PREVENTION THROUGH DESIGN
2021 & Beyond

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SIGNIFICANT ADVANCES IN PREVENTION THROUGH DESIGN (PTD) have been made in recent years. ANSI B11.0-2010 introduced a model for life cycle risk assessment in general industry machinery and equipment. That voluntary standard has continued to build on the concepts of PTD with its updates in 2015 and 2020. Other ANSI standards and articles continue to keep opportunities and challenges at the forefront in the global community of safety professionals.

This article addresses the narrow slice of PTD for machine guarding and control of hazardous energy to explore several issues: 1. how we got to today's current state; 2. how beliefs of safety professionals and engineers sometimes conflict with the strict language of OSHA; and 3. how voluntary ANSI standards can guide us in pursuits of PTD. With that understanding, this article builds on the work of Main (2020) in "New Opportunities in Safety: Lessons From a Risk Assessment Journey." It also shows how ANSI B11.0 can be used to comply with OSHA's General Duty Clause and assist in compliance with the complexities of process safety management.

KEY TAKEAWAYS
- **Beliefs in the myths of zero energy and zero risk coupled with myths of guarding constrain efforts for prevention through design (PTD).**
- **Understanding the history of OSHA and the agency's encouragement of the use of voluntary standards allows safety professionals to have a realistic assessment of the current state.**
- **With safety professionals leading the way for risk assessment and feasible risk reduction based on the hazard control hierarchy, PTD can move forward with potential significant strides in the decade of the 2020s.**

Current State Assessment

The first step in improvement planning for anything is to take a realistic look at the current state. The authors have found that using a whiteboard and asking workers and management about their current beliefs and practices regarding common issues such as guarding and lockout/tagout is often a good way to understand the client's current state beliefs. To begin, it is often best to challenge current state myths. Unless myths are addressed, real improvement based on the combination of OSHA regulation and voluntary ANSI standards is constrained. Table 1 identifies some myths and comments to seed reader thinking for issues addressed in this article.

Beliefs drive actions, and this introduction is intended to have readers reflect on the current state of their personal beliefs and those in their organizations. This article focuses on a narrow slice of PTD opportunities, specifically designing for better safeguarding and control of hazardous energy, concurrent with facilitating better understanding of supplier and user responsibilities related to PTD. In all scenarios, the authors rely on the strict language of OSHA and applicable voluntary ANSI standards, not their own beliefs. With that understanding, the thinking is expanded to process safety and other industries where questions exist on the appropriate level of safeguarding.

Continuing to expand on some of the myths and comments in Table 1, consider the following: Do you perform a risk assessment before using the hazard control hierarchy? If so, one of the first steps requires defining both the task and the hazard (ANSI B11.0-2020). In this step, it is critical to fully understand the task. If the task requires that an authorized worker access a hazard zone to perform service or maintenance, the worker will necessarily be safeguarded by a procedure such as lockout/tagout. Because of OSHA regulation, one knows immediately that the worker may necessarily remove physical guards or disable or bypass other engineered controls and safeguarding devices. That is both legal and safe if the hazardous energy is controlled before performing the task.

Let's now challenge another common myth. Do you believe, as do many safety professionals and engineers, that a guard should *prevent access* to a hazard in all situations? If so, you are hanging on to a misguided belief that preceded OSHA and carries on to this day. In the limited situations where workers manually load a mechanical power press, OSHA and good safety practice require guarding "that prevents entry of the operator's hands or fingers into the point of operation." If you do not distinguish this narrow requirement from the much broader tasks in today's world of automation, you will fail to distinguish the appropriate safeguard for a given task. Without clarification from safety professionals that not all guards/safeguards must prevent access, engineers will typically confuse design intent of guarding and try to prevent access with all physical guarding.

More myths constrain the control of hazardous energy. When an authorized worker must necessarily bypass guarding, the worker is now protected by a procedure such as lockout/tagout. Once it is determined that lockout/tagout is the proper safeguard, still more design challenges await. Was the machine designed such that only hazardous energy is controlled? For example, in operations where control circuit energy to the human-machine interface or control panel is shut down when the primary energy is locked out, it is probable that the designers did not recognize the difference in hazardous energy, nonhazardous energy and beneficial energy. They might have a misguided belief in zero energy and failed to design for a trickle charge to keep the software or battery backup energized for easy restart when service and maintenance are done.

Another issue to consider in the design phase is the span of control for 480-V disconnects as well as determining the span

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of control for control circuits (e.g., emergency stops, interlocks). With today's increasingly complex automation, it is prudent and often necessary to shut down only a portion of the operation for service or maintenance while safely keeping another part of the manufacturing system in operation.

Now a major issue for safety professionals: Where necessary, do you know how to use risk assessment and feasible application of the hazard control hierarchy to develop effective alternative methods to full lockout/tagout? If not, read on.

Lesson: Opportunities for improved PTD will only be realized by a thorough understanding of OSHA regulations, definitions and fundamental issues such that risk assessment begins in the concept phase of new machines and equipment.

