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NUREG-2170

A Risk-Informed Approach to Understanding Human Error in Radiation Therapy

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A Risk-Informed Approach to Understanding Human Error in Radiation Therapy

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ABSTRACT

A critical part of the U.S. Nuclear Regulatory Commission (NRC) mission is licensing and regulating the use of byproduct materials, including in radiation therapy. More than half of the reported misadministration events in the medical use of byproduct materials in radiation therapy are attributed to human error.

In support of the NRC recommendation to continue to apply and extend a risk-management framework (as discussed in NUREG-2150 [1], *A Proposed Risk Management Regulatory Framework*), this report discusses an approach to improve patient safety that is based on human reliability analysis (HRA), traditionally part of probabilistic risk assessments (PRAs). Using HRA and related disciplines, four key elements for improving patient safety are highlighted: 1) improved understanding of human error in radiation therapy; 2) improved ability to anticipate errors; 3) effective strategies for supporting humans in managing complexity; and 4) methods to evaluate and monitor the effectiveness of corrective actions. This report also includes reviews of studies conducted by the NRC using human reliability analysis methods and recommends the continued application of these methods. Successful safety improvements from commercial aviation and nuclear power industries are examined and offered as an example of the feasibility of this approach. It is important to emphasize that target audiences for this document include, but are not limited to, decision makers, regulators, designers, and external vendors engaging with the risk-informed framework.

FOREWORD

It is widely recognized that human error is an important contributor to significant events for a variety of complex technologies. Studies of various technologies have examined the accident record and developed estimates for the contribution from human error. For commercial aviation, industrial applications, and nuclear power, these estimates typically range from 70 percent to 80 percent. Among the complex technologies that the U.S. Nuclear Regulatory Commission (NRC) regulates are commercial nuclear power and the use of byproduct materials in radiation therapy. As such, the human error contributions for these two technologies have been of particular interest to the NRC.

For commercial nuclear power, the 1979 event at Three Mile Island Unit 2 led to dramatic changes, including an intensified concern for how nuclear power plant (NPP) operators are supported in responding to NPP events. Responding to concerns about the safety of commercial nuclear power, the NRC implemented new requirements, including improvements in control room design, emergency operating procedures, and operator training. To support this effort, the NRC needed human factors engineering staff to review and inspect such changes. Also, as the NRC transitioned to a risk-informed agency, research and development has occurred in the area of human reliability analysis (HRA) (which incorporates understanding from multiple disciplines, including human factors engineering and psychology) in order to support broader scope probabilistic risk assessment (PRA) studies. Consequently, the NRC is widely recognized as one of the leaders in identifying and addressing human error for commercial nuclear power.

The history for radiation therapy has been different. Although notable events have occurred (for example, the overdose of a patient at Indiana, PA, in 1992 [2]) or the widely publicized series of misadministration's of radioactive iodine seeds for treatment of prostate cancer over several years at the Philadelphia Veteran's Administration Medical Center [3], with increasing mention of "human error" in conferences, journal papers, and workshops, it is clear that the need for attention to the issue has registered within the healthcare community. However, as evidenced by the Institute of Medicine's (IOM's) report in 2000, To Err is Human [4], and its follow-up in 2012 [5], the improvement in quality in much of the health care system is "still proceeding at a glacial pace."

This report lays out simply and clearly, for both experts and non-specialists, how to understand human error and anticipate future errors. It summarizes the NRC research to date on understanding radiation therapy from an HRA and human factors engineering perspective, and identifies unique and critical differences between therapeutic uses of radioactive materials and other complex technologies that are important to reducing human error. This report also aims to identify different approaches in other countries such as France where previous accidents led to very large scale consequences for patients. In France, the reports show how the French regulator has undertaken collaboration with radiotherapy professionals to improve the management of the safety and quality of the care given to patients. Finally, this report provides risk-informed strategies and recommendations, building on the success stories in commercial nuclear power and other industries, for effective human error reduction in radiation therapy.

Again, based on past experience in several industries and with several technologies and endeavors (e.g., NASA, commercial aviation, nuclear power, Yucca Mountain waste repository, chemical processing), it is known that implementing a risk-informed framework or regulatory strategy comes with challenges. In particular, the authors are familiar with the learning curve for effective technology transfer between HRA/PRA experts and experts working in specific applied technologies. However, the NRC staff knows how to highlight the benefits of using a risk-informed

process that can make existing jobs (e.g., designing, regulating, and using licensed equipment and associated procedures) more effective and efficient.

Because the licensing and regulatory responsibilities for radiation therapy are distributed among multiple agencies and organizations (of which the NRC is only one), the challenges are likely to be greater than those typical of other industries or technologies that have transitioned to a risk informed perspective. However, the success stories in human error reduction summarized in this report are evidence that the effort and resources definitely can provide a positive return. Consequently, it is the staff's sincere hope that those of us in the HRA and PRA disciplines will be called on to help make the next steps in reducing human errors in radiation therapy.

Richard Correia

Director, Division of Risk Analysis
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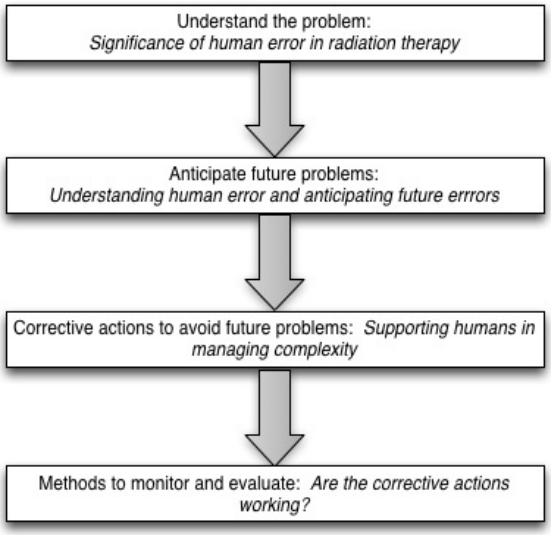
EXECUTIVE SUMMARY

The mission of the U.S. Nuclear Regulatory Commission (NRC), quoted from NUREG-2150 [1], is to "License and regulate the Nation's civilian use of byproduct, source, and special nuclear materials to ensure adequate protection of public health and safety, promote the common defense and security, and protect the environment." A critical part of this mission is licensing and regulating the medical use of byproduct materials, including in radiation therapy. This report is intended to support NRC staff in understanding the role of human error in the medical use of byproduct materials. The overall goals are to highlight the importance of the NRC role in healthcare and to provide a human reliability analysis (HRA) framework for characterizing human error and developing meaningful corrective actions in a healthcare context.

A report published by the Institute of Medicine in 2000, *To Err is Human* [4], brought national attention to patient safety and medical errors, reporting that between 44,000 and 98,000 people die each year as a result of preventable medical errors.



Unfortunately, in spite of efforts to reduce the number of medical errors and reduce risk factors, the Institute of Medicine's more recent report [5] noted that, while some progress has been made in specific processes (e.g., surgical mortality rates), the improvement in quality in much of the health care system is "still proceeding at a glacial pace."

In fact, a new estimate of the number of preventable adverse events (i.e., harm resulting from an error) leading to premature death put the lower bound (based on medical records) at 210,000 per year and suggested a minimum two-fold adjustment be applied to that number "to compensate for the known absence in the medical records of errors of commission and the inability… to detect errors of omission." [6, p. 127]

Examination of radiation therapy where the NRC has oversight responsibility reveals similar themes. Bogdanich [7] authored a series of articles examining radiation therapy errors between 2001 and 2009, highlighting a troubling recurrence of similar errors over time and across events, including miscalculations and misuse of positioning equipment resulting in wrong dosages and wrong sites. While many of the events reviewed by Bogdanich did not involve the same specific modalities of treatment that are the scope of the NRC's regulatory actions, many of the underlying causes are similar.

In this report, the authors outline an HRA perspective on radiation therapy and propose four related elements for improving safety: 1) improved understanding of human error in radiation therapy; 2) improved ability to anticipate errors; 3) effective strategies for supporting humans in managing complexity; and 4) methods to evaluate and monitor the effectiveness of corrective actions.

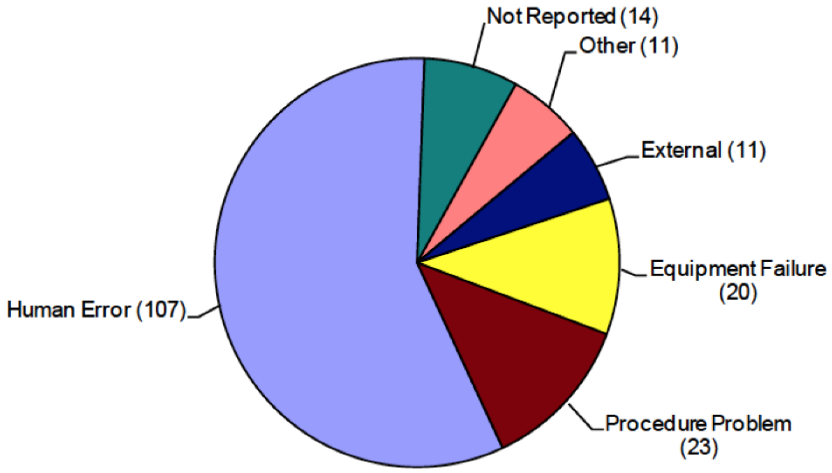
The illustration above shows these four elements as a progression in which, for example, understanding human error in radiation therapy is required in order to anticipate future problems.

Each of these elements is discussed below, with a mention of which report section provides the supporting discussion.

Significance of human error in radiation therapy

As shown in the figure below, more than half of the reported misadministration events in the medical use of byproduct materials in radiation therapy are attributed to human error (in data from the Nuclear Material Event Database). In spite of the prevalence of human error as a cause, investigations into contributing contextual factors and trends in error events over time and across facilities are limited. The NRC, however, has conducted a series of studies that provide:

- important examples of HRA in practice, including examination of error trends in misadministrations [8, 9, 10, 11];
- strategies for disseminating an HRA perspective [12, 13]; and
- an examination of the effectiveness of corrective actions [14].



Understanding human error and anticipating future errors

Section 2 presents a summary of these studies. Each represents important foundational research illustrating HRA methods. The authors contend that an extension of this foundational research would lead to improved safety in radiation therapy.

Section 3 focuses on an improved ability to anticipate errors. HRA integrates multiple disciplines (including human factors and ergonomics, cognitive and behavioral science, engineering, design, and operations) and provides a risk focus by virtue of its connection to probabilistic risk assessment (PRA). Understanding human capabilities provides insight into predictable aspects of human performance, as well as system vulnerabilities that are likely to lead to error. The practical application of this perspective is illustrated by a study and associated paper that reviewed misadministration events to identify risk significant human actions [12].

Looking across these incidents, researchers were able to identify specific circumstances likely to result in misadministration, overexposure of workers to radiation, or exposure of members of the public to radiation.

Supporting humans in managing complexity

Effective strategies for supporting humans in managing complexity are discussed in Section 4. Complexity and error are inherent in healthcare and in many of its processes of treatment. Rather than focusing on eliminating error, HRA seeks to identify common features of error events and to examine trends for aspects of the system or the environment that increase risk in a predictable way. This knowledge also highlights leverage points for designing systems and technology to support humans in managing complexity. The authors began with an examination of radiation therapy events and then integrated these findings with vulnerabilities identified in other industries. Six aspects that increase the risk for error are discussed, namely:

1) "Black box" aspects of automation,
2) Repetition and automaticity,
3) The role of user interfaces in mode errors,
4) The role of user interfaces in data entry errors,
5) Independent verification for noticing and correcting errors, and
6) Prospective memory demands.

For each aspect, the authors describe the vulnerability or increased risk and also discuss strategies for better supporting human capabilities and thereby reducing risk. In addition, risk measures, through the HRA approach proposed, allow different strategies to be prioritized by the amount of risk contribution or reduction.

Success stories: Are the corrective actions working?

Application of an HRA or a risk perspective has proved successful in many industries, including civil aviation and commercial nuclear power. In Section 5, the authors summarize the dramatic success these industries have had in reducing error, in spite of estimates indicating that human error contributes to between 70 percent and 80 percent of civil and military aviation incidents [15] and that similar rates of human error contribution to adverse events occur in the nuclear power industry [16]. One of the key lessons learned from the remarkable success of these industries is the need to constantly monitor and evaluate the effectiveness of corrective actions. It is not enough to implement corrective actions based on accident analysis. It is only after the corrective actions have been in place that the positive and/or negative impacts of the change can be assessed.

A human reliability approach to risk-management

NUREG-2150 [1] includes the NRC's recommendation to continue to extend and apply a risk-management framework to the oversight and regulation of medical use of byproduct materials. The efforts described in this report are consistent with the risk-management framework presented in NUREG-2150. Although challenges remain, the HRA perspective and methods detailed in this report, especially those noted in Section 6, are important components of a risk-management framework.

Summary and conclusions

Error will occur despite best intentions, careful design, and skilled personnel. From an HRA point of view, there is a dual aim: to reduce the likelihood of error and to increase the likelihood of recovery from error before negative consequences occur. HRA offers:

1) A perspective for understanding human capabilities,
2) Strategies for identifying system vulnerabilities or "error traps,"

3) Methods for analyzing errors when they do occur, and
4) Recommendations for developing effective corrective actions.

An HRA approach also advocates a process in which an organization deliberately articulates safety-related goals and evaluates corrective actions to determine whether they are, in fact, contributing to increased safety.

The NRC has been conducting human reliability studies about the use of byproduct materials in radiation therapy since the early 1990s. Transitioning from research to operations is not trivial in any industry, and perhaps more challenging in healthcare than in many others. For example, the NRC's scope of regulations is limited to the ***use*** of byproduct materials in medicine, while the U.S. Food and Drug Administration (FDA) regulates the ***design*** of medical devices. Additionally, it is the NRC's policy not to intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public. In spite of these and other challenges, the remarkable success in other complex industries such as aviation and commercial nuclear power are powerful examples of the feasibility of this approach.

The authors offer two recommendations to better incorporate a human reliability approach in the use of byproduct materials in radiation therapy.

1. *Human errors should be recognized as important contributors to radiation therapy events. Strategies for reducing such errors are best addressed by a combination of disciplines, including the medical and health physics fields, HRA, human factors, and cognitive science. In particular, HRA can be used to integrate inputs from multiple disciplines and provide a risk-informed perspective, allowing prioritization of potential fixes and balancing of competing needs.*

2. *Historical experience in addressing human errors in technologies such as commercial nuclear power and aviation has shown that, while there are multiple approaches to incorporating "human factors" into an error reduction effort, not all approaches are equally effective. The NRC has in-house experience on these "more effective approaches" (predominantly in the Offices of Nuclear Regulatory Research and Nuclear Reactor Regulation) that could assist or guide human error reduction efforts for radiation therapy.*

ACKNOWLEDGMENTS

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- The Brookhaven National Laboratory's (BNL's) Principal Investigator throughout the effort, John Lehner, for facilitating BNL staff and contractor support and contract management.

ACRONYMS

AO	abnormal occurrence
ASEP	Accident Sequence Evaluation Program
ASN	Autorité de sûreté nucléaire or Nuclear Safety Authority
ATHEANA	A Technique for Human Event ANAlysis
CAST	Commercial Aviation Safety Team
DRF	Dose rate factor
FDA	U.S. Food and Drug Administration
GSR	gamma stereotactic radiosurgery
HDR	high dose rate (brachytherapy)
HRA	human reliability analysis
IATA	International Air Transport Association
ICAO	International Civil Aviation Organization
INPO	Institute of Nuclear Power Operations
IV	intravascular (brachytherapy)
LDR	low dose rate (brachytherapy)
NMED	Nuclear Material Events Database
NRC	U.S. Nuclear Regulatory Commission
PEAT	Procedure Event Analysis Tool
PRA	probabilistic risk assessment
RAB	remote afterloading brachytherapy
RIDM	Risk-informed decision making
RIRIP	Risk-Informed Regulation Implementation Plan
RPP	Risk-Informed and Performance Based Plan
THERP	Technique for Human Error Rate Prediction

1 INTRODUCTION

A critical part of the U.S. Nuclear Regulatory Commission's (NRC's) mission is to license and regulate the medical use of byproduct materials, including in radiation therapy.[1] This is a key component of the larger mission to "license and regulate the Nation's civilian use of byproduct, source, and special nuclear materials to ensure adequate protection of public health and safety, promote the common defense and security, and protect the environment" [1, p. 2-1]. In fact, safety in the context of the medical use of byproduct materials raises challenges not found in the more predictable environment of nuclear power. The goal of this report is to support NRC personnel (both staff and management) in understanding the role of human error in the medical use of byproduct materials. In particular, the aim is to highlight the importance of the NRC's role in healthcare and to provide a framework for characterizing human error and developing risk-informed corrective actions in a healthcare context to reduce the likelihood of error.

1.1 Why Human Error is a Problem

The report published in 2000 by the Institute of Medicine entitled *To Err is Human: Building a Safer Health System* brought national attention to patient safety and medical errors [4]. The report estimated that between 44,000 and 98,000 people die each year as a result of preventable medical errors and set ambitious goals for reductions in the number of errors. Among the strategies recommended by the report were 1) creating an environment that encourages organizations to identify errors, evaluate causes, and take appropriate actions to improve performance in the future, and 2) applying what has been learned in other industries about ways to prevent error.

Unfortunately, in spite of efforts to reduce the number of medical errors and reduce risk factors, the Institute of Medicine's more recent follow-up report [5] noted that, while some progress has been made in specific processes (e.g., surgical mortality rates), the improvement in quality in much of the health care system is "still proceeding at a glacial pace." In fact, a new estimate [6] of the number of preventable adverse events leading to premature death put the lower bound (based on medical records) at 210,000 per year and suggested a minimum two-fold adjustment be applied to that number "to compensate for the known absence in the medical records of errors of commission and the inability… to detect errors of omission."

In 2009, medical errors involving a treatment modality regulated by the NRC became front-page news when *The New York Times* reported on events at the Veterans Affairs Medical Center in Philadelphia [3]. During a period of six years, prostate cancer patients who were prescribed low dose rate (LDR) brachytherapy treatment received substandard treatment. The treatment involves implanting small radioactive seeds into the prostate to treat the cancer. Ninety-seven of the 116 treatments completed during the timeframe in question resulted in medical events[2] due to incorrect placement of seeds. The incorrectly placed seeds resulted in higher than expected does to organs and tissues outside the area the physician intended to treat, including healthy organs such as the bladder and rectum. An investigation by the NRC found that a serious lack of safety culture at the facility allowed the medical events to continue for so long. Normal safety measures,

[1] The NRC is responsible for licensing and regulating the use of byproduct materials (e.g., materials made radioactive in a reactor). The NRC has no authority in radiation therapy involving accelerators.

[2] The term "misadministrations" was changed to "medical events" in 2002. This report uses "misadministrations" only when describing events prior to 2002.

such as peer review and regular use of equipment to measure whether patients received the appropriate dose, were not in place at the Philadelphia facility.

A subsequent investigation undertaken by The New York Times [17] used records from the New York State Department of Health (which monitors radiation therapy) to examine the prevalence and causes of errors. The analysis revealed that between January 2001 and January 2009, there were 621 mistakes in radiation therapy (both source and accelerator based) in the State of New York. Most mistakes had two or more causes (see Figure 1-1). Errors included wrong dosages or even the wrong patient treated. The identified causes included miscalculations and misuse of positioning equipment. The recurrence of similar errors over time and across events is particularly troubling.

Leape, who is considered the founding father of the study of medical errors and the leader of the specific study that developed the data quoted in the first Institute of Medicine (IOM) report, published an important journal paper [18] in which he points out that "errors are usually discovered only when there is an incident—an untoward effect or injury to the patient," and that, when they do come to light, the corrective measures are likely to be "directed toward preventing a recurrence of a similar error, often by attempting to prevent that individual from making a repeat error. Seldom are underlying causes explored." As a consequence, Leape holds that "… although the individual may learn from a mistake and change practice patterns accordingly, the adjustment often takes place in a vacuum. Lessons learned are shared privately, if at all, and the external objective evaluation of what went wrong often does not occur." [18, p.1852]

The effect of all this is to make it difficult to detect trends and promulgate effective countermeasures. The tradition of covering up errors, blaming an individual and recommending additional training or admonishing the individual to be more careful is not conducive to increasing patient safety.

It is important to note that these problems are not limited to healthcare in the United States. Recent information from the National Quality Board in the United Kingdom highlights similar issues and proposes that a "wider understanding of Human Factors principles and practices will contribute significantly to improving the quality (effectiveness, experience and safety) of care for patients." [19, p. 5].

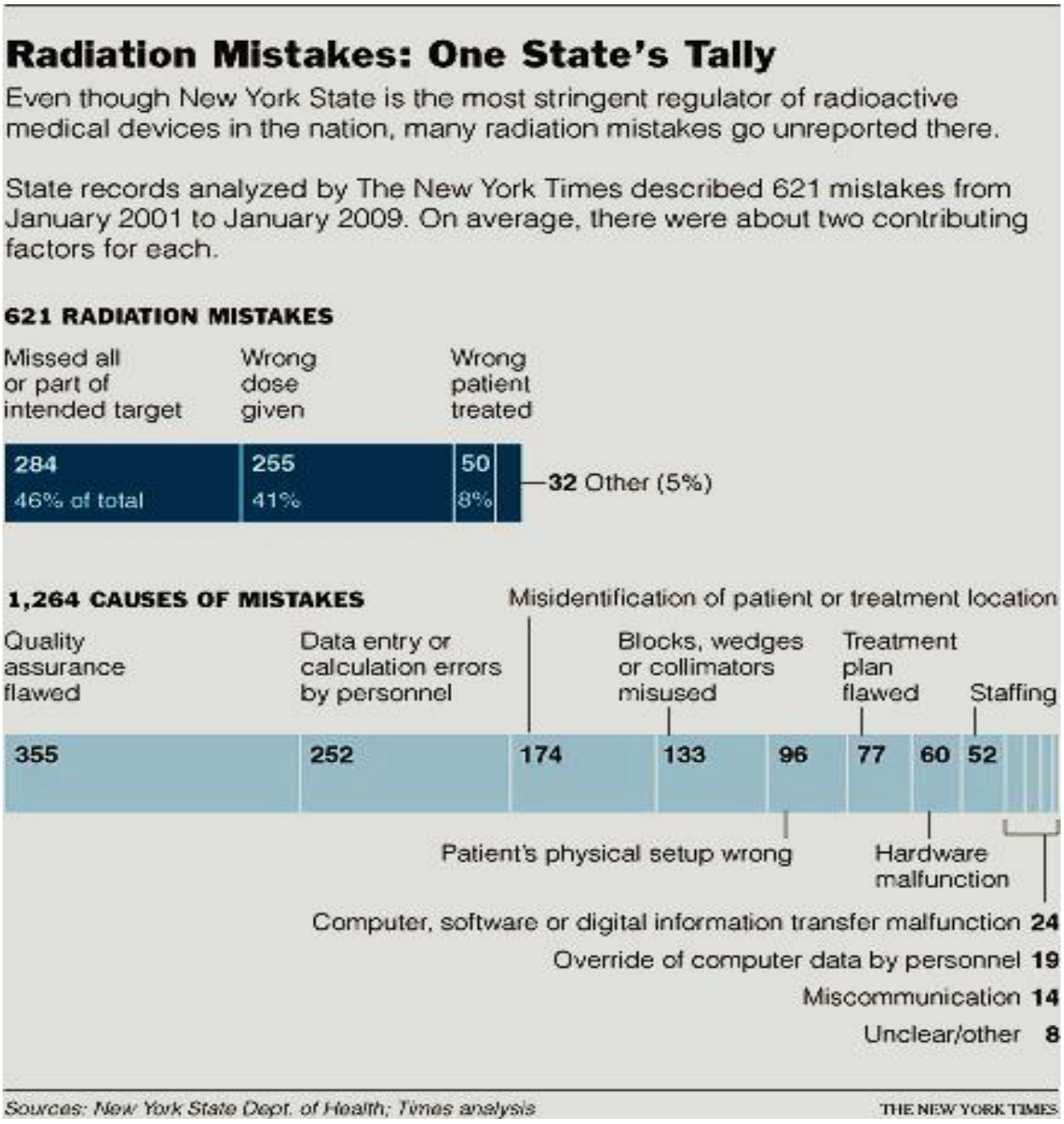

Figure 1-1 Summary of an analysis from The New York Times

1.2 Addressing Human Error

Drawing from a human reliability analysis (HRA) perspective, four key elements to improving safety are proposed (Figure 1-2):

1. Improved understanding of human error in radiation therapy (Section 2)
2. Improved ability to anticipate errors (Section 3)
3. Effective strategies for supporting humans in managing complexity (Section 4)
4. Methods to evaluate and monitor the effectiveness of correction actions (Section 5)

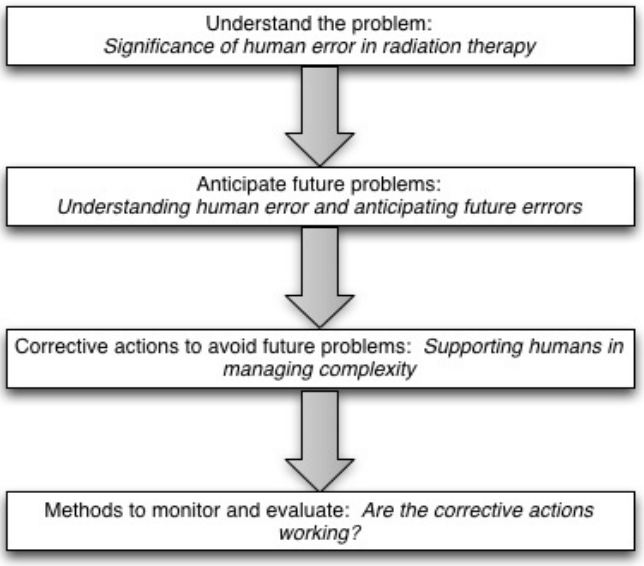

Figure 1-2 Four key elements for improving safety

Each element: 1) builds on the previous one, 2) incorporates HRA approaches (and related or underlying disciplines), and 3) has been demonstrated to contribute to improved safety. In addition, a fundamental starting point for achieving all four elements described above (which has proved effective in other domains) is the use of a systems level approach or perspective, as opposed to a solely person centered approach, as a basic premise. Within the framework of a systems approach, the following HRA concepts can be used to understand and predict human error:

- A basic understanding of HRA and human factors is that many human errors are predictable and preventable.
- Human error is most often the result of latent conditions within a system which have gone unnoticed or which are undetected by the user until the use of the system triggers an unexpected response or interaction (e.g., system fails to function); such situations are sometimes described as “error traps” [20].
- The person who makes the error is usually the last link in a chain of error traps that have been present in the system without users being aware of them until conditions in the environment make it possible for them to impact performance.
- It is simple during root cause analysis to “blame, shame, and retrain” the person who erred. However, it is more effective to analyze the system to determine what pre-existing factors set up the event. In order for that to occur, designers and system reviewers need to ask what can go wrong with the system; that is, look at the entire process (not just the person involved) from a “failure mentality.”

