Introduction

"What activities, if performed less than adequately,
pose the greatest risks to the well-being of the system?[1]

-Dr. James Reason
Author and Professor Emeritus

"Unlike people in most other organizations, however, [HROs*] have a good sense of what needs to go right and a clearer understanding of the factors that signal that things are unraveling."[2]

-Drs. Karl Weick and Kathleen Sutcliffe
Authors: *Managing the Unexpected*

Absolute safety is impossible to achieve, especially with any human endeavor.[3] Absolute safety exists only when a system, device, product, or material can *never* cause or have the potential to cause harm. Risk arises otherwise. Safety is thought to exist when there is an "acceptable risk" for a particular operation, where work occurs consistently and predictably without harm to assets—person, property, product, or environment, among others. Many of society's operations are operator-dependent, which suggests that these operations are inherently risky—people are fallible; they make mistakes. As the following tragedy reveals, safety and survival are often in the hands of people on the front lines doing normal work every day.

Deadly Medication Error[4]

The nurse providing initial care of a troubled, pregnant 16-year-old mistakenly injected an epidural painkiller instead of antibiotic directly into her bloodstream. The young girl was ready to give birth to her baby. Her heart stopped beating and the girl could not be revived. However, the baby was delivered successfully by emergency Caesarean section. How could a registered nurse with years of experience in this women's unit do such a thing? Easily.

The veteran nurse bypassed several safety practices. However, most organizational systems required to support the practices were flawed, encouraging nurses to work around them to deliver care. These system flaws conspired, so to speak, contributing to her fatal mistake. Here are the facts.

- The nurse had 15 years of experience working the obstetric unit with an unblemished work record.
- At the time of the incident, the nurse had worked two consecutive eight-hour shifts the day before and slept in the hospital before coming on duty the following morning. Hospital management encouraged nurses to work long hours, rewarding those with the most overtime hours each year with a free professional development trip.

* High Reliability Organizations

- The nurse was working with two patients concurrently, both involving emotional trauma. The other patient was in labor about to deliver a deceased baby. The nurse's supervisor assigned this patient to her because she ran the hospital's grief program.
- The 16-year-old was suffering from a strep infection and was afraid and crying. She had no prenatal care. One report says she was terrified.
- A doctor prescribed an antibiotic to protect the unborn baby from the mother's strep infection.
- A patient identification wrist band had been prepared and placed in the pocket of the teen's medical chart. However, the nurse did not place the bracelet on the girl promptly as her focus was on alleviating the teen's fears and anxiety.
- The nurse did not use the hospital's new bar-coding system for intravenous (IV) fluids, installed a couple of weeks before, designed to match the right medication to the right patient. The hospital's nurses, many of whom had not been trained on the system, often bypassed the system because software glitches hampered its reliability. It failed to register IV bags 30 to 70 percent of the time.
- Knowing an epidural painkiller would be used later during delivery and to ease the teen's anxiety, the nurse acquired a 100 ml IV bag from the automated medication-dispensing machine to show it to the 16-year-old patient to relieve her fears. Afterward, the nurse placed the bag on the bedside table, continuing to comfort the young mother-to-be.
- Moments later another nurse delivered a 100 ml IV bag of antibiotic, placing it on the same bedside table alongside the other 100 ml bag. A bag of epidural painkiller looks the same as a bag of antibiotic, with the only differences being the label and an orange dot instead of a yellow dot.
- Both medications were brought into the patient's room before doctors' orders were given, contrary to hospital policy.

While talking to the patient, the nurse inadvertently picked up and hung the incorrect IV bag on the pole near the girl's bed, thinking it was an antibiotic. Apparently, she inserted the IV tube into the girl's IV access line on her arm, and then opened the tubing clamp, feeding the epidural painkiller directly into the teen's bloodstream—the point of no return.[*] Later, she was charged by the state with a felony alleging criminal negligence and was subsequently dismissed from the hospital. Charges were later reduced to two misdemeanors. Regardless, her nursing license was suspended. She was barred for several years from working for any hospital. For what it's worth, punishing those who err does not improve safety.

