

The Risk Assessment Process

Part 2 of 5 in a series addressing the primary milestones to a safe machine

Introduction

When undertaking machine safety activities, it is always important to have a clearly structured process to be used as a guideline. With such a process in place, it is easier to ensure consistent results that coincide with the EH&S goals of an organization. A well-conceived risk assessment process is the answer to many of the pitfalls that disturb companies implementing safety measures. When the organization is multinational, the importance of a standardized approach is even more apparent.

To confirm that appropriate risk reduction measures have been taken, one must first assess the inherent risk(s) associated with a machine or process. "Risk Assessment," as it is aptly named, is the methodology of analyzing and evaluating the risks. When combined with a risk reduction process to eliminate, reduce, or otherwise address the risks, an organization can demonstrate that appropriate measures have been taken to suitably reduce the risk, while also ensuring that the measures applied are not grossly over dimensioned for the level of the associated hazards.

What is Risk Assessment?

As mentioned earlier, risk analysis and risk evaluation comprise the basics of risk assessment, while the addition of risk reduction measures ensure that the desired goal of safe machinery is achieved. To truly understand the nature of this methodology, however, it is important to further comprehend the details of these individual components.

In order to analyze risk, three elements must be combined and considered; the specification of the limits of the machine, identification of hazards, and risk estimation. Together, these attributes are considered to define a level of risk, which is then evaluated to determine whether the risk reduction objectives have been achieved, also known as achieving tolerable (or acceptable) risk.

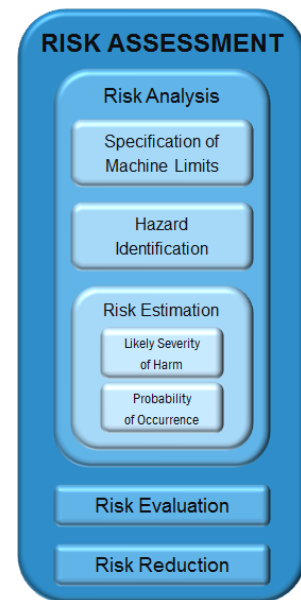


Figure 1: Components of Risk Assessment

Why Perform Risk Assessment?

As discussed in Part 1 of this series ([Selecting Safety Standards for Machine Safeguarding Requirements](#)), both the obligations as well as the market expectations regarding who is ultimately responsible for safety differ in various regions of the world. Regardless of the motivating factors to implement risk reduction measures, the common denominator is that the risk assessment methodology provides a consistent approach with a proven track record.

Although risk assessment is not a legal requirement of the Occupation Safety & Health Administration (OSHA) in the United States, the Administration places the legal burden for safety on the employer. The [General Duty Clause](#) of the Occupation Safety and Health (OSH) Act of 1970 states in Section 5(a)(1):

Each employer 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.

OSHA and other North American regulatory agencies do not dictate that a particular process is used to meet this legal obligation, but rather that the specific goals are achieved. When an inspection or investigation occurs, organizations that have performed and documented a risk assessment are able to explain the actions taken, defend the timeline developed, and justify the protective measures applied. Without such a process in place, the results are subject to further scrutiny of the agency.

Additionally, a growing number of consensus standards require that a risk assessment be performed in order to assure compliance with the best practices available at the time of publication. While most of these standards are technically voluntary, the market expectation for safe equipment leads progressive organizations to apply these methodologies as if they are mandatory.

Technical Guidance from Standards

Furthermore, standards provide an abundant amount of information pertaining to the risk assessment process. As discussed below, many standards provide detailed outlines of the process, and in some cases, also provide clear models which can be applied. In other cases, standards dictate that design and application decisions be based on the results of a thorough risk assessment.

As the [Part 1](#) of this series examined, many standards developing organizations use a three tiered structure of standards, often delineated as type-A, -B, and -C standards. To ensure the most thorough approach to risk identification and mitigation, it is imperative that both horizontal and vertical standards are used together to achieve the safest equipment and workplace attainable. As represented in Figure 2, type-A standards provide a general overview of hazard identification, while type-C standards probe deeper into the details as they apply to a specific industry or machine group. By applying this approach, the general requirements applicable to all machines will be addressed by the type-A standards while additional scenarios that may be specific to a subset of equipment will most likely be dealt with by the type-C standards, when available.

