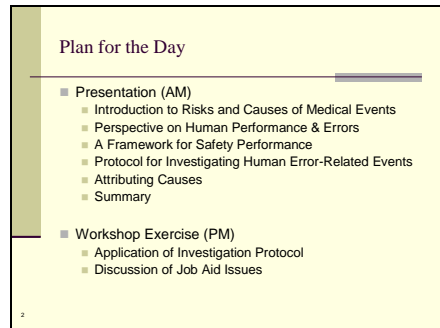

Human Performance in Medical Uses of Byproduct Materials

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

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2



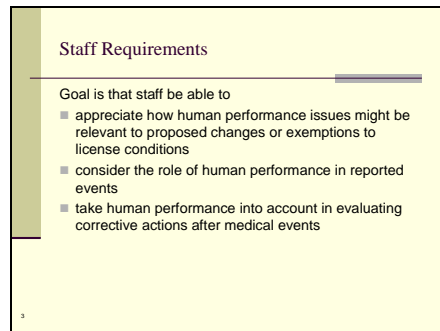
Plan for the Day

- 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

2

Slide

3



Staff Requirements

Goal is that staff be able to

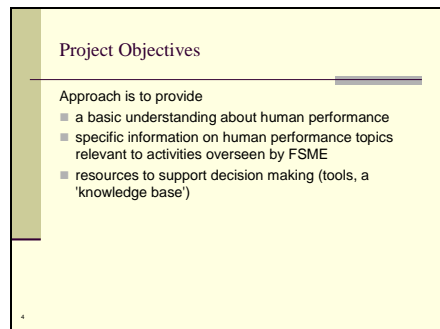
- appreciate how human performance issues might be relevant to proposed changes or exemptions to license conditions
- consider the role of human performance in reported events
- take human performance into account in evaluating corrective actions after medical events

3

NRC is engaged in an initiative to risk-inform the materials and waste safety arenas. Operating experience indicates that human actions play a dominant role in most of the NMSS regulated activities. The overall risk of these activities is strongly influenced by human performance. Hence, an improved understanding of human error, its causes and context and human reliability analysis (HRA) can provide better risk insights to risk-inform NMSS activities.

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4



Project Objectives

Approach is to provide

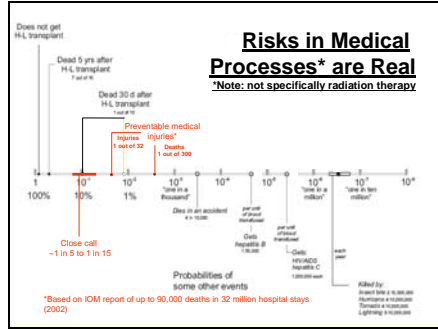
- a basic understanding about human performance
- specific information on human performance topics relevant to activities overseen by FSME
- resources to support decision making (tools, a 'knowledge base')

4

This training presentation is intended to convey a useful general perspective on human error, supplemented (principally for illustrative purposes) with specific information on human performance topics and contexts. A job aid is being developed in tandem with this training; it will address specific topics and contexts in greater detail and will provide a knowledge base to support staff in dealing with human performance considerations in NMSS-regulated activities.

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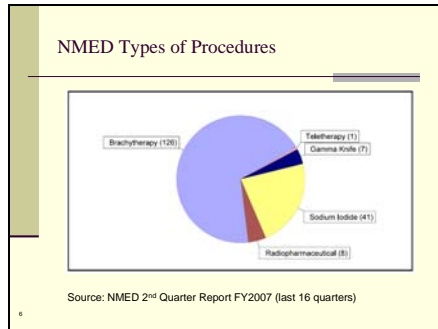
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Unlike the risks from reactor safety events, risks in the world of healthcare are significant. The Institute of Medicine's report *To Err is Human* suggested there are up to 90,000 avoidable deaths in US healthcare settings. Given that there were about 32 million hospital stays in 2002, this suggests a rate of avoidable death of up to 1 in 300. This is for all of healthcare, not specifically for radiation therapy, but it provides a framework for considering risks in the medical uses of byproduct materials.

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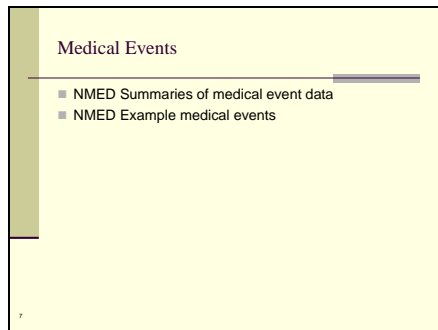
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By far the largest numbers of events are associated with brachytherapy, the most frequent of the modes of treatment overseen by NRC. However the use of gamma knives is increasing and is in some ways more complex.

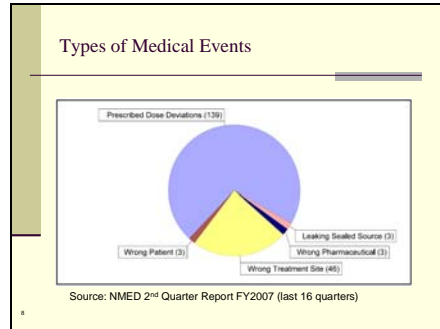
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7



The Idaho Nuclear Materials Events Database (NMED) provides summaries of materials events, including medical events. It can be searched just to look for specific types of events using key words or selected classes of events.