Before discussing opportunities, it is important to understand how beliefs originated and impact the current state of thinking.

Brief History of Guarding

The belief in preventing access to a hazard began in the early days of manufacturing when amputations occurred with far too much frequency while workers were loading a mechanical power press. In the 1940s, 50s and 60s, industry focused primarily on protecting employees manually loading points of operation on presses and other types of manufacturing machines. Many injuries occurred because employees disabled the two-hand controls, barrier guards and pullbacks. Hence, guarding for the task of manually loading a mechanical power press became a concept of preventing access to the hazard.

As technology advanced, manufacturing used increasingly more automated equipment where there was no exposure from manually loading a point of operation. Certainly, exposure to other hazards existed that required guarding such as power transmission apparatus and moving parts. Access to these hazards was typically gained by skilled trades and maintenance workers who were authorized to lockout equipment when performing their work. (It would be years before the common industry term of "lockout/tagout" was more properly defined by OSHA in 1990 with the promulgation of 29 CFR 1910.147, Control of Hazardous Energy.) Lockout/tagout was how; the control of hazardous energy was why. In these service or maintenance tasks, workers often had to bypass guards to perform their work.

An admonition from a toolmaker, shared by Taubitz (2018), is relevant for this discussion.

> When I was promoted . . . to safety supervisor, I sought advice from my older brother, an experienced and respected toolmaker. . . . My brother 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. (p. 28)

A question the authors pose to clients is, "If there is no point-of-operation hazard, why would you make it so difficult

TABLE 1
CURRENT STATE MYTHS

Myth	Comment
Zero injury goals equate to zero risk.	Risk only occurs when employees are exposed to hazards.
Compliance and safety are the same thing.	Compliance is not only nebulous but ignores exposures that can lead to serious injuries and fatalities.
Only higher order controls should be used for high-risk tasks.	What if elimination, substitution or guarding/safeguarding are not feasible?
It is not necessary to perform a risk assessment before determining risk reduction.	Unless you are doing full lockout/tagout, this is incorrect (see ANSI B11.0-2020).
It is OK to focus on hazards without regard to the nature of assigned tasks.	Understanding the nature of a task is critical for both compliance and risk reduction.
All machine hazards require guarding.	It depends on exposure and risk.
All guards should prevent access.	Incorrect. It depends on the exposure and risk.
The best way to lock out a machine is to have zero energy.	"Zero energy" is a well-intended but misguided term used in industry. The legal and technical issue is control of hazardous energy.
The minor servicing exemption to 29 CFR 1910.147, Control of Hazardous Energy, can be used for performing machine setup without lockout/tagout.	False. The OSHRC has ruled that setup is not part of normal production and lockout/tagout is required (tip: there is a compliance answer).
Under the OSH Act, suppliers of machinery are responsible for the safety of an employer's workers.	Incorrect. Only employers and employees have safety responsibilities for compliance under the OSH Act.
Suppliers of machinery and users (employers) are responsible for feasible risk reduction.	ANSI standards help suppliers design machines that will facilitate employers complying with OSHA requirements when a machine is in use or being maintained.
Feasibility is not an issue for safety professionals.	Feasibility is a key issue for safety professionals as well as engineers.

to remove a guard when an authorized worker is required to access a machine under lockout/tagout?" Invariably, the answer is some version of "The guard has to prevent access."

Before OSHA and the proliferation of ANSI standards, beliefs and concepts were often handed down by older staff and suppliers. The concept of preventing access was widespread and continues today. Next, let's explore the strict language of regulation and standards.

OSHA & the Literal Language of Regulation

When the OSH Act came into existence in 1970, it became the law governing employers and employees alike (OSH Act section 5, commonly referred to as the General Duty Clause). It is the standard of care for U.S. employers.

OSHA does not, nor has it ever, required that a guard *prevent access*. However, it does state:

> One or more methods of machine *guarding* [emphasis added] shall be provided to protect the operator and other employees. [1910.212(a)(1)]

> "Guard" means a barrier that prevents entry of the operator's hands or fingers into the point of operation. [1910.211(d)(32)]

> "Fixed barrier guard" means a die space barrier attached to the press frame. [1910.211(d)(34)]

Preventing "entry of an operator's hands and fingers into the point of operation" made sense in 1970, just as it does today. However, the regulation ignores that the world of manufacturing has changed dramatically, and few of today's production operations have workers manually loading a point of operation.

It is evident from a cursory review of OSHA requirements and definitions that the world of regulation was dominated by the focus on mechanical power presses and operator hazards. The world of manufacturing today is not a mechanical power press. With the exception of manually loading the point of operation on a press, OSHA did not address the intent of a guard, only what it was.

Section 1910.212 governs general machine guarding. Section 1910.212(a)(1) provides a performance as opposed to a specification requirement.

> Types of guarding. One or more methods of machine guarding shall be provided to protect the operator and other employees in the machine area from hazards such as those created by point of operation, ingoing nip points, rotating parts, flying chips and sparks.

General machine guarding requirements do not require that guards prevent access, only that they "protect the operator and other employees . . . from hazards."

