Human Performance in Medical Uses of Byproduct Materials

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

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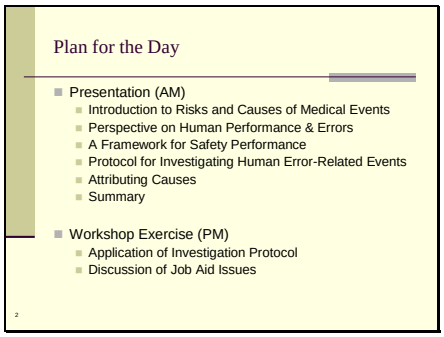

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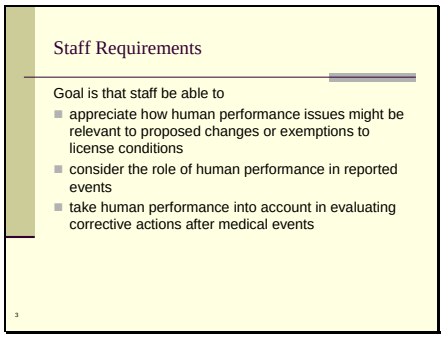

NRC is engaged in an initiative to risk-inform the materials and waste safety arenas. Operating experience indicates that human actions play a dominant role in most of the NMSS regulated activities. The overall risk of these activities is strongly influenced by human performance. Hence, an improved understanding 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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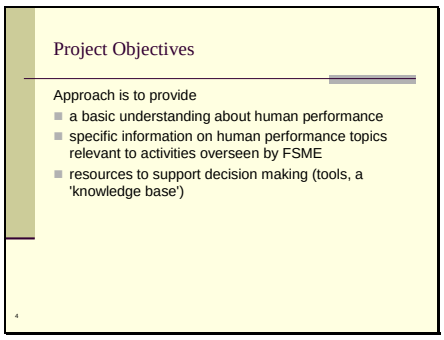

This training presentation is intended to convey a useful general perspective on human error, supplemented (principally for illustrative purposes) with specific information on human performance topics and contexts. A job aid is being developed in tandem with this training; it will address specific topics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

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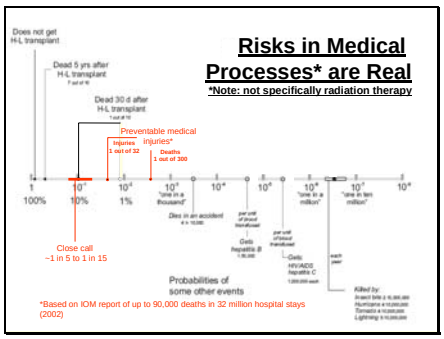

Unlike the risks from reactor safety events, risks in the world of healthcare are significant. The Institute of Medicine's report *To Err is Human* suggested there are up to 90,000 avoidable deaths in US healthcare settings. Given that there were about 32 million hospital stays in 2002, this suggests 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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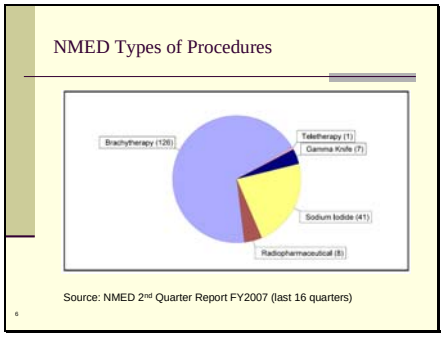

By far the largest numbers of events are associated with brachytherapy, the most frequent of the modes of treatment overseen by NRC. However the use of gamma knives is increasing and is in some ways more complex.

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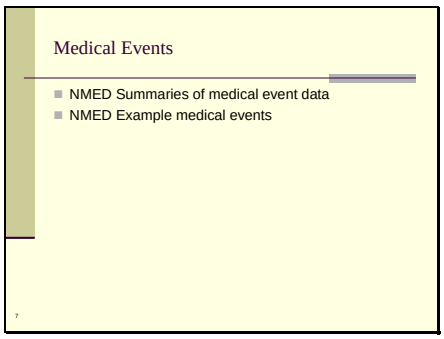

The Idaho Nuclear Materials Events Database (NMED) provides summaries of materials events, including medical events. It can be searched just to look for specific types of events using key words or selected classes of events.

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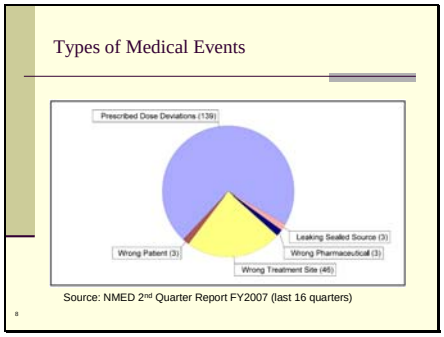

An analysis of medical events reported in NMED as failures:

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

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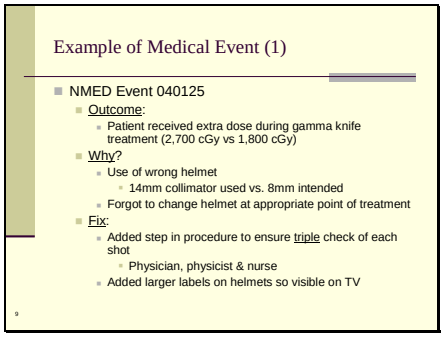

Missing a step in a routine process is not at all unusual, especially when an interruption or distraction occurs. Relying on multiple people double and triple checking adds relatively little to the reliability of the process because people rely on one another—it's human nature—especially when the failures 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

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.