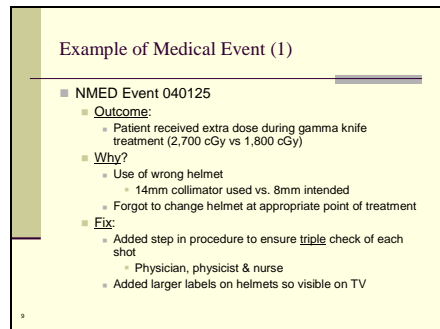
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8



An analysis of medical events reported in NMED as failures:

- Shows the types of categories of failures used in NMED
- Shows that dose deviations are the largest type of failure

Slide
9



Missing a step in a routine process is not at all unusual, especially when an interruption or distraction occurs. Relying on multiple people double and triple checking adds relatively little to the reliability of the process because people rely on one another—it's human nature—especially when the failures that the checker finds are rare. For example in work on organ transplants, it was found that double checking data entries for critical data like blood type added so little that a new type of data entry was developed, where different people had to actually enter data at different times that reconciled before the data was accepted into the database.

NMED Text: “The licensee reported that a patient received 2,700 cGy (rad) to a brain metastasis instead of the intended 1,800 cGy (rad) during gamma knife treatment. The physicist did not determine an error had occurred until the treatment was complete. The RSO determined that one of the four brain metastases received greater than the prescribed dose. The other three metastases received the prescribed dose. The tumor that received the incorrect dose was at the periphery of the brain next to the skull in a non-critical area so that much of the extra dose was delivered to the space between the brain and the skull. The cause of the incident was the use of the 14-mm collimator

Slide
10

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

10

helmet instead of the prescribed 8-mm collimator helmet. The personnel setting up the treatment neglected to change the helmet. The referring physician was notified of the event. Corrective actions taken by the licensee included establishing a new procedure requiring the physician, physicist, and nurse to sign off on the treatment time, helmet size, and position before each shot. Also, new labels identifying the size of the helmet were attached to each of the four helmets such that the helmet size can be determined outside the room on the TV monitor at the control. The physician will verify the correct size before the control panel button is pushed to start the treatment.” The same kinds of problems have been found in other industries where reliability is needed to be improved in performing routine steps, such as the rail industry.

Another event where some kind of double checking is added. Data entry errors are very common—how often do we experience this in our own typing? Format for data entry can make a significant difference. For example, selecting the right entry in a ‘drop down’ list is less reliable than choosing the right ‘radio button’. Having data entry fields pre-formatted can help (think of entering phone numbers where the area code space is already defined vs. entirely unstructured boxes), so long as they can accept all legitimate data types—what happens if the phone number is non-US? NMED Narrative: “The licensee reported that a patient received a therapeutic dose 39% greater than prescribed to the inferior right parietal of the brain. The patient was to receive 2,000 cGy (rad) to the 50 percent isodose line using Co-60 gamma stereotactic radiosurgery (gamma knife), but instead received 2,780 cGy (rad). This treatment was the first in a series of five geographically distinct treatments. The treatment was terminated when it was recognized that the elapsed treatment time had exceeded the prescribed time. The resulting treatment duration was 7.18

Slide

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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"

11

minutes longer than prescribed. This event was caused by the incorrect entry of the treatment time into the Leksell treatment unit and the failure to identify the error during the second verification of the treatment parameters. The remaining four treatment sites were subsequently treated in accordance with the patient's treatment plan. The patient and physician were notified of the event. To prevent recurrence, the licensee modified their Quality Management Program to improve the verification process for treatment plan time entry. The NRC contracted a medical consultant to review this event. The consultant concluded that the licensee took appropriate immediate actions and performed an appropriate assessment. The consultant also agreed with the licensee that the patient should not experience any adverse effects from this event because the delivered dose falls within the normal range of standard treatment.”

Procedures are notorious for containing errors or ambiguous instructions. They are often blamed for the cause of events. However, in a comparison of human performance at nuclear reactors, where some events involved excellent performance and some poor performance, procedures were equally bad in both cases. The difference was that the people were able to remedy the problems in some of the cases where things went well. Also important was the fact that in the cases where things went poorly, there was something unusual or off-normal going on that compounded the procedures problems.

NMED Narrative: “The licensee reported that a patient received 700 cGy (rad) to the tissue in the nasal passages rather than the bronchial area during a brachytherapy treatment. The dose was delivered to the unintended site using a Varian HDR remote afterloader (model VariSource) and an Ir-192 source (model VS2000, serial #02-01-2728-001-10300) with an activity of 144 GBq (3.891 Ci). The licensee measured and tested a catheter using the dummy source. After the test,

Slide

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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

12

the catheter was placed in a box and sent for sterilization. On the day of administration, the licensee used the wrong catheter during the first fraction. It was determined that the individual that entered the treatment data incorrectly entered 120 cm for the catheter length. The licensee stated that a contributing cause to the event was inadequate procedures. When the patient returned for the second fraction, a medical physicist discovered that the catheter was 30 cm too short. The attending physician was present at the time the error was discovered and was informed. The patient was advised of the error and given the option of discontinuing treatment. The patient elected to undergo treatment to the correct treatment site. Corrective actions taken by the licensee included generating a new procedure.”