One way to explore a system with a systems-level approach or perspective is to use the concept of “defense in depth” as is done in commercial nuclear power. In this approach, all parts of a “system” (e.g., the overall design, the design of the user interface, training, procedures, and supervision) represent “barriers” or defenses against a possible event.

For most systems, a secondary or even tertiary defense lies between any failure and the resulting adverse event.

However, adapting the defense-in-depth approach for use in healthcare has its own challenges. The technology involved in nuclear power production is not as varied as that associated with radiation therapy. Furthermore, in medicine, each individual patient is different. For example, tumors occur in different locations, patients are different sizes, and new applications for equipment are constantly introduced. Also, medical treatment problems are often unexpected, require rapid response, and services of different medical disciplines must be coordinated. Healthcare 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 technologies and procedures that are used, and thus patient safety can be degraded. So, while the defense-in-depth approach has been highly successful in the commercial nuclear power industry, adaptation will be required to generalize this approach to healthcare.

This report recommends an approach that involves characterizing errors in a way that highlights the potential systemic issues from which the errors originated. This requires an understanding of human cognition in the context of complex systems. Multiple fields of study focus on errors in this manner. This report focuses on four fields that have different academic and applied roots, yet have evolved complementary methods and principles. Although these fields overlap, each brings a different emphasis:

1. The field of HRA seeks to identify and articulate human caused risks, often with the intent of quantifying the probability of specific errors [16].

2. The field of cognitive systems engineering focuses on identifying system-level factors that increase the likelihood of error and developing corresponding design changes to ameliorate vulnerabilities to error [21].

3. “Human factors” is a broader term that encompasses a number of human centric approaches to accident investigation and the design of robust systems [22].

4. Resilience engineering has emerged in recent years with the intent of creating a paradigm shift, moving away from legacy perspectives and focusing on how people and organizations “recognize, adapt to and absorb variations, changes, disturbances, disruptions, and surprises” [23].

This report draws on tools, techniques, insights, and understanding from all four of these fields.

HRA is traditionally performed to support a more broadly scoped study, probabilistic risk assessment (PRA), by addressing the “as operated” portion of the facility, equipment, process, or other analysis focus. As noted above, the performance of HRA requires integration of multiple disciplines, including human factors and ergonomics, cognitive and behavioral science, engineering, design, and operations. HRA also has been used separately from the larger PRA study, either quantitatively or qualitatively, in order to provide:

1) A risk focus (which facilitates prioritization of goals such as the safety of the public, workers, and patients that need to be addressed), and

2) A means of integrating and prioritizing the results of various analysis tools (e.g., from engineering, failure modes and effects analysis (FMEA), and human factors task analysis) with

respect to risk and human performance drivers, potentially effective design improvements, and effective improvements in training, procedures, and administrative controls.

Consequently, this report has adopted an approach that can take advantage of both the risk prioritization and multidisciplinary benefits that an HRA informed analysis can provide. Also, because HRA integrates all of the four fields above and a risk focus, the term “human reliability analysis” or HRA is used throughout this report for simplicity and brevity.

1.3 The Role of The NRC

The NRC makes decisions regarding the licensing and application of medical devices that use nuclear isotopes (radiation therapy). Note that the NRC only reviews the clinical application of the use of nuclear isotopes; it does not review the treatment of medical conditions or the prescription of medicine. In order to make these decisions, the NRC advocates a risk-informed decision making process, which means that risk information, along with other information (i.e., costs and benefits) are included in the decision making. As such, the purpose of this report is to explore and discuss human error in radiation therapy, using risk-informed perspective so that latent errors can be detected and removed before the circumstances for an event can occur.

In addition to the NRC, it is important to be aware of the role of the U.S. Food and Drug Administration (FDA) in regulating radiation therapy and other medical devices. Patient safety is a complex issue that crosses multiple disciplines and processes and requires an integrated, comprehensive approach to improvement. The Federal Food, Drug, and Cosmetic Act [24] requires a reasonable assurance of safety and effectiveness before a device can be marketed. The FDA enforces this requirement. The 510(k) process [25] is used to approve devices that are rated as having moderate risk to patients; this includes many radiation therapy devices.

As a result of the attention focused on errors in medicine, the FDA has increased efforts to investigate the devices used for treatment of patients and patient safety strategies. The FDA’s guidance on incorporating human factors engineering into risk management [26] describes how designers of medical systems can use human factors principles to design systems that will support decision making by the user, allow the medical professional to understand what is occurring in the systems, and reduce the potential for human error. More recently, the FDA issued draft guidelines for applying human factors and usability engineering to optimize medical device design [27] that closely resemble NRC's NUREG-0700 [28]. Although this new guidance is not yet in effect, it reflects the FDA’s current approach to human factors, encouraging manufacturers to conduct thorough testing in simulated environments to identify risks and vulnerabilities before a device is released for use.

The FDA approach is consistent with NRC direction. A continued focus on the critical role of HRA is expected in both the 510(k) review process and the NRC licensing and regulation of the use of byproduct, source, and special nuclear materials in radiation therapy.

1.4 How This Report Develops an Understanding of Human Error

An HRA approach requires a shift in perspective as well as the application of appropriate methods. This report will focus primarily on communicating an HRA perspective relative to errors in radiation therapy. Throughout this report, the reader is referred to relevant literature for guidance on implementing specific human reliability methods. The following sections will:

- Explore and discuss human error in radiation therapy
- Provide an HRA perspective for understanding human error and anticipating future errors
- Discuss strategies for supporting humans in managing complexity
- Examine success stories in using a risk perspective on human error (e.g., are the corrective actions working?)
- Describe an HRA approach to risk management in the medical use of byproduct materials

In each section, the authors offer relevant examples. Additional details and examples can be found in the appendices.

1.5 Organization of This Report

Section 1 of this report makes the case that human error is an important issue in healthcare and that the NRC has an important role in addressing this issue. Section 2 contains a discussion of human error in radiation therapy specifically, and recounts the foundational studies that the NRC has conducted to better understand human error and corrective actions in this context. Section 3 communicates a perspective for understanding human error and for anticipating future errors. Section 4 highlights situations in which human error is more likely to occur, characterizing these as leverage points for better supporting humans in managing complexity. Section 5 reviews success stories from the aviation and nuclear power arenas in reducing error and discusses the concept of two-loop learning to continually assess the effectiveness of interventions in achieving improved safety. Section 6 integrates concepts introduced previously in the report to advocate for an HRA approach to risk management in the medical uses of byproduct materials. Section 7 summarizes the main points of this report and draws conclusions.

2 SIGNIFICANCE OF HUMAN ERROR IN RADIATION THERAPY

Over half of the misadministration events reported in the Nuclear Material Event Database (NMED) involving the use of byproduct materials in radiation therapy are attributed to human error (see Figure 2-1). The figure is taken from the report of the second quarter of fiscal year (FY) 2013 [29], but it is worth noting that the percentage of events attributed to error varies little over time[3]. Although many of the reportable events do not result in harm to patients or healthcare staff, those that do can have devastating effects [30, 7]. One goal of the inspection and reporting process is to aid the NRC and the radiation therapy industry in recognizing and preventing errors before catastrophic events occur.

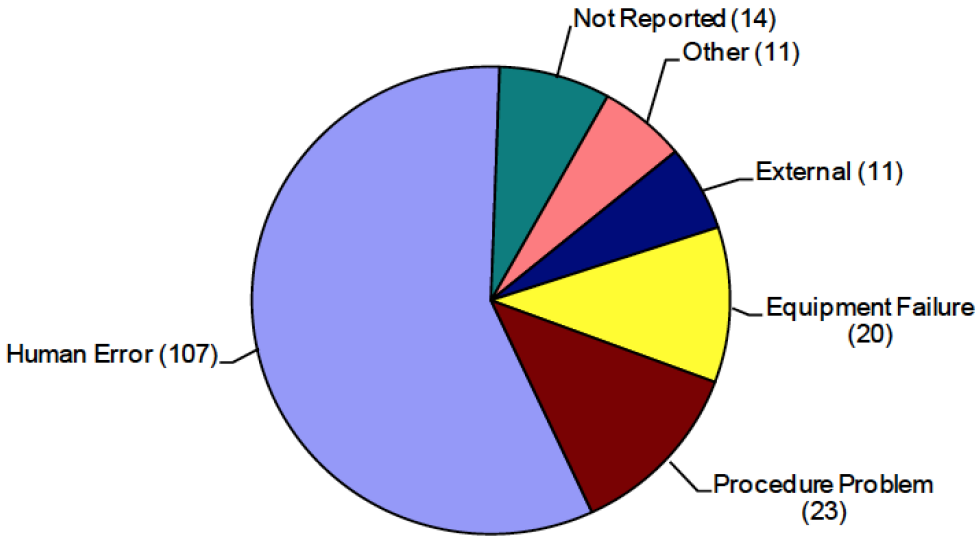

Figure 2-1 Causal factors events reported in NMED's second quarterly report for FY 2013

Given the large proportion of reportable events classified as being caused by human error, it follows that an improved understanding of human error represents a significant opportunity for improving safety.

2.1 The Age of Human Error

The approach of investigating and classifying events simply as "human errors" is an outdated approach that was popular in the 1960s and 1970s. Hale & Hovden describe this era of safety management as "the age of human error" to distinguish it from the earlier period of focusing only on hardware faults [31]. Using tools such as root cause analysis; it identified only a limited set of contributing factors for the event that could be improved. Appendix A provides a description of how root cause analysis has been used in healthcare and power plant settings.

[3] Data do not include a record of how many procedures are conducted during each period. Although we know what percentage of events reported are classified as human error, we do not know what percentage of procedures result in a reportable misadministration event.

In the age of human error, accidents like those at Three Mile Island Unit 2 in1979 were explained in terms of human fallibility and how they were caused. In this age, the goal was to develop an understanding of the factors that lead to increased likelihood of errors occurring, 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.

In the1980s the focus for understanding accidents moved to the area of safety culture and management, particularly as a response to the Chernobyl accident as well as lesser (at least in scale) such as the sinking of the ferry Herald of Free Enterprise [32] 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 (for example, it is listed in The Joint Commission's list of root causes; see Appendix A for more detail), few approaches to developing effective responses to these types of events are included.

As a result of knowledge gained from these evolutions, a new paradigm emerged that in many ways integrated the previous perspectives. Perhaps the archetypal model of this era is the so called "Swiss cheese" model of accident causation [33, 34, 35] 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 cause accidents. In order to respond to events using this model, there is considerable need to evaluate and audit the different kinds of factors at the multiple levels in order to uncover the gaps or "holes" in the "Swiss cheese." This can be a demanding and resource intensive effort. Figure 2-2 shows an early version of the Swiss cheese model of accident causation. Figure 2-3 shows another version highlighting the need for "defenses," a key driver of the defense-in-depth approach described in the introduction of this report.

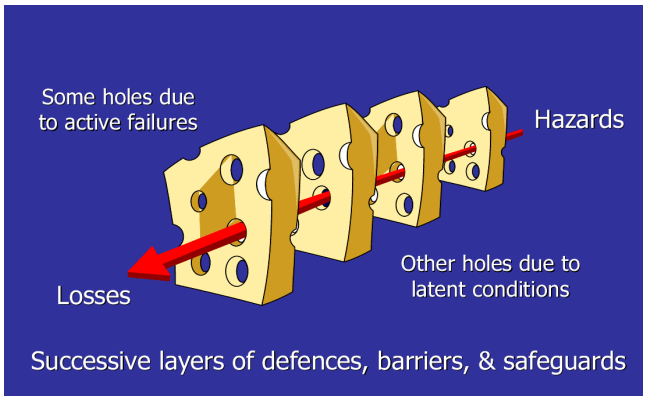

Figure 2-2 Early depiction of the Swiss Cheese Model

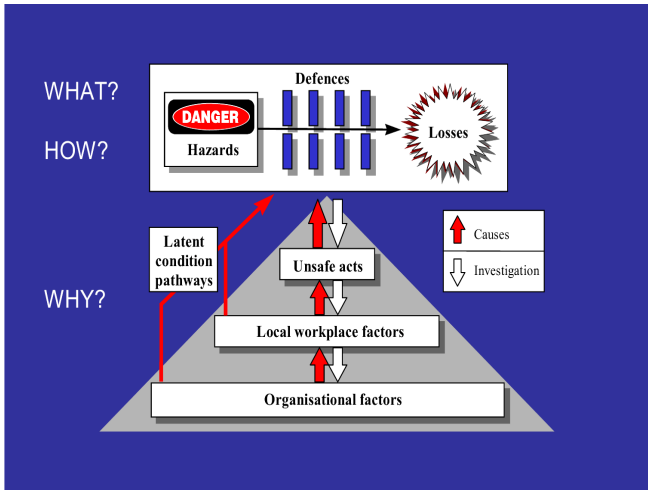

Figure 2-3 Later version illustrating organizational influences on defenses in depth

Hollnagel and others [23] have described the emergence of the next era of safety analysis, which 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 refer to this perspective, though the terms *Resilience, Complex Adaptive Systems*, and *The Adaptive Age* are used to describe it.

Its characteristics include:

1. The goal, unlike those of all of the previous eras (which relied on continuously analyzing events and learning from them), is to anticipate and prevent or mitigate the circumstances that can lead to accidents so that accidents do not happen;

2. The recognition that successful safety performance is the result of positive adaptation, as opposed to the elimination of bad behaviors (thus, lessons can be learned from both successful performance and failures); and

3. The realization that understanding accidents and other events requires models based on how work is actually performed (as opposed to being based on the designer's intentions).

Currently, healthcare, in general, appears to be preoccupied with safety management principally at the second era and to a lesser degree the third era, the eras of human error and of management. For example, the website of the U.S. Agency for Healthcare Research & Quality (the Federal Government agency responsible for improving patient safety) hosts a preponderance of tools for improving patient safety that are focused on improving individual human performance. Similarly, the Institute for Healthcare Improvement (a major not-for-profit organization aimed at improving patient safety) indicates an emphasis on skills improvement for human performance. However, there is also an interest in the "high reliability organizing" approach on the part of healthcare organizations [36, 37]. This approach represents a kind of midpoint between an HRA perspective and a management perspective; in theory it is about the desirable attributes of a highly reliable organization, but in practice these attributes are primarily related to the attitudes of people (e.g., a preoccupation with failure).

The NRC, in contrast, has conducted a series of studies from a human reliability perspective, focusing on strategies for understanding misadministration events in the context of work as it is actually performed, seeking to understand what factors increase the likelihood of error. This work is discussed in the next section, immediately below.

2.2 NRC Studies of Error in Radiation Therapy

Over the last 20 years, the NRC has conducted a series of studies to better understand the significance and nature of human error in radiation therapy events (see Figure 2-4). These careful studies illustrate NRC efforts to predict and prevent error in radiation therapy, highlighting the significance of human error and demonstrating the use of human reliability methods in radiation therapy.

2.2.1 Overview of NRC Research in Radiation Therapy: The 1990s to the Present Day

In the early 1990s, the NRC undertook studies of evolving medical treatment modalities involving radioactive material. These included investigations and analyses of misadministration events in NUREG/CR-6088 [8] and human factors evaluations of remote afterloading brachytherapy (RAB) in NUREG/CR-6125 [9, 10] and teletherapy in NUREG/CR-6277 [11]**.** The initial studies of misadministration in the early 1990s illustrate the range of errors that fall into the category of human error. Through an exploration of direct and contributing causes of the events, the authors also discuss the effectiveness of corrective actions. Starting in 2005, the focus shifted from individual analyses to strategies to capturing HRA perspectives and methods for reviewers and inspectors through the development of a job aid [38] and associated training materials [39], then presenting this work at technical conferences [12, 13]. This job aid built on the 1990s studies,

offering examples and articulating strategies for recognizing factors likely to increase vulnerability to human error.

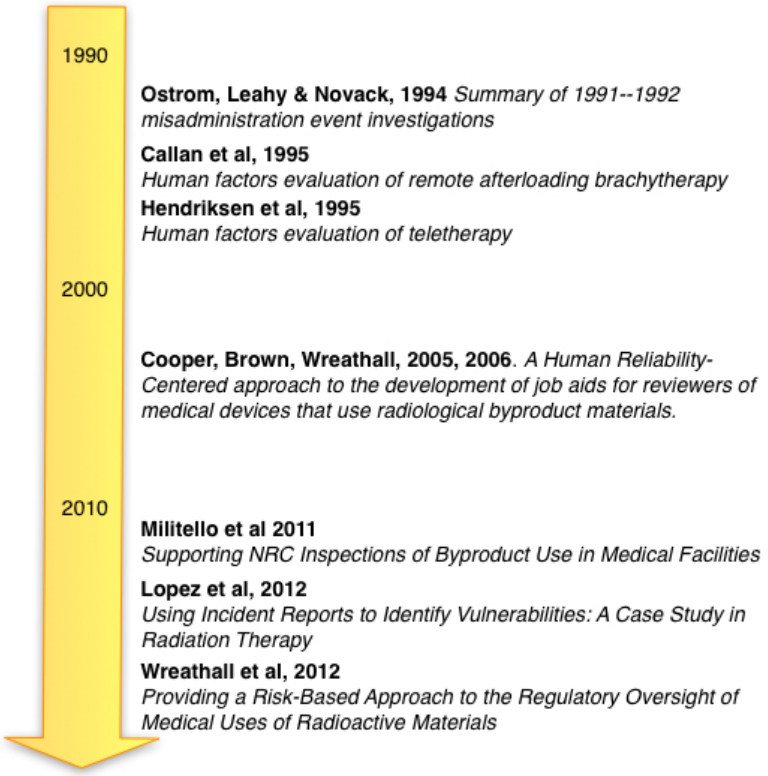

Figure 2-4 Timeline of NRC studies of human error in radiation therapy events

Efforts to disseminate HRA perspectives and methods to the radiation therapy community and across the NRC continued in 2010 and 2011 with a series of papers highlighting success stories such as redesigned features of the gamma knife to reduce specific error types [40], and analysis of incident reports to identify vulnerabilities [41].

The most recent publication goes a step further, examining the effectiveness of corrective actions [14]. Although understanding human error and identifying system-level vulnerabilities are critical steps toward increased safety, it is not enough. Corrective actions that effectively reduce error are necessary if real improvement is to be realized.

2.2.2 Summary of Insights From Early NRC Research in Radiation Therapy

The relevant findings from the early NRC research are described immediately below, along with discussions of ways the findings can be used to improve understanding of human error and effects on radiation therapy safety. The analyses reported in NUREG/CR-6088 [8] are helpful. This work formed the basis for this report, which includes NRC research from the early 2000s up to the present day. Section 2.3 discusses the most recent research and associated insights.

NUREG/CR-6088 [8] details a series of investigations of a representative sample of misadministrations reported during 1991 and 1992. The authors identified direct and contributing causes for each of seven events. These included:

- deficiencies in policies and procedures (cited as direct causes of all of the events investigated and as the initiating cause of two of them)
- inadequacies in training and experience (direct causes of five of the seven events)
- changes and unique conditions (contributing causes in all but one of the events)
- organizational structure/culture (contributing cause)
- hardware incompatibilities (contributing cause)
- workplace design (contributing cause)
- labeling (contributing cause)

To learn more about specific aspects of misadministrations, the authors compiled a database of misadministrations that were reported between 1987 and 1992. They found more evidence of the causes listed above as contributing to misadministrations, adding inadequate communication to the list. They further noted that data entry and software errors were dominant causes of such multiple misadministrations, in which more than one patient was affected as a result of the same underlying cause. While these multiple misadministrations were infrequent, they had the potential to impact a large number of patients.

This report is helpful in defining the categories of causes of misadministrations. Many of the causes listed above involve human actions, thus introducing the potential for human error. It is important to note that the authors found the corrective actions narrow in scope because they dealt only with the factors directly related to the cause of an event. These narrow corrective actions would be more useful in preventing the same type of event from recurring, but may not be as effective at preventing other related events. In addition, the authors recognized that an examination of more general trends for identifying corrective actions might have larger-scale benefit (i.e., benefits for human actions beyond those directly tied to the events that occurred).

NUREG/CR-6125 [9, 10] describes a human factors evaluation of remote afterloading brachytherapy (RAB). In this study, a task analysis was used to decompose each of the functions comprising RAB (patient preparation, treatment planning, treatment delivery, post-treatment, and quality assurance and maintenance) into individual steps. For each critical step, the authors describe and evaluate practices associated with the step, and suggest and evaluate alternative techniques that might be employed to reduce the likelihood of misadministration. They offer three primary strategies for reducing error: decreasing the likelihood of human error, increasing the detectability of human error, and limiting the consequences of human error.

An example of a critical task associated with RAB is the entry of the treatment plan into the treatment system. The vulnerabilities associated with this task include the need to manually enter the treatment plan into the treatment console, calculations that are not easily visible or verifiable by the user, and difficulties in identifying differences between the initial directive and the final parameters. The authors suggest two strategies to mitigate the vulnerabilities associated with the task: 1) the direct electronic transfer of the treatment plan to the treatment console and 2) better feedback from the system. See Appendix B for full descriptions of all the critical tasks, associated vulnerabilities, and mitigating factors.

NUREG/CR-6277 [11] describes a human factors evaluation of teletherapy undertaken around the same time as the RAB evaluation described above, using a similar approach**.** The main functions that were articulated include clinical evaluation, therapeutic decision, target volume localization, treatment planning, treatment, periodic evaluations during treatment, and follow-up evaluation. Specific steps that had a high likelihood of producing an error were identified and labeled as critical. The vulnerabilities associated with each of these steps that can lead to errors were articulated, along with ways that these vulnerabilities could be mitigated.

For example, one of the critical tasks relates to setting up the equipment and treatment environment. The vulnerabilities associated with this particular step include high workload and rapid pace of treatment schedules, understaffing, poor layout of the workstation, and presence of distractions and competing tasks (e.g., having to answer phones). The authors suggested that these vulnerabilities could be mitigated by scheduling patients in a more evenly distributed manner, improving staffing levels, redesigning the workspace, and using computerized record and verification systems to check deviations from the prescriptions. See Appendix C for full descriptions of all the critical tasks, associated vulnerabilities, and mitigating factors.

Both of these studies looked critically at the key steps involved in the administration of specific types of radiation therapy. They identified critical steps during which an error would most likely result in a misadministration. This type of analysis is important in building an understanding of the contexts in which errors are likely to occur.

2.3 Examining Trends: Current Research

The authors of the present report analyzed relevant abnormal occurrences (AOs) found in NUREG-0090, *Reports to Congress on Abnormal Occurrences.* Specifically, the analysis examined events associated with radiation therapy from 2001 through 2010 [41] in terms of risk and the nature of events that have occurred. These events were associated with the high dose rate (HDR) brachytherapy, gamma knife, intravascular (IV) brachytherapy, and low dose rate (LDR) brachytherapy modalities of treatment. AOs include incidents or events having a moderate or more severe impact on public health or safety, including moderate exposure to or release of radioactive material. Although the reports do not include a great level of detail about each event, the analysis revealed that specific errors recur with specific technologies.

Events were analyzed based on whether they involved a wrong dose or a treatment to the wrong site, and what types of errors caused the event. These error categories include:

- data entry/planning software errors, involving an issue with inputting data or the software interface
- equipment errors, in which equipment did not function properly
- target errors, in which the treatment site was not properly identified before treatment administration
- verification errors, in which verification processes that were in place did not catch errors
- procedural errors, in which inadequate procedures directly led to unsafe conditions
- visualization errors, in which the target was not clearly visualized either before or during treatment administration
- patient movement errors, in which the patient's movement during treatment resulted in an error

Because many of these events were complex, several fell into multiple error categories. Also, because the analysis was conducted solely from the event narratives rather than first-hand, in-depth investigation, it is possible that other errors contributed to the events. For example, there were probably many more verification errors than appear in the analysis, because facilities usually employ multiple checks and verifications of medical treatments before, during, and after procedures.

Table 2-1 below shows the distribution of errors in each category for each treatment modality that was analyzed, including a frequency count and percentage within each modality. As the table shows, different treatment modalities seem to be prone to different types of errors, probably

because of the different procedures needed to implement each type of treatment and the different types of equipment used. HDR brachytherapy had more data entry errors than any other category (14), while the errors associated with gamma knife were almost evenly distributed among target, verification, and equipment errors. Most of the errors associated with IV brachytherapy were equipment errors (4), and the most common errors associated with LDR brachytherapy were target errors (18) followed by visualization errors (10).