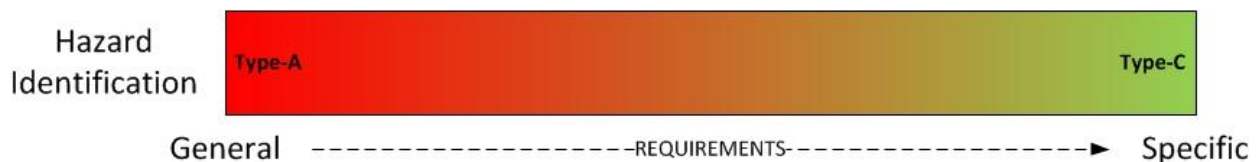


Figure 2: Coordinated Application of Standards

Elements of Risk

To better understand the risk estimation process, it is important to first explore the concept of risk. As defined by most authorities, risk is the combination of the severity of harm that can result from the considered hazard and the probability of occurrence of that harm.

Severity

Severity addresses the degree of injury or illness that could occur (such as slight, serious, or death), as well as the extent of harm (such as how many people could be affected).

Probability

Probability of occurrence is estimated taking into account the frequency, duration and extent of exposure; speed of occurrence; human errors; training and awareness; and the characteristics of the hazard. Occurrence probability of an incident is often further divided into three influencing factors of exposure of people to the hazard, occurrence of a hazardous event, and possibility of avoiding or limiting harm (either technical or human).

When evaluating **exposure** of a person to the hazard, some of the factors to be considered include:

- Need for access to the hazard (e.g., during normal operation, maintenance / repair, correction of malfunction, cleaning, etc.)
- Nature of access (e.g., manual feeding of material, clearing jams, etc.)
- Time spent in the hazard zone
- Number of people requiring access
- Frequency of access (typically measured over a single work shift)

Another influential element of probability is **occurrence** of a hazardous event. The occurrence of a hazardous event may result from either a technical or human origin, and factors to study include:

- Reliability / other statistical data
- Accident history
- History of damage to health
- Comparison of risks (either on identical or similar equipment)

The last meaningful component of probability to consider is **possibility** of avoiding or limiting harm, and factors to be taken into account include:

- Different people who can be exposed to the hazard (e.g., skilled versus unskilled)
 - NOTE: Specialized training alone cannot be used as a means of reducing the probability if it cannot be assured that all exposed individuals will have an equivalent level of training or knowledge.
- How quickly the hazardous situation could lead to harm
- Awareness of risk, if any (e.g., identified in the user manual / information for use, awareness means, etc.)
- Human ability to avoid or limit harm (e.g., reflex, agility, possibility to escape, etc.)
- Practical experience and knowledge, if any, of the machinery or similar machinery

Considerations when Assessing Risk

When performing a risk assessment, there are a number of details that cannot be overlooked.

Concurrent Factors

As represented in Figure 3, both elements (severity and probability) are required concurrently for risk to be present. A potentially fatal hazard that no one is ever exposed to represents no risk, just as a common event with no severity of harm is not considered a risk.

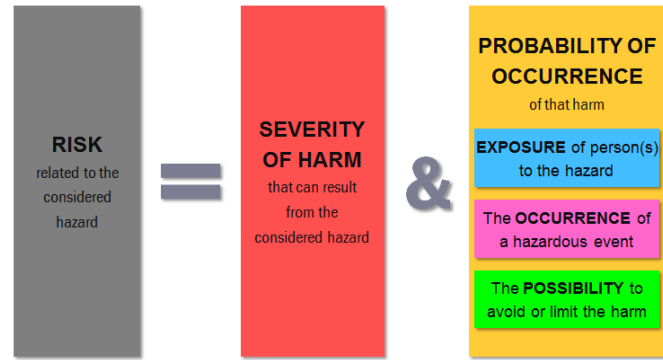


Figure 3: Elements of Risk

Design Effects on Severity

Other factors may affect the elements of risk above and must also be considered. For instance, the location of a hazard may drastically change the associated risk. Consider the hazard of a slip / trip / fall on a walkway as an example. If we can assume that the probability of such an occurrence is the same for a given task, we must acknowledge that the potential severity is much different if the walkway is at floor level as opposed to one that is elevated. Furthermore, the higher the elevation of the walkway, the more likely it is that the associated severity of harm will increase as well.

Conflicting Opinions

When estimating both severity and probability, the highest credible level shall be selected. If disagreement arises amongst the team performing the evaluation, a more conservative approach will ensure that sufficient attention and measures are applied to effectively reduce risk of harm.

