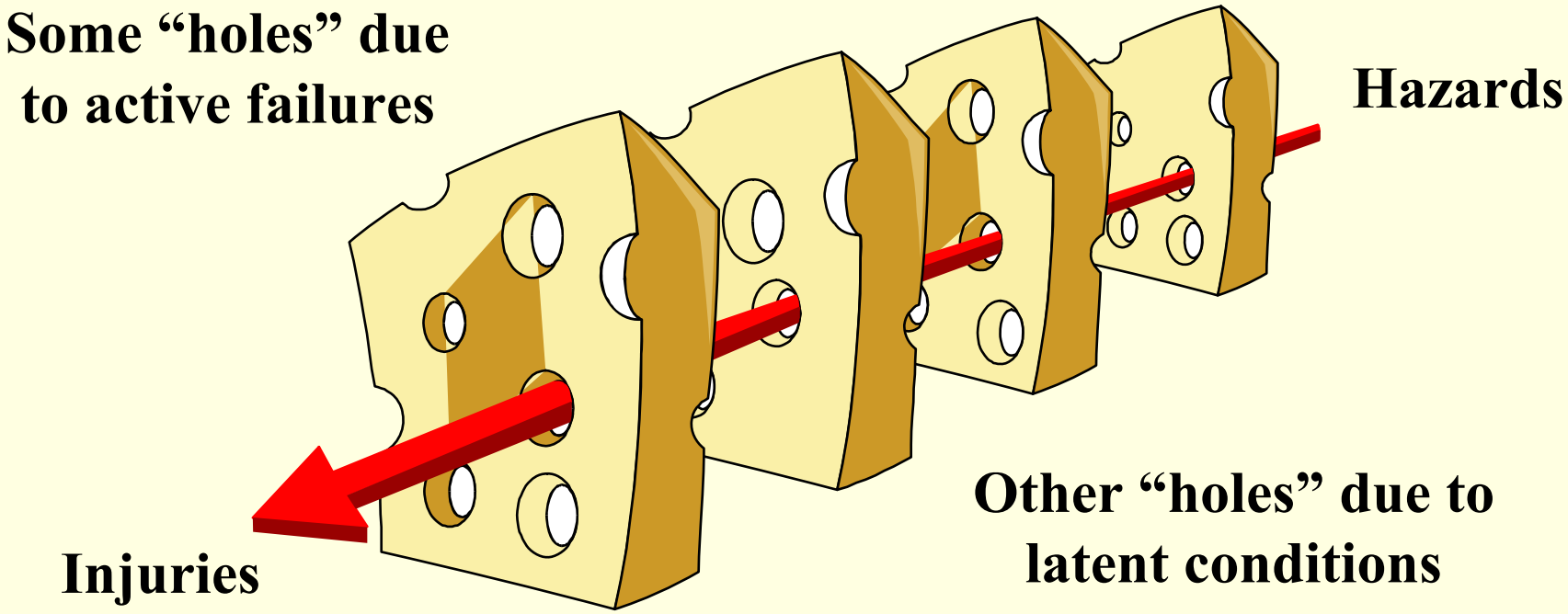
A Framework of Safety Performance



‘Hard’ defenses

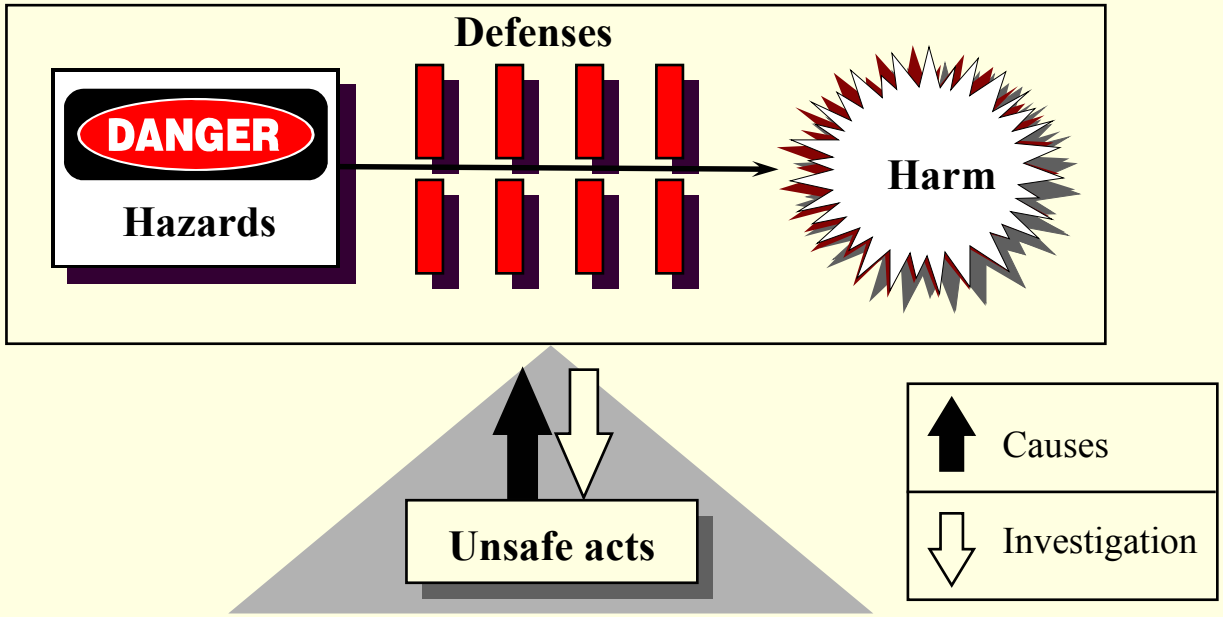
‘Soft’ defenses

