Providing a Risk-Informed Approach to the Regulatory Oversight of Medical Uses of Radioactive Materials

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Abstract: The safety of patients undergoing radiation therapy procedures is receiving increased attention from both the popular press and the scientific community. In the US, the Nuclear Regulatory Commission (NRC) is responsible for public health and safety through regulating the use of byproduct and other nuclear materials, including the oversight of patient safety in medical uses of nuclear materials. For some years, the NRC has been using a risk-informed perspective to examine issues surrounding medical events involving inappropriate applications of radiation therapy. By far the largest numbers of events involve human performance issues.

The NRC has an established history of looking beyond simplistic causes of accidents and events, such as "human error" to understand underlying systemic problems. Human reliability analysis is an important part of these efforts, focusing on contributions of humans to the resilience of systems and to possible adverse consequences of human errors or oversights. Issues identified in reviews of medical events for a range of therapies relate to the increased use of automation, work practices, and user interfaces. Ongoing research is focused on evaluating medical events and developing guidance regarding how to approach the investigation and prevention of human performance problems, given the limits of the regulatory authority of the NRC.

Keywords: HRA, Medical Isotopes, Patient Safety, Radiation Therapy.

1. INTRODUCTION

A series of articles by Bogdanich [1] noted that in New York State, between January 2001 and January 2009, there were 621 mistakes in radiation therapy; most mistakes had two or more causes. Errors included wrong dosages or even the wrong patient treated. The identified causes included miscalculations, and misuse of positioning equipment – causes that have been identified in many dosing errors. We note that the vast majority of these events involved machine-based beam teletherapy, a treatment modality for which the US Nuclear Regulatory Commission (NRC) has no oversight. In 1999, the United States Institute of Medicine (IOM) issued the report *To Err Is Human*, which brought US national attention to patient safety and medical errors [2]. According to the IOM report, between 44,000 and 98,000 people die each year as a result of *preventable* medical errors. With respect to medical errors, Brown [3] related that in health care there is a 'time honored tradition' of blaming the nurse or assistant for anything that goes wrong, concluding that the physicians think only of how the treatment will succeed, often neglecting to consider worst case scenarios. The article indicated that one further effect of this attitude was to reduce communication between members of the medical team and reduce the likelihood that a junior staff would speak up for the patient when a problem is noted. Similarly, the article cited a report by the US Institute of Medical Safety Practices 2004 survey that found that these types of poor communication degraded patient safety.

The NRC reviews the licensing and application of only the use of medical devices using nuclear isotopes for radiation therapy; the devices themselves are approved by the US Food and Drug Administration. Nor does the NRC review the physician's treatment of medical conditions or the prescription of therapies. In the nuclear-power arena, human reliability analysis (HRA) is used to determine the potential risk from human error within a system. As such, the purpose of this research is to explore the potential causes of human error in radiation therapy, and to risk-inform the license-review process so that latent failures can be detected and removed before an event can occur.

2. ROOT CAUSE ANALYSIS

In the U.S. nuclear power industry, the NRC requires that [4]:

> "…In the case of significant conditions adverse to quality, the measures shall assure that the cause of the condition is determined and corrective action taken to prevent repetition."

Performing a systematic root cause analysis and identifying the direct, contributing and root causes for human performance problems aids in ensuring that the problem is understood with sufficient depth to support the development of effective correction actions [5].

The recurrent theme with these definitions is that the depth of investigation should be sufficient to lead to corrective actions that eliminate or reduce significantly the likelihood of this and similar failure events. While from the nuclear power field, the healthcare community has developed a similar approach to defining root causes and corrective actions. Specifically, the Joint Commission on the Accreditation of Healthcare Organizations (hereafter "The Joint Commission")[1] requires hospitals and other health providers to perform root cause investigations on sentinel events. The Joint Commission defines a sentinel event as:

> "any unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injuries specifically include a loss of limb or function. The phrase "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome." [6]

The list of specific events to be included as sentinel events only partly overlaps with the NRC's definition of a medical event. Specifically for radiotherapy, doses in excess of 1500 rad (15Gy), any dose to the wrong site, and doses in excess of 25% above the planned dose are considered sentinel events by The Joint Commission. The Joint Commission's discussion of a root cause [6] encompasses:

- "Fundamental reason(s) for the failure or inefficiency of one or more processes.
- Point(s) in the process where an intervention could reasonably be implemented to change performance and prevent an undesirable outcome.
- The majority of events have multiple root causes."