More recent publications provide clarification with the more modern concept of safeguarding. OSHA (2007) makes clear that the purpose of machine safeguarding and guarding is to prevent *inadvertent* access to hazards. 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)

OSHA properly addresses the concept of inadvertence. When a worker *intentionally* enters into a hazard area, the individual must be protected by a procedure to control hazardous energy. That procedure may be full isolation and lockout of the primary energy source or a defined alternative method for lockout/tagout.

In Basics of Machine Safeguarding, OSHA (2020a) notes:

> A good rule to remember is: Any machine part, function or process which may cause injury must be safeguarded. When the operation of a machine or accidental contact with it can injure the operator or others in the vicinity, the hazards must be either controlled or eliminated.

Lesson: It is clear that, for general industry machines, OSHA does not require guards that prevent access.

Before exploring the language of relevant ANSI standards on this topic, let's review the historic relationship between OSHA and ANSI, more specifically, ANSI B11, the family of general industry machine safety standards.

29 CFR 1910.212 & ANSI B11

Because it is not feasible for OSHA standards to address the vast number of machines and equipment, the agency has a long-established practice of relying on voluntary standards to provide specific guidance for safeguarding general industry and other types of machines.

Consider the following excerpt from The Utilization of Industry Consensus Standards (OSHA, 2020b), taking special note of the last paragraph.

> OSHA uses industry consensus standards related to the safe operation of equipment as guidance of the industry accepted practice for safe operations. . . . OSHA may determine that the safety/health practices described by that industry consensus standard are deficient when related to the requirement(s) set forth by the pertinent OSHA regulation(s). However, many of the various ANSI safety standards devoted to the safe use of equipment and machines are pertinent and provide valuable guidance as they relate to the multitude of safe operating procedures. . . .
>
> The proper application of devices [is] not described [in 29 CFR 1910.212]; therefore, other similar OSHA or pertinent industry standards must be referred to for guidance. . . .
>
> Employers [that] comply with the requirements of an industry consensus standard rather than a specific OSHA standard, where such compliance deviates from the OSHA requirements but provides for a more conservative safeguarding concept, are categorized as having created a de minimis violation of the specific OSHA standard. . . .
>
> OSHA encourages employers to abide by the more current industry consensus standards since those standards are more likely to be abreast of the state of the art than an applicable OSHA standard may be. Furthermore, the industry consensus standards will usually discuss a variety of techniques for averting exposure to the identified hazards of the machine or process.

Another reference that shows the linkage between 29 CFR 1910.212 and ANSI B11 comes from OSHA's (n.d.-a) Machine Guarding eTool. That source states that OSHA can cite violations by referencing standards such as the ANSI B11 series, followed by a list of B11 standards available at the time (Note: ANSI B11.0, first published in 2010, is not included in the list).

The B11 standards for machine tools were first approved beginning with safety requirements for power presses in 1922. Since that time, safety requirements for various machine tools have been developed and continually updated and revised to become the series of B11 standards and technical reports. These machine-specific standards are known as type-C standards.

ANSI B11.0-2020, Safety of Machinery, is the foundation for all ANSI B11 standards. In 2010, this standard reorganized the B11 family of standards by gathering requirements common to most of the B11 standards into this document while retaining the machine-tool-specific requirements in the machine-specific (type-C) standards.

ANSI B11.0 was developed as a type-A foundation standard for the entire series of B11 standards. Type-C standards take precedence where they apply. B11.0 provides a framework to "fill in blanks" using risk assessment where a type-C standard might not account for a specific task-hazard pair or hazardous situation.

ANSI B11.19, Performance Requirements for Risk Reduction Measures: Safeguarding and Other Means of Reducing Risk, is one example of a type-B standard because it applies to all type-C standards. Once the type of safeguarding is determined (e.g., hard guard, light screen, laser beam) by risk assessment, B11.19 provides the performance criteria necessary to establish acceptable risk. This standard does not determine the risk reduction method. Figure 1 shows a model of the A-B-C organization of the B11 standards.

Lesson: OSHA has long encouraged employers to use ANSI B11 and other voluntary standards to assist in compliance with OSHA regulation. Because ANSI B11.0 is risk based, the authors have found that this standard can be used for equipment outside the scope of ANSI B11.

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Today's safety professionals have many sources of tools and methods for PTD that were not readily available just 20 years ago. U.S. voluntary standards such as ANSI Z244.1, ANSI Z590.3, ANSI Z690.3, the family of ANSI B11 standards and others have steadily advanced in the direction of making PTD a reality.

The most important advancement is in the area of practical risk assessment that leads to feasible risk reduction based on the hazard control hierarchy.

Risk, Hazard Control Hierarchy & Risk Assessment

Before determining a safeguard that is compliant with OSHA standards, readers must understand risk and the application of the hazard control hierarchy for feasible risk reduction.

Both U.S. and international safety standards recognize that zero risk of injury or illness in a workplace does not exist. Risk can be reduced or insured but not eliminated.

