

# The Risk Reduction Process Utilizing a Hierarchy of Controls

Part 3 of 5 in a series addressing the primary milestones to a safe machine

### 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, Figure 1 represents a common delineation of the key elements.

Preference	Protective Measure	Examples	Influence on Risk Factors	Classification
Most Preferred Least Preferred	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	

Figure 1: Typical Hazard Control Hierarchy

# Who Should Apply Risk Reduction Measures?

The most effective risk reduction measures result when steps are taken by <u>both</u> the supplier (OEM and/or integrator) and the end user. Regardless of which entity is applying risk reduction measures, a hierarchical approach is always recommended to ensure the

largest steps of risk reduction are achieved by the most reliable methods.

As discussed in Part 1 of this series (Selecting Safety Standards for Machine Safeguarding Requirements), varying regulatory requirements and market expectations exist in different world regions addressing who is 'responsible' for reducing risk. Regardless, the approach of applying risk reduction measures in a tiered approach is a common methodology in both International and North American standards. In the International market, the primary standard addressing this concept is ISO 12100:2010 -Safety of machinery - General principles for design - Risk assessment and risk reduction. Historically, this standard has roots in previous European Norms (EN 292-1 and -2), which address the European concept of placing new equipment on the market in a safe condition. The approach recommended in this standard is often referred to as an iterative "Three-Step Method." When examined closely, it is clear that the three steps establish a tiered approach applied in a preferential order (Figure 2).

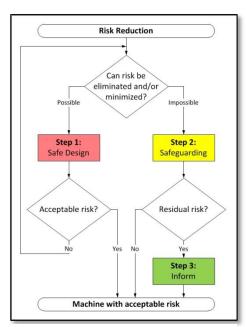


Figure 2: Three-Step Method

While the ISO 12100 approach includes additional risk reduction steps to be applied by the user (employer), these measures are considered outside the scope of the International Standard. Additionally, this standard was adopted in the U.S. as an American National Standard as ANSI/ISO

12100:2012. To better focus on the North American regulatory requirements for employers to make all equipment safe (regardless of the vintage of the equipment), other consensus standards exist which also focus on the importance of the user's role in overall mitigation of risk, with the most broadly applicable standard being **ANSI B11.0-2010** – Safety of Machinery – General Requirements and Risk Assessment. This standard includes the hierarchy shown in Figure 1 above, and parallels ISO 12100 in both scope and applicability to a broad category of equipment.

It should be noted that both ISO 12100 and ANSI B11.0 (as well as other standards) follow the direction provided by ISO/IEC Guide 51 -Safety aspects – Guidelines for their inclusion in standards, which was recently updated in April 2014. The intent of the guide is to establish common terminology and methodologies to standards writers when addressing key concepts of risk reduction for inclusion in safety standards around the world. A graphical representation is included in Guide 51, illustrating that risk reduction directly follows the risk assessment process and is a combination of efforts applied at both the design and use phases of equipment. Figure 3 is an adaptation of this image, modified to express that each iterative application of additional risk reduction measures following a hierarchical approach further reduces the associated residual risk.

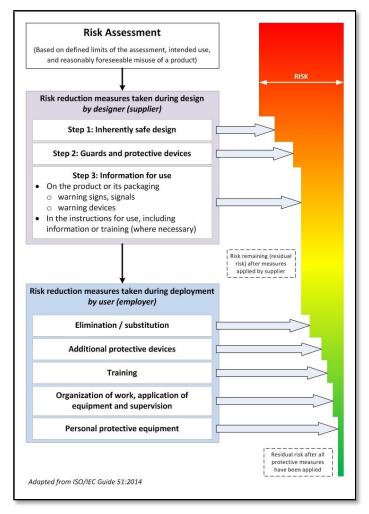


Figure 3: Risk Reduction Efforts Applied During
Design and Use Phases

By combining these approaches, proactive organizations can reap great benefits. Machinery suppliers are the most equipped to understand the design and intended use of the equipment, and therefore are in the best position to successfully implement cost effective risk reduction measures at the design phase. However, as is the case with most common 'off the shelf' machine designs, many OEMs are not fully aware of each end user's intended use of the equipment. In these instances, the user is best positioned to select and apply risk reduction measures that are most effective based on the process and intended use of the machinery.