Figure 1 shows the relative contributions of The Joint Commission's categories for all sentinel events reported in 2010 (the last full year at the time of writing this report), and Figure 2 shows the breakdown of root causes for just the category of radiation overdoses [6]. Seen together, both The Joint Commission and the nuclear industry's approach to root-cause analysis and corrective-action planning are similar. Both require investigating safety-significant events beyond simply describing the surface actions of the people and any hardware faults, to identify underlying influences that can be modified. A good example of the levels of analysis to accomplish this level of understanding is discussed in "A Tale of Two Stories" [7]. This document was produced following a workshop on patient safety and took two approaches to the investigation of three actual medical events to illustrate that simply taking a look at the actions of people without digging down into the processes and context leads to ineffective changes.

3. US NRC MEDICAL EVENTS

US NRC regulations (Code of Federal Regulations, Title 10 Part 35 Subpart M Section 35.3045, Report and Notification of a Medical Event) requires the reporting of events associated with the treatment of patients with radiation therapy using byproduct materials in the following situations:

> (1) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv effective dose equivalent, 0.5 Sv to an organ or tissue, or 0.5 Sv shallow dose equivalent to the skin; and
>
> (i) The total dose delivered differs from the prescribed dose by 20 percent or more;
>
> (ii) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

[1] An independent, not-for-profit organization, The Joint Commission accredits and certifies health care organizations and programs in the United States.

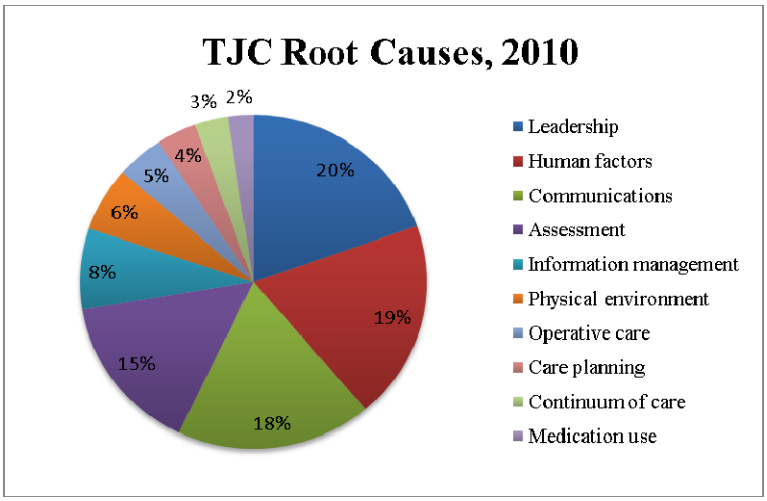

Figure 1. Root causes for all sentinel events, 2010 [6]

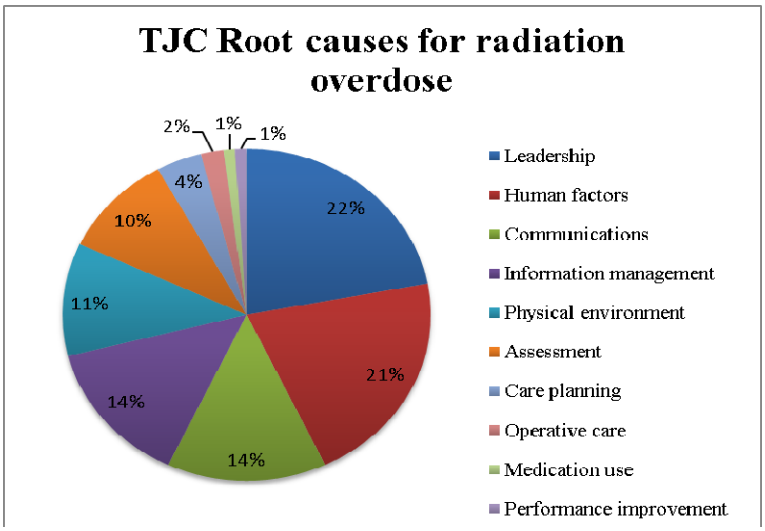

Figure 2. Root causes for sentinel events involving radiation overdoses, 2004 - 2011 (3rd quarter) [6]

