Risk assessment is not a new term—but it took impetus from Europe to bring it more fully into the domestic machine lexicon. This article explores how several groups, each with their own insight, came together to not only incorporate the best of what Europe had to offer, but improve on it. Over the past four years, a new document—ANSI B11.TR3—has been conceived and brought to life through the efforts of more than 70 ANSI subcommittee members and observers. It is bringing about a paradigm shift in the way tasks and hazards, risk assessment, and the incremental and cumulative effects of risk reduction are assessed, leading toward innovation and away from the “cookie-cutter” approach to machine safeguarding that often ignores the realities of the workplace.

Here’s what’s been said about this document:

“The greatest stride forward in the field of safety in the past 25 years.”
—Fred Manuele, P.E., CSP, author and ASSE Fellow

“. . . fills the gap where no consensus standard exists. We know how important this document will be in promoting safety in the workplace.”
—Richard Sauer, OSHA Standards Development Group

“. . . a document that is of great importance in the U.S.”
—Jim Howe, assistant safety director, UAW

“Risk assessment has gone from a novel, untested concept to a practical method to improve safety through design. This is a great improvement over EN1050.”
—Bruce Main, P.E., CSP, Design Safety Engineering

“. . . critical in promoting safety-through-design.”
—Wayne Christensen, director, NSC Safety-Through-Design Program

“. . . With the release of the document, a paradigm shift toward more cooperative efforts between the suppliers and users . . . and toward documenting risk assessments . . . is taking place.”
—Steve Dukich, product manager, Rockwell Automation

“. . . a great tool, since ‘prescriptive safeguarding’ often fails to recognize workplace realities.”
—Mike Taubitz, global safety liaison, General Motors Corp.

ANSI B11.TR3, “Risk Assessment and Risk Reduction: A Guide to Estimate, Evaluate and Reduce Risks Associated with Machine Tools” is a “technical reference,” not a standard. After four years of work by a diverse cadre of more than 70 committee members and observers, it was released in November 2000. Ostensibly written to serve only as a guide for the writers of B11 (Machine Tool) standards, it is already having great influence throughout the world.

Although described as a paradigm shift in safety, what is occuring in TR3 is not revolutionary, as its findings, concepts and methodology are really quite simple:

1) Zero risk simply does not exist. No matter what protective measures are taken for a given machine, system or process, some degree of “residual risk” will always exist.

2) Risk assessment is best accomplished with input from many disciplines.

3) Suppliers, users and modifiers of machines and processes all share responsibility for proper risk assessment and communication of residual risk.

4) Hazard identification is a key element in risk assessment, but many hazards can be overlooked in conventional hazard analysis. Identification and analysis of tasks is essential in ensuring that all relevant hazards and potentially hazardous situations are addressed.

5) The safety hierarchy provides the basis for application of protective measures to reduce risk.

6) Selected “safeguards” and other protective measures should be appropriate to the desired degree of risk reduction.
WHAT IS “TASK-BASED” HAZARD IDENTIFICATION?

Mike Taubitz, global safety liaison for General Motors (GM), provides some history: “In 1986, the United Auto Workers and GM hosted a joint annual conference, the theme of which was ‘Design-In Safety.’ It was the cornerstone for future efforts.

“Ultimately, it came to be recognized that many maintenance tasks could not be performed according to stated policy due to machine and safeguarding design. Only by changing machine design and safeguarding could we allow risk to be reduced and concurrently improve production. The question was how.”

Taubitz adds, “In 1994, GM established a new Engineering for Health and Safety function. The new group was soon charged with developing a robotics specification that would provide common safeguarding for automated body shops in assembly plants. A cross-functional team of engineers, management and union safety professionals began work and embraced a couple of important issues that would guide future accomplishments.

“First, every issue was to be dealt with openly and second, the realities of the workplace would not be ignored. In other words, the group would deal affirmative-ly with situations where power had to be on and the employee could have exposure to a hazardous condition. Without a defined methodology, the team undertook the first steps to perform a task-based risk assessment for a major project inside the company. It proved to be an important cornerstone for future developments.

“The importance of the ‘task-based’ approach proved itself in early 1996, when a dispute over robot logic occurred with the controls engineering group. GM, as with most of industry, employed the use of servomotor disconnects which allowed power to remain on the program-mable logic controllers while isolating the potentially hazardous energy of motion. However, pulling and locking the servo disconnect also eliminated input-output power on the end effector.