Table 2-1 Summary of error distributions for each treatment modality

	HDR Brachytherapy	Gamma knife	IV Brachytherapy	LDR Brachytherapy
Data entry errors	**14 67%**	2 14%	1 14%	1 3%
Equipment errors	5 24%	3 21%	**4 57%**	3 8%
Target errors	0 0%	**4 29%**	1 14%	**18 49%**
Verification errors	2 10%	**4 29%**	0 0%	1 3%
Visualization errors	0 0%	1 7%	1 14%	10 27%
Errors caused by patient movement	0 0%	0 0%	0 0%	3 8%
Procedural errors	0 0%	0 0%	0 0%	1 3%

(Note: Percentages represent the error percentage within that modality. For example, 67 percent of the errors in HDR brachytherapy were data entry errors. See Appendix D for more details about each error category and the events that fell within each.)

This analysis highlights the importance of understanding the underlying reasons and context for errors so they can be correctly classified. For example, an event might occur because the doctor placing small radioactive seeds for LDR brachytherapy inserted them in the wrong spot (the bladder instead of the prostate). This could be classified as “human error.” A deeper investigation, however, might reveal that the seeds were placed incorrectly because the visualization equipment that was used was misleading or made the patient’s anatomy difficult to distinguish. This additional distinction as a visualization error or equipment error suggests a different approach to reducing risk. Rather than a reprimand and additional training for individuals, the problem might be more effectively addressed on a larger scale by improved technologies and/or procedures to support visualizing seed placement.

Understanding error trends over time and across treatment modalities is vital to understanding where errors are likely to occur and what corrective actions are more likely to be effective in preventing future adverse events. Capturing and recording events is an important first step in conducting this type of analysis.

The NMED database (e.g., Reference 29) represents a powerful repository for examining trends. The NMED quarterly and annual reports further summarize events that have occurred, as well as their causes and corrective actions. However, many of the events listed are attributed to "human error" (see Figure 2-1) with very little context about why they were classified that way [29].

Without the context, it is difficult to implement corrective actions that truly address the source of the error. For example, a review of nineteen events associated with HDR brachytherapy reported in NMED for the period from 2009 to late 2011 [14] revealed that all of the reports identified "human error" as the root cause; however, the reports indicated the following corrective actions:

- new or modified procedure—100 percent
- staff retrained—56 percent
- person reprimanded—11 percent
- new management plan—6 percent
- new equipment—6 percent

The high percentage of reported events identifying human error as a root cause and the implementation of seemingly ineffective corrective actions (note that each event was usually followed by more than one corrective action) reveals a worrisome tendency.

When considered in the context of Manuele's safety decision hierarchy [42], the weakness of the current approach to corrective action becomes clear. Manuele's hierarchy has six levels, ranging from the most effective at reducing risk (#1) to the least effective at reducing risk (#6):

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 or interlocks)
4. Provide warning systems
5. Apply administrative controls (work methods, training, etc.)
6. Provide personal protective equipment.

Of the corrective actions listed above as responses to events caused by human error, the one most frequently used is also one of the least effective types of intervention: administrative control. This analysis suggests that although human error is listed most frequently as a causal factor of adverse medical events, the corrective actions that are most often implemented are not ideally suited for either mitigating the effects of human errors or preventing them from causing adverse events in the first place.

More recently, human factors researchers created a model of sustainable and effective corrective actions following root cause analysis in healthcare [43]; the model is illustrated in Figure 2-5. The authors of this journal paper carried out a qualitative analysis of 344 root cause analysis investigations, conducting interviews with frontline staff one to five years after interventions were implemented. Findings are consistent with Manuele's hierarchy in that solutions aimed at the individual, such as counseling or disciplinary action, were minimally effective and had little sustained impact. Changes at the institutional level (e.g., creating a new pediatric inpatient pharmacy) and enhancements to information technology infrastructure (i.e., improved usability and improved interoperability) were found to be highly effective and to have high sustainability.

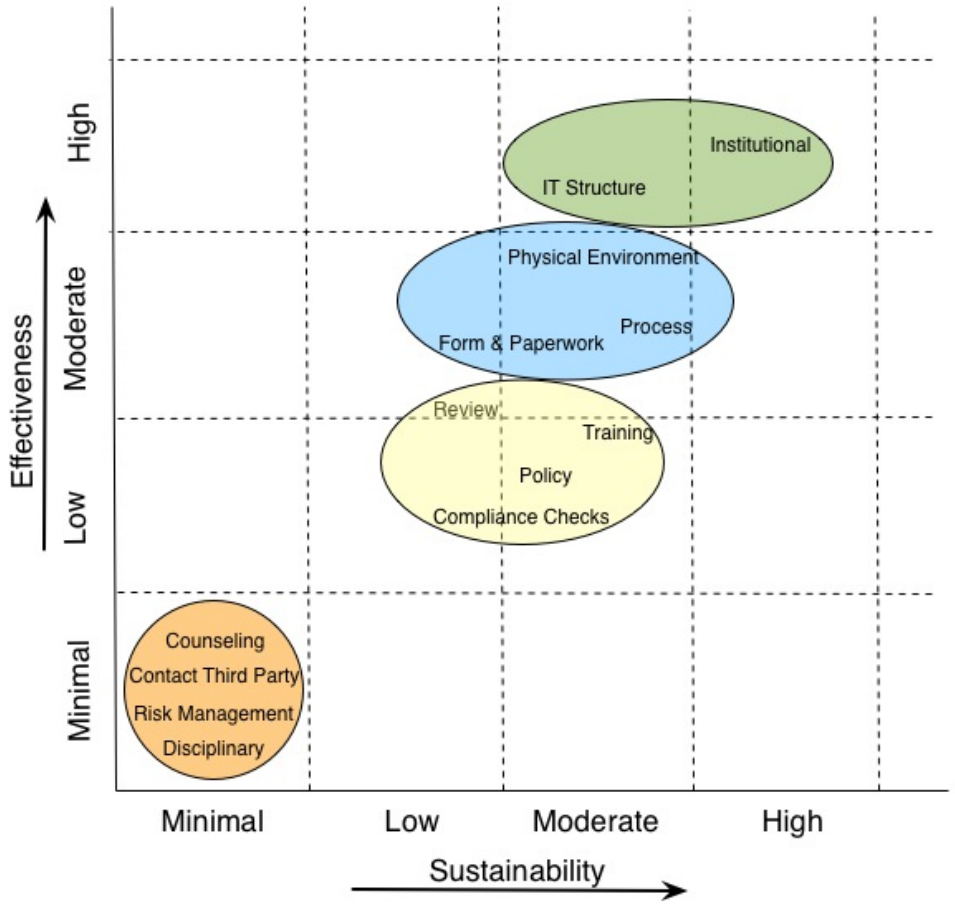

Figure 2-5 The model of sustainability and effectiveness of corrective actions

2.4 Summary

The series of NRC sponsored studies reviewed in this section help to characterize the nature of human error in radiation therapy. Studies ranging from in-depth analysis of an individual modality to broader examination of error types across modalities highlight the complexity of error in radiation therapy, but also illustrate HRA approaches for understanding error and strategies for developing effective corrective actions.

3 PERSPECTIVE FOR UNDERSTANDING HUMAN ERROR AND ANTICIPATING FUTURE ERRORS

After discussing the nature of human error in radiation therapy, the attention is turned to HRA as a perspective for understanding human error. An important aspect of HRA is taking a systems view; that is, considering humans, technology, and the environment as interdependent components of a system. Complex systems rely on humans for resilience in the face of adverse events or oversights. These large systems rely on humans to recognize novel events, technology malfunctions, and errors in order to quickly adapt and recover before catastrophic events occur. An HRA perspective focuses on understanding human capabilities and identifying system vulnerabilities as a means to anticipate error.

3.1 Understanding Human Capabilities

As discussed in Section 2, "human error" is listed as the cause of many incidents, but this superficial label offers limited insight into root causes and strategies for appropriate corrective actions. The term human error often connotes random, unpredictable events that cannot be anticipated or prevented. HRA offers a different perspective, some precepts of which are given below.

3.1.1 Human Error is NOT Random

Because error reports are often superficial and focus primarily on the events immediately before an incident, most human errors appear to be idiosyncratic. By examining the context in which an error occurs, however, factors influencing human performance become visible. Human error is more likely to occur when people must contend with competing demands, interruptions, and technology with poor usability, fatigue, or any number of other contextual factors [12]. An HRA approach advocates for an investigation of errors that includes contextual factors, along with an examination of similar errors that occur in different locations at different times. This type of analysis reveals trends and systemic issues that contribute to human error and often suggests interventions likely to increase human reliability. Section 3.2 describes recent efforts to identify system vulnerabilities in radiation therapy.

3.1.2 Human Error Is Not The "Cause" of a Mishap

Although many mishaps are attributed to a single root cause, most are the result of an accumulation of factors and acts. Reason [44] posits multiple levels of failure, including organizational influences, unsafe supervision, preconditions for unsafe acts, and the unsafe acts themselves. These have been described in the context of the "Swiss Cheese Model" in which individual parts of the system are depicted as slices of Swiss cheese (see Figure 2-2 at the beginning of Section 2). Errors occur all the time, but few result in any real harm because of redundancy and checks. Real failures occur only when all of the holes in each of the slices momentarily align, permitting a "trajectory of accident opportunity" [33]. In this instance, a hazard passes through holes in all the defenses resulting in a failure. Thus, while human error might have been among the immediate causes of an incident, several other factors had to fail as well.

3.1.3 Human Error Can Be Predicted

There is no question that human behavior is highly variable. An understanding of human cognition, however, reveals important patterns that allow us to predict situations in which human error is most likely to occur. Some examples include:

- **In the context of accomplishing real world tasks, people tend to engage in goal-directed, practical, and economical behavior.** People tend to work toward goals based on a mental model of the situation, using whatever time and resources are available. People are also highly adaptive, often seeking innovative strategies to accomplish goals efficiently even as the context and constraints change. Understanding these often undocumented strategies can highlight important behavior patterns that are highly adaptive most of the time, but increase vulnerability to error when something unexpected occurs.

- **Furthermore, work environments such as healthcare, nuclear power, and aviation prescribe processes that people tend to follow.** This allows people to follow predictable paths, maximizing routines and automatized actions to minimize mental effort. In fact, these highly practiced, smooth, seamless actions are a hallmark of expert performance. However, while this means that human behavior in these environments is fairly predictable, the tradeoff is that, when in this "automatic mode," people are less likely to interact with the environment mindfully. In other words, they are more likely to see what they expect to see and to miss important anomalies that might indicate a problem.

- **As people gain expertise in an area, they develop sophisticated pattern-matching skills that allow them to recognize typical situations and interpret problems.** These skills allow experts to see things that are invisible to the novice. Experts build up an experience base that allows them to make use of heuristics and develop expectations about future events. These strategies allow experts to effectively and quickly adapt to a range of contexts, manage different types of complexity, and move forward in spite of uncertainty. Understanding expert strategies also provides insight into vulnerabilities or situations in which even experts may be misled by heuristics.

While these human tendencies are highly adaptive most of the time, each one can cause susceptibility to certain types of error. Human errors are not isolated breakdowns, but rather are the result of the same processes that allow a system's normal functioning. Take the example of the common dissociative phenomena that are often experienced when driving to a very familiar location. Many people forget details of the drive because they have done it so often. Most of the time, it does not matter if the driver was not paying very close attention. The driver is able to safely navigate the route while mentally reviewing the events of the day, preparing for an upcoming appointment, enjoying radio programming, or any number of activities. However, occasionally an unexpected event will occur that could prove catastrophic to a driver who has slipped into mindless, automatic driving behaviors.

Section 3.2 includes examples and a discussion of how these typically highly adaptive strategies can be vulnerable to error in certain circumstances. Identifying the circumstances that increase the likelihood of error is a core component of HRA.

3.2 Identifying System Vulnerabilities

Working from the premise that human error is not random; an HRA perspective recommends strategies for identifying system vulnerabilities that lead to predictable types of errors. To illustrate this approach, consider a project conducted in 2003 to investigate the effects of human error on the risks associated with medical use of byproduct material for the NRC [12]. Medical events associated with selected modalities of treatment were reviewed: HDR brachytherapy, teletherapy, gamma stereotactic radiosurgery (the "gamma knife"), and IV brachytherapy.

These modalities were selected because they involve high dose rate sources so there is very little margin for error (or opportunity for recovery) for the safety of the patient because the treatments involve short durations and very small volumes. In addition, because of the source strengths, the clinical workers, family, or others near the patient can also be at risk.

The authors began by reviewing the events to identify risk significant human actions. Seven risk significant human actions were identified across the four modalities. These were:

- data entry
- use of planning software
- miscommunications (of prescription or source orders)
- selection of sources
- calculations of source strength and location
- source handling and installation
- verification of planned actions

A next step was to identify specific circumstances having the potential to lead to unintended events such as misadministration, overexposure of workers, or exposure of members of the public. These included circumstances in which:

Source activity can change. Changes in source activity tend to happen very slowly as the source decays over time, culminating in an eventual replacement of the source, which might represent a significant change in source activity. If calibration tasks are not completed as scheduled or are not completed accurately, an incorrect level of source may be assumed in treatment planning, resulting in an incorrect dose delivery to the patient.

Material can be supplied by others. Handoffs of any sort tend to be vulnerable to error. In radiation therapy, unit conversion errors are of particular interest because of the likelihood of harm. The possibilities of errors associated with unit conversion are most likely to arise when operators order radiopharmaceuticals. In addition, misidentification and mislabeling can occur when multiple doses are prepared and transported.

Treatments can be performed by personnel other than the prescribing physician. When treatment is carried out by someone other than the prescribing physician, two types of errors are more likely. First, misidentification of patients is more likely to occur when the person administering the treatment is not acquainted with the patient. Second, orders that are vague or not transmitted accurately may result in therapeutic doses being administered when diagnostic procedures were intended.

Source configurations (e.g., physical dimensions, activity) can vary. For some modalities, the source can have multiple configurations, such as the different seed types used in low dose

rate brachytherapy. This variability introduces the possibility of incorrect selection of source configuration (e.g., seed type), including errors owing to lack of familiarity and mislabeling.

Untrained personnel may encounter radioactive sources. For some modalities such as brachytherapy, the source is small and portable enough that it may be dropped without being noticed while being inserted or become dislodged during the treatment.

Treatment planning can be computer-aided or partially or fully automated. Although automation offers the opportunity to reduce some error types, new types of error are often introduced. These can include number transpositions and other data entry errors, inappropriate default values, or the presence of multiple draft treatment plans.

Checks can become ineffective owing to repetition or production pressure. In many radiation therapy processes and procedures, multiple clinicians are required to review the treatment plan before it is administered in order to notice and correct any errors before they are implemented. However, the repetitive procedures and need to work quickly and efficiently can actually reduce the effectiveness of these cross-checks.

These circumstances were involved in one way or another in large numbers of the events reviewed. Despite the differences in actions performed, the purposes for which they are carried out, and the environments in which they are conducted, the events have some common features. This examination of predictable error-prone tasks and circumstances reveals potential leverage points for both system and technology design in the context of radiation therapy. In Section 4, generalizable elements are discussed that make a system vulnerable to error and challenge humans' ability to operate it reliably. Within each, we provide examples from radiation therapy events and suggestions for supporting humans in managing these types of complexity.

3.3 Summary

Understanding human capabilities and identifying system vulnerabilities are important elements of recognizing potential error traps. By focusing on how humans function in complex environments and on specific circumstances and system factors that are likely to disrupt or degrade human performance, it is possible to anticipate errors before they occur. The next section takes this discussion a step further, highlighting factors that increase the risk of error and serve as leverage points for improved system design.

4 SUPPORTING HUMANS IN MANAGING COMPLEXITY

Complexity is inherent in the healthcare system. Complexity and error are parts of the system that will never go away. Rather than focusing on eliminating complexity (or error), the focus should be on supporting the human in managing this complexity. From an HRA perspective, the authors' intent was to identify common features of error events and to examine these trends for aspects of the system or the environment that increase the risk of error in a predictable way. Authors began with an examination of radiation therapy errors documented in NMED and then integrated these findings with vulnerabilities identified in other industries. Discussed below are six aspects or vulnerabilities that increase the risk for error:

1. "black box" aspects of automation,
2. repetition and automaticity,
3. the role of user interfaces in mode errors,
4. the role of user interfaces in data entry errors,
5. lack of independent verification for noticing errors, and
6. prospective memory demands.

These vulnerabilities become leverage points for improvement to the system, as discussed below. Appendix E contains a longer description of each event cited in this section.

4.1 "Black Box" Aspects of Automation

The impact of increasingly sophisticated automation, both positive and negative, has been well documented in the context of healthcare [45, 46], as well as with automated cockpits [47, 48] and spacecraft incidents [49]. There is a constant tension between goals of simplifying workflow for the human (e.g., through reduced need for calculations, filtering of low priority data, or automation of repetitive, predictable tasks) and encouraging the operator to stay engaged in the task and aware of the current system state. 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 [50].

These "black box" issues are compounded in radiation therapy 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 (AS 04-09 in Appendix E), 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. Thus 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.

Increased automation has raised concerns in Gamma Knife teletherapy devices as well. In new versions of the device, automation has eliminated the opportunity for the most frequently reported errors such as forgetting to change the collimator helmet and incorrect shot coordinates and

treatment times. However, at the same time, the reduction in the amount of practitioner interaction with the treatment mechanism potentially reduces the opportunity for other errors to be recognized and recovered before treatment is completed. Because the collimators are internal to the newer device and the operator no longer sees the calculations that generate coordinates, the operator has a limited ability to observe and notice anomalies. Although the latest version of the Gamma Knife is new enough that no adverse events have been reported at the time of this publication, one experienced operator reported a sense of uneasiness about the "black box" nature of the newest model. He was concerned that if something went wrong with the device, he would not be able to recognize it and diagnose the problem quickly.

Increasing automation is not necessarily a bad thing to do in many cases, it helps ease workload so operators can focus on more important tasks. However, when there is no clear mechanism through which the operator can gain an understanding of what the automation is doing, the situation may become more prone to errors that are difficult to detect and recover from before harm occurs. Strategies to keep the operator aware of what the automation is doing and engaged enough to recognize an anomaly are critical. Some have encouraged designers to consider the automation to be another team player to encourage information sharing and transparency [51]. Modern nuclear power plant control rooms include displays designed specifically to increase transparency and provide an authentic view of both the state of the power plant and the current state/actions of the automation.

4.2 Repetition and Automaticity

Radiation therapy devices are generally used as frequently as is practical, and for good reason. Radiation therapy technology requires a large investment and is in limited supply. Their frequent use results in benefits for patients in that more patients receive treatment in a timely manner and costs for the device are spread over many treatments. 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. In other words, experts are able to complete routine tasks very smoothly and efficiently, often with very little conscious effort. For the most part, this type of expertise is generally adaptive and allows people to work efficiently and effectively. However, this type of skill-based automaticity is also vulnerable to certain types of error [33].

Radiation therapy is complicated. The automaticity that comes with repetition makes it possible to carry out complicated activity with high reliability. Generally speaking, errors in skill-based behavior occur when deviations from routine and distraction create competing demands for cognitive resources [33]. Unfortunately, both of these circumstances frequently occur in the medical context. The nature of radiation therapy facilities is such that technicians are subject to interruptions and often need to do two (or more) things at once. Under these circumstances, errors in skill-based behavior are infrequent, but inevitable.

Reported events indicate that vulnerabilities associated with departures from routine and distractions are not adequately guarded against, even though (in light of the discussion above) errors are predicted in these circumstances. For example, in one vascular brachytherapy misadministration, incident AS 02-4 in Appendix E, an error was made in the treatment plan because the physician used a device that he or she was unfamiliar with but that was similar to a device he or she had used before. The physician had extensive experience with one device that uses the *diameter* of the artery in treatment planning calculations; on this day, however, the physician a different device that used the artery *radius* in calculations.

Following the normal routine, the diameter was entered, resulting in an incorrect dosimetry calculation, with an actual dose of 14.6 Gray (Gy) being administered (1460 rad) rather than the prescribed 8 Gray (800 rad).

Departure from routine also played a role in the highly publicized Beatson event in which a patient treated for a brain tumor at the Beatson Oncology Centre in Glasgow, Scotland received an overdose. In this case, new software required that units be normalized to "per treatment fraction" rather than "per 100 centigray" (cGy) as the treatment planner was accustomed to [52]. In this case, a range of other factors made it difficult to detect the problem, such as not enough staff, inadequate training on the new software and pressure to accommodate a backlog of patients waiting for cancer treatment. Such complicating factors increase the likelihood of automaticity errors.

Strategies to reduce vulnerability to departures from routine and distraction include interventions that highlight anomalies. Here the intent is to engage the operator in mindful behavior (rather than relying on routine, automatized actions) when it is most needed. This sort of "hypervigilance for the presence of latent problems and loopholes that may develop into unsafe events" [53] has been discussed as part of a work culture in the context of high reliability organizations [54, 55]. This should not be confused with superficial attempts to encourage operators to pay more attention. Rather, mindfulness is about the quality of attention. It includes noticing anomalies, even ones that are subtle (i.e., "weak signals"), and a willingness to act on potential hazards [54].

4.3 User Interfaces: Mode Errors

Mode errors occur when the operator performs a task appropriate to one mode when the device is in another mode. For example, some wrong site Gamma Knife procedures have been attributed to the use of the magnetic resonance imager (MRI) in caudal mode orientation rather than cranial mode orientation (see NRC 08-03 in Appendix E)—a change that is not obvious to the physician reading the images. In these cases, the physicians assumed the images were taken in the more common mode (cranial mode) and interpreted the image as a mirror of the actual anatomy, resulting in procedures being done at the wrong site. 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 [56]. Strategies for decreasing mode errors include:

- *Eliminating Modes*—Mode errors cannot occur if there is only one mode. However, while adding dedicated control and display devices normally eliminates multiple modes, 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.

- *Making Modes Distinct*—The goal of the second strategy is to ensure that the user is aware of the currently active mode by providing distinct, salient indications of the mode state.

- *Coordinating Inputs across Modes*—The consequences of mode errors can be reduced by ensuring that a command does not have very different meanings in different modes.

A special mode error consideration relates to systems that change modes automatically. 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 sources about how to assume control without "fighting" the system or causing unnecessary disturbances.

4.4 User 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. Appendix E contains several examples of events resulting from such errors (see AS 07-05, AS 07-06, AS 09-03, AS 09-04, AS 10-02, and AS 11-06).

The use of default values can increase vulnerability to data entry errors. In an event involving HDR for breast treatment (see NRC 11-04 in Appendix E), the operator failed to change the default from "start at connector end" to "start at tip end," resulting in the mispositioning of the source in the patient's body. However, 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. 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 noticing and recovering from errors as quickly as possible. One strategy that is widely used is to include a warning if a value entered is outside a normal range. The operator still has the opportunity to enter an out of range value if desired, but the warning requires confirmation that this was not a data entry error. Another strategy is to identify common errors (i.e., reversed MRI images) and infrequent but potentially high consequence errors (i.e., treatment plan entered for wrong patient) based on error reports and trend data. Checks and warnings can then be built into the system to reduce the likelihood that these specific types of errors will go undetected.

4.5 Independent Verification for Noticing Errors

Because there is no way to eliminate errors altogether, checking of one kind or another is relied on 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 as described in Section 4.4 . While very useful at catching potential errors of magnitude, other types of errors will go unnoticed by this type of algorithm (e.g., entries can be incorrect while still being within the normal range, thus not signaling a warning). As a result, most facilities require multiple signoffs 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 "signoff" policy failed, allowing a misadministration to occur. In one event involving an HDR device (NRC 10-07 in Appendix E), catheter distances were recorded and confirmed with two manufacturer representatives present at the time of treatment. In spite of this "independent verification," the measurements were incorrect and the radioactive source was placed 10 cm proximal to the intended position.

In another example (NRC 10-02 in Appendix E), the written directive stated the correct site (the nerve on the right) on the top half of the form, but an error was entered in the daily treatment log on the lower half of the form indicating the nerve on the left. Even with multiple signoffs, no one

noted the discrepancy from the top of the form to the bottom of the form, and the procedure was conducted on the wrong site (the left side).

There are several reasons why errors might not be detected in spite of multiple signoffs. Checks mandated by good practice or administrative procedures might not actually be performed. In some cases, personnel might "sign off" without having inspected the work. When checks are performed, errors might still go undetected, especially in settings in which experienced personnel repeatedly carry out routine actions. In such cases, personnel doing the checking, knowing that the work is being done reliably will tend to "see" what they expect to see even when it is a simple case of matching and no interpretation is required. In other words, expectancy effectively nullifies the desired human redundancy. This effect is known as the fallacy of social redundancy[4] and was a major contributor to the "friendly fire" event involving the shooting down of Black Hawk helicopters by U.S. fighter aircraft in 1994 [57]. In that case, two U.S. Air Force F-15 pilots misidentified two U.S. Army Black Hawk helicopters as hostile in spite of multiple levels of "checks," including the publication of a daily list of all friendly aircraft in the airspace and a weapons director tasked with providing real-time verification of the location of friendly aircraft. The Black Hawk helicopters were on a non-routine mission; given the actions of the Black Hawk helicopters, the F-15 pilots "expected" to see hostile aircraft.

Limiting or eliminating the effect of expectancy can improve the effectiveness of checking. For example, consider the task of setting device coordinates based on a written prescription. A typical double-check might involve one person looking over the shoulder of another to see that the settings were as specified (i.e., as expected). If the person setting the device is perceived to be reliable, the subsequent check will not be very effective in detecting the rare error, owing to expectancy. Compare this to a different type of double-check described in NUREG/CR-6323 [58], in which the checkers are required to independently determine the device settings, so that their reading of the settings is not influenced by knowledge of what the setting "ought" to be:

> An impressive double-blind checking routine would consist of one person setting the shot coordinates from the prescriptions, which are left unknown to the checkers. Each of two checkers separately records their inspection of the set coordinates. Then both checks are compared to each other and the prescription. If there is any discrepancy among the records, the coordinates are reset and the checking procedure is repeated [58, p. 42].