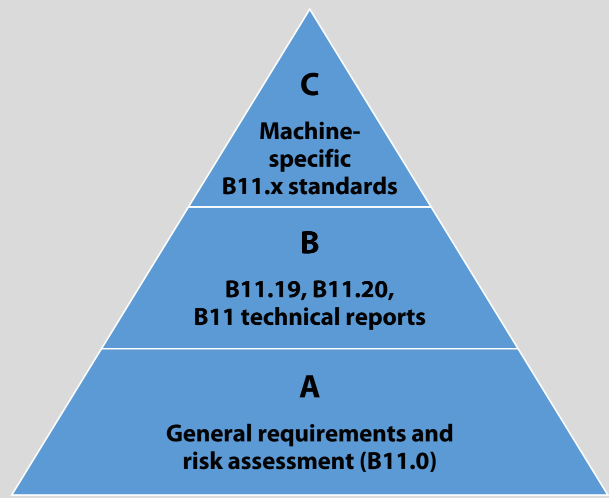
The foreword to ANSI B11.0-2020 provides:

> "Safe" is the state of being protected from recognized hazards that are likely to cause physical harm. There is no such thing as being absolutely safe, that is, a complete absence of risk. In turn, there is no machine that is absolutely safe. All machinery contains hazards, and some level of residual risk. However, the risk associated with those hazards should be reduced to an acceptable level.

FIGURE 1

ORGANIZATION OF THE B11 SERIES OF DOCUMENTS

Type-A standards (basis standards) give basic concepts, principles for design, and general aspects that can be applied to machinery; type-B standards (generic safety standards) deal with one or more safety aspects or one or more types of safeguards that can be used across a wide range of machinery; and type-C standards (machinery safety standards) deal with detailed safety requirements for a particular machine or group of machines.



Note. Adapted from "Safety of Machinery (ANSI B11.0-2020)," by ANSI, 2020.

The feasible application of the hazard control hierarchy is the accepted method of protecting workers from recognized hazards. The hierarchy is endorsed by OSHA, safety professionals, engineers and writers of voluntary safety standards as a best practice for reducing risk. The most preferred method of achieving acceptable risk is eliminating the risk (of a specific hazard). Typically, this can only be done in the concept and design stages of machinery, equipment and processes.

Safeguarding/engineered control is the next preferred step for mitigating risk in the hazard control hierarchy. Properly designed safeguarding should begin during the concept and design phases of PTD. It is critical that safety professionals, engineers and designers of automation have a solid grasp of the design intent of physical guards and safeguards.

Lesson: Where exposure to a hazard is intentional (e.g., an authorized worker removing a guard to remove a major jam) the worker is protected by a procedure, not the guard or safeguarding device.

If a task is routine, repetitive in nature and integral to the operation and qualifies for the minor servicing exemption to 29 CFR 1910.147, a properly designed system not requiring lockout/tagout may be used to safeguard the worker who, again, may intentionally access the zone of danger to remove a minor jam. Understanding design intent is fundamental to having safeguarding systems or methods that are OSHA-compliant and appropriate to the task.

When elimination, substitution and safeguarding are not feasible, a combination of lower-order controls must be used to achieve acceptable risk. For example, we know that an electrician performing diagnostic work on a live 480-V panel cannot be protected by elimination, substitution or engineered controls/safeguards. It is an extremely high-risk task with the possibility of death, but the only feasible means of protection comes from the knowledge and awareness of a skilled authorized worker following arc-flash procedures using proper PPE. No other feasible means exist to do that work.

TABLE 2

HAZARD CONTROL HIERARCHY

Most preferred → Least preferred

Classification	Risk reduction measures	Examples	Influence on risk factors
Inherently safe by design	Design out (elimination or substitution)	• Eliminate pinch points (increase clearance) • Intrinsically safe (energy containment) • Automated material handling (e.g., robots, conveyors) • Redesign the process to eliminate or reduce human interaction • Reduce force or speed through selection of inherently safe components • Substitute less hazardous chemicals	• Impact on overall risk (elimination) by affecting severity and probability of harm • May affect severity of harm, frequency of exposure to the hazard under consideration, or the possibility of avoiding or limiting harm depending on which method of substitution is applied
Engineering controls	Guards, control functions and devices	• Guards • Interlock devices • Presence sensing devices (e.g., light curtains, safety mats, area scanners) • Two-hand control and two-hand trip devices • Alternative methods to lockout to control hazardous energy	• Greatest impact on the probability of harm (occurrence of hazardous events under certain circumstances) • Minimal, if any, impact on severity of harm
Administrative controls	Awareness means	• Lights, beacons and strobes • Computer warnings • Signs and labels • Beepers, horns and sirens	• Potential impact on the probability of harm (avoidance) • No impact on severity of harm
	Information for use (training and procedures)	• Safe work procedures • Training	• Potential impact on the probability of harm (avoidance or exposure) • No impact on severity of harm
	Administrative safeguarding methods	• Safe-holding safeguarding method	• Potential impact on the probability of harm (avoidance or occurrence) • No impact on severity of harm
	Supervision	• Supervisory control of configurable elements	
	Control of hazardous energy	• Lockout/tagout	
	Tools	• Work-holding equipment • Hand tools	• Potential impact on the probability of harm (avoidance or occurrence) • Potential impact on severity of harm
	PPE	• Safety glasses and face shields • Earplugs • Gloves • Protective footwear • Respirators	• Potential impact on the probability of harm (avoidance) • Potential impact on severity of harm

Note. Adapted from "Safety of Machinery (ANSI B11.0-2020)," by ANSI, 2020.

