WHITE PAPER SERIES ADDRESSING THE PRIMARY MILESTONES TO A SAFE MACHINE

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BONUS WHITE PAPER:
Decoding Ranking Systems Related to Industrial Safety

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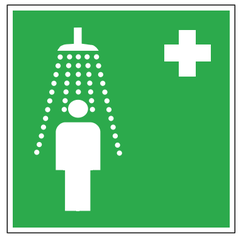
Selecting Safety Standards for Machine Safeguarding Requirements

WHITE PAPER # 1

Introduction

When embarking on a path to implement machine safeguarding (protective) measures, one cannot dismiss the influence and importance of documented safety requirements – whether they are mandatory versus voluntary; normative opposed to informative; and regardless of their designation as a law, directive, regulation, harmonized standard, consensus standard, technical guideline, or merely best practice [herein referred to simply as 'safety standards'].



"Safety standards" are requirements designed to ensure the safety of people around products, activities, or processes. They may be advisory or compulsory and are typically laid down by either a voluntary or statutory body that may be advisory or regulatory.

When it comes to safety standards, there is no shortage of documentation outlining specific requirements. Before defaulting to a laundry list of requirements that your organization has bought into for guidance, it is important to first understand why referencing specific sources is important to an organization.

Why Reference Standards?

Generally speaking, we reference documented material as a measurement we can compare to. In terms of machine safety, this is a sort of litmus test; selecting appropriate standards will clearly define the minimum allowable requirements, specifications and expectations for comparison, which in turn will ease the burden of determining if those goals have been achieved – either by internal team members retrofitting equipment or external suppliers contracted to provide equipment with appropriate safeguards.

Identifying EH&S Goals

Before we can get into which safety standards are 'right' for an organization, we must also address what the goals of the organization are. There are many different factors that influence the needs and desires to provide a safe workplace (which we won't address here), but understanding the intentions will provide guidance throughout the process.

One of the major factors to consider is if the organization is striving for compliance, safety, or a combination of the two. While at first glance these aspects may appear to be one and the same, they are in fact very distinctive. 'Compliance' is the practice of adhering strictly to published standards and could be viewed as a reactive or defensive approach to safety, in that the primary purpose is to evade prosecution – either in a court of law or in the court of public opinion. 'Safety,' on the other hand, is viewed as a proactive approach to provide protection from danger or to achieve a condition with as little risk as possible, or as low as reasonably practical (ALARP).

It is important to recognize that 'compliant' equipment is not always 'safe' and that 'safe' equipment is not always 'compliant', leading many of us to desire BOTH 'safety' and 'compliance.' While it could be argued that as long as the true goal of providing a safe workplace is maintained, compliance may not truly matter. For many, however, compliance is extremely relevant because it provides a decisive result regarding how safe is 'safe enough' while also protecting organizations from further liability. Clearly understanding your organization's view on this issue will provide great assistance with this endeavor.

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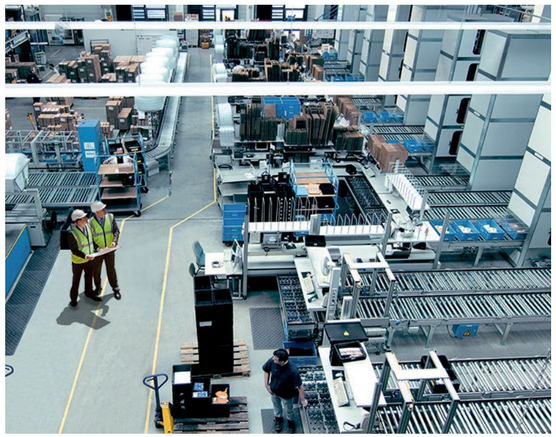
WHITE PAPER # 2