Assume No Protective Measures Present

A key consideration that must also be factored in when performing a risk assessment is that hazards must be identified *regardless of the existence of risk reduction measures*. No machine should be considered risk free as shipped and guarded. To assure that all potential risks are addressed, hazard identification, as well as the subsequent risk estimation, should be conducted with all risk reduction measures (safeguards) conceptually removed. This will help assure that hazards are not ignored due to an assumption that a supplied safeguard is adequate for all tasks, including reasonably foreseeable misuse. During the validation and verification portion of the process, the performance of existing protective measures will be evaluated. If it is confirmed that these measures help meet the risk reduction goals, they can be retained as part of the final risk reduction solution.

Simply put, identifying the inherent level of risk for each hazard will ensure that the appropriate minimum requirements are established for the associated protective measures. With these requirements in place, existing risk reduction measures, if any are present, can be evaluated to determine their efficacy. If existing measures meet or exceed the minimum established requirements, the documented risk assessment will justify their presence; if they do not, replacement or supplemental measures are warranted.

Stakeholder Involvement

When evaluating equipment, it is also imperative that the relevant stakeholders are provided with early and ample opportunity for involvement. All too often have protective measures been implemented without buy-in from the individuals who actually have to live and work with the system, such as operators and maintenance personnel. In many of these cases, exclusion of stakeholder feedback results in further modifications to the solution – with increases to both budget and time as common consequences. In other instances, these modifications may render the protective measures ineffective. When safeguards are modified – or even bypassed entirely – without proper due diligence through a

verification and validation process, remaining components of the risk reduction strategy can create a perception of safety. An inaccurate perception of safety could increase the associated risk on a machine because individuals may assume that certain hazards are already eliminated or controlled. Without protective measures in place, an individual may be more likely to proceed with caution. Part 5 of this series will further address the concerns of perceived safety and the importance of the verification and validation process.

It is sometimes assumed that people without a safety background cannot add value to the risk reduction process. However, time and time again it has been proven that those who are most intimate with the process often have the most effective solutions to achieving the necessary level of risk reduction, while still providing means for required tasks to be performed.

Types of Risk Assessment

Task-Based Risk Assessment

Generally speaking, there are two basic types of risk assessment. The first, known as task-based risk assessment, identifies task / hazard pairs based on expected and foreseeable interactions with the equipment. When applying this approach, it is common to begin by listing all affected personnel, defined as any role of individuals who may come in contact or proximity with the equipment under review. This list includes the usual suspects – such as operators, maintenance personnel, skilled tradesmen, and supervisors – as well as other less common groups – like administrative personnel, salespeople, and other visitors.

With a comprehensive list of exposed people in hand, the next step is to identify each task associated with each classification of person. In this usage, the word ‘task’ means any possible hazardous situation, whether it be from an expected job function of the person while completing their normal job duties or a foreseeable interaction which may result from readily predictable human behavior. When performing a risk assessment, it is important to identify which part(s) of the machine lifecycle are to be considered, as this will also affect the types of tasks which will be identified. Since each role may be associated with multiple tasks, the list will expand according to each pairing.

After all tasks have been identified for the equipment, all reasonably foreseeable potential hazards associated with each task are then identified. Various standards and documents are available to assist with the identification of hazards, but the common categories of hazards are those originating from the following sources, or any combination thereof:

- Mechanical
- Electrical
- Thermal
- Noise
- Vibration
- Radiation
- Materials / substances
- Ergonomics
- Environmental

Hazard-Based Risk Assessment

In a hazard-based risk assessment, the approach is to identify all potential sources of harm, regardless of whether or not they are directly associated with a foreseeable task related to specific affected personnel. Using any available C-type standards, information from similar machines, as well as the list above, a comprehensive inventory of all hazards must be compiled.

Comprehensive Risk Assessment

While a hazard-based approach may appear to save time by eliminating repetition of identical task / hazard pairs, a task-based approach provides a more systematic methodology to ensure that all foreseeable tasks are considered. Alternatively, a hazard based approach will ensure that hazards not related to tasks area also identified, such as hazardous environments, noise, and radiation. In order to provide the most comprehensive assessment of risk, it is recommended that a combination of these methodologies be applied.

Acceptable Level of Residual Risk

The risk remaining after risk reduction measures are taken is referred to as residual risk. As we will see, the residual risk is not evaluated to determine if it is acceptable for a given hazardous situation until after protective measures have been implemented. Experience shows, however, that before the residual risk can be reviewed to determine if it is acceptable, the organization must first define what level of remaining risk is deemed acceptable or tolerable.

This concept, known as acceptable risk (or tolerable risk), is a somewhat subjective matter. Addressing this important discussion as early in the process as possible will greatly assist the team later in the process, so that a higher level of objectivity can be applied. If this discussion is postponed until after risk reduction measures have been applied, the subjectivity can be biased by the specific application or prejudices of the team.