The ‘Swiss Cheese’ Model of Event Causation



Successive layers of defenses, barriers, & safeguards

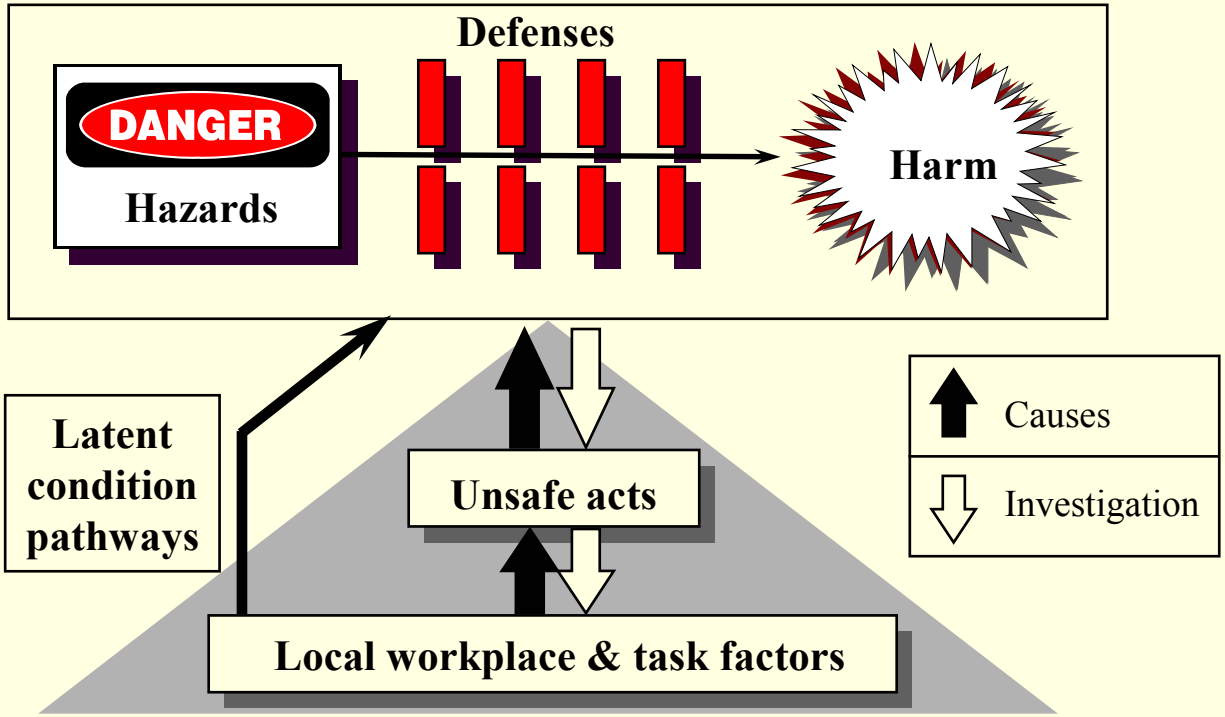
How and Why Defenses Fail: The Human Error View