Introduction

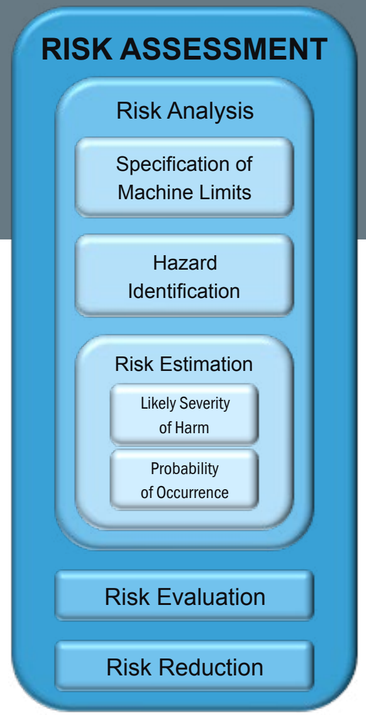
When undertaking machine safety activities, it is always important to have a clearly structured process to be used as a guideline. With such a process in place, it is easier to ensure consistent results that coincide with the EH&S goals of an organization. A well-conceived risk assessment process is 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.

Why Perform Risk Assessment?

As discussed in White Paper #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 likey to cause death or serious physical harm to his employees.*

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The Risk Reduction Process Utilizing a Hierarchy of Controls

WHITE PAPER # 3

Introduction

After risks have been identified, evaluated and analyzed as outlined in Part 2 of this series (The Risk Assessment Process), there will inevitably be some – if not many – residual risks not at an acceptable level. In these instances, it is important to take action to mitigate the risk to a level deemed tolerable for your organization. Before rushing into a knee-jerk reaction to implement possible solutions, however, it is important to consider the rational approach to risk reduction known as the "Hierarchy of Controls."

Why Use a Hierarchy?

The ultimate goal of implementing protective measures is to reduce risk of harm. This objective can be achieved by the elimination of hazards, or by separately or simultaneously reducing each of the elements that determine the associated risk. Risk reduction can be accomplished by:

- Decreasing the potential severity of harm presented by a hazard,
- Improving the possibility of avoiding the associated harm, and/or
- Reducing the need for access to the hazardous area, either by number of people exposed or duration of each exposure.

Also referred to as the "Hazard Control Hierarchy," the approach described here identifies risk reduction measures in a ranked order of preference. As the name implies, the risk reduction measures (principles of controlling hazards) are categorized according to both their effectiveness and preference. When correctly applied in the proper order, the level of residual risk will continue to decline and approach the goal of a tolerable or acceptable level of risk. Furthermore, following the preferential order can result in overall reduction of costs associated with safety, both in terms of initial application, as well as long term deployment. By following this well-tried methodology, the frustrations and misuse of resources associated with a trial and error approach to reducing risk can be eliminated.

What is the Hazard Control Hierarchy?

The theory of applying risk mitigation concepts in a preferential order has been addressed in many regulations and standards for some time. While there are many different representations of the hierarchy, the table below represents a common delineation of the key elements.

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Preference	Protective Measure	Examples	Influence on Risk Factors	Classification
Most Prefered ↓ Least Prefered	Elimination or Substitution	• Eliminate pinch points (increase clearance) • Intrinsically safe (energy containment) • Automated material handling (robots, conveyors, etc.) • Redesign the process to eliminate or reduce human interaction • Reduce energy • 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, and/or the possibility of avoiding or limiting harm depending on which method of substitution is applied	Design Out
	Guards and Safeguarding Devices	• Barriers • Interlocks • Presence sensing devices (light curtains, safety mats, area scanners, etc.) • Two-hand control and two-hand trip devices	• Greatest impact on the probability of harm (occurrence of hazardous event under certain circumstances) • Minimal if any impact on severity of harm	Engineering Controls
	Awareness Devices	• 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	Administrative Controls
	Training and Procedures	• Safe work procedures • Safety equipment inspections • Training • Lockout / Tagout / Tryout	• Potential impact on the probability of harm (avoidance and/or exposure) • No impact on severity of harm	
	Personal Protective Equipment (PPE)	• Safety glasses and face shields • Ear plugs • Gloves • Protective footwear • Respirators	• Potential impact on the probability of harm (avoidance) • No impact on severity of harm	