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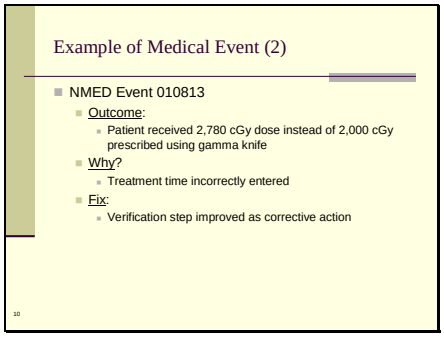

Another event where some kind of double checking is added. Data entry errors are very common—how often do we experience this in our own typing? Format for data entry can make a significant difference. For example, selecting the right entry in a 'drop down' list is less reliable that choosing the right '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

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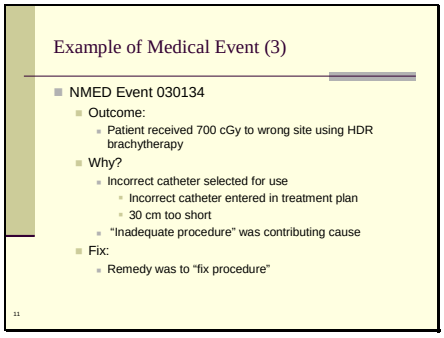

minutes longer than prescribed. This event was caused by the incorrect entry of the treatment time into the Leksell treatment unit and the failure to identify the error during the second verification of the treatment parameters. The remaining four treatment sites were subsequently treated in accordance 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,

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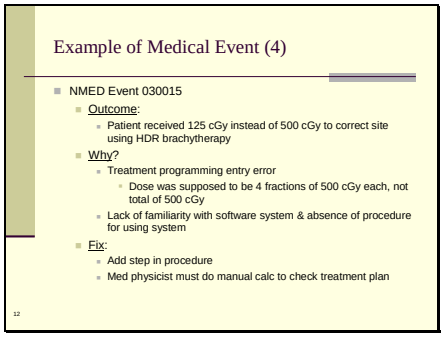

the catheter was placed in a box and sent for sterilization. On the day of administration, the licensee used the wrong catheter during the first fraction. It was determined that the individual that entered the treatment data incorrectly entered 120 cm for the catheter length. The licensee stated that 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 buy 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."

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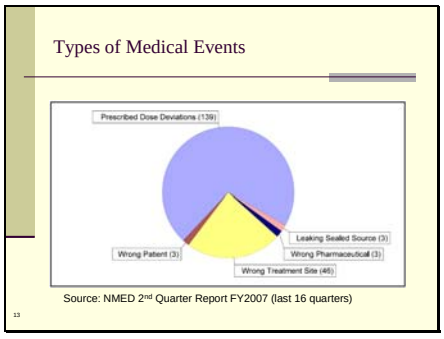

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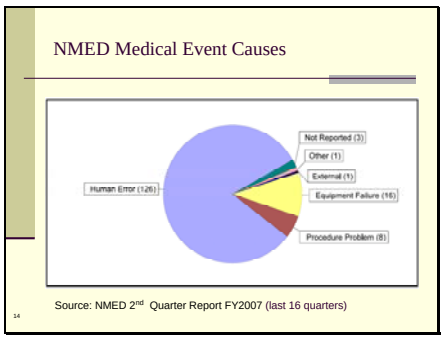

Again, from the NMED data base, pie chart shows breakdown of medical events according to what are reported "causes" in NMED:

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

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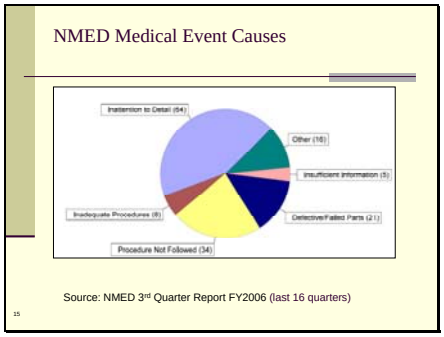
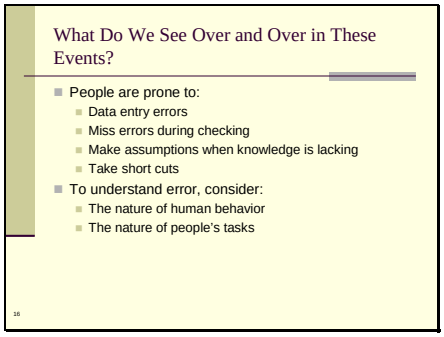


Can these identified causes help you find effective fixes?
The main purpose of finding the causes of events is to make sure that fixes can significantly reduce the likelihood of the same type of event recurring. But that means finding out what 'type of event' it is. (We will cover much more on this later 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



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.