Ambiguity in patient treatment plans is not unique to the kinds of therapies reviewed by NRC. This is a common medication error, where the patient is either given individual doses that should have been the total over numerous administrations, or vice versa (as happened here). The need for standardized communications is a major issue in healthcare. Here this was compounded by the lack of familiarity with the software and how it interpreted input dose information.

NMED Narrative: “The licensee reported that a patient received only 125 cGy (rad) instead of the intended dose of 500 cGy (rad) during a brachytherapy procedure to the bronchial passage. The procedure used a Varian HDR remote afterloader (model VariSource S-2000, serial #VS052) and an Ir-192 source (model VS2000, serial #02-01-2722-001-103002-09863-47) with an activity of 192.4 GBq (5.2 Ci). The prescribed dose to the patient was 2,000 cGy to be administered in four 500 cGy (rad) fractions. However, due to an error during the development of the treatment plan, the computer was programmed for a total dose of 500 cGy (rad) to be administered in four 125 cGy (rad) fractions. The first fraction was

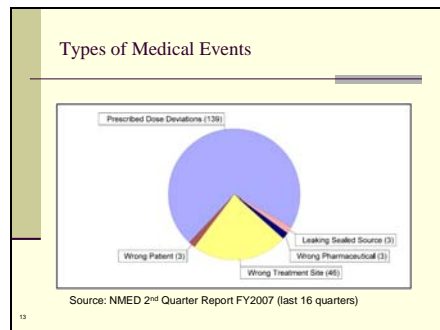
administered as 125 cGy (rad). The patient and the attending physician were notified of the event on 1/7/2003. The licensee modified the treatment plan and delivered 625 cGy (rad) during each of the three remaining fractions to achieve the total prescribed dose of 2,000 cGy (rad). The cause of this event was the licensee's inadequate written procedures for the use of their HDR treatment planning software and the medical physicist's lack of familiarization with the software. To prevent recurrence, the licensee made modifications to procedures in the development of HDR treatment plans and the medical physicist must manually calculate the treatment dose and compare it to the dose developed in the treatment plan prior to patient administration. The licensee also disseminated the results of its investigation, including the root cause and corrective actions to all medical physics staff and authorized user physicians involved in HDR treatments."

An analysis of medical events reported in NMED as failures:

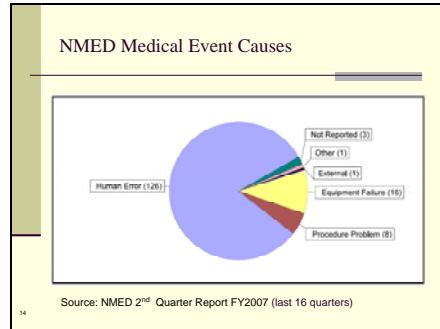
- Shows the types of categories of failures used in NMED
- Shows that dose deviations are the largest type of failure

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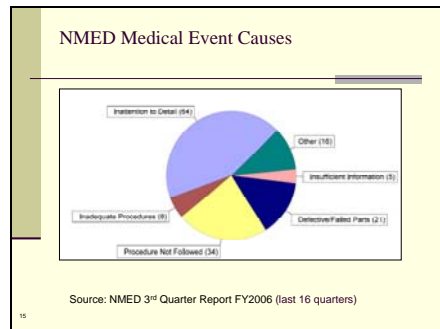
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Again, from the NMED data base, pie chart shows breakdown of medical events according to what are reported “causes” in NMED:

- Note that ~80% failures are called “human errors”
- Also, ~5% are called “procedure” problems.

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Can these identified causes help you find effective fixes?

The main purpose of finding the causes of events is to make sure that fixes can significantly reduce the likelihood of the same type of event recurring. But that means finding out what ‘type of event’ it is. (We will cover much more on this later in the training.)

Note that NMED no longer provides this sort of breakdown—the 3rd quarter of FY2006 is the last one published.


Slide
16

- 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

Events show that ‘people are people’. These kinds of errors are seen in everyday life over and over again. The following discussion will discuss why these occur constantly.

Slide
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Why do people make errors?



17

“Knowledge and error flow from the same mental sources, only success can tell the one from the other.”
- Ernst Mach *Knowledge & Error* (1905)

Slide
18

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 under "normal conditions".

18

The idea that errors arise from the same behavioral mechanisms that, in most cases, allow successful human action is not, strictly speaking, new. See Mach's quote from 1905 (above)—this quote appears on the first page of James Reason's seminal 1990 book, *Human Error*.

NRC's ATHEANA (A Technique for Human Reliability ANALYSIS) HRA method views human errors as the result of the interaction of basic psychological mechanisms with specific task contexts.