(iii) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

(2) A dose that exceeds 0.05 Sv effective dose equivalent, 0.5 Sv to an organ or tissue, or 0.5 Sv shallow dose equivalent to the skin from any of the following--

(i) An administration of a wrong radioactive drug containing byproduct material;

(ii) An administration of a radioactive drug containing byproduct material by the wrong route of administration;

(iii) An administration of a dose or dosage to the wrong individual or human research subject;

(iv) An administration of a dose or dosage delivered by the wrong mode of treatment; or

(v) A leaking sealed source.

(3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

The US NRC's Nuclear Materials Event Database (NMED) program[2] provides a single repository for medical event reports. As part of this program, events are classified according to cause. Figure 3 shows the breakdown of causes of medical events for FY 2011, up to the 3rd quarter, and is typical of other years.

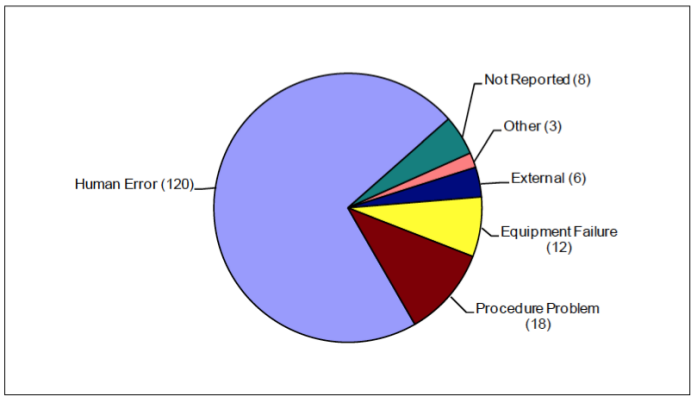

Figure 3. NMED Analysis of Causes of Medical Events, 3rd Q 2011

4. IDENTIFYING CAUSES OF FAILURES

There are striking similarities between the causes identified in Figure 3 by NMED and those by The Joint Commission for radiation therapy events in Figure 2. NMED does not differentiate the category of human error but this category typically could be expected to include The Joint Commission's categories of leadership, human error and communications as a minimum. In The Joint Commission's case, therefore, these human-factors categories amount to 57% of identified causes, and in the case of NMED, human factors amounts to 72%; that is, in both cases, the dominant contributing cause.

4.1 Evolution of Ages of Safety

It is interesting to note that these types of root causes seem to be characteristic of what has become known as the "age of human error" in the history of safety management [8]. This age came to prominence in the 1960's and 1970's to replace the earlier view that accidents were primarily a result of simple technical failures; human error was treated just like a mechanical fault—a direct cause not requiring further explanation. For example, accidents could be described as resulting from "operator error" or "pilot error" with no further explanation. In the age of human error, accidents like those at Three Mile Island in 1979 were explained in terms of human fallibility. In this age, the move was to develop an understanding of the factors that lead to an increased likelihood of errors, such as the influence of human-machine interface design, the effectiveness of training, use of procedures, and so on. This allowed designers and facility owners to develop designs and practices that reduce the occurrence of human errors.

Subsequently, in the 1980s the focus of understanding accidents moved to the area of safety culture and management, particularly as a response to the Chernobyl accident as well as other lesser (at least in scale) accidents such as the sinking of the ferry, *Herald of Free Enterprise,* [9] and a series of major railway accidents in the UK. While the topic of safety culture and management influences has been included as a factor in healthcare safety programs (it is listed in The Joint Commission's list of root causes), there are few approaches to identifying related responses to events with such causes identified.

Hassall, et al., [10] have described the progression past these three eras. A fourth era emerged that represented an integration of many of the previous perspectives, recognizing that technical failures and human errors leading to accidents do not occur in a vacuum. Rather, management is only one of the forces at work in shaping behavior. Perhaps the archetypal model of this era is the so-called "Swiss Cheese" model of Reason [11] that shows how it is the *combinations* of factors at multiple levels of the organization—each with its own sets of vulnerabilities—that are necessary to allow accidents to occur. In order to respond to events using this model, there is considerable need to evaluate and audit the different kinds of factors at the

[2] NMED is not a publicly accessible database

multiple levels in order to uncover their gaps, or "holes" in the "Swiss Cheese". This can be a demanding and resource-intensive effort.