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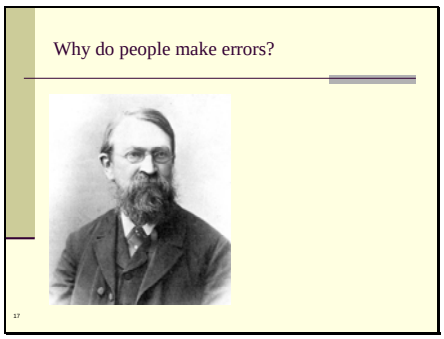

"Knowledge and error flow from the same mental sources, only success can tell the one from the other."
- Ernst Mach *Knowledge & Error* (1905)

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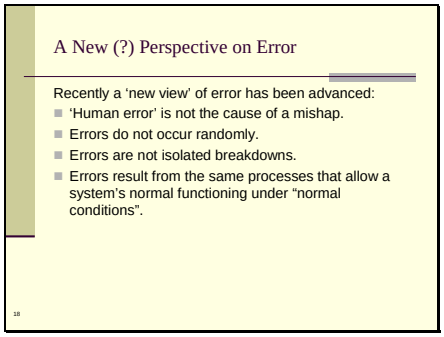

The idea that errors arise from the same behavioral mechanisms that, in most cases, allow successful human action is not, strictly speaking, new. See Mach's quote from 1905 (above)—this quote appears on the first page of James Reason's seminal 1990 book, *Human Error*.
NRC's ATHEANA (A Technique for Human Reliability ANAlysis) HRA method views human errors as the result of the interaction of basic psychological mechanisms with specific task contexts.

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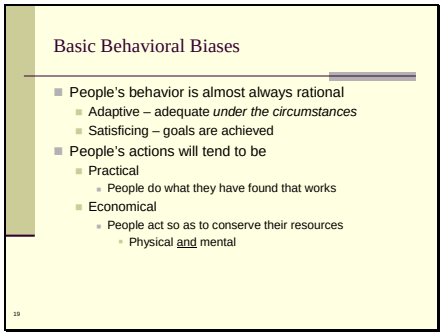

If these basic behavioral biases are kept in mind, it will be easier to anticipate or understand the actions that people will take or have taken.

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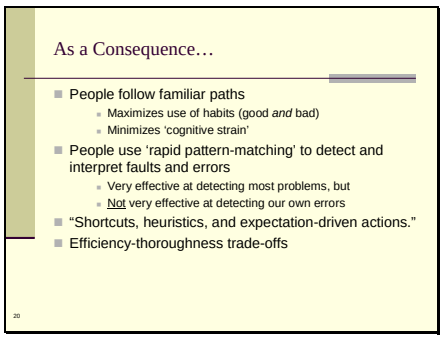

Based on these biases, people's behavior is largely predictable. As a result, we can anticipate many kinds of errors.

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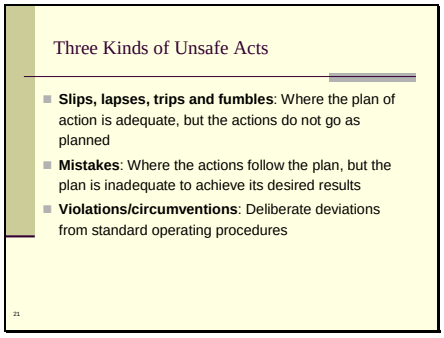
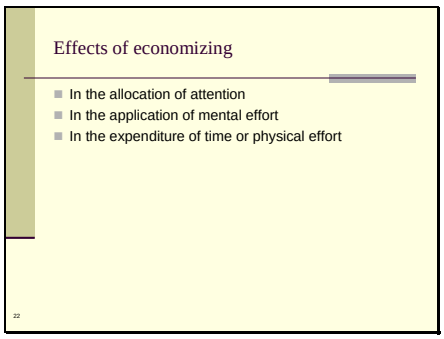


Behavioral scientists have identified a few basic types of error; they are distinguished by the role of intention in the action. In a *slip*, the person intends to do the correct action, but the execution is faulty. In a *mistake*, the intended action is not the correct one, typically owing to an incorrect 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 22



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

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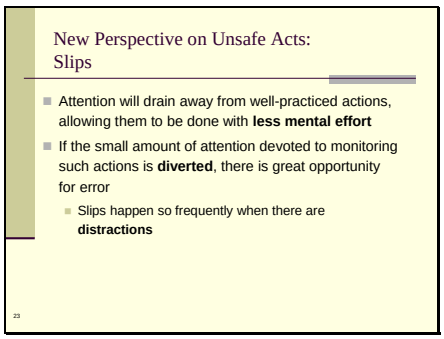
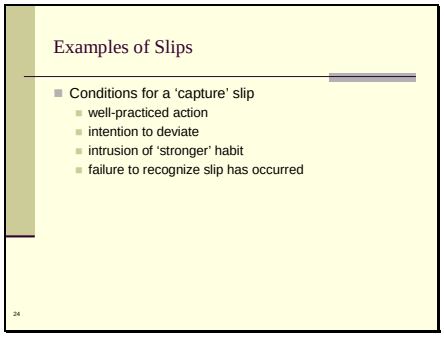


Slips will occur predictably when specific conditions are met. As humans, we try to give little *active* attention as we can to tasks we are performing. If we can do them by habit, without thinking, we do. Think of the amount of conscious effort we give to driving a familiar route in the car. Very little!

Slide 24



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.

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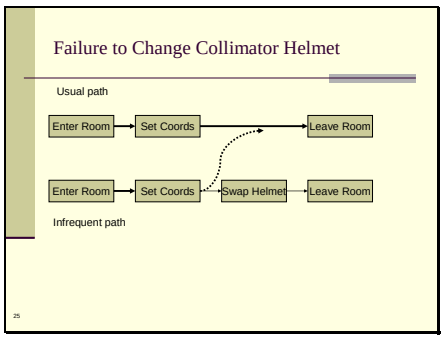

Failure to change the collimator helmet as called for in the treatment plan accounts for a significant number of the errors reported for gamma knife treatment. Positioning adjustments (i.e., setting coordinates) are made prior to every 'shot.' For efficiency, shots using the same collimation are grouped, 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.