# What are the Elements of the Hierarchy?

As John Tyler, the tenth President of the United States, correctly remarked, "Everything dependent on human action is liable to abuse." This observation succinctly identifies the basis of the hazard control hierarchy in that the measures most dependent on human action or behavior are less preferred, and therefore placed near the bottom of the hierarchy.

Numerous documents have been developed to outline the hazard control hierarchy and provide guidance on its implementation. As such, different models exist; some go to great detail to define each minute approach, while others are more general in their examination of the concepts. Figure 4 below identifies a few of the more common classifications (into either three, five, or eight tiers) of the hierarchy, some of the guidance associated with each, as well as a number of justifications for the preference of order of the elements. The classifications of risk reduction measures are explored in more detail further on.

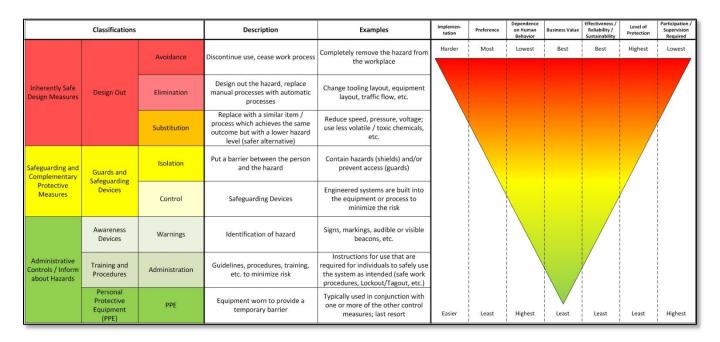


Figure 4: Evaluation of the Hazard Control Hierarchy

### Inherently Safe Design

In many circumstances, risk avoidance (also known as risk transfer) simply cannot be performed. Through the nature of the process, many risks simply cannot be avoided. In such cases, the concept of safe design must be applied.

It is widely acknowledged that safe design measures are most effective when applied as early in the lifecycle of the equipment or process as possible – whether for the design of a new piece of equipment or the creation of a new process utilizing older components. Even for relatively low risk applications, safe design concepts may prove to be a simple and effective approach to mitigate residual risks. A simple example is that of a hand wheel which may rotate automatically in certain modes of operation; rather than using a spoked design, a solid wheel can eliminate risks associated with crushing or severing if located near the edge of a non-moving member of the machine.

# Prevention through Design

Measures which can be incorporated at the earliest stages of the machine lifecycle – including conceptualization and design of the process – are preferable to (and generally more effective than) those which are implemented at later stages. The concept of moving prevention upstream in the design process is the core principle of a relatively new movement call "Prevention through Design."

<u>Prevention through Design</u> (PtD) is a national initiative lead by the National Institute for Occupational Safety and Health (NIOSH), a U.S. federal agency under the Center for Disease Control and

Prevention (CDC) that conducts research and makes recommendations to prevent worker injury and illness. PtD incorporates all of the efforts to predict and design out hazards to workers and its focus is on individuals who execute the designs or have to work with the products of the design. The initiative has been developed to support designing out hazards, the most reliable and effective type of prevention because it lessens the reliance on lower hierarchy control measures. Additional benefits of PtD include greater ease of implementation as well as lower overall cost, as depicted in Figure 5.

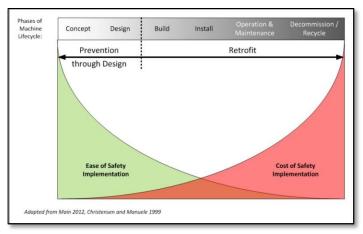


Figure 5: Model of Prevention through Design

The multi-year initiative, started in 2006, has resulted in a number of work items, including the consensus standard *ANSI/ASSE Z590.3-2011* – *Prevention through Design Guidelines for Addressing Occupational Hazards and Risks in Design and Redesign Processes.* As addressed in Part 1 of this series, this standard includes guidelines and requirements for risk assessment as a key element to identify sources of potential risk.