Hassall, et al., go on to describe the emergence of the so-called fifth era of safety analysis; this is aimed at understanding the complexity of events rather than treating them as combinations of independent failures. No single commonly accepted term has yet emerged to describe this perspective, though the terms *Resilience*, *Complex Adaptive Systems*, and *The Adaptive Age* are used to describe it. Its characteristics include: (1) that, unlike all the previous eras that rely on continuously analyzing events and learning from them, the goal is to anticipate and prevent or mitigate the circumstances that can lead to accidents such that nothing appears to happen; (2) that successful safety performance is the result of positive adaptation, not eliminating bad behaviors and thus we need to learn from successful performance as well as failures; and (3) that understanding accidents and other events requires models based on work as actually performed (as opposed to models based on the designers intentions – a prescriptive approach used in earlier phases).

4.2. The Human Performance Perspective

What are the implications of the human performance perspective for studying and preventing future radiotherapy incidents? Studies dating as far back as World War II have focused on how to design technology and processes to best support human performance in aviation, manufacturing, power plant design, healthcare, and other domains [12]. As technological innovation has advanced, so has our understanding of human cognition, including decision making, perception, and judgment. Drawing from human performance issues that have been identified and studied in other domains, we have identified 6 key human performance issues in the use of isotopes for radiation therapy:

- "Black box" aspects of automation
- Repetition and automaticity
- Computer interfaces and mode errors
- Computer interfaces and data entry errors
- Cross checking and independent verification
- Prospective memory challenges

We reviewed events found in the Nuclear Medical Events Database (NMED) to identify examples of human performance issues for discussion and illustration. Although the reports were not written for this purpose, we found the NMED database to be a rich source of information. Each of the 6 key issues is discussed in turn.

4.2.1 "Black Box" Aspects of Automation

The impact of increasingly sophisticated automation, both positive and negative, has been well documented in the context of healthcare [13, 14], as well as with automated cockpits [15, 16] and spacecraft incidents [17]. As automation becomes increasingly sophisticated in pursuit of simplifying workflow, often the operator becomes further removed from the task, transitioning from an active role to a more supervisory and passive role. Not only is it more difficult for the operator to maintain engagement in the task from this supervisory perspective, but the system becomes a black box, making it harder to detect and notice errors and anomalies with fewer direct cues about how the task is being accomplished [18]. These "black box" issues are compounded in radiotherapy where automation *purposefully* keeps the practitioner at arm's length from the process in order to limit radiation exposure (typically, in other domains, the 'distance' is an unwanted side effect of automation). The fact that operators cannot actually see or feel the device that is transporting the source is a particular problem in brachytherapy; there is no true compensatory feedback feature. For example, in one intravascular brachytherapy event, an error resulted because the operator could not see a kink in the delivery catheter. In this case, the kink was not substantial enough to affect the flow of sterile water used to send and retrieve the source train, but it was severe enough to prevent accurate dose delivery. Because the source train traveling the length as planned, no sensors detected the problem, no error messages or alarms appeared, and the operators had no way of detecting that the actual dose did not travel the full length of the catheter. The kink was discovered the next day during medical physics quality checks.

4.2.2 Repetition and Automaticity

Radiotherapy technology requires a large investment and is in limited supply. Its increased use results in benefits in that more patients receive treatment in a timely manner, and costs for the device are spread over many patients. However, administering multiple treatments per day involves a significant amount of repetitive behavior. This repetition can lead to finely honed skills and automaticity that allows for efficiency in completing repetitive tasks. While this type of expertise is generally adaptive, skill-based automaticity is vulnerable to certain types of error. Generally speaking, error in skill-based behavior occurs when there are deviations from routine and distraction (competing demands for cognitive resources). Unfortunately, both of these circumstances occur in the medical context. The nature of human beings (and disease) is a source of constant variation, which, although manageable in the vast majority of cases, can occasionally strain skill-based behavior. The nature of radiotherapy facilities is such that technicians are subject to interruptions and the need to do two (or more) things at once. Under these circumstances errors in skill-based behavior are infrequent but inevitable.