“Union representatives familiar with downtime and maintenance issues pointed out that tasks like diagnostics and intentionally cycling the gripper in manual mode could not be accomplished without ‘I-O’ power. Controls engineers were concerned that an employee could receive a pinching injury from the gripper and were unwilling to change the design specification. The joint team felt strongly that the risk of such a minor injury was low and that far-more-serious injury could result if employees attempted to bypass safeguards.

“While the debate [continued], a very serious near-hit occurred in an assembly plant when a skilled trades employee jumped over a safety mat without pulling the servo disconnect. While he was in the cell, the robot arm moved suddenly, and he narrowly escaped serious injury. The debate was over and a major principle was established: Employee tasks and task requirements must be considered before prescribing safeguards!”

THE IMPORTANCE OF SAFETY IN THE DESIGN STAGE

For decades, safety professionals have advocated that good safety practice in the design and use of machines or processes is based on the application of the hierarchy of controls, commonly called the “safety hierarchy”:

- Eliminate the hazard.
- Provide engineering controls.
- Warn.
- Train.
- Provide and use personal protective equipment (PPE).

The higher-order controls—elimination and engineering—are preferred, but to be most cost-effective, such controls must be implemented during concept and design stages. Thus, engineers must be fully competent to perform necessary analysis and design. Unfortunately, engineers typically receive little or no safety-related training; they have few engineering “tools” to assist them; and simple methods to assess risk in general industry have not existed.

The confusion regarding roles and responsibilities of engineering and safety personnel also contributes to subsequent deficiencies. Engineers without a background in safety design usually leave safeguarding issues to safety professionals, who often become involved late in the process—when they can only decry what has and has not been done.

THE RISK ASSESSMENT PROCESS

The challenge of developing a risk assessment protocol was no easy task. Bruce Main, president of Design Safety Engineering, says something was needed that “more appropriately reflected the product liability circumstances of the U.S. than the ‘manufacturer is responsible for everything’ approach of EN1050” and other European standards. In Europe,
For decades, safety professionals have advocated that good safety practice in the design and use of machines or processes is based on the application of the hierarchy of controls, commonly called the “safety hierarchy.”

As an example, use of two-hand controls and guards when performing maintenance are typical safeguarding solutions. These professionals believe that management, for inclusion into TR3, is more important than which company and its culture, or within an industry, is more important than which model is chosen.” According to Taubitz, “GM’s experience suggests ‘the simpler, the better.’”

The most-common risk determination models are quantitative, such as that described in BS5304 (the “Lego block” diagrams in STI literature) or qualitative, such as the binary “tree” method (as adapted in Schmersal-USA literature from EN954) or a matrix method (similar to MILSTD 882D, the example selected for inclusion into TR3).

**APPROPRIATENESS OF SAFEGUARDING MEASURES**

Some safety professionals still espouse a simplistic safety philosophy. For example, use of two-hand controls and guards when running parts, and a policy to lock-out when performing maintenance are a typical safeguarding solution. These professionals often believe that management does not enforce lockout only because it puts profit ahead of employee safety.

However, prescriptive safeguards without regard to task do not always work in application, and current standards seldom give any guidance when this occurs. Commitment and enforcement cannot overcome this reality. As Taubitz explains, “It is akin to asking a mechanic to tune-up a car without ever turning on the engine because his/her hand could become entangled in the fan. Spark plug and other parts replacement can be done without power, but it is impossible to set timing and perform diagnostic work without the engine running.”

A common result of this approach is capricious safeguarding. For example:

- demand for physical guarding of a power hacksaw sitting in a corner, operating with an automatic shutoff, with no one within 20 ft.;
- dictate for “rear guarding” of a press brake placed against a wall, where there is neither opportunity nor motivation to access the rear of the brake;
- citation for not having a guard on the underside of a coupling on a floor-mounted motor/pump combination, because it is possible for someone to get down on the floor and reach up under the guard to touch the coupling;
- manufacturer’s “guard” that must be removed in order to properly adjust a running machine.

Such cases ignore the realities of the workplace. How can a worker form two small, hand-held parts on four-ft. hydraulic press brake equipment using a typical “compliant” light curtain or a holdout device? Does the actual risk posed by the operation warrant such prescriptive safeguards? Are they really used—or do they waste money and possibly pose additional risk?

Safety engineers should deal in probabilities—not possibilities. However, Taubitz brings up a good point that must be considered in the risk reduction process. “It is necessary to get the input of experienced employees when doing a task-based risk assessment. Some do not take kindly to the thought that the posed risk and, therefore, the level of control, might be diminished because of frequency of exposure. What do you say to a skilled trades employee who asks, ‘If the hazard is such that I can lose my life, should the safeguarding be any less because the frequency/probability is less?’”