Zero Risk

Before the discussion of tolerable risk can occur, it is important to first discuss the concept of 'zero risk.' While most EH&S professionals will always strive for 'zero risk,' it must be recognized that this concept does not exist in the real world. However, based on a good faith approach to risk reduction through the process of risk assessment, an organization can approach zero risk by achieving acceptable (or tolerable) risk.

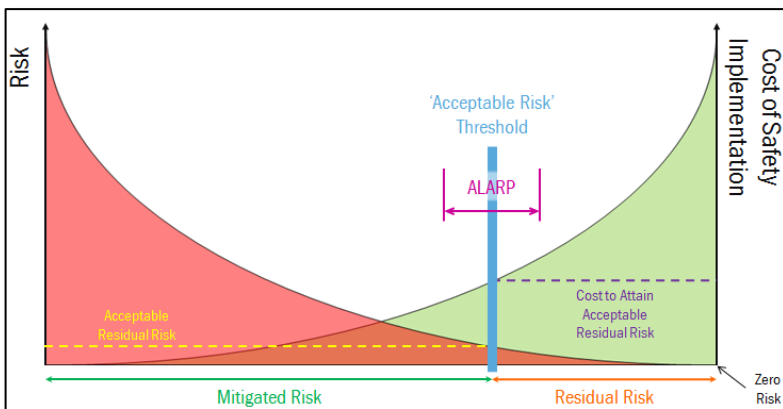


Figure 4: Law of Diminishing Returns Applied to Industrial Safety

This is not to say that the hypothetical concept of zero risk should be discarded. Instead, it must be balanced with the practicalities of reality. Based on the law of diminishing return, we know that beyond a certain point, there are progressively smaller benefits in output based on the increased application of a variable input to a fixed quantity. When this theorem is applied to safety in an industrial setting as represented in Figure 4, we realize that no organization is financially capable of

achieving zero risk for every potential hazard present in the workplace. To achieve the correct balance, however, monetary cost alone should never be a justification for limiting risk reduction activities.

Acceptable (Tolerable) Risk

Once the myth of zero risk is understood and accepted, the representatives of each organization must try to impartially define what level of residual risk is acceptable. This definition will help achieve a balanced level of safety, either within an individual facility or across many locations.

When characterizing acceptable risk, it is inevitable that the concept of As Low As Reasonably Practicable will arise. This principle, also known as **ALARP**, is a common best practice to judge the balance of risk and societal benefit. A component of this idea states that it must be possible to demonstrate that the cost involved in reducing the risk further would be grossly disproportionate to the benefit gained, as discussed above in Figure 4. The ALARP concept arises from the fact that infinite time, effort, and money could be spent attempting to reduce the associated risk to zero. The fundamental factors to be considered include:

- Health and safety guidelines
- Specifications
- Applicable laws, directives, regulations, and standards
- Suggestions from advisory bodies (best practices)
- Comparison with similar hazardous events in similar industries

The ALARP principle is also known as So Far As Is Reasonably Practical (SFAIRP) in other regions of the world, and is often represented as shown in Figure 5. Note that the risk magnitude never reaches zero.

