Prevention Through Design
THE TIME IS NOW

By Michael Taubitz and Kenji Furukawa

This article describes how applying prevention through design (PTD) concepts can solve problems on the factory floor. The goal of PTD is to consider feasible risk reduction in the early stages of concept and design for machinery, equipment and facilities.

PTD concepts are also helpful in solving problems on legacy or existing equipment. This article presents real-world examples to show how risk assessment, feasibility analysis and risk-reduction methods based on the hazard control hierarchy can achieve acceptable risk and OSHA compliance.

ANSI B11.0-2023, Safety of Machinery, is an essential guide for PTD practitioners to attain acceptable risk for specific tasks. This standard is particularly useful for analyzing feasible risk reduction for jobs cited by OSHA as being noncompliant with regulations. Using this tactical approach to solving what management considers a "hot issue" can prove that PTD methods work. In turn, this can open the door for strategically moving the analyses upstream into the concept and design phase of new or rebuilt equipment. The authors hope that readers will agree: The time for PTD is now.

Example Management "Hot Issue"

Following is a real-world example where Company X was cited for not locking out the primary energy source when changing die tooling on its injection mold machines (Photo 1). Each month, 40 to 50 mold tool changes were necessary to produce various small rubber parts. The sliding door on the operator side of each molding machine had two interlocks and a mechanical switch. The door on the nonoperator side also had two interlocks.

Photo 2 pictures a mold tool when the door was opened to perform a changeover for a new product. Typically, two operators worked together to perform a mold change, which took approximately 20 minutes. In addition to the four interlocks and the mechanical switch, the operators were protected by the pump being off and the machine not being in auto.

Photo 3 shows the control panel or human machine interface. Further protection was provided by the selected functional machine mode (e.g., inch, jog). The machines could not run until the doors were closed, the pump was running, and the controls were set to automatic. The company was cited for changing mold tools without isolating and locking the primary energy source.

Analysis of the issues followed ANSI B11.0-2020, Safety of Machinery, with the first step being a task-based risk assessment. The control reliable circuits on the injection molding machines were designed with multiple redundancies such that failures within the circuit would not result in unexpected or unintended energization that could create a hazard. Table 1 shows a two-column format for documenting a feasibility assessment using lockout/tagout (LOTO) to perform the task of changing mold tools.

With documented infeasibility of LOTO, it was then necessary to determine whether the existing limit switches and control functions met the test of control reliability as defined in ANSI B11.0-2020 and ANSI B11.19-2019:

> Control reliability: The capability of the [machine] control system, the safeguarding, other control components and related interfacing to achieve a safe state in the event of a failure within their safety-related functions.

In addition to documenting LOTO as infeasible, Company X's existing control reliable safety circuits were engineered controls, while LOTO is an administrative control. When applying the hazard control hierarchy, engineered controls are preferred over administrative controls. Analysis showed that the existing safeguarding system did not have the potential for harmful exposure to unexpected startup or energization during tool changes. The control reliable engineered controls coupled with existing safe operating procedures were an effective alternative to LOTO.

Note that there is no shortcut to a proper and compliant alternative method (e.g., locking an E-stop is neither safe nor will it meet the test of compliance). The safety profession now has the necessary tools and methods needed to make PTD actionable and find solutions that achieve acceptable risk and OSHA compliance.

Evolution From Hazard Identification to Risk Assessment

When Congress passed the OSH Act of 1970, general industry best practices addressed hazards without the benefit of risk assessment. Hence, the U.S. legal

(From top) Photo 1: Injection molding machine at Company X. Photo 2: Mold tool with safety door open. Photo 3: Human machine interface.

Vantage Point

Vantage Point articles in *Professional Safety* provide a forum for authors with distinct viewpoints to share their ideas and opinions with ASSP members and the OSH community. The goal is to encourage and stimulate critical thinking, discussion and debate on matters of concern to the OSH profession. The views and opinions expressed are strictly those of the author(s) and are not necessarily endorsed by *Professional Safety*, nor should they be considered an expression of official policy by ASSP.

structure for employee safety is based on hazards without consideration of the probability and severity of harm. Industrial hygiene, noise control, toxicology and the control of hazardous materials dealt with the fundamentals of exposure, dose and risk in the 1970s, but the preponderance of industrial safety dealt only with hazards and hazard identification. OSHA's website details the background for the entire OSH Act of 1970. Table 2 (p. 34) examines terms relevant to PTD that appear in the OSH Act.