## **Safeguarding and Complimentary Protective Measures**

Safe design measures are often more difficult to implement without undergoing a complete redesign as the equipment or process advances through its lifecycle. Instead, engineered controls can be provided to detect and/or prevent access to hazards that cannot be eliminated.

#### Isolation

Barriers are most commonly used to provide a physical boundary to a hazard. Depending on the level of identified risk, barriers can be used to deny intentional access to a hazard area, prevent unintended exposure, provide simple guarding against inadvertent exposure, or create tactile or visual awareness of the hazard. It is important to note that there are different types of barriers:

- Barrier guards are used to prevent exposure to hazards. Proper design (including materials
  used, size, and location) must adhere to established guidelines in order to perform as expected.
- <u>Shields</u> are barriers used to either keep hazards (e.g., chips or coolant) within the confines of
  the machine, or to reduce the potential of hazards (e.g., tooling parts, work pieces, or radiation)
  from being ejected or emitted from the machine. Effective design must account for the nature
  and energy of the hazards to be contained.
- Awareness barriers are devices that warn individuals by means of physical contact. Awareness
  barriers, although physical obstructions, do not provide complete isolation from hazards, and
  therefore do not suffice as safeguards. Instead, these are grouped under awareness means
  (discussed below).

### Access and/or Hazard Control

When complete and permanent isolation cannot be achieved through the use of barriers, other safeguarding devices may either:

- be used to prevent access until the hazard has ceased, or
- be located such that an individual cannot reach the hazard before it has reached a safe condition (typically at a safe or zero speed).

Many categories of engineering controls exist, as portrayed in Figure 6. Some may be integrated into barriers (such as interlocking devices), while others may detect the presence of an individual or other obstruction at a predetermined location (such as light curtains, area scanners, and safety mats). Furthermore, some measures may detect the absence of an individual at a predetermined location (such as two-hand controls), and others may be used to control access to the hazard area (such as pull-backs and restraints).

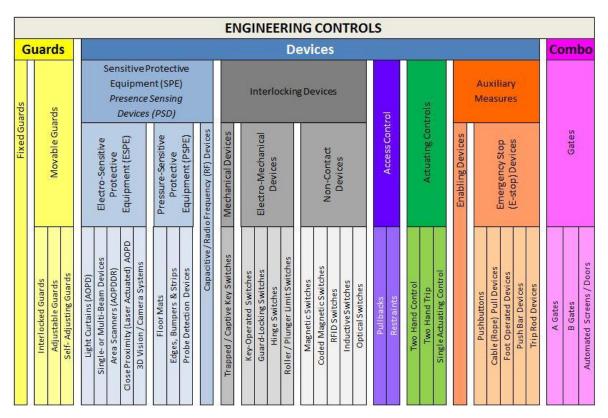


Figure 6: Examples of Engineering Controls

#### **Complimentary Measures**

Some engineering controls cannot be relied upon as primary safeguarding measures, although they do assist in reducing risk. A common example is emergency stop (e-stop) devices. E-stops are not considered safeguarding devices because they neither detect nor prevent access to a hazard. However, because these devices can help minimize the extent of injury in the event exposure to the hazard does occur, they clearly qualify as a risk reduction measure.

### Safety-Related Part of the Control System

As part of an overall risk reduction strategy, some measure of risk reduction is typically achieved through the application of safeguards and/or complimentary measures employing one or more safety functions. When this occurs, engineering control components also become elements of the safety related part of the control system (SRP/CS). By definition, the SRP/CS is the part of a control system that responds to safety-related input signals and generates safety-related output signals. These are parts of machinery control systems that are assigned to provide safety functions, can consist of hardware and 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

two-hand controls as a means of cycle initiation). The combined elements start at the point where the safety-related input signals are initiated (for example, obstruction of an optical beam of the safety light curtain) and end at the output of the power control elements (for example, the main contacts of a contactor), as shown in Figure 7.