It is impossible from a human perspective to be fully alert and vigilant 100 percent of the time, completely informed, always rational, and error-free—especially for long periods. If you need 100 percent reliability, then you had better use a machine.[†] However, to date machines do not have sufficiently sophisticated adaptive capacity (intelligence) to take the place of human operators. Most operations require some degree of human oversight and control of work processes. That means that some human actions MUST go right the first time, every time, where

[*] The exact error is vague. No report or reference accurately describes the physical act the nurse explicitly did to initiate the flow of epidural painkiller into the vein of the young girl. Common words used to describe her mistake include "gave," "infused," and "injected," all ambiguous. We do know that the critical act is in embedded in those words somewhere.

[†] We attribute this idea to Dr. Todd Conklin, a prolific H&OP speaker and author.

a loss of control is unacceptable. As Gene Kranz, former NASA flight director, is so famously known to have said during the Apollo 13 incident, "Failure is not an option."[5] CRITICAL STEPS address those aspects of work that are intolerant of human error—human single-point failures. *A CRITICAL STEP is any human action that triggers immediate, irreversible, and intolerable harm to something important if that action or a preceding action is performed improperly*.

By design, CRITICAL STEPS happen every day at work and at home. The aim of this book is to help you manage those operational aspects that depend on the human operator getting things right. As tragically illustrated above, the health care system depends greatly on people getting things right the first time every time. Presumably, the nurse's CRITICAL STEP was opening the tubing clamp on the IV tube that allowed the flow of the epidural painkiller into the bloodstream of the young girl. Nurses open IV clamps every day in hospitals and other health care facilities.

Other human actions important to the success and resilience* of the performance of CRITICAL STEPS include what are known as Risk-Important Actions (RIAs), the "preceding actions" mentioned above. One RIA presumably done earlier by the nurse was inserting the IV tube into the IV access line attached to the girl's arm. That act created the pathway between the IV bag and her bloodstream, protected only by a closed tube clamp. RIAs are not something to avoid. They are necessary to create the conditions for work to occur. Chapter 4, Risk-Important Actions, explores their relationship with CRITICAL STEPS and their importance to safety.

Together, human fallibility and complex systems† cast a shadow of uncertainty over all hazardous operations. The combinations of fallible human beings, designs and procedures based on faulty assumptions, many difficult tasks, complex technologies, the marshalling of hazards, and numerous regulatory prescriptions can make every operation seem critical. Despite our best efforts, events still occur. Organizations and their systems are not always aligned for safety—things change, hidden pitfalls arise, equipment wears out, priorities shift, people make trade-offs when goal conflicts arise, resources are limited, and so on. That's why it's so important to single out the most important human actions that pose the greatest risk, and make sure they go right. But if they don't go right, minimize the harm to the most important assets, to *fail safely*. Therefore, front-line workers need latitude for safety, what is known as *adaptive capacity*, in the workplace, able to respond with some degrees of freedom to unforeseen work situations—to *do* safety and achieve success.

The Principal Goal of Managing CRITICAL STEPS

The principal goal of managing CRITICAL STEPS is to *maximize the success of people's performance in the workplace, creating value without losing control of the built-in hazards necessary to do work*. Dr. Ron Westrum suggested three practical meanings (applications) of resilience, two of which we address in this book, 1) preventing something bad from happening,

* Resilience is the intrinsic (built-in) ability of a system (and its organization) to adjust its functioning before, during, and after a challenge, disturbance, or failure to sustain and improve operations under both expected and unexpected conditions. Resilience is the capacity to sustain safety, productivity, quality, etc.—to adapt—in the face of unexpected conditions and challenges; the ability to succeed under varying conditions.

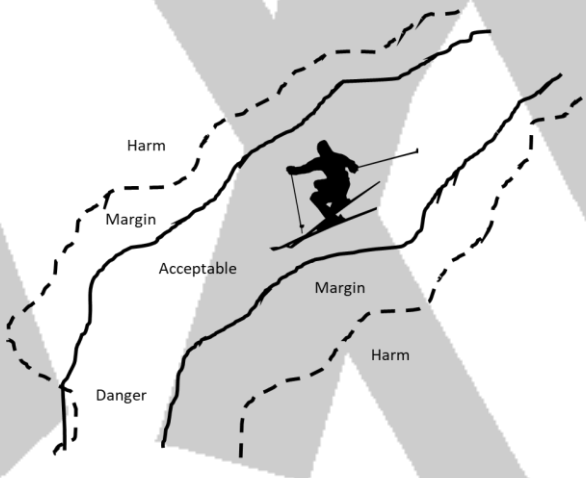
† Complex systems are characterized by the presence of many components, with concurrent and possibly obscure interactions, and individually adaptive components (mostly people and sophisticated software), the effects of which are not easily comprehensible by any one person.