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.

  A different perspective might include different goals, responsibilities, functions, authority, stance, expertise, resources, methods, or knowledge/information.

- *Knowledge of "typical mistakes"*— An experienced cross-checker 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.

[4] Redundancy in systems can lead to a diffusion of responsibility and a tendency for inaction; that is, a decrease in individual effort because of the social presence of other persons. "Sometimes, when everyone is responsible, no one is."

- *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*—Distractions 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 or a potentially disruptive patient) is unlikely to be effective [59].

Cross-checking is least effective when it is conducted routinely for a process with a low base rate for errors. This is characteristic of many healthcare procedures requiring cross-checks; most of the time the original act is correct. The hope is that the cross-checker will notice the anomaly or error that happens very infrequently. The difficulty of staying alert to potential errors in such circumstances is exacerbated by noise, uncomfortable environmental temperature, fatigue, circadian changes/shift work, and boredom [59].

4.6 Prospective Memory

Prospective memory involves remembering to perform an action at the appropriate time [60]. 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 [61, 62]. However, even more mundane work settings leave us vulnerable to prospective memory errors. Reason [44] highlights the common error of leaving the last page of the original in the photocopier. When manually feeding a document, the user must remove each page to place the next one. For the last page, however, there is no cue to remind you to remove it. As Dismukes [63] further explains:

> Prospective memory is distinguished by three features: (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. Thus the critical issue in prospective memory is not retention of the content of intentions but retrieval of those intentions at the appropriate moment, which is quite vulnerable to failure [63, p. 909].

An event from the healthcare domain that is analogous to forgetting to remove the last page from the copier 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 (e.g., AS 04-06 and NRC 09-02 in Appendix E). Because all shots for a given helmet size are run consecutively, personnel usually set the stereotactic coordinates, leave the room, and administer the shot. The operator has every intention of changing the helmet at the appropriate time, but there is no cue telling the operator at the right moment that *this time* the collimator helmet should be changed after setting the coordinates but before leaving the room.

In another example of prospective memory challenges (see AS 02-5 in Appendix E), a patient was prescribed radiation treatment to the left eye and received a larger than intended dose because the nurse and authorized user became distracted with other tasks and forgot to stop the treatment. A routine administration of the eye applicator requires one person to time the event with a stopwatch while the authorized user administers the dose. The nurse and the authorized user became distracted in conversing with the patient and lost track of the time. The stopwatch used was the old style that simply counted time up and the nurse lost focus in trying to make the patient more comfortable and at ease. At the same time, the authorized user was reminding the patient to gaze in a certain direction to treat the affected area. The treatment time administered was 109 seconds instead of the prescribed 44 seconds, resulting in a larger than intended dose.

Strategies for reducing prospective memory load generally involve the introduction of deliberate cues based on an event or on time [63]. 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. The stopwatch used for radiation treatments to the eye now counts down and includes an auditory alarm when the treatment time has elapsed. The first step in ameliorating prospective memory problems is to identify instances in which the operator must remember to do something in the future with no obvious prompt. When these prospective memory challenges are identified, often simple solutions such as appropriately timed or cued prompts can be implemented.

4.7 Summary

HRA, as an integrator of multiple disciplines and with a risk focus, offers a valuable perspective for understanding human error. Study of human cognition reveals predictable aspects of human behavior. Examination of error events reveals tasks and circumstances that represent system vulnerabilities. Furthermore, generalizable elements that introduce system vulnerability provide valuable leverage points for improving system design to better support humans in managing complexity.

5 SUCCESS STORIES IN USING A RISK PERSPECTIVE ON HUMAN ERROR: ARE THE CORRECTIVE ACTIONS WORKING?

Using a risk perspective to understand human error and to guide improvements in systems to reduce the risks has proved successful in many industries. The most notable of these industries are civil aviation and commercial nuclear power. This section examines efforts in these complex, high-profile industries to reduce errors through implementation of a risk perspective (i.e., HRA).

Because of the potential for catastrophic consequences to occur, in both civil aviation and commercial nuclear power, there has been a long-standing realization that the consequences of accidents are unacceptable. Both industries continue to work to reduce accident risks regardless of the current levels.

As with healthcare, the commercial aviation and nuclear power industries have found from experience that most accidents and significant events are the result of human performance issues. For example, Boeing reports that:

> Human error has been documented as a primary contributor to more than 70 percent of commercial airplane hull-loss accidents [64].

This estimate is consistent with other evaluations of the contributions of human performance problems for aviation; the estimate provided by the Federal Aviation Administration, for example, is 70 percent to 80 percent in civil and military aviation [15]. In commercial aviation, work has been performed by all parts of the industry to improve human performance:

- The aviation manufacturing sector (see, for example, the description of the human performance improvement programs at Boeing) [64]
- The regulator, FAA [15]
- The International Civil Aviation Organization (ICAO) [65].

Interestingly, Dougherty and Fragola [16] report similar rates of human performance issues in the nuclear power industry. More recently (in NUREG/CR-6751 [66]), an evaluation of the contribution of human errors to events involving a substantial increase in the risk of core damage in commercial nuclear power plants found the average human error contribution to the change in risk was 62% . This is consistent with the estimate of the worldwide nuclear industry as reported by the International Atomic Energy Agency (2010) [67], where human and organizational factors contributed up to 75 percent of the operational problems reported.

5.1 Improvements in Managing the Contributions of Human Error to Risk

In spite of the relatively high rates of human error, the risk associated with flying in commercial aviation has never been lower for flight operations in the developed world. The Aviation Safety Network, which maintains the database of worldwide aviation accidents for the Flight Safety Foundation, described the year 2012 as the safest year since 1945 in terms of absolute numbers of fatalities and flight accidents [68]:

> The year 2012 was an extremely safe year for civil aviation, Aviation Safety Network data show. The Aviation Safety Network recorded a total of 23 fatal

airliner accidents, resulting in 475 fatalities and 36 ground fatalities. Both figures are extremely lower than the ten-year average of 34 accidents and 773 fatalities.

In fact, 2012 was the safest year since 1945 by number of accidents. The number of accidents involving passenger flights was the lowest since 1945: eleven accidents, as compared to the ten-year average of 16 accidents.

The low number of accidents comes as no surprise, according to Aviation Safety Network President Harro Ranter: “Since 1997 the average number of airliner accidents has shown a steady and persistent decline, probably for a great deal thanks to the continuing safety-driven efforts by international aviation organizations such as ICAO, International Air Transport Association (IATA), Flight Safety Foundation and the aviation industry.”

Not only is the absolute number of accidents continuing to decline, but the rates of accidents per departure have also decreased significantly as shown in Figure 5-1 [69].

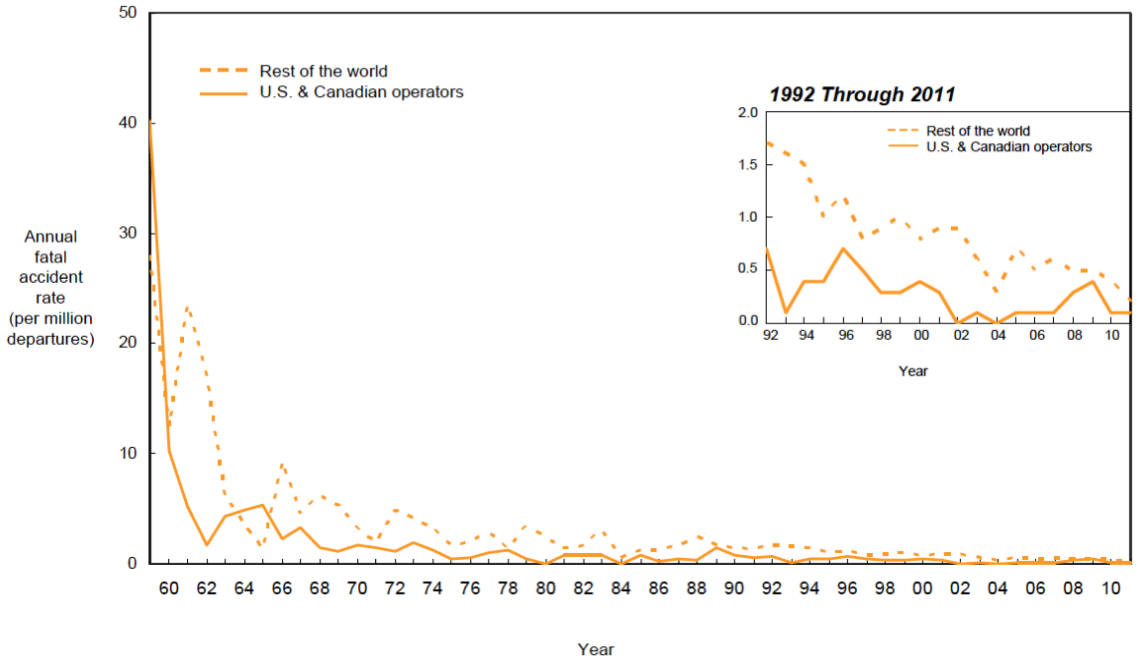

Figure 5-1 Safety performance in the aviation industry

Similarly, there has been a steady improvement in the safety performance of U.S. nuclear power plants as measured by the numbers of “significant events”; this is shown in Figure 5-2. Significant events are events that have a significant adverse implication for safety. Examples include events that add to the likelihood of core damage, an event rated 2 or more on the International Atomic Energy Agency’s International Nuclear Event Scale [70], or a finding rated yellow or red in the NRC’s Reactor Oversight Process [1].

The reductions in the occurrences of events through time shown in Figure 5-1 and Figure 5-2 have been accomplished in large part by implementing programs to improve human performance.

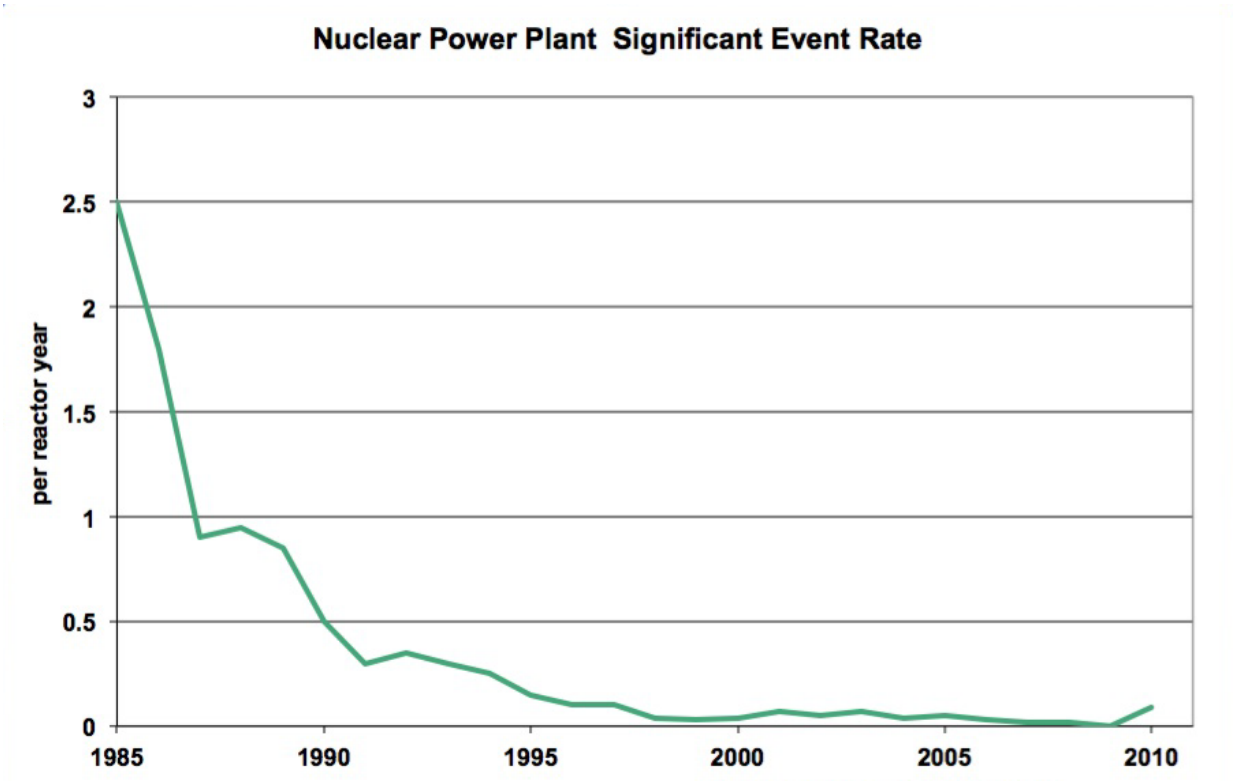

Figure 5-2 Rates of significant events at U.S. commercial nuclear power plants

In both industries, these improvements have been accomplished through systematic approaches to the understanding of the causes of human errors, identifying the factors influencing them, and making changes based on this knowledge.

One significant example for aviation is the work of the Commercial Aviation Safety Team (CAST), which includes representatives from international safety authorities, employee groups (pilots and air traffic controllers), and the aviation industry (airplane and engine manufacturers and airlines). Focusing on U.S. experience, CAST, along with the new aircraft regulations and other activities, successfully reduced the fatality risk for commercial aviation in the United States by 83 percent from 1998 to 2008. CAST aims to reduce the U.S. commercial fatality risk by another 50 percent between 2010 and 2025.

The Procedural Event Analysis Tool (PEAT) process developed by Boeing [64] is an example of the kinds of tools developed by the aviation industry specifically to identify the causes of and effective corrective actions for human errors. The PEAT process is focused specifically on errors involved in using procedures. More information about PEAT is provided in Appendix F.

In the U.S. commercial nuclear power arena, both the NRC and the industry undertook significant efforts to improve performance—particularly human performance in the years following the accident at Three Mile Island Unit 2 (TMI-2). As part of its TMI Action Plan [71], the NRC required licensees to carry out detailed control room design reviews and to correct human factors deficiencies [72]. The NRC also developed human factors guidance [73, 74] to be used by staff reviewing these activities. Overall, NUREG-1355 [75] summarizes the variety and breadth of changes resulting from TMI-2 lessons learned in a 10-year review. A participant in the detailed control room design review process observed that its greatest influence “was a change in attitude and perspective about the viability of the input Human Factors makes to the design process” [76]. The NRC continues to update its guidance and technical basis [28] in order to keep pace with changing technology and support its use in designing and evaluating control room modernizations

such as digital control and computer based procedures [77, 78]. The NRC also developed a model for evaluating the human factors programs supporting new plant designs being submitted for licensing [79]. As noted in NUREG/KM-0001 [80], TMI-2 investigations and lessons learned brought about sweeping changes in the U.S. nuclear industry, including improvements in emergency response planning, reactor operator training, human factors engineering, radiation protection, and many other areas of nuclear power plant operations. The NRC and industry continue to respond to TMI-2 and other events worldwide to improve safety.

Improvements also came as a result of efforts by the Institute of Nuclear Power Operations (INPO), an industry group formed in response to recommendations by the Kemeny Commission after TMI to improve the standards of safety performance. One of the key recommendations was improvement in human performance. INPO has developed a variety of human performance improvement resources for use by the industry [81, 82].

The NRC has established a long history of using risk as one of its main guiding principles for regulation to protect the stakeholders of the domains it regulates. The agency developed the Probabilistic Risk Assessment Implementation Plan in 1994 to focus the agency's efforts on PRA-related activities. The Risk-Informed Regulation Implementation Plan (RIRIP) superseded this plan in 2000. Then, in April 2007, the NRC replaced the RIRIP with the Risk-Informed, Performance-Based Plan (RPP). Each of these plans has guided the NRC in developing risk-informed, performance-based regulations. Within this umbrella of programs, the agency has developed methods particularly aimed at improving the modeling and management of human reliability, a key contributor to risks as quoted above. These include the Technique for Human Error Rate Prediction (THERP) found in NUREG/CR-1278 [83], the Accident Sequence valuation Program (ASEP) HRA Procedure found in NUREG/CR-4772 [84], and more recently A Technique for Human Event Analysis (ATHEANA) in NUREG-1624 [85]. Using these and similar approaches, the NRC has implemented a formalized risk perspective to: (1) understand the risk significance and the causal contributions to events that have occurred and (2) evaluate the adequacy of remedial actions.

5.2 Improving the Effectiveness of Error and Risk Reduction

One common theme to these improvements has been a focus on both the causes of human errors and a process to ensure that the results are leading to an improvement in overall safety. Often, organizations put in place some kind of event analysis and/or corrective action process as a matter of course, but rarely check that the process is having any substantive effect. Figure 5-3 shows a typical performance improvement process. Often the cycle is triggered by some event that indicates a problem in performance that can be associated with safety or whatever metric is of concern to the system owner or regulator.

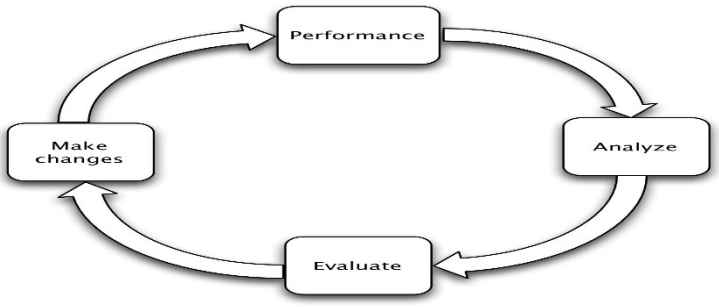

Figure 5-3 Performance evaluation

The event is then analyzed using tools to identify its causes and potential changes or improvements are then evaluated based on the causes identified. Following the evaluation, changes are made to the process in the belief that the performance will improve.

The problem with this simple process is that the changes made may or may not be effective in the "big scheme of things". This limitation has been addressed in work by Argyris, who has articulated what has become known as "double-loop" learning [86, 87].

A second example might include considering whether specific corrective actions will contribute to higher-level goals such as reducing the risks to the public from nuclear radiation. For example, the NRC is considering a broader consideration of risk, including in the area of medical uses of byproduct materials. NUREG-2150, titled "A Proposed Risk Management Regulatory Framework," recommends more explicit implementation of risk management and defense in depth, as well as environmental reviews [1]. Thus, if this framework were to be adopted, a relevant response to the question "What is my real goal?" could be "Am I accomplishing a reduction in risks consistent with this framework? Has there been a reduction in reportable events?" The intent of the second loop (as shown in Figure 5-4) is to evaluate whether the first loop process is accomplishing the real goal. Thus, if there is no effective reduction of the risks of medical events, what must be done to the first loop to make it so?

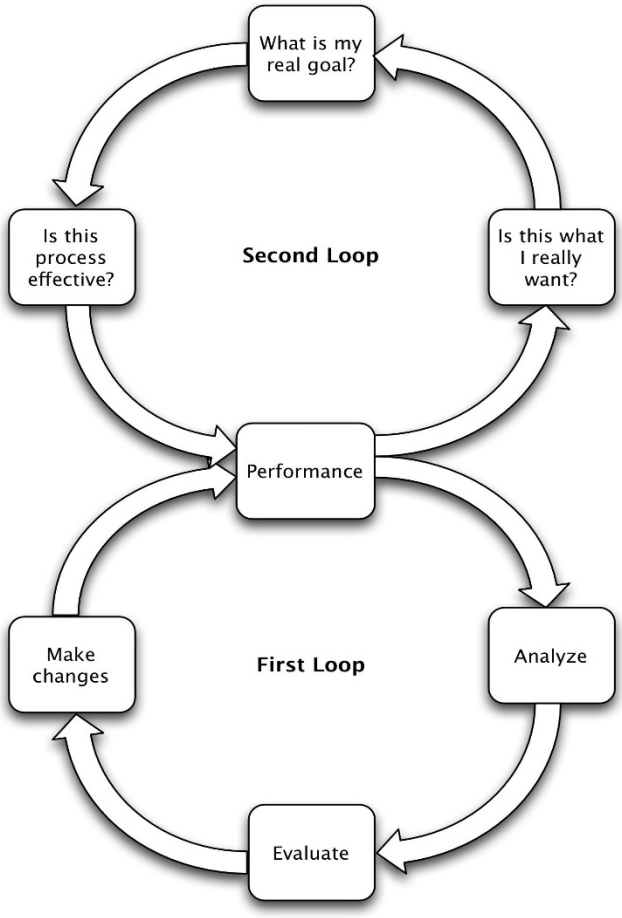

Figure 5-4 Double loop learning

5.3 Significance for Reducing the Risks from Human Error in Radiation Therapy

The experience indicated in this section suggests that substantial reductions in the risks of technological activities, especially those dominated by human performance, have been accomplished by systematic approaches to understanding the causes of, and contributing factors to, human errors. In the case of aviation, which features multiple aspects of human performance (e.g., design, selection and qualification, training, and operational practices), this has been accomplished in part through a collaborative program (i.e., the CAST program) and in part through the leadership of the international regulatory body (ICAO). As a result of their and other related activities, human errors and the resulting risks of commercial aviation accidents have fallen substantially. In the case of the U.S. commercial nuclear power industry, the joint efforts of the NRC and the industry group, INPO, have led to substantial reductions in the incidence of significant events by focusing on the area of human performance.

Both of these efforts have been effective in large part because of the use of accident and incident investigation tools that not only concentrate on the immediate causes of events but also look to make sure the framework of analysis addresses the deeper concerns of accomplishing risk reduction and performance improvements.

5.4 Safety Developments from the Nuclear Safety Authority in France

Since 2007, ***Autorité de sûreté nucléaire*** (ASN), the French Nuclear Safety Authority, has received 1614 radiotherapy event notifications. For some, no health consequences have as yet come to light, while others entail serious complications for the patients, even resulting in death in a few cases, as in the Epinal overexposures between 2004 and 2005 [88]. In this context, ASN has since 2007 been inspecting all of the radiotherapy centers, concentrating in particular on organizational and human factors, and has published on July 1, 2008, technical decision No. 2008-DC-103 setting out the obligations of quality assurance in radiotherapy. In addition to publishing criteria for the notification of significant radiation protection events, ASN in conjunction with Société Française de Radiothérapie Oncologie (SFRO, the French society for oncologic radiotherapy) developed a scale for rating the severity of events affecting patients undergoing a medical radiotherapy procedure [89].

5.4.1 Why Notifying the Regulator is Important

Following each radiation protection event (e.g., technical anomalies or deviations from procedures), it is necessary to understand which measures will prevent its repetition. For patients or workers, only an event notification from the radiation therapy center to the regulator will allow an independent analysis of radiation protection events. Results of such independent analyses serve a key role in defense in depth by:

- Supporting the development of lessons learned in order to prevent event recurrence.
- Limiting the occurrence of worse events.
- Serving as a source of operating experience.
- Supporting the improvement of medical practices in hospitals and radiation therapy centers.

5.4.2 The Notification Approach in France

The reporting system defined in the ASN guide is not intended to identify or punish a person; it aims to analyze significant events, provide a source of knowledge, facilitate the subsequent

evaluation of an incident or accident, and improve the practices of an institution and/or the radiation therapy sector.

As a consequence, with the objective to make permanent progress for patients' and workers' radiation protection, the ASN defined an approach and issued guidance and newsletters for radiation therapy professionals [90] in order to help radiation therapy centers to declare their radiation protection events more easily.

This approach rests on:

- the definition, by both ASN and SFRO, of understandable criteria for radiation protection events,

The ability of ASN:

  - to check radiation therapy centers analyses as well as the relevance of their corrective actions and implementation of operating experience, and
  - to contribute to the public information.

5.4.3 The Notification Criteria

In order to better assess consequences (to patients, workers, and/or the public) and causes (sources, waste, security issues, etc.) of adverse events, different criteria were established in France. Criteria defined in guide n°16 [89] and published on ASN's Web site aim to:

- Deal with in-depth event analysis in order to take into account events' real or potential consequences, through which ASN would like to:
  - Ensure the accuracy of individual analyses.
  - Identify corrective actions and provide a source of operating experience from the radiation therapy center.
- Develop a justification for regulatory decisions.
- Allow for a consistent treatment of events.

Thus, different criteria were established to better assess consequences (to patients, workers, and/or the public) and causes (e.g., sources, waste, security issues). These criteria can be found on the French Nuclear Safety Authority website.

Each declared event provides feedback that should help improve the quality and safety of radiation therapy. The radiotherapists who agree to join in this move towards transparency (by declaring events that have occurred) contribute to strengthening of radiation protection. Between 205 and 2013, annual radiation protection event notifications to the French regulator increased by more than 60 percent, rising from 158 events declared in 2005 to 263 in 2013 [91]. The declaration of incidents/accidents by these professionals indicates a positive change in cultural attitudes to radiation protection in France.

5.5 Summary

The aviation and commercial nuclear power industries are powerful examples of success stories with regard to improving safety. Success has been achieved, in part, because of the implementation of a two-loop process in which corrective actions are monitored and evaluated with regard to whether they adequately achieve safety-related goals. This effort to move beyond a process and toward an active evaluation of the real-world impact of interventions is key to safe operations in complex environments.

6 HUMAN RELIABILITY ANALYSIS APPROACH TO RISK MANAGEMENT IN THE MEDICAL USES OF BYPRODUCT MATERIALS

In order to effectively apply HRA principles at the level of inspection and corrective action, there must be a higher level regulatory framework in place to support these activities. The NRC, in its relatively recently published NUREG-2150, *A Proposed Risk Management Regulatory Framework* [1], stated that:

> The materials program has successfully developed and incorporated risk insights and performance considerations into its rulemaking, policy development, and routine licensing and inspection activities. (Finding M-F-1)

Furthermore, it recommended:

> The NRC materials program should continue to apply risk insights and performance-based considerations, as appropriate, in rulemaking, guidance and policy development, and implementation in accordance with the proposed risk management framework. (Recommendation M-R-1)

The present work is consistent with this recommendation, in that it recognizes that the dominant source of risk in the medical uses of materials is from human performance issues, as discussed in earlier sections.

