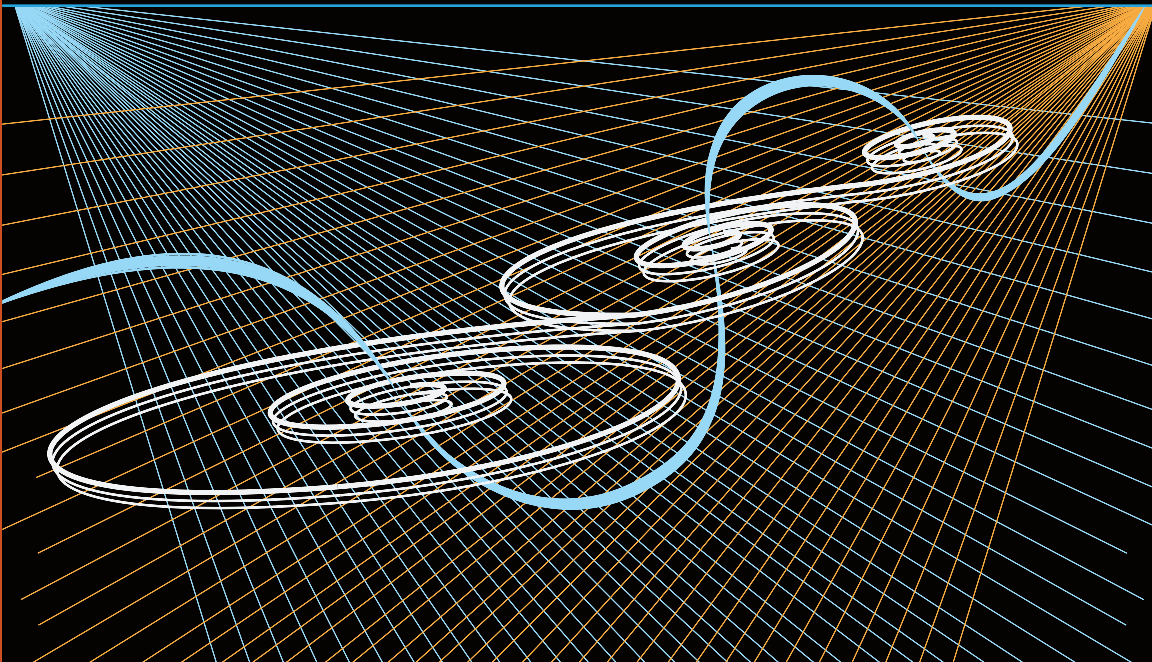
Engineering Patient Safety in Radiation Oncology

University of North Carolina's Pursuit for High Reliability and Value Creation



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with contributions from

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We dedicate this book to the concept of interprofessional collaborations. The practice of radiation oncology relies on the fusion of multiple fields (e.g., clinical medicine, physics, dosimetry, radiation therapy, engineering). The improvement work described in this book resulted from the infusion of industrial engineers into the clinical arena. Advances in the sciences often result from the concerted and interactive efforts of people from diverse professions/disciplines, and the same is true for our clinical and research activities. The world would be a better place if we were better able to leverage each other's expertise in a synergistic and productive manner.

This book is also dedicated to the many patients who suffer with cancer, whose outcomes we hope to improve through our efforts. We especially dedicate this book to patients and families harmed by the healthcare delivery system.

Contents

Preface

Radiation is a central curative and palliative therapy for many patients. It is therefore important for us to have safe and efficient systems to plan and deliver radiation therapy. However, several factors (e.g., rapid technological advances, financial reorganization, aging population, and evolving societal expectations) may be compromising our ability to deliver care in a highly reliable and efficient manner.

In this book, we portray our initial efforts at the University of North Carolina to address these challenges, that is, keeping our patients safe while continuously improving our care delivery processes. We presume little theoretical knowledge on high reliability and value creation, although some familiarity with these topics is clearly an advantage. Thus, the book is written with a mixed readership in mind: medical and administrative radiation oncology employees, industrial and management engineers, human factors professionals, safety managers, and reliability engineers—and, of course, their current and future students.

The book is divided into two sections and eight chapters. **Section I** consists of Chapters 1 to 3. It provides an introduction to basic concepts, methods, and tools that underlie our approach to high reliability and value creation and an overview of key safety challenges within radiation oncology.