Trying to enforce something more opens the door for the "malicious compliance" concept first espoused by the toolmaker previously noted ("If I follow your rules, I'll shut you down and you will never run again").

In today's world, with proven risk assessment methodologies and the entire tool kit that is commonly called the hazard control hierarchy, safety professionals have all of the tools to address any and all exposures that workers may encounter. Table 2 shows the hazard control hierarchy from ANSI B11.0-2020. This is the foundation for determining appropriate risk reduction measures that form the basis for safeguarding employees. In the ANSI B11.0-2020, the hazard control hierarchy is accompanied by the following note:

> Informative Note 1: Not all potential risk reduction measures are feasible. Many factors determine if the risk reduction measure is feasible. It is necessary to evaluate the application of the risk reduction measure against the following factors:
> •regulatory obligations and introduction of new hazards;
> •effectiveness and machine performance;
> •usability and productivity;

TABLE 3
PRACTICABILITY/FEASIBILITY ANALYSIS

Analysis of practicability/feasibility for hard-to-remove guard where service and maintenance is performed under lockout/tagout.

Element of practicability/feasibility	Comment
Regulatory obligations	Lockout/tagout required; not a guard
Effectiveness	Guard must, of necessity, be bypassed
Usability	Hard-to-remove guard hinders task
Durability and maintainability	Likely that guard will not be properly reinstalled
Ergonomic impact	Often creates ergonomic stressors for the maintenance worker
Cost	No difference in cost to design a proper guard
Introduction of new hazards	Conceivable that the guard may add new risk based on hundreds of task-based risk assessments
Productivity	Extra time and hassle for the worker will negatively impact production
Machine performance	No impact
Technological feasibility	Lockout/tagout can and should be used

•durability, maintainability and ability to clean;
•ergonomic impact;
•economic and technological feasibility. (ANSI B11.0-2020, p. 44)

Lesson: Informative Note 1 is one of the most important issues to consider for PTD. Feasible risk reduction has been a significant consideration of the OSH Review Commission (OSHRC) bearing on its rulings over the decades.

Let's explore this informative note in the context of a worker who is authorized to perform service and maintenance using lockout/tagout on a machine and who is confronted with removing a physical guard designed to *prevent access* through the use of special means of attachment, too many bolts and other means. Table 3 shows an analysis of each element of practicability/feasibility for this scenario.

Lesson: Feasibility is a key assessment for compliance and developing risk reduction methods that provide for the safety of workers.

Control of Hazardous Energy & Alternative Methods

Let's assume that you have now arrived at the conclusion that an alternative method is required to control hazardous energy. Alternative methods are recognized by OSHA, ANSI/ASSP Z244.1 and ANSI B11.0-2020.

ANSI/ASSP Z244.1 defines "alternative method" as "a means of controlling hazardous energy (other than energy isolation) to reduce risk to an acceptable level."

If isolation and locking the primary energy is not feasible, steps for developing an alternative method can be found in both ANSI/ASSP Z244.1 and ANSI B11.0. For sake of simplicity, the following captures the relevant steps found in ANSI B11.0:

•Identify tasks and hazards.
•Perform task-based risk assessment.
•Document infeasibility of lockout/tagout or another safeguard.
•Assess feasible controls from hazard control hierarchy using criteria for feasibility identified in Informative Note 1 to the hazard control hierarchy in ANSI B11.0.
•Develop and validate the control(s).
•Implement feasible control(s).
•Assess final risk level with controls in place to achieve acceptable risk.

This article does not address the myriad similar terms describing "alternative measures" and "alternative protective methods" used in the minor servicing exemption to 29 CFR 1910.147. For PTD concepts, safety professionals should recognize that the OSHRC has ruled that setup and changeover to a new product run is not part of normal production, and lockout/tagout is required.

Lesson: The fact that lockout/tagout is not feasible is a different compliance argument than claiming the minor servicing exemption as too many employers have attempted. Without the proper legal argument, organizations will lose before the OSHRC.

Because so many terms are used to describe alternative methods, it is prudent to understand that use of the term "alternative method" in this article addresses an alternative to full energy isolation. When lockout/tagout is not feasible, infeasibility must be documented and alternative methods developed based on risk assessment and feasible application of the hazard control hierarchy.

Determining whether isolating and locking the primary energy source is feasible is the same analysis process noted for guards and safeguards. However, there is yet another unique challenge for this effort. How does the safety professional, engineer or machine designer know whether the energy is hazardous? If the energy poses no hazard for the task being performed, it does not have to be controlled to protect the authorized worker. Similarly, what if the energy is beneficial?