Slide
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Basic Behavioral Biases

- People's behavior is almost always rational
 - Adaptive – adequate *under the circumstances*
 - Satisficing – goals are achieved
- People's actions will tend to be
 - Practical
 - People do what they have found that works
 - Economical
 - People act so as to conserve their resources
 - Physical and mental

19

If these basic behavioral biases are kept in mind, it will be easier to anticipate or understand the actions that people will take or have taken.

Slide
20

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

20

Based on these biases, people's behavior is largely predictable. As a result, we can anticipate many kinds of errors.

Slide
21

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/circumventions:** Deliberate deviations from standard operating procedures

21

Behavioral scientists have identified a few basic types of error; they are distinguished by the role of intention in the action. In a *slip*, the person intends to do the correct action, but the execution is faulty. In a *mistake*, the intended action is not the correct one, typically owing to an incorrect decision being made in selection the course of action. A *violation* (sometimes called a 'circumvention' to avoid conflicting use with the regulatory use of 'violation') consists of an intention to deviate from a procedure; it is deliberate, although not malicious.

Slide
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Effects of economizing

- In the allocation of attention
- In the application of mental effort
- In the expenditure of time or physical effort

22

Each of the three types of error can be thought of in terms of the basic behavioral biases described above.

Slide
23

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 great opportunity for error
 - Slips happen so frequently when there are **distractions**

23

Slips will occur predictably when specific conditions are met. As humans, we try to give little *active* attention as we can to tasks we are performing. If we can do them by habit, without thinking, we do. Think of the amount of conscious effort we give to driving a familiar route in the car. Very little!

Slide
24

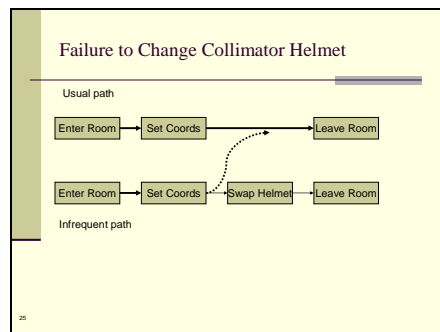
Examples of Slips

- Conditions for a 'capture' slip
 - well-practiced action
 - intention to deviate
 - intrusion of 'stronger' habit
 - failure to recognize slip has occurred

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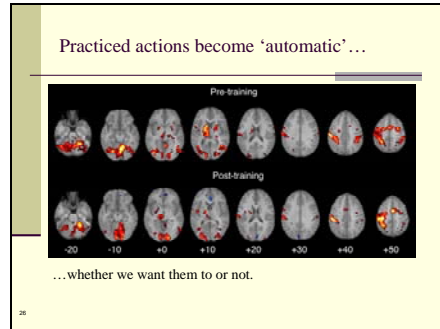
In a 'capture' slip, the correct (i.e., intended) performance relies on a well-practiced (i.e., nearly automatic) pattern of action being interrupted at a certain point—for example, diverting from “a well trodden path.” Some incremental amount of attention is required to maintain the intention to deviate. If it is not applied, or if this small amount of attention is drawn away at the moment the deviation is to occur (e.g., a distraction), the stronger habit will 'capture' the action sequence.

Slide
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Failure to change the collimator helmet as called for in the treatment plan accounts for a significant number of the errors reported for gamma knife treatment. Positioning adjustments (i.e., setting coordinates) are made prior to every 'shot.' For efficiency, shots using the same collimation are grouped, so that helmet changes are much less frequent than coordinate settings. Technicians performing these actions repeated may be 'set up' by the strong habit that associates completion of positioning with leaving the treatment room and ignores the need to change the helmet.

Slide
26



It can be shown that, when actions are performed repeatedly, the actions can become, to some extent, automatic. It seems that the resources required to support the activity somehow decrease. Figure 4, Poldrack et al. (2005). The neural correlates of motor skill automaticity. *Journal of Neuroscience*, 25 (22), 5356-5364.

Slide
27

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

27

The new perspective is based on what we know about decisionmaking from experiments in the 1970's and before.

Slide
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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 often been made previously

28

Without thinking about it, people make decisions based on their experiences. Because the world is to a large extent predictable and the ways in which things work don't usually change, these tendencies allow people to make the right choice in the great majority of cases, even without fully considering all of the evidence and contingencies that bear on a decision. Unfortunately, when circumstances are somehow atypical these same tendencies can lead to error.

Slide
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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

29

The "default" explanation at each stage was very much biased by the previous experience of the clinicians. Alternative explanations were not even considered.

Slide
30

New Perspective on Unsafe Acts:
Violations/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

30

Violations/circumventions are deviations from recommended or prescribed procedures. They are typically not malicious and are often routine, coming to light only when something goes awry. James Reason draws a distinction between 'taking risks' and 'running risks.' In the Tokai-mura criticality accident, a workaround that increased throughput became accepted procedure; managers were apparently aware of the practice, but ignored (or condoned) it. It was only when circumstances changed (material with a higher enrichment level was introduced) that the implications of the shortcut became evident, resulting in a tragedy.

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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.

31

Efficiency - thoroughness tradeoffs are the ways we avoid having to do an extra amount of work when it is "clear" to us that the work is not necessary. Previous successes are often enough to tell us not to worry, even if the circumstances have changed. Of course, we can't analyze everything in depth every time so it is important to know what the critical assumptions are.