In passing the OSH Act, Congress did not have the opportunity to consider factors such as risk assessment and the feasible application of the hazard control hierarchy because that thinking was still decades away in general industry. "Lock it or guard it" was a common mantra for manufacturing during the 1970s. Well-intended risk-reduction efforts without the benefit of risk assessment led to safeguarding that sometimes made doing a given task impossible without breaking the "safety rule," as represented in the following anecdote:

> When I was promoted . . . to safety supervisor, I sought advice from my older brother, an experienced and respected toolmaker who said, "If I listen to all that stuff you guys tell me, I'll follow your rules, shut you down and you will never run again." To underscore his point, he continued, "If a car was an industrial machine, you guys would interlock the hood and never allow the engine to run with the hood open." He noted that it was impossible to troubleshoot problems and set engine timing without the engine running. (Taubitz, 2018, p. 28)

The first author met Fred Manuele at a National Safety Council (NSC) board of directors meeting in the late 1980s, where Manuele proclaimed that safety would only become a profession when the practitioners diligently applied risk assessment after hazard identification. In his book, *On the Practice of Safety*, Manuele challenged the safety profession to embrace new thinking and use risk assessment as the foundation for risk reduction:

> Every safety professional who writes a recommendation to eliminate or control a hazard makes a risk acceptability decision. It cannot be presumed that complying with the recommendation achieves zero risk. No thing or activity is risk-free. (Manuele, 1993, p. 187)

At the time, there were no usable risk assessment tools and methodologies available for use in general industry, yet Manuele foresaw the evolution of the safety practice into what is now called PTD: "As safety practice evolves, the required attention will be given to the avoidance of hazards in design and engineering processes" (Manuele, 1993, p. 184).

In a PTD journey, practitioners must demonstrate that the results not only provide for safety (acceptable risk) but are compliant with OSHA regulations. The OSH Act of 1970 General Duty Clause is the relevant law and regulation for employers and employees in the U.S. The 2020 OSHA Field Operations Manual states, in part:

> In general, Review Commission and court precedent have established that the following elements are necessary to prove a violation of the general duty clause:
> 1) The employer failed to keep the workplace free of a hazard to

TABLE 1

FEASIBILITY ASSESSMENT

A two-column format for documenting a feasibility assessment using lockout/tagout (LOTO) to perform the task of changing mold tools.

Criteria for feasibility	Assessment
Regulatory obligations and introduction of new hazards	• Company X complied with OSHA requirements because the control reliable system would not allow "unexpected energization." • Safe operating methods used by Company X were compliant with OSHA requirements and conformed to applicable ANSI standards. • Machine disconnecting devices are not duty rated for frequent use and increase the risk of potential failure resulting in an arc-flash incident.
Effectiveness and machine performance	• The control circuit power was needed for setup; the task could not be performed without power. • LOTO by both operators would have to be performed five times during each mold change. Each LOTO required two trips to the disconnect: one to shut down the power and lock the device and a second to go back and restore power for the next step. • After each LOTO, it took 2.5 to 3 minutes for the PLC to reboot and be ready for the next step. • Using LOTO, the task would be infeasible.
Usability and productivity	• TaBRA showed more than 20 steps. The existing time to perform a changeover was 20 to 25 minutes. The workers estimated that LOTO would double that, requiring at least 40 to 50 minutes per changeover. • Problems with machine startup and malfunctions would likely occur after restoring power and cause even more downtime. (e.g., computers sometimes react unpredictably when power is removed)
Durability, maintainability and ability to clean	• It was not possible for Company X management to maintain insistence on LOTO when the change and setup work required power.
Ergonomic impact	• The ergonomic impact was insignificant; however, unnecessary walking to and from the disconnect increased the risk of slip, trip and fall, and added stress on the operators.
Economic and technological feasibility	• It was not technologically feasible to set up without power. • The use of redundant control reliable safeguarding made LOTO unnecessary, as employees were not exposed to a startup or unexpected energization hazard.

TABLE 2
KEY TERMS IN THE OSH ACT OF 1970

Terms in the OSH Act of 1970 relevant to PTD.