TR3—THE CONCEPT IS BORN

At the 1994 ASSE Professional Development Conference in Las Vegas, NV, the author (then administrator of the Society’s Engineering Division) met briefly with Joe Dear, then Assistant Secretary of Labor for OSHA. Problems posed by the language and multiple interpretations of 1910.212, the “General Guarding Clause,” were discussed; both parties agreed that valuable safety resources were being wasted on unnecessary safeguards, while other needs were being ignored. Dear stated that the best course of action would be to develop a consensus standard on risk assessment and reduction that OSHA could point to as an applicable standard in the enforcement of 1910.212, rather than try to rewrite the section. He ultimately committed several OSHA staff members to help with this task.

In addition, members of the machine tool industry were finding it increasingly difficult to prepare goods for sale in European markets because of the lack of a domestic counterpart to EN292 and EN1050—the European Standard for Risk Assessment and Reduction. The effort to establish this link to Europe was spearheaded by Chuck Carlsson, safety director for the Assn. for Manufacturing Technology (AMT), and John Bloodgood, a consultant to AMT, who represented

### TABLE 1 Risk Estimation Matrix

<table>
<thead>
<tr>
<th>Probability of Occurrence of Harm</th>
<th>Hazard Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very Likely</td>
<td>Catastrophic</td>
</tr>
<tr>
<td>Likely</td>
<td>Serious</td>
</tr>
<tr>
<td>Unlikely</td>
<td>Moderate</td>
</tr>
<tr>
<td>Remote</td>
<td>Minor</td>
</tr>
</tbody>
</table>

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the Capital Goods Coalition and U.S. industry on various European and International Organization for Standardization (ISO) committees. Joined by Dennis Cloutier and Dave Withrow, long-time members of the B11 community, all saw the need for a domestic standard on risk assessment and reduction in the machine tool industry. According to Jim Howe, UAW’s assistant safety director, the union “saw the importance of the European Union standards and their effect on major corporations in the U.S. Risk assessment was being mentioned in standards such as RIA 15.06 (1992), but with very little explanation or detail.”

In April 1996, the efforts coalesced, as work began on what was to become a controversial, far-reaching document. An unprecedented appeal for members outside the B11 community brought together subcommittee members and observers from such diverse sectors as the military, System Safety Society, machinery manufacturers and users, UAW, OSHA, NIOSH and consultants in various fields. Thanks to the Internet, ideas were exchanged freely, as the convenience of e-mail brought input from around the world and enabled extensive communication among committee members between meetings.

**ANSI B11.TR3 TAKES SHAPE**

From the onset, the committee attempted to write a document that would emulate EN1050. The methodology ultimately established is similar and compatible with EN1050 and ISO-14121, with several important improvements.

- Task analysis adds greatly to the hazard identification process, and both tasks and hazards are to be identified before risk assessment is initiated.
- The document addresses the roles of machine supplier and user, as well as any entity involved in modification. It encourages synergism between all parties.
- The methodology does not encourage prescriptive safeguards without regard to specific task demands.

**FIGURE 1 Cumulative Efforts by Supplier and User to Reduce Risk**

- The focus is on feasible and appropriate risk reduction, and communication of residual risk.
- During the development process, several issues were uncovered.
  - A major paradigm shift and culture change is needed to accept that “zero” risk does not exist.
  - Ignoring this fact leads to inadequate communication of “residual risk” to the user.
  - Higher-order controls are usually only feasible when integrated into a design at an early stage.
  - Prescriptive safeguards often ignore high-risk tasks.
  - Such safeguards also generalize without regard to risk, often resulting in misapplication of resources.
  - Task-based risk assessment is a significant contributor to the safety-through-design process.
  - The type of risk assessment model used is not nearly as important as the methodology used and employment of the basic hierarchy of controls for risk reduction.

As a result, several new terms were incorporated into the document.

- **Harm** is defined as “physical injury to health of people.” References to property were intentionally omitted because damage to property is generally beyond the scope of the safety discipline.
- **A hazard is defined as “a potential source of harm,” and a hazard area or hazard zone is the area or space where the hazard is immediate or impending. A hazardous situation (also known as a task/hazard pair) is a circumstance in which a person is exposed to the hazard(s).**
- **The lifecycle of a machine, often neglected in hazard identification and risk assessment, includes everything from “design and construction” of the machine to “decommissioning and disposal.”**
- **Protective measures are those steps taken throughout the design, manufacture, installation, use, maintenance and disposal of the machine to reduce risk of injury.** The committee found this phrase more appropriate than “safeguarding,” which has
“Risk assessment has gone from a novel, untested concept to a practical method to improve safety through design. This is a great improvement over EN1050.”

been historically used in domestic standards.
• *Reasonably foreseeable misuse* is largely a legal term. TR3 defines it as the “predictable use of a machine in a way not intended by the supplier or user” resulting from human behavior.
• *Residual risk* is that which is present after all protective measures have been applied. The goal is to reduce risk as much as practicable for a given task/hazard pair (hazardous situation), recognizing that the level of risk that is tolerable or acceptable in a given instance may be influenced by numerous factors.