Slide
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Efficiency-Thoroughness Trade-Offs:
Patterns of Organizational Behavior

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

32

As shown later, events often have organizational as well as local causes. The actions and decisions taken by organizations in response to challenges and resource limitations can be understood in terms of the same behavioral biases introduced earlier.

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

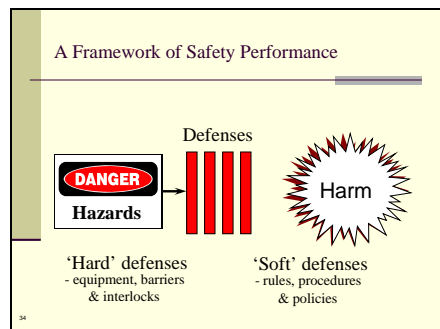
- In the great majority of situations, the trade-offs work
- Efficiencies typically free up resources, allowing improved performance
- As a result of trade-offs, errors are common – however events are prevented
- There are typically barriers against unwanted outcomes
 - self-monitoring
 - engineered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

33

We have become very effective in using trade-offs without suffering accidents, especially as the pressure for increased efficiencies (and lower costs) grow. Errors can increase but most do not result in accidents.

Amalberti has observed several errors /hour is common in commercial aircraft cockpits & ATC operations, but very few aircraft crash (approximately 0.3 per million departures in 2006 world-wide). Crews self- or cross-detect errors and are able to recover with no significant consequence.

Slide
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Harm is largely prevented by defenses that stop hazards from affecting patients and clinical staff. Often there are multiple defenses or barriers to prevent hazards causing harm, any one of which may be sufficient to prevent harm.

Defenses can be 'hard' (usually physical), like shielded safes for sources and interlocks (preventing access to radiation areas), or 'soft', like procedures and rules, that rely on people's compliance.

Slide

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Examples of Soft Defenses

- Work is performed in accordance with the approved plan
- Work is performed with requisite expertise
- Work is checked appropriately
- Errors in the work are detectable and correctable before overall failure occurs
- Alarms are present to warn of failures and other conditions of concern

35

These are just a few examples.

Slide

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Defenses Can and Do Fail

The diagram illustrates the relationship between hazards, defenses, and harm. On the left, a box labeled 'DANGER Hazards' has an arrow pointing to a set of four vertical red bars labeled 'Defenses'. From the right side of these bars, an arrow points to a starburst shape labeled 'Harm', indicating that when defenses fail, harm occurs.

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Defenses are never perfect. Equipment can fail. Rules can be broken. But because there are usually multiple defenses, most times these events go unnoticed since no harm occurs. Audits and inspections can spot failed defenses but these are often not very frequent.

Slide

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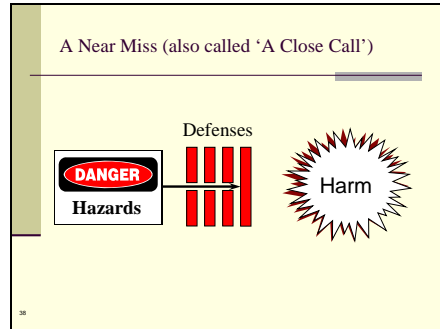
The 'Swiss Cheese' Model of Event Causation

The diagram shows four slices of Swiss cheese stacked together. A red arrow labeled 'Hazards' enters from the right, passing through the holes in each slice. The holes in the first two slices are labeled 'Some "holes" due to active failures', and the holes in the last two slices are labeled 'Other "holes" due to latent conditions'. The arrow exits the stack on the left, labeled 'Harm'. Below the stack, the text reads 'Successive layers of defenses, barriers, & safeguards'.

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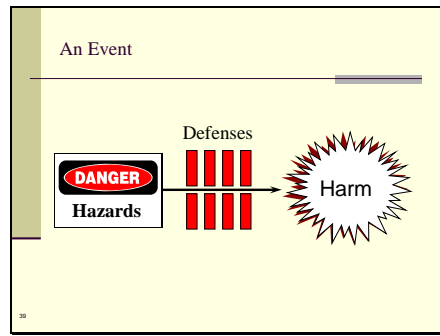
James Reason has described the real-world nature of defenses as being like slices of Swiss cheese. Most of the defenses are very effective and other parts have gaps. Some of the gaps occur because equipment fails at the time of the event (such as a failure of a radiation alarm). These are called 'active' failures because they occur dynamically, just before or during the accident and play an 'active' role in the accident. There are also gaps that can sit unnoticed, called 'latent failures' because they just sit there. Examples of latent failures are gaps in safety procedures or omissions in training that are not apparent until the 'right' event occurs that uncovers the failure.

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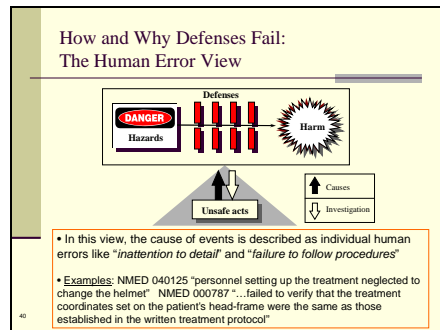
A near miss occurs when almost all the barriers fail and only the last one (which may be a matter of luck or a heroic human action) saves the day. These are often (but not always) visible to the participants at risk. Often the last barrier is a human action taken at the time of the event. If it fails, the human action is often blamed for 'causing the event.'