What is beneficial energy? Hydraulic energy used to keep overhead automation safely in place while workers perform tasks at the factory floor level is, in fact, beneficial energy. Not understanding beneficial energy can lead to the kind of high-risk, high-downtime situation described by Taubitz (2018).

> Hard lessons were also learned when skilled workers pushed back that zero energy would crash overhead robots that were used to weld and assemble vehicles in assembly plant body shops. Energy was needed to hold these robots in the up position. When all energy was shut down, the overhead robots came down and created an unplanned maintenance situation, commonly referred to as "crashing the body shop." Blind insistence on zero energy and not understanding the control of hazardous energy forced skilled workers into what the company's safety professionals termed malicious compliance. Following supervisory instruction resulted in significant downtime and increased hazards to get the plant running again. (p. 29)

Risk Assessment Before Risk Reduction

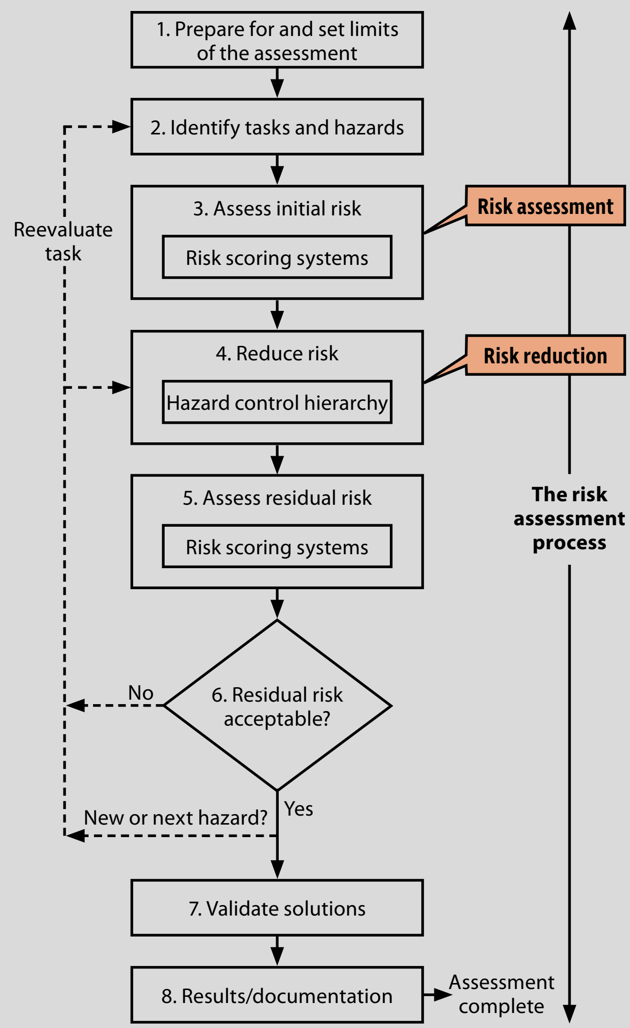
Whether the risk reduction method is guarding, safeguarding or an administrative control such as an alternative method to lockout/tagout, it is first necessary to perform risk assessment.

Figure 2 (p. 28) presents the risk assessment process from ANSI B11.0-2020 to show that feasible risk reduction cannot proceed without a proper risk assessment of the specific task. Before proceeding with risk reduction, risk assessment participants must identify tasks and hazards.

The authors find that the concept of "task" is often not fully understood or is given only cursory consideration. If a task is service and maintenance, the proper safeguarding is to control the hazardous energy. To reiterate for emphasis: When access

FIGURE 2

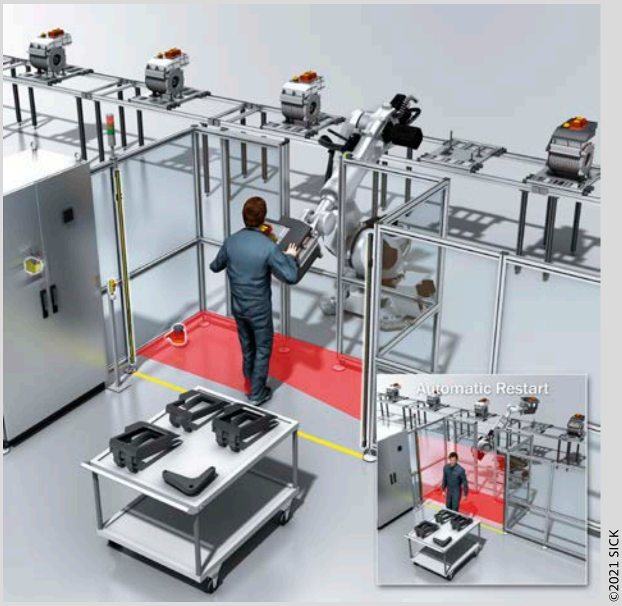
ANSI B11.0 RISK ASSESSMENT



Note. Adapted from "Safety of Machinery (ANSI B11.0-2020)," by ANSI, 2020.