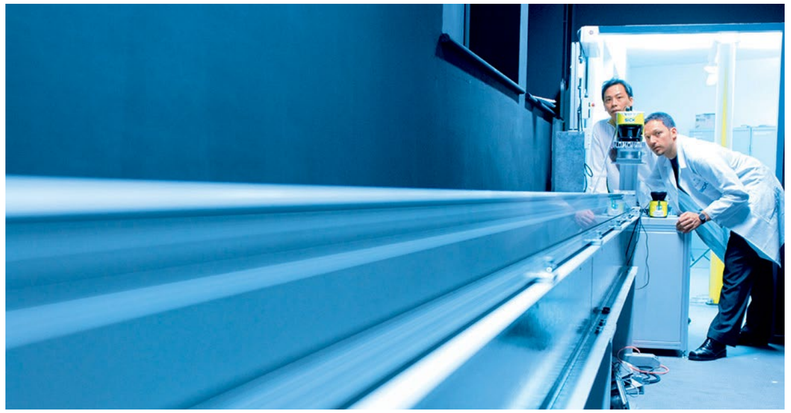
Functional Safety for Machine Controls

WHITE PAPER # 4

Introduction

When implementing technical protective measures (also referred to as “safeguards”) from the hierarchy of controls, as discussed in Part 3 of this series (The Risk Reduction Process Utilizing a Hierarchy of Controls), each risk reduction measure will be associated with a safety function or combination of safety functions. In order for these safety functions to be designed and installed to a degree of reliability commensurate with the risk level of the associated hazard(s), the concepts of functional safety must be applied.

What is Functional Safety?



Functional safety is a part of the process used to design, test, and prove that the safety-relevant components and circuits of a machine’s control system meet the intended reliability and risk reduction capability as determined by a risk assessment. As part of the overall risk reduction strategy for industrial machinery, it is typical to apply safeguards employing one or more safety functions (as described below) to achieve some measure of risk reduction. Parts of machinery control systems that are assigned to provide safety functions are called “safety-related parts of control systems” (SRP/CS). These can consist of hardware and/or software and can either be separate from the machine control system or an integral part of it. In addition to providing safety functions, SRP/CS can also provide operational functions, such as initiation of machine motion under safe conditions.

> “Functional Safety” is the term used to refer to the portions of the safety of the machine and the machine control system, which depend on the correct functioning of the SRP/CS. To best implement functional safety, safety functions must first be defined. Once identified, the required safety level must also be determined and then implemented with the correct components necessary to achieve acceptable risk reduction. To confirm that the minimum requirements have been met (if not exceeded), subsequent verification must be performed and documented.

To look at it from another aspect, functional safety is an engineering approach to quantify the performance level of the SRP/CS to a level commensurate with the associated risk for a given technical protective measure. This includes the verification and validation aspects of the safety functions that have direct interaction with the machine control system, as represented in the chart to the right.

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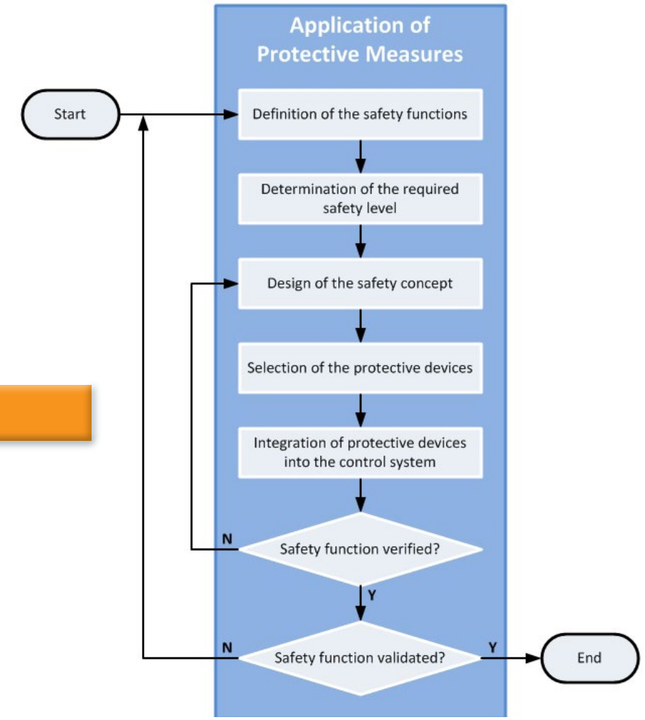