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When all defenses fail, there is an accident.

Slide
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All defenses are affected by human performance, even physical barriers (which require periodic maintenance and correct use by people to be effective). Soft defenses require compliance with rules and procedures, etc. This does not mean that all defense failures result from human actions—they can fail from other means of course, including degradation and wear out, for example.

A common view is to blame these failures on human error. An event or near miss occurs, and the investigation identifies a human action that led to failure of a defense. This is seen as a sufficient reason to stop the investigation and blame the person involved. This is called the 'human error' view of accidents. It is very common in healthcare. But it is too narrow


a perspective today. It is VERY hard to change the underlying tendencies of human behavior that are so often shaped by the tasks and the workplace setting.

Slide
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Examples of Unsafe Acts

- Failures to follow procedures
- Failure to use expertise appropriately
- Failure to perform checking
- Failure to detect errors and failures

Often focusing on the last person who was involved!

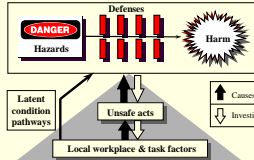


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These are examples of the kinds of human errors found in event investigations that have led to defenses failing. These can lead to failed hard defenses (incorrect maintenance, etc.) or be the actual means of failure of soft defenses. They are found in event investigations and the event is then blamed on “human error”. Most often, the focus is on the last failure that occurred just prior to the event, which almost always involved a human error.

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How and Why Defenses Fail:
Workplace & Task Factors



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• 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”


But human actions do not take place in a vacuum. The level of performance and the likelihood of error is very much shaped by the workplace setting and the tasks being performed. Therefore the analysis of any event needs to look, not just at the human errors involved, but also the workplace and task factors to understand how they shaped the human performance AND how they need to be changed. Without changing the workplace and task factors appropriately, the same human errors will keep recurring. Over and over again. ‘Latent condition pathways’ recognize that failures can occur in defenses without involving human errors directly. For example, a procedure not being written for a critical task (for example, a new type of hazard) can lead to a gap in a defense

without necessarily a person making an error. It represents a gap in the understanding of the hazard.

Slide
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Examples of Workplace & Task factors

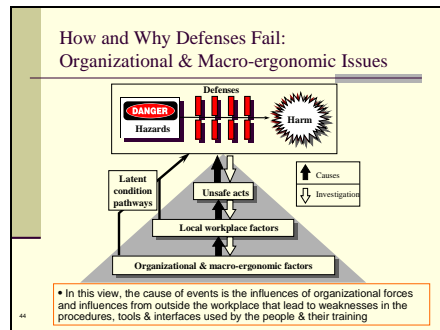
- Procedures
 - Nonexistent
 - Too complex
 - Not usable as written
 - Out of date
- Training
 - Incomplete
 - Not practical
- Checking
 - Not performed
 - Performed superficially
- Error recovery
 - Not detectable
 - Not noticed
 - Not recovered
 - Unrecoverable in time available



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These are examples of workplace and task factors seen in many industries, not just healthcare. But they apply here, too. [Discussion Note: What other factors can apply? Which are the most important? Why have they not been fixed?]

Slide
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But the workplace and task factors do not exist in isolation either, but are products of management decisions in the organization. Has the organization learnt from previous incidents? Does it starve key areas important to safety of resources (like staffing and training)? What about providing workplace features like adequate lighting, video linked communications, etc.?

Slide

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Examples of Organizational Factors

- Under-resourcing
- Denial of problems & ignorance
- Diffusion of responsibilities
- Over-emphasis on commercial/production goals



46

Discussion point: What recent incidents have been mostly attributable to organizational factors? The above is just a set of examples.

Slide

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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" (WYLFYFYF)
- 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)
- We will use the 'triangle model'

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We are going to spend a lot of time on this topic because it drives almost everything else.

Slide

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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

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We will examine the use of different frameworks of analysis for some sample event groups.

Slide

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

- Iridium-192 source used for HDR brachytherapy
- Source detached from cable in patient but not realized by staff
 - Design of equipment
 - Radiation alarms when patient removed from treatment room disregarded as 'frequent occurrence'
- Pt returned to nursing home
- Source exited pt after 4 days into bed linen but not detected
- Finally detected as truck carrying waste set off radiation alarms at waste transfer site

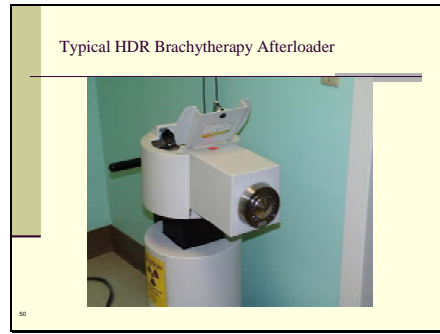
48

Classical human performance issues:

- design does not include provision for detection of failure conditions (like TMI PORV position)
- history of false alarms from the radiation portal
- occurred when regular staff were absent
- patient almost at end of life, so death following treatment was not a surprise

Slide

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Example of a HDR afterloader

Slide

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Expected Sources of Defense for Rad Hazard to Public & Workers

- Alarm on afterloader concerning loss of source
- Area radiation alarm(s)
 - Tested frequently
- Training of staff in radiation hazards
- Emergency procedures
- Radiation survey equipment to be used in event of doubt about source safety

50

What would you expect *a priori* to be defenses against the Indiana PA event?
Anything in addition to those listed here?