Selecting the appropriate performance requirements for SRP/CS based on the level of risk is a core principle of many risk assessment and risk reduction processes. There are many standards available to provide guidance on this topic, including but not limited to those identified in Table 1, as follows.

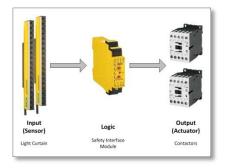


Figure 7: Basic Elements of SRP/CS

STANDARD	YEAR AFFIRMED (REAFFIRMED)	TITLE		
<b>ANSI B11.0</b> 2010		Safety of Machinery – General Requirements and Risk Assessment		
ANSI B11.19	2010	American National Standard for Machines – Performance Criteria for Safeguarding		
ANSI B11.26 <sup>1)</sup> DRAFT		Functional Safety for Equipment (Electrical/Fluid Power Control Systems) – Application of ISO 13849 – General Principles for Design		
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		
ANSI B11.TR4 <sup>2)</sup>	2004	ANSI Technical Report for Machine Tools – Selection of Programmable Electronic Systems (PES/PLC) for Machine Tools		
ANSI B11.TR6 2)	2010	ANSI Technical Report for Machine Tools – Safety Control Systems for Machine Tools		
ANSI / PMMI B155.1	2011	Safety Requirements for Packaging Machinery and Packaging Related Machinery		
ANSI / RIA R15.06 3)	1999 (R2009)	American National Standard for Industrial Robots and Robot Systems – Safety Requirements		
CSA Z432	2004	Safeguarding of machinery		
ISO 12100 <sup>4)</sup>	2010	Safety of machinery – General principles for design – Risk assessment and risk reduction		
EN 954-1 <sup>5)</sup>	1996	Safety of machinery – Safety-related parts of control systems – Part 1: General principles for design		
ISO 13849-1	2006	Safety of machinery – Safety-related parts of control systems – Part 1: General principles for design		
IEC 61508 (all parts)	2010	Functional safety of electrical/electronic/programmable electronic safety-related systems		
IEC 62061	2005	Safety of machinery – Functional safety of safety-related electrical, electronic and programmable electronic control systems		
		NOTES		
This standard is in final draft phase and is expected to be published by end of 2014 or early 2015.				
This standard is ex	This standard is expected to be withdrawn upon publication of ANSI B11.26.			
This standard is in not include specific	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 specific guidance, but rather references ISO 13849-1 and IEC 62061.			
	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.			
	sequently elevated to 19 ISO revision as of	o ISO 13849-1 in 1999. In turn, ISO 13849-1 was revised in 2006, effectively replacing both EN 1 January 2012.		
Information listed is be information regarding s		e at time of publication; subject to change at any time. Check with appropriate SDO for additional standards listed.		

Table 1: Examples of Standards Addressing Safety-Related Parts of Control Systems (SRP/CS)

# **Administrative Controls (Informing about Hazards)**

Following design and engineering control methods to reduce risk, additional risk reduction measures are applied to further reduce risk to a level considered As Low As Reasonably Practical (ALARP). Steps taken here are at the lower end of the hierarchy since they are all essentially dependent upon human actions or behaviors to achieve the fullest level of mitigation possible. Due to the inconsistency of human nature, these lower order measures should always be applied later in the process. It is worthy to point out, however, that these lower value controls may be used in the interim until long-term controls are implemented.

### Awareness Means

Awareness means inform people of any significant residual risks which have not been eliminated by design or protected by guards or safeguarding devices. Awareness devices include warnings (such as signs or labels), lights, alarms, awareness barriers or other measures. Visual signals (such as flashing lights) and audible signals may be used to warn of an impending hazardous event (such as machine start-up or over-speed). The most common type of awareness means are as follows.