FIGURE 3

CONTROL RELIABLE SENSORS



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or exposure is intentional, an authorized worker is protected by a procedure, not by guards or traditional safeguards.

As long-time practitioners of PTD and users of voluntary standards, the authors remain hopeful that we may yet see the day when OSHA allows the use of properly designed control circuitry that will have passive, control-reliable engineered controls protecting an authorized worker doing predetermined service and maintenance.

In ANSI B11.19-2019, "control reliability" is defined as "the capability of the [machine] control system, the engineering controls—devices, other control components, and related interfacing to achieve a safe state in the event of a failure within the safety-related parts of the control system" (p. 16).

Further guidance is found in ANSI B11.20-2017, Safety Requirements for Integrated Manufacturing Systems, in definition 3.6 "engineering controls: guards or devices and associated safety-related parts of the control system (SRP/CS) used to reduce risk" (p. 5).

The explanatory note to definition 3.6 reads:

> SRP/CS include parts of machinery control systems that provide safety functions which can consist of hardware and software and can either be separate from the machine control or an integral part of it. See also ANSI B11.0, ANSI B11.19 and ANSI B11.26. (p. 5)

Imagine the improvement in safety and productivity when a worker can walk into a machine and the control-reliable sensors and controls put the machine in a safe mode for performing a given task. Such a system, shown in Figure 3, looks simple and is sometimes referred to as "passive safeguarding."

From the perspective of workers and nontechnical personnel, the adjective "passive" seems accurate because a worker can safely enter the safeguarded space, perform a task and exit with automatic restart (see Figure 3 inset). From the perspective of the controls engineer who designed the SRP/CS noted in Figure 3, the system is far from passive. It has many active engineered controls, including a light curtain (which detects access at the yellow line), an area scanner (red sensing field created by the device at far left of access area) and a control-reliable interface in the control cabinet (incorporated into the panel at the left).

This simplistic view of a highly complex safety system should be the goal of safety professionals and OSHA for the future of PTD in real-world applications.

In all situations involving manufacturing operations, designers following ANSI standards should include a task-based risk assessment (TaBRA). It is a methodology recognized by OSHA for assessing hazards and risks to determine effective employee protection. In a Dec. 16, 1999, letter to Thomas Weekley, Assistant Director, UAW General Motors Department, the agency noted:

> However, an MPS [monitored power system, GM's term for control reliable safeguarding], which meets the above referenced ANSI consensus standards on control reliability and control component failure protection [ANSI B11], would provide alternative safeguarding measures, which constitute effective employee protection. Thus, such an MPS may be used to protect employees who are performing minor tool changes and adjustments, and other minor servicing activities, which take place during normal production opera-

tions, provided that each element of the §1910.147(a)(2)(ii) exception is met. In other words, the MPS system may be used in cases in which minor tool changes and adjustments, and other minor servicing activities are performed during normal production operations, **and** are routine, repetitive and integral to the use of the equipment for production. It is important, as you have stated, to apply this safeguarding technique (MPS) through an analysis process (TaBRA) on a case-by-case basis in order to [ensure] that it, in fact, provides effective employee protection. (OSHA, 1999)

Feasibility of Guarding/Safeguarding Summary

For guidance regarding feasibility, we again refer to the ANSI B11 series of general industry machine safety standards. In ANSI B11.0-2020, we find the correlation of acceptable risk and feasible risk reduction, as follows:

> 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.
>
> Informative Note 1: *The expression "acceptable risk" usually, but not always, refers to the level at which further technologically, functionally and financially feasible risk reduction measures or additional expenditure(s) of resources will not result in significant reduction in risk* [emphasis added]. The decision to accept (tolerate) a risk is influenced by many factors including the culture, technological and economic feasibility of installing additional risk reduction measures, the degree of protection achieved through the use of additional risk reduction measures, and the regulatory requirements or best industry practice. (p. 18)

Hence, in the world of general industry machines, technology, functionality and financial issues are all part of feasible risk reduction.

Lesson: TaBRA complements existing job safety analyses and is used when questions arise for a given task.

ANSI B11.0 for Process Safety Management & Other Industries

Main (2020) notes an issue of great importance for all industries and safety professionals:

> The beauty of the risk assessment process for a standard such as ANSI B11.0 is that it applies broadly. Although the hazards and subsequent risk reduction measures vary greatly from one application to another, the overall process of identifying hazards, assessing risks, reducing risks to an acceptable level, documenting the results and following up remain consistent across all applications. . . .
>
> *The author has not encountered a situation in which the risk assessment process cannot be applied* [emphasis added]. (p. 39)

The authors agree, as we have also applied ANSI B11.0 to numerous litigation cases outside the scope of general industry machine safety. In some cases, regulation and voluntary standards did not address the specific issue. ANSI B11.0 uses risk assessment to identify opportunities leading to feasible risk reduction based on the hazard control hierarchy. It is this foundation that allows ANSI B11.0 to fill the gaps and answer questions regarding an employer's duty to meet the test of standard of care.