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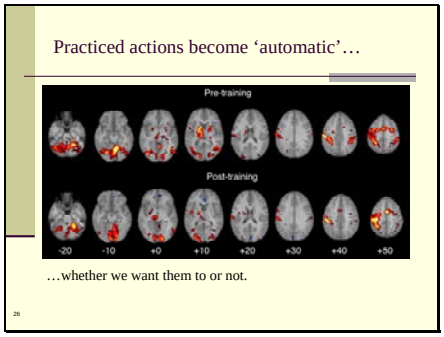

It can be shown that, when actions are performed repeatedly, the actions can become, to some extent, automatic. It seems that the resources required to support the activity somehow decrease. Figure 4, Poldrack et al. (2005). The neural correlates of motor skill automaticity. *Journal of Neuroscience*,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

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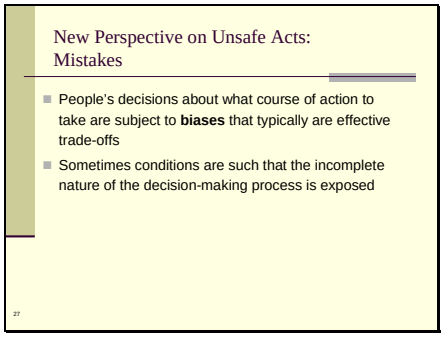

The new perspective is based on what we know about decisionmaking from experiments in the 1970's and before.

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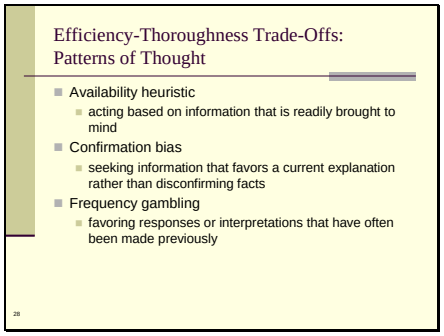

Without thinking about it, people make decisions based on their experiences. Because the world is to a large extent predictable and the ways in which things work don't usually change, these tendencies allow people to make the right choice in the great majority of cases, even without fully considering 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 29

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/circiumventions 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.

Slide 31

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.

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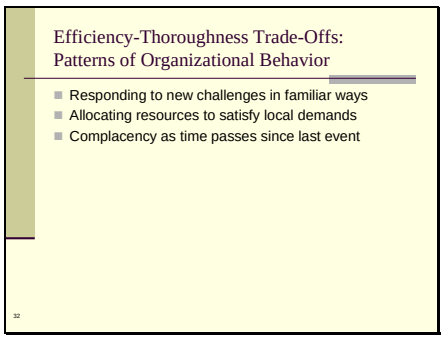

As shown later, events often have organizational as well as local causes. The actions and decisions taken by organizations in response to challenges and resource limitations can be understood in terms of the same behavioral biases introduced earlier.

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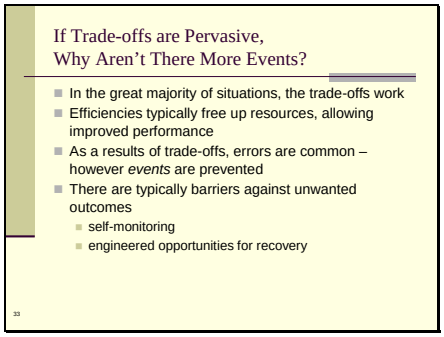

We have become very effective in using trade-offs without suffering accidents, especially as the pressure for increased efficiencies (and lower costs) grow. Errors can increase but most do not result in accidents.
Amalberti has observed several errors /hour is common in commercial aircraft cockpits & 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.

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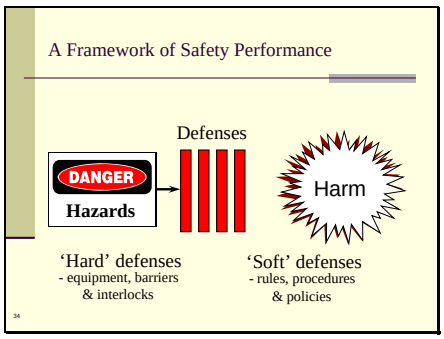
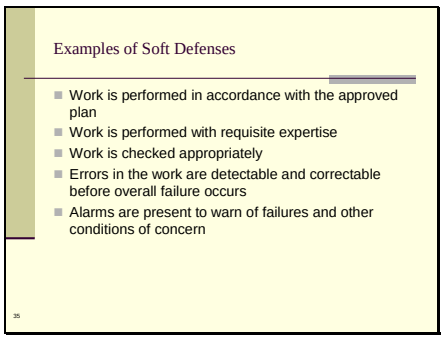


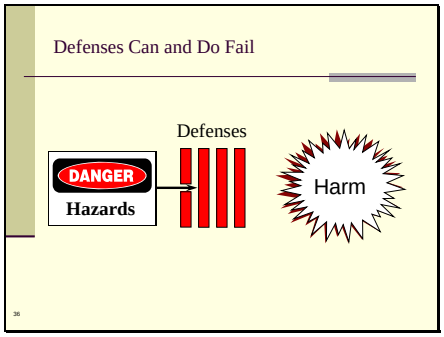
Harm is largely prevented by defenses that stop hazards from affecting patients and clinical staff. Often there are multiple defenses or barriers to prevent hazards causing harm, any one of which may be sufficient to prevent harm.
Defenses can be 'hard' (usually physical), like shielded safes for sources and interlocks (preventing access to radiation areas), or 'soft', like procedures and rules, that rely on people's compliance.