6.1 Overall Approach to Risk Management

There are several levels at which risk-management activities can be applied in this area. Risk-management can be seen as applying to the entire process of delivering radiation therapy, including the design and use of therapy devices. It also can be seen as applying to just the area of the application and use of devices, and it can be seen as applying to just the human performance issues related to their use.

In an ideal world, risk-management is best accomplished when all aspects of the relevant system are controllable within a common framework. The responsibility for managing the medical uses of radioactive materials is, however, divided among different agencies. Most importantly, the evaluation and approval of devices is the responsibility of the Food and Drug Administration (FDA), part of the U.S. Department of Health and Human Services. The NRC regulates the use of such devices. Given this division of roles, the NRC can provide design review input to the FDA (including the review of human-device interactions errors) if a significant design flaw is found to have led to a medical event (i.e., after an event has occurred). However, the NRC does not evaluate potential causes of human error related to equipment design before a medical event occurs (e.g., during the FDA licensing review). While there currently is coordination and cooperation between the NRC and FDA, more coordination within their respective frameworks for managing risk could contribute to making effective reductions in the current levels of human error.

There is a history of collaboration and communication between the NRC and FDA. However, given the improved understanding of how the interaction between design issues and user issues can lead to sources of risk to patients, workers, and the public, an increased level of coordination and collaboration could be important to making significant improvements in the levels of safety. This separation of responsibilities is not unique to this area. In the aviation world, for example,

manufacturers are responsible for the design of the aircraft, including its cockpit design, and the airlines are responsible for the training and qualification for the pilots. Different parts of the U.S. Federal Aviation Authority (FAA) are responsible for regulating these. In addition, the U.S. National Transportation Safety Board investigates all aspects of aviation accidents, thus providing the capability to identify and integrate contributions from the interactions of displays and human errors, for example.

In order to provide systematic strategies for identifying and implementing improvements, the aviation community has used a team approach to identify and implement improvements. The team-based CAST approach is credited, for example, with contributing to the continuous improvements in risk reduction in commercial aviation.

Given the distributed regulation of medical devices, the NRC might wish to consider strengthening the existing team approach with FDA to lead to a broader scope of the NRC's regulatory influence, to allow failures in the operation of equipment to be traced back to causes associated with the design.

6.2 Framework for Risk Management for Patient Safety

The NRC and similar regulatory bodies have evolved risk-management processes to provide a structured basis for ensuring that acceptable standards of safety are met through the phases of licensed operations. Such an approach has been used widely by NRC in its licensing of nuclear plants as discussed in several appendices of NUREG-2150 [1].

The NRC's PRA Policy Statement [92] suggests that medical devices (specifically identified as devices used in radiation oncology in the Policy Statement) do not require PRA studies:

> Events associated with industrial and medical uses of nuclear materials generally involve a simple system, involve radiation overexposures, and result from human error, not equipment failure. Because of the characteristics of medical and industrial events, as discussed above, analysis of these events using relatively simple techniques can yield meaningful results.

These "relatively simple techniques" are not identified. This report presents a range of techniques for addressing such a need. As noted earlier, this report has adopted an HRA-informed approach which, while not specifically supporting a PRA study, still provides a systematic way to structure the analysis of events, to prioritize types of events and human actions for performance improvements (i.e., establish a risk focus), and to identify successful approaches for making these improvements by leveraging a variety of multidisciplinary tools and knowledge.

In 2000, the NRC sponsored NUREG/CR-6642 [93], which developed a risk-informed framework specifically for byproduct materials, including their use in medical applications. The risks considered in this framework were to the workers and the public but specifically not to patients.

This framework describes a generic risk concept based on the simple view that answering three simple questions provides a measure of risk:

1. What can go wrong?
2. What is the likelihood?
3. What are the consequences?

The framework identifies how risk is managed by identifying:

- What kinds of hazards exist
- What physical barriers and controls are present to reduce the chances of or prevent people from receiving radiation doses from the hazard inappropriately

The report goes on to consider how this concept applies to different kinds of uses of byproduct materials, including HDR and LDR brachytherapy, gamma knife, and manual afterloading brachytherapy.

Later, in 2008, the NRC developed a document called Risk-Informed Decision making for Nuclear Material and Waste Applications [94]**,** which described a risk-informed decision making (RIDM) framework with the intention that the staff could use this framework to supplement its approach to decision making on regulatory relief, safety considerations, and additional requirements. Figure 6-1 shows the generic form of risk-informed decision making presented in that document. Again the emphasis is on risks to workers and the public, but not those to patients in medical applications. Human error is identified in both reports as a major contributor to risk significant events.

In principle, the issue of risks to patients can be viewed in the same light as the risks to workers and the public. The steps involved in the framework analysis (identifying the potential hazards and the barriers and controls against them) can apply equally to the patient-related hazards. In 1995, the NRC published studies of human factors issues relating to patient misadministration events of some medical uses [10, 11] that indicated that an HRA approach could be used to identify potential reductions in risk to patients during treatments. The work described in this current report is, in some ways, an extension to, and updating of, those studies.

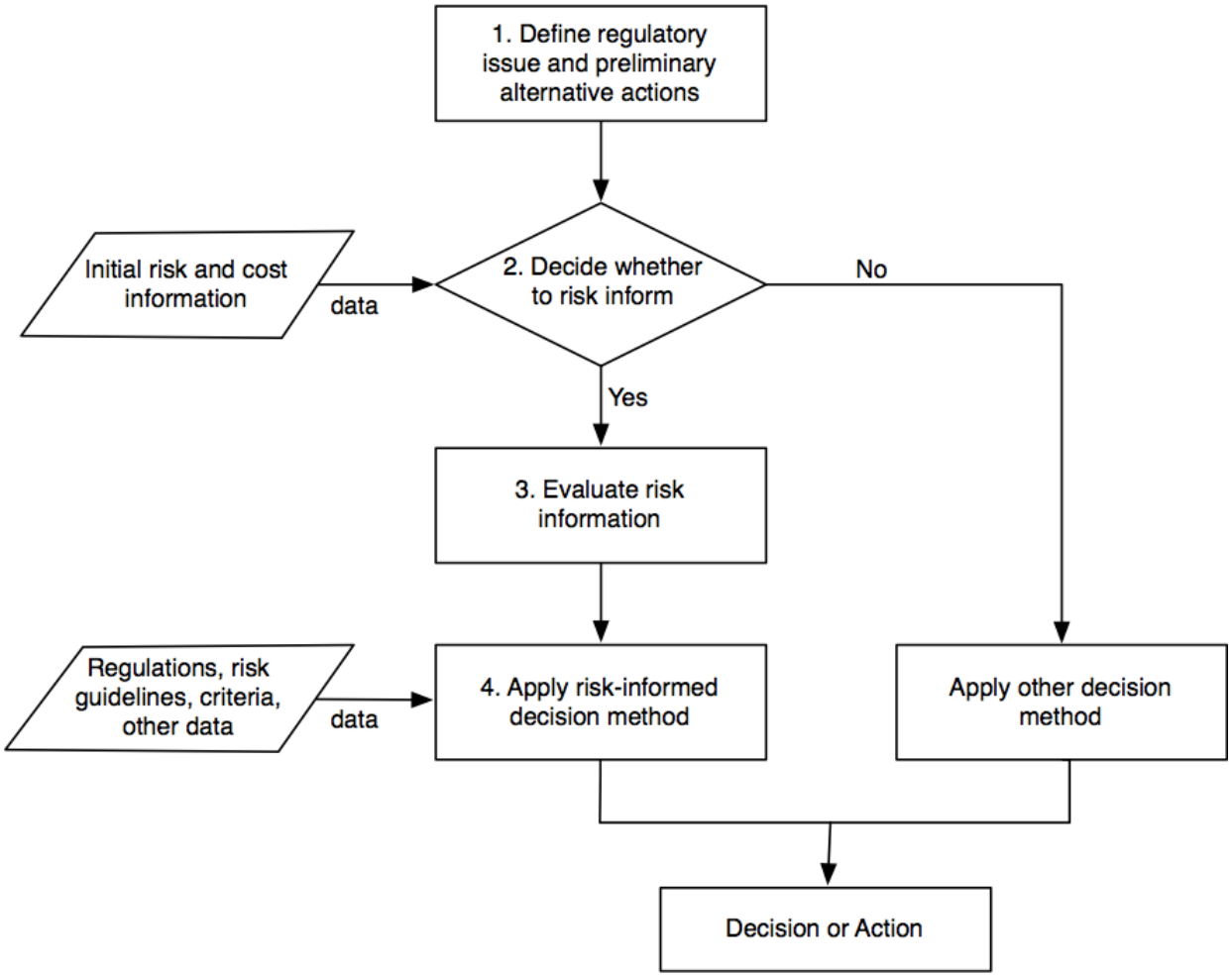

Figure 6-1 Generic form of risk-informed decision making

The recent NRC discussion of the Proposed Risk Management Regulatory Framework presented in NUREG-2150 [1] highlights the robust requirements for medical uses of radioactive materials:

> For example, the requirements for therapeutic applications of byproduct material, particularly those involving high activity sources, such as high dose rate afterloaders or gamma stereotactic radiosurgery units, are more robust than those for diagnostic nuclear medicine and may include multiple physical barriers and administrative controls to protect workers, patients, and members of the public.

However, as seen from the events associated with such devices described earlier in this report, there are opportunities for significant human errors during the use of high activity sources. The activity levels require treatment teams to operate devices remotely, requiring increased use of automation to operate the barriers and controls. These levels of automation create, for example, new opportunities for human errors to result in increased risks of erroneous treatments.

The NRC might wish to consider the increased use of human error analyses and HRA improvement techniques within a risk management framework to identify both significant causes of medical events and appropriate corrective actions to reduce the risk to patients. One simple approach could be to provide systematic feedback to all licensees about the occurrence of events,

the causes of those events, and relevant corrective actions. This should parallel the approach taken for feedback about reactor operating experiences.

6.3 Recommendations Summarized

Human performance issues are a dominant source of risk in the medical use of byproduct materials. Given the complexity of human performance in healthcare and the division of regulatory responsibilities, the NRC might wish to consider increasing its teaming efforts with the FDA to provide more comprehensive and effective oversight and guidance. An increased emphasis on an HRA-informed perspective in the context of the medical use of byproduct materials is likely to lead to a better understanding of error, the role humans play in managing error, and effective corrective actions. The NRC might also wish to consider increased use of human error analyses and HRA improvement techniques within a risk-management framework.

7 SUMMARY AND CONCLUSIONS

Error will occur despite the best intentions, careful design, and skilled personnel. From a human reliability point of view there is a dual aim: 1) to reduce the likelihood of error and 2) to increase the likelihood of recovery from error before negative consequences occur. HRA offers a perspective for understanding human capabilities, strategies for identifying system vulnerabilities or "error traps," methods for analyzing errors when they do occur, and recommendations for developing effective corrective actions. A comprehensive HRA-informed approach would also include two-loop learning (Figure 5-4), in which an organization deliberately articulates safety-related goals and evaluates corrective actions to determine whether they are, in fact, contributing to increased safety.

The NRC has been conducting human reliability studies about the use of byproduct materials in radiation therapy since the early 1990s. An important next step is to increase the emphasis on human reliability in operations. Although adapting HRA-informed approaches for use in healthcare is not a trivial undertaking, the authors of this report anticipate that application of HRA-informed approaches will lead to a better understanding of individual incidents, as well as error trends across sites. An improved understanding of error will lead to more effective corrective actions that reduce the likelihood of error and increase the likelihood of recovery from error. The aviation and commercial nuclear power industries stand as powerful examples of the value of an HRA-informed approach for increasing safety.

Of course, the scope of NRC's regulatory responsibilities is currently limited. The agency is not directly involved in assessing the design of medical equipment, for example. However, if there are to be improvements made in the safety to patients, workers, and the general public, a start can be made on addressing the human reliability issues within NRC's sphere of regulation, while setting the stage to address the potential for influencing the areas currently beyond that sphere. Enhanced teaming efforts with the FDA to coordinate efforts may be an effective strategy for additional improvement.

In conclusion, it is recognized that the NRC has a strong track record in developing and implementing HRA methods, particularly in the nuclear power domain. Although healthcare provides new and different challenges, the authors believe an HRA framework will have value for increasing safety for the medical use of byproduct materials, as well.

Two recommendations are offered to follow up on these conclusions:

1. *Human errors should be recognized as important contributors to radiation therapy events. Strategies for reducing such errors are best addressed by a combination of disciplines, including the medical and health physics fields, HRA, human factors, and cognitive science. In particular, HRA can be used to integrate inputs from multiple disciplines and provide a risk-informed perspective, allowing prioritization of potential fixes and balancing of competing needs.*

2. *Historical experience in addressing human errors in technologies such as commercial nuclear power and aviation has shown that, while there are multiple approaches to incorporating "human factors" into an error reduction effort, not all approaches are equally effective. The NRC has in-house experience on these "more effective approaches" (predominantly in the Offices of Nuclear Regulatory Research and Nuclear Reactor Regulation) that could assist or guide human error reduction efforts for radiation therapy.*

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APPENDIX A

ROOT CAUSE ANALYSIS

Many strategies for analyzing human error have been proposed. Root cause analysis is one of the most common, has been used extensively in nuclear power industry, and in more recent years has been adapted for use in healthcare. This section takes a closer look at the issue of root cause analysis, as defined in NUREG/CR-6751 [66] regarding human performance evaluation:

> Root cause analysis generally is described as being a systematic method for analyzing the evidence collected about a hardware failure or human performance problem. The purpose of root cause analysis is to identify the basic set of conditions that, if eliminated or modified, would minimize the likelihood of the same and similar problems from happening again.

Because root cause analysis techniques have evolved to support specific technologies and applications, there is no definitive reference for these techniques. However, many approaches are likely to be based on early work in this area performed by the U.S. Department of Defense [95].

A.1 Root Cause Analysis in the Power Industry

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

> …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 preclude repetition." (10CFR50, Appendix B, Criterion XVI) [95]

Similarly, the U.S. Department of Energy [96] defines root causes as "the causal factors that, if corrected, would prevent recurrence of the same or similar accidents. Root causes may be derived from or encompass several contributing causes." With respect to corrective action, the DOE guidance notes that root causes "are higher order, fundamental causal factors that address classes of deficiencies, rather than single problems or faults" and that "correcting root causes would not only prevent the same accident from recurring, but would also solve line management, oversight, and management system deficiencies that could cause or contribute to other accidents." Performing a systematic root cause analysis and identifying the direct, contributing and root causes of human performance problems, aids in ensuring that the problems are understood with sufficient depth to support the development of effective corrective actions.

A.2 Root Cause Analysis in Healthcare

The recurrent theme of these definitions is that the depth of investigation should be sufficient to lead to corrective actions that eliminate or reduce significantly the likelihood of the event being investigated and similar failure events. 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 (JCAHO, also commonly referred to simply as "The Joint Commission")[5] requires hospitals and other health providers to perform root cause investigations on "sentinel events."

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

A.2.1 The Joint Commission's 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 [97].

The list of specific events to be included as sentinel events only partly overlaps the NRC's definition of a medical event. Specifically for radiation therapy, doses in excess of 1500 rad (15 Gy), any dose to the wrong site, and doses in excess of 25 percent above the planned dose are considered sentinel events by the Joint Commission. The complete list of representative events provided by the Joint Commission is shown in Table A-1. The Joint Commission's representative categories and subcategories of root causes of sentinel events [98], listed in Table A-2, encompass:

- "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."

It goes on to state that:

- "The majority of events have multiple root causes."

Table A-1 The Joint Commission's definition of a sentinel event

- The event has resulted in an unanticipated death or major permanent loss of function, not related to the natural course of the patient's illness or underlying condition, or
- The event is one of the following (even if the outcome was not death or major permanent loss of function):
  - suicide of any individual receiving care, treatment or services in a staffed around the clock care setting, or within 72 hours of discharge
  - unanticipated death of a full-term infant
  - abduction of any individual receiving care, treatment or services
  - discharge of an infant to the wrong family
  - rape
  - hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities
  - surgical and nonsurgical invasive procedure on the wrong patient, wrong site or wrong procedure
  - unintended retention of a foreign object in an individual after surgery or other procedure
  - severe neonatal hyperbilirubinemia (bilirubin > 30 milligrams/deciliter)
  - prolonged fluoroscopy with cumulative dose > 1500 rads to a single field, or any delivery of radiation therapy to the wrong body region or 25 percent above the planned radiation therapy dose

Table A-2 The Joint Commission's categories of root causes and sentinel events

Anesthesia Care—Planning, monitoring and/or discharge

Assessment—Adequacy, timing, or scope of assessment; pediatric, psychiatric, alcohol/drug, and/or abuse/neglect assessments; patient observation; clinical laboratory testing; care decisions

Care planning—Planning and/or collaboration

Communication—Oral, written, electronic, among staff, with/among physicians, with administration, with patient or family

Continuum of Care—Access to care, setting of care, continuity of care, transfer of patient, and/or discharge of patient

Human Factors—Staffing levels, staffing skill mix, staff orientation, in service education, competency assessment, staff supervision, resident supervision, medical staff credentialing/privileging, medical staff peer review, other (e.g., rushing, fatigue, distraction, complacency, bias)

Information Management—Information management needs assessment, confidentiality, security of information, data definitions, availability of information, technical systems, patient identification, medical records, aggregation of data

Leadership—Organizational planning, organizational culture, community relations, service availability, priority setting, resource allocation, complaint resolution, leadership collaboration, standardization (e.g., clinical practice guidelines), directing department/services, integration of services, inadequate policies and procedures, non-compliance with policies and procedures, performance improvement, medical staff organization, nursing leadership

Medication Use—Formulary, storage/control, labeling, ordering, preparing/distributing, administering, and/or patient monitoring

Nutrition Care—Nutrition care planning, timing, storage, and/or patient monitoring

Operative Care—Operative care planning, blood use, and/or patient monitoring

Patient Education—Planning education, providing education, effectiveness of education

Patient Rights—Informed consent, participation in care, end-of-life care, pain management, privacy

Performance Improvement—Improvement planning, design/redesign testing, design/redesign measurement, data collection, data analysis, improvement actions

Physical Environment—General safety, fire safety, security systems, hazardous materials, emergency management, smoking management, equipment management, utilities management

Rehabilitation—Rehabilitation care planning, patient monitoring

Special Interventions—Special intervention planning, assessment, restraint equipment, patient monitoring

Surveillance, Prevention, and Control of Infection—Sterilization/contamination, universal precautions

Figure A-1 shows the relative contributions of The Joint Commission's categories for all sentinel events (roughly 2500) reported for 2010 through the second quarter of 2012 (the last time period available at the time of writing this report), and Figure A-2 shows the breakdown of root causes; there were 29 such events in the category of radiation overdoses alone. The proportions of events attributed to human error are virtually the same.

Seen together, both The Joint Commission's and the nuclear industry's approaches 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," a report produced following a workshop on patient safety [99]. The report takes 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.

The "comparison and contrast" approach used in the "A Tale of Two Stories" illustrates a difference between getting at the superficial causes of an event and the more in-depth understanding of how complexity and attention to the whole story can identify causes that are not otherwise understood. For example, in a case that involved using a computer managed infusion device, a patient was inadvertently administered a free flowing infusion of a vasoactive drug instead of a measured/timed dose. The event was originally classified as a user error in the setting up of the infusion device, with phrases like "You can't make devices idiot-proof" and "You have to be careful, it can burn you" being used. However, when the "second story" investigation took place, it was found that similar events had occurred in the past and that, when the setup process was videotaped and analyzed, there were many opportunities for failure. As a result, use of the particular device was reduced and alerts were published in the professional press about the risk.

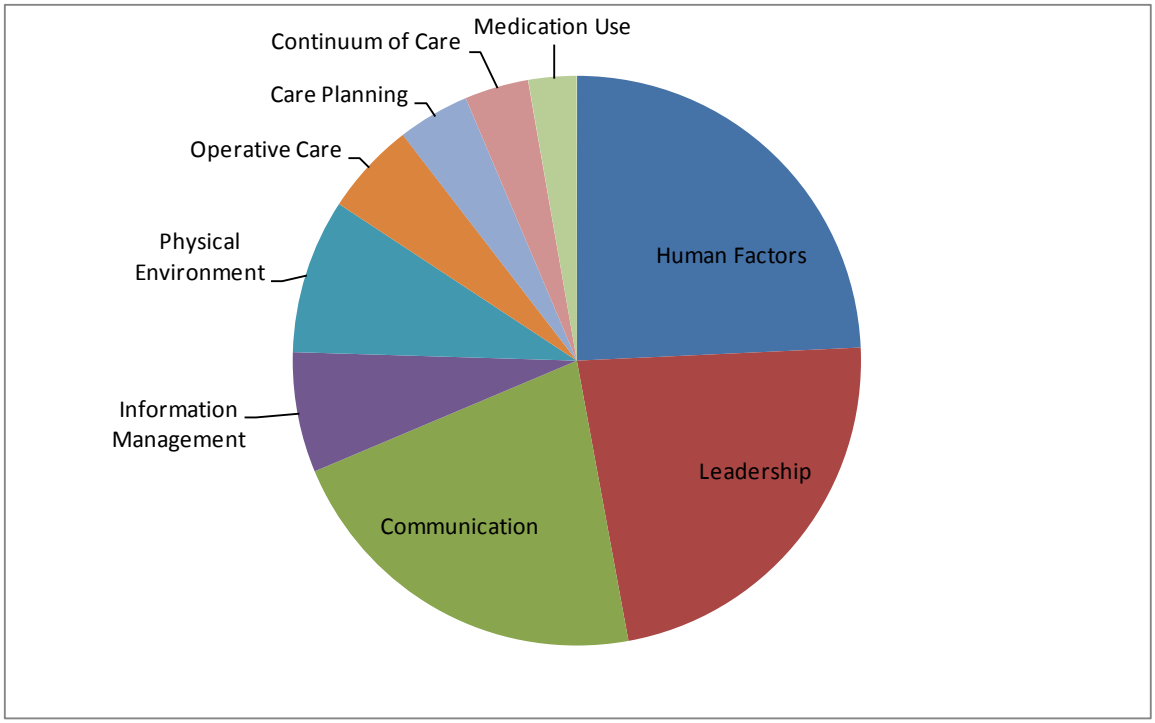

Figure A-1 Root causes for all of The Joint Commission sentinel events, 2010 through 2012, 2nd quarter

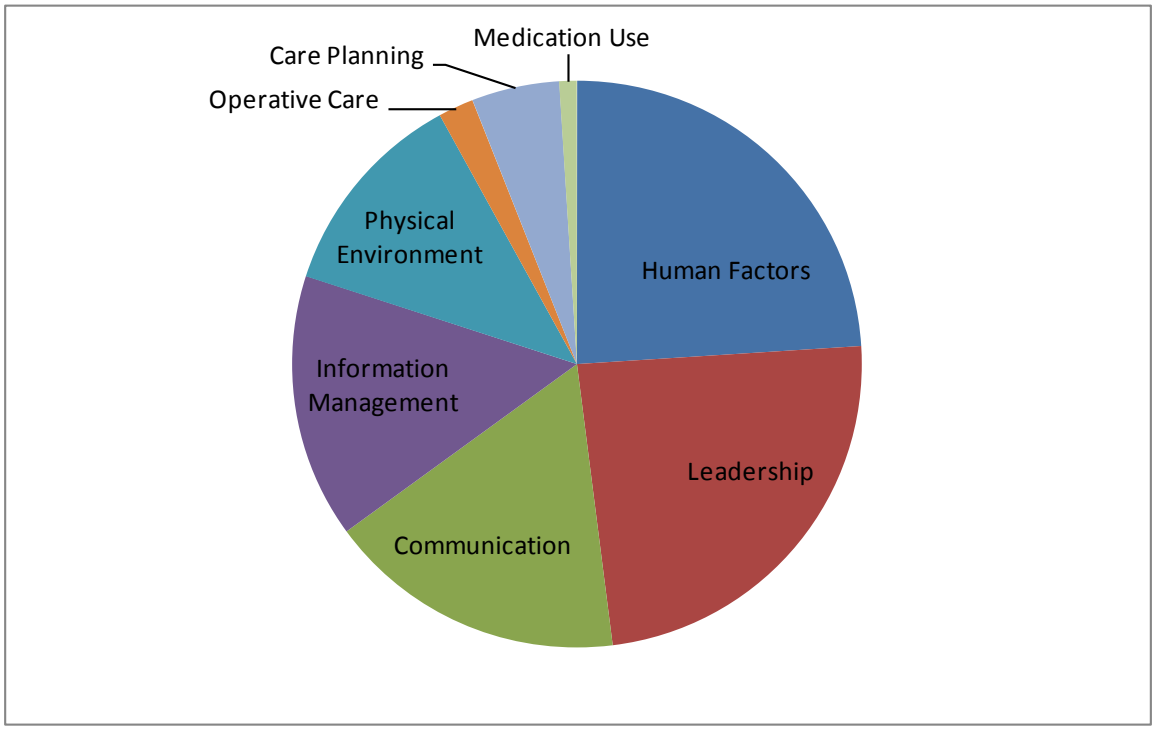

Figure A-2 Root causes for The Joint Commission sentinel events involving radiation overdoses

A.2.2 NRC Medical Events

NRC regulations (in 10 CFR 35.3045 Part M, , "Report and Notification of a Medical Event") require the reporting of events associated with the treatment of patients with radiation therapy using byproduct materials when a dose differs significantly from the prescribed dose; exceeds a specified dose to organ, tissue, or skin; or is administered to the wrong site. See Table A-3 for specific criteria.