Term	Usage count	Comment
ANSI	0	No reference to ANSI or any other voluntary safety standard
Hazard	26	Appears in the General Duty Clause and 25 other related instances.
Risk	3	Twice for "risk for bioterrorist threat"; once for "exposure health effects and relative risks associated with specific agents"
Feasibility	3	Three times for "to the extent feasible"
Standards	44	Primarily reference related "To assure safe and healthful working conditions for working men and women; by authorizing enforcement of the standards developed under the Act" and "conducting other research relating to health problems, in recognition of the fact that occupational health standards present problems often different from those involved in occupational safety"
Voluntary	3	• "voluntary efforts that employers may undertake to establish and maintain safe and healthful employment and places of employment" • "accept and utilize the services of voluntary and no compensated personnel" • "evaluate current statutory, regulatory, and voluntary industrial hygiene or other measures used by small, medium, and large employers to prevent or remediate home contamination"

which employees of that employer were exposed;
2) The hazard was recognized;
3) The hazard was causing or was likely to cause death or serious physical harm; and
4) There was a feasible and useful method to correct the hazard.

Other OSHA publications underscore the importance of feasibility. OSHA's (2008) enforcement policy for its standards addressing the control of hazardous energy mentions "feasible" 13 times. OSHA's (2007) publication, "Safeguarding Equipment and Protecting Employees From Amputations," mentions "feasible" and "infeasibility" in 20 different instances for different types of machines. For example:

> Secondary safeguarding methods are acceptable only when guards or safeguarding devices (that prevent you from being exposed to machine hazards) cannot be installed due to reasons of infeasibility. (OSHA, 2007, p. 16)

Employers must design and implement feasible risk reduction measures to properly mitigate risk from a recognized hazard. The legitimate reasons that industry safety professionals and OSHA did not make risk assessment and analysis of feasibility forefront no longer apply to today's current state. It is time for today's professionals to pick up the challenge.

Evolution of PTD
Task-Based Risk Assessment

From the 1970s to the 1990s, general industry safety focused on hazard identification and hazard control. While necessary, this focus was insufficient to address serious injuries and fatalities (SIFs) because:

1) recordable and days-away cases were used as measurement of safety performance, but exposures for SIF cases are often substantially different,
2) the task being performed might be unknown to management,
3) if the task was unknown, hazard assessment was not possible, and
4) hazard identification alone does not consider the probability and severity of the hazard.

Without that risk assessment of the specific task, management might install more safeguards than necessary or, of greater concern, not address an unknown exposure where protection was needed. Job safety analyses, safety audits and standard work typically focused on production tasks without regard to specific service and maintenance tasks. Standard safety protocols such as LOTO and fall hazard control were provided for authorized workers without knowing whether these protective measures were feasible and usable for a given task. Additionally, general hazard identification was not designed to identify tasks where power might be required or where climbing into or on a machine (assuming full lockout) might pose a serious risk of a slip, trip or fall.

With a goal of reducing SIFs, General Motors (GM) and the United Auto Workers (UAW) began addressing the problem in the mid and late 1990s. Working with skilled trades, the project team developed a new method to control hazards based on task requirements and applying the hazard control hierarchy. With strong input from the maintenance workforce, the joint team developed a simple method to determine protective measures that allowed the task to be performed by an authorized worker. GM and the UAW called this method task-based risk assessment (TaBRA).

In a 1999 letter to UAW, OSHA recognized the TaBRA methodology when designing alternative methods using control reliable systems in lieu of lockout for robot cells (Note: MPS refers to monitored power systems, GM's term for control reliable safeguarding systems):

> The pilot program involved a task-based risk assessment (TaBRA) process through which the MPS was incorporated into specific machines and equipment at the pilot sites. TaBRA has three basic output categories consisting of lockout, MPS, and other solutions. The use of the monitored power

systems [is] integrated into the existing hazardous energy control procedures and a validation process is in place to verify that the key safety requirements in the TaBRA are met. It is understood that lockout must still be performed whenever the exposure cannot be controlled or eliminated as determined by the risk assessment process. (OSHA, 1999)

Mike Douglas, GM's manager of engineering for safety, put the concept of TaBRA into action working with the UAW and brought that knowledge to the ANSI B11 standards development committee. Those efforts led to development of an important ANSI technical report, ANSI B11.TR3, Risk Assessment and Risk Reduction—A Guide to Estimate, Evaluate and Reduce Risks Associated With Machine Tools, the seminal work for what came to be known as TaBRA.