In one vascular brachytherapy misadministration incident, an error was made in the treatment plan because the physician used a device subtly different from the one normally used. The physician had extensive experience with a device that uses the diameter of the artery in treatment planning calculations. On this day, however, the physician used a different device, which uses the artery radius in calculations. Consistent with the routine for the more familiar device, the diameter was entered, which resulted in an incorrect dosimetry calculation, with an actual dose of 14.6 Gy being administered rather than the prescribed 8 Gy.

4.2.3 Computer Interfaces: Mode Errors

Mode errors occur when the operator performs a task appropriate to one mode when the device is in another mode. Some wrong site procedures have been attributed to the use of the MRI in caudal mode rather than cranial mode – a change that is not obvious to the physician reading the images. In these cases, the physician assumed the images were taken in the more common mode (cranial mode) and interpreted the image as mirror of the actual anatomy, resulting in a wrong site procedure. Situations in which the user's understanding of a device's actions is based on an incorrect understanding of the current mode have been well documented in a range of devices [19]. Strategies for decreasing mode errors include:

1. *Eliminating Modes* – Adding dedicated control and display devices normally eliminates multiple modes, but this is not always possible for equipment where there may be insufficient space. Also, adding more devices may increase the likelihood of choosing the wrong one.
2. *Making Modes Distinct* – Ensure that the user is aware of the currently active mode by providing distinct, salient indications of mode state.
3. *Coordinating Inputs Across Modes* – Ensure that a command does not have very different meanings in different modes.

A special mode error consideration relates to systems that change modes automatically. If automatic mode changes must be used, automated systems should be designed to inform the operator of their current operating mode, mode transition points, limits on operator actions, and circumstances under which the operators need to assume control. In addition, the operator must be aware of indications from the automated system or other means, of how to assume control without "fighting" the system or causing unnecessary transients.

4.2.4 Computer Interfaces: Data Entry

Errors associated with data entry, including digit transpositions and misordering of parameters are particularly worrisome in the context of developing a treatment plan. These types of mistakes are easy to make, difficult to detect, and can have serious consequences for the patient. The use of default values can increase vulnerability to data entry errors. In an event involving high dose-rate remote afterloader brachytherapy for breast treatment, the operator failed to change the default from "start at connector end" to "start at tip end," resulting in mispositioning of the source in the patient's body. Further, it is important to note that at this facility, all HDR procedures started at the connector end *except* breast treatments. Thus, one had to remember to change the default only for breast treatments, leaving the default untouched in all other cases. In a similar incident, the dosimetrist appropriately clicked the "catheter tip" selection, but s/he did not

highlight and choose “catheter tip.” The computer cursor stayed on the “connector end” selection. In this case, the operator mindfully intended to change the default and believed it had been accomplished successfully. The awkward interface design was misleading. While intended to decrease data entry burden, the use of a default value makes it possible for the software to proceed without operator interaction with the default field. Although operators intend to inspect each field when creating a treatment plan (and generally do), in a busy clinic with many distractions errors of this type are likely.

Fortunately, data entry errors appear to be a diminishing problem as electronic transfer of data from treatment planning systems to therapy devices becomes more common. However, it is unlikely that data entry errors will go away completely. Therefore, it is important to consider strategies for detecting errors (as quickly as possible) and recovery from the error.

4.2.5 Independent Verification of Treatment Parameters

Because there is no way to eliminate errors altogether, checking of one kind or another is relied upon to intercept the inevitable errors. As a first level of checking, software programs often present a warning if an entry is out of a typical range. While very useful at catching potential errors of magnitude, many errors will go unnoticed by this type of algorithm. As a result, most facilities require multiple sign-offs on a treatment plan before treatment can be administered. Software can be designed to support these types of checks, preventing treatment until the proper signatures have been entered electronically.