Importantly, the authors have found ANSI B11.0 to be of value in the area of process safety. OSHA's General Duty Clause, 29 CFR 1910.119, Process Safety Management of Highly Hazardous Chemicals (PSM), and a host of voluntary standards come into play for compliance purposes. Yet, PSM's complexities sometimes leave questions for employers and engineers. One such area is recognized and generally accepted good engineering practices (RAGAGEP).

Blair (2007) notes:

> Recognized and generally accepted good engineering practices are analogous to the legal term "standard of care." . . . There is no established or official list of what constitutes a RAGAGEP. RAGAGEPs encompass the whole body of guidelines, standards, generally accepted principles (both taught in school and learned from others) that establish the ways in which responsible engineers accomplish their tasks.

The authors agree; RAGAGEP is so broad and nebulous that it provides little in the way of specific guidance for engineers and designers. The authors also concur that RAGAGEP is linked directly to the standard of care for process safety and believe that reliance on the OSHA General Duty Clause provides better guidance for meeting that standard of care.

Under the General Duty Clause, employers are required to provide employees a place of employment that is "free from recognized hazards that are causing or are likely to cause death or serious physical harm." OSHA interprets the General Duty Clause to mean that an employer has a legal obligation to provide a workplace free of conditions or activities that either the employer or industry recognizes as hazardous and that cause, or are likely to cause, death or serious physical harm to employees when there is a feasible method to abate the hazard.

To issue a General Duty Clause violation, OSHA must first establish that a hazard is recognized. Recognition of a hazard can be established in one of three ways:

1. OSHA can establish industry recognition if the hazard is recognized in the employer's industry. Recognition by an industry other than the industry to which the employer belongs is generally insufficient to prove a Section 5(a)(1) violation.
2. A recognized hazard can be established by evidence of actual employer knowledge.
3. If industry or employer recognition of the hazard cannot be established, recognition can still be established if OSHA concludes that any reasonable person would have recognized the hazard.

Next, OSHA must confirm that it is a hazard likely to cause serious physical harm or death if not addressed. Finally, to establish a General Duty Clause violation, OSHA must show that a feasible, available way to correct the hazard exists.

Once those elements are present, an employer must use good engineering practices to identify and implement the most effective means of remediating it, otherwise the employer violates the OSHA General Duty Clause. Following is an excerpt from the OSHA (2016) publication, "Recommended Practices for Safety and Health Programs":

> Employers should select the controls that are the most feasible, effective and permanent.
>
> • Eliminate or control all serious hazards (hazards that are causing or are likely to cause death or serious physical harm) immediately.

•Use interim controls while you develop and implement longer-term solutions.

•Select controls according to a hierarchy that emphasizes engineering solutions (including elimination or substitution) first, followed by safe work practices, administrative controls and finally PPE.

•Avoid selecting controls that may directly or indirectly introduce new hazards. Examples include exhausting contaminated air into occupied workspaces or using hearing protection that makes it difficult to hear backup alarms.

•Review and discuss control options with workers to ensure that controls are feasible and effective.

•Use a combination of control options when no single method fully protects workers.

Note: *Whenever possible, select equipment, machinery and materials that are inherently safer based on the application of [PTD] principles* [emphasis added]. Apply PTD when making your own facility, equipment or product design decisions. (p. 21)

Risk assessment with corresponding feasible risk mitigation is fundamental to demonstrating due diligence for meeting the standard of care as defined by OSHA. As noted, the objective of a feasibility assessment is to select the highest level of risk reduction measure(s) from the hazard control hierarchy. In many cases, application of any single control methodology may not be adequate to provide an effective level of protection for personnel. It may be necessary to use a combination of methodologies and risk reduction measures to achieve acceptable risk.

Lesson: The elements of feasibility are more easily understood than the somewhat nebulous concepts of RAGAGEP. Documenting feasible risk reduction based on the hazard control hierarchy is necessary to show compliance with OSHA and the employer's due diligence for meeting the standard of care in the U.S.

Conclusion

A host of existing U.S. national standards provide relevant information for safety professionals and engineers to "push" risk reduction efforts into the concept and design phases of machines, equipment and processes. The authors offer the following points as foundations for PTD efforts in 2021 and beyond.

1. Employers and employees are legally responsible for compliance to OSHA regulation; standards help both machine suppliers and users ensure that new and modified equipment allow the user (employer) to comply with OSHA.
2. OSHA is the standard of care for employers as defined by the OSH Act.
3. Safety professionals should lead the way in helping suppliers and users understand feasibility (practicability) of risk reduction measures. Feasible risk mitigation is necessary to demonstrate due diligence in complying with the OSH Act.
4. Risk assessment and compliance assessment are predecessors to risk mitigation.
5. OSHA and industry have long accepted the use of the hazard control hierarchy as the most appropriate means to control or mitigate risk. Feasible application of the hazard control hierarchy allows employers to achieve acceptable risk using means and methods that are practicable in the real world.
6. Risk assessment with corresponding feasible risk mitigation is fundamental to demonstrating due diligence and standard of care when assessing a General Duty Clause issue. This also applies to RAGAGEP and PSM. PSJ

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