Events caused by patient interventions are not reportable for the types of events described above. However, a licensee is required to report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

The NRC's NMED program provides a single repository for medical event reports for both the NRC and the Agreement States. As part of this program, events are classified according to cause. Figure A-3 shows the breakdown of causes of medical events for Fiscal Year (FY) 2011 through the 3rd quarter.

Table A-3 NRC criteria for a reportable event

(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 [Sieverts] (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) 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
(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 (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) 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 (50 rem) 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).

While not a one-to-one match, there is considerable overlap with The Joint Commission categories of leadership, human error, and communications. In The Joint Commission's case, therefore, these human factors categories amount to 57 percent of identified causes, and in the case of NMED, human factors amounts to 71 percent; that is, in both cases, human factors are the dominant contributing causes.

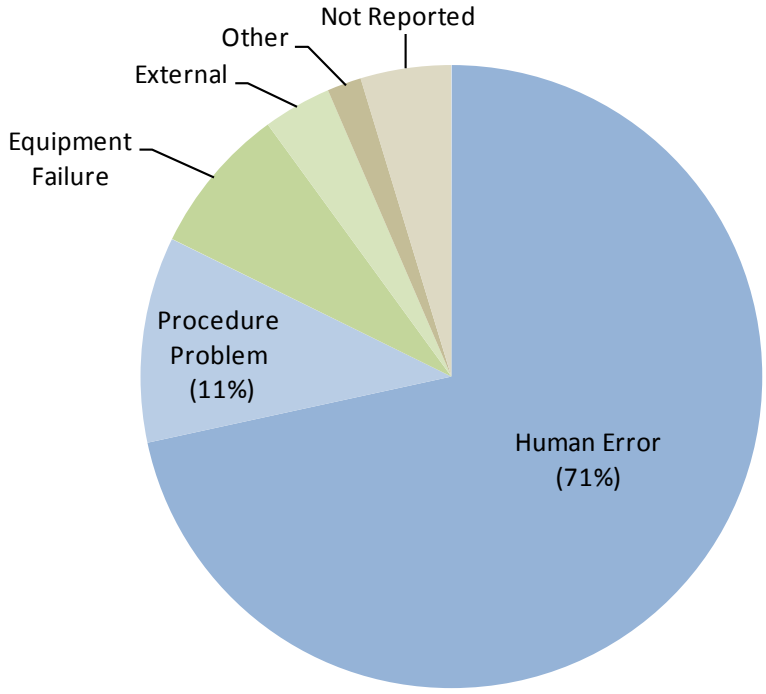

Figure A-3 Causes assigned to Abnormal Events from FY2008 through FY2011

The NMED database uses "cause" breakdowns of human error that are similar to those for radiation therapy events shown in Figure A-3. For example, within the category of human error, NMED includes the following possible causes:

- communication problems
- failure to follow procedure or wrong procedure used
- inadequate training, inattention to detail, and management deficiency

APPENDIX B

ERRORS IN REMOTE AFTERLOADING BRACHYTHERAPY

As discussed in Section 2.2.4, NUREG/CR-6125 [9, 10] describes a human factors evaluation of remote afterloading brachytherapy (RAB). In that study, a task analysis was used to decompose each of the functions comprising RAB into individual steps. For each critical step, the authors evaluated practices associated with the step and alternative techniques that might be employed to reduce the likelihood of misadministration.

The following summary table is based on those evaluations. The table shows the critical tasks, the contributing factors that were related to human performance vulnerabilities, and mitigating actions that could address the human performance vulnerabilities.

Table B-1 Contributing and mitigating factors for error in RAB from NUREG/CR 6125

Critical Task (RAB)	Human Performance Vulnerability Contributing Factors")	Potential Mitigating Actions ("Alternative Approaches")
Patient Scheduling, Identification, Tracking	ID wrist bands not used on all RAB patients (inpatient treatments only); wrist band ID codes long and hard to remember; reliance on memorized information	Provide job performance aids; redesign ID and linkage procedures; staff training
Applicator Selection, Placement, and Stabilization	Must distinguish applicators from many similar ones; lack of feedback about applicator placement; mental calculations needed to translate 2D images into 3D relationships	New methods/procedures to ID, preserve, and transfer applicator characteristics information; methods/procedures to detect and compensate for applicator movement; increased training
Target Volume Localization	Primitive interfaces with no feedback regarding performance or detection of translation errors; need for staff to do mental calculations to combine images of different magnifications and sources	Transfer images electronically without requiring staff to do mental calculations; visualization and calculation aids to help in translating different scales/magnifications into set of parameters; standardize records for magnification and view angles; train staff in mental imagery skills
Dwell Position Localization	Measurement of distances to treatment site and from machine to source guide tube; must identify end of applicator; must rely on dummy source measurements	Measurement of insertion distance after placement of dummy source; graphic feedback of orientation of entered dwell positions; make it easier to distinguish dummy sources in imaging; standardize dwell position measuring procedures
Dosimetry	Manual entry of dwell positions and targets into planning system; no feedback on digitization accuracy; poor interface design; time pressure; distractions	Ability to scan entire simulation view into treatment planning computer manual numeric entry; increase computer feedback; improve document labeling; limit distractions and time pressure for dosimetrists; better training on software

Critical Task (RAB)	Human Performance Vulnerability Contributing Factors")	Potential Mitigating Actions ("Alternative Approaches")
Treatment Setup	Applicator labels usually small and low-contrast; difficult to assess whether applicators are connected correctly	Supply a map of connection specifications; improve labeling to make wrong connections more obvious; training in correct connections
Treatment Plan Entry	Manual entry into treatment console; calculations not easily visible/verifiable by users; "swap" errors could occur with magnetic cards or disks; difficult to identify erroneous differences between initial directive and final parameters	Direct electronic transfer to treatment console; better feedback from system; erase old treatment plans from cards and disks; staff training in detecting errors
Quality Assurance and Maintenance	Inadequate checklists; hidden QA checks performed by equipment	Integrate equipment/software QA with manual QA procedures; use more checklists; clear feedback regarding which QA checks should be done, how often, and what passing/failing means for performance; training on QA/emergency procedures
Source Exchange	Inadequate emergency procedures; emergency retraction devices difficult to operate; can't inventory sources while in their safes	Means for detecting presence of a source (vs. absence); supply tools to cut stuck sources free from cables; test equipment after source exchanges to detect any changes; staff training (if exchanges aren't done by manufacturer)
Source Calibration	Inadequate feedback regarding calibration errors; lack of consensus on standard calibration procedures; calibration requires time and special equipment in some cases	Standard chamber to measure activity of each radionuclide; regular calibrations should be performed and compared to expected decay; staff training

APPENDIX C

ERRORS IN TELETHERAPY

As discussed in Section 2.2.4, NUREG/CR-6277 [11] describes a human factors evaluation of teletherapy. In that study, a task analysis was used to decompose each of the functions comprising teletherapy into individual steps. For each critical step, the authors evaluated practices associated with the step and alternative techniques that might be employed to reduce the likelihood of misadministration.

The following summary table is based on those evaluations. The table shows the critical tasks, the contributing factors that were related to human performance vulnerabilities, and mitigating actions that could address the human performance vulnerabilities.

Table C-1 Contributing and Mitigating Factors for Error in Teletherapy from NUREG/CR 6277

Critical Task (Teletherapy)	Human Performance Vulnerability ("Contributing Factors")	Potential Mitigating Actions ("Alternative Approaches")
Pre-Treatment Planning	Absent or informal because treatment is considered routine; time pressure; language difficulty	Stipulate plan conference for difficult cases; address workload issues; review communication processes and target improvements
Treatment Planning Computer Data Files	Opaque nature of systems; absence of procedures for performing "hidden" tasks; training isn't thorough and relies on self-teaching	Render functions more visible; include interlocks; procedures to prevent out-of-date files from being used; more systematic training
Use of Patient Chart	Poor layout and design, including inconspicuous location of key information; illegible or ambiguous entries	Formal, iterative design process and consideration of best practices to improve chart layout; education regarding bad and good practices in chart entry
Patient Positioning and Immobilization	Reproducible patient positioning across different treatments; lack of critical analysis of existing aids; on skin tattoo markers, which can vary; high workload	Critically review and share info on different techniques; avoid sole reliance on skin markers; address workload issues
Treatment Setup Slips and Lapses	High workload and rapid pace of treatment schedules; understaffing; poor workstation layout, leading to distractions; competing tasks (i.e., answering phones)	Schedule patients in a more evenly distributed manner; address staffing issues; redesign workspace layout to reduce distractions; use computerized record and verify systems to check deviations from prescriptions; educate managers

Critical Task (Teletherapy)	Human Performance Vulnerability ("Contributing Factors")	Potential Mitigating Actions ("Alternative Approaches")
Data Transfer	Treatment calculations being made while the patient waits; uncritical review of computer-generated treatment plans	Schedule patients in an evenly distributed manner and minimize calculations that are done while the patient waits for treatment; independent verification of all computer inputs; improve layout of interfaces to improve vigilance for errors
Equipment Checks and Calibration	Equipment failures; inadequate or nonexistent procedures; operator errors; lack of organizational equipment for conducting recommended procedures	Create panel of users to address organizational commitment issues and implement new ways of increasing vigilance; during transitions, employ a monitor or run old and new procedures in parallel until everyone shows proficiency in the new procedure; use systematic training
Radiation Field Alignment Accuracy	Day-to-day variations of treatment field alignment; discrepancies between simulated and actual treatment conditions; mechanical changes to equipment; changes in tumor/body contours/size	Take portal images about once a week; electronic imaging options available during treatment to better visualize radiation field; review films often as part of facility's QA program
Radiation Treatment Delivery	Therapists having to perform other tasks during treatment time (increases workload); habituation to warning cues; lack of training in emergency procedures	Address therapist workload issues; add an auditory alarm that is unique to an emergency situation (stuck source); scenario-based training for emergency procedures
Quality Assurance (QA) Procedures	Lack of resources for implementing a QA program; knowledge and skill base needed; sustaining QA programs is difficult because many of the tasks are mundane and of low visibility	Involve upper management; develop strong QA program based on written guidelines; develop structure to support QA activities within a department

APPENDIX D

ANALYSIS OF RADIATION THERAPY EVENTS FROM 2001 THROUGH 2010: ERROR CATEGORIES AND SAMPLE EVENTS

In Section 2 of this report (in particular, Table 2-1), we refer to an analysis that was conducted to identify error trends across different types of treatment modalities. Below is a summary of the results of that analysis.

D.1 High Dose Rate (HDR) Brachytherapy

Event review. Of the 16 Abnormal Occurrences (AOs) reviewed, four events resulted in the wrong dose being administered and 12 events resulted in the wrong site being treated. There were a total of 21 errors, most of which involved human performance issues. Many errors involved mistakes in interacting with the treatment planning software (typographical errors or interface issues). There were several measurement errors in which the length of the catheter was not measured accurately, leading to the source treating the wrong site. There were a few errors in which the equipment was improperly set up, mainly because the connections between the catheters were not correct. It's also interesting to note that some errors went unnoticed during verification checks of treatment plans. Each type of error is described below.

D.2 Data Entry and Planning-Software Errors

14 HDR brachytherapy errors fell into the category of data entry and planning software errors. In many of these events, the medical physicist simply committed a typographical error when entering a value (i.e., catheter length, starting location, or step distance) in the treatment planning software. Some event reports state that the software reset to default values after the other data had been entered.

An example event that fell into this category is event AS 07-06, which involved a patient who was prescribed to receive several HDR brachytherapy fractions. The wrong isodose line was chosen and entered into the treatment planning system, which then normalized the calculations and produced a treatment plan around the incorrect isodose line. The oncologist signed and approved the plan and the radiation safety officer performed a second calculation check. An independent physicist identified the error before the second treatment fraction.

Another example event, uncovering a serious interface issue, is event AS 11-07. A therapist accidentally hit an "auto radiography" button instead of the "treatment" button while administering HDR treatment to a patient's ear. This resulted in the patient receiving a dose that was nine times the intended dose. The facility had to disable the "auto radiography" function after this occurred.

D.3 Equipment Errors

There were 5 HDR brachytherapy equipment errors. Due to the nature of the HDR brachytherapy procedure, several equipment connections must be properly set up. The errors in this category involve the incorrect connections of catheters to the HDR unit.

An example event in this category is event AS 09-05. The aluminum connector to an HDR unit's needle detached from the unit, which prevented the patient from receiving the full dose. The adhesive that attached the connector to the unit failed because hospital staff had sterilized the needle and the plastic extension adaptor that connects the aluminum connector to the unit had

been used more than once. The manufacturer's written product information warns that sterilization may cause adhesive failure, and that the plastic extension adaptors (to which the aluminum connector attaches to the unit) should only be used once. The corrective actions in response to this event included procedure modifications.

D.4 Verification Errors

There were two verification errors in HDR brachytherapy. Both events are categorized as one of the above error types (i.e., data entry) and as a verification error. Verification errors are usually secondary errors, in which review of the treatment plan did not identify the original error. These errors are troubling, because many corrective actions that are implemented after an event occurs involve adding additional checks and reviews.

One example of an event in this category is event AS 07-06, mentioned in the section on data entry and treatment planning software errors. An initial error (choosing the wrong isodose line) was used to create a valid treatment plan. The oncologist signed and approved the plan, and someone else did a calculations check. Neither of these verification checks picked up on the initial error because the initial error was in the original parameters of the calculations and not in the calculations themselves.

D.5 Gamma Knife

Event review. There were ten gamma knife AOs were reviewed, four of which resulted in a wrong dose, being administered and six of which resulted in the wrong site receiving treatment. A total of 14 errors were associated with these 10 events, all involving human performance issues. Many older events (late 1990s to early 2000s) involved data entry and treatment planning system errors. Because of changes (i.e., electronic transfer of information) in the gamma knife units and software, some of the errors in this category are becoming less prevalent. However, there have still been events in which the wrong site was treated because of imaging and laterality errors. Errors have also resulted from the incorrect setup of the gamma knife equipment and verification errors. Each category of error is discussed in turn.

Data entry and planning software errors

Two events were associated with data entry and planning software errors for the gamma knife. Many older events that occurred before an updated treatment planning software package happened because *x, y,* and *z* coordinates were transposed (e.g., the values x-y-z were entered as y-z-x instead). However, newer software does not involve manually typing in these coordinates, thereby reducing the likelihood of this type of error. Other types of data entry errors still occur, however, such as entering the incorrect treatment time. Some events resulted from issues with the planning software itself, such as the inadvertent use of default values, and a system that had an incorrect date, which affected source strength calculations.

Event AS 07-05 is an example of a data entry error in this category. A physician prescribed a gamma knife treatment of 18 Gy (1800 rad) for a patient. Instead of waiting for the medical physicist to enter the prescribed value in the computer treatment plan (as was the usual procedure), the physician erroneously entered it into the computer as 28 Gy (2800 rad). The event description implies that the physician was in a hurry to leave for the day, so decided to enter the information directly. The mistake was not identified until after the patient received the full incorrect dose (a 56% overdose).

Equipment errors

Three errors were categorized as resulting from the incorrect setup of the gamma knife equipment. With older models of the gamma knife, errors usually arose when the medical physicist failed to change the collimator helmet between treatment fractions. However, newer gamma knife models do not need separate collimator helmets; instead, the computer controls the size of the radiation beam. There are still several possibilities for error in setting up the gamma knife equipment, though.

For example, event NRC 10-05 describes an equipment malfunction that was also compounded by an ambiguous error message. Two patients were scheduled to receive gamma knife treatments on the same day. During the first patient's treatment, the automatic positioning system reported an error. The operators called the manufacturer, who told them to reinitialize the positioning system, then complete the treatment. During the second patient's treatment, the same error appeared. The manufacturer sent a service representative to inspect the unit. The representative noted that one of the axis indicators was off by 4.5 mm. An NRC investigation concluded that one of the causes of this event was inadequate procedures that did not require physical verification of the automatic position system's coordinates against the electronic coordinates before treatment. This was probably a result of overconfidence in, or the opacity of, the automation.

Target errors

There were four target errors with the gamma knife. These errors were mainly laterality errors, in which one side of the head received treatment instead of the intended side of the head. There were also errors in which the fiducial marker was not aligned properly in the imaging process, which led to the incorrect site being designated for treatment.

Event NRC 10-02 is an example of this category of error. A laterality error occurred while a patient was being treated for trigeminal neuralgia with a gamma knife procedure. The prescribing physician had mismarked the treatment planning sheet with the wrong location of treatment (the planning sheet was marked as the left side of the face to receive treatment, when in reality the right side needed treatment). The error was not identified during review of the planning sheet document, and the patient received the incorrect treatment.

Another example of this type of error is event AS 09-04. A patient was prescribed to receive 8000 centigrays (cGy) (8000 rad) to the 5th intracranial nerve during a gamma knife treatment for trigeminal neuralgia. All necessary people completed and signed the written directive; however, the wrong nerve was designated for treatment while preparing the gamma knife unit. The cause of this incident was a misidentification of the anatomical target site that was listed on the written directive.

Verification errors

Four verification errors were associated with the gamma knife. As with the other types of therapy, many gamma knife errors were able to slip past the verification and review processes that were in place at a facility, although one event fell under this category because the hospital staff failed to verify that the treatment plan matched the patient they were treating (02-2). Event NRC 10-02, listed above in the section about wrong site errors, is a typical example of verification procedures failing. In this event, the treatment planning sheet itself was mismarked as to the location to be treated and the error was not detected during review of the document.

D.6 Intravascular (IV) Brachytherapy

Event review. Six IV brachytherapy AOs were reviewed in connection with seven total errors. Two events resulted in a wrong dose being administered and the remaining four events resulted in the wrong site receiving treatment. Most errors involved equipment failures. All occurred before 2004, when IV brachytherapy was an emerging procedure and new technologies were being put to use for the first time in the field. The events that seemed to arise from human performance issues all dealt with dosage errors.

Data entry and planning-software errors

There was one data entry and planning-software error with IV brachytherapy. The authorized user was accustomed to operating a different treatment planning system that used the radius of the artery to be treated; however, the event resulted when the user operated a different system that used the diameter of the artery to create the treatment plan. This error resulted in a wrong dose to the artery that was being treated (AS 02-4).

Equipment errors

Four errors fell under the category of equipment errors for IV brachytherapy. One event involved a machine malfunction in which the source did not reach the intended site. When the physician noticed this error and tried to retract the source, it could not be retracted. The physician had to physically pull the catheter out of the patient with the source still inside the catheter (03-01). The rest of the events involved issues with the catheter that prevented the source from getting to the intended site either (1) kinks or (2) too much external pressure caused by the artery it was threaded through.

Target and visualization errors

One event in the IV brachytherapy review fell under both the target error and visualization error categories. In event 03-03, the source train failed to get to the intended target site because the licensee failed to properly visualize the source train's placement. This was partly because there is an inherent inability to differentiate between the proximal and distal markers of the source train.

D.7 Low Dose Rate (LDR) Brachytherapy

The term "low dose rate brachytherapy" is used to describe several different modalities of treatment in which sources are typically are left in a patient for extended periods of time (hours to days). These modalities are manual brachytherapy, manual afterloading brachytherapy, and manual implant brachytherapy. While the details of each are quite different medically, they are grouped together here because they represent typically much lower risks to workers and the public than do the high dose rate treatments, and there are strong similarities the kinds of human errors that occur.

Event review. Twenty-two AOs associated with LDR brachytherapy events were reviewed in connection with 37 total errors. Only one event was the result of a dosage error; the rest involved the wrong site being treated. Many events occurred as a result of incorrect source placement. Most of the events involved target errors in which the sources were incorrectly placed.

Data entry and planning-software errors

One error for LDR brachytherapy fell under this category. Event AS 07-03 resulted from the wrong Dose Rate Factor (DRF) being used in the treatment plan. This occurred because the licensee entered the DRF for air kerma, but the seed strength was entered in milligram radium equivalent in the treatment planning system. An additional facet of this event was that the treatment planning system that was used had undergone acceptance testing for treatments using Cs-137 and I-125, but not for Ir-192, which was the source called for in this particular patient's treatment (along with Cs-137). These discrepancies resulted in the patient receiving the wrong dose.

Equipment errors

There were three equipment errors in the review of LDR brachytherapy AOs. Two events resulted from a piece of equipment not being the correct length, resulting in treatment to the wrong site. The last event, event 05-03, was the result of improper source selection. The Cs-137 sources that were used to treat several patients were the wrong size for the applicator used. They migrated from the treatment site through a placement spring that was supposed to keep them in place when the patients moved as part of the treatment. This error was exacerbated by inadequate manufacturer instructions and inadequate management oversight and procedures.

Target errors

With 18 errors in this category, target errors were the most common errors relating to LDR brachytherapy. Most of these events involved the use of I-125 brachytherapy seeds to treat prostate cancer. For example, event AS 04-01 describes a typical occurrence for events in this category. The brachytherapy seeds were implanted under ultrasound guidance. However, when the patient returned for the post implant CT scan, it was discovered that the seeds were implanted 2 cm too low, and missed treating the upper portion of the prostate, making additional treatment necessary.

Many of the corrective actions that are implemented in response to this type of error, particularly with the use of I-125 brachytherapy seeds for prostate cancer treatment, involve the use of real-time imaging during the procedure. However, as this event demonstrates, modifying procedures to allow imaging during the actual treatment may not fully address the underlying issues.

Verification errors

One event was classified as a verification error as well as a data entry and treatment planning software error. Event AS 07-03, described in the data entry and treatment planning software error section, was also classified as a verification error because multiple checks should have caught the discrepancy in DRF but did not. For example, the treatment pre-plan should have been checked before the seeds arrived at the facility, but it was not. Also, the calculations should have been double-checked before implant or shortly after, but this did not occur either.

Visualization errors

Ten of the target errors identified above also fell under the category of visualization errors. All of these events involved the use of I-125 brachytherapy seeds to treat prostate cancer.

All of the event narratives in this category state that the misplacement of seeds was a result of failing to accurately identify the location and/or size of the prostate gland.

In event NRC 08-04, a prostate brachytherapy treatment was terminated after the placement of only 37 seeds. The procedure was terminated because it was determined that the first 37 seeds were placed 2 cm below the patient's prostate. The official cause of the event was misidentification of the patient's prostate because of inadequate procedures. Event NRC 10-03 involved the placement of 93 seeds outside the target site, also because of a failure to adequately visualize and identify the prostate before the procedure. Interestingly, the event narrative states that several of the staff, who were present for the procedure, including the Authorized Medical Physicist, questioned the accuracy of the prostate visualization, but no action was taken to resolve the question. Event AS 09-06 describes an under dose because of a miscalculation of the size of the patient's prostate gland.

Many corrective actions to address this type of error involve imaging during the procedure to ensure the proper placement of seeds. However, in event NRC 10-06, brachytherapy seeds were still placed incorrectly, even though ultrasound was being used during the procedure. This event was caused by inadequate ultrasound identification of the prostate during implant because of the patient's unusual anatomy and obesity. Events such as this one indicate that just adding procedures to allow imaging during the procedure may not be enough to ameliorate errors in this category.

Errors caused by patient movement

Three events occurred because the patient moved, which affected the placement of the source. In all three events, the patient was receiving brachytherapy seed implants for prostate cancer treatment. The patient's movement was not detected in any of the events. One event (NRC 10-04) occurred even though the seeds were being placed under ultrasound guidance.

Procedural errors

One event (NRC 08-02) involved over 90 patients receiving suboptimal brachytherapy seed treatments for prostate cancer. This is a very serious event because even though follow-up scans showed that seeds were not correctly placed, no corrective actions were taken to either retreat patients or modify the procedure to improve outcomes. Investigations showed that the procedures in place at the facility were inadequate to assure quality implants.

APPENDIX E

SUMMARIES OF EXAMPLE ABNORMAL EVENTS

The NRC issues (as serial volumes of NUREG-0090) [100-103] annual reports to Congress on "abnormal occurrences"—unscheduled incidents or events determined to be significant from the standpoint of public health or safety. The event reports originate with either the NRC or with Agreement States, which maintain their own compatible programs for the regulation of byproduct and source materials and of certain quantities of special nuclear materials.

This appendix contains selected sections of NUREG-0090 abnormal occurrence reports used in the present document to illustrate the various types of errors that are associated with medical events. The event summaries are ordered by fiscal year (i.e., according to the NUREG-0090 volume in which they appeared). The identifier for all Agreement State licensee AO reports starts with "AS." Similarly, the identification number for all U.S. Nuclear Regulatory Commission (NRC) AO reports starts with "NRC." The remainder of each event identifier (in the format FY-N or FY-NN) indicates the fiscal year (FY) covered by the volume in which the event description appears and the serial number.

The following are the FYs for which events in NUREG-0090 volumes were reviewed:

FY 2002
FY 2004
FY 2007
FY 2008
FY 2009
FY 2010
FY 2011

FY 2002

AS 02-4 Intravascular (IV) Brachytherapy Misadministration at Rhode Island Hospital, Providence, Rhode Island

Nature and Probable Consequences—A patient was prescribed a dose of 8 Gray (800 rad) to the coronary artery during a Cordis Checkmate™ IV brachytherapy procedure using 10 Ir-192 (Ir-192) seeds emitting a dose of 8991 megabecquerels (MBq) (243 millicuries (mCi)). On January 31, 2002, during a review of dosimetry and physician records, the licensee discovered that the diameter of the artery was used in the treatment plan calculation instead of the radius. This error resulted because the physicians (authorized users) using the Cordis device were more familiar with the procedures for a Novoste™ device also in use at this institution. The Novoste device uses the diameter of the artery in the dosimetry calculations whereas the Cordis device uses the radius. The authorized user provided the wrong dimension (diameter instead of radius) which led to an incorrect dose being calculated. As a result the patient received an actual dose of 14.6 Gray (1460 rad) to the outer coronary artery site instead of the prescribed 8 Gray (800 rad). The licensee indicated that there will probably be no adverse health effect to the patient.