In spite of these precautions, there is no shortage of examples of events in which an error was made and the ‘double-check’ or sign-off policy failed, allowing a misadministration. In one procedure (NRC08-03), a patient being treated for a metastatic brain tumor received treatment to the wrong side of the brain because the healthcare team was working with reversed MRI images. Prior to the treatment, the medical physicist, authorized user physician, and neurosurgeon reviewed the treatment plan but failed to identify that the MRI images were reversed. The reversed MRI images were scanned into the device treatment planning computer, and a treatment plan was generated based on the reversed MRI images under the assumption that they were not inverted. The authorized user physician and neurosurgeon reviewed and approved the treatment plan generated from the reversed MRI images, and yet again the reversed MRI images were not recognized. Treatment was administered and the patient received treatment to the wrong site.

There are several reasons why errors may not be detected in spite of multiple sign offs. Checks mandated by good practice or administrative procedure may not actually be performed. In some cases, personnel may 'sign off' without having inspected the work. In such cases, personnel doing the check, believing that the work is being done reliably, will tend to “see” what they expect to see, even when the correctness or incorrectness involves no interpretation. Limiting or eliminating the effect of expectancy can improve the effectiveness of checking. Other elements that increase the effectiveness of cross-checking for error detection include:

- *Different perspectives* – The cross-checker(s) should have a different perspective from the developer of the treatment plan, such as different goals, responsibilities, functions, authority, stance, expertise, resources, methods, or knowledge/ information.
- *Knowledge of “typical mistakes”* – An experienced cross-checker(s) who has knowledge of typical mistakes or vulnerable aspects of the process is more likely to detect errors.
- *Observable process* – Insight into the plan development process may increase the cross-checker’s engagement and ability to mentally simulate potential errors.
- *Visible rationale/intent* – Insight into the planner’s rationale or intent behind a plan provides important background for the cross-checker, and may expose inconsistencies or gaps.
- *Focused review* – Distracters or responsibilities competing for the cross-checker’s attention can reduce the effectiveness of cross-checking. The cross-checker’s time and attention should not be consumed by production pressures or competing cognitively challenging tasks.
- *Big picture view* – Cross-checkers must be able to detect anomalies. In order to do this, the cross-checker must have knowledge of the procedure to be accomplished and the context in which it occurs. The use of inexperienced staff, or automated software that cannot take into account contextual variability (i.e., overloaded staff, a potentially disruptive patient), is unlikely to be effective. [20]

4.2.6 Prospective Memory

Prospective memory involves remembering to perform an action at the appropriate time [21]. Dismukes [22] distinguishes three features of prospective memory:

> *(1) an intention to perform an action at some later time when circumstances permit, (2) a delay between forming and executing the intention, typically filled with activities not directly related to the deferred action, and (3) the absence of an explicit prompt indicating that it is time to retrieve the intention from memory – the individual must "remember to remember." ...Typically, if queried after forgetting to perform an action, individuals can recall what they intended to do. (p. 2242).*

Because the healthcare setting requires multi-tasking and is characterized by frequent interruptions and distractions, healthcare workers carry a particularly high load for prospective memory [23, 24]. However, even more mundane work settings leave us vulnerable to prospective memory errors. Reason [11] highlights the common error of leaving the last page of your original in the photocopier, termed an example of a premature exit error. When manually feeding a document, you must remove each page to place the next one. For the last page, however, there is no cue to remind you to remove it.

An analogous event from the healthcare domain is remembering to change the collimator helmet during gamma knife treatment. This is one example of a prospective memory challenge that has occurred in multiple events. All shots for a given helmet size are run consecutively; then, the helmet is changed and all the shots for the second helmet are run. Therefore, the most common sequence of events is to make the settings, leave the room, and administer the shot. The operator has every intention of changing the helmet at the appropriate time for the next round of shots, but there is no cue telling the operator at the right moment that *this time* the collimator helmet should be changed after you make the settings but before you leave the room. Strategies for reducing prospective memory load generally involve the introduction of deliberate cues based on an event or on time [22]. Often they seem obvious after the prospective memory challenge has been identified. For example, newer versions of the Gamma Knife run a check before the treatment is administered and will not proceed with an incorrect collimator helmet.