Slide

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Actual State of Defenses

- No alarm on HDR afterloader concerning loss of source
 - Not part of design
 - Failure messages were obscure
- Area radiation monitor alarm (Prim-Alert)
 - Alarmed continually and randomly
- Training of staff in radiation hazards
 - Minimal to none provided by facility
- Emergency procedures
 - Minimal and did not address rad hazards
- Radiation survey equipment
 - Use not understood by technical staff

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Here's what actually the state of the defenses were.

Slide

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Unsafe Acts

- Assumed source was intact in afterloader safe
 - Did not believe guide wire could fail
- Ignored Prim-Alert alarm
- Did not perform area survey with hand monitor
- Remained unaware of hazard from unshielded source

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Here are the principal unsafe acts that contributed to the failures in the defenses. Can you think of any more?

Slide

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Workplace & Task Factors

- Minimal training on HDR brachytherapy & its devices
 - Initial training by manufacturer
- Alarm messages on device were obscure
 - Reported blockage of catheter
 - No guidance on interpretation & significance of error messages
- Prim-Alert had long history of "false alarms"
- Minimal training on radiation safety
 - Content not recalled by RTTs
- Emergency & QM procedures did not consider rad safety issues
 - Emergency procedures not critically reviewed
 - Posted as provided by manufacturer
- Use of hand survey monitor not understood by staff
- No testing of alarms or interlocks

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What were the factors that led up to the unsafe acts? Given these, is the actual performance a big surprise?

Slide

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Org Factors

- HDR brachytherapy & risks not well understood by management or staff
 - Center principally a beam teletherapy treatment center
 - Brachytherapy was new modality
 - "Must be safe since licensed by NRC"
- Lack of awareness of afterloader design features
 - Expected "bells & whistles" if afterloader fails
- No awareness of need for reliable area alarms

55

How would this be addressed today?

Slide

55

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

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These are the top level findings of the INL investigation of events from the period 1991 – 92.

Slide

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ER Video

57

We will watch a short extract from an episode* from the TV series, "ER", that shows a medical event. While this does not comprise a use of radioactive sources, the circumstances are generally applicable.

First, just watch the video and generally follow the story line (the extract lasts about 3.5 minutes).

Then we will re-run the video and discuss the unsafe actions, the workplace and task factors, and the organizational issues you have seen in this clip.

* Series 3, Episode 13, "Post Mortem"

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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?

50

There are reasons why these are frequently cited as causes, and reasons for caution, when they are. But what can we do to reduce these causes of events?

- Tell people to pay attention to detail?
- To follow procedures?

We will discuss each of these in turn.

Slide
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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?

50

Constantly paying attention to detail is not what humans can do. What we do is learn a pattern of behavior that we find works, and then use it in “auto”.

Think of driving a car—once we have mastered the needed skills, we drive without consciously paying attention to the details of steering the wheels, which pedal do we use for braking and so on, to allow us to do other important things like concentrate on other traffic, navigation, and so on. The more skilled we are, the more we mean we take more actions “without thinking.”

Slide
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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?


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The quote is from Hollnagel (p.181?) This is the basis for newer HRA tools like ATHEANA.

Procedures are often written by well-intentioned designers who believe they know how work is done. But different facilities may work in different ways. Equipment usage changes over time. People learn more efficient ways of doing things. All of these lead to people not being able or choosing not to use procedures—at least as the designers intended. In some cases, procedures are only used to blame a worker because they didn’t use procedures (the rail industry).

Slide
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Example Cause Determination



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

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The Brookhaven Medical Research Reactor was used in the development and testing of radiation therapies and for the production of short-lived radioisotopes. It ceased operation in December 2000. While the process being controlled in this case was not a radiotherapy device, the particular equipment involved in the error has characteristics that are common to a wide variety of controls and displays found in medical and industrial settings. In addition, the event report is similar in tone and level of detail to those that are received from licensees.

Slide
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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.

63

The BMRR had been shut down for quarterly testing. The restart procedure included testing of the high temperature trip system. (Like any reactor, the BMRR had temperature sensors at the cooling water outlets; excessive temperature triggers an automatic shutdown). The low temperature of the water during shutdown provides an opportunity to test the temperature sensor. The sensor's set point is lowered to a point just above the (reduced) coolant temperature. The temperature is then raised and the performance of the high temperature trip system is verified.

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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.

64

The normal operating temperature of the BMRR was 114 degrees F. For the test, the setpoint was lowered to 104 degrees F using the digital temperature controller. Following the test, the procedure calls for the normal high temperature setpoint in the controller (134 degrees F) to be re-established before the reactor is restarted.