Chapter 1 provides a broad overview of how the safety challenges within radiation oncology are currently perceived (i.e., with the focus on advanced technologies). We think that a focus on technology is important but somewhat misguided. We then contrast this with (what we believe is) the necessary and desired future state, with safety being the natural by-product of increased reliability and value creation at the organizational, workplace, and people levels.

Chapter 2 gives a broad overview of "past" and "current" challenges of patient safety issues within radiation oncology. An overview of incident rates and reported events is included. Although we recognize and applaud the multiple technology-based initiatives aimed at improving patient safety, we believe that technical solutions alone (at least for now) are not going to bring our field to the desired level of reliability.

Chapter 3 introduces a broad overview of the best practices from high-reliability organizations. We focus on the following key areas:

- leadership style and behaviors;
- culture of safety with an emphasis on error-reporting infrastructure,
- a need for robust improvement cycles;
- the use of Human Factors Engineering principles to design work and environments; and
- ways to help individuals engage, transform, and feel respected during continuous quality and safety improvement efforts.

Chapter 3 also reviews constructs that are commonly used in the study of organizational structures and their relationship with safety events. We compare and contrast these constructs and offer a preliminary assessment of how these constructs can be applied to radiation oncology. The lesson is that the nature of our practice (both on a broad macroscale and on a smaller microscale) determines the optimal methods to ensure high reliability and value creation.

In **Section II**, based on the beliefs outlined in the previous chapters, we describe our journey to high reliability and value creation at the University of North Carolina.

Chapter 4 provides an in-depth account of changes and initiatives taken at the organizational level. This includes personal reflections on why this work was initiated, along with specific examples of how the organizational leadership supports high reliability and value creation.

Chapter 5 describes our efforts to optimize workplaces and work processes for people so that human error can be minimized. We rely heavily on the hierarchy of effectiveness for error prevention and the principles of Human Factors Engineering.

Chapter 6 focuses on people and their decision-making processes and behaviors. We offer ways to engage, transform, and respect people during transition to high reliability and value creation.

Chapter 7 summarizes our research program on mental workload that is synergetic with our clinical activities. We also provide ideas for future research at the organizational, workplace, and people levels.

Chapter 8 provides a summary of key points and concluding remarks. We emphasize that high-reliability and value creation organizations, despite all improvement efforts, are not immune to errors. Continuous diligence is needed, with continuous support from leadership to nurture a culture of safety and empower people to improve processes.

Acknowledgments

Portions of this book (e.g., text, illustrations, tables) were adapted from some of our previous publications and are cited as such. We thank Mark Kostich for many of the photographs. We thank the faculty and staff in the Department of Radiation Oncology at the University of North Carolina (UNC) for their participation and assistance with the improvement activities. We recognize that everyone does not necessarily share our enthusiasm for this work, and that people have many competing priorities; thus, we appreciate everyone's willingness to be involved in these improvement activities. We especially thank our department managers and members of our Quality and Safety Committee, including (in no particular order) Kathy Burkhardt, John Rockwell, Patricia Saponaro, Kenneth Neuvirth, Dana Lunsford, Lori Stravers, Lauren Terzo, Kinley Taylor, Nancy Coffey, Prithima Mosaly, and Gregg Tracton, who courageously help us lead our improvement work. We are indebted to Dr. Marianne Jackson, a board-certified gynecologist, retrained as an industrial engineer and Lean expert, who was instrumental in helping us spearhead our improvement agenda at UNC.

We also want to thank our students—resident physicians, physicists, dosimetrists, and radiation therapists—for their active and inspiring participation in our improvement activities. Special thanks go to Dr. Aaron Falchook and Dr. Michael Eblan for engaging with us on our research activities to quantify mental workload and performance during provider–computer interactions.