Slide 35



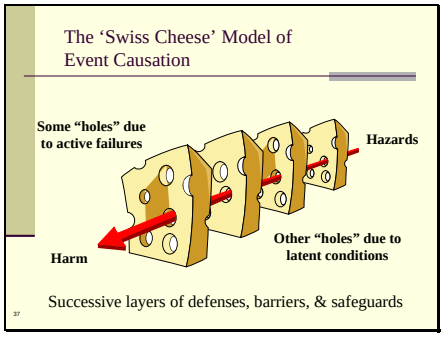
These are just a few examples.

Slide 36



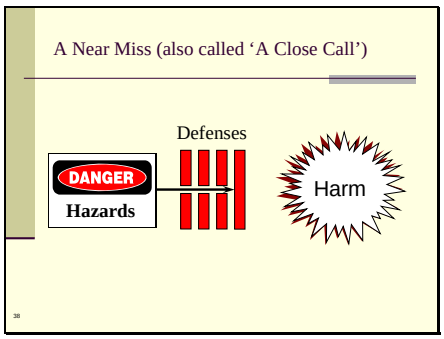
Defenses are never perfect. Equipment can fail. Rules can be broken. But because there are usually multiple defenses, most times these events go unnoticed since no harm occurs. Audits and inspections can spot failed defenses but these are often not very frequent.

Slide 37



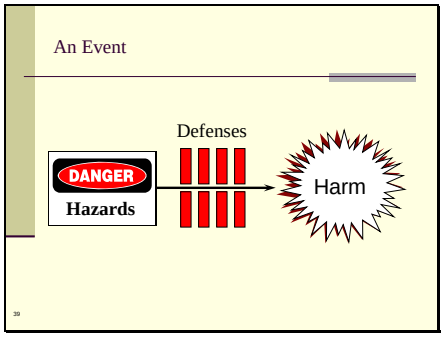
James Reason has described the real-world nature of defenses as being like slices of Swiss cheese. Most of the defenses are very effective and other parts have gaps. Some of the gaps occur because equipment fails at the time of the event (such as a failure of a radiation alarm). These are called 'active' 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.

Slide 38



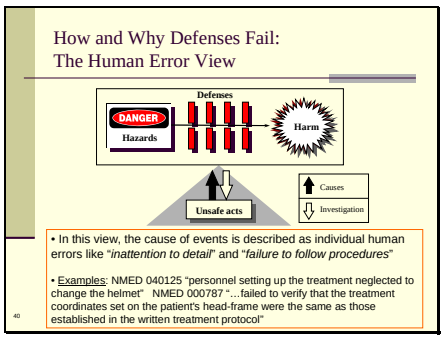
A near miss occurs when almost all the barriers fail and only the last one (which may be a matter of luck or a heroic human action) saves the day. These are often (but not always) visible to the participants at risk.
Often the last barrier is a human action taken at the time of the event. If it fails,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

Slide 39



When all defenses fail, there is an accident.

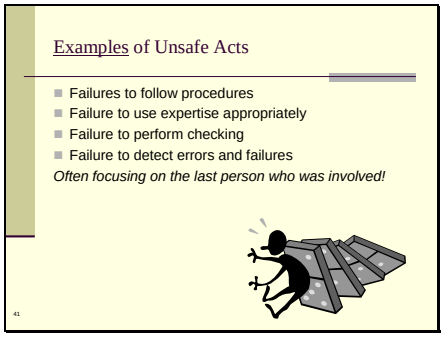
Slide 40



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

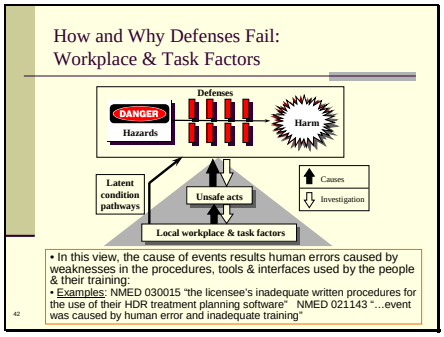
a perspective today. It is VERY hard to change the underlying tendencies of human behavior that are so often shaped by the tasks and the workplace setting.

Slide 41



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.

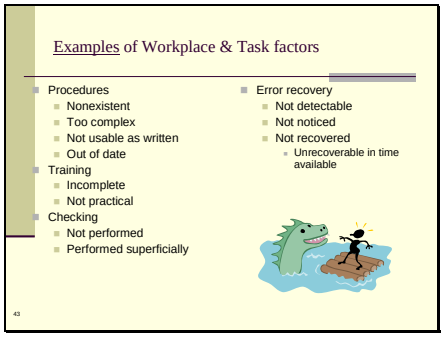
Slide 42



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

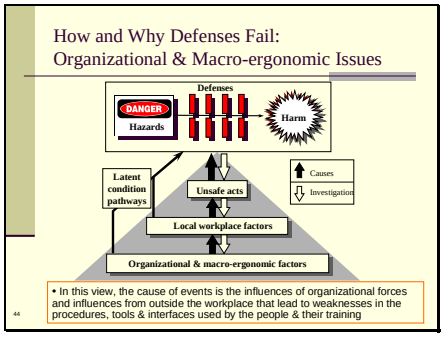
without necessarily a person making an error. It represents a gap in the understanding of the hazard.