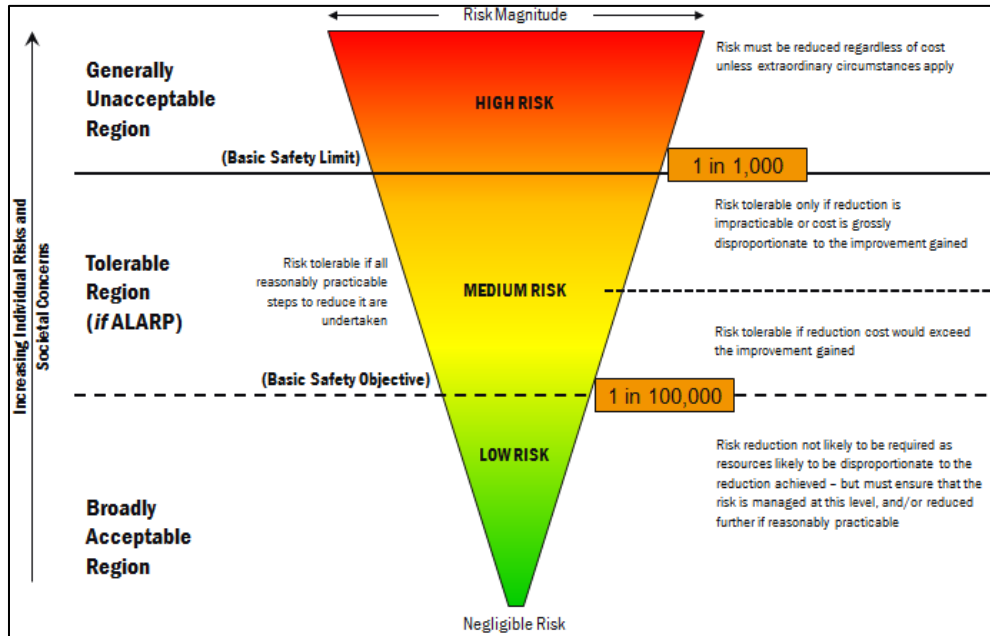


Figure 5: Basics of ALARP Principle

Preparation

Team Approach

When performing a risk assessment, it is important to utilize a diverse team of individuals. As with most other reviews, multiple sets of eyes are beneficial to ensure nothing is overlooked. Utilizing a multidisciplinary team of qualified individuals, each member can provide alternate viewpoints based on their own experiences and perception of risk. Furthermore, collaboration amongst the team through a consensus process will foster appropriate discussion and resolution of any concerns that arise. Roles to consider when forming the team include:

- Operators
- Maintenance personnel
- Safety manager
- Engineers
- Forman / supervisors
- Production personnel
- Material handlers
- Quality control personnel
- Equipment manufacturer / supplier / integrator representatives
- Qualified safety specialists

Collect Relevant Information

To aid the team in an effective assessment of risk, it is advantageous to gather information relevant to the application. As previously mentioned, any available risk data – from previous risk assessments on the same or similar equipment, accident or incident history, and knowledge about damage to health – will provide guidance to the team. Furthermore, details regarding the intended use (as well as foreseeable misuse) of the equipment are important factors, such as materials to be used, limits of the equipment, and requirements related to the lifecycle phases to be considered.

Design considerations must also be included, as these may affect the risk as discussed earlier. Any information establishing the nature of the equipment (drawings, sketches, system descriptions, etc.), the layout and proposed system integration within the facility or a larger process, as well as energy sources will assist with the accurate assessment of potential risk.

Lastly, the human factor must also be acknowledged. An accurate list of all potentially affected personnel, as well as their respective level of training and experience, will aid the assessment process.

Risk Estimation

Risk Scoring Systems












Another essential element of assessing risk is a risk scoring system. There are numerous models available on the market; some from international or domestic standards, others from commercially available software models or consultants, and countless others based on an amalgamation of those above. While there is no one 'right' model to use, it is important that a company try to standardize on a single model to be used throughout the organization. By normalizing the model used, the upper tiers of the organization will be able to better compare status of multiple locations on an apples-to-apples basis, while knowledge sharing and collaboration will be better facilitated at the plant level.

There are a number of factors to consider before selecting a unified model. First, an organization should consider the level of expertise already existing within the ranks of their EH&S department. Rather than invest in developing their own methodology – especially when considering the possible

consequences associated with incorrect implementation, most companies without a high level of inherent proficiency either tend to outsource their risk assessment process or rely on existing models. If selecting a prevalent model already available, one should also consider the stability of the model (has it been accepted by the market and stood the test of time?) as well as the process by which the model was developed (is the model from an industry standard based on the consent of all participants, or merely the opinion of a few individuals?). Additional aspects to take into account include choosing a model which:

- The team is comfortable with
- Best suits the EH&S objectives of the organization
- Can be easily and consistently applied to various types of equipment (repeatable)
- Has clear and discernable definitions for each risk factor and level per risk factor
- Best prioritizes actionable risk reduction measures
- Provides outputs that are understandable and actionable

As identified previously, there is an abundant list of resources which provide guidelines to performing risk assessment. Table 1 below identifies just some of the common consensus standards which provide guidance, direction, and in some cases scoring systems which can be used when performing risk assessment. As represented by this list, some of the standards solely address risk assessment – sometimes in reference to specific industries or machine types – while other standards include the premise to address other safety topics, such as occupational health and safety management systems, prevention through design, and functional safety of control systems.