• In this view, the cause of events is described as individual human errors like "*inattention to detail*" and "*failure to follow procedures*"

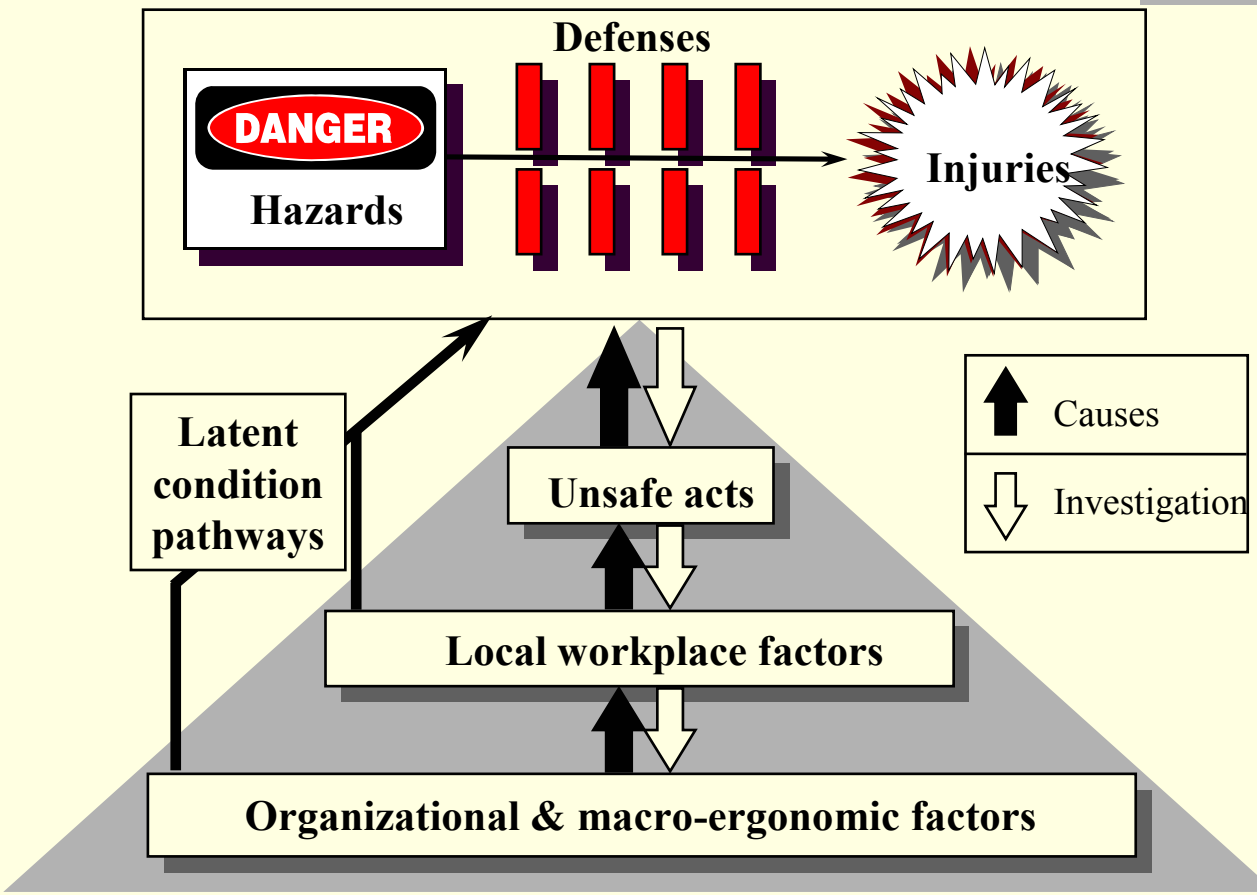
• Examples: NMED 040125 "personnel setting up the treatment neglected to change the helmet" NMED 000787 "…failed to verify that the treatment coordinates set on the patient's head-frame were the same as those established in the written treatment protocol")