Slide 43



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 44

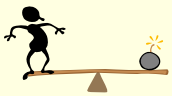


But the workplace and task factors do not exist in isolation either, but are products of management decisions in the organization. Has the organization learnt from previous incidents? Does it starve key areas important to safety of resources (like staffing and training)? What about providing workplace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

Slide 45

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 46

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)
- We will use the 'triangle model'

47

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

Slide 47

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

48

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

Slide 48

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

49

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 49

Typical HDR Brachytherapy Afterloader

50

Example of a HDR afterloader

Slide 50

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

51

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

Slide 51

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

52

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

Slide 52

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

53

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

Slide 53

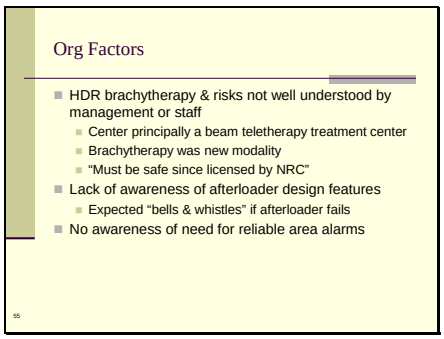
Workplace & Task Factors

- 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

54

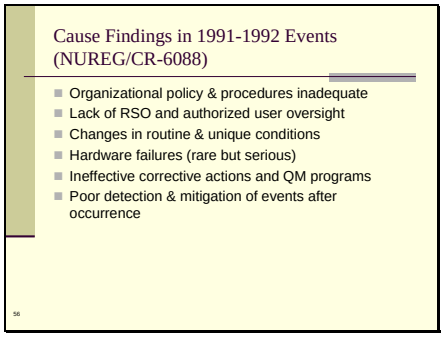
What were the factors that led up to the unsafe acts? Given these, is the actual performance a big surprise?

Slide 54



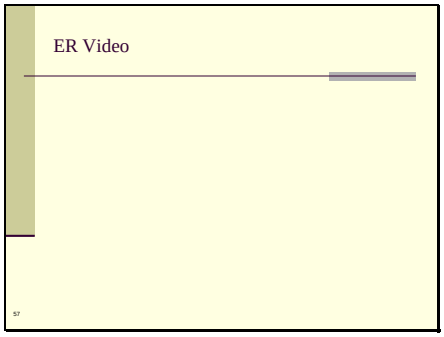
How would this be addressed today?

Slide 55



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

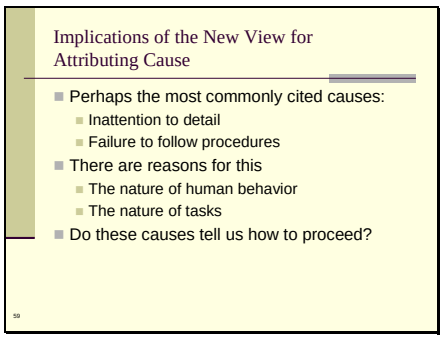
Slide 56



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*"

Slide 57

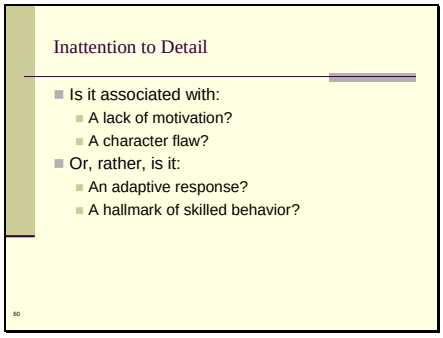


There are reasons why these are frequently cited as causes, and reasons for caution, when they are. But what can we do to reduce these causes of events?

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

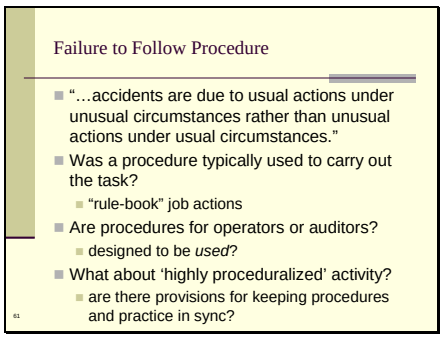
We will discuss each of these in turn.

Slide 58



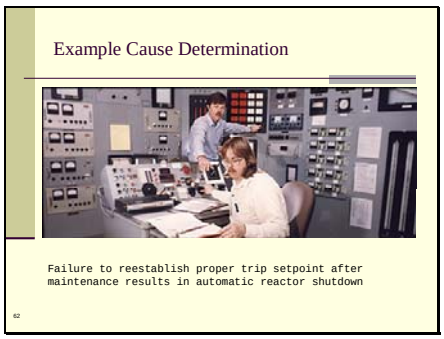
Constantly paying attention to detail is not what humans can do. What we do is learn a pattern of behavior that we find works, and then use it in "auto".
Think of driving a car—once we have mastered the needed skills, we drive without consciously paying attention to the details of steering the wheels, 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 59