Cause or Causes—As stated, the misadministration occurred because of human error in the use of the diameter of the artery instead of the radius of the vessel as required when using the Cordis system. The physicians' (authorized users') familiarity with the procedures for a Novoste device was a contributing factor.

Actions Taken to Prevent Recurrence

Licensee—The licensee informed the State of Rhode Island the next day by telephone of the potential misadministration and provided a written report of the incident on February 14, 2002. In-service training has been conducted concerning the misadministration. In addition, the prescription form has been modified to indicate whether the radius or the diameter of the vessel is being used for the treatment plan.

State Agency—The Agency has been in contact with the licensee concerning this matter and the effectiveness of the corrective measures implemented. The licensee indicated that there will probably be no adverse health effects to the patient. To date there has been no recurrence of the problem.

AS 02-5 Strontium-90 (Sr-90) Eye Applicator Brachytherapy at South Broward Hospital District in Hollywood, Florida

Nature and Probable Consequences—A patient was prescribed radiation treatment for pterygium in his left eye. The patient was to receive a total dose of 30 Gy (3000 rad) in three 10-Gy (1000-rad) fractions spaced approximately a week apart. Because of human error, the third and final fraction, given on January 4, 2002, was 24.84 Gy (2484 rad) instead of the prescribed 10 Gy (1000 rad).

The prescribed dose was to be administered through a 3M® Company Model 6D1A eye applicator using a 973-MBq (26.3-mCi) strontium-90 (Sr-90) source. The written directive called for each fraction to consist of a treatment duration of 44 seconds to deliver a 10 Gy (1,000 rad) dose. The correct fractionated dose was administered as planned on December 20, 2001, and December 28, 2001. A routine administration of the eye applicator required one person to time the event with a stopwatch while the authorized user administered the dose. The nurse and the authorized user became distracted in conversing with the patient and lost track of the time. The

stopwatch used was the old style that simply counted time up and the nurse lost focus in trying to make the patient more comfortable and at ease. The authorized user had to remind the patient to gaze in a certain direction to treat the affected area. As a result, the third fractionated treatment time was 109 seconds instead of the prescribed 44 seconds resulting in a dose of 24.84 Gy (2484 rad). The patient was counseled about the slight increase in latent effects, including cataract formation and scleral scar tissue formation.

Cause or Causes—The State found and the licensee agreed that the misadministration occurred because of human error and the failure of staff to attend to details as required in licensee's procedures.

Actions Taken to Prevent Recurrence

Licensee—The licensee has identified and made changes in their procedures for use of the Sr-90 ophthalmic applicator. The facility purchased a digital stopwatch that has a large display, counts time down and not up, audibilizes the time in the last 10 seconds, and sounds an alarm at the end of treatment. In addition, the nurse has been counseled and all personnel have received training in the revised procedures using the new stopwatch.

State Agency—The Florida Bureau of Radiation Control performed an onsite investigation on February 7, 2002, to review the licensee's corrective actions, which were found adequate by the State.

The State also determined that while the patient was informed verbally of the misadministration, the licensee did not inform the patient in writing as required. The licensee was cited for failure to notify the patient in writing within 15 days.

FY 2004

AS 04-01 Iodine-125 (I-125) Brachytherapy Seed Medical Event at Central Arkansas Radiation Therapy Institute in Conway, Arkansas

Nature and Probable Consequences—The licensee reported that a patient received a radiation dose to an unintended area during an I-125 prostate-seed implant procedure. The patient was prescribed treatment with 122 I-125 seeds, with each seed containing an activity of 13.3 MBq (0.36 mCi). During the patient's post-implant CT scan on December 18, 2003, the licensee discovered that the seeds had been implanted 2 centimeters (cm) too low and missed treating the upper portion of the prostate gland. As a result, 68 cm3 of adjacent tissue received the prescribed dose of 144 Gy (14,400 rads). The licensee reported that the adjacent tissue should not be affected adversely by the dose delivered by the seeds. The licensee administered additional treatment to deliver the intended dose to the upper 2 cm of the prostate gland. The licensee notified the patient and the patient's referring physician of the event.

Cause(s)—This event was attributed to human error in that the treatment site was not verified.

Actions Taken to Prevent Recurrence

Licensee—The licensee wrote a new procedure to implement the use of fluoroscopic guidance to ensure the correct placement of seeds.

State Agency—The State has reviewed and accepted the licensee's corrective actions.

AS 04-06 Gamma Stereotactic Radiosurgery (Gamma Knife) Medical Event at Radiosurgical Center of Memphis in Memphis, Tennessee

Nature and Probable Consequences—The licensee reported that a patient received 27 Gy (2700 rads) to a brain metastasis instead of the intended 18 Gy (1800 rads) during gamma knife treatment. The physicist did not determine that 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 brain 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 that a 14-millimeter (mm) (0.55-inch) collimator helmet was used instead of the prescribed 8-mm (0.31-inch) collimator helmet. The personnel setting up the treatment neglected to change the helmet. The tumor that received the unintended dose was located at the periphery of the brain, adjacent to the skull. Because most of the unintended dose was delivered to a non-critical space, between the brain and skull, the additional radiation exposure should have no significant effect on the patient.

The referring physician was notified of the event and informed the patient's family of the unintended dose.

Cause(s)—The cause was human error, in that the event resulted from use of the wrong collimator helmet.

Actions Taken to Prevent Recurrence

Licensee—The licensee established a new procedure to require 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.

These labels can be seen by personnel on the TV monitor located at the control panel outside the treatment room. The physician will verify the correct size before the control panel button is pushed to start the treatment.

State Agency- The State reviewed and approved the licensee's new procedures.

AS 04-09 IV Brachytherapy Medical Event at Ireland Cancer Center in Middleburg Heights, Ohio

Nature and Probable Consequences—The licensee reported that a patient received a radiation dose to an unintended site 3 cm proximal to the prescribed treatment site during an IV brachytherapy treatment procedure. The dose delivered to the unintended site was approximately 18.40 Gy (1840 rads). The event involved an IVB device that used a 3.5-mm catheter and a source train that contained Sr-90 with an activity of 2.0 gigabecquerels (GBq) (53.8 mCi). The source train traveled to a location approximately 3 cm proximal to the intended treatment site. It was determined that there was a kink in the delivery catheter which kept the source train from traveling to the correct site. The kink was not substantial enough to affect the flow of sterile water used to send and retrieve the source train. The kink was discovered the following day during medical physics quality checks. The referring physician and patient were notified of the event. According to the licensee, no adverse effects are expected.

Cause(s)—The cause of the event was determined to be a kink in the delivery catheter which kept the source train from traveling to the correct site.

Actions Taken to Prevent Recurrence

Licensee—Corrective actions incorporated by the licensee included additional films taken during procedures to verify the placement of the catheter. When there is any doubt of the placement of the catheter, the treatment will be aborted. The treatment team will then evaluate whether to attempt treatment with a different catheter.

State Agency—The Ohio Department of Health conducted an investigation, reviewed the licensee's corrective actions, and found them adequate to prevent recurrence.

FY 2007

AS 07-03 Medical Event in New York

Nature and Probable Consequences—The licensee reported a brachytherapy medical event to the New York State Department of Health. The event involved a 31-year-old female patient with a history of vaginal cancer. The treatment involved the use of both cesium-137 (Cs-137) and Ir-192 seeds. Each ribbon contained 8 seeds with an activity of 1.855 milligram radium equivalent (118 MBq or 3.19 mCi). The patient was to be administered a total dose of 25 Gy (2500 rad) through interstitial brachytherapy, to be delivered to the 0.5-Gy (50-rad) isodose line for a total treatment time of 50 hours.

On March 6, 2007, the Ir-192 seeds and the Cs-137 seeds were placed into the patient. Late in the morning of March 7, 2007, the medical physicist performed a manual check of the treatment plan calculations and discovered that the hand calculations indicated a significantly higher dose rate than was generated using the treatment planning software. The ensuing investigation revealed that the original treatment plan was in error. On March 7, 2007, after 27 hours of treatment, the seeds were removed from the patient.

The patient received an estimated dose of 45.9 Gy (4590 rad) to the treatment site rather than the intended 25 Gy (2500 rad). The rectal dose was 73 Gy (7300 rad). The radiation oncologist disclosed that the patient is at risk for radiation cystitis, rectal proctitis, and more importantly, fistula formation between the rectum and the vagina. The patient and the referring physician were informed of this event. The patient will be monitored closely over the next year by both her gynecologic oncologist and the radiation oncologist. The patient is being treated with broad-spectrum antibiotics along with daily treatments in a hyperbaric oxygen chamber.

Cause(s)—The primary cause was the use of an inappropriate Dose Rate Factor (DRF) in the treatment planning system. The value used corresponded to the DRF for air kerma; however, the seed strength entered was in milligram radium equivalent. Other causes and contributing factors included failure to check the treatment pre-plan before the seeds arrived, although there was time to do so; failure to double-check the calculations either before the implant or shortly thereafter; use of a treatment planning system that underwent acceptance testing for Cs-137 and I-125, but not Ir-192; and lack of recent experience preparing a treatment plan using Ir-192. Neither the physicist nor the radiation oncologist had prepared a treatment plan using Ir-192 in 6 years.

Actions Taken to Prevent Recurrence

Licensee—The licensee changed its policy and procedures to require a check of calculations for any single-fraction brachytherapy treatment.

State—The State plans to follow up on the licensee's implementation of their new procedures during the next scheduled inspection.

AS 07-05 Medical Event at University of Washington Harborview Gamma Knife of Seattle, Washington

Nature and Probable Consequences—University of Washington Harborview Gamma Knife (the licensee) reported that a patient who was prescribed to receive 18 Gy (1800 rad) during a gamma knife treatment actually received 28 Gy (2800 rad).

The gamma knife contained 267.7 terabecquerels (TBq) (7236 curies (Ci)) of Co-60 (Co-60). The patient and the referring physician were informed of this event. The licensee concluded that no significant adverse health effect to the patient is expected.

Cause(s)—The cause of the incident was determined to be human error. The prescribing physician prescribed 18 Gy (1800 rad) and erroneously entered 28 Gy (2800 rad). The physician entered the prescribed value into the computer treatment planning system rather than having the medical physicist enter the value as is the usual procedure, resulting in a failure to follow an established procedure.

Actions Taken to Prevent Recurrence

Licensee—Corrective actions taken by the licensee included a verification process to ensure that the prescribed treatment value is transferred from the treatment planning computer to the gamma knife computer before patient therapy. Also, a treatment plan signed by the treating oncologist, physicist, and neurosurgeon is now required. In addition, the treating oncologist and physicist will verify and initial the prescribed dose and isodose treatment parameters before patient therapy.

State—The State reviewed the licensee's corrective actions and determined that the procedures were adequate to ensure that this type of event should not happen in the future.

AS 07-06 Medical Event at Physician Reliance of Fort Worth, Texas

Nature and Probable Consequences—Physician Reliance (the licensee, doing business as (dba) Texas Oncology at Klabzuba) reported that a patient who was being treated for lung cancer with an HDR afterloader and an Ir-192 source received 2500 cGy (2500 rad) during the first fraction instead of the prescribed dose of 500 cGy (500 rad). The patient was prescribed to receive five fractions with 500 cGy (500 rad) per fraction over five weeks. The incident was discovered following an independent physicist's review of the treatment plan. The patient and the referring physician were informed of this event. The patient's pulmonologist concluded that no significant adverse health effect to the patient is expected.

Cause(s)—The incident occurred as a result of the incorrect isodose line being chosen and entered into the treatment planning system. The oncologist signed and approved the treatment plan and the radiation safety officer performed a second calculation to check the treatment plan. The treatment planning system then normalized the calculations to the incorrect isodose line and delivered the resulting treatment. The calculation error was identified by an independent physicist before administration of the second fraction.

Actions Taken to Prevent Recurrence

Licensee—The licensee's corrective action was to change their procedure to include a second check by a licensed medical physicist of all treatment plans.

State—The State issued two violations related to this event: (1)the licensee was cited for a violation of 25 Texas Administrative Code (TAC) §289.256(p)(4)(A) and (B) because the procedure as implemented was insufficient to ensure that a second check of the printed output of the treatment plan was performed to verify the accuracy of the planned treatment factors before treatment; and (2) the licensee was cited for a violation of 25 TAC §289.256(o)(1) and §289.256(p)(1) because the instructions of obtaining the authorized physician's signed and dated written directive for each therapeutic administration were not followed.

In addition, the State reviewed the licensee's corrective action of changing their procedures to include a second check by a licensed medical physicist of all treatment plans.

AS 08-02 Medical Event at University of Mississippi Medical Center in Jackson, Mississippi

Nature and Probable Consequences—University of Mississippi Medical Center (the licensee) reported that a medical event occurred during an HDR treatment for cervical cancer using an Ir-192 source with an activity of 185 GBq (5.0 Ci). The authorized user physician prescribed five fractionated doses of 600 cGy (600 rad) each to be administered using tandem and ovoid applicators. The licensee calculated that during the first, second, and third fractionated treatments, the patient received a total dose of 470 cGy (470 rad) to the treatment area and 1300 cGy (1300 rad) to the vaginal region inferior to the treatment area. The patient and the referring physician were informed of this event. The licensee concluded that no significant adverse health effect to the patient is expected.

Cause(s)—The medical event was caused by human error; namely, the incorrect catheter length being entered into the treatment planning system. The incorrect value of 128 cm was entered as the length instead of 120 cm, resulting in an 86-mm displacement. An HDR service technician identified the error in the treatment planning system on March 25, 2008.

Actions Taken to Prevent Recurrence

Licensee—The licensee committed to taking several corrective actions as a result of the medical event, including (1) verification of the length of all disposal catheters and checking the integrity of the catheters before treatment, (2) placing an order for and use of a single set of reusable catheters for HDR cervical cancer treatments, (3) the treatment plan and catheter measurement will be independently checked before treatment, and (4) review and modification, if necessary, of the quality assurance plan to ensure accuracy.

State—The State cited the licensee with two violations for failing to verify the treatment plan.

NRC 08-03 Medical Event at Karmanos Cancer Center in Detroit, Michigan

Nature and Probable Consequences—Karmanos Cancer Center reported that a medical event occurred associated with its gamma knife. A patient being treated for a metastatic brain tumor was scheduled to receive 18 Gy (1800 rad) to the lesion in the right cerebellum area of the brain but received 18 Gy (1800 rad) to an unintended area adjacent to the tumor. An error in the setup of the magnetic resonance imaging (MRI) unit caused the MRI scan to be reversed (i.e., the image of the right side of the head was on the left side and vice versa). The patient and the referring physician were informed of this event. Before the treatment, the medical physicist, authorized user physician, and neurosurgeon reviewed the MRI scan and treatment plan but failed to recognize the reversed MRI images. The reversed MRI images were scanned into the gamma knife treatment planning computer and a treatment plan was generated based on the reversed MRI images. The authorized user physician and neurosurgeon reviewed and approved the treatment plan generated from the reversed MRI images, and again the reversed MRI images were not recognized.

The NRC staff conducted a reactive onsite inspection on October 29, 2007. The NRC-contracted medical consultant reviewed the case and agreed with the licensee's analysis, stating that no significant adverse health effect to the patient is expected.

Cause(s)—The medical event was caused by the MRI technologist, who inadvertently performed the MRI scans in the "caudal" mode (from the jaw to the top of the head) rather than the "cranial" mode

(from the top of the head to the jaw). This change in device mode caused the MRI images to be reversed.

Actions Taken to Prevent Recurrence

Licensee—The licensee initiated several corrective actions to reduce the likelihood of recurrence of a similar event. Specifically, those corrective actions included (1) weekly meetings with the physics staff to discuss technical issues, focusing on the importance of good communication, and (2) new written procedures and policies for the MRI staff and gamma knife facility staff that require dual verification of the various steps in the process to ensure that the correct treatment plan is generated from the MRI images.

The NRC—On January 10, 2008, NRC issued a Notice of Violation related to this event.

NRC 08-04 Medical Event at Reid Hospital and Health Care Services in Richmond, Indiana

Nature and Probable Consequences—Reid Hospital and Health Care Services reported that a medical event occurred during a brachytherapy seed implant procedure to treat prostate cancer. The written directive prescribed a total dose of 110 Gy (11,000 rad) to the patient's prostate using 62 I-125 seeds as permanent implants. The licensee calculated that the patient received less than 15 Gy (1500 rad) to the prostate and that the region of the patient's perineum, where the seeds were placed, received a dose of 55 Gy (5500 rad). The patient and the referring physician were informed of this event.

According to the licensee, the base of the prostate was misidentified through ultrasound, causing 37 of the prescribed 62 seeds to be placed approximately 1 cm to 2 cm below the prostate in the perineum. When it was recognized that the seeds were not in the prostate, the procedure was halted. The licensee physicians stated that the patient may develop possible complications, including fibrosis and necrosis of the tissue in the perineum, where the seeds were implanted.

The NRC-contracted medical consultant agreed with the licensee's dose estimate and stated that it was unlikely that the patient would experience radiation-induced rectal wall necrosis or soft tissue necrosis below the prostate in the perineum area, but that it was possible to have delayed fibrosis of some areas of the genital tract. The NRC-contracted medical consultant further stated that because no tissue necrosis had occurred one month after the medical event, tissue necrosis was very unlikely to occur.

Cause(s)—The licensee determined that the root cause of the medical event was the misidentification of the base of the prostate. Specifically, the prostate/bladder interface was not identified properly using the ultrasound because of poor image quality. As a result, the needle used to implant the seeds was not located in the prostate during the implantation.

Actions Taken to Prevent Recurrence

Licensee—The licensee's corrective actions to prevent recurrence included revising its procedure for prostate seed implants to require that the needle location in the prostate be verified by x-ray imaging at the beginning of the procedure, before any seeds are implanted, and halting the procedure if the location of the needle in the prostate cannot be verified with certainty.

The NRC—On July 11, 2008, NRC issued a Notice of Violation related to this event.

FY 2009

AS 09-03 Medical Event at St. Vincent's Medical Center, Inc., in Jacksonville, Florida

Nature and Probable Consequences—St. Vincent's Medical Center, Inc. (the licensee), reported that a medical event occurred associated with an HDR mammosite treatment for breast cancer containing 199.8 GBq (5.4 Ci) of Ir-192. A patient was prescribed to receive 34 Gy (3400 rad) to the right breast but received 34 Gy (3400 rad) to the skin of the left breast.

On October 16, 2008, the patient notified her physician of erytherma on her left breast. During a records review, the medical physicist determined that an error in programming the catheter length in the HDR device caused the source to stop 10 cm short of the intended tumor site in the right breast. Because of this programming error, the dose intended for the right breast was delivered to the skin of the left breast. The authorized user concluded that no chronic health effect to the patient is expected.

Cause(s)—The medical event was caused by human error in failing to verify that the correct catheter length was entered into the treatment planning system.

Actions Taken To Prevent Recurrence

Licensee—The licensee committed to taking several corrective actions as a result of the medical event that include (1) using a catheter length worksheet to determine and verify the mammosite catheter length; (2) documenting the mammosite catheter length by two individuals—one a physicist and one a dosimetrist, physicist, or radiation therapist—during simulation treatment setup; (3) providing procedures for the medical physicist and authorized user on documenting the catheter length on the catheter worksheet during the review of the treatment control unit and treatment plan; and (4) conducting a second measurement of the catheter length to verify that the length agrees with the data in the treatment control unit.

State—The Florida Bureau of Radiation Control conducted an investigation and reviewed the licensee's corrective actions and found the corrective actions to be adequate.

AS 09-04 Medical Event at Presbyterian Hospital of Dallas in Dallas, Texas

Nature and Probable Consequences—Presbyterian Hospital of Dallas (the licensee) reported that a medical event occurred associated with its gamma knife containing 125.8 TBq (3400 Ci) of Co-60. A patient being treated for trigeminal neuralgia was prescribed to receive 80 Gy (8000 rad) to the fifth intracranial nerve but received 14.95 Gy (1495 rad) to the seventh intracranial nerve. The patient and the referring physician were informed of this event.

An error in entry of information into the treatment planning system caused the wrong nerve to receive treatment. The error was identified by the neurosurgeon 9 minutes into the 45-minute treatment. The licensee concluded that no significant adverse health effect to the patient is expected.

Cause(s)—The medical event was caused by the misidentification of the anatomical target site listed on the written directive.

Actions Taken to Prevent Recurrence

Licensee—The licensee modified its written procedure to include verification of the target sit, by the neuroradiologist for each treatment. In addition, an updated written directive will document the new procedure to ensure that the correct treatment site is targeted and treated in each procedure.

State—The State will conduct a review of at least 20 percent of the past treatment cases to ensure that this error has not previously occurred.

AS 09-05 Medical Event at Cancer Care Northwest PET Center in Spokane, Washington

Nature and Probable Consequences—Cancer Care Northwest PET Center (the licensee) reported that a medical event occurred associated with an HDR brachytherapy treatment for prostate cancer containing 185 GBq (5 Ci) of Ir-192. During patient treatment, the aluminum connector to needle 13 became detached from the plastic guide tube and a dose of 12.5 Gy (1,250 rad) was delivered to a small area of the patient's inner thigh (wrong treatment site). The patient and the referring physician were informed of this event.

The source wire for needle 13 hung about 6 inches past the disconnected guide tube, which resulted in the skin dose. The licensee conducted several follow-up examinations of the patient's inner thigh and noted that no skin reddening or injury has occurred and the patient is not experiencing any pain in this area. Therefore, the licensee concluded that no significant adverse health effect to the patient is expected.

Cause(s)—The cause of the medical event was that the source wire for needle 13 snagged on the seam between the aluminum connector and the plastic guide tube during retraction.

Actions Taken to Prevent Recurrence

Licensee—The licensee committed to taking several actions as a result of the medical event that include (1) requiring the staff to sign the patient quality assurance list when they check the applicators, transfer guide tubes, and aluminum connectors; (2) inspecting the guide tube catheters daily and examining the aluminum connectors before patient use; and (3) revising the refresher training to include new procedures for staff before patient treatment.

State—The State conducted follow-up inspection activities during April and May 2009 and reviewed the licensee's corrective actions. The State found the licensee's corrective actions adequate and did not take any enforcement action regarding this event.

AS 09-06 Medical Event at The Urology Center in Cincinnati, Ohio

Nature and Probable Consequences—The Urology Center (the licensee) reported that a medical event occurred associated with a brachytherapy seed implant procedure to treat prostate cancer. The patient was prescribed to receive a total dose of 144 Gy (14,400 rad) to the prostate using 64 I-125 seeds as permanent implants. Instead, the patient received an approximate dose of 76 Gy (7600 rad) to the urethra and bulb of the penis (unintended sites). The patient and the referring physician were informed of this event.

According to the licensee, an interpretation of the ultrasound image of the patient's prostate resulted in 30 of the 64 seeds being delivered to the prostate while the other 34 seeds were delivered outside the prostate. Because the patient's prostate was smaller than normal, the prostate received 68 Gy (6800 rad) of the prescribed dose and the urethra and bulb of the penis (unintended sites) received

approximately 76 Gy (7600 rad). Before the seeds were implanted, the urologist and radiation oncologist should have consulted on the ultrasound image of the patient's prostate to determine the correct seed placement. The licensee concluded that no significant adverse health effect on the patient is expected. On May 19, 2009, the patient returned for a second treatment to compensate for the original underdosing to the prostate.

Cause(s)—The cause of the medical event was the misinterpretation of the correct size of the patient's small prostate gland by ultrasound.

Actions Taken To Prevent Recurrence

Licensee—Corrective actions taken by the licensee included instituting a new policy requiring agreement by both the urologist and radiation oncologist on seed placement for all prostate glands measuring 20 cubic centimeters or less. On May 26, 2009, the licensee submitted a written report of this event to the Ohio Department of Health's Bureau of Radiation Protection (ODH BRP).

State—On June 12, 2009, ODH BRP conducted an inspection of this event and determined that the licensee had followed the correct procedures for administrations requiring a written directive. ODH BRP reviewed the licensee's corrective actions for this event and found the corrective actions to be adequate.

NRC 09-02 Medical Event at Gamma Knife Center of the Pacific in Honolulu, Hawaii

Nature and Probable Consequences—Gamma Knife Center of the Pacific (the licensee) reported that a medical event occurred associated with its gamma knife containing 104.86 TBq (2834 Ci) of Co-60. A patient being treated for multiple brain metastatic sites was prescribed to receive 24 Gy (2400 rad) to seven discrete brain sites using an 8-mm collimator. However, an 18-mm collimator was used to treat two of the discrete brain sites, resulting in a dose of 24 Gy (2400 rad) to additional brain tissue. The patient and the referring physician were informed of this event.

The patient received treatment to the first and second discrete brain sites; after receiving treatment to the second discrete site, it was discovered that an 18-mm collimator had been used to deliver treatment instead of the prescribed 8-mm collimator. The larger collimator caused the volume of each of the two discrete sites to increase by 2.45 cubic meters, resulting in a dose of 24 Gy (2,400 rad) to additional brain tissue. After the 18-mm collimator was discovered, it was replaced with the 8-mm collimator and the patient received treatment to the five remaining discrete sites as prescribed. The licensee concluded that no significant adverse health effect to the patient is expected.

Cause(s)—The cause of the medical event was human error in failing to check the collimator size before patient treatment.

Actions Taken To Prevent Recurrence

Licensee—Corrective actions taken by the licensee included (1) sending a notice to all authorized users, neurosurgeons, and medical physicists reiterating that they should each independently check the collimator size before patient treatment and (2) revising procedures to have a second independent verification of all treatment parameters, including the collimator size, by a treatment team member.

The NRC—The NRC conducted an onsite inspection and hired a medical consultant to review the event. The conclusions from the onsite inspection are pending and the medical consultant's review is ongoing.