and 2) preventing something bad from getting worse.[6] The third aspect of resilience, recovering from something bad that happened, is beyond the scope of this book. This book purposefully limits the scope to those front-line aspects of high-risk operations most related to managing the human performance risk, enhancing success during operations: exercising positive control of CRITICAL STEPS and failing safely after losing control.

In practical terms, managing CRITICAL STEPS is a necessary form of operational hazard control, where an alternate means—other than human—of reduction or control of a built-in hazard by design is not available.[7] Occasionally, operations are established for highly innovative systems that have never existed before (such as space exploration), for which there is limited experience. It is near impossible to prescribe detailed design safety solutions for such endeavors.[8] But, we still want to make sure the right things go right the first time, every time. The right things are those high-risk actions or processes that create value, that is, work. The concept of CRITICAL STEPS should promote successful operational hazard control even without a procedure. Most errors have no consequences; and, because of their trivial nature, most errors occur without our knowledge. However, what if error *is* unacceptable? What if people's lives and livelihoods are at stake? What if failure really is not an option, as was the case with the nurse in the medication event? But, what if failure does happen? How should people respond to minimize the harm if they lose control? Later we discuss preparations to "fail safely" in response to losses of control at CRITICAL STEPS, if practicable.

The practice of managing CRITICAL STEPS changes the emphasis from simple error avoidance to ensuring success proactively and systemically. An added benefit of this practice optimizes efficiencies and productivity as well as safety of operations that are indeed high risk. It provides a structure for everyone in the organization to have ongoing, robust, technical, interdisciplinary conversations about what must go right in the pursuit of business goals. While the practice of managing CRITICAL STEPS focuses on what's most important, it accordingly identifies low-risk work activities where the loss of control has little or no impact. There is no need to prevent all human error. One, it's impossible; two, it's expensive; and three, it distracts from your focus. To us it makes better sense to target high-risk activities, ensuring that they go right, and to avoid the truly high-risk errors. This has the effect of giving control of low-risk operations to the expert judgment of the workforce.

Consider downhill ski racing. Racers have practiced racing techniques for thousands of hours, honing their skills and creating muscle memory. In preparation, they slowly pre-ski the racecourse to evaluate slope, snow and light conditions, and optimal lines. They look for bad snow, trees and other hard objects close to the course, tricky transitions, and other conditions that could spell failure, making mental notes of when extra caution is prudent. Then they ski hard and fast, following the lines they planned. They look where they want to go, not where they don't. It's a choice, honed by experience. They know that if they look where they



don't want to go, it is more likely that they will go there—a phenomenon called "target fixation."[9] They know they must focus on success, the best line, while they remain mindful of incursions into their desirable lane caused by obstacles, and occasionally by chaos due to variabilities in the environment. If you turn your gaze toward an unanticipated danger, you can't see the line of success. Behavior choices in the workplace are a form of CRITICAL STEP management. We will show you how this works, keeping your eye on the goal, exercising positive control, while factoring in information just outside your target view—a persistent sense of unease—developing and taking advantage of expert intuition.

Drs. Karl Weick and Kathleen Sutcliffe state in their third edition of *Managing the Unexpected*, on high reliability organizations (HROs), "HROs develop capabilities to detect, *contain*, and *bounce back* from those inevitable errors that are part of an [uncertain] world. The hallmark of an HRO is not that it is error-free but that errors don't disable it."[10] To fail safely—to keep something bad that has happened from getting worse. In our world of high-hazard, complex, and interconnected operations, it is important to understand how we can organize to enable positive control of CRITICAL STEPS and to minimize harm to assets should control be lost.