B11.TR3 adopted the TaBRA methodology recognized by OSHA and started on the path of defining "tolerable risk," a term that would later be changed to "acceptable risk." The technical report enabled a TaBRA for addressing hazards with knowledge of employee tasks and task requirements. It became a foundation in both ANSI/PMMI B155.1 and ANSI B11.0.

Parallel to the GM/UAW and ANSI B11 efforts, Manuele (2000) wrote about the necessity to understand not only hazards, but also the tasks performed by workers, a relatively new concept to general industry safety. His article reached a far wider audience and stressed the importance of tasks and task analysis in the broader forum of safety professionals.

The seeds of new thinking were being planted in many forums. Task-based analysis was new and would become an important part of the overall PTD efforts that were still years away when NIOSH instituted its PTD program. TaBRA was and is well-suited to analyzing exposures that could lead to a serious or fatal injury. The safety profession has recognized for some time that our progress in reducing recordable and less severe injuries has been admirable, but not so with more serious cases. Data from the U.S. Bureau of Labor Statistics (BLS) show that we have realized a significant reduction in recordable cases in the past 20 years, but with much less reduction in more severe cases.

From the authors' perspective, a contributing factor to this issue could be that common safety methods and tools for injury reduction (e.g., job safety analyses, behavior-based safety observations, standard operating procedures) focus on routine exposures to hazards identified in routine tasks. These methods do not predict exposures and hazards that can lead to SIFs because the potential highest risk of an SIF could be from exposures realized during an unidentified, unplanned maintenance task.

The large number of tasks handled by maintenance personnel would make analysis of each task impossible. Think of an entire manufacturing facility broken into 2- to 3-sq-ft cubes, which can be used to describe the working space of a maintenance worker performing a specific task. Every task on every machine and maintenance of the facility, conveyors and so forth could be a different exposure. What might be considered low risk in one spot could be high risk in another.

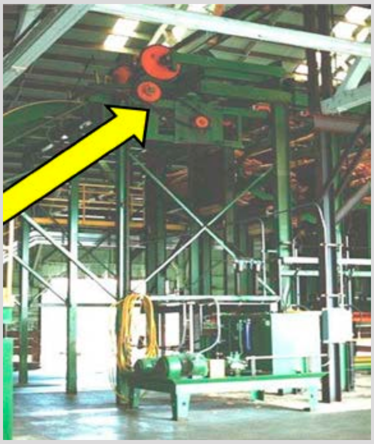
TaBRA was designed to capture the knowledge of an experienced worker on a given task. The authors have found that the first step in addressing unknown potential high-risk exposures is to ask, "Which task would give you the most concern if your child or family friend came to work here?" The input sometimes raises issues unknown to management. Employee involvement in an atmosphere of trust and candor is necessary to proactively identify task variables that could result in SIF exposure.

Understanding the task is important for OSHA compliance. This understanding is necessary to delineate when safeguarding is required to prevent inadvertent exposure to a hazard during normal production versus tasks where intentional access is needed to perform service and maintenance work. Intentional access requires bypassing safeguarding used during normal production and relying on procedures such as LOTO to provide protection. The move to analyzing tasks helped to align safety analysis with existing OSHA regulations on machine guarding (29 CFR 1910.212) and the control of hazardous energy (29 CFR 1910.147).

In 2007, NIOSH launched its PTD national initiative with a conference involving more than 300 stakeholders from 10 industry sectors, developing a strategic plan to guide work in PTD among interested parties. This effort remains the foundation for current and future efforts. Importantly, PTD now has the foundation of a respected government agency collaborating with professional organizations such as NSC and ASSP, and other companies and groups.

FIGURE 1
GUARDED BY LOCATION

Example of no exposure to a hazard during normal production. Pulleys and belts are situated in an overhead location that is not accessible by production workers.



An exchange of evolving best practices between organizations was brought about by Bruce Main, who was an avid participant in the 1995 NSC initiative for the Institute for Safety Through Design. Main later published several articles, was an active member of the PMMI B155.1 effort and took that thinking over to the ANSI B11 general industry machine safety standards as chair of ANSI B11.0-2010. The methods and tools within each of these standards enabled the use of TaBRA and led to the feasible application of the hazard control hierarchy. Without these practical tools, PTD would have remained an excellent concept that is difficult to put into practice.