- <u>Awareness barriers</u>, as noted above, differ from engineered barrier guards because they must be installed such that a person cannot reach into the hazardous area without a conscious effort and/or contact with the barrier. Examples include railings, chains, or other devices, which allow entry of work pieces of varying sizes, but prevent the operator from reaching the hazard without their awareness. Additionally, awareness barriers provide a visual boundary to the operator's movements and indicate the location of the hazard area.
- <u>Awareness signals</u> are devices that warn individuals by means of audible sound or visible light. Effective design of visible indicators will address unambiguous positioning, patterning, labeling or flashing to ensure clear communication of the hazard zone. Consideration should also be given to the prevalence of color blindness, as well as consistent color coding within the facility and in accordance with applicable standards. Audible signals should have a distinctive sound and intensity that distinguishes them from the highest ambient noise level in the area.
- Awareness signs (also referred to as <u>safety signs</u>) are used to warn individuals of potential or existing hazards. These too must be in compliance with applicable regulations and standards to ensure that proper formats, colors, and symbols are used to provide appropriate hazard avoidance information for risks that may be encountered.

### Training and Procedures

Proper training, procedures, and supervision are essential to the care and use of risk reduction measures applied to mitigate risk. Safe work procedures and training should be used to supplement existing guards, safeguarding, and awareness devices – not as a replacement. Procedures and training may include, but are not limited to:

- Formal or informal training
- Standard operating procedures
- Checklists
- Personnel certifications

When developing training material, the content should include, but is not limited to:

- Nature of the hazards
- Significance of the risk reduction measures applied
- Capabilities/options of risk reduction measures
- Description of risk reduction measures for a specific application and hazard
- Function of the risk reduction measures
- Proper installation and operation of the risk reduction measures

- Functional testing of the risk reduction measures
- Limitations of the risk reduction measures
- Abnormal or unexpected operation of the risk reduction measures
- Adjustment, maintenance, and operation of the risk reduction measures to ensure proper operation

The equipment supplier is obligated to furnish information about the intended use of the machine considering all intended operating modes as well as reasonably foreseeable misuse. This information must contain documentation (as appropriate) for the risk reduction measures applied, including installation requirements, operating instructions, and maintenance requirements. Furthermore, the supplier should provide all instructions necessary to ensure safe and proper use of the machine, and also inform and warn the user about residual risks, including need for additional protective measures, training, and personal protective equipment.

It is then the employer's responsibility to ensure that all exposed people (not just employees) are trained based upon the program developed. The employer must then verify the understanding and provide for the continued competency of each person. In turn, each individual has a responsibility to follow the training and safety procedures provided, to avoid the hazards that are identified or known to them, and not intentionally attempt to circumvent the risk reduction measures which have been applied.

## Personal Protective Equipment

Personal protective equipment (PPE) must be used in conjunction with – but not in lieu of – other risk reductions measures, or when no other control methods are available or feasible. Typical PPE includes, but is not limited to, eye protection, hearing protection, gloves, non-slip and/or steel toe footwear, respirators, etc. Again, many standards exist in industry regarding how specific PPE must be designed and tested. When different levels of PPE exist, selection of the appropriate PPE for the application is often based on the risk assessment process.

# **Considerations when Applying the Hierarchy**

# **Identify New Hazards**

After each iterative step through the hierarchy of applying risk reduction measures, it is important to evaluate the system to determine if new hazards have been introduced. If so, the risk assessment process (as discussed in <a href="Part 2">Part 2</a> of this series) must be repeated to effectively address new task / hazard combinations, and the hazard control hierarchy must be applied again to reduce the associated risks to an acceptable level.

### Confirm Effectiveness

After appropriate risk reduction measures have been identified and selected according to the hierarchy, it is imperative that the effectiveness of each measure is confirmed following implementation. Confirmation (also referred to as 'validation,' 'verification,' or 'test and check') is the process of confirming that a system design performs to a pre-defined confidence level. Confirmation of the effectiveness of risk reduction measures can include but is not limited to:

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

It is also important to note that confirming the effectiveness of any risk reduction measure must not expose an individual to potential harm should the measure not provide the protection expected.