STANDARD	YEAR AFFIRMED (REAFFIRMED)	TITLE	SCOPE	SCORING SYSTEM(S) PRESENTED
ANSI B11.0	2010	Safety of Machinery – General Requirements and Risk Assessment	Power driven machines, not portable by hand, used to shape and/or form metal or other materials by cutting, impact, pressure, electrical or other processing techniques, or a combination of these processes.	
ANSI B11.TR3	2000	ANSI Technical Report for Machine Tools – Risk assessment and risk reduction – A guide to estimate, evaluate and reduce risks associated with machine tools	Provides the procedures and methods to assess the risks associated with the design, construction, care and use of machine tools as included in the B11 series of machine tool safety standards. It serves as a guideline for suppliers and users of machine tools, providing a framework and procedure to identify tasks and hazards, and to estimate, evaluate, reduce and document the risks associated with these hazards under the various conditions of use of that machine or system.	
ISO 12100 ¹⁾	2010	Safety of machinery – General principles for design – Risk assessment and risk reduction	Machines assembled, fitted with or intended to be fitted with a drive system consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application. This also covers an assembly of machines which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole.	
ANSI / PMMI B155.1	2011	Safety Requirements for Packaging Machinery and Packaging Related Machinery	Packaging, processing and packaging-related converting machinery.	
ANSI / RIA R15.06 ²⁾	1999 (R2009)	American National Standard for Industrial Robots and Robot Systems – Safety Requirements	Automatically controlled, reprogrammable multipurpose manipulator, programmable in three or more axes, which can be either fixed in place or mobile for use in industrial automation applications.	
ANSI / AIHA / ASSE Z10	2013	American National Standard for Occupational Health & Safety Management Systems	Policy, organization, planning & implementation, evaluation, and action for improvement of employee health and safety.	
ANSI / ASSE Z590.3	2011	Prevention through Design: Guidelines for Addressing Occupational Hazards & Risks in Design & Redesign Processes	Design / redesign of work premises, tools, equipment, machinery, substances and work processes.	
AWS D16.3M / D16.3	2009	Risk Assessment Guide for Robotic Arc Welding	Arc welding robot systems.	
SEMI S10 ³⁾	2007	Safety Guideline for Risk Assessment and Risk Evaluation Process	Micro- and nano-electronics industries, including: <ul style="list-style-type: none"> • semiconductors; • photovoltaics (PV); • high-brightness LED; • flat panel display (FPD); • micro-electromechanical systems (MEMS); • printed and flexible electronics; • related micro- and nano-electronics. 	
MIL-STD-882E	2012	Department of Defense Standard Practice – System Safety	Identifies the Department of Defense (DoD) Systems Engineering (SE) approach to eliminating hazards, where possible, and minimizing risks where those hazards cannot be eliminated. This Standard covers hazards as they apply to systems / products / equipment / infrastructure (including both hardware and software) throughout design, development, test, production, use, and disposal.	
CSA Z432	2004	Safeguarding of machinery	Applies to the protection of persons from the hazards arising from the use of mobile or stationary machinery.	






STANDARD	YEAR AFFIRMED (REAFFIRMED)	TITLE	SCOPE	SCORING SYSTEM(S) PRESENTED
CSA Z1002	2012	Occupational health and safety – Hazard identification and risk assessment and control	Specifies requirements for the identification of OHS hazards, their elimination where practical, and assessment and control of risks associated with remaining hazards. This Standard is applicable to organizations of any size or type and can be applied at all stages in the lifecycle of a product, process, or service.	
ISO / TR 14121-2	2012	Safety of machinery – Risk Assessment – Part 2: Practical guidance and examples of methods	This Technical Report gives practical guidance on conducting risk assessment for machinery in accordance with ISO 12100 and describes various methods and tools for each step in the process. It gives examples of different measures that can be used to reduce risk and is intended to be used for risk assessment on a wide variety of machinery in terms of complexity and potential for harm. Its intended users are those involved in the design, installation or modification of machinery (for example, designers, technicians or safety specialists).	
EN 954-1 ^{4) 5)}	1996	Safety of machinery – Safety-related parts of control systems – Part 1: General principles for design	Provides safety requirements and guidance on the principles for the design and integration of safety-related parts of control systems (SRP/CS), including the design of software. For these parts of SRP/CS, it specifies characteristics that include the performance level required for carrying out safety functions. It applies to SRP/CS, regardless of the type of technology and energy used (electrical, hydraulic, pneumatic, mechanical, etc.), for all kinds of machinery.	
ISO 13849-1 ⁵⁾	2006	Safety of machinery – Safety-related parts of control systems – Part 1: General principles for design	Provides safety requirements and guidance on the principles for the design and integration of safety-related parts of control systems (SRP/CS), including the design of software. For these parts of SRP/CS, it specifies characteristics that include the performance level required for carrying out safety functions. It applies to SRP/CS, regardless of the type of technology and energy used (electrical, hydraulic, pneumatic, mechanical, etc.), for all kinds of machinery.	
IEC 62061 ⁵⁾	2005	Safety of machinery – Functional safety of safety-related electrical, electronic and programmable electronic control systems	Specifies requirements and makes recommendations for the design, integration and validation of safety-related electrical, electronic and programmable electronic control systems (SRECS) for machines. It is applicable to control systems used, either singly or in combination, to carry out safety-related control functions on machines that are not portable by hand while working, including a group of machines working together in a coordinated manner.	
NOTES				
¹⁾	ISO 12100:2010 was a consolidation without technical change to ISO 12100-1:2003, ISO 12100-2:2003, and ISO 14121-1:2007. ISO 12100:2010 was also adopted as an American National Standard, ANSI/ISO 12100:2012.			
²⁾	This standard is intended to be formally withdrawn at the end of 2014. The new revision of this standard, ANSI/RIA R15.06-2012, does not include guidance or a model for risk assessment.			
³⁾	SEMI is not an ANSI accredited Standards Developing Organization (SDO).			
⁴⁾	EN 954-1 was subsequently elevated to ISO 13849-1 in 1999. In turn, ISO 13849-1 was revised in 2006, effectively replacing both EN 954-1 and the 1999 ISO revision as of 1 January 2012.			
⁵⁾	While these standards are specific to functional safety requirements for control systems, the performance requirements established are based on the concepts of risk assessment using the risk factors from Figure 3.			
Information listed is believed to be accurate at time of publication; subject to change at any time. Check with appropriate SDO for additional information regarding scope and content of standards listed.				