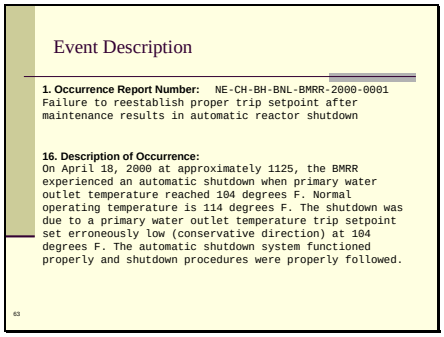
The quote is from Hollnagel (p.181?) This is the basis for newer HRA tools like ATHEANA.
Procedures are often written by well-intentioned designers who believe they know how work is done. But different facilities may work in different ways. Equipment usage changes over time. People learn more efficient 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 60



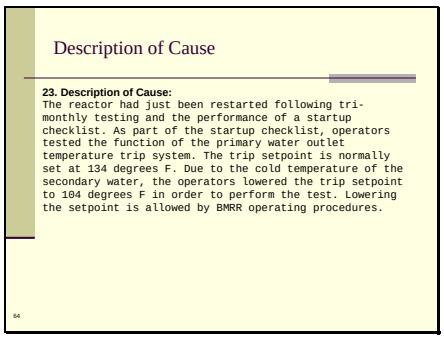
The Brookhaven Medical Research Reactor was used in the development and testing of radiation therapies and for the production of short-lived radioisotopes. It ceased operation in December 2000. While the process being controlled in this case was not a radiotherapy device, the particular equipment involved 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 61



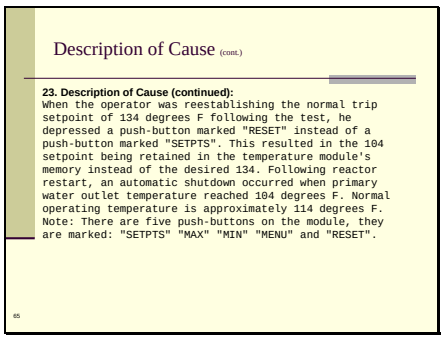
The BMRR had been shut down for quarterly testing. The restart procedure included testing of the high temperature trip system. (Like any reactor, the BMRR had temperature sensors at the cooling water outlets; excessive temperature triggers an automatic shutdown). The low temperature of the water during 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.

Slide 62



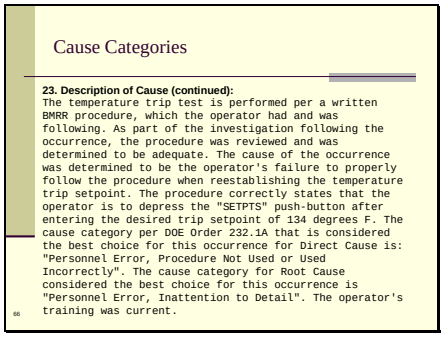
The normal operating temperature of the BMRR was 114 degrees F. For the test, the setpoint was lowered to 104 degrees F using the digital temperature controller. Following the test, the procedure calls for the normal high temperature setpoint in the controller (134 degrees F) to be re-established before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

Slide 63



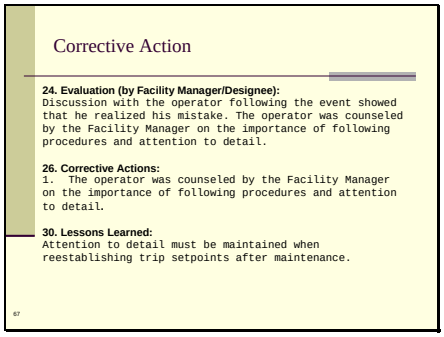
To restore the high temperature setpoint to its normal value, the operator changes the digital controller to the mode in which setpoints can be inspected and changed, caused the desired value to be displayed on the readout, and saves the setting. The event occurred because the operator did not press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

Slide 64



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 65



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?

68

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? 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 67

Newport INFT Temperature Meter

69

Slide 68

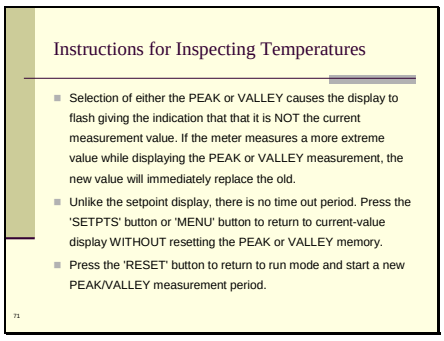
Instructions for Setting Limits

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

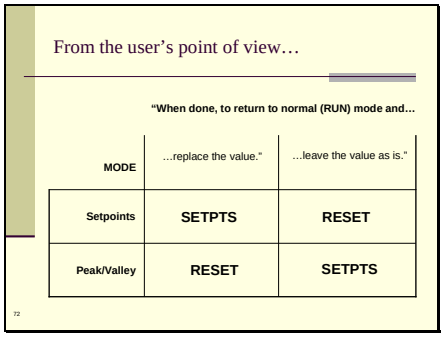
When the controller is in the SETPTS mode, the display cycles through the setpoints, showing each setpoint for 15 seconds; there are indicators below the numerals to show which setpoint is being displayed. Pressing the arrow keys pauses the cycling and allows the setpoint value to be changed. If nothing further is done, the device will continue through he 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.