We are grateful to the UNC healthcare system, the Medical Center Improvement Council, the School of Medicine, the Institute for Healthcare Quality Improvement, and the Cancer Center for their ongoing support of this work. Some of the research presented was funded by grants from Accuracy, Elekta, the Agency for Healthcare Research and Quality (AHRQ), and the UNC Innovation Center. We have also received support via a grant from the Centers for Disease Control and Prevention (CDC) to pursue some of these improvement initiatives in our breast cancer clinic. We are especially indebted to Dr. Prithima Mosaly, who assisted with much of the research work, and to Kinley Taylor, who helped coordinate the improvement aspects of the CDC-funded project as well as our global departmental quality initiatives. Thanks also to Adrian Gerstel, Jayne Camporale, Drs. Deborah Mayer, Donald Rosenstein, and Thomas Shea, and Jean Sellers, for their efforts on the CDC grant, and to Dr. Tina Willis, Celeste Mayer, and Glen Spivak for their continual encouragement and guidance in our improvement work. L. M. also thanks his many colleagues at Duke who helped him get started in this area for their support, encouragement, and participation.

Thanks to Michael Sinocchi, Jill Jurgensen, Jay Margolis, and Sophie Kirkwood at Taylor & Francis Group for their skillful assistance and patience in the bringing this book to fruition.

We are thankful for our families, who have supported and encouraged our professional careers and who patiently try to share our enthusiasm.

We are especially thankful to Ivette Duran-Mazur who assisted with the design of the cover.

ABOUT THE COVER

The artistic rendition by Ivette Duran-Mazur illustrates several of the concepts presented in this book. The three white swirls represent the three layers of the Swiss Cheese Model that we used to structure our book (e.g. organizational, workplace, and people). The thicker light blue line passing through the three swirls represents the complex interactions among these three layers that can lead to unforeseen events. The swirls and straight lines are meant to be reminiscent of cloud chamber tracings depicting the path taken by some "radiation beams." The back-projection of the lines to different points emphasizes the need for multiple perspectives when considering complex systems.

About the Authors

Lawrence Marks was born and raised in Brooklyn, New York. He studied chemical engineering at Cooper Union and earned his MD from the University of Rochester. He did his residency training in radiation oncology at Massachusetts General Hospital and then served on the faculty of Duke University for 19 years. There, he studied radiation-induced normal tissue injury and became interested in Human Factors Engineering and patient safety. In 2008, he moved to the University of North Carolina to become the Dr. Sidney K. Simon Distinguished Professor of Oncology Research and the chairman of the Department of Radiation Oncology. Over the last six years, he and Dr. Mazur and others have been systematically applying engineering principles from high-reliability and value creation organizations to improve safety. In his clinical work, he has particular interest in the care of patients with cancers of the lung or breast. He has been active in ASTRO (American Society for Radiation Oncology) and currently serves on its Board of Directors as the chairman of the Clinical Affairs and Quality Council. He lives with his wife of 29 years, Caryn Hertz, in Chapel Hill. They have three sons, none of whom is planning a career in medicine.

Lukasz Mazur earned his BS, MS, and PhD in industrial and management engineering from Montana State University. As a student athlete at Montana State University, he earned a spot in the Bobcats Hall of Fame for his efforts on a tennis team. While working at North Carolina State University, he was awarded the Alumni Outstanding Extension Service Award for his outreach work, highlighting his passion for quality and safety work in the healthcare industry. Currently, he is an assistant professor in the Radiation Oncology Department at the UNC School of Medicine. His research interests focus on engineering management as it pertains to continuous quality and safety improvements and human factor engineering with a focus on workload and performance during human–computer interactions.

Robert Adams earned his BS in biology/radiology from Averett University, a MS in healthcare administration from the University of North Carolina, and a doctorate in higher education administration from North Carolina State University. He is an assistant professor in the Radiation Oncology Department at the UNC School of Medicine, and directs both the UNC healthcare radiation therapy and the medical dosimetry educational programs. He is certified in radiation therapy and medical dosimetry. His research interests focus on clinical work practices, patient safety, and educational issues for radiation therapists and medical dosimetrists. He has served on several national and international boards of directors and editorial review boards. He is both a Fellow and an Award of Excellence recipient from the American Association of Medical Dosimetrists. He has published over 50 peer-reviewed articles, 10 book chapters, and recently completed an R25 National Cancer Institute recent grant developing "Computer-Based Medical Dosimetry Clinical Learning Modules."