Table 1: Examples of Standards Addressing Risk Assessment Methodology

Defined Limits of a Risk Scoring System

An effective risk scoring system will include well-defined criteria for evaluating the severity and probability factors which comprise risk. Without clear limits defined for the different levels of each factor, the team will often get diverted into discussions of what is 'serious' versus 'severe,' or 'likely' as opposed to 'unlikely.' Therefore, clearly defining the criteria for each level will facilitate more efficient use of time during the process.

Additionally, a successful risk scoring system will also include distinct minimum performance requirements for the risk reduction measures associated with each level of identified risk. Sometimes referred to as the 'bridge' between the risk assessment and risk reduction elements of the process, this fundamental component is what drives the upcoming step of risk evaluation.

Assess Initial Risk

Once the foreseeable hazards have been identified and a risk scoring system has been selected, the process requires estimation of the inherent risk level of the equipment – assuming no protective measures are in place – to determine the initial risk level of the system. The **initial risk level** (sometimes also referred to as 'Risk In') creates a baseline for the system. Based on the 'bridge' discussed above, the initial risk level establishes the minimum performance criteria for effective risk reduction measures.

Risk Evaluation

The risk evaluation process is a judgment to determine if the risk reduction objectives have been achieved based on the results of the risk analysis. This process begins with a comparison of any existing protective measures to the minimum performance defined by the risk scoring system to determine if the expectations have been achieved, if not exceeded.

As mentioned earlier, existing measures for risk reduction which are already in place on the equipment during the preliminary risk assessment are to be ignored when identifying the initial risk level. During the risk evaluation, however, the efficacy of these elements can be measured to determine if the defined goals have been met. When this happens, the risk assessment process can be used as justification that further safeguarding measures are not required.

In the event that the minimum requirements have not be met, risk reduction measures must be applied to either replace or supplement any measures already present, or fill gaps not previously addressed. Following the application of protective measures in accordance with the risk reduction process (briefly discussed below), the resulting risk must again be evaluated using the process described here. This resulting risk, known as the residual risk level, must be sufficiently lowered to a tolerable level. Multiple cycles of this process may be required before acceptable risk is achieved, but experience and expertise with risk reduction options will help streamline this part of the overall process. As addressed earlier, clearly defining tolerable levels of risk before the need arises will ensure that reasonable objectivity is applied at this stage of the process.

Risk Reduction

Risk reduction is the part of the risk assessment process involving the elimination of hazards or selection of other appropriate risk reduction measures (protective measures) to reduce the associated risk by addressing either or both the probability of harm or its severity. Risk reduction measures, also known as protective measures or safeguards, are any action or means intended to achieve risk reduction. Conventional risk reduction measures include the following:

- Inherently safe design through elimination or substitution (e.g., automating the process to limit exposure)
- Guards
- Safeguarding devices (e.g., presence sensing devices, interlocks, two-hand controls, etc.)
- Complementary equipment
- Awareness devices including warnings

- Safe work practices / procedures
- Training or other administrative controls
- Personal protective equipment (PPE)

These measures can be implemented by the designer (supplier or integrator), typically through inherently safe design, safeguarding and complementary protective measures, and information for use, as well as by the user (employer), often with additional safeguards, safe work procedures, training, supervision, administrative controls and personal protective equipment.