Validation and Deployment Concerns to Maintain Acceptable Risk

WHITE PAPER # 5

Introduction

In order to ensure an acceptable level of residual risk has been achieved prior to deploying equipment for active service, it is imperative to implement one final series of steps. This stage is necessary to confirm that all risk reduction measures applied (design and build, technological, and organizational) are working together effectively to reduce the risk of all identified hazards to a tolerable level. This validation process must be

documented to provide a written record of the current assumptions and decisions to aid future iterations of the risk assessment and risk reduction process.

Additionally, it must be acknowledged and accepted that the dynamics of the real world may – and probably will – eventually change the use of any machine. An effective change management program must therefore be in place to ensure that a process exists to catch even the slightest modifications, which could have a large impact to the overall level of safety of the equipment.

The concepts of final validation and documentation, combined with a recurring review process, will help maintain the lowest possible level of residual risk associated with the machine or process throughout the equipment lifecycle.

Types of Validation Steps

As part of the overall risk reduction process, protective measures are applied in a preferential order, as discussed in Part 3 of this series (The Risk Reduction Process Utilizing a Hierarchy of Controls). Typically, more than one measure is selected from the hierarchy to achieve an accumulated outcome of reducing the risk to an acceptable level. To ensure the effectiveness of the risk reduction strategy selected, however, each measure must be validated after it has been implemented. This validation process is intended to ensure that the initial goals have been fully achieved through proper selection, implementation, and execution of each protective measure.

The methods used to validate protective measures can vary depending on the type of measures applied, but often include one or more of the following:

- Testing and verifying operation of safety devices and circuits
- Review of training
- Presence of warning labels
- Presence of lockout procedures and safe job procedures
- Functioning of complementary equipment

Decoding Ranking Systems Related to Industrial Safety

WHITE PAPER # 6

Introduction

When EH&S personnel and controls engineers collaborate with suppliers to implement protective measures for industrial equipment, the discussion can quickly run astray as various terminologies are used – often with little to no true understanding of what the terms actually mean. For the uninitiated, the jargon can (and often does) appear to be an entirely different language.

As is the case in many specific fields of study, one must first be acquainted with the basic expressions that are often used in order to speak intelligently about a given topic – and industrial safety is no different. In the safety marketplace, safety standards are heavily relied upon to present basic concepts and specific definitions to establish common ground. For better or worse, many of the nomenclatures used in these standards rely on seemingly simple ranking systems, but confusion is introduced because many of the classifications utilize alphabetical or numerical designators, as shown in the table below.

Brief descriptions of the ranking systems are provided within the white paper in no particular order. These can be used as an aid to translate language that is already understood by industry insiders, but often misapplied by newcomers.

Performance Levels (PL) ISO 13849-1	a	b	c	d	e		
Standards (Type) ISO/IEC & ANSI B11	A	B	C				
Circuit Categories (Cat) EN 954-1		B	1	2	3	4	
Safety Integrity Levels (SIL) IEC 61508			1	2	3	4	
Safety Integrity Levels (SIL) IEC 62061			1	2	3		
Stops (Category) IEC 60204-1		0	1	2			
ESPE Devices (Type) IEC 61496				2	3	4	
Interlocking Devices (Type) ISO 14119			1	2	3	4	
Two-Hand Controls (Type) ISO 13851			I	II	IIIA	IIIB	IIIC

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