Origins of the CRITICAL STEP Concept

The concept of CRITICAL STEPS exists in several domains of work. In food service, *critical control points* (CCPs) are identified and controlled. According to the U.S. Food and Drug Administration (FDA), a CCP is *a point in the food service process where controls can be applied and are essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level*.[11] Most food handling and preparation activities contain a variety of biological, chemical, and physical hazards to those who not only handle and prepare the food, but ultimately to those who consume the food. A CCP is more focused on defenses and thus is oriented in identifying where to apply a control to avoid contamination of the food.

To point out another source, the U.S. Department of Defense (DOD) uses the concept of a *safety-critical function*. This is a "*function, which if performed incorrectly or not performed, may result in death, loss of the system, severe injury, severe occupational illness, or major system damage*."[12] Safety-critical functions include all human, hardware, and software processes necessary to either work when demanded (such as actuating a fire suppression system in case of a fire) or not work if activated inadvertently or untimely (such as interlocks associated with raising an aircraft's landing gear while on the ground).[13]

The phrase "critical step" originated with the handling of nuclear weapons. Understanding which actions really matter the most was significant because no one wants to experience a detonation of a nuclear bomb. Nuclear weapons are assembled, dismantled, and maintained at the U.S. Department of Energy's (DOE) Pantex facility near Amarillo, Texas, where "much ado" is paid to CRITICAL STEPS. The facility originally crafted the following definitions:[14]

- *Hazardous step* – a procedure step that, if performed incorrectly, has a 'potential' to 'immediately' result in a dominant high-energy detonation…
- *Critical step* – a procedure step, that if skipped or performed incorrectly, will increase the 'likelihood' of a high-energy detonation … at some later step in the procedure

By the above definitions, "critical step" as used by Pantex was less serious than "hazardous step," which seems contradictory. To us, the term CRITICAL STEP has a greater sense of dread—the fear and apprehension of an unwanted outcome—than the word hazardous (dangerous or risky). Also, the description of a critical step is similar to what we refer to as an RIA. The real critical step is what the description refers to as "some later step in the procedure."

As you can see, the FDA, DOD, and DOE definitions have similar purposes but leave room for rationalization. For sure, there has never been an unintended detonation of a nuclear weapon, however, we believe the words *likelihood*, *may*, *acceptable*, and *potential* lack sufficient specificity and clarity for front-line workers. Since the mid 2000's, Pantex, along with other DOE facilities, have incorporated the concept of CRITICAL STEPS in its operations, tailoring it to the nuances of the various technologies and missions of the department and its contractors. Human beings are notoriously inept at estimating probabilities. We usually underestimate the likelihood of an occurrence. That's why we describe CRITICAL STEPS in more concrete terms that minimize doubt as to what can happen. Vague terms, such as mentioned previously, tempt people to rationalize their sense of control—especially in the throes of production pressures. You and your organization are better off adopting more concrete terms that keep the red lights flashing in the minds of those who perform CRITICAL STEPS. Front-line workers must know 1) what absolutely must go right, anticipating what can go wrong; 2) what to pay attention to (high-risk actions and the asset's *safety-critical parameters*); and 3) what to do before they start their work to respond properly to achieve success and protect assets from harm. The foregoing mental aspects of high-risk work are closely aligned with the cornerstone elements of RISK-BASED THINKING (see description in Appendix 2).

Who Benefits Using CRITICAL STEPS?

The short answer is that anyone involved with hands-on work, in direct contact with key assets and their built-in hazards, benefits from using CRITICAL STEPS. We live in a world where our actions control or moderate the transfer of energy, movement of matter (solids, liquids, or gases), or the transmission of information that can and do cause something of value to happen or to cause harm. Whether we are turning into traffic from a side road on to a busy city street, walking with an infant in our arms down a flight of stairs, making an incision during surgery, starting a high-pressure pump, or clicking "Enter" for financial transactions, each of us performs CRITICAL STEPS every day of our lives, both at home and at work.

CRITICAL STEPS occur naturally in many aspects of high-risk operations, maintenance, engineering, research, and administrative work. People doing physical work perform CRITICAL STEPS as an essential part of their jobs—it's normal and necessary to be successful in the marketplace. However, there is a broad range of functions performed by support staff, usually removed in time and space from the front line, who establish conditions that influence workers' behavior choices in the workplace. This is an organizational aspect of H&OP.