The selection of risk reduction measures is best implemented by means of a hierarchy of controls, which is based on the effectiveness of protective measures. An iterative process of applying the hierarchy, combined with repetitive risk evaluation, will ensure that an acceptable level of residual risk is achieved. Further discussion of the hierarchy of controls will be discussed in the next white paper in this series.

Documentation

In addition to the regulatory requirements for documentation, organizations should also consider the expectations of the consumers and the local market. In a global marketplace, concise documentation of the process and results provides many benefits, such as establishing baseline expectation for tolerable risk, standardized methods for risk reduction, and overall efficiency by building on past experiences. For end users, documentation of the risk assessment process is a tremendous aid to explain and substantiate the process applied, including the timeline implemented and the investments made toward reducing risk. For suppliers, documentation can be used as a competitive advantage in the market place where safety continues to garner increasing attention.

Various standards and guidelines outline the minimum expectations of what should be included in documentation, but it is important to note that purchase agreements between organizations may dictate additional requirements. At a minimum, one should consider including the following in the documentation of the risk assessment:

- Information of the machinery addressed by the assessment, including specifications, limits, and intended use
- Any relevant assumptions which have been made (e.g., loads, strengths, safety factors applied during the design)
- Information used as a basis for the risk assessment
- Names of the risk assessment team
- Date(s) of the risk assessment
- All identified hazards and associated tasks, if relevant
- Initial risk levels associated with the machinery (based on the assumption that no protective measures are present)
- Risk reduction measures implemented to eliminate identified hazards or to reduce risk (e.g., from standards or other specifications)
- Residual risk levels associated with the hazards
- Validation of the risk reduction measures, including the responsible individual(s) and the date of validation
- Supplier documentation should also include recommendations for additional risk reduction measures (to be implemented by the user, system integrator or other entity involved in machine utilization)

The documentation of the risk assessment process will best serve its intended purposes when retained for the life of equipment, and include any subsequent modifications which may require repeating the process.

Change Management

Contrary to what some may think, risk assessment is a living process with no definitive end until the equipment lifecycle has concluded. At a minimum, best practice suggests that the risk assessment cycle should be a continually ongoing event, and should take place at least annually to ensure minor modifications to the equipment or process have not inadvertently increased the residual risk associated with the equipment. Even without modifications, age (including wear and tear) can have a detrimental effect on the risk reduction system. As an example, the stopping performance of a machine will inevitably increase over time; beyond a certain point, this increase will render certain safeguards (such as presence sensing devices or two-hand controls) ineffective. In addition, other events within the lifecycle of a machine should also automatically trigger a new risk assessment, including when the following activities occur:

- Existing equipment is automated
- A new process is created by utilizing previously used components
- An existing machine is repaired / refurbished with comparable components
- An existing machine is reconfigured
- An existing machine is moved to a new facility or a different space in the existing facility but not reconfigured
- Components are added to or removed from the system
- Equipment in an existing system is modified or replaced with new equipment that has new features that are not comparable to the original equipment
- Components in an existing system are modified or replaced with new components that have new features that are not comparable to the original components

Easy and ready access to past risk assessment documentation will further assist with the management of change process.

Conclusion

Although not a legal requirement in all world markets, the risk assessment process is a clearly defined methodology to ensure that acceptable levels of machinery safety are achieved. Even for organizations with limited resources, the benefits of a pragmatic assessment process are easily rationalized by ensuring a consistent approach to risk reduction. With clearly defined limits for risk factors, acceptable risk, and minimum performance expectations, a company can ensure that enough protective measures have been applied while also preventing over-dimensioning.

Achieving balance between the ideology of safety, the realities of existing production concerns, and ever-present budget constraints can be intimidating. Rather than trying to short-cut the process and jump right into implementing protective measures, progressive companies realize that a systematic approach to outlining the process and goals is an essential prerequisite to meet EH&S goals and market expectations in a cost effective manner. As with any new process, evaluating internal competencies and supplementing them with external resources when required will help ease the initial discomfort.

This white paper is meant as a guideline only and is accurate as of the time of publication. When implementing any safety measures, we recommend consulting with a safety professional.

For more information about the risk assessment process visit our web site at www.sickusa.com.