### A WALK THROUGH TR3
The following discussion summarizes the content of ANSI B11.TR3.

#### The Need for Multidisciplinary Collaboration
Hazard identification and risk assessment are dramatic examples of the need for multidisciplinary input. Everyone looks at a machine or process differently. The installer may see one set of hazards, while the operator and maintenance personnel will see others. Sales personnel may be able to share valuable input from other users, and outside consultants can add their multidisciplinary experience.

#### Setting Limits of the Machine
The risk assessment process begins by first determining the limits of the machine/system. This helps define what the designer intended with regard to use, space, time, interface and environmental requirements. Taking a machine beyond its design limits introduces unforeseen hazards—and may greatly increase risk.

#### Hazard Identification & Severity: Using Tasks to Identify Relevant Hazards
Hazard identification is the basic element in the risk assessment process. In evaluating a machine/system over its lifecycle, much more must be considered than hazards at the point of operation. Some hazards may be easily identified and addressed during the design process. However, if tasks to be performed on or in conjunction with a machine/system are not considered, many hazards may be ignored. Thus, the identification process is extended to include:
- packing, transportation, unloading and installation;
- commissioning, setup, startup and try out;
- all modes of operation;
- production setup, tool changes, jam clearing;
- planned (and unplanned) maintenance, troubleshooting, major repair, crash recovery, housekeeping;
- decommissioning and disposal.

The two primary elements of risk are 1) severity of the most-credible injury that could result from a hazardous situation; and 2) probability of that occurrence.

Adopting commonly used terminology and guidelines, the severity of harm example used in the document lists four levels. Because the nature of actual costs comes into play, these levels reflect the worker’s ability to return to productive activity:

**1) Catastrophic:** Death or permanently disabling injury or illness that would prevent return to work. This category may also include serious injuries to many people.

**2) Serious:** Severe debilitating injury or illness. Such an injury might prevent return to work at the same job, but would permit return to work at some point.

**3) Moderate:** Significant injury or illness requiring more than first aid. Although lost time may result, the injured party would be able to return to work at the same job within a short period of time.

**4) Minor:** No injury or slight injury requiring no more than first aid. This would mean little or no lost time.

#### Factors Affecting Probability of a Hazardous Event
Probability of the occurrence of harm from human behavior.

Factors Affecting Probability of a Hazardous Event

1. **Probability to Determine Risk**
   - Very likely: Near certain to occur.
   - Likely: May occur.
   - Unlikely: Not likely to occur.
   - Remote: So unlikely to occur as to be near zero.

Consider these analogies. Suppose a turtle crosses a two-lane road with moderate traffic in upstate New York. The probability of getting hit is likely—but not as high as on the California freeway. The turtle crosses a dirt road in New Mexico at 3 a.m. on Monday. It is not likely any traffic will be present, so the probability of the hazardous incident is unlikely to remote.

In each case, the hazard severity has remained the same. Only the probability has changed.

#### Using Hazard Severity & Probability to Determine Risk
Risk is determined by equating hazard severity and probability. By nature, the entire process is highly subjective. One can cite almost as many models for determining risk as industries and organizations to develop them. A model is just a tool; other tools may also be available. The thinking process involved in the analysis—not the conclusion—is the crucial element.

The list of hazards and probabilities given earlier is only an example. The risk determination matrix (Table 1) selected for ANSI B11.TR3 is based on MILSTD 882D (although it is not identical). Other matrices and charts are avail-
Risk is determined by equating hazard severity and probability. By nature, the entire process is highly subjective.

**Risk Reduction:**

*The Cumulative Efforts of the Supplier & User*

If the level of risk identified is not tolerable, it must be reduced. In most machines, however, the supplier can only do so much. The supplier must then communicate to the user what has been done, and what remains to be done to reduce risk. The user must perform a risk assessment to ensure that all hazards are addressed and appropriate protective measures are taken.