As this evolution took place, lengthy debates occurred in many areas about risk. Was the goal tolerable risk, acceptable risk, or zero risk? Sufficient credible sources quickly discounted zero risk as something that was not attainable. Ultimately, "acceptable risk" became the preferred term, which is synonymous with "tolerable risk."

Risk

Manuele's continued writings helped thrust risk concepts into the everyday world of safety professionals. A 2010 article increased attention on an important issue embodied in ANSI/PMMI B155.1-2006 and ANSI B11.0-2010. Those standards made clear that zero risk did not exist and that acceptable risk applied to a specific task.

Acceptable risk: A risk level achieved after risk-reduction measures have been applied. It is a risk level that is accepted for a given task (hazardous situation) or hazard. For the purpose of this standard, the terms "acceptable risk" and "tolerable risk" are

> considered to be synonymous. (ANSI B11.0-2010)

Piampiano and Rizzo (2012) note an important issue: "With no exposure to the hazard, injury is not possible" (p. 43). Figure 1 (p. 35) shows a good example of no exposure to a hazard during normal production. Pulleys and belts are positioned in an overhead location that is not accessible by production workers. Injury is not possible because there is no exposure from inadvertence. No guarding is required because the hazards of motion are safeguarded by distance and location during normal operation. If maintenance personnel must access the equipment for lubrication or other service work, 29 CFR 1910.147 applies. In this case, both LOTO and proper fall protection, at a minimum, are required to achieve acceptable risk and compliance.

Exposure is a key issue, and whether the exposure is inadvertent or intentional is central to selecting appropriate risk reduction. By OSHA regulation, guarding and safeguarding are predicated on inadvertent exposure to a hazard during normal production. This concept is discussed in various OSHA documents as well as Occupational Safety and Health Review Commission rulings. OSHA's (2007) publication, "Safeguarding Equipment and Protecting Employees From Amputations," is helpful not only to better understand feasibility but to understand that the purpose of machine guarding is to prevent *inadvertent* access to a hazardous machine area. The term "inadvertent" is cited 22 times. For example:

> Safeguarding devices are controls or attachments that, when properly designed, applied and used, usually prevent **inadvertent** [emphasis added] access by employees to hazardous machine areas. (p. 13)

> Guards may include barriers, enclosures, grating, fences, or other obstructions that prevent **inadvertent** [emphasis added] physical contact with operating machine components, such as point of operation areas, belts, gears, sprockets, chains, and other moving parts. (p. 28)

> The following primary safeguards may be used to protect employees from the hazardous portions of the slitter and auxiliary equipment:
>
> •Install a fixed or adjustable point-of-operation guard to prevent **inadvertent** [emphasis added] entry of body parts into a hazardous area of the slitter system. (p. 47)

FIGURE 2

"GRAY AREA" FOR FEASIBLE RISK REDUCTION

If access to a hazard zone or area is intentional, such as for service or maintenance, authorized workers must be protected by a procedure. In this situation, 29 CFR 1910.212, Machine Guarding, no longer applies because 29 CFR 1910.147, The Control of Hazardous Energy, is the correct regulation for these tasks. The authors wish to emphasize the importance of understanding the task and how law and regulation come into play. Figure 2 illustrates the gray area that sometimes creates confusion over the best, most effective risk reduction measure.

Engineers and other practitioners of PTD need an understanding of the task, employee exposure, and tangible risk assessment data (qualitative or quantitative) to design machinery, equipment and processes. Debates regarding zero risk, zero energy, or zero access offer little in the way of addressing the exposures that may be inherent in certain tasks. Without understanding the task and its associated exposures, PTD remains merely a concept. That information is a prerequisite for feasible risk mitigation using the hazard control hierarchy, with risk assessment being the first step of the process.