Slide 69



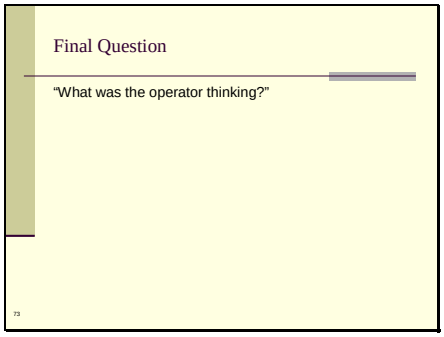
In the Peak/Valley mode, the highest or lowest value measured since the device was last reset is shown (with a flashing display); the display remains in this mode until the operator takes an action. To return to the normal measurement mode without resetting the peak/valley memory, operator can press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

Slide 70



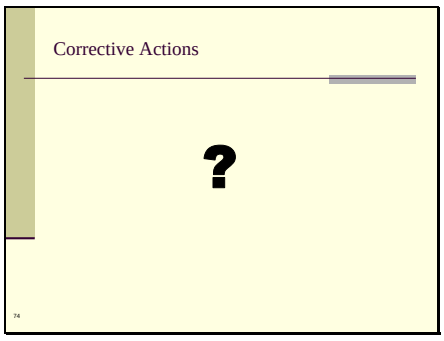
Owing to the need to conserve space, there is not a separate button for each function; buttons serve different functions depending on the mode that the device is in. The designers' choice of which buttons to use for the meter's functions (and what labels to use for the multi-function buttons) probably 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 71



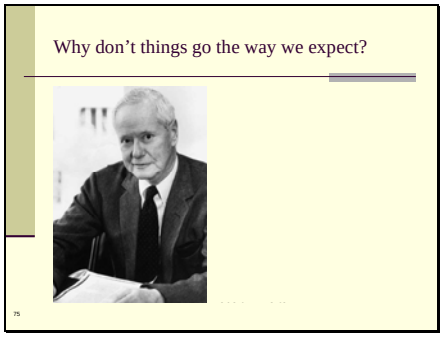
Was there a subtle user trap in this activity?

Slide 72



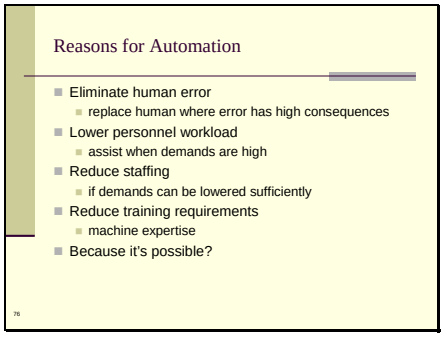
There is no doubt that the error is less likely when the operators are attending closely to the procedure and the required actions. However, in light of our understanding of how attention naturally 'drains away' from routine actions, we may question whether simply insisting that operators pay more attention 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 73



The failure to anticipate the consequences of actions & decisions…

Slide 74



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.

Slide 75

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

77

Slide 76

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)

78

Slide 77

"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)

79

Slide 78

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

80

Slide 79

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

81

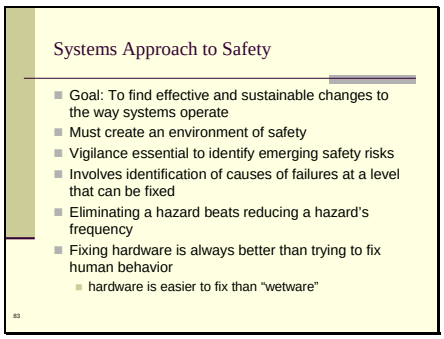
Slide 80

However…

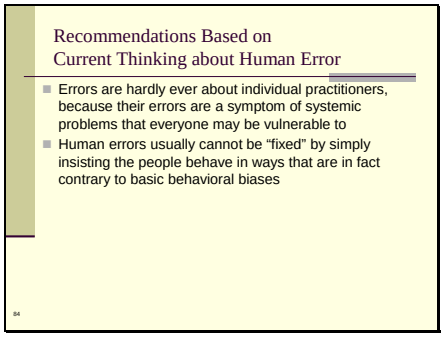
- Software newly upgraded for planning and treatment tools, to allow automatic transfer of data from planning to treatment program
  - Reduction in human errors expected because potential failure mode eliminated
    - Removed manual transcription of data from planning form to treatment software
    - 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

82

Slide 81

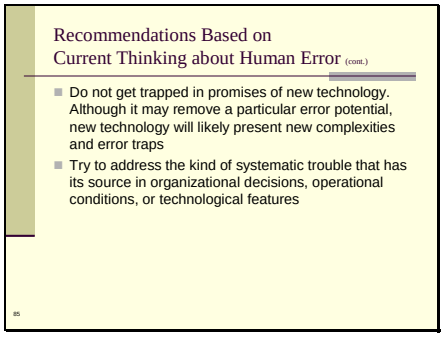


Slide 82



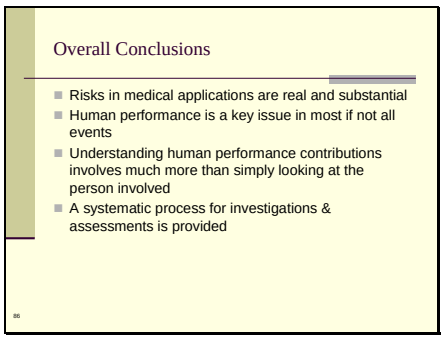
Dekker p.64

Slide 83



Dekker p.64

Slide 84


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
86