Bishamjit S. Chera is an assistant professor and director of patient safety and quality in the Department of Radiation Oncology at the University of North Carolina. He earned his BS in biology from Winthrop University in 2000 and an MD from the Medical University of South Carolina in 2004. He completed his residency training in radiation oncology at the University of Florida. His clinical expertise is in head and neck and skin cancers. His major areas of research pertain to head and neck cancer and translating quality assurance/control/improvement principles and methodologies from high-reliability organizations to radiation oncology. He has written on the incorporation of practical quality assurance approaches (e.g., process/Human Factors Engineering and Lean methodologies) in the daily activities of radiation oncology departments/clinics.

Section I

This section provides an introduction to basic concepts, methods, and tools that underlie our approach to high reliability and value creation and an overview of key safety challenges within radiation oncology.

1

An Introduction and Guide to This Book

LEARNING OBJECTIVES

After completing this chapter, the reader should be able to:

1. Broadly understand some of the current challenges to safety in radiation oncology;
2. Understand the Swiss Cheese Model (e.g., the interdependence of the organizational, workplace, and people levels); and
3. Broadly understand how changes at the organizational, workplace, and people levels affect reliability and value creation within radiation oncology.

1.1 A BRIEF OVERVIEW OF THE SAFETY CHALLENGES WITHIN RADIATION ONCOLOGY

Radiation oncology is a modest-size field with about 4,000 practicing radiation oncologists in the United States. Nevertheless, the clinical impact of radiation therapy (RT) is significant. Approximately 50% of patients with cancer receive RT, with about 600,000 patients treated annually in the United States alone. RT plays an important role in the curative and palliative management of most malignancies and is also used to treat some benign conditions.

The clinical practice of RT enjoys a long-standing reputation for being generally safe. This is a tribute to the founding members of our field, who, recognizing the risks of RT, instilled within the very fabric of our field the need for careful oversight and clinical observation. Furthermore, the involvement of physicists, engineers, and other technical and quantitative-minded individuals, integral to our practice, brings an objective and systematic approach to quality assurance (QA).[1] For decades, radiation treatment centers have used numerous techniques to ensure high reliability and patient safety and have generally been successful.

The rate of "potential quality/safety events" within radiation oncology is difficult to estimate, as there are marked interstudy and interdatabase differences in the methods used to define an event. Further, there are certainly inaccuracies and biases in the reporting of events. Nevertheless, based on the available data, a reasonable estimate is that there is an event during the course of treatment in approximately 1%–3% of patients, but the vast majority of these events are not clinically relevant.[2–18] Importantly, however, about 1 in 1,000–10,000 treated patients is affected by a reportable event with potentially serious consequences (the supporting data are detailed in Chapter 2). This rate may compare unfavorably with highly reliable industries such as commercial aviation (≈1 death in 4.7 million passenger flights)[19] or other areas of medicine, such as anesthesiology (≈1 death in 200,000 procedures).[20] However, these comparisons might not be totally fair because the reporting thresholds are different. If in aviation we were to count faulty take-offs, landings, or unplanned returns to the airport, and if in anesthesiology we reported intubation failures or ventilator equipment/tube malfunctions, aviation and anesthesiology might not appear as favorable. Nevertheless, the relatively high rate of any type of event within radiation oncology is cause for concern as it suggests inherent shortcomings of our current systems.

Further, the event rates noted may not be reflective of modern practice. Recent technological advances (e.g., medical imaging, computer-based planning systems, and radiation delivery/control systems) have driven a rapid evolution in clinical practice and have had a mixed effect on event rates. Some technologies clearly have dramatically *reduced* the rate of some errors. For example, computer-based systems obviate the need for manual data transfer (e.g., by dosimetrists from the planning system to the patient's chart and by therapists from the patient's chart to the treatment machine), thereby essentially eliminating that type of data transfer error. However, other changes in practice appear to have strained our existing QA procedures (e.g., tracking of the technical review of the RT chart has become more difficult). These and other evolving safety challenges within RT are discussed in detail in Chapter 2.

There is reason to suspect that the *risks associated with incidents* (defined as events reaching the patients) might be *increasing*. Given the uncertainties in collected quantitative data related to the probability of an incident and their clinical severities, it is challenging to prove or disprove this suspicion. Conceptually,

$$Risk_{incident} = Probability_{incident} \times Severity_{incident}$$

Changes in radiation oncology practice may have influenced both the probability of incidents and their severity. It is unclear if the probability of incidents is increasing or decreasing, but there is a suggestion that the severity per incident might be increasing, leading to a net increasing risk (Figure 1.1).