The authors have encountered various issues that constrain risk assessment and its subsequent steps for PTD including:

•fear of risk assessment

•efforts to make risk assessment more precise by adding numbers and complexity when the process is inherently subjective

•believing risk assessment will lead to more work

Main (2020) describes real-world fears that sometimes constrain PTD and the necessary use of risk assessment as a first step. He concludes:

> Do not let fear dissuade or derail risk assessment efforts. Learn the process and lead it. Do not allow engineers' fear of subjectivity to drive the risk assessment process into gymnastics to try to appear scientific. Risk assessment is subjective. Do the homework and be able to support the decisions. Teamwork and collaboration coupled with input from the factory floor can help to overcome obstacles.

Taubitz and Contos (2023) address other not-well-understood issues within general industry that are crucial to developing proper procedures for service and maintenance tasks that may involve potential high-risk exposures. That article made full use of the PTD tools and methodologies available in ANSI Z244.1-2016(R2020), The Control of Hazardous Energy, Lockout/Tagout, and Alternative Methods, and the previously referenced ANSI B11.0-2020. The article embraced:

•TaBRA

•documented infeasibility of LOTO

•using a combination of controls from the hazard control hierarchy to achieve acceptable risk for an alternative method to LOTO

•the literal language of 29 CFR 1910.147 and relevant rulings from the Occupational Safety and Health Review Commission

The combination of OSHA and ANSI standards makes possible the development of safe alternative methods to isolating and locking the primary energy source when power is needed for a service or maintenance task.

Industry Progress on PTD

Progress has been steady within ANSI standards, with other national initiatives and books providing tactical and technical means and methods to implement an overall risk management structure. This chronological summary is a quick reference of credible sources for use by PTD practitioners to proactively address potential SIF exposures using PTD concepts.

•NSC's Institute for Safety Through Design from the mid-1990s to its intended sunset of 2005 and the resulting book, *Safety Through Design*, laid a foundation for the subsequent NIOSH initiative of PTD (Christensen & Manuele, 1999).

•ANSI B11.0-2010, Safety of Machinery, built upon the content of both B11.TR3 and ANSI/PMMI B155.1. The original version of B11.0 referenced PTD in its foreword:

> Prevention through design or PTD is a recent term in the industry; the objectives of risk assessment, risk reduction and elimination of hazards as early as possible are integral and not new to this standard.

•ANSI/PMMI B155.1-2006 and ANSI B11.0-2010 addressed a global issue of particular importance to multinational companies that have responsibilities beyond the U.S. and OSHA compliance. These two voluntary standards demonstrated that risk assessment (ISO 14121) and risk reduction (ISO 12100-2) could be integrated into a single standard.

International Organization for Standardization (ISO) efforts quickly followed, resulting in an integrated ISO 12100 in 2010. This was an important alignment of U.S. and ISO efforts to reduce risk globally.

•ANSI/ASSP Z590.3, Prevention Through Design Guidelines, was published in 2011, reaffirmed in 2016 and updated in 2021. The document's scope states:

> This standard provides guidance on including prevention through design concepts within an occupational safety and health management system. Through the application of these concepts, decisions pertaining to occupational hazards and risks can be incorporated into the process of design and redesign of work premises, tools, equipment, machinery, substances, and work processes including their construction, manufacture, use, maintenance, and ultimate disposal or reuse. (ANSI/ASSP, 2021)

The 2012 book *Risk Assessment: Challenges and Opportunities* discusses the root causes of common problems in deploying the risk assessment process and provides practical guidance on solutions to those challenges. In a review of the book, Manuele (n.d.) notes:

> Real-world examples illustrate the methods and results, or lack thereof when the process has not been followed. The challenges of the risk assessment process are many and complex, yet at the same time, the challenges make risk assessment quite interesting and current.

Echoing this observation, the authors wish to reinforce the concept that PTD is not an arcane, abstract idea but rather a concept that is built around risk assessment, feasibility analysis and selection of proper risk-reduction measures using the hazard control hierarchy. These tools are practical guidance for solving today's problems.

•ANSI/ASSP Z244.1-2016 (R 2020), The Control of Hazardous Energy, Lockout, Tagout and Alternative Methods, is important to those seeking feasible alternative methods to traditional lockout when a service or maintenance task requires power. When the task is service or maintenance but LOTO is not feasible because power is needed, a proper alternative method is required to reduce risk. The foreword to the standard states:

> Advanced control systems provide new opportunities for addressing energy control where conventional lockout is not feasible, where energy is required to perform a task, where repetitive cycling of an energy-isolating device increases risk, and where energy is required to maintain equipment in a safe state.