Support staff—engineers, scientists, accountants, instructors, procedure writers, and other knowledge workers—who function in the information domains are expected to perform their activities without error. Error is never acceptable, but it is managed by means of redundant

checks and reviews. Every engineer or scientist intends to turn out a work product that is 100 percent accurate, that is 100 percent complete, that meets 100 percent of the requirements, and that results in a defect-free product. Regardless, errors by knowledge workers do not trigger immediate harm. One could define a human action that would *eventually* produce harm if that action or subsequent checks downstream the production process were performed improperly. This is a classic latent error, not an active error. These actions do not satisfy the CRITICAL STEP definition.

However, there are occasions when knowledge workers perform hands-on work. It is during these times when CRITICAL STEPS are applicable to what they do, whether they are working with physical mockups, running high-energy particle experiments, or executing buy or sell stock trades on an exchange. Sometimes knowledge workers trigger the worst outcomes for organizations.

Organization of the Book

1. Chapter 1 defines CRITICAL STEPS and describes its attributes. This chapter discusses how identifying and controlling CRITICAL STEPS promotes organizational success while eliminating harm to the company and its key assets.
2. Chapter 2 orients the reader as to how to think about human performance (frequently abbreviated **Hu**[*] herein**)** risk in front-line operations. Most importantly, we reframe human error as a loss of control because events—harm to assets—are caused by hazards, not by front-line workers.
3. Chapter 3 examines the *Work Execution Process*, which describes how work is planned, executed, and improved. Understanding the three phases of work help in the systematic preparation and performance of CRITICAL STEPS, as well as learning from surprises.
4. Chapter 4 examines those human actions—*Risk-Important Actions*—that precede CRITICAL STEPS that establish the required preconditions to ensure success when front-line workers perform CRITICAL STEPS.
5. Chapter 5 addresses the performance of CRITICAL STEPS in the workplace, emphasizing the need for positive control, shifting between fast and slow thinking, applying RISK-BASED THINKING using **Hu** Tools; providing time-tested methods to manage the leadup to and execution of CRITICAL STEPS.
6. Chapter 6, the longest chapter, guides the reader with a workable strategy for managing CRITICAL STEPS—learning to more effectively and consistently identify and control CRITICAL STEPS from a systems perspective; includes ways and means for augmenting adaptive capacity to respond to the unexpected.
7. Chapter 7 details the CRITICAL STEP MAPPING process to systematically identify perpetual CRITICAL STEPS in existing technical procedures and pinpoint means of their control.
8. Chapter 8 examines the integration and implementation of the principles and practices of managing CRITICAL STEPS into operations while reinforcing systems thinking.

[*] The abbreviation, **Hu**, (letters pronounced separately: "aitch u") was adopted by the commercial nuclear electric generating industry in the mid-1990s as a cause category of events. 'HP' had already been adopted to represent "health physics," a domain of knowledge associated with the study of the effects of radiation on human health. Consequently, Hu was used instead of HP. **Hu** is bolded to represent the abbreviated form of human performance of individual performers.

Because a new vocabulary is associated with H&OP and with CRITICAL STEPS in particular, Appendix 1 provides a glossary of terms and phrases commonly encountered in the following pages. You are encouraged to flag this appendix, as you will likely refer to it often during your reading. We refer to H&OP and RISK-BASED THINKING frequently throughout the book. Appendix 2 provides a brief primer on these topics including the principles for managing H&OP. We recommend reading this appendix before starting Chapter 1.

Stories, experiences, and events that reveal the reality of CRITICAL STEPS in ordinary work and in everyday life are spread throughout the book. Most are true or else inspired by actual events, some tragic, some humorous; all denoted with a gray background. Each chapter begins with an account of an event relevant to that chapter's content. Each chapter concludes with *Key Takeaways* that summarize the most important principles or ideas of the chapter, as well as *Checks for Understanding* with a few quiz questions associated with the chapter's content to confirm your understanding and application of the content. Appendix 3 provides answers to the quiz questions. As with Appendix 1, we suggest flagging that page also for quick access. Finally, with application in mind, each chapter concludes with *Things You Can Do Tomorrow*, practical suggestions on how to apply the concepts described in the respective chapter, with little or no resource allocation.

We hope this book will help you think more systematically about how success happens each day not only in your organizations, but also in your personal and professional lives, ensuring that the CRITICAL STEPS in your life and work result only in adding value.

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