How and Why Defenses Fail: Workplace & Task Factors



- In this view, the cause of events results human errors caused by 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 cause of events is 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

[Classroom Exercise on differences]

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

Contextual Influences on Human Performance

- Routine activity
  - repetition
    - reduced attention
    - reduced effectiveness of checking
  - schedule driven
    - development of shortcuts
    - trade-offs
- Multiple roles
  - handoffs, substitutions
    - communication
  - organizational issues (e.g., status)
    - likelihood of questioning
    - reduced opportunity for recovery

Contextual Influences on Human Performance

- Computer-mediated tasks
  - frequent changes (‘upgrades’)
    - hidden changes
  - limited space
    - multi-function controls / sequential display
  - multiple modes
    - feedback
- Automation
  - reduced observability of / involvement in process
    - loss of awareness
    - reduced opportunity for recovery
  - loss of manual skills

Examples of recent events involving computers

- Repeated NMED events at St Vincent Hospital with default data left when the treatment should have changed values (2004-05)
  - NMED 050504 – step length in HDR (6 events)
- Beatson Oncology Centre, January 2006
  - Teletherapy event, but typical of computer issues
    - Upgrade in software created need for changed units when manually entering treatment plan (rare)
    - Patient overdosed by 58%, died ~8 months later

Some Comments on Computer Systems Problems

- "Software temptations are virtually irresistible."

  G. F. McCormick

  When Reach Exceeds Grasp

- "Computers do not produce new sorts of errors. They merely provide new and easier opportunities for making the old errors"

  Trevor Kletz

  Wise after the Event

- "Interface: An arbitrary line of demarcation set up in order to apportion the blame for malfunctions"

  S. Kelly-Bootle

  The Computer Contradictionary

Problem for Reviewers of Events

- It is ALWAYS easy to focus on the human failures:
  - "…automation is at an intermediate level of intelligence, powerful enough to take over control that used to be done by people, but not powerful enough to handle all abnormalities.

    Moreover, its level of intelligence is insufficient to provide the continual, appropriate feedback that occurs naturally among human operators. …automation should either be made less intelligent or more so, but the current level is quite inappropriate…"

    Don Norman

    The Problem with Automation

Human-System Issues with Computer-based Systems

- Computer-based systems have unique properties that can create unforeseen problems (if not designed correctly)
  - Operations are opaque
    - Design decisions lead to user “traps”
      - *Therac-25*
      - *NMED 060376 – QC test data taken as part of the treatment*
  - Operators can view only small parts of the system at any one time
    - Limited views on the world allow for getting lost
      - *Infusion pumps*
  - User actions, data, often couple in unexpected ways leading to unexpected errors
    - Interfaces between modules
      - *Beatson OC*
      - *Mars Orbiter*

Therac-25 (1985-1987)

- Teletherapy mode
  - Not regulated by NRC but system failures could apply to any computerized system
- Unforeseen errors in software led to opportunity for high doses without filter in place
  - Safeguards were mostly software-based
- Feedback to operators was limited when equipment faults occurred
  - Faults occurred up to 40/day/unit
- “Massive overdoses” to 6 people at 5 centers