The risk reduction effort emphasizes application of the safety hierarchy in the selection of protective measures. Safety always begins at the design stage. Not only is “engineering out” the hazard the most-effective protective measure, it is generally the least expensive. As noted,
the hierarchy approaches risk reduction in this order:

1) Eliminate the hazard or reduce its effects by design.

2) Apply safeguards—barrier guards, protective devices and control systems—appropriate to the degree of risk reduction desired.

3) Implement administrative controls, such as warnings, information for use, training, supervision and safe work practices.

Figure 1 shows the incremental and cumulative efforts of the supplier and user.

**Appropriate Protective Measures for the Desired Degree of Risk Reduction**

Every protective measure—from those taken by the designer of the machine to those taken by the ultimate user—provides an incremental reduction in risk. The greater the degree of risk reduction demanded of a protective measure, the more important it becomes that the measure will provide the safety function when required.

For example, the door on a bank vault is thick and secure because it must deliver a high degree of assurance that it will perform its function. An exterior door on a house provides less reliability, but considerably more protection than a closet door in the same house because the desired degree of risk reduction varies.

Therefore, doesn’t it make sense that industrial safeguarding (proactive) measures also be risk appropriate? On one hand, does a facility want a spring-operated single-contact pushbutton E-Stop determining whether a dangerous machine will stop when needed? On the other, who wants to spend thousands of dollars on a full barrier enclosure for equipment that poses low risk? Risk assessment is the tool to facilitate intelligent decisions.

**The Need for Validation & Documentation**

The risk assessment and reduction process is iterative (Figure 2). After a reduction measure is applied, risk estimation must be repeated. Has the application of safeguards or other protective methods introduced additional hazards? If so, the process must be repeated. In some cases, one measure may achieve tolerable risk. In other cases, more than one measure may need to be applied.

Regardless of the cumulative efforts of suppliers, modifiers and users, some degree of residual risk will always exist with any machine. No matter how much is done, all stakeholders must take responsibility for safety. Throughout the risk assessment and reduction process, all tasks, hazards and risks must be identified. Whatever risk remains after all protective measures available to the given entity have been taken, the remaining risk must be communicated to the next in line. Consider this scenario. A machine manufacturer knows, and can properly address, hazards posed by the rotating flywheel and clutch by using physical guarding. But the manufacturer is also aware of hazards that may arise during operation and maintenance that it cannot directly address. After taking feasible steps to reduce risk (e.g., installing properly spaced two-hand control actuators in a 'control-reliable' system), the manufacturer must communicate the following information to the user:

- what has already been done to identify and reduce risk;
- the machine’s limits and foreseeable use and misuse, and any additional protective measures that must be taken by the user;
- need for the user to conduct his/her own task-based risk assessment and apply appropriate protective measures to address particular use(s).

**CONCLUSION**

Although TR3 was written specifically for the B11 community for inclusion in the B11 Machine Tool Standards, it has application to a wide variety of machines and processes. It presents a paradigm shift in thinking about safeguarding machines.

The procedure and methodology:
- takes a shared approach to responsibility, recognizing that all parties can play a significant role in assessing and reducing risk;
- identifies more hazards than traditional methods;
- focuses on effective and appropriate risk reduction measures;
- can reduce legal liability for manufacturers, modifiers and users;
- virtually eliminates prescriptive safeguarding by requiring justification;
- is compatible with, but superior in many ways to European counterpart(s);
- provides a proven, practical methodology that allows application of the safety hierarchy during the design process for enhancement of safety and productivity.

The advent of ANSI B11.TR3 is a first step toward ensuring that safety will be moved toward the front of the machine design process; that protective measures to reduce risk will be applied in a scientific and logical manner to best utilize available resources; and that domestic machine manufacturers are helped to conform to worldwide standards. What the future holds is anyone’s guess. However, TR3 has already made its mark in the development of the latest revision of RIA 15.06 (the robot safety standard) and several B11 standards now in process.

**REFERENCES**


**ACKNOWLEDGMENTS**

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Robert N. Andres, CSP, CPE, CMfgE, is CEO of OSHEX Associates Inc., Baldwinsville, NY. He is a consultant in the field of machine and facility safety, and noise/vibration control. Andres is a past administrator of ASSE’s Engineering Division, and a member and past president of the Society’s Central New York Chapter. He serves on the ANSI B11.3 and B11.20 subcommittees, and chairs the ANSI B11.TR3 subcommittee.

**For More Information**

Copies of ANSI B11.TR3 are available from:

Assn. for Manufacturing Technology
7901 Westpark Dr.
McLean, VA 22102-4206
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