5. CORRECTIVE ACTION PROGRAMS

In general, healthcare is preoccupied with safety management principally at the second era of safety management, and to a lesser degree the third era—those of human error and management. For example, on the US Agency for Healthcare Research & Quality (AHRQ—the Federal government agency responsible for improving patient safety) website there is a preponderance of tools for improving patient safety that are focused on improving individual human performance. Similarly, the Institute for Healthcare Improvement (IHI) (a major not-for-profit organization aimed at improving patient safety) indicates an emphasis on skills improvement for human performance—see, for example, the topics listed on their website [25]. However there is also an interest in the High Reliability Organization (HRO) approach by healthcare organizations [26]. This approach represents a kind of midpoint between a human factors and a management perspective in that it discusses the desirable attributes of an organization to be highly reliable, but in practice these are primarily related to attitudes of people (e.g., a focus on preventing failure).

5.1 General Approach to Corrective Actions

In the safety industry in general, there has been a general emergence of what is termed a "safety hierarchy"—a hierarchy of safety measures that can lead to greater or lesser improvements in safety. There are a number of versions but all follow the same general structure. In its simplest form this structure is [27]:

1) Design; 2) Guard; 3) Warn.

The Safety Hierarchy is a standard safety practice that reduces the impact of a hazard by a redesign to remove the hazard [27]. That is not always possible, however, in which case a guard would be used to separate the user from the hazard. If that is not possible, a warning is put in place. While based on this general principle, there are many individual interpretations. One particular version that seems relevant here is the Safety Decision Hierarchy [28]:

1. Eliminate hazards and risks through system design and redesign;
2. Reduce risks by substituting less hazardous methods or materials;
3. Incorporate safety devices (fixed guards, interlocks);
4. Provide warning systems;
5. Apply administrative controls (work methods, training, etc.); and
6. Provide personal protective equipment.

In essence, warning or methods that rely on the user are not as likely to prevent reoccurrence as methods that remove the source of the event. Green [27] ordered the methods based on their reliance on the human and their decreasing order of effectiveness:

- *Those which do not depend on user behavior - design, use of less hazardous materials and guards that are tamper-proof and that provide complete separation of the user from the hazard;*
- *Those which may depend somewhat on human behavior - guards that are not complete or tamper-proof. In some cases, users can circumvent guards, forget to use them or actively attempt to defeat them, i.e., disabling a lockout;*
- *Those which depend almost entirely on user behavior - warnings, training, procedures and protective clothing (since the user must put them on).*

The safety hierarchy, however, is not a scientific principle but instead is a useful rule-of-thumb [27].

5.2. Corrective Actions Approach to Medical Events

A review of 19 events reported in NMED associated with HDR brachytherapy for the period 2009 to late 2011 that identify "human factors" as the root cause. Corrective actions include: new or modified procedures (100%), staff retrained (56%), person reprimanded (11%), new management plan (6%), and new equipment (6%). One event had no corrective action identified and was removed from the analysis. Most of the remaining events identified two or more corrective actions.

In comparing these corrective actions to the safety hierarchy discussed above, it is clear that these responses are very much towards the least effective end of the spectrum. Even though the vast majority of events are reportedly associated with "human factors" (Figure 3 above), there seems to be minimal consideration of actions that might improve the design or usability of the systems. To quote Reason [29]: *"We cannot change the human condition, but we can change the conditions under which humans work."*

6. CONCLUSIONS

An accident is most often the result of latent errors within the system that have gone unnoticed or are undetected by the user until conditions trigger an unexpected interaction. The person whose action precipitates the event is usually the last link in a chain of latent errors that inhabited the system, waiting for the environment to let them impact performance. It is overly simplistic and ineffective to 'blame, shame, and retrain' the person who erred. It is more effective to analyze the system to determine what pre-existing factors set up the event. In order for that to occur, users and designers must adopt a 'failure mentality'. One way to explore a system with a 'failure' mentality is the defense-in-depth approach taken in the arena of nuclear power. In this approach, a secondary or even tertiary defense lies between any individual failure and the event. However, nuclear power production does not have the high degree of variability that is characteristic of radiation therapy. In medicine, each individual patient is different. Tumors occur in different locations, patients are different sizes, and new applications for equipment are determined. Health care providers must multi-task and are frequently interrupted, so the flow of the task and thought process are disrupted. These characteristics are often not supported in the systems that are used, and thus patient safety is degraded. The use of human reliability concepts to understand and prioritize corrective actions will permit the systemic improvements whose absence seems to limit safety improvements in healthcare currently. Prior work to explore such concepts is reported in [30].

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