### Incentives to Defeat or Circumvent Risk Reduction Measures

Incentives to defeat or circumvent risk reduction measures must not be overlooked when confirming the effectiveness of risk reduction measures. The incentives depend on the circumstances considered, the combination of multiple measures from the hierarchy, and the design details of each measure applied. Incentives to render a risk reduction measure ineffective may include but are not limited to the following factors:

- Risk reduction measures prevent the task from being performed
- Additional tasks exist which were not identified and assessed for hazards and risks
- Risk reduction measures slow down production or interfere with other activities or preferences
  of the user
- A specific risk reduction measure is difficult to use
- Personnel other than the intended operator(s) are needed to perform the task, such as:
  - o Operator resets a safeguard while maintenance personnel are inside the hazard area
  - Safeguards intended to protect an individual are inappropriately used for multiple personnel (such as two-hand controls)
- Individuals do not recognize a risk reduction measure and/or its associated hazard
- Risk reduction measures are not accepted as suitable, necessary or appropriate for their function

When risk reduction measures are applied properly, they not only reduce the associated risk to a tolerable level, they also allow personnel to effectively complete necessary tasks without defeating or circumventing the prescribed measures.

### Assess Residual Risk

Once viable risk reduction measures have been applied following the hierarchy, the residual risk must be assessed. When assessing the residual risk, the risk factors are estimated assuming that the selected risk reduction measures are in place and have been confirmed to be functional. The residual risk must be assessed to verify that the selected measures are appropriate for the application and that they sufficiently reduce the risk to an acceptable level. After the residual risk has been established for each hazard, a decision must be made to either accept or further reduce the residual risk.

Following application of the hierarchy, adequate risk reduction is typically achieved when:

- All operating conditions and all expected tasks have been considered
- The hazards have been eliminated or risks reduced to the lowest practicable level (ALARP)
- Any new hazards introduced by the risk reduction measures have been properly addressed
- Affected individuals are sufficiently informed and warned about the residual risks
- Risk reduction measures are compatible with the equipment and one another
- Sufficient consideration has been given to the consequences that can arise from the foreseeable misuse of the machine
- The risk reduction measures do not adversely affect the working conditions of personnel or the usability of the machine
- The risk reduction measures do not jeopardize the ability of the equipment to perform its function
- The risk reduction measures implemented are adequately reliable for the associated risk(s) and their functionality can be appropriately sustained

Risk reduction is complete when the measures are correctly applied and acceptable residual risk has been achieved. When deciding if acceptable risk has been reached, it is also important to determine if compliance with local, regional, and national regulations has also been attained.

### Maintenance of Risk Reduction Measures

Confirmation that all risk reduction measures are provided, installed and functional must be completed as part of the commissioning process. This applies whether the equipment is new, recently rebuilt and/or modified, or simply relocated. The concept of change management was addressed in further detail in Part 2 of this series.

Following the initial commissioning of all safety functions, proper use and maintenance of the risk reduction measures will preserve the acceptable level of residual risk throughout the lifecycle of the equipment. A regular inspection program is a proven method to ensure that measures used to reduce risk maintain proper functionality and are still effective to the application even after seemingly minor process changes have occurred. Greater focus on this topic will be provided in Part 5 of this series.

#### Conclusion

As discussed in the previous white paper in this series, 'zero risk' is virtually unattainable and all machinery applications have some level of residual risk. However, application of the hazard control hierarchy is essential to achieving adequate risk reduction. By applying effective risk reduction measures from each step of the hierarchy of control, reaching an acceptable or tolerable level of resulting risk is possible.

As stipulated in most consensus guidance documents, the hazard control hierarchy is a proven approach to ensure that acceptable levels of machinery safety are achieved. Even for organizations with limited expertise selecting and applying risk reduction measures, the benefits of a rational and organized process are easily realized. When implemented as part of an overall risk assessment methodology, results can be fulfilled which are consistent, justified, and practical.

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 hierarchy of controls visit our web site at www.sickusa.com.