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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".

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To restore the high temperature setpoint to its normal value, the operator changes the digital controller to the mode in which setpoints can be inspected and changed, caused the desired value to be displayed on the readout, and saves the setting. The event occurred because the operator did not press the button that saved the displayed value; he pressed on marked "RESET" rather than the one marked "SETPTS."

Slide
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Cause Categories

23. Description of Cause (continued):
The temperature trip test is performed per a written BMRP 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.

66

The procedure for the activity, as would be expected, calls for the operator to press the button that will save the displayed setpoint – therefore the operator failed to follow the procedure. More to the point (but still not very illuminating), it is noted that there had been 'inattention to detail.'

Slide
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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.

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Fortunately the operator was counseled, so that this error will not recur. Right?

Slide
66

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?

66

If it is important to prevent this error, one should try to determine what conditions or contexts might have caused the operator to make the error. While the task of entering the setpoints was done infrequently, using the temperature meter was probably a routine activity, and in any case not a very demanding one. One might speculate that just as the operator was supposed to press the button that saved the normal setpoint values, the small amount of attention devoted to operating the meter was drawn to something else, e.g., perhaps it shifted in anticipation of beginning the next part of the startup procedure. Why was a greater amount of attention needed?

Slide
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Newport INFT Temperature Meter



67

Looking at the design of the temperature meter and reading its instruction manual can answer most of the questions posed in the last slide.

Slide
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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.

70

When the controller is in the SETPTS mode, the display cycles through the setpoints, showing each setpoint for 15 seconds; there are indicators below the numerals to show which setpoint is being displayed. Pressing the arrow keys pauses the cycling and allows the setpoint value to be changed. If nothing further is done, the device will continue through the display cycle and revert to its normal (RUN) mode, without storing the changed value. Likewise, pressing RESET will cause the entered value to be abandoned. The value is retained only if SETPTS is pressed.

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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.

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In the Peak/Valley mode, the highest or lowest value measured since the device was last reset is shown (with a flashing display); the display remains in this mode until the operator takes an action. To return to the normal measurement mode without resetting the peak/valley memory, operator can press SETPTS or MENU. To set the peak/valley memory to the current value, the operator presses RESET.

Slide
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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

72

Owing to the need to conserve space, there is not a separate button for each function; buttons serve different functions depending on the mode that the device is in. The designers' choice of which buttons to use for the meter's functions (and what labels to use for the multi-function buttons) probably represents a reasonable compromise. The design may even be logical and consistent in terms of the inner workings of the meter – but it may not seem so to the user.

Slide
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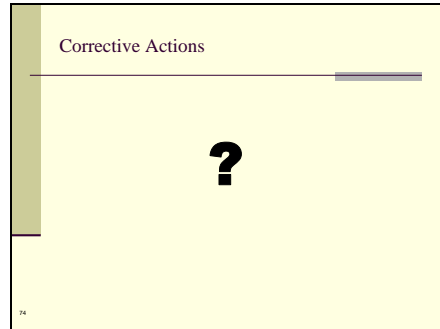
Final Question

"What was the operator thinking?"

73

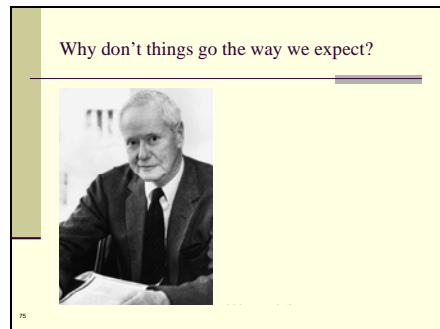
Was there a subtle user trap in this activity?

Slide
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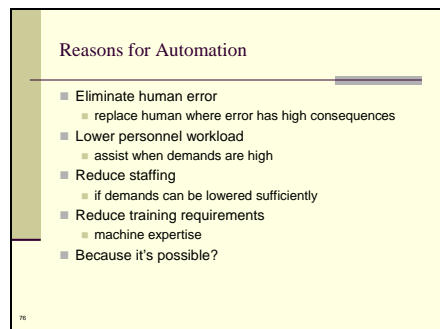
There is no doubt that the error is less likely when the operators are attending closely to the procedure and the required actions. However, in light of our understanding of how attention naturally 'drains away' from routine actions, we may question whether simply insisting that operators pay more attention will be effective. Is it possible to specifically counter the tendency to perform routine actions with minimal attention? Or should that be assumed and the focus shifted to detecting and recovering from the error before it has any consequences?

Slide
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The failure to anticipate the consequences of actions & decisions...

Slide
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Automation is great but in practice things don't always go as you expect. Sometimes automation is used simply because it can be. But can you anticipate what may happen?

The following slides illustrate how automation can create unanticipated problems.

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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 coordinates
 - failure to change helmet, check settings
- Operators enter room after each shot to prepare the next shot
 - demanding, repetitious

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Slide

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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)

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Slide

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"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)

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Slide

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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

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Slide

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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

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Slide

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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

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Slide

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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"

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Slide

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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

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Dekker p.64

Slide

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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

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Dekker p.64

Slide

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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

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