FY 2010

NRC 10-02 Medical Event at Chippenham & Johnston-Willis (CJW) Medical Center in Richmond, Virginia

Nature and Probable Consequences—Chippenham & Johnston-Willis (CJW) Medical Center (the licensee) reported a medical event with its gamma stereotactic radiosurgery (GSR) unit. A patient being treated for trigeminal neuralgia (inflammation of the nerve) was prescribed a treatment of 40 Gy (4000 rad) to the right trigeminal nerve but received the treatment dose to the left trigeminal nerve (wrong treatment site). The patient and referring physician were informed of this event.

The licensee noted that on the day of the treatment, the top portion of the written directive correctly documented the prescribed treatment site; however, while the staff was preparing the daily patient treatment log, it was inadvertently annotated that the dose was to be delivered to the left trigeminal nerve. This error was carried through by the medical physicist during preparation of the patient's treatment plan and completion of the bottom part of the written directive. On completion of the procedure and after reviewing the patient's file, the treatment team identified the inadvertent treatment of the left trigeminal nerve. An NRC-contracted medical consultant concluded that although the patient suffered no immediate adverse consequences, 1) an unlikely injury to the brain stem could have resulted from a high radiation dose to a tiny volume of the brain-stem tissue and 2) the patient might have an increased risk of cataract formation.

Cause(s)—The cause of the medical event was the licensee's failure to have adequate procedures that verify the location of treatment sites and to ensure that any inconsistencies in the written directives are resolved before administration.

Actions Taken to Prevent Recurrence

Licensee—The licensee revised their GSR treatment procedures to affirm that (1) a "Physician Order" will be the primary source of documentation of the treatment site and will accompany the patient through the entire course of the treatment, (2) the radiation oncologist and the neurosurgeon will independently verify and document the treatment site, (3) the nurse and the medical physicist will confirm that the treatment site identified by the radiation oncologist in the written directive and the neurosurgeon's "physician order" both match, (4) the neurosurgeon will mark the treatment site with ink in the presence of a nurse, and (5) a "Time-Out" process involving independent verification of the final treatment plan by each of the four members of the clinical team (who are required to sign off on their presence and acceptance of time-out in the presence of the patient before moving ahead with the treatment) will be used with the patient or the patient's authorized representative to confirm the treatment site.

The NRC—The NRC initiated an inspection on December 18, 2008; completed the inspection on November 30, 2009; and issued one Severity Level III violation to the licensee on January 21, 2010.

NRC 10-03 Medical Event at Virtua Health System in Marlton, New Jersey

Nature and Probable Consequences—Virtua Health System (the licensee) reported that a medical event occurred associated with a brachytherapy seed implant procedure to treat prostate cancer. The patient was prescribed to receive a total dose of 145 Gy (14,500 rad) to

the prostate using 93 I-125 seeds. Instead, the patient received an approximate dose of 12.2 Gy (1220 rad) to the rectum (wrong treatment site). The patient and referring physician were informed of this event.

On January 19, 2009, the urologist inserted needles in the patient's prostate gland under transrectal ultrasound guidance while the radiation oncologist left the operating room to obtain the radioactive seeds. The licensee's staff (including the authorized medical physicist (AMP)) questioned the accuracy of prostate visualization before implantation of the seeds but took no action to resolve the question. On February 23, 2009, following a post-implant computed tomography (CT) scan, it was noted that some mispositioning of the sources had occurred and the patient was notified that additional treatment might be necessary. On March 19, 2009, the AMP reviewed the case and determined that 100 percent of the seeds were implanted outside the prostate, which received about 10 Gy (1000 rad). The NRC contracted with a medical consultant who concluded that although the probability of long-lasting negative health effects to the patient was low, an increased risk of impotency and fibrosis was possible because of the high radiation dose.

Cause(s)—The cause of the medical event was failure of the medical implant team to adequately visualize and identify the prostate before the implant.

Actions Taken To Prevent Recurrence

Licensee—The licensee revised its policy and procedures to require that (1) all members of the implant team be present before the patient is brought to the operating room and placed under anesthesia, (2) the AMP be included in the pre-implantation ultrasound, (3) the authorized user consult with the urologist before needle insertion, (4) both the radiation oncologist and the urologist agree on the positioning and the visualizing of the target anatomy, (5) any objection or question by an implant team member is cause for stopping the implant and performing a review, and (6) the implant is to be stopped if there are any ultrasound image questions. The licensee's staff was also trained on the revised procedures, the definition and reporting requirements of a medical event, and the communication of any CT-scan abnormalities or seed misplacement to the radiation safety officer (RSO).

The NRC—The NRC initiated an inspection on March 20, 2009; completed the inspection on August 26, 2009; and issued one Severity Level III violation to the licensee on October 21, 2009.

NRC 10-04 Medical Event at Nanticoke Memorial Hospital, in Seaford, Delaware

Nature and Probable Consequences—Nanticoke Memorial Hospital (the licensee) reported that a medical event occurred involving a brachytherapy seed implant procedure to treat prostate cancer. The patient was prescribed a total dose of 145 Gy (14,500 rad) to the prostate using 61 I-125 seeds. Instead, the patient received an approximate prostate dose of 26 Gy (2600 rad) (18 percent of the prescribed dose) and a dose of 139 Gy (13,900 rad) to unintended tissue (wrong treatment site). The patient and referring physician were informed of this event.

The seeds were implanted under ultrasound guidance using an axial view; however, following the implant, the urologist performed a cystoscopy to remove 22 of the seeds from the bladder. When the patient returned to the hospital for a post-implant CT scan, the images revealed that 32 seeds were displaced superiorly to the prostate and 7 seeds were implanted in the

prostate. The NRC contracted with a medical consultant who concluded that no significant adverse health effects to the patient were expected.

Cause(s)—The cause of the medical event was a miscalculation of the prostate depth in relation to the skin surface because of possible patient movement during the procedure.

Actions Taken to Prevent Recurrence

Licensee—The licensee revised its prostate implant procedure to include the use of both the axial and sagittal views of an ultrasound probe to determine prostate depth. In addition, the licensee revised its medical event policy to ensure timely reporting of medical events and to clearly state the parameters under which a medical event must be reported. The licensee provided training on the revised policies and procedures to its staff.

The NRC—The NRC initiated an inspection on July 19, 2009; completed the inspection on January 6, 2010; and issued one Severity Level III violation to the licensee on February 2, 2010.

NRC 10-05 Medical Event at Yale New-Haven Hospital, in New Haven, Connecticut

Nature and Probable Consequences—Yale New-Haven Hospital (the licensee) reported that a medical event occurred associated with its GSR unit. A patient being treated for brain metastases was prescribed 18 Gy (1800 rad). However, while treating a patient earlier in the day, an equipment malfunction occurred with the GSR unit that resulted in a positioning shift of the x-axis by 4.5 mm. The positioning shift in the x-axis resulted in an underdose to the treatment site and an overdose to a wrong treatment site. The patient and physician were informed of this event.

The malfunction occurred following the treatment of the first patient on August 5, 2009. The automatic positioning system (APS) malfunctioned and, after discussion with the GSR manufacturer, the position error codes were cleared by the AMP. A second patient was treated for multiple brain metastases later that day. GSR service personnel noted on August 5, 2009, that the APS positioning was off by about 5 mm. After further evaluation, the manufacturer determined that a position shift (offset) occurred when licensee personnel accepted an error message concerning position deviation. The NRC contracted with a medical consultant who concluded that no clinically significant side effects from radiation damage to the wrong treatment sites would be expected.

Cause(s)—The cause of the medical event was failure of licensee personnel to verify that the APS coordinates were in accordance with the written directive.

Actions Taken to Prevent Recurrence

Licensee—The licensee issued a memorandum to all personnel involved in GSR treatments to require visual verification of the physical coordinates against the electronic coordinates before the start and at the end of each treatment run. The licensee also retrained all GSR personnel on the importance of fully understanding error conditions and reviewing unexpected errors with other staff involved in the treatment (e.g., radiation oncologist, AMP, etc.) before clearing any unexpected error.

The NRC—The NRC initiated an inspection on August 13, 2009; completed the inspection on April 7, 2010; and issued one Severity Level III violation to the licensee on May 21, 2010.

NRC 10-06 Medical Event at Valley Hospital in Paramus, New Jersey

Nature and Probable Consequences—Valley Hospital (the licensee) reported that a medical event occurred associated with a brachytherapy seed implant procedure to treat prostate cancer. The patient was prescribed a total dose of 65 Gy (6500 rad) to the prostate using 46 cesium-131 seeds. Instead, the licensee determined that an unintended volume (30.1 ml) of soft tissue received 100 percent of the prescribed prostate dose. The patient and referring physician were informed of this event.

On August 6, 2009, the patient returned to the hospital for a post-implant CT scan. The images revealed that the seeds were implanted in soft tissue 4 to 5 cm from the prostate. Post-implant dosimetry calculations indicated that none of the prostate received the prescribed dose of 6500 cGy (6500 rad). The NRC contracted with a medical consultant who concluded that the additional dose could increase the risk of soft tissue fibrosis or increase the risk of impotency.

Cause(s)—The cause of the medical event was the licensee's failure to identify the position of the prostate because of the patient's unusual anatomy and obesity.

Actions Taken To Prevent Recurrence

Licensee—The licensee revised their prostate implant procedures to include steps to ensure that the prostate and surrounding anatomy is adequately visualized before implant.

The NRC—The NRC initiated an inspection on August 13, 2009; completed the inspection on October 29, 2009; and determined that no violations of NRC requirements occurred.

NRC 10-07 Medical Event at Christiana Care Health Center in Wilmington, Delaware

Nature and Probable Consequences—Christiana Care Heath Center (the licensee) reported that a patient was prescribed an HDR mammosite (brachytherapy) multi-lumen catheter treatment of 34 Gy (3400 rad) over a 5-day period to the left breast. The patient received an average dose of 17 Gy (1700 rad) to 100 cm3 of unintended breast tissue; 68 Gy (6800 rad) to 7.5 cm3 of unintended skin and underlying tissue; and 3.4 Gy (340 rad) to 35 cm3 of intended breast tissue. The patient and referring physician were informed of this event.

On February 22, 2010, during a follow-up examination, the patient complained about skin reddening on the external breast. In reviewing the treatment plan, it was discovered that the AMP performed measurements using a source position simulator (SPS) measurement tool following a CT scan to determine the treatment distance for each catheter. The catheter distances were recorded and confirmed with two manufacturer representatives that were present at the time of the treatment. However, it was noted that an incorrect measurement caused the placement of the radioactive source 10 cm proximal to the intended position. The NRC-contracted medical consultant concluded that the dose that was administered to the unintended left breast tissue is unlikely to result in any significant or unusual adverse effect. However, a significant risk exists that local tumor recurrence could occur if additional intervention is not performed.

Cause(s)—The cause of the medical event was human error in the failure to identify that the measurement tool was functioning improperly and to identify an incorrect measurement distance.

Actions Taken To Prevent Recurrence

Licensee—The licensee revised its procedures for HDR brachytherapy to require a double-check of all patient measurements, a daily and monthly quality assurance requirement to confirm that the SPS tool is functioning properly, and a process to ensure that all members of the treatment team agree on the specifics of the treatment. In addition, the licensee acquired a new SPS tool, developed and posted a reference table at the HDR control console, provided training on revised procedures to staff involved in the HDR program (to be repeated annually), and implemented a “New Product” committee to review all new product plans.

The NRC—The NRC conducted an inspection on July 12, 2010, and issued one Severity Level III violation to the licensee on August 24, 2010.

FY 2011

AS 11-06 Medical Event at University Community Hospital in Tampa, Florida

Nature and Probable Consequences—University Community Hospital (the licensee) reported that two patients were prescribed single-channel HDR brachytherapy treatments of 34 Gy (3400 rad). An actual average dose of 17 Gy (1700 rad) to the first patient, and 26 Gy (2600 rad) to the second patient, were delivered to the target area of the breast, and some parts of the planned volume received greater than 700 percent (first patient) and 220 percent (second patient) of the prescribed dose. In addition, other areas of the breast not in the target region received up to 136 Gy (13,600 rad) in the first patient and 75 Gy (7500 rad) in the second patient. The maximum skin dose was calculated to be 42.5 Gy (4250 rad) to the first patient and 75 Gy (7500 rad) to the second patient. The patients and their referring physicians were informed of the events.

On February 14, 2010, the licensee noted that the source within the mammosite catheter was erroneously positioned *approximately* 2 to 2.5 cm away from the tumor. This was the result of the operator entering the wrong dwell *position* into the planning system. The licensee concluded that no significant adverse health effects to the patients are expected.

Cause(s)—The cause of the medical events was human error involving entering the wrong position of the reference end of the catheter into the planning system.

Actions Taken to Prevent Recurrence

Licensee—Corrective actions included implementing various quality assurance steps to ensure that the correct treatment calculations and data are used for future treatments. Additional procedural guidance will be created with detailed instructions.

State—The Florida Bureau of Radiation Control initiated an inspection on February 18, 2010; completed the inspection on March 1, 2010; and determined that the licensee's corrective actions were adequate. No enforcement action was taken and the State forwarded the final update of the event to the NRC on February 1, 2011.

NRC11-04 Medical Event at Community Hospitals of Indiana in Indianapolis, Indiana

Nature and Probable Consequences—Community Hospitals of Indiana (the licensee) reported that a medical event occurred associated with an HDR brachytherapy treatment for breast cancer; the treatment consisted of 340.4 GBq (9.2 Ci) of Ir-192. The patient was prescribed to receive a total dose of 34 Gy (3400 rad) in 10 fractionated doses to the postsurgical cavity in the left breast following excision of a cancerous tumor (treatment site). It was determined that the first eight treatment fractions resulted in a portion of the treatment site receiving a dose of 266 Gy (26,600 rad). In addition, a portion of the patient's skin on the left breast and the chest muscle tissue (tissue other than the treatment site) received doses of 105 Gy (10,500 rad) and 1,002 Gy (100,200 rad), respectively. The patient and referring physician were informed of this event.

On October 6, 2010, following the eighth fractionated treatment dose, an error was discovered in the treatment plan by the medical physicist who remembered that he had not changed a default entry in the treatment planning system. This error caused the source placement to be flipped 180 degrees along the applicator's long axis which resulted in a portion of the treatment site at the tip end of the applicator receiving less than the prescribed dose and a portion of the treatment site at the connector end of thentrye applicator receiving more than the prescribed dose.

The licensee concluded that no long-term medical effects are expected for the patient. The NRC contracted with a medical consultant who determined that the overall impact to the patient is minimal.

Cause(s)—The medical event was caused by human error in that the medical physicist failed to change a default entry in the treatment planning system as required by the licensee's procedure.

Actions Taken to Prevent Recurrence

Licensee—The licensee revised its written directive form to remind staff to change the default entry in the treatment planning system as applicable, added a step to its procedure for multicatheter HDR breast treatments to verify that the default was changed as applicable, and trained its staff on the revised written directive form. In addition, the licensee evaluated all of the other HDR breast treatments that were conducted in 2010 to verify that the applicators were accurately reconstructed in the treatment planning computer.

The NRC—The NRC conducted a reactive inspection on October 18 through 20, 2010, with continued in office review through January 18, 2011, and issued two Notices of Violation to the licensee on March 1, 2011, and April 20, 2011, respectively.

APPENDIX F

PROCEDURAL EVENT ANALYSIS TOOL (PEAT) FOR UNDERSTANDING HUMAN ERROR AND IMPROVING PERFORMANCE

The field of aviation has had a long history of recognizing the importance of human factors in ensuring safety. For example, Boeing reports that more than 70% of hull-loss accidents[6] result from human error [64]. As a result the industry has collectively invested significant resources in understanding the causes of human errors and developing ways to improve safety performance by making changes to the underlying causes. An example of a process used in aviation is the Boeing Airplane Company's Procedural Event Analysis Tool (PEAT). The following is quoted from Boeing's description:

"PEAT originated from an extensive effort to identify the key underlying cognitive factors that contributed to procedural noncompliance in past accidents. In 1991 Boeing concluded a 10-year study that showed that flight crew deviation from established procedures contributed to nearly 50 percent of all hull-loss accidents. The aviation industry still lacks sufficient knowledge about the reasons for these deviations, however, and had no formal investigation tool to help identify them."

PEAT was developed to address this lack of understanding of the causes of such errors. Figure F-1 depicts the overall PEAT process, which shows the essential nature of the feedback from investigations of operational events to enhancements in operational practices. Of interest is the model, shown in Figure F-2, used to identify the causes and contributing factors for the identified procedural errors. On this basis, information is gathered in the investigation for explaining the causes of errors and developing the improvements. This model is essentially the same as that used in this report to explain human performance issues in radiation therapy, though with an aviation context.

As discussed earlier, accident rates for commercial aviation showed an initial strong downward trend from 1959 that largely resulted from improvements in mechanical and structural changes in aircraft design. However, it later became clear to the International Civil Aviation Organization (ICAO) that human performance was becoming a significant cause of accidents; recall Boeing's estimate that 70 percent of major accidents were caused by human error. In a speech given by the then president of ICAO [104], the organization realized that human errors required attention:

[6] An accident so severe that the damage to the aircraft means it must be written off, or in which the aircraft is totally destroyed.

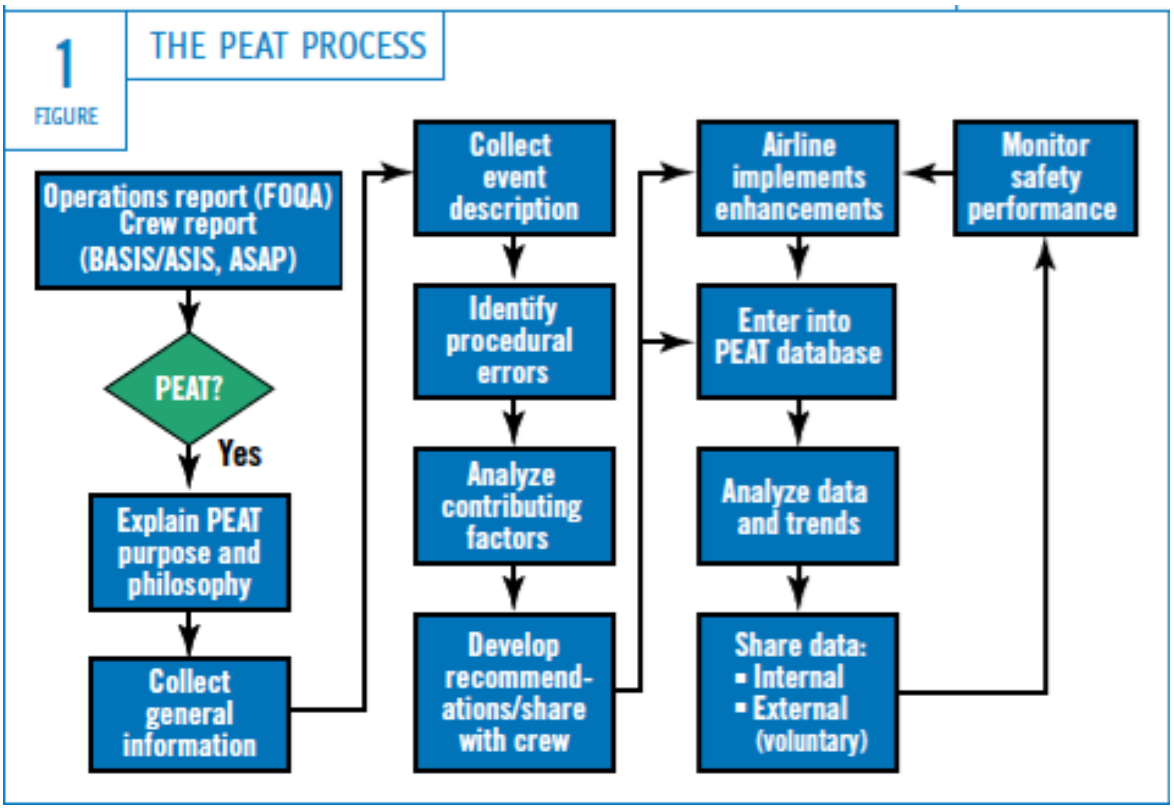

Figure F-1 The Boeing PEAT Process for Aviation Errors in Using Procedures

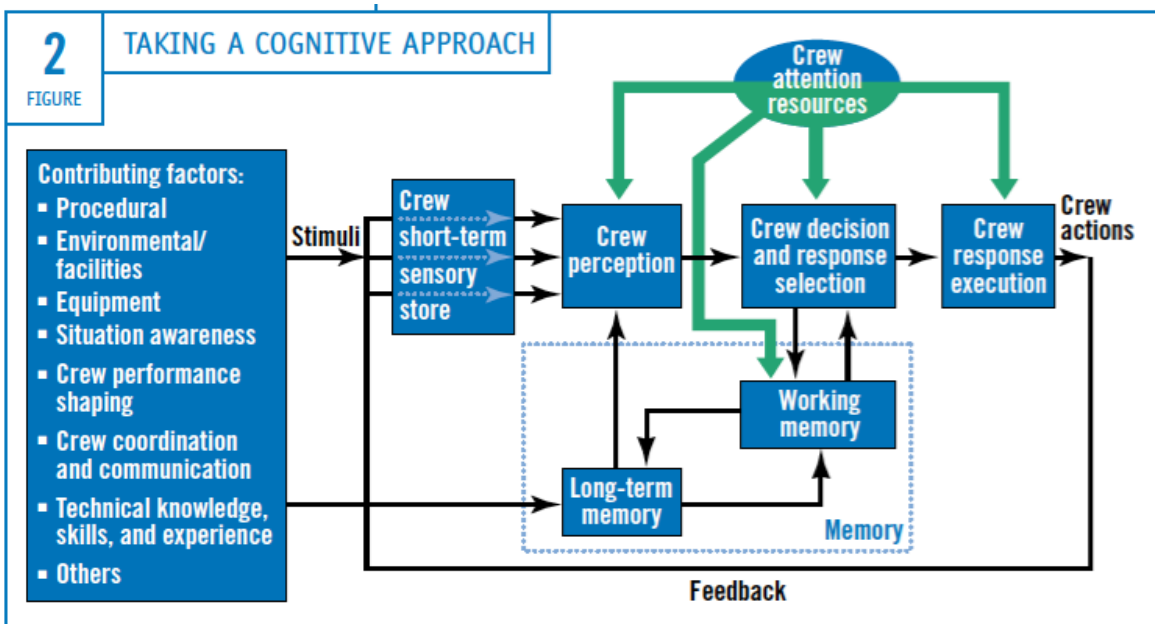

Figure F-2 The Model of Human Performance used in Boeing's PEAT Process

"Around the mid-seventies, it was becoming obvious that human error was capable of circumventing even the best designed technical safety defenses. The authors consequently

shifted our thinking to the *human perspective*. Two points are worth noting from this era. First, our human factors endeavors at that time were *focused on the individual*; they were aimed at improving individual performance, mainly through training and regulations. Second, a substantial part of our human factors efforts attempted to *eliminate* error through design, to replace human functions with machine functions, thus seeking to minimize human intervention and, therefore, opportunities for error. Addressing human error and its negative effect on safety from an *individual* perspective was an important step. It had to be taken, and yet it was not enough.

This realization came in the nineties, when there was an understanding that human performance does not take place in a vacuum but rather within social contexts. Individual human behavior is modelled after behavior that organizations foster and expect from their members. The safety concerns were addressed from the *organizational perspective.* In this way, authors acquired a systemic view of aviation safety, including the interactions not only among people, but also between people and technology, and between people and the organizations to which they belong. Most importantly, and for the first time the role was scrutinized, and the relationship between, management and safety."

In response to this realization, the industry has put in place programs to reduce these events, including the PEAT process. For instance, the ICAO presently provides guidance in human factors for aviation professionals in the following 12 areas:

1. fundamental human factors concepts
2. flight crew training: Cockpit resource management and line-oriented flight training
3. training of operational personnel in human factors
4. operational implications of automation in advanced technology flight decks
5. investigation of human factors in accidents and incidents
6. ergonomics
7. human factors in air traffic control
8. human factors, management and organization
9. human factors in CNS/ATM[7] systems
10. human factors in aircraft maintenance and inspection
11. human factors in cabin safety
12. cross cultural factors in aviation safety

[7] Communications, Navigation, Surveillance / Air Traffic Management.

APPENDIX G

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10. SUPPLEMENTARY NOTES

11. ABSTRACT (200 words or less)

A critical part of the U.S. Nuclear Regulatory Commission (NRC) mission is licensing and regulating the use of byproduct materials, including in radiation therapy. More than half of the reported misadministration events in the medical use of byproduct materials in radiation therapy are attributed to human error.

In support of the NRC recommendation to continue to apply and extend a risk-management framework (as discussed in NUREG 2150 [1], A Proposed Risk Management Regulatory Framework), this report discusses an approach to improve patient safety that is based on human reliability analysis (HRA), traditionally part of probabilistic risk assessments (PRAs). Using HRA and related disciplines, four key elements for improving patient safety are highlighted: 1) improved understanding of human error in radiation therapy; 2) improved ability to anticipate errors; 3) effective strategies for supporting humans in managing complexity; and 4) methods to evaluate and monitor the effectiveness of corrective actions. This report also includes reviews of studies conducted by the NRC using human reliability analysis methods and recommends the continued application of these methods. Successful safety improvements from commercial aviation and nuclear power industries are examined and offered as examples of the feasibility of this approach. It is important to emphasize that target audiences for this document include, but are not limited to, decision makers, regulators, designers, and external vendors engaging with the risk-informed framework.

12. KEY WORDS/DESCRIPTORS (List words or phrases that will assist researchers in locating the report.)

Radiation Therapy
Medical
Risk
Human Reliability Analysis

13. AVAILABILITY STATEMENT

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14. SECURITY CLASSIFICATION

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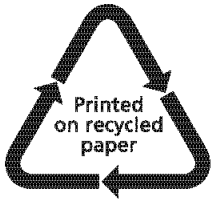

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