Therac RCA

- Overconfidence in software
  - Initial event analyses only looked for hardware/operator faults
    - One hardware fault at one center was taken as explanation for failures, but was not a contributor
- Inadequate RCAs performed for early events
  - Different explanations & fixes
- Lack of defensive design
  - Few self-checks built in to equipment
  - Most barriers to failure were built into software
- Complacency
  - Previous history of “reliable” performance was basis for believing that it would remain safe despite changes to system

Infusion Pump Video

- [Classroom discussion]

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)

Example ‘Real World’ Analysis

ER, Season 3, Episode 12: *Post Mortem*

Beatson Oncology Centre, 2006

- Beatson Oncology Centre (BOC) major oncology treatment centre in Scotland
- Teletherapy event, but could happen with any modality controlled by computer
- 15 year old patient dosed in 19 fractions (20 prescribed) with 58% overdose
- Treatment & planning software recently upgraded

BOC Event

- Software upgraded for planning and treatment tools, to allow automatic transfer of data from planning to treatment program
  - However because of complexity in this case, manual calculation of plan was required
    - ~6 out of ~5,000 new plans per year
  - Required change in units for 1 key parameter to ensure compatibility between systems
    - 'Monitor units' used to identify when treatment finished for day
    - Changed from normalized Monitor Units/100 cGy to MU /treatment fraction but old planning form used
  - Treatment planner omitted conversion step
    - Not detected in reviews by senior planners
- Patient received 58% overdose; died 10 months later

BOC Event Causes in Government Report[1]

- "…critical error was that the treatment planner B…was unaware of the difference [change in units] and failed to take action to accommodate changed data"
- "The error was not identified in checking process…"

1. "Unintended overexposure of patient Lisa Norris during radiotherapy treatment at the Beatson Oncology Centre, Glasgow, in January 2006 Report of an investigation by the Inspector appointed by the Scottish Ministers for the Ionising Radiation (Medical Exposures) Regulations 2000." Scottish Executive, Edinburgh (Scotland), October 2006.

BOC Event as Reported in Press

- "Paperwork error led to teen's radiation overdose" *(Reuters, October 27, 2006)*
  - "… mistakenly given massive overdoses of radiation…mainly because of a mistake in paperwork"
  - "Checks by senior staff also failed to spot the mistake"
  - "Calls for immediate inspection of all Scotland's five specialist cancer centres."
  - "…training records were out of date, written procedures failed to reflect current practices, & inexperienced staff were used in the planning of the treatment."

Report's main contributing factors
(in order of report's listing)

1. Delays in complying with IR (ME) regulations
2. Failure to assess impact of software change
3. Failure to keep written procedures & training records up-to-date
4. Over-reliance on planner B's limited experience
5. Failure to provide supervision in treatment planning
6. Failure to provide full independent checking of plan
7. Lack of written statements & common understanding of responsibilities
8. Failure to address lessons & recommendations from events at other centres
9. Underlying shortage of staff resources
10. Underlying culture of changing underlying practices without assessment

Nine Steps to Move Forward*

Classroom discussion on how these change the lessons

1. Pursue ‘second stories’
2. Escape the hindsight bias
3. Understand work as performed ‘at the sharp end’
4. Search for systemic vulnerabilities
5. Study how practice creates safety
6. Search for underlying patterns
7. How can change create new vulnerabilities & paths to failure?
8. Use technology to support human expertise
9. Tame complexity through new forms of feedback

*. “Nine Steps to Move Forward from Error”, Woods, D D & Cook, R I, Cognition, Technology & Work (4) pp.137-144, 2002

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 simplistic measures, such as “tighter” procedures, because humans need the discretion to deal with complex and dynamic circumstances for which pre-specified rigid rules are badly suited

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

Approaching an Event Differently

- Why did behaviors that are usually adaptive lead to an event is this instance?
- Why did barriers that usually prevent events not do so in this instance?
- Why did the actions taken make sense at the time?