•The 2017 book *The Battle for the Control of Hazardous Energy* was written to assist employers and engineers in designing workplaces, equipment and procedures such that employees are protected from the unexpected release of hazardous energy, and to achieve a workplace where risks were reduced to an acceptable level.

•After their original publications, updates of ANSI/PMMI B155.1, ANSI B11.0, ANSI/ASSP Z590.3 and ANSI/ASSP Z244.1 remained well aligned and continued to advance the foundations of risk assessment and principles of PTD. ANSI B11 remains uniquely important because of OSHA's and industry's historical reliance upon and reference to ANSI B11.19, an influential safeguarding and risk reduction standard for many decades (OSHA, n.d.a). Significant improvements, restructuring and additional content were made to the 2019 revision of ANSI B11.19, Performance Requirements for Risk Reduction Measures: Safeguarding and Other Means of Reducing Risk. The changes were, in part, to better align with ANSI B11.0 and make better use of the hazard control hierarchy.

The authors, both long-time members of the B11 standards, urge readers to note an important point that can pose a problem for feasible risk reduction. Perhaps because of the decades of reference by OSHA, some PTD practitioners go to B11.19 without first performing a risk assessment. As the foreword to B11.19 clearly states, "Throughout its history, ANSI B11.19 has not provided the requirements for the selection of the risk-reduction measures, but only the implementation of the risk reduction measure once chosen."

ANSI B11.0-2023

Today's practitioners can turn to the recently published ANSI B11.0-2023, Safety of Machinery. For those concerned with EU regulations and ISO standards, note the following excerpt from the foreword:

> ANSI B11.0 differs from ISO 12100 in that it specifically includes requirements for **both** suppliers and end users of machinery. It also includes numerous requirements and informative guidance and other information related to the safety of machinery which goes beyond that which is contained in ISO 12100. As a result, conforming with the requirements of ISO 12100 will not assure conformance to the requirements of ANSI B11.0. Conversely, conforming with the requirements of ANSI B11.0 **will** automatically result in conformance to the requirements of ISO 12100. (p. 10)

ANSI B11.0 is considered the seminal, compressive and current machinery safety standard for the U.S. Key changes include:

•reorganization of Clauses 4 (responsibilities) and 5 (life-cycle requirements)

•additional and updated definitions

•expanded information on the feasibility of risk-reduction methods, which is crucial for OSHA compliance

•updated and improved annexes

•clarified text related to responsibilities of machinery suppliers, users, modifiers, purchasers of used machinery and other entities

•introduction of concepts of comanufacturer and associated responsibilities

•updated and clarified responsibilities for existing (legacy) machinery

•inclusion of requirements for when whole-body access applies

•improved information about validation

•improved information related to remote or tele-operation of machinery

•expanded requirements for radiation hazards and associated risk-reduction measures

•updated requirements for information for use and manuals

•clarified content of the standard's Table D1 on estimating severity of harm

•new annexes to assist the reader in applying the content of the standard

When desiring to expand the use of B11.0 beyond its general industry scope, PTD practitioners need a basic understanding of the OSHA General Duty Clause that governs the roles and responsibilities of employers and employees in the U.S. as stated in Section 5 of the OSH Act:

> (a) Each employer
> (1) shall furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees;
> (2) shall comply with occupational safety and health standards promulgated under this Act.
> (b) Each employee shall comply with occupational safety and health standards and all rules, regulations, and orders issued pursuant to this Act which are applicable to his own actions and conduct. (OSHA, n.d.b)

Compliance with law and regulation is necessary, but using ANSI standards is voluntary. ANSI standards are not only helpful but often necessary for an employer to come into compliance, especially for complex issues such as designing control reliable safety systems. Yet, the law does not demand that voluntary standards be used. An employer can choose to conform to voluntary standards on the path to compliance. Hence, ANSI B11.0 can be (and often is) used in applications outside of general industry. It is the employer's decision.

Conclusion

The legitimate technical issues that constrained PTD in the 1990s have mostly been addressed. Risk assessments in the early stages of concept and design are both proven and practical for PTD practitioners. It is hoped that safety professionals will avail themselves of tools and methodologies found in existing ANSI standards to help move the profession forward as envisioned by Manuele several decades ago. The time for PTD is now. **PSJ**

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