A summary of some of the factors in modern radiation oncology practice that generally tend to decrease and increase the probability of events and their severities is given in Table 1.1.

Based on these forces, we submit that the slope in Figure 1.1A might be positive or negative, and that the slope of Figure 1.1B is almost certainly strongly positive. In concert, this leads us to believe that the slope of Figure 1.1C is most likely positive, although the degree of positivity is uncertain. We further explore many of these factors in more detail in Chapter 2.

Recent developments in our professional community also suggest a growing concern with safety. In 2008, the American Society for Radiation Oncology (ASTRO), American Association of Physicists in Medicine (AAPM), and the National Cancer Institute (NCI) held a conference

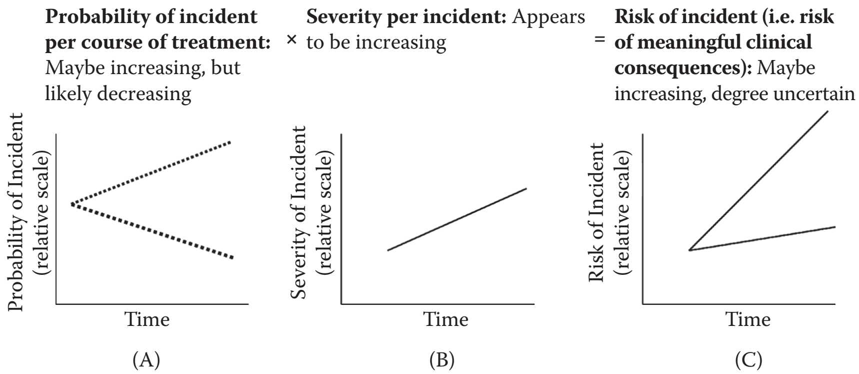

FIGURE 1.1
Left, probability of event; middle, severity of event; right, risk of event. All are presented in a relative and arbitrary scale.

TABLE 1.1

Example Factors Tending to Change the Probability or Severity of Events

Factors Tending to *Decrease* the *Probability* or *Severity* of Events	Factors Tending to *Increase* the *Probability* or *Severity* of Events
• Increased number of clinical guidelines. • Increased availability of "dose/volume/outcome" data/standards. • Readily available information via the Internet. • Enhanced communication technology better facilitating information transfer. • Electronic medical records systems (making information more readily available). • Record and verify systems. • Better-integrated computer systems. • Hardware/software interlocks to prevent incorrect treatment or alert users to potential issues. • Image-guided RT. • Collision detection software and hardware on machines reducing the risk for potentially catastrophic collisions. • End-to-end testing for many procedures.	• Older/sicker patients. • Increased use of combined modality therapy and complex multidisciplinary care. • Staff working in an increasing number of clinical sites, with more handoffs. • Higher doses per fraction, shorter fractionation schedules. • Trend toward using tighter margins. • Increased demands on staff, reduced reimbursement. • Increasing amount of data to consider. • Multiple electronic medical record systems to contend with (often where some critical information is not readily apparent or readily highlighted). • Data transfer is automatic and some errors may not be readily apparent. • A single software/hardware problem can affect a large number of patients. • Increased number of computer systems, often outpacing the ability to integrate systems. • Electronic systems may propagate errors such that a single error may have broader consequences. • Technical review of the chart often cumbersome and difficult to track. • Loss of some traditional downstream "QA checks" (e.g., light fields, portal films) in the era of IMRT. • Monitor unit calculations are less intuitive with fancier treatment techniques (e.g., IMRT vs. non-IMRT). • Overall complacency with information technology.

dedicated to growing safety concerns related largely to the introduction of new technologies. In 2010, a series of articles in the *New York Times* reported several disturbing clinical events that highlighted safety issues in our field.[21–24] The incidents and concerns brought to the fore in the lay and academic press were largely focused on technical factors; thus, many of the more recent quality initiatives within RT have understandably focused on the mechanical and computer aspects of new high-technology treatments (e.g., intensity-modulated radiation therapy, IMRT). RT safety was the focus of subsequent congressional hearings, a public meeting sponsored by the Food and Drug Administration (FDA), and the ASTRO/AAPM-sponsored “Call to Action” meeting (which was filled to capacity). In 2010, ASTRO also responded with a multifaceted Target Safely campaign with key elements that included[25]:

1. Create a national database for event reporting (the Radiation Oncology Incident Learning System [RO-ILS] was recently launched).
2. Accelerate an ongoing effort (Integrating the Healthcare Enterprise-Radiation Oncology [IHE-RO]) to ensure device manufacturers can transfer treatment information from one machine to another seamlessly to reduce the chance of medical incidents.
3. Enhance the radiation oncology practice accreditation programs (the Accreditation Program for Excellence [APEx] recently launched).
4. Advocate for new and expanded federal initiatives to help protect patients from radiation incidents; support the immediate passage of the Consistency, Accuracy, Responsibility, and Excellence in Medical Imaging and Radiation Therapy (“CARE”) Act, which among other things requires national standards for RT treatment team members.
5. Work with cancer support organizations to help cancer patients and their families know what to ask their doctors when radiation is a possible treatment option.
6. Expand educational programs related to QA and safety.

1.2 THE FOCUS OF SAFETY INITIATIVES ON TECHNICAL/EDUCATION VERSUS ORGANIZATIONAL/WORKPLACE/BEHAVIORAL ISSUES

We applaud the multiple technology-based initiatives aimed at improving patient safety, such as the efforts to promote interconnectivity between different RT-related products. We understand the need for a strong focus on these technical factors. We also applaud the education and training

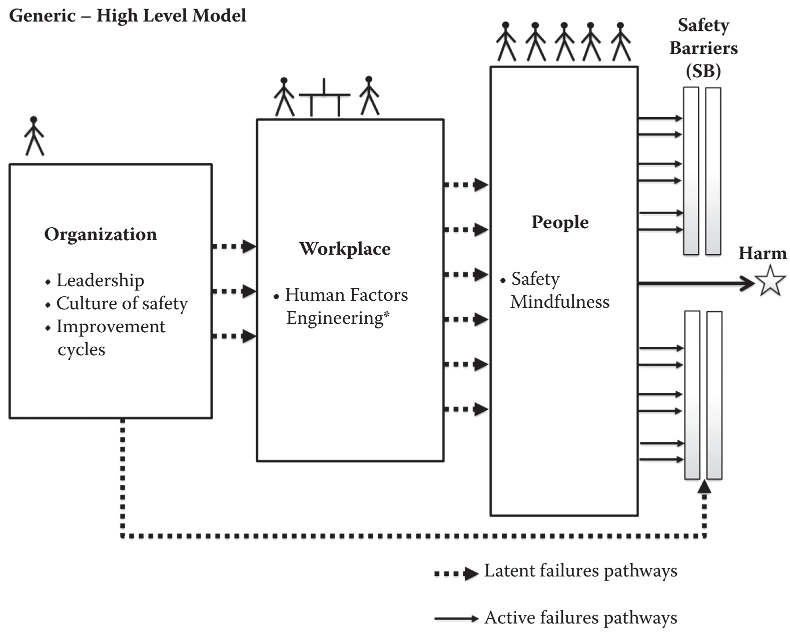

FIGURE 1.2
Conceptual representation of the Swiss Cheese Model. Left, organizational level with three key elements: leadership, culture of safety, and improvement cycles. Middle, workplace with Human Factors Engineering. Right, people with one key element: safety mindfulness. *In this book, for convenience, we place Human Factors Engineering at the workplace level to emphasize the interplay between a person and the person's physical environment that markedly influences the worker's human ability to perform his or her job well and directly influences reliability, safety, and quality. We recognize that the discipline of Human Factors Engineering is broader (see Section 1.3.2.1).

efforts to promote safety and quality. However, we believe that technical solutions alone are not going to bring our field to the desired level of reliability and value creation.

The successful practice of radiation oncology rests with people and in their ability to repeatedly perform diverse tasks in a reliable and predictable manner. However, people do not perform their tasks in a vacuum. We embrace a concept (often termed the Swiss Cheese Model) that people's actions (far right-hand side of Figure 1.2) are influenced by upstream *latent* failure pathways (contributory factors that may lie dormant for long periods of time) at the organizational, workplace, and people levels (e.g., policies, programs, schedules, work flows, training, perceptions).[26] The worker's action that is linked to the incident (e.g., forgetting to do something) is often referred to as the *active* failure.

Highly reliable organizations embrace this concept and are preoccupied with ways latent and active failure pathways can occur in the system. They work hard to detect and correct small emerging latent failure pathways and to see these as potential clues to additional latent failures pathways elsewhere in the system. They anticipate specific pathways that are at risk of occurring and build into their processes initiatives intended to prevent occurrence of these pathways. For example, the workplace and work flows should be "engineered" to minimize/prevent human errors (e.g., it is not physically possible for an anesthesiologist to attach a tube intended to carry oxygen to a gas tank containing nitrogen). For most activities involving human performance, the goal of the upstream initiatives is to facilitate worker behaviors and decisions that maximize the likelihood of the desired outcome.

Further, essentially all upstream initiatives are imperfect and may even generate additional latent failure pathways. Even if the upstream initiatives were optimal, this is still a probabilistic matter, and the involvement of humans creates some uncertainty. High-reliability and value creation organizations acknowledge this uncertainty. They acknowledge that their staff operates under variable abilities and training, conditions, equipment configurations, and work scenarios. It is recognized that the total composite of these elements and the human component determine the safety of the system. Thus, *multiple* methods are used to maximize worker behaviors, decisions, and task execution under any circumstances. A worker's broad awareness of, and appreciation for, these concepts (e.g., the potential presence of latent failures pathways, the risk of active failures pathways, and the critical role that they play in improving their [and the broader system's] overall performance) is often referred to as *safety mindfulness*. Safety mindfulness is particularly important in interactively complex systems, such as medicine, for which the overall performance of the system can be difficult to predict (this concept is developed more fully in Chapter 3).

In recognition that our systems are often imperfect, most processes have multiple built-in safety barriers, formally and informally defined QA and quality control (QC) steps to identify errors or question something that seems out of the ordinary. An interesting question is whether one considers these safety barriers as part of a reliable system or as a symptom/acknowledgment of upstream unreliability. High-reliability and value creation organizations are structured to detect unexpected active and latent failures and their pathways. Workers operate with safety mindfulness to more readily notice and act on *weak signals of potential failures* (i.e., associated with subtle deviations from the expected) before they evolve into *larger signals* (i.e., associated potentially with "large" system accidents). This is analogous to having the mindset to bring your car in for service when there is a subtle noise or dysfunction rather than waiting for the breakdown. Because medicine is a human endeavor, it is not possible to prevent all human errors; thus, safety barriers will always be considered. This can perhaps be better represented by the Venn diagram-like representation shown in Figure 1.3, which emphasizes this point; workers function within workplaces, and workplaces are defined by organizational decisions, in nested configuration. If one considers the three components of organization, workplace, and people to be in series as presented in Figure 1.2, it is instinctive to place the barriers only on the far right-hand side where people directly interact with patients. In the nested configuration, it becomes clear that those safety barriers can also be applied to the organization and workplace as shown in Figure 1.3.

Patient harm usually occurs as a result of one or several latent failure pathways interacting with active failure pathways, depicted as the arrow propagated throughout organizational, workplace, and people levels to the "patient harm" in Figure 1.3 (top). Typically, most human errors do not cause patient harm as sufficient safety barriers are present in work flows to prevent them (Figure 1.3, bottom). However, final outcomes alone are not the primary interest of high-reliability and value-creating organizations. Rather, they mainly focus on their practices to produce a robust and reliable system. They closely monitor metrics that assess the system's performance in the hopes of detecting signals of latent and active failures and their respective pathways. Further, they continuously promote staff safety mindfulness.

It is important to emphasize that the Swiss Cheese Model described is the classical form that is widely understood among safety experts. An alternative interpretation of the term Swiss Cheese Model has been offered by which the different pieces of cheese represent *sequential steps* in a multistep process, and that errors manifest at the end of the process may have had their nidus at an earlier step. A sequential process-oriented representation of the Swiss Cheese Model is shown in Figure 1.4. Although this is true, the message of the classical Swiss Cheese Model shown in Figures 1.2 and 1.3 is more powerful.

Our desire to write this book was based on our strong belief that our field of radiation oncology needs to embrace the concepts of the